

statements will be limited to 3–5 minutes by each person or organization. Any person who wishes to file a written statement may do so before or after a TRAC meeting. These statements will become part of the official record and will be provided to the TRAC members. The official record will be available for public inspection at the address listed under "Addresses" at the beginning of this document.

List of Subjects

Environmental protection, Agriculture, Chemical, Foods, Pesticides, Tolerance reassessment and Pests.

Dated: October 4, 1999.

Marcia E. Mulkey,

Director, Office of Pesticide Programs.

[FR Doc. 99–26371 Filed 10–7–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–894; FRL–6384–2]

Notice of Filing a Pesticide Petition to Establish a Tolerance for Certain Pesticide Chemicals 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 certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by docket control number PF–894, must be received on or before November 8, 1999.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the "SUPPLEMENTARY INFORMATION" section. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–894 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Susan Stanton, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–5218; and e-mail address: stanton.susan@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Cat-egories	NAICS	Examples of poten-tially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufac-turing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "**Federal Register**--Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF–894. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of

the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–894 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by E-mail to: "opp-docket@epa.gov," or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 5.1/6.1 or ASCII file format. All comments in electronic form must be identified by docket control number PF–894. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as 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 version of the official record.

Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the "FOR FURTHER INFORMATION CONTACT" section.

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 control 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 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.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: September 24, 1999.

Peter Caulkins,

Acting 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 it 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.

Bayer Corporation

PP 9F6011

EPA has received a pesticide petition (9F6011) from Bayer Corporation, 8400 Hawthorne Road, Kansas City, Missouri 64120-0013 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 tolerances for residues of flucarbazone sodium: 4,5-dihydro-3-methoxy-4-methyl-5-oxo-N-[[2-(trifluoromethoxy)phenyl]sulfonyl]-1H-1,2,4-triazole-1-carboxamide, sodium salt; and its N-desmethyl degradate, 4,5-dihydro-3-methoxy-5-oxo-N-[[2-(trifluoromethoxy)phenyl]sulfonyl]-1H-1,2,4-triazole-1-carboxamide in or on the raw agricultural commodities (RACs):

Commodity	Parts per million
Wheat Forage	0.30
Wheat Hay	0.10
Wheat Straw	0.05
Wheat Grain	0.01
Milk	0.005
Meat (cattle, goats, sheep, horses, hogs).	0.01
Liver (cattle, goats, sheep, horses, hogs).	0.60

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 metabolism of flucarbazone-sodium in wheat was rapid and extensive. Little or no parent flucarbazone-sodium was found in the RACs. A primary metabolic pathway in wheat involved the N-demethylation of flucarbazone-sodium to give N-desmethyl flucarbazone-sodium. N-desmethyl flucarbazone-sodium was found in all of the wheat RACs. The N-desmethyl flucarbazone-sodium was then either hydrolyzed or conjugated with glucose. Another primary metabolic pathway was hydrolysis of flucarbazone-sodium yielding sulfonic acid and sulfonamide which were isolated, and N,O-dimethyl triazolinone which was not isolated. Other metabolites were then subsequently formed by oxidative reactions, hydrolytic reactions, and conjugation.

2. *Analytical method—Plants.* The proposed tolerance expression is parent flucarbazone-sodium and N-desmethyl flucarbazone-sodium. An analytical method was developed to measure these two analytes in plant matrices. This method was validated in wheat tissues. The flucarbazone-sodium and N-desmethyl flucarbazone-sodium residues are extracted from the wheat samples with 0.05 M NH₄ OH by accelerated solvent extraction (ASE). The extracts are purified by a combination of C-18 solid phase extraction (spe) and ethylene diamine-N-propyl (PSA) spe. The resultant analytes are detected by liquid chromatography/tandem mass spectroscopy (lc/ms/ms) and quantified against known amounts of deuterated internal standards. The method limit of quantitation (LOQ) is 0.01 milligram/kilogram (mg/kg) of either analyte in all wheat matrices. The method limit of detection (LOD) is 0.005 mg/kg of either analyte in all wheat matrices.

3. *Animals.* An analytical method was developed to measure the residues of flucarbazone-sodium in animal tissues and milk. Since the flucarbazone-sodium-related residues were present in ruminant tissues as a mixture of bound, conjugated, and unconjugated residues, a method was developed that simultaneously extracted and hydrolyzed the majority of the flucarbazone-sodium-related residues to flucarbazone-sodium sulfonamide. The flucarbazone-sodium residues are simultaneously hydrolyzed to flucarbazone-sodium sulfonamide and extracted from the animal tissues and milk by heating with 8% trifluoroacetic acid (TFA) in water. The analysis of fat was complicated by the large quantities of lipids that were released during

hydrolysis and extraction. Therefore, the flucarbazon-sodium residues are extracted into acetonitrile/water (9:1) before they are hydrolyzed to flucarbazon-sodium sulfonamide. After conversion to flucarbazon-sodium sulfonamide, the residues are purified and partitioned. The residues are detected by lc/ms/ms and quantified against known amounts of deuterated internal standards. The LOQ in the tissues and milk is 0.020 and 0.005 mg/kg, respectively. The estimated LOD (3x highest background response) in the liver, muscle, and milk is 0.014 0.002 and 0.004 mg/kg, respectively. The recoveries of flucarbazon-sodium were determined in all tissues and milk after fortification with flucarbazon-sodium. The average recoveries of flucarbazon-sodium from liver fortified at 0.020 and 0.100 mg/kg were 104% and 100%, respectively. The average recoveries of flucarbazon-sodium from muscle fortified at 0.020 and 0.100 mg/kg were 97% and 102%, respectively. In milk the average recoveries of flucarbazon-sodium at fortifications of 0.005, 0.010, and 0.050 mg/kg were 111% (after correction for background in the control samples, the average recovery was 92%), 97% and 91%, respectively. An independent laboratory validation of the analytical method was performed. The method was successfully validated indicating that the method could be satisfactorily run by following the written procedure.

3. *Magnitude of residues.* Field trials were conducted with wheat at 36 locations to evaluate the quantity of flucarbazon-sodium residues in wheat forage, hay, straw, and grain following treatment with flucarbazon-sodium 70WG at a rate of 30 grams active ingredient/hectare (g ai/ha). The highest average field trial (HAFT) residue detected in forage, hay, and straw were 0.27, 0.08, and 0.04 mg/kg, respectively. Residues of flucarbazon-sodium were < 0.01 mg/kg in wheat grain.

B. Toxicological Profile

1. *Acute toxicity*—i. Flucarbazon-sodium is not toxic to fasted rats following a single oral administration. The oral lethal dose (LD₅₀) is > 5,000 mg/kg body weight (bwt) for males and females.

ii. Flucarbazon-sodium is not toxic to rats following a single dermal application. The dermal LD₅₀ is > 5,000 mg/kg bwt for males and females.

iii. An acute inhalation study with rats showed low toxicity with a 4-hour dust aerosol lethal concentration (LC₅₀) > 5,130 mg/m³ air for males and females.

iv. An eye irritation study in rabbits showed only very slight, reversible irritation.

v. A dermal irritation study in rabbits showed flucarbazon-sodium is not irritating to skin.

vi. Flucarbazon-sodium has no skin sensitizing potential under the conditions of the maximization test in guinea pigs.

2. *Genotoxicity.* The genotoxic action of flucarbazon-sodium was studied in bacteria and mammalian cells with the aid of various *in vitro* test systems (*Salmonella* microsome test, hypoxanthine guanine phosphoribosyl transferase (HGPRT) test with Chinese hamster V79 cells, cytogenetic study with Chinese hamster V79 cells and unscheduled DNA synthesis test) and in one *in vivo* test (micronucleus test). None of the tests revealed any evidence of a mutagenic or genotoxic potential of flucarbazon-sodium. The compound did not induce point mutation, DNA damage, or chromosome aberration.

3. *Reproductive and developmental toxicity.* In a 2-generation reproduction study, Wistar rats were administered dietary levels of flucarbazon-sodium at levels of 0, 50, 4,000, and 20,000/12,000 (dose reduction week 6). The no observed adverse effect levels (NOAELs) for reproductive parameters was established at 4,000 ppm, based on slight reduction in pup weight development at 12,000 ppm. The NOAELs established for parental males and females were 4,000 ppm and 50 ppm, respectively.

i. A developmental toxicity study was conducted with Sprague-Dawley rats via oral gavage of flucarbazon-sodium at levels of 0, 100, 300, and 1,000 mg/kg bwt/day on days 6 through 19 of gestation. There were no signs of maternal toxicity, embryotoxicity, fetotoxicity, or teratogenicity at the level of 1,000 mg/kg bwt/day. Therefore, the maternal and developmental NOAELs for rats were established at 1,000 mg/kg bwt/day, the limit dose for this study type.

ii. Himalayan rabbits were administered flucarbazon-sodium at levels of 0, 100, 300, 500, or 1,000 mg/kg bwt by oral gavage days 6 through 28 post coitum in a test for developmental toxicity. A maternal NOAEL of 100 mg/kg bwt/day was established based on clinical findings, bwt loss, decreased feed consumption, gastrointestinal changes, increased liver weights and fatty liver changes at 300 mg/kg bwt/day. The gestation rate NOAEL of 100 mg/kg bwt/day was based on one abortion (assessed as secondary due to maternal toxicity) at 300 mg/kg bwt/day. The NOAEL for fetal parameters of 300

mg/kg bwt/day was based on decreased fetal weights and delayed ossification at 500 mg/kg bwt/day. No teratogenic potential of flucarbazon-sodium was evident in rabbits.

iii. A 90-day feeding study with male and female B6C3F1 mice established a NOAEL of 7,000 (equivalent to 2,083 and 3,051 mg/kg bwt/day for males and females, respectively). The dose of 7,000 ppm was the highest dose tested (HDT).

4. *Subchronic toxicity*—i. A 28-day dermal rat study established a systemic NOAEL of 1,000 mg/kg bwt/day (the dermal limit dose) for males and females. The local dermal effects, skin thickening, seen at 1,000 mg/kg were regarded as a result of mechanical friction and of no toxicological relevance.

ii. A 90-day rat feeding study defined a NOAEL at 250 ppm (17.6 mg/kg bwt/day) for males and 1,000 ppm (101.7 mg/kg bwt/day) for females based on a decreased spleen weight in males at 1,000 ppm and on immunologic changes at 4,000 ppm in females.

iii. A 90-day feeding study with male and female B6C3F1 mice established a NOAEL of 7,000 ppm (equivalent to 2,083, and 3,051 mg/kg bwt/day for males and females, respectively). The dose of 7,000 ppm was the HDT.

iv. A 90-day dog feeding study at levels of 0, 1,000, 5,000, and 50,000 ppm established a NOAEL of 1,000 ppm (equivalent to 33.8 mg/kg bwt/day in males and 35.2 mg/kg bwt/day in females) based on decreased thyroxine levels and increased thyroxine-binding capacity, macroscopic and microscopic effects on the gastric mucosa and an eosinophilic hepatocellular cytoplasm occurring at 5,000 ppm and above. The liver enzyme induction at 1,000 ppm was assessed as a slight adaptive response in the detoxification process of flucarbazon-sodium but not as an adverse effect, due to the absence of clinical chemical changes that would indicate liver damage and due to the absence of any histopathologic liver changes at this dietary level.

5. *Chronic toxicity*—i. A 2-year chronic toxicity/oncogenicity study was conducted with male and female Wistar rats at dietary levels of 0, 2.5, 7.5, 125, and 1,000 mg/kg bwt. A NOAEL of 125 mg/kg was established based on increased food consumption (both sexes) and lower bwts (females) at 1,000 mg/kg. No carcinogenic potential was indicated.

ii. B6C3F1 mice were administered flucarbazon-sodium via the diet at levels of 0, 50, 1,000, and 7,000 ppm in a 2-year carcinogenicity study. The NOAEL was established in males and females at 1,000 ppm (equivalent to

274.5 and 458.9 mg/kg bwt/day, respectively) based on reduced bwt gain in both sexes and on increased feed consumption in males at the 7,000 ppm level. No carcinogenic potential was indicated.

iii. A 1-year feeding study in dogs at levels of 0, 200, 1,000, and 5,000 ppm established a NOAEL of 1,000 ppm for males (equal to 35.87 mg/kg bwt/day) based on decreased bwt development, increased ALAT- and ASAT-levels and slightly increased N-demethylase levels. The NOAEL of 200 ppm for females (equal to 7.43 mg/kg bwt/day) was based on elevated ALAT-, ASAT-, and GLDH-levels at 1,000 ppm in one female. Histopathology revealed no treatment-related effects.

6. *Animal metabolism.* Flucarbazon-sodium was metabolized via two pathways. The major pathway involved the hydrolysis of the urea linkage forming sulfonamide and N,O-dimethyltriazolinone. The sulfonamide was shown to be the major metabolite in the blood, fat, liver, and muscle at 4 to 6 hours following oral administration of [phenyl-UL-¹⁴C] flucarbazon-sodium. The sulfonamide was conjugated with glucuronic acid or acetate [sulfonamide N-glucuronide or N-acetyl sulfonamide] or hydroxylated and then conjugated with glucuronic acid to form hydroxysulfonamide-O-glucuronide prior to elimination in the urine. A minor pathway involved N-demethylation of flucarbazon-sodium to form N-desmethyl flucarbazon-sodium followed by hydrolysis to form the sulfonamide and O-methyltriazolinone. Demethylation of N,O-dimethyltriazolinone led to the formation of N-methyltriazolinone, O-methyltriazolinone, and ultimately, urazole; methyl urethane was probably formed from the cleavage of O-methyltriazolinone.

7. *Metabolite toxicology*—i. The animal and plant metabolite flucarbazon-sodium sulfonamide (trifluoromethoxysulfonamide) has a low acute oral toxicity ($LD_{50} > 2,000$ mg/kg bwt) in fasted rats.

ii. The plant metabolite flucarbazon-sodium sulfonamide lactate conjugate has no acute oral toxicity (NOAEL: 5,000 mg/kg bwt) in fasted rats.

iii. The plant metabolite flucarbazon-sodium sulfonamide alanine has no acute oral toxicity (NOAEL: 5,000 mg/kg bwt) in fasted rats.

iv. The soil metabolite O-desmethyl flucarbazon-sodium has an acute oral LD_{50} value in fasted male and female rats of $> 2,500 - < 5,000$ mg/kg bwt.

v. The plant, animal, and soil metabolite, MKH 10868 (flucarbazon-sodium sulfonic acid Na-salt), has no

acute oral toxicity ($LD_{50} > 5,000$ mg/kg bwt) in fasted male and female rats.

vi. MKH 10868 was considered non-mutagenic with and without S9 mix in the plate incorporation as well as in the preincubation modification of the *Salmonella*/microsome test.

8. *Endocrine disruption.* There is no evidence to suggest that flucarbazon-sodium has an effect on the endocrine system. Studies in this data base include evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following short- and long-term exposure. These studies revealed no endocrine effects due to flucarbazon-sodium.

9. *Other studies*—i. An acute neurotoxicity screening study in rats established an overall NOAEL for males and females of 500 mg/kg based on transient neurobehavioral effects. Evidence of toxicity was only slight at a limit dose of 2,000 mg/kg and complete recovery occurred within 7 days following treatment.

ii. A subchronic neurotoxicity screening study in rats established an overall NOAEL of 2,000 ppm for males (equal to 147 mg/kg bwt/day) and 20,000 ppm (equal to 1,730 mg/kg bwt/day) for females based on a slight decrease in bwt and food consumption. The NOAEL for microscopic lesions was 20,000 ppm for males and females, the highest dose tested (HDT). There was no evidence of neurotoxicity at any dietary level.

iii. A plaque-forming-cell assay (to investigate immunotoxicological potential) was performed on rats after a 4-week dietary exposure. The NOAEL of 20,000 ppm (equivalent to 2,205, or 2,556 mg/kg bwt/day in males or females, respectively) was based on the lack of specific effects in the HGT.

iv. The immunotoxicity potential of flucarbazon-sodium was additionally investigated in antibody plaque-cell forming assays and in assays examining splenic T-cells, B-cells, and NK-cells after 4-week dietary administrations in male and female rats at levels up to and including 1,000 mg/kg bwt/day. There was no statistically significant effect on the humoral immune system and no effects on splenic cell populations, cell-mediated immune response or the innate immune response in males or females. The NOAEL for immunotoxicity from these studies was 1,000 mg/kg bwt/day, the immunotoxicity limit dose.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food.* Estimates of chronic dietary exposure to residues of flucarbazon-sodium

utilized the proposed tolerance-level residues for wheat forage, wheat hay, wheat straw, wheat grain, meat, liver, and milk of 0.30, 0.10, 0.05, 0.01, 0.01, 0.60, and 0.005 ppm, respectively. Other assumptions were that 100% of the target crop would be treated with flucarbazon-sodium and that no loss of residue would occur due to processing and or cooking. A reference dose (RfD) of 0.04 mg/kg/day was assumed based on the NOAEL of 4 mg/kg/day from the 2-generation study in Wistar rats. A safety factor of 100 was used based on interspecies extrapolation (10x) and intraspecies variability (10x). Using these conservative assumptions, dietary residues of flucarbazon-sodium contribute 0.0002 mg/kg/day (0.5% of the RfD) for children 1-6 years, the most sensitive sub-population. For the U.S. population the exposure was 0.00008 mg/kg/day (0.2% of the RfD). For acute dietary exposure, the same conservative assumptions were made. Based on the NOAEL of 500 mg/kg/day from the acute neurotoxicity study, the calculated MOE's for acute risk from flucarbazon-sodium and its degradates for the general U.S. population was 386,108 and for the most exposed subgroup, children 1-6 years the margin of exposure (MOE) was 141,262. These figures are well above 100 which is the level of concern based on interspecies extrapolation (10x) and intraspecies variability (10x).

ii. *Drinking water.* Given the post-emergence application pattern, low use rates and rapid soil degradation of flucarbazon-sodium, the risk of ground and surface water contamination and exposure via drinking water is negligible. The surface water model generic expected environment concentration (GENEEC) and the ground water model SCI-GROW were used to determine whether drinking water from surface or ground water sources represented a worst-case exposure scenario. These models predict residues of flucarbazon-sodium would be higher in surface water. Assuming a worst-case GENEEC scenario where residues of flucarbazon-sodium occur in surface water used for drinking water at the highest predicted acute and chronic concentrations, the risk from exposure to residues of flucarbazon-sodium are well within EPA's acceptable limits.

The GENEEC model predicted an acute surface water concentration of flucarbazon-sodium of 1.22 μ g/L. Assuming a 70 kg adult drinks 2 liters/day containing 1.22 μ g/L, the acute exposure would be 0.000349 mg/kg/day for adults. Assuming a 10 kg child drinks 1 liter/day containing 1.22 μ g/L, the exposure would be 0.000122 mg/kg/day.

day. Based on the the NOAEL of 500 mg/kg/day from the acute oral neurotoxicity screening study in rats and assuming a safety of 100 (10x for interspecies variability and 10x for interspecies extrapolation), the MOE for adults of 143,000 and for children of 41,000 do not exceed EPA's level of concern for adults or children. This assessment is based on the GENECC highest predicted acute concentration of flucarbazon-sodium in drinking water using worst-case assumptions.

Using GENECC, the highest predicted chronic concentration of flucarbazon-sodium was 1.14 µg/L. Assuming a 70 kg adult consumes 2 L of water per day containing 1.14 µg/L of flucarbazon-sodium residues for a period of 70 years, less than 0.04% of the RfD was consumed from residues of flucarbazon-sodium in surface water used for drinking water (worst-case scenario). For a 10 kg child drinking 1 L of water per day containing 1.14 µg/L of flucarbazon-sodium residues only 0.15% of the RfD was consumed by drinking water.

2. *Non-dietary exposure.* There are no current non-food uses for flucarbazon-sodium registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. No non-food uses are proposed for flucarbazon-sodium. No non-dietary exposures are expected for the general population.

D. Cumulative Effects

Flucarbazon-sodium falls into the category of sulfonamide herbicides. There is no information to suggest that any of this class of herbicides has a common mechanism of mammalian toxicity or even produce similar effects so it is not appropriate to combine exposures of flucarbazon-sodium with other herbicides. Bayer Corporation is considering only the potential risk of flucarbazon-sodium.

E. Safety Determination

1. *U.S. population.* As presented previously, the exposure of the U.S. general population to flucarbazon-sodium is low, and the risks, based on comparisons to the reference dose, are minimal. The margins of safety from the use of flucarbazon-sodium are well within EPA's acceptable limits. Bayer Corporation concludes that there is a reasonable certainty that no harm will result to the U.S. population from aggregate exposure to flucarbazon-sodium residues.

2. *Infants and children.* The complete toxicological data base including the developmental toxicity and 2-generation reproduction studies were considered in assessing the potential for additional

sensitivity of infants and children to residues of flucarbazon-sodium. The developmental toxicity studies in rats and rabbits revealed no increased sensitivity of rats or rabbits to *in-utero* exposure to flucarbazon-sodium. The 2-generation reproduction study did not reveal any increased sensitivity of rats to *in-utero* or postnatal exposure to flucarbazon-sodium. Furthermore, none of the other toxicology studies revealed any data demonstrating that young animals were more sensitive to flucarbazon-sodium than adult animals. The data taken collectively clearly demonstrate that application of a Food Quality Protection Act (FQPA) uncertainty factor for increased sensitivity of infants and children is not necessary for flucarbazon-sodium.

F. International Tolerances

There are currently no international (Codex) tolerances established for flucarbazon-sodium. It is not currently registered in any other countries. There are no harmonized Maximum Residue Levels (MRLs) at the European Union level at present. Petitions for MRLs for flucarbazon-sodium in/on wheat, meat, milk, and liver have been submitted to the Pesticide Management Regulatory Agency in Canada.

[FR Doc. 99-26335 Filed 10-7-99; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[FRL-6454-3]

Peer Reviews Associated With the Guide for Industrial Waste Management

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: On June 11, 1999, the EPA released for public comment a draft guidance document entitled "Guide for Industrial Waste Management." The purpose of the draft voluntary Guide is to assist facility managers, State and Tribal environmental managers, and the public in evaluating and choosing protective practices regarding the management of non-hazardous industrial wastes. The Guide is available on a CD-ROM format. The CD-ROM also contains user-friendly ground-water and air models. The ground-water model is called the Industrial Waste Evaluation model, while the air model is called the Industrial Waste Air Model. When the draft Guide, CD-ROM, and models were noticed for comment in June, the EPA stated that both models

would undergo peer review by independent experts. These peer reviews have been completed and the EPA is making the comments developed by the peer reviewers publicly available by this notice. Persons wishing to comment on the models may wish to review the independent peer review comments.

DATES: Public comments on the draft "Guide for Industrial Waste Management", the CD-ROM, and the models are due on or before December 13, 1999.

ADDRESSES: Any public comments received to date on the draft Guide, the CD-ROM, or the models and these peer review comments are available for viewing in the RCRA Information Center (RIC), located at Crystal Gateway I, First Floor, 1235 Jefferson Davis Highway, Arlington, VA. The RIC is open from 9 a.m. to 4 p.m., Monday through Friday, excluding Federal holidays. To review docket materials (docket number F-1999-IDWA-FFFFF), it is recommended that the public make an appointment by calling 703-603-9230. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost \$0.15 per page. The index and some supporting material are available electronically.

These peer review comments are also available on the Internet. Follow these instructions to access the information electronically.

WWW: <http://www.epa.gov/industrialwaste>

FTP: <ftp://ftp.epa.gov>

Login: anonymous

Password: your Internet address

Files are located in pub/epaowner.

FOR FURTHER INFORMATION CONTACT: For general information and copies of the Ground-Water peer review comments or the Air peer review comments, contact the RCRA Hotline at 800-424-9346 or TDD 800-553-7672 (hearing impaired). In the Washington, DC, metropolitan area, call 703-412-9810 or TDD 703-412-3323. A limited number of paper copies of the peer review comments are available for distribution. These are available on a first-come first-serve basis.

Questions regarding any aspect of the Ground-Water peer review comments may be directed to Virginia Colten-Bradley (703-308-8613) while questions regarding the Air peer review comments should be directed to Charlotte Bertrand (703-308-9053). Questions for these individuals can also be e-mailed to their e-mail address: [colten-](mailto:colten-bradley.virginia@epamail.epa.gov)

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