Department of Agriculture, the Oregon Department of Agriculture, and the Washington State Department of Agriculture have requested the Administrator issue specific exemptions for the use of quinoxyfen on hops to control powdery mildew. Information in accordance with 40 CFR part 166 was submitted as part of this request.

As part of this request, the Applicants assert that currently registered products and non-chemical control measures do not provide adequate season long control of powdery mildew on susceptible hops varieties. Powdery mildew (*S. macularis*) is a serious hop disease in many hop growing areas throughout the world. During the early part of this century, a commercial hop production industry in the State of New York was devastated due to what is believed to have been an uncontrolled outbreak of powdery mildew. Before June of 1997, this disease had not been observed in the Pacific Northwest. Quinoxyfen has been shown to be an effective fungicide against hop powdery mildew over the past 4 years of testing. Quinoxyfen has not shown any plant growth regulatory effects or adverse impact to cone size. Additionally, quinoxyfen is a quinoline fungicide, which will provide growers with a new mode of action to control powdery mildew.

The U.S. is the second largest producer of hops in the world. The States estimate that there will be an 8% to 30% loss of gross revenues without the use of quinoxyfen.

The Applicants propose to apply no more than 6 to 8 fluid ounces of formulated product, containing 22.58% quinoxyfen (0.098 to 0.13 pound/active ingredient) per acre per application. No more than four applications per acre per year will be made. A total of 19,500 acres of hops may be treated; up to 3,000 acres of hops in Idaho, 3,500 acres of hops in Oregon, and 13,000 acres of hops in Washington State. Applications will be made from July 1, 2003, through September 15, 2003. Based on the maximum application rate and a total of four applications per acre, up to 10,140 pounds of quinoxyfen could be applied.

This notice does not constitute a decision by EPA on the application itself. The regulations governing section 18 of FIFRA require publication of a notice of receipt of an application for a specific exemption proposing ''use of a new chemical (i.e., an active ingredient) which has not been registered by EPA.''

The Agency, will review and consider all comments received during the comment period in determining whether to issue the specific exemptions requested by the Idaho Department of Agriculture, the Oregon Department of Agriculture, and the Washington State Department of Agriculture.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: March 13, 2003.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 03–6947 Filed 3–25–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0008; FRL–7289–2]

Vinclozolin; 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 to make permanent the tolerances for residues, and to extend existing tolerances for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP– 2003–0008, must be received on or before April 25, 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: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9354; e-mail address: *waller.mary@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 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)
- Antimicrobial pesticides (NAICS 32561)

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 identification (ID) number OPP–2003–0008. 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, 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–2003–0008. 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–2003–0008. 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–2003–0008.

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–2003–0008. 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: March 18, 2003.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view 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.

BASF Corporation

PP 1F6278

EPA has received a pesticide petition (1F6278) from BASF Corporation, Agricultural Products, P.O. Box 13528, Research Triangle Park, NC 27709–3528 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180.380 by making permanent the tolerances for residues of vinclozolin, 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety in or on the raw agricultural commodities canola at 1.0 parts per million (ppm); eggs, milk, and the meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.05 ppm; and in the meat, fat, and meat byproducts of poultry at 0.1 ppm. In addition, BASF had proposed extending the existing tolerance on succulent beans at 2.0 ppm for an additional 2 years. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. BASF Corporation notes that metabolism in plants is understood, the residues of concern are vinclozolin, 3-(3,5-dichlorophenyl)-5-methyl-5-vinyl-1,3-oxazolidine-2,4-dione) and metabolites containing the 3,5-dichloroanaline moiety.

2. *Analytical method*. The proposed analytical method involves extraction, hydrolysis, distillation, partition, and deriviatization followed by detection of residues by gas chromatograph/electron capture detector (gc/ecd). An enforcement method has been published in FDA's Pesticide Analytical Methods, Volume II pg. 876–887.

3. *Magnitude of residues*. Data previously submitted in support of the tolerances in canola, succulent beans and meat, milk, poultry, and eggs have been reviewed by the Agency and been found adequate to support the tolerances requested.

B. Toxicological Profile

1. *Acute toxicity*. On July 18, 2000, EPA published in the **Federal Register** (65 FR 44453) (FRL–6594–8), time limited tolerances for vinclozolin in canola, succulent beans and meat, milk, poultry and eggs. The toxicological profile as reported in that **Federal Register** is repeated in this Notice. A battery of acute toxicity studies placed technical vinclozolin in toxicity category IV for acute oral toxicity lethal dose (LD_{50} of > 10,000 milligrams/kilograms (mg/kg)), and acute inhalation toxicity (LC_{50} of 29.1 mg/liter (L)); and toxicity category III for acute dermal toxicity (LD_{50} of > 5,000 mg/kg). Technical vinclozolin caused minimal eye and dermal irritation and the technical material is positive for skin sensitization.

2. *Genotoxicity*. Genotoxicity testing showed no evidence of mutagenic activity. (For details see the July 18, 2000 **Federal Register** (65 FR 44453)).

3. *Reproductive and developmental toxicity*—i. In four developmental toxicity studies, vinclozolin was given orally from gestational day (gd) 6 through 19 as follows: Study 4—dose levels of 0, 15, 50, or 150 mg/kg/day; study 5—dose levels of 0, 50, 100, 200 mg/kg/day; study 6—dose levels of 0, 200, 400 mg/kg/day; and study 8—dose levels of 0, 600, and 1,000 mg/kg/day. At the gd 20, the fetuses were evaluated.

The developmental toxicity no observed adverse effect level (NOAEL) was set at 15 mg/kg/day and the developmental lowest observed adverse effect level (LOAEL) was 50 mg/kg/day. The maternal toxicity LOAEL was < 600 mg/kg/day.

ii. A developmental study in rats via dermal exposure for 6 hours/day on intact skin with dosages of 0, 60, 180, and 360 mg/kg/day highest dose tested (HDT) had a developmental NOAEL of 60 mg/kg/day and a maternal NOAEL of 60 mg/kg/day.

iii. A developmental study in rabbits via oral gavage resulted in dosages of 0, 20, 80, and 300 mg/kg/day HDT with a developmental NOAEL of 300 mg/kg/day and a maternal NOAEL of 300 mg/kg/day.

iv. A second developmental study in rabbits via oral gavage resulted in dosages of 0, 50, 200, and 800 mg/kg/day HDT with a development toxicity NOAEL of 200 mg/kg/day and a maternal toxicity NOAEL of 50 mg/kg/day.

A two-generation rat reproduction study (consisting of two studies: Study A—dose levels of 0, 2.0 and 4.1 mg/kg/day; study B—dose levels of 0, 4.9, 29, 100, and 307 mg/kg/day) with a reproductive NOAEL of 4.9 mg/kg/day and pup effects at 29 mg/kg/day; and with a parental NOAEL of 4.9 mg/kg/day. (For a detailed discussion of the

results of these studies see the **Federal Register** of July 18, 2000 (65 FR 44453)).

4. *Chronic toxicity*—i. A 1–year chronic feeding study in dogs fed dosages of 0, 1.1, 2.4, 4.9, and 48.7 mg/kg/day with a NOAEL of 2.4 mg/kg/day.

ii. A combination of 2 chronic feeding studies and 1 carcinogenicity study resulted in rats being fed combined dosages of 0, 1.2, 2.4, 7.0, 23, 71, 143, and 221 mg/kg/day (males) and 0, 1.6, 3.1, 7.0, 23, 71, 180, and 221 mg/kg/day (females) with a NOAEL of 1.2 mg/kg/day (males) and 1.6 mg/kg/day (females). An increased incidence of neoplasms occurred at dose levels greater than the maximum tolerated dose (MTD) of greater than or equal to 23 mg/kg/day in the liver, adrenal, pituitary, prostate (males), uterus (females), and ovaries (females) at dose levels greater than or equal to 143 mg/kg/day. In the testes (males), Leydig cell adenomas were seen at the MTD for dose levels greater than or equal to 23.0 mg/kg/day due to the anti-androgenic nature of vinclozolin.

5. *Carcinogenicity*. A carcinogenicity study in mice fed dosages of 0, 2.1, 20.6, 432, and 1,225 HDT mg/kg/day (males) and 0, 2.8, 28.5, 557, and 1,411 (HDT) mg/kg/day (females) with a NOAEL of 20.6 mg/kg/day (males) and 28.5 mg/kg/day.

An increased incidence of neoplasms occurred at dose levels greater than the maximum tolerated dose (> 28.5 mg/kg/day) in the liver of female mice. (For a detailed discussion of the results of these studies see the **Federal Register** of July 18, 2000 (65 FR 44453)).

C. Toxicological Endpoints

EPA determined the following toxicological endpoints as reported in the **Federal Register** Notice of July 18, 2000. That reference provides a complete description of the Agency's rationale for the values assigned.

1. *Acute toxicity*. EPA selected the NOAEL of 6 mg/kg/day. The population subgroup of concern is females (13+) because the endpoint is an *in utero* effect applicable only to females of childbearing age. An uncertainty factor (UF) of 100 was used to account for interspecies extrapolation and intraspecies variation. On this basis, the acute reference dose (aRfD) is 0.06 mg/kg/day. EPA determined that a 10X FQPA safety factor is applicable. The acute population adjusted dose (aPAD) is 0.006 mg/kg/day. An acute dose and endpoint were not identified for other population subgroups.

2. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for vinclozolin at 0.012 mg/kg/day. This RfD is based on a NOAEL of 1.2 mg/kg/day from the combined chronic toxicity/carcinogenicity study in rats. An UF of 100 was used to account for interspecies extrapolation and intraspecies variation. A 10X FQPA safety factor was added resulting in a chronic population adjusted dose (cPAD) of 0.0012 mg/kg/day.

3. *Short- and intermediate-term toxicity*. For short- and intermediate-term dermal and inhalation toxicity, the NOAEL of 3 mg/kg/day from a rat developmental toxicity study was selected for the population subgroup of concern, females (13+). A dermal absorption factor of 25% was used to correct for route-to-route extrapolation (oral to dermal exposure) and a default inhalation absorption factor of 100% was assumed for oral to inhalation exposure. The margin of exposure (MOE) for females (13+), infants and children is 1,000X.

4. *Long-term dermal and inhalation toxicity (cancer and non-cancer)*. For chronic non-cancer and cancer dermal and inhalation toxicity, EPA selected the chronic NOAEL of 1.2 mg/kg/day from the combined rat chronic toxicity/carcinogenicity study. The Q^{1*} calculated in a low-dose linear extrapolation is 2.9×10^{-1} (mg/kg/day). A dermal absorption factor of 25% was used to correct for route-to-route extrapolation (oral to dermal exposure) and a default inhalation absorption factor of 100% was assumed for oral to inhalation exposure. The cancer assessment includes not only the adult U.S. population but also infants and children as well.

5. *Carcinogenicity*. Vinclozolin is classified as a Group C carcinogen based on Leydig (interstitial testicular) cell tumors in a perinatal rat developmental toxicity study. A non-linear (MOE) approach was determined to be appropriate based on a weight-of-the-evidence conclusion that tumor induction is via an anti-androgenic mechanism. Use of the PAD for overall anti-androgenic effects (0.0012 mg/kg/day) is also protective of cancer effects because it is protective of the anti-androgenic effects that are, in effect, precursors to tumor formation.

6. *Overall anti-androgenic effects*. The Agency has determined that use of the most sensitive regulatory toxicity endpoint and the highest UF would be protective of the anti-androgenic effects on all population subgroups caused by vinclozolin including developmental/reproductive effects as well as carcinogenic effects. In the case of vinclozolin, the most sensitive toxicity endpoint/dose and UF are derived from the rat oral chronic/carcinogenicity study, i.e., the NOAEL of 1.2 mg/kg/day and an UF of 1,000. The PAD of 0.0012 mg/kg/day was used in assessment of risks resulting from the anti-androgenic activity of vinclozolin.

7. *Endocrine disruption*. A series of mechanistic studies (*in vivo* and *in vitro*) were conducted to define the anti-androgenic properties of vinclozolin. The results of these studies showed that vinclozolin elicits the anti-androgenic effects by binding to androgen sensitive organs.

D. Aggregate Exposure

For a detailed discussion of the results of these exposure calculations see the **Federal Register** of July 18, 2000 (65 FR 44453).

1. *Dietary exposure*. The Agency has previously calculated exposures and risks for the canola green beans, meat, milk, poultry and eggs. The same calculations should be applied to re-establishing these tolerances.

i. *Food—a. acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. The Agency concluded that acute dietary exposure estimates for the only population subgroup of concern, females (13+), that ''The very conservatively estimated acute dietary risk (food only) does not exceed the Agency's level of concern (LOC).''

b. Chronic exposure and risk. The chronic dietary exposure estimates expressed as a percentage of the cPAD (0.0012 mg/kg/day) were 4% for the U.S. population and 7% for the most highly exposed population subgroup, children (1–6 years old). EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risk to human health. Therefore, the chronic dietary risk (food only) does not exceed the Agency's LOC.

ii. *For cancer and anti-androgenic risk assessment*. EPA believes that vinclozolin should be classified as a Group C carcinogen. However, due to the relationship between vinclozolin's anti-androgenic properties and its carcinogenic effects, the Agency believes protecting against the anti-androgenic effects would also be protective against potential carcinogenic effects to all population subgroups (including infants and children).

Accordingly, the cPAD will be protective against potential carcinogenic effects as well as the developmental/reproductive effects. The cPAD already incorporates the full, additional 10x

safety factor for the protection of infants and children (i.e., it is derived from the NOAEL of 1.2 mg/kg/day with an MOE of 1,000 – 10x for intraspecies extrapolation; 10x for interspecies variation; and 10x for FQPA). Since this approach (using the cPAD) would be more protective than the proposed POD for cancer risk assessment of 3 mg/kg/day, and includes an additional 10x factor for the protection of infants and children, a separate non-linear risk assessment for cancer is not necessary.

Exposure estimates expressed as a percentage of the anti-androgenic PAD (0.0012 mg/kg/day) were 4% for the general U.S. population and 7% for the most highly exposed population subgroup, children (1–6 years old). In addition, as a point of comparison, the MOE was calculated to be 75,000 for the general U.S. population and 38,000 for children (1–6 years old).

2. *Drinking water*. In general, available monitoring data are of limited use because metabolite concentration measurements were not performed. For both surface water and ground water, the sum of vinclozolin and its principal metabolites, assumed to degrade completely to 3,5-dichloroaniline (herein-after referred to as 3,5-DCA), have been used to assess the cancer risk associated with 3,5-DCA whereas vinclozolin per se has been used for the vinclozolin risk assessments.

In the absence of reliable, available monitoring data, EPA uses models to calculate the estimated environmental concentrations (EECs) of pesticides in ground water and surface water. However, EPA does not use these model estimates to quantify risk. Currently, EPA uses drinking water level of concerns (DWLOCs) as a surrogate to capture risk associated with exposure to pesticides in drinking water. A DWLOC represents the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses (if any). A DWLOC will vary depending on the residue level in foods, the toxicity endpoint and the drinking water consumption patterns and body weights for specific population subgroups. The calculated DWLOC is compared to the model estimate (EEC), and if the model estimates are below the DWLOC, the risks are not considered to be of concern.

For estimating ground water concentrations of vinclozolin and 3,5-DCA, EPA used the Screening Concentration in Ground Water (SCI-GROW) model. Using SCI-GROW, the acute and chronic ground water EEC of vinclozolin per se is 0.53 parts per billion (ppb), and the acute and chronic ground water EEC of 3,5-DCA is 2.65 ppb.

For estimating surface water concentrations of vinclozolin and 3,5-DCA, EPA used tier II models, Pesticide Root Zone Model (PRZM) 3.12 and Exposure Analysis Modeling System (EXAMS) 2.975. The acute (peak) surface water EEC for vinclozolin is 5.68 ppb and for 3,5-DCA is 26 ppb. The chronic (annual mean) surface water EEC for vinclozolin is 0.165 ppb and for 3,5-DCA is 3.12 ppb.

i. *Acute exposure and risk*. For the population subgroup of concern, females (13+), the DWLOCs for vinclozolin per se at the various percentiles of exposure are as follows: 0 ppb at the 99.9th percentile; 4 ppb at the 99.85th percentile; 30 ppb at the 99.8th percentile; 47 ppb at the 99.75th percentile; 80 ppb at the 99.6th percentile; and 92 at the 99.5th percentile. At all but the very highest percentiles of exposure (99.85th and above), the DWLOC for vinclozolin per se is higher than the EEC of 5.68 ppb in surface water and 0.53 ppb in ground water. Given the level of refinement in the vinclozolin exposure estimate, using the highest percentiles of exposure in estimating risk would unreasonably overstate risk. Therefore, there is reasonable certainty that exposure to vinclozolin per se in drinking water will result in no harm.

ii. *Chronic exposure and risk*. The following chronic DWLOCs were calculated for vinclozolin per se: General U.S. population, 41 ppb; females (13+) 35 ppb; and children (1–6 years old), 11 ppb. The lowest DWLOC of 11 ppb for children 1–6 years old is higher than the EEC of 0.165 ppb in surface water and 0.53 ppb in ground water. Therefore, there is reasonable certainty that exposure to vinclozolin in drinking water will result in no harm.

3. *Non-dietary exposure*. From non-dietary exposure. There are no vinclozolin pesticide products registered for use by homeowners. Therefore, there is no potential for homeowner handler exposure to vinclozolin pesticide products. Vinclozolin can, however, be occupationally used in a manner that may lead to post-application exposures to the general population, in particular, golfers playing on treated golf courses and homeowners and their families coming into contact with or playing on sod which was previously treated on a sod farm. A chemical-specific turf exposure study was used to measure human exposure as well as residue dissipation over time.

All residential exposures are considered to be short-/intermediate-term duration (i.e., 1 day to 1 week and 1 week to several months, respectively), and the same endpoint applies to both durations of exposure. As the endpoints selected are from oral toxicity studies (NOAEL of 3 mg/kg/day for females (13+)) and NOAEL of 5 mg/kg/day for infants and children, route-to-route exposure was corrected by applying a 25% dermal absorption factor and a 100% default inhalation absorption factor was assumed. A 100% safety factor was used and a 10X FQPA safety factor was added raising the Agency's LOC to 1,000.

Post-application risks to the general population were considered for golfers following treatment of greens, tees, and fairways. Adult golfer exposures, women (13+), were less than the Agency's LOC even on the day of application (MOE = 1,700). Given the magnitude of the MOE for adult women golfers, the Agency does not believe that the risks to child golfers would exceed the Agency LOC either because the skin surface area/body weight ratio of the typical child golfer is similar to that of adults (within 15%). Therefore, the MOE for a child golfer is only slightly less than the MOE for adult golfers.

Since the risk assessment published in the **Federal Register**, of July 18, 2000 (65 FR 44453) establishing the tolerances in canola, BASF has established a 24 day preharvest interval for the harvest of turf for transplant into residential settings. The MOE calculated under this scenario is 1,100 which is below the Agency's LOC.

E. Cumulative Effects

Cumulative exposure to substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Vinclozolin, procymidone, and iprodione are members of the imide group of the dicarboximide class of fungicides. Each of these three pesticides can metabolize to 3,5-DCA. FQPA requires EPA to estimate cumulative risk from consumption of food and water containing 3,5-DCA derived from vinclozolin, iprodione, and procymidone.

1. *Acute exposure and risk*. EPA has certain evidence that these compounds induce similar toxic effects but has not

yet determined whether or not these compounds modulate androgens by a common mechanism of toxicity. In fact, there is evidence that iprodione does not share a common mechanism of toxicity as it disrupts the endocrine system by inhibiting androgen synthesis rather than competing for the androgen receptor as vinclozolin does. In addition, these three chemicals do not have any known metabolites/degradates in common with the possible exception of 3,5-DCA which is structurally and toxicologically different from the parent compounds and unlikely to be an androgen receptor antagonist.

EPA has, at this time, some data which suggests that vinclozolin and procymidone have a common mechanism of toxicity. An article published in *Toxicology & Industrial Health* (Vol. 15, ISS 1–2, 1999, pg. 80–93) which reports the findings by Dr. Earl Gray, National Health and Environmental Effects Research Laboratory, U.S. EPA, Research Triangle Park, NC, suggests that procymidone alters sexual differentiation in the male rat by acting as an androgen-receptor antagonist *in vivo* and *in vitro*. The Agency has yet to make a conclusion as to whether these data are sufficient to evaluate whether vinclozolin and procymidone have a common mechanism of toxicity.

Even if it is assumed that vinclozolin and procymidone share a common mechanism of toxicity, a finding of reasonable certainty of no harm for vinclozolin can be made because any cumulative risk resulting from adding procymidone residues in wine to vinclozolin exposure is unlikely to differ significantly from the risk of vinclozolin alone. This conclusion is based on a number of factors. The exposure assessment for vinclozolin estimates that vinclozolin exposure through wine grapes contributes < 2% of the total vinclozolin exposure. The percent of imported wine grapes that are treated with procymidone is similar to that of vinclozolin (estimated 10% of wine grapes treated with vinclozolin and 9.4% of wine grapes treated with procymidone), and therefore, the exposure pattern for these chemicals is similar. In addition, the exposure estimates conservatively assume that all wine bearing vinclozolin residues also contain procymidone residues. In all likelihood, wine grapes would be treated with either vinclozolin or procymidone but not both chemicals. Vinclozolin exposure and procymidone exposure through wine grapes would each add < 2% to the ''cumulative exposure.'' As noted above, the acute food-only risk of vinclozolin is 83% of the aPAD at the 99.8th percentile of exposure, and the acute ground water EEC of 0.53 ppb and the acute surface water EEC of 5.68 ppb are lower than the drinking water DWLOC which is 30 ppb at the 99.8th percentile of exposure. There is ultimately enough room in the risk cup to accommodate vinclozolin and procymidone risk, even, if in the future, EPA does determine that procymidone and vinclozolin share a common mechanism of toxicity.

2. *Carcinogenic exposure and risk*. Since 3,5-DCA is not a registered pesticide, there is no FIFRA toxicology data base for this compound. In previous risk assessments, EPA has used the Q^{1*} for p-chloroaniline (PCA) to assess the carcinogenicity (only toxicological endpoint identified for 3,5-DCA) for other structurally related chloroanilines. EPA's approach on chloroanilines is to consider chloroaniline metabolites to be toxicologically equivalent to PCA unless there is sufficient evidence that the metabolite is not carcinogenic. A Q^{1*} of 6.38×10^{-2} (mg/kg/day) has been calculated for p-chloroaniline based on the spleen sarcoma rate in male rats from a National Toxicology Program bioassay.

Exposure to 3,5-DCA was evaluated from the following sources: Residues of vinclozolin- and iprodione-derived 3,5-DCA in food and wine, residues of procymidone-derived 3,5-DCA in imported wine, and 3,5-DCA residues in water from domestic agricultural uses of iprodione and vinclozolin. There are no U.S. registrations for procymidone. Therefore, an evaluation of exposure to procymidone-derived 3,5-DCA in water is not appropriate.

3. *Food risk*—i. *From vinclozolin-derived 3,5-DCA residues*. Cancer risks were 2.6×10^{-7} for all crops, excluding strawberries and stone fruits. BASF notes that the last day for legal use of vinclozolin in either strawberries or stonefruit was January 2000. In effect neither commodity has been treated with vinclozolin since the 1999 use season. In addition, the last day for legal use of vinclozolin on onions and raspberries was December 15, 2001. As a result the theoretical cancer risk calculated is an overestimation and these risks do not exceed the Agency's LOC.

ii. *From iprodione-derived 3,5-DCA residues*. As stated in the July 1998 Iprodione RED fact sheet, the cancer risk associated with 3,5-DCA derived from iprodione was 6×10^{-9}. This risk does not exceed the Agency's LOC.

iii. *From procymidone-derived 3,5-DCA residues*. The cancer risk associated with 3,5-DCA in imported wine produced from grapes treated with procymidone was estimated to be 3.7×10^{-7}. This risk does not exceed the Agency's LOC.

4. *Drinking water risk*—i. *From vinclozolin derived 3,5-DCA*. Since the use on onions has been eliminated, the carcinogenic DWLOC for 3,5-DCA (based on the commodities currently available for consumption) has been calculated to range from 0.46 ppb to 1.6 ppb. Using Tier II PRZM/EXAMS, the modeled EECs are 0.64 ppb for lettuce and 0.34 ppb for canola. The use site which represents the highest modeled exposure in drinking water is golf courses. Application to golf course turf is currently permitted on grass mowed at 1 inch or less. Using the Tier I generic expected environmental concentration (GENEEC) model, the Agency has calculated a chronic EEC of 0.29 ppb based on application to tees and greens and a chronic EEC of 2.33 ppb assuming application to tees, greens, and fairways. These EECs were the result of refinements to the GENEEC model. These refinements included the incorporation of an 87 percent crop area factor as well as the percentage of the golf course that actually receives pesticide treatment, bringing the resulting PCA factor down to 17%. It was assumed that tees and greens comprise 2.8% of the acreage of a golf course. When fairways are included, an additional 16.7% of the golf course is treated. The EEC of 2.33 ppb exceeds the DWLOC. In evaluating whether this EEC indicated a risk of concern EPA considered the following factors:

ii. *The drinking water assessment on turf is based on GENEEC, a screening-level Tier I model*. At present, PRZM-EXAMS, the Tier II model, does not have the appropriate parameters to accurately model turf runoff. Although GENEEC is not an ideal tool for use in drinking water risk assessments, it can provide high-end estimates of the concentrations that might be found in a confined pond of one hectare. Drinking water from surface water sources does not typically come from this type of scenario, but rather from bodies of water that are substantially larger than such ponds and from diverse watersheds. Unlike a confined pond, there is always some flow (in a river) or turn over (in a lake or reservoir) resulting in an over-estimation of the persistence of the chemicals near the drinking water utility intakes. Although a PCA of 17% was used to refine the model, the Agency recognizes that there are still uncertainties in the accuracy of the model to represent drinking water concentrations.

iii. *The GENEEC model uses the 56–day average of pesticide concentrations immediately after an event (application of pesticide).* This short time-period may not adequately characterize a person's average daily exposure over a year, even more so, over a life time of 70 years.

iv. *The GENEEC model assumes that once in every 10 years the EEC will be exceeded.* For the other 9 out of 10 years the level of residue in drinking water is likely to be below the EEC with at least one half of the years falling significantly below by a factor of 5 to 10. Therefore, a person may be exposed to the EEC once in every 10 years or a total of 7 times during a lifetime of 70 years. The Agency believes the potential for such a lifetime exposure is minimal.

v. *Iprodione 3,5-DCA.* As stated in the RED, the DWLOC for 3,5-DCA derived from domestic uses of iprodione was estimated to be 0.55 ppb. The 3,5-DCA EEC in surface water associated with the use of iprodione alone was estimated to be 0.45 ppb. Thus, the iprodione derived 3,5-DCA carcinogenic DWLOC is not exceeded.

vi. *From procymidone 3,5-DCA.* There is no drinking water exposure because procymidone is not registered for use in the United States.

The cumulative, food-only cancer risk associated with 3,5-DCA derived from all three of these imide fungicides is 6.3 x 10^{-7} when stone fruit and strawberries are excluded from consideration. There is uncertainty in the above risk estimates in that a surrogate Q^{1*} is being used for 3,5-DCA. However, due to the structural similarities of 3,5-DCA and p-chloroaniline (PCA), EPA believes that for 3,5-DCA, the use of the PCA Q^{1*} represents an upper-bound estimate.

The 3,5-DCA DWLOC from all three imide fungicides and those currently registered vinclozolin uses which are not being supported after this use season ranges from 0.26 ppb to 1.4 ppb. The estimated concentration of 3,5-DCA in water from applications of iprodione (1998 iprodione RED) is 0.45 ppb and falls within the range of the aggregated DWLOC cited above. The estimated concentration of 3,5-DCA in water from applications of vinclozolin is estimated to range from 0.29 ppb to 2.33 ppb.

As already stated, this range could potentially present a risk of concern based on the model, however, based on how the model estimates residue concentrations for cancer assessment, it is unlikely that a cancer risk of concern is present.

F. Safety Determination

1. *U.S. population*—i. *Acute risk.* The acute dietary (food only) risk does not exceed the Agency's LOC at the percentiles of exposure up to the 99.8th percentile. Using anticipated residues, PCT data, and PICT data, the population subgroup of concern, females (13+) utilized 83% of the dietary (food only) aPAD at the 99.8th percentile of exposure. For drinking water, the EEC of 5.68 ppb in surface water and the EEC of 0.53 in ground water did not exceed the DWLOC of 30 ppb at the 99.8th percentile of exposure.

ii. *Chronic risk.* Using the exposure assumptions described above, aggregate dietary exposure to the U.S. population will use 4% of the cPAD and exposure to the most highly exposed population subgroup, children (1–6 year old) will use 7% of the cPAD. The chronic DWLOCs for vinclozolin were 41 ppb for the general U.S. population and 35 ppb for the most highly exposed population subgroup, women (13+). The chronic DWLOCs were higher than the chronic EEC of 0.53 ppb in ground water and 0.165 ppb in surface water. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

2. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. All residential exposures are considered to be short- and intermediate-term duration and since the same endpoint applies to both durations of exposures, the dermal and inhalation exposures must be aggregated together with the food and water exposures for each population subgroup of concern, females (13+) and infants and children. Since the risk assessment published in the **Federal Register** of July 18, 2000 (65 FR 44453), establishing the tolerances in canola, BASF has established a 24–day preharvest interval for the harvest of turf for transplant into residential settings. The MOE calculated under this scenario is 1,100 which is below the Agency's LOC.

3. *Aggregate cancer risk for U.S. population.* Because the overall anti-androgenic effects are a prerequisite for hyperplasia and tumor formation, and are considered to be protective of the potential carcinogenic outcome of exposure to the anti-androgenic vinclozolin and its metabolites, the overall anti-androgenic aggregate risk which are identical to the chronic aggregate risk. The chronic aggregate risks are presented. The chronic (non-cancer) aggregate risk was below the Agency's LOC for food and drinking water sources of exposure. Chronic food-source risks were less than or equal to 7% of the cPAD when stone fruit and strawberries are excluded (uses have been canceled). EECs were compared to the chronic DWLOCs. The chronic EEC for residues of vinclozolin per se in ground water (0.53 ppb) was below the chronic DWLOCs for water consumption by adults (41 ppb for the general U.S. population and 35 ppb for females (13+)) and by children (11 ppb).

Cancer risks from vinclozolin derived 3,5-DCA were 2.6 x 10^{-7} for all crops, excluding strawberries and stone fruits. This risk does not exceed the Agency's LOC. The 3,5-DCA DWLOC from all three imide fungicides (including canola, succulent beans, onions, and raspberries) ranges from 0.26 ppb to 1.4 ppb. It should be noted that vinclozolin is no longer used in onions and raspberries. The 3,5-DCA EEC resulting from iprodione use is 0.45 ppb and falls with the range of the aggregated DWLOC cited above. The 3,5-DCA EEC resulting from vinclozolin use is estimated to range from 0.29 ppb to 2.33 ppb. As already stated, this range could potentially present a risk of concern based on the model, however, based on how the model estimates residue concentrations for cancer assessment, it is unlikely that a cancer risk of concern is present.

4. *Determination of safety.* Based on these risk assessments, there is a reasonable certainty that no harm will result from aggregate exposure to vinclozolin residues.

5. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of vinclozolin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation.

Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children.

6. *Prenatal and postnatal sensitivity*. The rationale for retaining the 10X FQPA safety factor is explained below:

i. There is evidence of increased susceptibility of offspring following *in utero* exposure to vinclozolin in the prenatal developmental toxicity study in rats.

ii. A developmental neurotoxicity study in rats with an expanded protocol is required for vinclozolin as a result of concern for the anti-androgenic properties of vinclozolin and its metabolites.

G. Conclusion

Based on the developmental and reproductive data for vinclozolin, EPA determined that an additional 10X safety factor for the protection of infants and children (as required by FQPA) should be retained.

1. *Acute risk*. No study with vinclozolin indicated that acute exposure to vinclozolin is likely to cause an adverse effect of concern on infants or children or the general public with the exception of the *in utero* effects on the developing fetus. Risks to the fetus are estimated by examining exposure to women of child-bearing age.

2. *Chronic risk*. Using the exposure assumptions described in this unit, it is concluded that aggregate exposure to vinclozolin from food will utilize 7% of the cPAD for infants and children. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Since the EEC's for residues of vinclozolin per se are lower than the chronic DWLOC's, aggregate exposure will not exceed 100% of the cPAD.

3. *Short- or intermediate-term risk*. The MOE is greater than or equal to 1,010 for aggregate risks to infants and children resulting from use of vinclozolin. Therefore, the risks do not exceed the Agency's LOC.

4. *Determination of safety*. Based on these risk assessments, there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to vinclozolin residues.

H. International Tolerances

CODEX maximum residue limits (MRLs) for residues of vinclozolin and its metabolites containing the 3,5-DCA moiety have been established in common bean at 2 ppm, rape seed at 1 ppm (no limit for canola), cattle meat and milk at 0.5 ppm, and chicken meat and eggs at 0.05 ppm. No Canadian or Mexican tolerances have been established for vinclozolin residues in succulent beans, rape, canola, meat, milk, poultry, or eggs.

The CODEX MRLs for canola (rapeseed), cattle meat, cattle milk, and poultry eggs are in harmony with the proposed tolerances associated with this petition. The chicken meat MRL (0.05 ppm) is not in harmony with the proposed tolerance in poultry meat (0.1 ppm) due to recovery discrepancies with the analytical method.

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BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0324; FRL–7282–2]

Revised Final Health Effects Test Guideline; Skin Sensitization; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: With this notice, EPA is announcing the availability of the revised final test guideline for Series 870–Health Effects Test Guidelines, OPPTS 870.2600 Skin Sensitization. EPA has established a unified library for test guidelines issued by the Office of Prevention, Pesticides and Toxic Substances (OPPTS) for use in testing chemical substances to develop data for submission to EPA under the Toxic Substances Control Act (TSCA), the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These test guidelines represent an Agency effort that began in 1991 to harmonize the test guidelines within OPPTS, as well as to harmonize the OPPTS test guidelines with those of the Organization for Economic Cooperation and Development (OECD). The process for developing and amending these test guidelines includes public participation and the extensive involvement of the scientific community, as warranted, including peer review by the Scientific Advisory Panel (SAP), the Scientific Advisory Board (SAB) and other expert scientific organizations, as well as determination of validation status by the Interagency Coordinating Committee for Validation of Alternative Methods (ICCVAM).

FOR FURTHER INFORMATION CONTACT: *For general information contact*: TSCA information contact: TSCA Hotline at TAIS/7408, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: TSCA-Hotline@epa.gov.

FIFRA information contact: Communications Services Branch (7506C), Field and External Affairs Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5017; fax number: (703) 305–5558.

For FIFRA technical information contact: Deborah McCall, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7109 e-mail address: mccall.deborah@epa.gov.

For TSCA technical information contact: Ronald Ward, Ph.D., Risk Assessment Division (7403M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8926; e-mail address: ward.ron@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who are or may be required to conduct testing of chemical substances under TSCA, FFDCA, or FIFRA, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. How Can I Get Copies of This Document and Other Related Information?

A. Docket

EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0324. 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