4. Special studies, the Fathead Minnow assays, Vitellogenin assay, and Avian Dosing Protocol.

5. The steroidogenesis detailed review paper.

6. The aromatase detailed review paper.

7. A proposed standard suite of chemicals for testing in the Tier 1 Screening assays.

8. The current efforts related to evaluating the relevance of animal data to human health.

9. EPA's approach to addressing low-dose issues.

June 2002

The objective of the June 2002 teleconference meeting (docket ID number OPPT–2002–0020) was for the EDMVS to provide input and advice on the steroidogenesis detailed review paper.

July 2002

The objectives of the July 2002 meeting (docket ID number OPPT–2002–0029) were:

1. To review the screening criteria, recommended by EDSTAC and adopted by EDSP for screens.

2. To receive an update of the NICEATM estrogen and androgen receptor binding efforts.

3. To discuss and provide advice on general dose setting issues; and to provide comments and advice on:

- A pubertal (special study)—restricted feeding.
- A mammalian 2-generation (draft)—Propylthiouracil (PTU) special study.
- An amphibian metamorphosis detailed review paper.
- An invertebrate detailed review paper.

December 2002

The objective of the December 2002 teleconference meeting (docket ID number OPPT–2002–0059) was for the EDMVS to provide input and advice on the Tier 2 Fish Life Cycle assay detailed review paper.

June 2003

The objectives of the June 5–6, 2003 meeting (docket ID number OPPT–2003–0016) were for the EDMVS to provide input and advice on:

1. The Tier II Mammalian 2-Generation Special Study and the 1-generation extension results.

2. The Tier I Steroidogenesis (Sliced Testes) Study results and validation plan.

3. The Tier I Pre-Optimization, substrate characterization for Aromatase Placental Microsomes Study results.

August 2003

The objectives of the August 18–20, 2003 meeting (docket ID number OPPT–2003–0027) were:

1. Review and discuss the status/results of the prevalidation work on:

- The Fish Screening assay, specifically: The survey of vitellogenin methods in Fathead Minnow, Zebrafish, and Medaka; the comparative evaluation of the Fathead Minnow assays; and the Fish Screen (Non-Spawning) assay.
- The Steroidogenesis Assay Optimized Protocol.

2. Provide input and advice on the:

- EDSP's validation plans for the Fish Screening assay and Steroidogenesis assay.
- Strain/species white paper.
- Chemicals used in EDSP's prevalidation and validation.
- Avian detailed review paper.
- Issues related to the Pubertal assays.

3. Receive an update on the amphibian workshop conducted recently.

III. Meeting Objectives for the December 2003 Meeting

The objectives for the December 10–12, 2003 meeting (docket ID number OPPT–2003–0064) are for EDMVS to provide input and advice on:

1. Discuss the Pubertals assay and Aromatase assay prevalidation results and recommend next steps.

2. Receive introductory presentation on Adult Intact Male assay.

3. Receive updates on:

- Androgen Receptor Binding assay.
- Efforts to finalize reference chemicals.
- OECD Fish Drafting Group.
- Activities regarding *In Vitro* Fish assays.

A list of the EDMVS members and meeting materials are available on our web site (*http://www.epa.gov/scipoly/oscpendo/edmvs.htm*) and in the public docket.

List of Subjects

Environmental protection, Endocrine disruptors, Hazardous substances, Health, Safety.

Dated: November 14, 2003.

Joseph J. Merenda, Jr.,

Director, Office of Science Coordination and Policy.

[FR Doc. 03–29186 Filed 11–20–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0336; FRL–7333–7]

Dichlormid; 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 ID number OPP–2003–0336, must be received on or before December 22, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Princess Campbell, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8033; e-mail address: *campbell.princess@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of

this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2003–0336. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper form, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also, include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2003–0336. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID number OPP–2003–0336. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington,

DC 20460–0001, Attention: Docket ID number OPP–2003–0336.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP–2003–0336. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

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

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

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

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

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

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

5. Provide specific examples to illustrate your concerns.

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

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

II. What Action is the Agency Taking?

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

List of Subjects

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

Dated: November 13, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by Dow AgroSciences LLC, and represents the view of the petitioner. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Dow AgroSciences LLC

PP 3E6676

EPA has received a pesticide petition (3E6676) from Dow AgroSciences LLC, 9330 Zionsville Rd., Indianapolis, IN 46268 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 180.469 by establishing time-limited tolerances for residues of dichlormid (N,N-diallyl dichloroacetamide) (CAS Reg. No. 37764-25-3), in or on sweet corn commodities at 0.05 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

1. *Plant metabolism.* A plant metabolism study has now been completed. Previously, the nature of the residue in corn was understood based on the published metabolism studies of N,N-diallyl-2- chloroacetamide. At that time, it was concluded that the metabolism of dichlormid would follow the pathway of N,N-diallyl-2-chloroacetamide. However, the metabolism of dichlormid in corn is extensive and occurs via two metabolic pathways. In one pathway, dichlormid is de-chlorinated and oxidized to generate N,N-diallyl glycolamide. An alternative pathway is the loss of an allyl group followed by oxidation to form dichloracetic acid. There is also extensive incorporation into natural constituents. Dow AgroSciences LLC now believes that the qualitative nature of the residue in plants is adequately understood based on a study depicting the metabolism of dichlormid in corn plants.

2. *Analytical method.* As stated in the Agency's Final Rule published August 7, 2002 (67 FR 51102) (FRL–7192–5) establishing time-limited tolerances for dichlormid in field corn and pop corn:

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: *furlow.calvin@epa.gov.*

3. *Magnitude of residues.* Fourteen field trials in sweet corn with dichlormid were conducted covering the major growing areas in the United States. Dichlormid was applied preplant incorporated or pre-emergence at an application rate of 0.5 lb active ingredient (a.i.) per acre. In all trials, no detectable residues of dichlormid (LOD 0.01 ppm) were found in the forage, stover or kernels plus cobs with husks removed (K+CWHR)

B. Toxicological Profile

1. *Acute toxicity.* Dichlormid has low acute toxicity as indicated by a range of studies including: A rat acute oral study with a lethal dose (LD_{50}) of 2,816 milligrams/kilogram (mg/kg) for males and 2,146 mg/kg for females, respectively; a rat acute dermal study with an LD_{50} of >2,040 mg/kg, and a rabbit acute dermal study with an LD_{50} of >5,000 mg/kg; a rat inhalation study with an LD_{50} of >5.5 milligrams/liter (mg/L); a primary eye irritation study in the rabbit showing mild ocular irritation; a primary dermal irritation study in the rabbit showing severe skin irritation; and a skin sensitization study which showed that dichlormid was a mild skin sensitizer in the guinea pig.

2. *Genotoxicty.* Dichlormid was not mutagenic in a range of *in vitro* assays, including the Salmonella/microsome (Ames) assay, the human lymphocyte cytogenetic assay (both assays with and without metabolic activation), and an unscheduled DNA synthesis (DNA repair) assay in hepatocytes. In the L5178Y mouse lymphoma assay, small increases in mutant frequency were observed only at cytotoxic concentrations, and were not considered to be significant. *In vivo*, dichlormid was negative in the mouse micronucleus test and in the rat unscheduled DNA synthesis assay, when tested at the maximum tolerated dose.

3. *Reproductive and developmental toxicity.* In a developmental toxicity study, rats were dosed orally by gavage with 0, 10, 40, or 160 mg/kg/day. The no observed adverse effect level (NOAEL) for maternal toxicity was 10 mg/kg/day based on a reduction in body weight gain and food consumption at 40 and 160 mg/kg/day. The developmental NOAEL was determined to be 40 mg/kg/day based on marginal foetotoxic effects, including extra 14^{th} ribs probably due to maternal stress, slight sternebra misalignment and some centra unossified, at 160 mg/kg/day.

In a developmental toxicity study, rabbits were dosed orally by gavage with 0, 5, 30, or 180 mg/kg/day. The lowest observed effect level (LOAEL) for both maternal and fetotoxicity was 180 mg/kg/day characterized by reduced body weight gain and food consumption, and a small increase in post implantation loss, an increased number of early resorptions, a decreased number of fetuses per litter and evidence of foetotoxicity (partial ossification and misshapen/fused sternebrae). The NOAEL for both maternal and developmental toxicity was 30 mg/kg/day.

In a two-generation reproduction study in rats fed diets of 0, 15, 75, and 500 ppm of dichlormid, dietary administration of 500 ppm dichlormid (48.5 mg/kg/day) for two successive generations resulted in decreased body weights and increased liver weights in parents and pups of both generations. There were no effects on reproductive performance or reproductive organs at dose levels up to and including 500 ppm dichlormid. There were no toxicologically significant effects in parents or offspring at a dose level of 75 ppm dichlormid (>7.4 mg/kg/day).

4. *Subchronic toxicity.* In a subchronic toxicity study, groups of 12 male and 12 female Wistar-derived alpk:ApfSD rats were fed diets containing 0, 20, 200, or 2,000 ppm dichlormid for 90 days. Significant reductions in body weight gain and food consumption were seen in male and female rats receiving 2,000 ppm dichlormid, and to a lesser degree, in females at 200 ppm. The liver was identified as the principal target organ (enlargement increased APDM activity in females, centrilobular hypertrophy, increased bile duct pigmentation) in the 2,000 ppm group. The NOAEL was 20 ppm (equivalent to approximately 1.8 mg/kg/day), and the LOAEL was 200 ppm based on reduced body weight gain and food consumption, and a marginal increase in APDM activity in females and liver enlargement in males.

In a 90–day dog feeding study, previously submitted and reviewed by EPA, animals were dosed (4 dogs/sex/dose) at 0, 1, 5, 25, and 50 mg/kg/day. The NOAEL was 5 mg/kg/day, and the LOAEL 25 mg/kg/day based on reduced body weight gain, increased liver weight and degenerative changes involuntary muscle with an associated increase in plasma creatine kinase and alkaline phosphatase activity between 6 and 10 weeks.

In a 14–week rat inhalation study, groups of 18 male and 18 female Sprague-Dawley CD rats were subjected to a whole body exposure of 0, 2.0, 19.9, or 192.5 mg/m^3 for 6 hours per day, 5 days per week. The NOAEL was 2.0 mg/m^3 based on histopathologic tissue alterations to the nasal olfactory epithelium at 19.9 and 192.5 mg/m^3, suggesting that dichlormid was a mild irritant to the nasal cavity. An increase in relative liver, kidney and lung weights at 19.9 and 192.5 mg/m^3 was not supported by gross or histopathological observations.

5. *Chronic toxicity.* Rats (64/sex/group) were fed diets containing 0, 20, 100, or 500 ppm dichlormid (0, 1.3, 6.5, 32.8 mg/kg/day for males and 0, 1.5, 7.5, 37.1 mg/kg/day for females) for up to 2 years. At 500 ppm in both males and females, there were treatment-related effects on growth and food consumption, minor reductions in plasma triglycerides, and in males, increased liver weights accompanied by hepatocyte vacuolation and pigmentation effects. In females, there was a slight overall increase in malignant tumors, primarily uterine adenocarcinomas, at 500 ppm, but this specific increase was within the spontaneous incidence observed in historical data. It was concluded that there was no evidence of oncogenicity associated with dichlormid treatment. The NOAEL for chronic toxicity was 100 ppm (6.5 and 7.5 mg/kg/day for males and females, respectively).

In an 18–month oncogenicity study, mice (55/sex/group) were fed dichlormid at doses of 0, 10, 50, or 500 ppm (0, 1.4, 7.0, 70.7 mg/kg for males and 0, 1.84, 9.2, 92.4 mg/kg for females). At 500 ppm, there was a slight increase in mortality for females from week 64 onward, and body weights and food utilization were reduced in males, and to a lesser extent, in females. Also, mice fed 500 ppm dichlormid showed non-neoplastic changes which were minor and consisted of changes in severity or incidence of common spontaneous findings. Based on these effects, the chronic NOAEL was 50 ppm (7.0 and 9.2 mg/kg/day for males and females, respectively). There was a marginal increase in Harderian gland adenomas in males at 500 ppm, but this was considered to reflect the variable spontaneous tumor rate seen in this strain and sex of mouse. It was concluded there was no evidence of oncogenicity associated with dichlormid treatment.

Based on available chronic toxicity data, the reference dose (RfD) for dichlormid is 0.07 mg/kg/day. This RfD is based on the 2–year feeding study in rats with a NOAEL of 7 mg/kg/day. An uncertainty factor of 100 was used to account for interspecies extrapolation and intraspecies variability. The 2–year rat study is consistent with, but supersedes the 90–day rat study. The 2–year rat NOAEL of 7 mg/kg/day lies between 1.8 and 18 mg/kg/day derived from the NOAEL and LOAEL figures of 20 and 200 ppm, respectively, for the most recent 90–day rat study. Thus, the overall NOAEL in the rat for both chronic and subchronic exposure should be regarded as 7 mg/kg/day. Based on the proposed Guidelines for Carcinogenic Risk Assessment (July 1999), dichlormid is not likely to be a human carcinogen, and a margin of exposure (MOE) approach should be used for human risk assessment.

6. *Animal metabolism.* Dichlormid was well absorbed, extensively metabolized and eliminated mainly in the urine within 24 hours. A significant proportion of the dose, up to 11%, was exhaled as CO_2. Two routes of biotransformation have been identified. One route involved the formation of an alcohol N,N-diallylglycolamide before subsequent oxidation to N,N-diallyloxamic acid, a major metabolite present in the urine and feces of both sexes. N,N-diallylglycolamide also undergoes further biotransformation to minor dechlorinated metabolites. In the second metabolic pathway, dichloroacetic acid present in the urine of both sexes is formed either directly from dichlormid or indirectly by transformation of N-allyl-2,2-dichloro-N-(2,3-dihydroxypropyl)acetamide. Entero-hepatic recirculation plays a major role in the distribution, metabolism and excretion of dichlormid. The elimination as CO_2, the even elimination in urine over the first 24 hours, and wide distribution of retained radioactivity indicates some incorporation into endogenous metabolic processes.

7. *Metabolite toxicology.* No unique plant or soil metabolites have been identified that warrant a separate toxicological assessment.

8. *Endocrine disruption.* There is no overall trend in the toxicology data base that indicates that dichlormid would have endocrine disrupting activity. The mammalian and ecotoxicology data bases do not indicate significant adverse effects associated with endocrine disrupter activity.

C. Aggregate Exposure

1. *Dietary*—i. *Food.* In conducting a chronic dietary risk assessment, reference is made to the conservative assumptions made by EPA in establishing dichlormid time-limited tolerances on March 27, 2000 (65 FR 16143) (FRL–6498–7), 100% crop treated (CT), and that all commodities contain residues at the tolerance or proposed tolerance. The analysis was determined using the Novigen Dietary Exposure Evaluation Model (DEEM Version 6.2) software and the United States Department of Agriculture (USDA) nationwide Continuing Surveys of Food Intake by Individuals (CSFII) survey that was conducted from 1994 through 1996.

ii. *Drinking water.* Dichlormid is very rapidly degraded in soil (laboratory measured aerobic half-life of 8 days) and applied at a maximum rate of 0.5 lb/acre, so despite only exhibiting moderate adsorption to soil (Koc 36–49), the leaching potential for dichlormid to reach ground water is expected to be low. The impact of the interactive processes of adsorption and degradation on leaching have been assessed using EPA mathematical models of pesticide movement in soil. Drinking water estimate concentrations (DWEC) were calculated for ground water using Screening Concentration in Ground water (SCI-GROW) modeling, and surface water estimate concentrations were calculated using Generic Estimated Environmental Concentration (GENEEC) modeling. These models predict a ground water concentration of 0.05 ppb and surface water concentrations of 27.3 parts per billion (ppb) for an instantaneous peak, and 26.9 ppb for a 56–day average. However, the interim Agency policy allows the average 56–day GENEEC values to be divided by 3 (9.0 ppb) to obtain a value for chronic risk assessments. Drinking water levels of concern (DWLOC) were calculated for both chronic and acute exposure. As stated in the March 27, 2000 final rule:

> . . .the modeled groundwater and surface water concentrations are less than the DWLOCs for dichlormid in drinking water for acute and chronic aggregate exposures. Thus, the Agency is able to screen out dichlormid drinking water risks.

Dow AgroSciences LLC does not expect exposure to dichlormid residues in drinking water to be a concern, as a result of the increased exposure pattern.

2. *Non-dietary exposure.* The general population is not expected to be exposed to dichlormid through non-dietary routes since dichlormid is used only on agricultural crops and is not used in or around the home.

D. Cumulative Effects

The potential for cumulative effects of dichlormid and other substances that have a common mechanism of toxicity have been considered. There is no reliable information to suggest that dichlormid has any toxic effects that arise from toxic mechanisms common to other substances. Therefore, a consideration of common mechanism and cumulative effects with other substances is not appropriate for dichlormid.

E. Safety Determination

1. *U.S. population*—i. *Chronic risk.* Using the conservative exposure assumptions described earlier, and based on the completeness and reliability of the toxicity data base for dichlormid, the theoretical maximum residue concentration (TMRC) for the general U.S. population is calculated to be 0.0009 mg/kg/day, or 4.1% of the cPAD (0.0022 mg/kg/day). The most highly exposed subgroup are children aged 1–6 years with a TMRC of 0.000211 mg/kg/day, or 9.6% of the cPAD. As 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, Dow AgroSciences LLC believes that there is a reasonable certainty that no harm will result from aggregate exposure to dichlormid residues.

ii. *Acute risk.* The acute toxicity of dichlormid is low, and there are no concerns for acute-dietary, occupational or non-occupational exposures to dichlormid.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of dichlormid, data from developmental toxicity studies in the rat and rabbit have been considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. There was no evidence to suggest that dichlormid was a developmental toxicant in either the rat or rabbit. It was also observed that there was no risk below maternally toxic doses as the NOAEL for developmental effects in the rat was 40 mg/kg/day, compared to the maternal NOAEL of 10 mg/kg/day; and in the rabbit study, the NOAEL for both maternal and developmental effects was 30 mg/kg/day. EPA has previously concluded, that the additional 10x safety factor should be retained due to the qualitative evidence of increased susceptibility demonstrated following *in utero* exposure in the prenatal developmental toxicity in rabbits and an incomplete toxicity data base. It should be noted that in the rabbit developmental toxicity study, the LOAEL for both maternal and developmental toxicity was 180 mg/kg/day. The effects on resorptions at this dose were observed in dams which showed an average weight loss (–3.8g) during the treatment period compared with an average weight gain in controls of 272g. Also, a multigeneration study has now been completed, and therefore, Dow AgroSciences LLC believes that an additional safety factor should no longer be necessary.

Additional uncertainty factors are not warranted for the safety of infants and children as reliable data support the appropriate use of a 100–fold uncertainty factor margin of exposure (MOE) to account for interspecies extrapolation and intraspecies variability. However, using the conservative exposure assumptions above for the determination in the

general population, it is concluded that the percentage of cPAD that will be utilized by aggregate exposure to dichlormid is 9.6% for children aged 1–6 years (the group at highest risk). Therefore, based on the completeness and reliability of the toxicity data base and the conservative exposure assessment, Dow AgroSciences LLC, concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to dichlormid residues.

F. International Tolerances

There is neither a codex proposal nor Canadian or Mexican limits for residues of dichlormid in corn commodities.

[FR Doc. 03–29188 Filed 11–20–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7590–2]

Underground Injection Control Program: Hazardous Waste Injection Restrictions; Petition for Exemption—Class I Hazardous Waste Injection, Rubicon, Inc.

AGENCY: Environmental Protection Agency.

ACTION: Notice of final decision on Rubicon Inc., no migration petition reissuance.

SUMMARY: Notice is hereby given that an exemption to the land disposal restrictions under the 1984 Hazardous and Solid Waste Amendments to the Resource Conservation and Recovery Act has been granted to Rubicon, Inc., for five Class I injection wells located at Geismar, Louisiana. As required by 40 CFR part 148, the company has adequately demonstrated to the satisfaction of the Environmental Protection Agency by petition and supporting documentation that, to a reasonable degree of certainty, there will be no migration of hazardous constituents from the injection zone for as long as the waste remains hazardous. This final decision is for injection Well Nos. 1, 2, 3, 4, and 5, all located at the Rubicon facility in Geismar, Louisiana.

As required by 40 CFR 148.22(b) and 124.10, a public notice was issued September 12, 2003.

The public comment period closed on November 4, 2003. No comments were received. This decision constitutes final Agency action and there is no Administrative appeal.

DATES: This action is effective as of November 12, 2003.

ADDRESSES: Copies of the petition and all pertinent information relating thereto are on file at the following location: Environmental Protection Agency, Region 6, Water Quality Protection Division, Source Water Protection Branch (6WQ–S), 1445 Ross Avenue, Dallas, Texas 75202–2733.

FOR FURTHER INFORMATION CONTACT: Rafael Casanova, Acting Chief, Ground Water/UIC Section, EPA—Region 6, telephone (214) 665–7165.

Oscar Ramirez Jr.,

Acting Director, Water Quality Protection Division (6WQ).

[FR Doc. 03–29180 Filed 11–20–03; 8:45 am]

BILLING CODE 6560–50–U

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than December 5, 2003.

A. Federal Reserve Bank of Kansas City (James Hunter, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. John H. Bergmeyer, Lincoln, Nebraska; to acquire control of SSB Management LLC, and thereby indirectly acquire Wilber Co., and its subsidiary, Saline State Bank, both of Wilber, Nebraska.

Board of Governors of the Federal Reserve System, November 17, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–29064 Filed 11–20–03; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 15, 2003.

A. Federal Reserve Bank of Atlanta (Sue Costello, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30303:

1. Alabama National BanCorporation, Birmingham, Alabama; to merge with Indian River Banking Company, and thereby indirectly acquire Indian River National Bank, both of Vero Beach, Florida.

B. Federal Reserve Bank of Kansas City (James Hunter, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. SSB Management LLC, Wilber, Nebraska; to acquire an additional 27.78 percent, for a total of 50 percent, of the voting shares of Wilber Co., Wilber, Nebraska, and thereby indirectly acquire additional shares of Saline State Bank, Wilber, Nebraska.