consensus or to generate a formal SAB position. The Board, via a brief letter, simply notifies the Administrator that a Consultation has taken place. While no written report will be prepared of the Subcommittee's thoughts, individual members may provide their comments in writing to the DFO who will include these with the minutes of the meeting.

Charge to the Committee for the Microbial Risk Assessment Framework—EPA asks the SAB to consider and to discuss with it: (1) Whether the current framework includes all the essential components and a logical flow needed to allow microbial risk assessments to be conducted for all waterborne pathogens and water media (waste waters, drinking waters and ambient waters); (2) any apparent missing components that would be needed to properly conduct risk assessments, as well as why the additional components would be needed; (3) any tools and methods (e.g., dose response and susceptibility models dealing with uncertainty, and data gaps, etc.) that can be used in the risk analysis portion of the methodology which would assist risk assessors who would be using this guidance, and (4) suitability of the framework for establishment of formal guidelines for microbiological risk assessment.

Availability of Review Materials—(1) *CCL Research Plan:* Information on the Agency's CCL Research Plan can be obtained by contacting Dr. Robert Clark, US EPA, National Risk Management Research Laboratory, Cincinnati, OH by telephone at (513) 569–7201 or by e-mail at *clark.robertm@epa.gov.* (2) *Microbiological Risk Assessment Framework:* Additional information on the framework for microbial risk assessment can be obtained from Dr. Stephen Schaub, US EPA, Office of Water, Office of Science and Technology, Washington, DC by telephone at (202) 260–7591 or by e-mail at *schaup.stephen@epa.gov.*

For Further Information—Any member of the public wishing further information concerning this meeting or wishing to submit brief oral comments (10 minutes or less) must contact Thomas O. Miller, Designated Federal Officer, Science Advisory Board (1400A), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone (202) 564–4558; FAX (202) 501–0582; or via e-mail at *miller.tom@epa.gov.* Requests for oral comments must be in writing (e-mail, fax or mail) and received by Mr. Miller no later than noon Eastern Time on Tuesday, June 5, 2001.

Providing Oral or Written Comments at SAB Meetings

It is the policy of the Science Advisory Board to accept written public comments of any length, and to accommodate oral public comments whenever possible. The Science Advisory Board expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements. *Oral Comments:* In general, each individual or group requesting an oral presentation at a face-to-face meeting will be limited to a total time of ten minutes. For teleconference meetings, opportunities for oral comment will usually be limited to no more than three minutes per speaker and no more than fifteen minutes total. Deadlines for getting on the public speaker list for a meeting are given above. Speakers should bring at least 35 copies of their comments and presentation slides for distribution to the reviewers and public at the meeting. *Written Comments:* Although the SAB accepts written comments until two days after the date of the meeting (unless otherwise stated), written comments should be received in the SAB Staff Office at least one week prior to the meeting date so that the comments may be made available to the committee for their consideration. Comments should be supplied to the appropriate DFO at the address/contact information noted above in the following formats: one hard copy with original signature, and one electronic copy via e-mail (acceptable file format: WordPerfect, Word, or Rich Text files (in IBM–PC/Windows 95/98 format). Those providing written comments and who attend the meeting are also asked to bring 25 copies of their comments for public distribution.

General Information

Additional information concerning the Science Advisory Board, its structure, function, and composition, may be found on the SAB Website (*http://www.epa.gov/sab*) and in The FY2000 Annual Report of the Staff Director which is available from the SAB Publications Staff at (202) 564–4533 or via fax at (202) 501–0256. Committee rosters, draft Agendas and meeting calendars are also located on our website.

Meeting Access

Individuals requiring special accommodation at this meeting, including wheelchair access to the conference room, should contact the appropriate DFO at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: April 6, 2001.

John R. Fowle, III,

Acting Staff Director, Science Advisory Board.

[FR Doc. 01–9487 Filed 4–16–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[PF–1015; FRL–6773–3]

Notice of Filing Pesticide Petitions 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 pesticide petitions 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–1015, must be received on or before May 17, 2001.

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–1015 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Dennis McNeilly, Insecticide/Rodenticide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–6742; e-mail address: mcneilly.dennis.@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 codes	Examples of potentially affected entities
Industry	111 112 311	Crop production Animal production Food manufacturing

Categories	NAICS codes	Examples of potentially affected entities
	32532	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'' ''Regulation 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–1015. 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–1015 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–1015. 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 pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals 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 the petitions contain 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 petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

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

Dated: March 27, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

PP 6F4677 and 9E6013

The petitioner summary of the pesticide petitions is printed below as

required by section 408(d)(3) of the FFDCA. The summary of the petitions was prepared by the petitioner and represents the view 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.

EPA has received a pesticide petition (6F4677) from Aventis CropScience, P.O Box 12014, 2 T.W., Alexander Drive, Research Triangle Park, NC 27709 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of aldicarb and its metabolites aldicarb sulfoxide and aldicarb sulfone for the crop group #10 ''citrus fruits'' at 0.3 parts per million (ppm). This crop group includes: calamondin, citrus citron, citrus hybrids (includes chironja, tangelo, tangor), grapefruit, kumquat, lemon, lime, mandarin (tangerine), orange (sour), orange (sweet), pummelo, and Satsuma mandarin. There are currently aldicarb tolerances (40 CFR 180.269) for orange, lemon, lime, and grapefruit at 0.3 ppm.

EPA has also received a pesticide petition (9E6013) from Aventis CropScience, proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing an import tolerance for residues of aldicarb and its metabolites aldicarb sulfoxide and aldicarb sulfone in banana, pulp at 0.008 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. This notice includes a summary of the petitions prepared by the petitioner, Aventis, CropScience.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of aldicarb in plants is adequately understood. Adequate data on the nature of the residues in plants, including identification of major metabolites and degradates of aldicarb in citrus and other crops are available.

2. *Analytical method*. There is an adequate method available for enforcement purposes to detect and measure levels of aldicarb, aldicarb sulfoxide and aldicarb sulfone in bananas with a limit of quantitation (LOQ) of 0.008 ppm. The high performance liquid chromotography (HPLC) method can detect residues at levels of detection (LOD) of 0.003 and 0.005 ppm for aldicarb and its primary metabolites, respectively. Residue studies to support tolerances of aldicarb and its primary degradates on oranges, lemons, lime and grapefruit were conducted between 1977 and 1993. Samples from earlier studies were analyzed via a gas chromotography (GC) method which converted aldicarb and aldicarb sulfoxide to aldicarb sulfone and reported total toxic residue. Later an HPLC method was developed which was capable of quantifying each of the three toxic residues. The LOQ for both methods was 0.02 ppm.

3. *Magnitude of residues*. No new citrus residue data are being filed with this petition. Aventis believes that adequate residue data have been provided to the EPA to support the proposed crop group tolerance for citrus at the current tolerance level of 0.3 ppm already established for oranges, lemons, limes and grapefruit. The EPA crop grouping #10 citrus requires that data be filed for representative commodities to include sweet orange, lemon and grapefruit. Aventis has submitted extensive data for these representative crops that serves as a strong basis for the proposed crop group tolerance.

Banana crop residue trials were conducted using a new application methodology that will be used to treat bananas. A total of 15 field sites in 7 Latin American countries were treated with 1 application at 0.8 grams of aldicarb per banana plant mat in a GLP RAC study. In addition, a GLP study to determine the magnitude of residues for processed banana fractions was conducted in Costa Rica at a 5X rate of 4.0 grams of aldicarb per plant mat. The application for each study was made using a new patented application method developed by Aventis, the aldicarb Banana In-Plant System®. The System utilizes a unique package or ''sachet'' to deliver an exact dose of granules containing 15% aldicarb into the already harvested ''mother'' banana plant. Within a short time after the fruit is harvested, the mother plant is cut into a stump, leaving a single selected sucker or offshoot plant (the ''daughter plant'') to produce the next crop. A ''plug'' is first removed from the stump with a special tool. The sachet is then placed into the hole and the plug is replaced. The fluids from the mother plant are slowly transferred to the daughter plant, taking with them the aldicarb from the granules in the sachet to provide nematode protection for the daughter plant's roots. Only one application is made per crop, compared to two applications that are required with typical soil applied nematicides. When TEMIK® brand 15G aldicarb was previously used in this region as a soil treatment, two applications of 2 grams active ingredient per mat were applied. Due to the necessity to apply the Banana In-Plant System® sachet soon after harvest of the previous crop, the minimum preharvest interval to obtain mature green fruit is approximately 190 days. No residues were detected in either composite or individual pulp or peel samples from the 15 RAC study sites. Likewise, no residues were detected in samples of processed fractions from the processing study.

B. Toxicological Profile

1. *Acute toxicity*. Aldicarb is highly acutely toxic. Signs of toxicity are those commonly associated with acetylcholinesterase inhibition (ChEI) caused by a carbamate pesticide; that is, cholinergic signs and symptoms. These symptoms are dose-dependent, and are rapidly reversible. Aldicarb is in acute toxicity category I by the oral, dermal and inhalation routes of exposure, is in toxicity category III for eye irritation and IV for dermal irritation. Aldicarb is not a sensitizer. Aldicarb has two metabolites of toxicological significance, aldicarb sulfoxide and aldicarb sulfone. The sulfoxide has comparable toxicity to parent aldicarb while the sulfone is approximately 20-fold less toxic.

There is a complete neurotoxicity data base consisting of acute, subchronic, and developmental neurotoxicity studies. In addition, there is a time to peak behavioral effects study of a single oral administration of aldicarb technical. Finally, there are acute neurotoxicity studies on both aldicarb sulfoxide and aldicarb sulfone. Effects on ChEI were always the most sensitive indicators of both exposure and toxicity in these studies. The aldicarb dose-effect relationship for ChEI was quite consistent across studies. A dose of 0.05 mg/kg gives the first indications of plasma and erythrocyte inhibition with no concomitant brain inhibition nor behavioral changes. At 0.2 mg/kg, marked plasma and erythrocyte ChEI is observed accompanied by measurable inhibition in the brain and moderate clinical signs. Higher dose levels result in nearly complete plasma ChEI, marked erythrocyte and brain ChEI and clinical signs, the magnitude of which increases with dose.

2. *Genotoxicity*. In a September 15, 1998 Hazard Identification Assessment Review Committee (HIARC) report, EPA reported that studies covering gene

mutations, chromosomal aberrations, unscheduled DNA synthesis, and dominant lethal effects were all negative. The Agency stated that there was no concern for mutagenicity for aldicarb. A limited battery of studies on the primary aldicarb metabolites, aldicarb sulfoxide and sulfone, were also negative.

3. *Reproductive and developmental toxicity*. There is a complete developmental and reproductive toxicity data base on aldicarb including a developmental neurotoxicity study; aldicarb did not cause developmental or reproductive effects in studies in the absence of maternal (or parental) toxicity.

i. *Rat*. In a developmental study, rats were given doses of 0, 0.125, 0.25 or 0.5 mg/kg/day. Maternal toxicity was indicated by maternal death and other effects (NOAEL of 0.125 mg/kg/day). Gestational parameters were not affected. No increased incidence of malformation was observed in the absence of clear maternal toxicity. The NOAEL for fetal toxicity was 0.25 mg/kg/day; fetal effects at the highest dose included dilated ventricles. In a 2-generation reproductive toxicity study, rats were fed a diet with 0, 2, 5, 10, or 20 ppm aldicarb (0, 0.1, 0.25, 5, or 10 mg/kg/day). Parental toxicity was indicated by ChEI and body weight changes (NOAEL 0.25 mg/kg/day). The reproductive NOAEL was 0.5 mg/kg/day based on decreased pup weight and reduced viability. There were no reproductive effects in the absence of parental toxicity. In a developmental neurotoxicity study in rats, the dose levels were 0, 0.05, 0.1, or 0.3 mg/kg/day. This study provides strong evidence that aldicarb does not cause permanent effects on the nervous system, and that the young are not more sensitive to the effects of aldicarb than mature animals. The maternal NOAEL was 0.05 mg/kg/day based on miosis at 0.1 mg/kg/day. The developmental NOAEL was 0.05 mg/kg/day based on post-weaning body weight decrement, reduced hindlimb grip strength, and foot splay in F_1 females on post-partum day 35. The dose of 0.05 mg/kg/day was a clear developmental NOAEL in the developmental neurotoxicity study. These results demonstrate the lack of increased sensitivity to developing animals relative to adults because there were no developmental effects even in the presence of maternal ChEI.

ii. *Rabbit*. In a rabbit developmental study with doses of 0, 0.1, 0.25 or 0.5 mg/kg/day, there were no fetal effects. Maternal toxicity was clearly established. The maternal NOAEL was 0.1 mg/kg/day based on body weight changes at 0.25 mg/kg/day.

4. *Subchronic toxicity.* In an oral study, rats were fed aldicarb in their diet for 93 days at dose levels of 0, 0.02, 0.1, or 0.5 mg/kg/day. The no observed adverse effect level (NOAEL) was 0.1 mg/kg/day, and the lowest observed adverse effect level (LOAEL) was 0.5 mg/kg/day. There were no consistent dose-related effects on ChEI except for plasma ChEI in both sexes after 30 days at the highest dose tested. In addition, mortality was increased and food consumption and body weight were decreased at the highest dose level. There were no compound-related effects noted in organs examined. There was no indication in the study as to how soon after feeding the ChE determinations were performed, which could account for sporadic ChEI results in the study.

In an oral study in dogs, animals were fed aldicarb in the diet at dose levels of 0, 0.2, 0.3, or 0.7 mg/kg/day for 100 days. There was no mortality in the study, and growth was comparable within all dose groups. A slight decrease in testes weight and a slight increase in adrenal weight were noted in males in the highest dose tested. Microscopic analyses did not reveal any abnormalities in these tissues. ChE values were unaffected by the presence of aldicarb in the diet. However, the animals were removed from aldicarb exposure for 24 to 48 hours prior to ChE analysis. Since ChEI caused by aldicarb is rapidly reversible, this procedure could well have influenced study results. The NOAEL was 0.3 mg/kg/day.

Another oral dog study was conducted to further investigate the ChEI dose-response curve of aldicarb. During the 5-week study, the dogs were fed diets mixed with aldicarb technical at levels of 0.35, 0.7, and 2 ppm (0.013, 0.023, and 0.069 kg/kg/day in males, and 0.012, 0.025, and 0.067 in females). There was also a control group. There was no mortality or any changes in body weight, food consumption or clinical observation data indicative of a compound effect. Plasma ChEI by more than 20% occurred in high dose males and females.

In a 21-day dermal toxicity study in rats, the effect of TEMIK® 15G (an aldicarb 15% granular product) on plasma, erythrocyte, and brain ChEI was evaluated. The dose levels were 0, 100, 250, and 500 mg/kg/day. Blood samples were taken 1 hour post-dosing on the first and fifth day of each week of the study. For both males and females, there were no effects on daily body weights, absolute and relative brain weights, and food consumption. There were no dose-related clinical signs of toxicity. The NOAEL for plasma ChEI was 100 mg/kg/day, for erythrocyte ChEI was 250 mg/kg/day, and for brain ChEI was at least 500 mg/kg/day.

5. *Chronic toxicity*. Aldicarb has been shown to have no oncogenic potential when administered to rats and mice in lifetime experiments. ChEI is the most sensitive indicator of exposure in chronic studies in rats and dogs. No other clear indicators of toxicity have been demonstrated. A chronic NOAEL of 0.05 mg/kg/day and 0.59 mg/kg/day based on plasma and erythrocyte ChEI has been determined for aldicarb in male and female rats, respectively. A chronic NOAEL of 0.027 mg/kg/day based on plasma ChEI and 0.054 mg/kg/day based on erythrocyte ChEI has been determined for aldicarb in dogs. In addition, there is a chronic NOAEL of 0.54 mg/kg/day for aldicarb sulfone based on plasma and erythrocyte ChEI in dogs.

i. *Rat*. In a 2-year study, rats were fed aldicarb at levels of 0, 1, 10, or 30 ppm in the diet. There were no compound-related effects on survival. The principal treatment-related clinical effect was limited use of the tail in high dose males and females. Body weights and body weight gains were reduced in high dose males and females. Atrophy of the iris also occurred in this dose group. There was no evidence of direct organ toxicity, and no evidence of oncogenic effects. The NOAEL was 0.05 mg/kg/day in males and 0.59 mg/kg/day in females based on plasma and erythrocyte ChEI.

In a National Cancer Institute (NCI) study, rats were fed aldicarb in the diet at concentrations of 0, 2 or 6 ppm. There was no mortality attributed to aldicarb and no effect on body weight was noted. It was concluded that aldicarb was not oncogenic.

In a third rat study, groups of rats were fed aldicarb at dose levels of 0 or 0.3 mg/kg/day. In addition, other groups were fed aldicarb sulfoxide at dose levels of 0, 0.3, or 0.6 mg/kg/day, aldicarb sulfone at dose levels of 0, 0.6, or 0.24 mg/kg/day, or a mixture of aldicarb sulfoxide and aldicarb sulfone at doses of 0, 0.5 or 1.2 mg/kg/day. Neither aldicarb nor its major metabolites was found to be oncogenic. There were slight increases in mortality and slight depressions in growth at certain stages for some of the test materials. ChE activity was measured at 6, 12 and 24 months during the study. Plasma, erythrocyte, and brain ChE activity were examined only at a time 24 hours after animals were removed from test diets; this may have influenced results. No ChEI was noted other than a slight inhibition with respect to plasma ChE.

ii. *Mouse*. There are three mouse oncogenicity studies. The first is an NCI study in which mice were fed 0, 2 or 6 ppm of aldicarb in the diet. It was concluded that aldicarb was not oncogenic. No effects on mortality or body weights were noted.

In a second study, mice were fed aldicarb at doses of 0, 0.1, 0.2, 0.4, or 0.7 mg/kg/day. Mortality was evident in males at the two highest dose levels, and in females at the three highest dose levels during the first few months of the study. Following this period, aldicarb was mixed in the diet in a different manner that appeared to eliminate the acutely toxic effects. Based on the mortality observed in this study, these data are not appropriate for the evaluation of an oncogenic response.

In a third study, conducted in an effort to verify the results of the previous mouse study, mice were fed aldicarb at dose levels of 0, 0.1, 0.3, or 0.7 mg/kg/day. There was no effect on mortality or growth. Inclusion of aldicarb in the diet did not result in an increased incidence of oncogenic response.

iii. *Dog*. In a 1 year study in dogs, groups of beagles were fed dietary concentrations of 0, 1, 2, 5, or 10 ppm daily for 52 weeks. The study was designed to produce maximum ChEI by limiting feeding time to 2 hours per day to mimic a bolus administration of aldicarb. Plasma and erythrocyte ChE activity was measured from blood samples approximately 2 hours after the feeding period. There were no observable effects other than ChEI. The NOAEL for plasma ChEI was 1 ppm or 0.027 mg/kg/day.

In another 1 year feeding study, aldicarb sulfone was administered at dietary concentrations of 0, 5, 25 or 100 ppm. ChE determinations were taken approximately 2 hours after feeding to measure maximum ChEI. No mortality or treatment-related clinical signs were seen. Some slight changes in spleen and thyroid/parathyroid weights were noted. Slight effects in the mandibular lymph nodes and adrenal cortex were observed. The NOAEL based on plasma and erythrocyte ChEI was 25 ppm, equal to 0.54 mg/kg/day.

6. *Animal metabolism*. The mode of biochemical conversion of aldicarb to a variety of metabolites has been evaluated in rats, dogs, dairy cows, goats and hens. The metabolic pathway for aldicarb appears to be the same in all animals studied. In animals, aldicarb is metabolized predominantly via biochemical oxidation, hydrolysis and elimination reactions. Aldicarb is oxidized to aldicarb sulfoxide; then a small portion of aldicarb sulfoxide is oxidized to aldicarb sulfone. Both products further undergo detoxification either through hydrolysis or elimination process to the corresponding oximes and nitriles, respectively. The oximes and nitriles, in turn, slowly degrade into the corresponding aldehydes, acids, and alcohols, none of which are toxicologically relevant.

The presence of aldicarb metabolites in tissues, urine and feces has been examined in several mammalian species following administration of radiolabelled aldicarb under a variety of treatment regimes. Similar results have been found in all species tested, regardless of sex, and under all treatment regimes. When aldicarb is given orally to mammals, it is absorbed readily and excreted rapidly.

When rats were administered single oral doses of radiolabelled aldicarb, most of the aldicarb metabolites were excreted within 24 hours; after 4 days, more than 95% of the administered dose had been excreted and no residues were detected in body tissues by the fifth day. Within the first 24 hours of the study, 80% of the administered dose of aldicarb was eliminated in the urine and 5% in the feces. Aldicarb given orally to rats as a single acute dose was excreted primarily as aldicarb sulfoxide (40%) and the sulfoxide oxime (30%); only trace amounts of aldicarb were found in the urine.

The principal metabolites found in milk following acute administration of aldicarb to cows were aldicarb sulfoxide oxime and nitrile. When dairy cows were given aldicarb for 14 days, however, the major metabolite in the milk was aldicarb sulfone and its nitrile derivative, with little aldicarb sulfoxide present. This suggests that more complete metabolism occurs with continuous dietary exposure to aldicarb. The major urinary metabolites in dogs and in dairy cows were the same as in rats.

In summary, aldicarb ingested by animals is rapidly absorbed and metabolized and is not stored in body tissues. Its metabolites are mostly excreted in the urine within 24 hours, and elimination is complete in about 5 days.

7. *Metabolite toxicology*. There have been a number of acute, subacute, and subchronic studies using aldicarb sulfoxide and aldicarb sulfone, which are the major metabolites of aldicarb, as, discussed in the metabolism section. The sulfoxide metabolite is of similar or lesser toxicity in comparison to aldicarb and the sulfone metabolite is much less toxic than aldicarb. In each case, ChEI is the indicator of exposure.

8. *Endocrine disruption*. The existing aldicarb toxicity data base, including reproduction and developmental toxicity studies, a dominant lethal study, chronic toxicity and oncogenicity studies, and a developmental neurotoxicity study all provide no indication that aldicarb is a potential endocrine disruptor.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Chronic risk*. The toxic effects of aldicarb are limited to rapidly reversible cholinesterase inhibition. EPA determined the chronic RfD is the same as the acute RfD based upon acute exposure symptoms from a study conducted with human volunteers with a NOAEL of 0.01 mg/kg body weight/day. Only acute risk is considered for dietary exposure. This NOAEL was established primarily on the basis of plasma cholinesterase inhibition. Although EPA also cites sweaty palms and red blood cells (RBC) inhibition at this dose, Aventis does not believe that these effects were statistically significant at this dose. Since review of this human study, EPA has revised their policy on endpoint selection for cholinesterase inhibition. According to current policy, inhibition of RBC cholinesterase is the appropriate toxicological endpoint. The European Union currently regulates aldicarb on the basis of RBC cholinesterase inhibition in this human study. Based on RBC cholinesterase inhibition, they have concluded that 0.025 mg/kg/day is the appropriate regulatory endpoint for the aldicarb human study. For purposes of this petition, the acute dietary risk assessment has been based on a RfD of 0.001 mg/kg/day as recommended by EPA in a 1998 and 1999 HIARC report.

The remainder of this notice will reference this EPA established RfD. However, as current EPA policy states, the correct RfD for aldicarb should be 0.0025 mg/kg/day based on RBC cholinesterase inhibition in the human study.

ii. *Acute risk*. Based upon all available data, EPA has established a reference dose (RfD) of 0.001 mg/kg/day using a 10 fold safety factor to account for intraspecies differences and a NOAEL of 0.01 mg/kg body weight/day based upon a human subject study. In September 1998, the EPA FQPA Safety Factor Committee recommended an additional 3X margin of safety be applied for all populations containing infants and children based solely upon an unpublished study. Aventis CropScience and independent reviewers have determined that the conduct of the study and related studies were seriously flawed; therefore, Aventis contends that

the additional 3X is inappropriate. An acute dietary risk assessment was prepared. The assessment included residue trial and monitoring data from treated fields, including individual commodity item residue data, from established and proposed uses of aldicarb, including bananas and citrus. USDA's 1989–91 Continuing Survey of Food Intake by Individuals (CSFII) consumption data, actual and anticipated market share, processing factors, and the 8-hour cholinesterase reversibility approach. The assessment assumes that the duration of exposure is 8 hours. However, data from the aldicarb human study confirm that at doses comparable to expected exposure levels, cholinesterase inhibition is reversed much faster thus shortening the actual exposure period. Thus 8 hours is a conservative assumption for the analysis. In previous assessments, children 1 to 6 years of age had the highest theoretical exposure; therefore, the analyses were conducted for children 1–6 years. The estimate of the 99.9th percentile of the per-capita 8–hour exposure distribution to aldicarb in food from all current and proposed uses for children 1–6 years old, is 0.000191 mg/kg body weight or 19.1% of the RfD.

iii. *Food*. The conservatively estimated exposure to aldicarb from use on bananas for children 1–6 years old is 0.000016 mg/kg body weight or 1.6% of the RfD. Including the entire citrus crop group in the risk assessment increased exposure estimates by less than 0.5%. While this analysis confirms the acceptability of the establishment of the proposed tolerances for the citrus crop group and bananas, Aventis is currently developing further state-of-the-art refinements to the acute dietary risk assessment.

iv. *Drinking water*. There currently are no known drinking water wells with aldicarb residues above guideline outside of Long Island, NY (NY guideline of 7 ppb); wells with residues above guideline on Long Island are fitted with maintained filters that mitigate exposure. The absence of contamination to drinking water in current use areas is attributable to label use restrictions that regulate use of the product based upon vulnerable soils and mandated minimum setbacks from drinking water wells. The potential for aldicarb to contaminate surface water is low since the product is soil incorporated. The proposed citrus hybrid and banana import tolerance uses are not expected to increase dietary risk from drinking water. For purposes of determining aggregate exposure from drinking water, a conservative assessment for all current and proposed uses was conducted. The assessment utilized data from sampled wells and conservatively assumed that those wells represent all private rural wells in regions where aldicarb is used, when in fact the monitoring program only obtained samples from susceptible areas. In addition, the assessment assumed that all private wells in states where aldicarb could be used are expected to contain aldicarb residues, and used a national estimate of the proportion of the population drinking from private wells, rather than state-specific proportions. This approach potentially overestimates the proportion of private wells that could contain aldicarb and conservatively omits consideration of the label use restrictions. Water consumption data for children 1 to 6 years old from USDA's 1989–91 CSFII were used in the assessment. The data refer to 24-hour intervals and represent all tap water and non-food based water consumption. This approach results in a conservative estimate of the potential exposure to aldicarb in water since cholinesterase inhibition from aldicarb exposure is rapidly reversible (8 hours or less). In previous assessments, children 1 to 6 years of age had the highest theoretical exposure, therefore the analyses were conducted for children 1–6 years. The estimate of the 99.9th percentile of the per capita 24-hour exposure distribution to aldicarb in water for that subpopulation is 0.000120 mg/kg body weight or 12.0% of the RfD. (It should be noted that the calculated exposures for food and drinking water cannot be added since the calculations for food are based upon 8–hour consumption data and the water calculations are based upon consumption data for a 24–hour period.) For obvious reasons, an import tolerance for the use of aldicarb on bananas will not contribute to increased exposure in drinking water in the U.S. Since the planned banana use is not soil applied, minimal risk to ground water exists in banana growing areas as well.

2. *Non-dietary exposure*. There are no residential, non-dietary uses for aldicarb.

D. Cumulative Effects

An aggregate assessment based upon common mechanisms of toxicity has not been conducted for aldicarb since EPA policies and consensus scientific methodology have not been established to conduct a cumulative assessment. Aldicarb, a carbamate, is a rapidly reversible cholinesterase inhibitor and therefore generally shares a common mechanism of toxicity with other carbamates; however, for aldicarb's food crop uses, the application of aldicarb generally precludes the use of other carbamates and therefore minimizes the potential for multiple carbamate residues to include aldicarb. At planting, and uses of aldicarb also replace the use of organophosphates at planting reduce the number of foliar applications of those products and as well as other carbamates. Since no residues result from the application of aldicarb to bananas with the Banana In-Plant System®, cumulative exposure with products sharing a common mechanism of toxicity is not a concern for that use.

E. Safety Determination

1. *U.S. population*. Aggregate acute dietary exposure assessments previously demonstrated that there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure (food and drinking water) to aldicarb from current and pending uses.

2. *Infants and children*. Based upon all available data, EPA has established a reference dose (RfD) of 0.001 mg/kg/day using a 10 fold safety factor to account for intraspecies differences and a NOAEL of 0.01 mg/kg body weight/day based upon a study conducted with human volunteers. In September 1998, the EPA FQPA Safety Factor Committee recommended an additional 3X margin of safety be applied for all populations containing infants and children based solely upon an unpublished study. Aventis CropScience and independent reviewers have determined that the conduct of the study and related studies were seriously flawed; therefore Aventis contends that the additional 3X is inappropriate. In previous assessments, children 1 to 6 years of age had the highest theoretical exposure, therefore the analyses were conducted for children 1–6 years. The estimate of the 99.9th percentile of the per-capita 8-hour exposure distribution to aldicarb in food from all current and proposed uses, including citrus and banana, for children 1–6 years old, is 0.000191 mg/kg body weight or 19.1% of the RfD. The conservatively estimated exposure to aldicarb from use on bananas for children 1–6 years old is 0.000016 mg/kg body weight or 1.6% of the RfD. Including the entire citrus crop group in the risk assessment increased exposure estimates by less than 0.5%. The estimate of the 99.9th percentile of the per-capita 24-hour exposure distribution to aldicarb in water for children 1 to 6 years of age is 0.000120 mg/kg body weight or 12.0% of the RfD. Considering that the proposed import tolerance for the use of aldicarb on bananas is for use outside the U.S. and that the unique

application method for the use does not expose the product to the soil in the locations of use, the proposed use on bananas will not contribute to exposure in drinking water. There are no residential, non-dietary uses for aldicarb. Based on the above conservative estimates, Aventis CropScience does not expect the aggregate exposure to aldicarb for children ages 1 to 6 (the population subgroup with the highest theoretical exposure) to exceed one third of the RfD. Therefore, Aventis CropScience concludes that no harm will result to infants and children from aggregate exposure to aldicarb residues.

F. International Tolerances

Codex maximum residue levels are established for residues of aldicarb on barley, barley straw and fodder (dry), beans, Brussels sprouts, citrus fruits, coffee bean, cotton seed, cotton seed oil (edible), grape, maize, maize fodder, maize forage, meat, milk, onion (bulb), peanut, peanut oil (edible), pecan, potato, sorghum, sorghum straw and fodder (dry), soya bean (dry), sugar beet, sugar beet leaves or tops, sugarcane, sunflower seed, sweet potato, wheat, wheat straw and fodder (dry).

[FR Doc. 01–9489 Filed 4–16–01 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

April 6, 2001.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before June 18, 2001. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Les Smith, Federal Communications Commissions, 445 12th Street, SW., Room 1–A804, Washington, DC 20554 or via the Internet to lesmith@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Les Smith at (202) 418–0217 or via the Internet at lesmith@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Approval Number: 3060–0360.

Title: Section 80.409(c) Public coast station logs.

Form No.: N/A.

Type of Review: Extension of existing collection.

Respondents: Business or other for-profit, individuals or households, non-profit institutions, state and local governments.

Number of Respondents: 316.

Estimated Time Per Response: 95 hour.

Total Annual Burden: 30,020 hours.

Total Annual Cost: 0.

Needs and Uses: The recordkeeping requirement contained in this rule section is necessary to document the operation and public correspondence service of public coast radio telegraph, public coast radiotelephone stations and Alaska-public fixed stations, including the logging of distress and safety calls where applicable. A retention period of more than one year is required where a log involves communications relating to a disaster, an investigation, or any claim or complaint. If the information were not collected, documentation concerning the above stations would not be available.

OMB Approval Number: 3060–0364.

Title: Section 80.409(d) and (e) Ship radiotelegraph logs, Ship radiotelephone logs.

Form No.: N/A.

Type of Review: Extension of existing collection.

Respondents: Businesses or other for-profit, state, local or tribal government, not-for-profit institutions.

Number of Respondents: 10,950.

Estimated Time Per Response: 47.3 hours per response.

Total Annual Burden: 517,935 hours.

Needs and Uses: The recordkeeping requirement contained in these rule sections is necessary to document that compulsory radio equipped vessels and high seas vessels maintain listening watches and logs as required by statutes and treaties (including treaty requirements contained in appendix 11 of the international Radio Regulations, chapter IV, Regulation 19 of the International Convention for the Safety of Life at Sea, the Bridge-to-Bridge Radio telephone Act, the Great Lakes Agreement, and the Communications Act of 1934, as amended.) A retention period of more than one year is required where a log involves communications relating to a disaster, an investigation, or any claim or complaint. If the information were not collected, documentation concerning station operations would not be available and treaty requirements would not be complied with.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 01–9444 Filed 4–16–01; 8:45 am]

BILLING CODE 6712–01–U

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission for Extension Under Delegated Authority, Comments Requested

April 6, 2001.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's