absorbed amount were calculated using methods recommended by EPA.

ii. *Per cutaneous absorption from dandruff shampoo.* Information on the absorption of zinc pyrithione from the use of dandruff shampoos was obtained from FDA's docket supporting formal rulemaking leading to a monograph establishing conditions under which over-the-counter drug products for the control of dandruff, seborrheic dermatitis, and psoriasis are ''generally recognized as safe and effective.'' In a study involving 30 human subjects, a shampoo containing radio labeled zinc pyrithione (^{14}C in the 2- and 6-positions) was applied in both a sink shampoo procedure (head exposure only) and a shower shampoo (total body exposure). All wash water and towels, etc. were retained and biological samples of skin, hair, blood and urine collected for a period of ten days following application. Recovery of radio label was essentially 100%.

An average upper level systemic load of zinc pyrithione was calculated from the urinary output data to be 1 µg/kg/day. Absorption was greatest for subjects with seborrheic dermatitis, and the absorbed material was derived from solid zinc pyrithione deposited on the head, rather than from the soluble zinc pyrithione complexed with detergent in the commercial shampoo.

For this aggregate exposure analysis, in the realistic adverse case it was assumed that all persons have chronic dandruff and use a dandruff shampoo every day, absorbing the maximum dose of the active ingredient. In the worst case and exaggerated worst case, it is assumed that all persons have seborrheic dermatitis and use the dandruff shampoo every day for life (i.e., the treatment has no curative effect on the seborrheic dermatitis). It was also assumed that infants and small children do not use dandruff shampoo on a regular basis. Using these assumptions, exposure from use of zinc pyrithione in dandruff shampoo was found to be three orders of magnitude higher than exposure from all other uses of zinc pyrithione.

EPA assumed 3% dermal absorption of zinc pyrithione for non-dietary exposures. In contrast, for assessments involving dermal exposure to sodium pyrithione, the Agency has used an absorption value of 0.1% in risk assessments. In its assessment of aggregate risk for the sponge, EPA did not consider exposures through the use of dandruff shampoos containing zinc pyrithione.

D. Cumulative Effects

It is 3M's position that zinc pyrithione should not be expected to have any effects cumulative with any other substances. It is EPA's position that the Agency ''does not at this time have the methodology to resolve scientific issues concerning common mechanisms of toxicity.'' Hence, for the time being EPA has not assumed that zinc pyrithione has a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population.* EPA has established an oral NOAEL for zinc pyrithione of 0.5 mg/kg/day based upon a chronic rat study. This value is confirmed in the NOAEL for a subchronic neurotoxicity study and a 2–generation reproduction study. Using a substantial number of high exposure assumptions, the absolute upper limit exposure to zinc pyrithione was calculated for all uses in the realistic adverse case presented above. When exposure to zinc pyrithione through daily lifetime use of dandruff shampoo is included, a minimum adult MOE of 128,000 was found, with total aggregate exposure at 7.81×10^{-4} mg/kg/day. The exposure from the assumed daily use of dandruff shampoo is huge compared to the aggregate adult exposure from use of zinc pyrithione in sponges. Total adult exposure (oral + dermal) not counting shampoo is 1.20×10^{-6} mg/kg/day. The maximum possible daily intake of zinc pyrithione for all uses other than shampoo was calculated to yield an aggregate adult MOE of over 400,000, assuming an individual does not routinely (i.e., daily) use dandruff shampoo (see Table 2).

2. *Infants and children.* Aggregate exposure to children was determined by adjusting the assumptions used for adults. The assessment was designed to examine exposure for non-nursing infants, the subpopulation that most often is calculated to have the highest exposure to pesticides in the diet in EPA's own assessments for most chemicals.

In this assessment, it was assumed that the dietary consumption of food and water by infants was 2.5 times more per kg of body weight than for adults. Because a large portion of an infant's diet is liquids, the additional assumption was made that a smaller portion of the diet for infants than adults would be exposed to counters and other surfaces washed with dishwater. Therefore, absorption of zinc pyrithione from washed surfaces would be expected to be less. Non-nursing infants are also not expected to wash dishes or use dandruff shampoo on a regular basis, eliminating these routes of exposure. Maximum possible aggregate dietary exposure for non-nursing infants is calculated to be 1.92×10^{-6} mg/kg/day, yielding an MOE of 260,000, far in excess of the 1,000 fold safety factor applied by EPA in its assessment to calculate an RfD. The use of sponges for teething for a lifetime, which EPA included in its assessments, was not considered.

F. International Tolerances

No international tolerances have been issued for the use of zinc pyrithione as a preservative in cellulose sponges.

[FR Doc. 00–24210 Filed 9–19–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–974; FRL–6742–7]

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 control number PF–974, must be received on or before October 20, 2000.

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**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–974 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James Tompkins, Herbicide Branch, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5697; e-mail address: tompkins.jim@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:

Categories	NAICS	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 under **FOR FURTHER INFORMATION CONTACT**.

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,'' ''Regulations and Proposed Rules,'' 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–974. 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–974 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, 1200 Pennsylvania Ave., NW., 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 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–974. 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 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 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 a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic 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 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: September 11, 2000.

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 view of the petitioners. 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.

Valent U.S.A. Corporation

PP 9F6044

EPA has received a pesticide petition (PP 9F6044) from Valent U.S.A. Corporation at 1333 North California Boulevard, Suite 600, Walnut Creek, CA 94596–8025 as agent for K-I Chemical U.S.A. Inc. proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of bispyribac-sodium, sodium 2,6-bis [(4,6-dimethoxypyrimidin-2yl)oxy]benzoate in or on the raw agricultural commodities (RAC) rice grain, and rice straw at 0.02 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

Summary. Radiocarbon plant and animal metabolism studies have demonstrated that the residue of concern is best defined as parent, bispyribac-sodium. Practical, validated enforcement residue methodology is available to analyze all appropriate matrices for bispyribac-sodium residue with limit of quantitation (LOQ) of 0.02 ppm, adequate to enforce all proposed tolerances. The magnitude of residues of bispyribac-sodium has been evaluated in rice grain, rice straw, and in the appropriate processed products. Finite residues in fed ruminants, and poultry are not expected. These studies are adequate to support appropriate tolerances and dietary risk analyses.

1. *Plant and animal metabolism*. Rice plants extensively metabolize bispyribac-sodium and the terminal residues in the RAC are low. Application of radio labeled bispyribac-sodium to 5–6 leaf rice resulted in total radiocarbon residues (TRR) of 0.007 and 0.021 ppm (bispyribac-sodium equivalents) in mature rice grain and 0.116 and 0.274 ppm in mature rice straw in the [pyrimidine-2–^{14}C] and [U–^{14}C-benzene] metabolism studies, respectively.

No parent or parent related metabolites were detected in grain with much of the grain radioactivity incorporated into starch. Bispyribac-sodium was detected in straw at 0.010 and 0.042 ppm in the [pyrimidine-2–^{14}C] and [U–^{14}C-benzene] metabolism studies, respectively. The maximum residue values for the metabolites that were found in straw are:

- BX–180 (0.024 ppm)
- Me2BA (0.006 ppm)
- DesMe–180 (0.002 ppm)
- DesMe–2023 (0.001 ppm)

No single metabolite in rice straw was greater than 10% of the total radiocarbon residues, and all of the aglycones identified in rice straw were also identified in the rat metabolism study.

Bispyribac-sodium is extensively metabolized and rapidly excreted by lactating goats. Treatment was at highly exaggerated feeding levels (11 ppm) relative to the proposed 0.02 ppm rice grain and straw tolerances. These study feeding levels correspond to more than 650 times the tolerance level dietary burden for goats (using cattle diet values). Even at this exaggerated treatment level the total radioactive residue TRR concentrations in milk were extremely low (0.002 ppm, bispyribac-sodium equivalents).

The edible tissue concentrations (bispyribac-sodium equivalents) indicate the very low bioaccumulation potential of bispyribac-sodium residues:

- Muscle (0.002 ppm)
- Fat (<0.003 ppm)
- Kidney (<0.041 ppm)
- Liver (<0.204 ppm)

The metabolites identified in goat liver and kidney were:

- Glucuronide conjugates of bispyribac-sodium
- Me_2BA
- BX–180
- 2,6–DBA
- Me_2BA
- DesMe–180

All the metabolites are polar and easily excreted. Based on the low concentrations of metabolites in goat milk and tissues from the exaggerated doses used in the ruminant metabolism study, residues expected in milk and edible tissue from a tolerance level (1X) feed intake of bispyribac-sodium are extremely low (<<0.02 ppm). Thus, there is no reasonable expectation of finite secondary residues in meat, meat by-products, or milk, and tolerances are not necessary.

Laying hens were treated with radiocarbon labeled bispyribac-sodium in their diets at 12 ppm. This high feeding level represents 600 times the maximum theoretical dietary burden. The TRR concentrations in radiocarbon bispyribac-sodium equivalents in most tissues and eggs were very low—0.009 ppm in muscle, 0.016 ppm in fat and eggs. TRR concentration in hen liver was much higher, 4.98 ppm, virtually all of which was unconjugated bispyribac (4.82 ppm). Based on the low concentrations of metabolites in eggs and most tissues from the exaggerated doses used in the hen metabolism study, residues anticipated in eggs, and edible tissue from a tolerance level (1X) feed intake of bispyribac-sodium are extremely low (<<0.005 ppm). In chicken liver, the tissue with the highest radiocarbon content, maximum theoretical residues are still well below the enforcement LOQ of 0.02 ppm. Finite residues were not detected in rice grain samples from any of the field residue trials. The limit of detection (LOD) of the method was determined by statistical analysis of instrument responses in untreated versus treated field samples. The LOD for rice grain and bran is 0.001 ppm with 0.005 ppm for hulls. Even at 2X application rates, residues in rice grain were not detected. Assuming anticipated residues in rice derived poultry feed at half the LOD from the field residue samples, gives a maximum anticipated dietary burden for poultry of 0.0008 ppm, and maximum residues in poultry liver of 0.0003 ppm. Thus, there is no reasonable expectation of finite secondary residues in meat, meat by-products or eggs, and tolerances are not necessary.

2. *Analytical method*. Practical analytical methods for detecting and measuring levels of bispyribac-sodium have been developed and validated in/on the RAC, rice grain, and rice straw; processing fractions polished rice, rice hulls, and rice bran; and environmental samples. The extraction methodology has been validated using aged radio chemical residue samples from ^{14}C-metabolism studies. Bispyribac-sodium is a benzoic acid salt. To allow gas/liquid chromatography, the residues are methylated and measured as the methyl

ester of the benzoic acid. The analytical methods have been validated in rice, rice straw, and environmental matrices at an independent laboratory. The LOQ of bispyribac-sodium in the enforcement method is 0.02 ppm which will allow monitoring of food with residues at the levels proposed for the tolerances. Because the enforcement methodology uses a different methylating agent, the methodology used for analysis of the field residue trials had a LOQ of 0.01 ppm, a defined LOD of 0.005 ppm, and a statistical LOD of 0.001 ppm in rice grain.

3. *Magnitude of residues*—i. *Crop*. Data from sixteen (16) field trials in rice conducted in 1996 and 1997 in six (6) states throughout the rice growing regions of the U.S. show that at the proposed maximum total seasonal application rate (24 g active ingredient/Acre (ai/a), 0.053 lb ai/a) all measured residue values in rice grain were less than 0.005 ppm (n = 32). Data from three trials at a 2X rate (48 g ai/a) also all showed measured residue in the six samples of rice grain to be less than 0.005 ppm (n = 6). Nine (9) out of thirty–two (32) samples of rice straw from the sixteen 1X field sites showed finite residues of bispyribac-sodium. The average of the nine finite residues in rice straw is 0.007 ppm (n = 9, σ_{n-1} = 0.003 ppm) with a maximum value of 0.013 ppm. There were no finite residues (<0.005 ppm) observed in the six samples of rice straw from the 2X treatment rates. The processing study in rice using grain from a plot treated at 2X demonstrated that bispyribac-sodium was not detectable (<0.005 ppm) in rice grain, and did not concentrate (<0.005 ppm) in polished rice, rice hulls, or rice bran. No separate tolerances are necessary for processed rice products. The actual limit of detection of the analytical methodology used for all these studies was 0.001 ppm in rice grain and bran and 0.005 ppm in rice hulls. Finite residues were not detected in any treated rice grain sample even at exaggerated (2X) rates, or in any processed fraction. Because of the reduced sensitivity of the enforcement methodology, tolerances are proposed in rice grain and straw at 0.02 ppm. The field residue data indicate that the proposed tolerances are more than adequate to support bispyribac-sodium use on rice.

ii. *Secondary residues*. Using proposed tolerances to calculate the maximum feed exposure to fed animals, and using the generally very low potential for residue transfer demonstrated in the milk goat and laying hen metabolism studies, quantifiable secondary residues (>0.02 ppm) of bispyribac-sodium in animal tissues, milk, and eggs are not expected. Poultry liver is the tissue with the highest treatment to residue ratio. Using anticipated residues in poultry feed from rice, and rice products derived from the limit of detection of the field residue methodology, the potential residues in poultry liver would be a maximum of 0.0003 ppm. This is 60–fold below the RAC enforcement LOQ. The refore, tolerances are not proposed for secondary residues in any fed animal commodity.

iii. *Rotational crops*. Rotational crops planted 28 and 48 days after soil treatment with the 1X rate of bispyribac-sodium all showed radiocarbon equivalent residues of less than 0.01 ppm at normal harvest. This study demonstrates that bispyribac-sodium is not adsorbed by following crops, and that no rotational tolerances or labeling restrictions are necessary.

iv. *Irrigated crops*. Tomatoes, table beets, and bok choy were sprinkler irrigated with water containing 0.07 ppm bispyribac-sodium. No residues were detected in any sample of tomato fruit or table beet roots. Immature whole beet plants, mature beet tops, and bok choy leaves contained 0.015 to 0.025 ppm. Bispyribac-sodium in the soil from treated plots did not exceed 0.012 ppm. Sprinkler application of water containing high concentrations of bispyribac-sodium (the highest time zero concentration in paddy water from the aquatic field dissipation studies) led to low residues in leafy crops. This study demonstrates that bispyribac-sodium is not adsorbed by irrigated crops and thus tolerances or use restrictions are not necessary.

B. Toxicological Profile

Summary. A full battery of toxicology testing including studies of acute, chronic, oncogenicity, developmental, mutagenicity, and reproductive effects has been completed for bispyribac-sodium. The acute toxicity of bispyribac-sodium is low by all routes. Bispyribac-sodium is not a developmental or reproductive toxicant, and is not mutagenic or oncogenic. The toxicology reports for bispyribac-sodium have not yet been reviewed by EPA and thus, the Agency has not yet established toxic endpoints of concern, specifically chronic and acute oral toxicity endpoints for the compound. For the purpose of chronic dietary risk analysis, Valent proposes 0.017 milligrams/kilograms (mg/kg) body weight (bwt/day) as a chronic reference dose (RfD). This proposed RfD is based on a chronic endpoint of 1.7 mg/kg bwt/day no observed adverse effect level (NOAEL) for females from the two year oncogenicity feeding study in mice, and an uncertainty factor of one hundred. Bispyribac-sodium is of very low toxicity in all short-term evaluations, however, for the purposes of discussion, Valent proposes to use the NOAEL for maternal toxicity from the rabbit developmental toxicity study of 100 mg/kg bwt/day as an acute oral toxic endpoint. Valent is unable to identify toxicity endpoints of concern for acute, short term or chronic human exposures by any route other than oral.

1. *Acute toxicity*. Bispyribac-sodium technical produces very low to slight toxicity following oral, dermal or inhalation acute exposures. Bispyribac-sodium is slightly irritating to the eye, is not irritating to the skin and does not cause dermal sensitization in guinea pigs. Technical bispyribac-sodium and its formulated product should be classified in toxicity category III.

2. *Genotoxicty*. Bispyribac-sodium does not present a genetic hazard. Bispyribac-sodium technical was negative in the following genotoxicity assays:

- Reverse mutation (Ames).
- Chinese hampster ovary (CHO), chromosomal aberration (*in vitro*).
- Unscheduled DNA synthesis.
- Micronucleus in mice (*in vivo*).

In a bacterial DNA repair assay with *Bacillus subtilis*, bispyribac-sodium was potentially damaging to DNA. Overall, however, it is unlikely that bispyribac-sodium presents a genetic hazard.

3. *Reproductive and developmental toxicity*. Bispyribac-sodium is not a developmental or reproductive toxicant. Developmental toxicity studies have been performed in rats and rabbits, and multi-generational effects on reproduction were tested in rats.

In the developmental toxicity study conducted with rats, bispyribac-sodium. technical was administered by gavage at levels of 0, 100, 300, and 1,000 mg/kg bwt/day during gestation days 6–15. All animals were necropsied on gestation day 20 followed by a teratologic examination of the fetuses. One–half of the fetuses were examined for skeletal malformations and one–half for visceral malformations. There were no deaths in any of the groups. There were no treatment-related observations at necropsy. No other biologically relevant differences were noted. The incidence of fetal malformations and developmental variations was comparable with the controls. The maternal toxicity observed at 1,000 mg/kg bwt/day consisted of ano-genital staining. The maternal NOAEL was 300 mg/kg bwt/day and the developmental NOAEL was 1,000 mg/kg bwt/day.

In the developmental toxicity study conducted with rabbits, technical bispyribac-sodium was administered by gavage at levels of 0, 30, 100, and 300 mg/kg bwt/day during gestation days 6–18. Does were sacrificed on day 28. An external, visceral and skeletal examination was performed on all fetuses. Maternal toxicity included one death, two premature deliveries, and slight depression of body weight gain and food consumption in the high dose group. There were no specific changes noted at necropsy and no effects on fetal mortality, number of live fetuses or fetal weights. The NOAEL for maternal toxicity was 100 mg/kg bwt/day, and for developmental toxicity the NOAEL was 300 mg/kg bwt/day.

A two-generation reproduction study in rats was conducted with bispyribac-sodium technical at doses of 0, 20, 1,000, and 10,000 ppm. Systemic adult toxicity included decreased bwt gain and food consumption; increased liver weight; and histopathological changes in the liver and bile duct. The growth of the F1 and F2 offspring was inhibited at 10,000 ppm. The NOAELs for systemic adult toxicity and offspring developmental parameters were 20 and 1,000 ppm, respectively. No effects on reproduction were produced at 10,000 ppm, the highest dose tested.

4. *Subchronic toxicity*. Subchronic oral toxicity studies conducted with bispyribac-sodium technical in the rat and dog indicate a low level of toxicity.

Bispyribac-sodium technical was tested in rats at dose levels of 0, 100, 1,000, 10,000, and 20,000 ppm in the diet for 13 weeks. Effects observed at higher doses included organ weight changes; histopathological changes in the liver, and the bile duct; increased serum GOT, GPT, ALP, and BUN; various alterations in hematology parameters; and reduced food consumption, food efficiency and bwt gain. The NOAEL was 100 ppm (7.2 mg/kg bwt/day) in males and 1,000 ppm (79.9 mg/kg bwt/day) in female rats.

Bispyribac-sodium technical was also tested in dogs for 13 weeks at doses of 0, 30, 100, and 600 mg/kg bwt/day. Vomiting, salivation, and loose stools were observed in animals exposed to 600 mg/kg bwt/day. Histopathological changes in the liver and bile ducts were also noted in males at 600 mg/kg bwt/day. The NOAEL was 100 mg/kg bwt/day.

In a 21–day dermal toxicity study in rats, there was essentially no significant indication of toxicity. The NOAEL for this study was the highest dose tested (HDT) of 1,000 mg/kg bwt/day (the limit dose).

5. *Chronic toxicity*. Bispyribac-sodium technical has been tested in chronic studies with dogs, rats, and mice.

Bispyribac-sodium technical is not a carcinogen. Studies with bispyribac-sodium technical in rats and mice have shown that repeated high dose exposures produced decreased bwt gain, changes in hematological, blood biochemistry values, and histopathological lesions of the liver, and bile duct in rats; and reduced bwt gain, decreased liver weight, increased kidney weight, and histopathological changes in the liver in mice; but did not produce cancer in test animals. No oncogenic response was observed in a rat 2–year chronic feeding/oncogenicity study or in the two–year feeding oncogenicity study in mice.

Bispyribac-sodium technical was tested in rats for 2 years at doses of 0, 20, 200, 3,500, and 7,000 ppm in males and 0, 20, 200, 5,000, and 10,000 ppm in females. Effects observed at higher doses included decreased bwt gain, changes in hematological and blood biochemistry values, and histopathological lesions of the liver, and bile duct. No neoplastic lesions were observed. The NOAEL was 200 ppm (male 10.9 mg/kg b.w./day, female 13.9 mg/kg bwt/day).

Bispyribac-sodium technical was tested in mice for 2 years at doses of 0, 10, 100, 2,500, and 5,000 ppm. Effects observed at higher doses included reduced bwt gain, decreased liver weight, increased kidney weight, and histopathological changes in the liver. No neoplastic lesions were observed. The NOAEL was 100 ppm (14.1 mg/kg bwt/day) in males and 10 ppm (1.7 mg/kg bwt/day) in females based on organ weight changes.

A 52–week chronic toxicity study of bispyribac-sodium technical was conducted in dogs at doses of 0, 10, 100, and 750 mg/kg bwt/day. Effects observed at higher doses included salivation, vomiting, and loose stools; increased liver weight; and histopathological changes in the bile duct. The NOAEL was 10 mg/kg bwt/day.

6. *Mechanistic studies*. Mechanistic studies were undertaken to investigate the histopathological effects on the common and, intralobular bile duct observed in the long-term rat studies. Similar histopathological effects were not noted in the chronic studies with the mouse or the dog, which, like the human, have an intact gall bladder. The results suggest that an increased production and flow of bile acids in the rat may relate to the histopathological changes observed.

7. *Animal metabolism*. The absorption, tissue distribution, metabolism, and excretion of ^{14}C-labeled bispyribac-sodium were studied in rats. Following administration to the rodent, the majority of bispyribac-sodium is excreted into the feces via the bile. The majority of material excreted in the feces is either unchanged parent compound or its desmethylated derivative. Approximately half of the material excreted into the urine was also unchanged parent material. The half-life of bispyribac-sodium in rats is between 28 to 30 hours. These data show that bispyribac-sodium is readily excreted but not extensively metabolized in the rodent. Very low concentrations of radiocarbon in tissues over time indicate that the potential for bioaccumulation is minimal. There were no significant sex or dose-related differences in excretion or metabolism. Animal metabolites are the same as those detected in rice and in the environment.

8. *Metabolite toxicology*. Studies show that bispyribac-sodium is extensively metabolized by rice. Therefore, a series of acute oral and genetic toxicity tests were performed to investigate the potential toxicity of the primary rice plant degradates. None of these tests indicates any acute or genetic hazard from these metabolites. Because parent and metabolites are not retained in the body, the potential for acute toxicity from *in situ* formed metabolites is low. The potential for chronic toxicity is adequately tested by chronic exposure to the parent at the maximum tolerance dose (MTD) and consequent chronic exposure to the internally formed metabolites.

9. *Endocrine disruption*. No special studies to investigate the potential for estrogenic or other endocrine effects of bispyribac-sodium have been performed. However, as summarized above, a large and detailed toxicology data base exists for the compound including studies in all required categories. These studies include acute, sub-chronic, chronic, developmental, and reproductive toxicology studies including detailed histology and histopathology of numerous tissues, including endocrine organs, following repeated or long term exposure. These studies are considered capable of revealing endocrine effects, and the results of all of these studies show no evidence of any endocrine-mediated effects and no pathology of the endocrine organs. Consequently, it is concluded that bispyribac-sodium does not possess endocrine disrupting properties.

C. Aggregate Exposure

1. *Dietary exposure*. The toxicology data base for bispyribac-sodium has not yet been reviewed by EPA and thus, the Agency has not yet established toxic endpoints of concern, specifically chronic and acute oral toxicity endpoints for the compound. As discussed above, for the purpose of chronic dietary risk analysis, Valent proposes 0.017 mg/kg bwt/day as a chronic RfD, including an uncertainty factor of one hundred. Bispyribac-sodium is of very low toxicity in all short-term evaluations. Valent proposes to use 100 mg/kg bwt/day as an acute oral toxic endpoint. Valent is unable to identify toxicity endpoints of concern for acute, short term or chronic human exposures by any route other than oral.

i. *Food— Chronic*. A Tier I chronic dietary exposure and risk analysis for bispyribac-sodium residues was calculated using tolerance level residues for the U.S. population and 26 population subgroups. The results from several representative subgroups are listed below in Table. Chronic dietary exposure was at or below 0.16% of the RfD. Generally, the Agency has no cause for concern if total residue contribution for published and proposed tolerances is less than 100% of the RfD.

TABLE 1.—TIER I CALCULATED CHRONIC DIETARY EXPOSURES TO THE TOTAL U.S. POPULATION AND SELECTED SUB-POPULATIONS TO TOLERANCE LEVEL BISPYRIBAC-SODIUM RESIDUES IN FOOD

Population subgroup	Exposure (mg/kg bwt/day)	Percent of RfD
Total U.S. population (all seasons)	0.000006	0.035
Non-hispanic other than black or white	0.000027	0.159
Females (20+ years, not preg. or nursing	0.000004	0.024
Children (1–6 Years)	0.000011	0.065
All Infants (<1 Year Old)	0.000016	0.094
Non-Nursing Infants (<1 Year Old)	0.000018	0.106
Nursing Infants (<1 Year Old)	0.000009	0.053

Acute. A Tier I acute dietary exposure and risk analysis for bispyribac-sodium residues was calculated using tolerance level residues and 100% of the crop treated for the U.S. population, females (13 +), and five infant and child subgroups. The calculated exposures and margins of exposure (MOE) for the higher exposed proportions of the subgroups are listed below in Table 2. In all cases, margins of exposure are very large, and for the 95th percentile, all exceed 1–million.

TABLE 2.—TIER I CALCULATED ACUTE DIETARY EXPOSURES TO THE TOTAL U.S. POPULATION AND SELECTED SUB-POPULATIONS TO TOLERANCE LEVEL BISPYRIBAC-SODIUM RESIDUES IN FOOD (PER-CAPITA DAYS)

Population subgroup	95th Percentile		99.9th Percentile	
	Exposure (mg/kg bwt/day)	MOE	Exposure (mg/kg bwt/day)	MOE
U.S. population	0.000031	>1,000,000	0.000152	787,000
Females (13+)	0.000023	>1,000,000	0.000097	>1,000,000
Children 1–6	0.000061	>1,000,000	0.000249	402,000
Children 7–12	0.000041	>1,000,000	0.000127	787,000
All Infants	0.000083	>1,000,000	0.000267	375,000
Nursing Infants (<1)	0.000044	>1,000,000	0.000235	426,000
Non-Nursing Infants (<1)	0.000087	>1,000,000	0.000268	373,000

ii. *Drinking water*. Since bispyribac-sodium is applied outdoors to rice, the potential exists for bispyribac-sodium or its metabolites to reach ground or surface water that may be used for drinking water. Bispyribac-sodium will not move to ground water because of the nearly complete lack of leaching from rice paddies along with the low use rate therefore a SCI-GRO estimation of groundwater contamination was not performed. To quantify potential high end bispyribac-sodium exposure from drinking water, ''Tier I'' potential surface water concentrations were estimated using the rice simulation in generic expected environmental concentration (GENEEC) 1.3. The highest average 56–day concentration predicted in the simulated paddy water by GENEEC 1.3 was 15.45 parts per billion (ppb). Reducing this estimate by a factor of three gives a high end estimate for drinking water contamination. Using standard assumptions about bwt and water consumption, the maximum chronic exposure from this drinking water would be 0.00015 and 0.00052 mg/kg bwt/day for adults and children, respectively; 3.03% of the RfD for children. Based on this worse case analysis, the contribution of drinking water derived from treated rice paddy water to the dietary risk is much greater than that from tolerance level food, but still well within the acceptable range.

2. *Non-dietary exposure*. Bispyribac-sodium has only proposed agricultural use on rice, and no other crop, homeowner, turf, or industrial uses. Thus, no non-dietary risk assessment is needed.

D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that the Agency must consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity''. Available information in this context include not only toxicity, chemistry, and exposure data, but also scientific

policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not, at this time, have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way.

There are no other pesticidal compounds that are structurally related to bispyribac-sodium and have similar effects on animals. In consideration of potential cumulative effects of bispyribac-sodium and other substances that may have a common mechanism of toxicity, there are currently no available data or other reliable information indicating that any toxic effects produced by bispyribac-sodium would be cumulative with those of other chemical compounds. Thus, only the potential risks of bispyribac-sodium have been considered in this assessment of aggregate exposure and effects.

Valent will submit information for EPA to consider concerning potential cumulative effects of bispyribac-sodium consistent with any schedule established by EPA pursuant to the Food Quality Protection Act (FQPA).

E. Safety Determination

The Food Quality Protection Act of 1996 introduces a new standard of safety, a reasonable certainty of no harm. To make this determination, at this time the Agency should consider only the incremental risk of bispyribac-sodium in its exposure assessment. Since the potential chronic and acute exposures to bispyribac-sodium are small even using worse case drinking water and Tier I dietary (food) exposures (<<100% of RfD, MOE >>100) the provisions of the FQPA of 1996 will not be violated.

1. *U.S. population*—i. *Chronic exposure*. Using the Tier I dietary exposure assessment procedures described above for bispyribac-sodium, calculated chronic dietary exposure resulting from residue exposure from the proposed rice use of bispyribac-sodium is minimal. The estimated chronic dietary exposure from food for the overall U.S. population and many non-child/infant subgroups is 0.159 to 0.018% of the RfD (0.000027 to 0.000003 mg/kg bwt/day). Addition of the worse case potential chronic exposure from drinking water obtained from treated rice paddy water increases exposure by 0.000147 mg/kg bwt/day to 0.000174 mg/kg bwt/day for the maximally exposed adult subpopulation, non-hispanic other than black or white, and the maximum occupancy of the RfD from 0.159% to 1.02 percent. Generally, the Agency has no cause for concern if total residue contribution is less than 100% of the RfD. It can be concluded that there is a reasonable certainty that no harm will result to the overall U.S. population and many non-child/infant subgroups from aggregate, chronic exposure to bispyribac-sodium residues.

ii. *Acute Exposure*. Using the Tier I acute dietary exposure assessment procedures described above for bispyribac-sodium, calculated acute dietary exposure resulting from tolerance level residue exposure to the U.S. population from the proposed rice use of bispyribac-sodium is minimal. The estimated acute dietary exposure at the 95th and 99th percentiles of exposure from food for the overall U.S. population is 0.000031 and 0.000152 mg/kg bwt/day, respectively. Addition of the worse case potential chronic exposure from drinking water increases exposure by 0.000147 mg/kg bwt/day. This addition of water exposure reduces the MOE value at the 99.9th percentile of exposure for the U.S. population from 658,000 to 334,000. Similarly, at the 95th percentile the MOE value is reduced from >1,000,000 to 562,000. In a conservative policy, the Agency has no cause for concern if total acute exposure in a Tier I calculation for the 95th percentile yields a MOE of 100 or larger. It can be concluded that there is a reasonable certainty that no harm will result to the overall U.S. population and many non-child/infant subgroups from aggregate, acute exposure to bispyribac-sodium residues.

2. *Infants and children. Safety factor for infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of bispyribac-sodium, FFDCA section 408 provides that EPA shall apply an additional margin of safety, up to ten–fold, for added protection for infants and children in the case of threshold effects unless EPA determines that a different margin of safety will be safe for infants and children.

The toxicological data base for evaluating prenatal and postnatal toxicity for bispyribac-sodium is complete with respect to current data requirements. There are no special prenatal or postnatal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies or the 2–generation reproductive toxicity study in rats. Valent concludes that reliable data support use of the standard 100–fold uncertainty factor and that an additional uncertainty factor is not needed for bispyribac-sodium to be further protective of infants and children.

i. *Chronic risk*. Using the conservative, Tier I exposure assumptions described above, the percentage of the RfD utilized by dietary (food only) exposure to residues of bispyribac-sodium is very small. Exposures range from 0.000018 mg/kg bwt/day for non-nursing infants (<1 year old) to 0.000007 mg/kg bwt/day for children 7–12 —0.106 to 0.041% of the RfD. Adding the worse case potential incremental exposure to infants and children from bispyribac-sodium in drinking water obtained from treated rice paddy water (0.000515 mg/kg bwt/day) materially increases the aggregate, chronic dietary exposure and increases the occupancy of the RfD by 3.03% to 3.14% for non-nursing infants (<1–year old). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. It can be concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate, chronic exposure to bispyribac-sodium residues.

ii. *Acute Exposure*. The potential acute exposure from food to the various child and infant population subgroups all provide very large MOE values exceeding 370,000. Addition of the worse case ''background'' dietary exposure from water (0.000515 mg/kg bwt/day) reduces the MOE values at the 99.9th percentile of exposure for non-nursing infants (<1 year old) from 373,000 to 128,000. Similarly, at the 95th percentile the MOE value is reduced from >1,000,000 to 166,000. In a conservative policy, the Agency has no cause for concern if total acute exposure in a Tier I calculation for the 95th percentile yields a MOE of 100 or larger. It can be concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate, acute exposure to bispyribac-sodium residues.

3. *Safety determination summary*. Aggregate acute or chronic dietary exposure to various sub-populations of children and adults demonstrate acceptable risk, even though total calculated dietary exposure is dominated by the unrealistic overestimation of potential drinking water concentrations. Chronic exposures to bispyribac-sodium occupy considerably less than 100% of the RfD,

and all acute MOE values greatly exceed 100. Chronic and acute dietary risk to children from bispyribac-sodium should not be of concern. Further, bispyribac-sodium has only agricultural uses and no other uses, such as indoor pest control, homeowner or turf, that could lead to unique, enhanced exposures to vulnerable sub-groups of the population. It can be concluded that there is a reasonable certainty that no harm will result to the U.S. population or to any sub-group of the U.S. population, including infants and children, from aggregate chronic or aggregate acute exposures to bispyribac-sodium residues resulting from pending uses.

TABLE 3.—SUMMARY OF EXPOSURE VALUES AND CORRESPONDING RISK QUOTIENTS FOR AGGREGATE EXPOSURES TO BISPYRIBAC-SODIUM BY DIFFERENT ROUTES AND DURATIONS (ALL EXPOSURE VALUES ARE IN MG/KG BW/DAY)

	Percentile	Food	Water	Aggregate	Percent RfD	MOE
Chronic dietary (RfD = 0.017 mg/kg b.w./day).						
Adult (Non-Hispanic other than black or white)	NA*	0.000027	0.000147	0.000174	1.02	NA
Infants and children (Non-nursing infants (<1 year old))	NA	0.0000187	0.000515	0.000533	3.14	NA
Acute dietary: Acute endpoint = 100 mg/kg bw/day.						
Adult (U.S. Population)	99.9th	0.000152	0.000147	0.000299	NA	334,000
	95.5th	0.0000312	0.000147	0.0001782	NA	561,000
Infants and children (Non-nursing infants (<1 year old))	99.9th	0.000268	0.000515	0.000783	NA	128,000
	95th	0.000087	0.000515	0.000602	NA	166,000

*Not applicable

F. International Tolerances

There are presently no Codex maximum residue limits (MRL) established for bispyribac-sodium. The compound is presently registered for use on rice in several countries in Asia, Southeast Asia, Japan, South and Central America, the Dominican Republic, and Turkey. The use pattern is very similar to that proposed for the United States. Two countries have established tolerances: Japan a minimum MRL of 0.1 ppm and Brazil a MRL of 0.01 ppm both bispyribac-sodium in/on brown rice.

[FR Doc. 00–24212 Filed 9–19–00; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 2438]

Petitions for Reconsideration and Clarification of Action in Rulemaking Proceeding

September 13, 2000.

Petitions for Reconsideration and Clarification have been filed in the Commission's rulemaking proceeding listed in this Public Notice and published pursuant to 47 CFR Section 1.429(e). The full text of this document is available for viewing and copying in Room CY–A257, 445 12th Street, S.W., Washington, D.C. or may be purchased from the Commission's copy contractor, ITS, Inc. (202) 857–3800. Oppositions to these petitions must be filed by October 5, 2000. See Section 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions has expired.

Subject: Amendment of Section 2.106 of the Commission's Rules to Allocate Spectrum at 2 GHz for Use by the Mobile Satellite Service (ET Docket No. 95–18)

Number of Petitions Filed: 7.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 00–24064 Filed 9–19–00; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

Previously Announced Date & Time: Thursday, September 14, 2000, 10 a.m., Meeting open to the public.

The following item was added to the agenda: (continued from open meeting of September 12, 2000)

Draft Statements of Reasons—Petitions to Deny Certification of Public Funds to Patrick J. Buchanan and Ezola Foster (LRAs#598/599).

Previously Announced Date & Time: Thursday, September 21, 2000, 10 a.m., meeting open to the public.

The following item was added to the agenda: (held over from open meeting of September 14, 2000)

Dole for President—Statement of Reasons (LRA#467)

Dole/Kemp '96, Inc.—Statement of Reasons (LRA#506)

Date & Time: Tuesday, September 26, 2000 at 10 a.m.

Place: 999 Street, NW., Washington, DC

Status: This meeting will be closed to the public.

Items To Be Discussed:

Compliance matters pursuant to 2 U.S.C. § 437g.

Audits conducted pursuant to 2 U.S.C. § 437g, § 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

Date & Time: Thursday, September 28, 2000 at 10 a.m.

Place: 999 Street, NW., Washington, DC (Ninth Floor).

Status: This meeting will be open to the public.

Items To Be Discussed:

Correction and Approval of Minutes.

Advisory Opinion 2000–23: New York State Democratic Committee by counsel, Joseph E. Sandler and Neil P. Reiff.

Advisory Opinion 2000–26: Joel Deckard, Reform Party candidates, U.S. Senate, Florida.

Status of Regulations: Soft Money Rulemaking.

Administrative Matters.

Person to Contact for Information: Mr. Ron Harris, Press Officer, Telephone (202) 694–1220.

Mary W. Dove,

Acting Secretary of the Commission.

[FR Doc. 00–24325 Filed 9–18–00; 3:26 pm]

BILLING CODE 6715–01–M