assessing the impact of any proposed or final rule on small entities. 5 U.S.C. sections 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the Act do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, the Administrator certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of the State action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *EPA.*, 427 U.S. 246, 256–66 (1976); 42 U.S.C. 7410(a)(2).

C. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995, signed into law on March 22, 1995, EPA must undertake various actions in association with any proposed or final rule that includes a Federal mandate that may result in estimated costs to state, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. This Federal action approves pre-existing requirements under state or local law, and imposes no new requirements. Accordingly, no additional costs to state, local, or tribal governments, or the private sector, result from this action.

D. Submission to Congress and the General Accounting Office

Under section 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a major rule as defined by section 804(2).

E. Petitions for Judicial Review

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 16, 1997. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Intergovernmental relations, Ozone.

Dated: July 8, 1997.

Michelle D. Jordan,

Acting Regional Administrator.

For the reasons stated in the preamble, part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

2. Section 52.777 is amended by adding paragraph (k) to read as follows:

§ 52.777 Control Strategy: Photochemical Oxidants (hydrocarbon).

* * * * *

(k) On June 26, 1995, and June 13, 1997, Indiana submitted a 15 percent rate-of-progress plan for the Lake and Porter Counties portion of the Chicago-Gary-Lake County ozone nonattainment area. This plan satisfies the counties' requirements under section 182(b)(1) of the Clean Air Act, as amended in 1990.

[FR Doc. 97–18972 Filed 7–17–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP–300507; FRL–5727–9]

RIN 2070–AB78

Vinclozolin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of the pesticide vinclozolin, [3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione] and its metabolites containing the 3,5-dichloroanaline (3,5-DCA) moiety at 2.0 parts per million (ppm) in or on the food commodity succulent beans. The tolerance will expire and is revoked on October 1, 1999. A petition was submitted by BASF Corporation to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170) requesting the tolerance. BASF has requested that EPA revoke the tolerances for prunes, plums, tomatoes, grapes (excluding grapes grown for wine production), raisins, dried prunes and grape pomace. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations. BASF has deleted all residential uses, as well as, turf in parks, school grounds and recreational areas which would be expected to result in significant exposure to children from its vinclozolin registrations under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

DATES: This regulation becomes effective on May 30, 1997. Written objections and hearing requests must be received on or before September 16, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–30507], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the docket control number and submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file

format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300507]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Mary Waller, Acting Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 265, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–9354, e-mail: waller.mary@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the March 19, 1997 **Federal Register** (62 FR 13000)(FRL–5592–6), which announced that BASF Corporation had submitted a pesticide petition (PP) 9F3762 to EPA requesting that the Administrator, pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C section 346a, amend 40 CFR part 180 to establish a tolerance for residues of the fungicide vinclozolin [3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione; EPA Chemical No. 113201; CAS Reg. No. 50471-44–8] and its metabolites containing the 3,5-dichloroanaline moiety in or on the food commodity, succulent beans. The proposed tolerance levels for vinclozolin and its metabolites were 5.0 ppm. As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act (FQPA), Pub. L. 104–170, BASF included in the notice of filing a summary of the petition and authorization for the summary to be published in the Federal Register in a notice of receipt of the petition. The summary of the petition prepared by the petitioner contained conclusions and assessments to support its contention that the petition complied with the FQPA elements set forth in section 408(d)(3) of the FFDCA.

EPA has accepted these amendments to the vinclozolin registrations. Revisions to existing tolerances and revocation of affected tolerances will be addressed by the Agency in later actions.

I. Statutory Background

Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., as amended by the Food Quality Protection Act of 1996 (FQPA), Pub. L. 104–170) authorizes the establishment of tolerances (maximum residue levels), exemptions from the requirement of a tolerance, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on food commodities and processed foods. Without a tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore ''adulterated'' under section 402(a) of the FFDCA, and hence may not legally be moved in interstate commerce. For a pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under the FFDCA, but also must be registered under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. 136 et seq.).

Section 408 was substantially amended by the FQPA. Among other things, the FQPA amends the FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. New section 408(b)(2)(A)(i) allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through food, drinking water, and from pesticide use in gardens, lawns, or buildings (residential and other indoor uses) but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue***.''

II. Discussion of Comments

Fifteen comments were received in response to the notice of filing of this petition. Most of the commentors supported the tolerance requested by BASF on economic grounds and thus raised issues outside the scope of section 408. Only one commentor submitted comments in opposition to the tolerance proposed in the notice of filing. The principal objections to the proposed tolerance were:

1. The notice of filing was not sufficient to provide the public a meaningful opportunity to comment.

2. The notice did not adequately address exposure to vinclozolin in drinking water.

3. The notice did not adequately address residential and other non-occupational exposures to vinclozolin.

4. The notice did not adequately address the issue of cumulative exposures to pesticides with a common mechanism of toxicity.

5. The notice did not adequately address vinclozolin's carcinogenic potential.

6. The notice did not adequately address risks to infants and children.

Each of these principal objections is addressed below. In addition, all of the scientific issues raised in the objections are addressed in more detail elsewhere in this document.

A. Sufficiency of Notice to Allow for Public Comment

While it is clear that the commentor believed that the discussion of various scientific issues in the summary provided by BASF was unconvincing, it is unclear whether the commentor was contending that the summary was legally insufficient for the Agency to proceed with the publication of the notice of filing pursuant to section 408(d) of the FFDCA or that EPA was obligated to include in the notice of filing any additional analysis or information it might eventually rely upon in determining whether to grant the tolerance. Whatever the basis for the argument, the commentor's conclusion was that the notice of filing was insufficient to allow for meaningful public comment.

The short answer to this comment is that the depth and breadth of the comments submitted by the commentor would seem to demonstrate that significant meaningful public comment was not foreclosed by any alleged inadequacies in the notice of filing. While the commentor asserted that more information should have been provided on the various scientific issues discussed below, the commentor did not explain why the failure to supply such additional information rendered the summary provided by BASF legally insufficient to meet the requirements set forth in section 408(d)(2) of the FFDCA. That section does not require the development of the additional information adverted to in the comments, and the Agency has not at this time required by regulation (or otherwise) the development of such additional information. The Agency believes the summary was legally sufficient to support publication of the notice of filing.

As is clear from the remainder of this document, the Agency did not agree with all the arguments propounded by BASF in its summary. Section 408(d) sets forth the procedures that must be followed in determining whether to grant a petition for a tolerance; that section does not require that the Agency publish its own analysis for comment before a tolerance can be granted. In light of the facts that section 408(g) provides an opportunity for a person objecting to the issuance of a tolerance to file with the Administrator objections challenging the issuance of a tolerance and the notice in this particular case allowed interested parties an opportunity to meaningfully comment on the significant issues raised by the petition (as demonstrated by the comments submitted by this commentor), the Agency does not believe publication of an additional notice was either necessary or appropriate.

B. Exposure to Vinclozolin from Drinking Water

The commentor challenged BASF's argument that the Agency should assume no exposure to vinclozolin from water, and instead argued that the Agency should at least apply a default figure of 10% to represent the portion of the allowable risk that could be attributed to residues in water. As the discussion of this issue in this document makes clear, the Agency did not ignore potential exposure to vinclozolin or its toxic metabolites in water. Rather than use the default figure identified in the comment, the Agency applied a more conservative model to identify an upper bound to the contribution to overall risk from vinclozolin and its metabolites in water. The use of this conservative model actually resulted in an estimate of the contribution to overall risk from water exposure greater than the 10% default that the commentor urged the Agency to use.

The commentor also seemed to argue that, pursuant to the new FQPA, BASF was obligated to submit additional data on water-related exposure (and on other issues). Section 408(b)(2)(D) obligates the Agency to consider ''available information'' concerning a number of factors, including non-dietary, non-occupational exposures. The Agency does not agree that the new section 408 requires that such information automatically be developed (although the Agency does have the authority to require that such information be developed and submitted to the Agency).

C. Exposure to Vinclozolin from Residential/Non-Occupational Use

The commentor challenged BASF's treatment of exposure from residential and other non-occupational uses of vinclozolin. Some time after publication of the Notice of Filing, BASF agreed to remove all residential uses from its labels and to request deletion of most of them from the registration, with the others not being revived on labels until such time as the Agency determines that any related exposures would be safe. BASF also agreed to add label language that specifically limits turf uses of vinclozolin to commercial and industrial sites, golf courses, and greenhouses and nurseries. The language does not permit use on turf in parks, school grounds, and recreational areas that could be expected to be significant sources of exposure to children; these uses have already been removed from BASF's new labels. Consistent with the procedures set forth in FIFRA section 6(f), the Agency expects to grant the requested use deletions later this year. In light of the above described circumstances, the Agency does not expect that residential and non-occupational uses will result in any further meaningful exposure to vinclozolin.

D. Common Mechanism of Toxicity

The commentor argued that vinclozolin, iprodione and procymidone should be treated as having a common mechanism of toxicity because the chemicals share similar toxicological and structural properties. Iprodione and vinclozolin share a common metabolite, and exposures to the metabolite resulting from iprodione have been included in the aggregate exposures considered in determining whether the requested tolerance for vinclozolin on snap beans meets the safety standard set forth in section 408(b)(2)(A). Although vinclozolin shares structural and toxicological similarities with iprodione and procymidone, the Agency does not have at this time sufficient methodologies in place to resolve common mechanism issues in such circumstances in any meaningful way. The Agency has therefore concluded that it does not have sufficient available and reliable information concerning common mechanism of toxicity of vinclozolin, iprodione, and procymidone to analyze the common mechanism issue in a scientifically valid manner in this tolerance decision. This tolerance decision was reached based upon the best available and useful information for these chemicals and the supporting risk assessment was performed assuming that no common mechanism of toxicity exists. Furthermore, this tolerance decision will be reexamined by the Agency after EPA establishes methodologies and procedures for integrating information concerning common mechanism into its risk assessments.

E. Carcinogenicity

The commentor argued that vinclozolin has more carcinogenic potential than BASF asserted in its summary. The Agency's conclusions on the carcinogenic potential of vinclozolin and its metabolite 3,5-DCA are set forth in detail elsewhere in this Final Rule.

F. Risk to Children

The commentor argued that the discussion of risks to children in the notice of filing was flawed for a number of reasons. The commentor contended that exposures should be considered separately for separate ages, rather than by considering children between the ages of one and six together. They also asserted that BASF failed to adequately address exposures *in utero*, breast milk, early infancy, or puberty, all periods when protective measures may be necessary to protect against vinclozolin's anti-androgenic effects. Finally, the commentor argued that application of separate, additional tenfold safety factors are compelled because of the lack of good data on exposure to children and because of uncertainties associated with how endocrine disrupting compounds actually work. Because of the need to include these additional safety factors, the commentor asserted that the RfD proposed for use in the notice of filing should be lowered by a factor of 100.

Given the completeness and reliability of the data base for vinclozolin, the Agency concluded that a margin of safety of 100 (without the additional safety factors suggested by the commentor) would be safe for children. In terms of different potential exposures to children between the ages of one and six, it should be noted that the most sensitive subgroup would be women of child-bearing age because of the potential *in utero* and post-natal effects. The Agency has determined that there is sufficient information to characterize the risk to this subgroup, and that the tolerance announced in this Final Rule is safe for this subgroup. The data on the anti-androgenic effects of vinclozolin are of sufficient quantity and quality that an additional uncertainty factor is not necessary in order to assure that infants and children will be safe from such effects.

III. Risk Assessment and Statutory Findings—Background

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. For many of these studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once the studies have been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. An aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered by EPA to pose a reasonable certainty of no harm. For threshold effects other than those assessed under the RfD, EPA generally calculates a margin of exposure (MOE). The MOE is a measure of how close the exposure comes to the NOEL. The NOEL is selected from a study of appropriate duration and route of exposure. The MOE is the NOEL from the selected study divided by exposure. MOEs greater than 100 are generally considered to show a reasonable certainty of no harm.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or margin of exposure calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water and exposures resulting from indoor and outdoor residential uses. Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100 percent of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Consistent with sections 408(b)(2)(C) and (D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has also assessed the toxicology data base for vinclozolin in its evaluation of the application for registration on succulent beans. EPA has sufficient data to assess the hazards of vinclozolin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for granting a tolerance for residues of vinclozolin on succulent beans at 2.0 ppm. EPA's assessment of the database, dietary exposures and risks associated with establishing this tolerance follows.

IV. Toxicology Database

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by vinclozolin are discussed below.

A. Data Evaluated

1. *Acute toxicity studies.* A battery of acute toxicity studies placing technical vinclozolin in toxicity category IV for acute oral toxicity (LD_{50} of >10,000 millgrams per kilogram (mg/kg)), and acute inhalation toxicity ((LD_{50} of 29.1 miligram per liter (mg/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 a positive skin sensitizer.

2. *Chronic feeding—dog.* A 1–year feeding study in dogs fed dosages of 0, 1.1 , 2.4, 4.9, and 48.7 mg/kg/day with a No-Adverse-Effect Level (NOAEL) of 2.4 mg/kg/day based on the following effects:

(i) Slight decrease in hematological and increase in clinical chemistry values in the 48.7 mg/kg/day dose group (highest dose tested - HDT).

(ii) Increased absolute and/or relative weights for the testes (male only), adrenal, liver, spleen, and thyroids in the 4.9 or 48.7 mg/kg/day dose groups.

(iii) A dose-related atrophy of the prostate in the 4.9 or 48.7 mg/kg/day dose groups; and (iv) microscopic findings in the adrenal and testes (males) in the 48.7 mg/kg/day dose group and liver findings for both male and female dogs in the 48.7 mg/kg/day dose groups and in the females in the 4.9 mg/kg/day dose group, only.

3. *Chronic feeding/carcinogenicity—rat.* A combination of two chronic feeding studies and one 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) based on the following effects:

(i) Decreased body weights in both male and female rats at dose levels >23 mg/kg/day with a progression of severity to the upper levels.

(ii) Decreased food consumption in both male and female rats at dose levels >71 mg/kg/day with a progression of severity to the upper dose levels.

(iii) Cataracts with associative histopathology at dose levels >23 mg/kg/day and lenticular changes at dose levels >7.0 mg/kg/day for male and female rats.

(iv) Hematological and clinical chemistry value changes at dose levels >71 mg/kg/day dose groups with increase of severity at the higher doses tested.

(v) Increased absolute and/or relative weights for adrenal at dose levels >143 mg/kg/day, for the liver at dose levels >71 mg/kg/day, for the testes at dose levels >23 mg/kg/day, and for the ovaries at dose levels >143 mg/kg/day.

(vi) Microscopic findings were observed in the liver, adrenal, pancreas, testes (males), ovaries and uterus (females) at dose levels of >7.0 mg/kg/day with a progression of severity of histological effects in the upper dose levels.

(vii) An increased incidence of neoplasms occurred at dose levels greater than the maximum tolerated dose (MTD) of 23 mg/kg/day in the liver, adrenal, pituitary, prostate (males), uterus (females), and ovaries (females) at dose levels >143 mg/kg/day. In the testes (males), Leydig cell adenomas were seen at the MTD for dose levels >23.0 mg/kg/day due the antiandrogenic nature of vinclozolin.

4. *Carcinogenicity— mice.* 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 (females) based on the following effects:

(i) Increased mortality in the highest dose tested (HTD) as compared to controls.

(ii) Decreased body weights and significant signs of clinical toxicity were observed in both male and female mice at the upper two dose levels with a progression of severity.

(iii) Hematological and clinical chemistry value changes were observed at the highest dose tested.

(iv) Increased absolute and/or relative weights for adrenal and liver were observed at the upper two dose levels, atrophic seminal vesicles and coagulation glands with reduction of the prostate (males) and atrophic uteri were observed at the upper two dose levels.

(v) Microscopic findings were observed in the liver, adrenal, testes (males), ovaries and uterus (females), and related sexual organs in the upper two dose levels.

(vi) 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.

5. *Developmental toxicity— rat.* 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, 1,000 mg/kg/day. At the gd 20, the fetuses were evaluated.

Maternal toxicity was demonstrated at 600 and 1,000 mg/kg/day by the statistically significant increase in absolute and relative adrenal and liver weight in study 8. This was the only study where organ weights were determined. A maternal NOEL could not be established and therefore, the study was not considered to demonstrate any extra sensitivity. No histology was conducted on the organs, but other studies have demonstrated lipid accumulation in the adrenals, and centrilobular cloudiness of the liver. In addition, a dermal developmental study has indicated adrenal and liver weight increases occurred at 180 mg/kg/day and higher. Statistically significant increases and decreases occurred in the body weight gain and in food consumption with no apparent dose relatedness in any of the studies. The relative efficiency of food utilization was too variable to be definitive.

Statistically significant male and female fetal body weight decrement occurred at 1,000 mg/kg/day. These weight decrements were considered test material related. A statistically significant decrease occurred in anogenital distance (ambiguous sex) among male fetuses. The term pseudohermaphroditism was used to describe the effect because these males exhibited decreased anogenital distances, but exhibited superficially normal internal testes. The anogenital distance in male fetuses was statistically decreased at 50 mg/kg/day and higher in studies 4, 6, and 8. (The anogenital index was statistically significantly depressed at 150 mg/kg/day and higher). The anogenital distance and index were not determined in study 5. The response was dose related. Although anogential index was not statistically significantly depressed at 50 mg/kg/day, it was nominally depressed. Considering the significantly depressed anogenital distance at 50 mg/kg/day and higher and the nominally depressed anal-genital index at 50 mg/kg/day, the NOEL for this study was considered to be 15 mg/kg/day, the LDT. These results are consistent with hormonal or anti-hormonal effects from the test material.

Soft tissue examination of fetuses indicated that increased incidence occurred in dilated renal pelvis and hydro-ureter at 400 mg/kg/day in study 6. At higher dose levels in study 8, the incidence of dilated renal pelvis and hydro-ureter was nominally increased. The failure of the dilated renal pelvis, and hydro-ureter to be significantly increased in study 8 was attributed to the fewer litters used (7, 5, and 8 in controls, 600, and 1000 mg/kg/day). The NOEL for these renal effects is considered to be 200 mg/kg/day.

Skeletal examination of fetuses indicated increased incidence of accessory 14th rib at 400 mg/kg/day and in fetuses and litters at 600, and 1,000 mg/kg/day. These effects on the 14th rib may be related to dose administration. Evaluation of the Preliminary Study suggested a dose related increase in 14th ribs at these high dose levels. No other dose related effects were reported.

The developmental toxicity NOEL was set at 15 mg/kg/day and the developmental LOEL was 50 mg/kg/day based on decreased anogenital distance in males (ambiguous sex). Increased incidence of dilated renal pelvis, hydro-ureter, and accessary 14th rib may have occurred at 400 mg/kg/day and higher. The maternal toxicity LOEL was < 600 mg/kg/day based on increases in absolute and relative adrenal and liver weight. Organ weights were not determined at lower dose levels.

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 (HDT) had a developmental NOAEL of 60 mg/kg/day and a maternal NOAEL of 60 mg/kg/day based on the following: (1) increased absolute liver weights at dose levels > 180 mg/kg/day; and (2) decreased anogenital distance and index at dose levels > 180 mg/kg/day.

6. *Developmental toxicity—rabbit.* 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 based on no signs of maternal or meaningful fetal toxicity observed at any of the dose levels mentioned.

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 based on the following: (1) severe maternal toxicity with simultaneous change in hematological values and high number of abortions at the HDT; and (2) increased absolute and/or

relative weights for adrenal in the mid and high dose groups.

7. *Two-generation reproduction— rat.* A two-generation 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 rats fed dosages of 0, 2.0, 4.1, 4.9, 29, 100, and 307 mg/kg/day with a reproductive NOAEL of 4.9 mg/kg/day based on feminization of males and their inability to mate at dose levels >100 mg/kg/day and pup effects at 29 mg/kg/day; and with a parental NOAEL of 4.9 mg/kg/day based on general toxicity consistent with previous rat studies at levels >29 mg/kg/day. Study A was performed to clarify an equivocal finding of decreased absolute and relative weight of the epididymides without any morphological correlation in the male FY and FZ generations in Study B. However, the Agency concluded that the effects at the 4.9 mg/kg/day dose level were minimal and considered sufficiently close to the NOAEL. The study is acceptable and 4.9 mg/kg/day dose level was considered to be the NOEL.

8. *Mutagenicity.* A Modified Ames Test (three studies, point mutation): a Host-Mediated Assay (point mutation), a Mouse Lymphoma Test (point mutation), *In Vitro* CHO Cells (point mutation), *In Vitro* Cytogenetics - CHO Cells (Chromosome Aberrations), *In Vivo* Dominant Lethal Test - Male NMRI Mouse (Chromosome Aberrations), Rec Assay (two test, DNA damage and repair) *In Vitro* UDS Test Using Hepatocyte (DNA damage and repair), *In Vivo* SCE Using Chinese Hamster (DNA damage and repair) showed no evidence of mutagenic activity.

9. *Mechanistic studies —anti-androgenicity activity.* 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 inhibition of the androgen receptor in androgen sensitive organs.

B. Toxicology Profile

1. *Toxicity endpoint for dietary exposure—* i. *Acute toxicity.* To assess acute dietary exposure, the Agency used a NOEL of 3.0 mg/kg/day from a rat developmental toxicity study for evaluating acute risk to females 13+ years. The dose of 5.5 mg/kg/day was calculated using the bracketed conversion (3 mg/kg/day × 3.91/2.12 = 5.5 mg/kg/day), in order to obtain the single day internal dose corresponding to the NOEL of 3 mg/kg/day.

ii. *Chronic effects.* A RfD of 0.012 mg/kg/day was established based on a 2–year rat feeding study with a NOEL of 1.2 mg/kg/day and an uncertainty factor of 100.

iii. *Carcinogenicity.* Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), EPA has classified vinclozolin as a Group C chemical - possible human carcinogen. The Agency Cancer Peer Review Committee (CPRC) chose a non-linear approach [MOE] based on a NOEL of 4.9 mg/kg/day for hormone-related effects [decreased epididymal weight at 30 mg/kg/day] in the 2-generation oral rat reproductive toxicity study to quantify human risk. The MOE approach was chosen because the remaining tumors [Leydig cell] were benign at dose levels which were not considered to be excessive.

2. *Toxicity endpoints for non-dietary exposure*—i. *Short- and intermediate term risk for infants and children ages 1-12.* For short- and intermediate-term MOE calculations, the Agency decided to use of a NOEL of 5.0 mg/kg/day from an oral rat study based on delayed puberty in young rats at the LOEL of 15 mg/kg/day based on available data.

ii. *Short and intermediate term risk for females age 13 and older.* For short- and intermediate-term MOE calculations, the Agency decided to use a NOEL of 3 mg/kg/day from an oral rat developmental study based on the occurrence of pseudohermaphroditism (reduced anogenital distance) in male fetuses and nipple development. The maternal toxicity NOEL/LOEL were also 3 and 6 mg/kg/day respectively based on reduced sex organ weights.

iii. *Chronic non-dietary exposure.* A chronic risk exposure scenario has not been identified for the proposed use, although the chronic tolerance endpoint selection is based on the NOEL of 1.2 mg/kg/day.

C. Dietary Exposure

1. *Food and feed uses.* For purposes of assessing the potential chronic dietary exposure (food only) from the use of vinclozolin, EPA has used the percent of crop treated/percent imported data to refine the risk estimates for selected commodities (apricots, beans, raspberries, cherries, cucumbers, lettuce, nectarines, onions, peaches, peppers, and strawberries), while other commodities were assumed to be 100% treated/imported (caneberries (other than raspberries), cranberries, endive, garlic, wine/sherry, kiwifruit, and shallots). No chronic anticipated residue refinement has been performed. Therefore, the resulting exposure (food only) estimates should be viewed as partially refined; further refinement using anticipated residues and additional percent of crop treated/percent imported data would result in lower chronic dietary exposure estimates. The Anticipated Residue Contribution (ARC) for chronic dietary exposure estimates is equivalent to 12% of the RfD for the U.S. population (48 states). The ARC for infants and children and other subgroups ranged from 7 to 15% of the RfD. In the best judgement of the Agency, the vinclozolin dietary (food source only) chronic risk from the currently registered uses and this section 3 registration on snap beans does not exceed the level of concern. No feed items are associated with succulent beans. Therefore, secondary residues are not expected as a result of this proposed section 3 registration.

Section 408(b)(2)(F) allows EPA to use data on the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings:

(1) That the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues.

(2) That the exposure estimate does not underestimate the exposure for any significant subpopulation.

(3) Where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition, EPA must provide for periodic evaluation of any estimates used.

The percent of crop treated estimates for vinclozolin were derived from Federal and market survey data. EPA considers these data reliable. A range of estimates are supplied by this data and the upper end of this range was used for the exposure assessment. By using this upper end estimate of percent crop treated, EPA is reasonably certain that exposure is not underestimated for any significant subpopulation. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Review of this regional data allows EPA to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To provide for the periodic evaluation of these estimates of percent crop treated, EPA has issued a data call-in under section 408(f) to all vinclozolin registrants for data on percent crop treated. That data call-in requires such data to be

submitted every 5 years as long as the tolerances remain in force.

The acute dietary (food only) risk assessment used Monte Carlo analysis which creates an exposure distribution by randomly pairing a distribution of residue chemistry data with a distribution of food consumption and percent of crop treated or percent imported data for selected commodities (apricots, beans, raspberries, cherries, cucumbers, lettuce, nectarines, onions, peaches, peppers, and strawberries.), while other commodities were assumed to be 100% treated/imported (caneberries, other than raspberries; cranberries; endive; garlic; wine/sherry; kiwifruit; and shallots). Tier 2 anticipated residue refinement was performed for the mixed commodity wine/sherry. For imported, single-serving commodities, acute anticipated residue refinement was performed by using the highest field trial value in the Monte Carlo analysis. For all commodities which have a corresponding Section 3 registration, the Monte Carlo analysis used the full range of field trial residue data which reflected the existing (or proposed) use directions.

For the subgroup of concern, females 13+ years, the resulting high-end (99.9th percentile) dietary (food only) exposure estimate of 0.013587 mg/kg/day resulting in a MOE of 405. This estimate should be viewed as a refined risk estimate; further refinement using additional percent of crop treated or percent imported data may result in a slightly lower acute dietary exposure estimate.

2. *Potable water.* The Agency does not have drinking water monitoring data available to perform a quantitative drinking water risk assessment for vinclozolin at this time. Tier 1 estimated environmental concentrations (EEC's) were produced for surface water using the Generic Expected Environmental Concentration (GENEEC) model to estimate the human health risk to vinclozolin. The calculated acute EEC is 27.04 g/L and the calculated chronic EEC is 1.06 g/L. The model was performed using residues of vinclozolin per se. However, due to the very conservative nature of the Tier 1 GENEEC run and the low estimated metabolite level in relation to the parent compound, this estimate should be applicable to the sum total of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety.

Exposure from surface water was calculated for various subgroups of the population from which risk estimates were developed. For acute risk, the MOE was estimated to be 6,100 for females 13 years and older which was the only subgroup of concern. For chronic risk, exposure was less than 1% of the RfD of 0.012 mg/kg/day for all subgroups. For cancer, an MOE (dietary water only) of 160,000 was calculated for the U.S. population from the exposure value of 0.0000303 mg/kg/day.

3. *Non-dietary uses.* Exposure in this category has been significantly reduced through elimination of all residential uses from product labeling. Therefore, any non-dietary, non-occupational exposure is expected to be minimal particularly for infants and children.

An approximation of the aggregate risk from the remaining non-dietary use (postapplication exposure to vinclozolin-treated produce at ''U-pick'' farms indicates that the calculated MOE's are ≤ 100 for children and adults. These are considered conservative risk estimates. The exposure estimates are based on studies of workers harvesting produce as wage earners. This may overestimate the exposure for non-occupational harvesters picking produce at ''U-pick'' farms for non-monetary purposes.

4. *Cumulative exposure to substances with 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.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

Vinclozolin, iprodione, and procymidone are structurally-related pesticides belonging to the imide class. Each of these three pesticides can metabolize to 3,5-dichloroaniline (3,5-DCA). Under FQPA, EPA is also required to estimate the risk for consumption of food and water containing 3,5-DCA across vinclozolin, iprodione, and procymidone.

There is no toxicological database; thus no RfD or Q_1* for 3,5-DCA. However, EPA has used the Q_1* for *p*-chloroaniline (PCA) to assess the carcinogenic risk for other structurally related chloroanilines because EPA does not have any evidence that 3,5-DCA is not carcinogenic. In 1988, the Q_1* for PCA was estimated to be 0.039 $(mg/kg/day)^{-1}$. However, a revised Q_1* of 0.059 $(mg/kg/day)^{-1}$ for PCA has been used for this assessment based on more recent data on male and female tumors.

The following routes of exposure for 3,5-DCA were evaluated: In food as a result of application of iprodione, in food as a result of application of vinclozolin, in imported wine as a result of application of procymidone, in water as a result of application of iprodione to a crop, and in water as a result of application of vinclozolin to a crop. There are no U.S. registrations for procymidone; therefore, an evaluation of exposure to procymidone in water was not appropriate.

Metabolism data of iprodione indicated that 3,5-DCA represented 1% TRR (total radioactive residue) in eggs, smaller proportions in other livestock commodities, and was not detected in primary or rotational crops. Metabolism data of vinclozolin indicated that 3,5-DCA represented 9.6% TRR in peaches, smaller proportions in strawberries and

was not detected in lettuce or grapes. Wine grapes were also included in the analysis even though the metabolism studies for procymidone indicated that the 3,5-DCA metabolite was not detected in grapes, but was formed in wine.

Two models were used for estimating potential concentrations of 3,5-DCA in surface water. PRZM/EXAMS was used to estimate 3,5-DCA concentrations as a result of applications of vinclozolin or iprodione on peaches. A conservative screening model, GENEEC, was used to estimate 3,5-DCA concentrations as a result of application of vinclozolin on strawberries. The estimation process also used surrogate fate data, a molecular weight conversion, proportion of acreage treated, and assumptions of the percent conversion of parent chemical to metabolite.

The following risk values were estimated for 3,5-DCA:

Route of Exposure	Dose	Estimated Risk
In food as a result of application of iprodione.	0.00000009219	5.4×10^{-9}
In food as a result of application of vinclozolin.	0.0000143224	8.4×10^{-7}
In imported wine as a result of application of procymidone.	0.0000058	2.5×10^{-7}
In water as a result of application of iprodione to peaches.	0.0000189	1.1×10^{-6}
In water as a result of application of vinclozolin to strawberries (not in California).	0.0000005	3.0×10^{-8}
In water as a result of application of vinclozolin to peaches.	0.000007	4.1×10^{-7}
Total Food and Wine only.		1.1×10^{-6}
Total Water as a result of application at a peach site.		1.5×10^{-6}
Total Food, Wine and Water.		2.6×10^{-6}

The total carcinogenic risk for consumption of food and wine containing residues of 3,5-DCA as a result of applications of iprodione, vinclozolin, and procymidone is 1.1×10^{-6}. This can be considered to be a slight over-estimate since metabolism studies were used to estimate the TRRs to convert iprodione or vinclozolin to 3,5-DCA used in the calculations. There is also an uncertainty to the risk estimate because a surrogate Q_1* was used for 3,5-DCA.

The total carcinogenic risk for drinking water containing residues of 3,5-DCA as a result of applications of iprodione and vinclozolin was estimated at 1.5×10^{-6} for the most highly exposed populations. Although, there is a high degree of uncertainty to this analysis, these are the best available estimates of concentrations of 3,5-DCA in drinking water. EPA believes that these risk numbers do justify asking for fate data and monitoring data for 3,5-DCA in both ground and surface water from both the registrants of iprodione and vinclozolin.

EPA believes that the total risk estimate estimated for 3,5-DCA for food, wine, and drinking water of 2.6×10^{-6} generally represents a negligible risk, as EPA has traditionally applied that concept. EPA has commonly referred to a negligible risk as one that is at or below 1 in 1 million (1×10^{-6}). Quantitative cancer risk assessment is not a precise science. There are a significant number of uncertainties in both the toxicology used to derive the cancer potency of a substance and in the data used to measure and calculate exposure. Thus, EPA generally does not attach great significance to numerical estimates for carcinogenic risk that differ by approximately a factor of 2½.

The registrant must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether vinclozolin shares a common mechanism of toxicity with any other substance and, if so, whether any tolerances for vinclozolin need to be modified or revoked.

V. Determination of Safety for Infants and Children

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 pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the no observed effect level in the animal study appropriate to the particular risk assessment. This hundredfold uncertainty (safety) factor/margin of exposure (safety) is designed to account for combined inter- and intra-species variability. EPA believes that reliable data support using the standard hundredfold margin/factor not the additional tenfold margin/factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin/factor.

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 reproductive toxicity study in rats. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to the mother. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

1. *Developmental toxicity—rats.* In oral developmental toxicity study in rats, the developmental NOEL was 3 mg/kg/day based on the occurrence of pseudohermaphroditism (reduced anogenital distance) in male fetuses and nipple development. The maternal toxicity NOEL/LOEL were not determined in this segment of the study.

2. *Developmental toxicity—rabbits.* From the developmental toxicity study in rabbits the maternal (systemic) NOEL was 50 mg/kg/day, based on increased absolute and relative liver weight, reduced defecation, and reddish-brown urine at the LOEL of 200 mg/kg/day. The developmental (fetal) NOEL was 200 mg/kg/day, based on early resorptions, fetal weight increase, decreased live litter size and possible increased skeletal anomalies at the LEL of 400 mg/kg/day.

3. *Reproductive toxicity— rats.* From the reproductive toxicity studyin rats, the parental (systemic) NOEL was 4.9 mg/kg/day, based on decreased epididymal weights at the LOEL of 30 mg/kg/day. The reproductive/developmental (pup) NOEL was 4.9 mg/kg/day, based on reduced epididymal

weights and lenticular degeneration at the LEL of 30 mg/kg/day.

Based on current toxicological data requirements, the database relative to pre- and post natal toxicity is complete. From these data EPA concludes that extra (greater than 100) uncertainty factors were not necessary when used with the developmental toxicity endpoint of 3 mg/kg/day. Agency documents are available through the docket which detail this decision. The bases of the Agency's finding is as follows:

- Vinclozolin has an adequate and extensive toxicity data base including mechanistic data.
- Mechanistic data (androgen receptor inhibition) showing that vinclozolin probably results in analogous developmental effects in the rat and human.
- There are probably only minor differences in kinetics and metabolism of vinclozolin between rats and humans.
- Postnatal studies show effects in parents and offsprings at similar dose levels, although, the effects in offsprings are more severe.
- The 3 mg/kg/day NOEL for decreased ano-genital distance (AGD) as a measure of developmental effects is a very sensitive measure of decreased androgenization of the fetus/offspring.
- The decreased AGD has only been seen in rat studies. Neither the rabbit nor the mouse developmental toxicity studies show obvious anti-androgen related effects.
- The 3 mg/kg/day endpoint may be overprotective since the next higher dose level (6 mg/kg/day) was not statistically significantly different from the control. Based on additional analysis by the Science Advisory Board (SAB) statisticians, the NOEL may be as high as 12 mg/kg/day.

VI. Determination of Safety for U.S. Population Including Infants and Children

1. *Chronic dietary exposure/risk*. Based of the exposure assumptions discussed above and the completeness and reliability of the toxicity database, the Agency estimates that the food only exposure to vinclozolin for the subgroup of concern, Non-Nursing Infants < 1 year old, will utilize 14% of the RfD. The population subgroup with the largest percentage of the RfD occupied is U.S. Population, Western Region at 15% of the RfD. EPA generally has no concern for exposure below 100 percent of the RfD.

2. *Aggregate risk*—i. *Acute aggregate risk*. For the subgroup of concern, females 13+ years, the calculated dietary (food only) MOE value is 405. This estimate should be viewed as a refined risk estimate; further refinement using additional percent of crop treated or percent imported data may result in a slightly lower acute dietary exposure estimate. When the surface water exposure estimate (it appears the surface water estimate is worst case) is added (based on limited data for ground water and environmental fate data), the aggregate acute dietary risk (food + water) estimate results in an MOE of 380. This MOE value does not exceed the Agency's level of concern for acute dietary exposure.

ii. *Chronic aggregate risk*. The aggregate chronic risk is equal to the sum of the chronic risk from food + water + non-dietary exposure. Vinclozolin is not currently registered for any residential uses and no other chronic exposure scenario's have been identified from the registered uses of vinclozolin. Therefore, the aggregate chronic risk for vinclozolin is equal to the sum of the chronic risk from food + water, and is equivalent to less than 13% of the RfD for the U.S. population. Other subgroups ranged from 8 to 16% of the RfD.

iii. *Short- and intermediate-term aggregate risk*. The aggregate short- and intermediate-term risk is equal to the sum of the chronic risk from food + water (considered to be a background exposure level) + non-dietary exposure (exposure from ''U-pick'' farms). The calculated MOE values for the aggregate short- and intermediate-term risk from vinclozolin range from 140 for children 1 to 6 years old to 150 for children 7 to 12 years old. The MOE's do not exceed the Agency's level of concern. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to vinclozolin residues.

iv. *Cancer aggregate risk*. The aggregate cancer risk for vinclozolin is equal to the sum of the chronic risk from food + water. The Anticipated Residue Contribution (ARC) for the U.S. Population was calculated to be 0.001383 mg/kg/day from food and 0.0000303 from dietary water, for a total dietary exposure (food + water) of 0.001413. Using the formula where the Margin of Exposure (MOE) = NOEL (mg/kg/day) ÷ Exposure (mg/kg/day), or 4.9 mg/kg/day ÷ 0.001413 mg/kg/day, the calculated MOE (food + water) is 2,100.

VII. Other Considerations

A. Endocrine Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) may effect humans similar to an effect produced by a naturally occurring estrogen, or such other endocrine effects. The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. The endocrine modulating effects of vinclozolin are adequately understood.

The *in vivo* studies show that vinclozolin or it's metabolites/degradation products disrupt the androgen endocrine system through inhibition of androgen receptors. This receptor inhibition results in reduced androgen to androgen sensitive organs, such as the prostate seminal vesicles and epididymides (anti-androgen effects). In the pituitary gland, this inhibition results in increased luteinizing hormone which in turn stimulates the testicular Leydig cells. Continuous stimulation of the testicular Leydig cells result in the Leydig cell adenomas seen in the chronic and carcinogenicity studies.

The *in vitro* data are studies on androgen receptor inhibition by two metabolism/degradation products (M1 and M2) of the vinclozolin. This androgen receptor inhibition results in the reduced ano-genital distance seen in the developmental toxicity studies with vinclozolin.

B. Metabolism in Plants and Animals

The metabolism of vinclozolin in plants and animals is adequately understood for the purpose of this tolerance. A CODEX Maximum Residue Limit (MRL) for residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety has been established for common beans at 2.0 ppm. Residue data were examined at the Joint meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. The field trials were conducted in Germany, the Netherlands, Japan, United Kingdom, and France. It was concluded that a 2.0 ppm MRL should be established based on rates of 0.19 (3 applications) to 1.0 kg a.i./ha. (three(3) applications) and a PHI of 7 days. These rates are equivalent to 0.17 to 0.89 lbs a.i./A.

Residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline (DCA) moiety are not expected to exceed 2.0 ppm in/on snap beans as a result of this Section 3

registration. There are no processed commodities or feed items associated with snap beans. Therefore, secondary residues are not expected as a result of this proposed Section 3 registration.

There is a practical analytical method available for determination of residues of vinclozolin. Adequate enforcement methodology (gas chromatography/electron capture detector) for plant and animal commodities is available to enforce the tolerances. As a condition of registration, EPA has requested that revisions and clarifications be made to the submitted methodology, and that the animal commodity method be improved by eliminating the use of hazardous materials. Once this method has been submitted, EPA will provide information on this method to FDA. In the interim, the analytical method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm 1128, 1921 Jefferson Davis Hwy., Arlington, VA 22202, 703–305–5805.

C. Tolerance Revocation and Data Requirements

1. *Tolerance Revocation.* BASF has requested that EPA revoke the tolerances for prunes, plums, tomatoes, grapes (excluding grapes grown for wine production), raisins, dried prunes and grape pomace, and that all residential uses, as well as, turf in parks, school grounds and recreational areas which would be expected to result in significant exposure to children be deleted from its vinclozolin registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA accepts these amendments to the vinclozolin registrations. Revisions to existing tolerances and revocation of affected tolerances will be addressed by the Agency in later actions.

2. *Data Requirements.* In accordance with section 408(b)(2)(E)(ii) of the Federal Food, Drug, and Cosmetic Act(FFDCA), the Agency is requiring, pursuant to subsection (f)(1), that data be provided five years after the date on which the tolerance is established, modified,, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1), or an order under subsection (f)(2), as appropriate, to modify or revoke the tolerance.

VIII. Summary of Findings

The risk analysis for vinclozolin shows that there is reasonable certainty that no harm will result from aggregate exposure to vinclozolin. This analysis includes all current tolerances including the tolerances that BASF requested to be cancelled. All population subgroups examined by EPA are exposed to vinclozolin residues at levels below 100 percent of the RfD for chronic effects. Based on the information and data considered, EPA concludes that the proposed tolerances will be safe. Therefore the tolerances are established as set forth below.

FQPA has eliminated all distinctions between tolerances for raw agricultural commodities and processed foods. Therefore, EPA is combining the tolerances that now appear in § § 185.1850 and 186.1850 with the tolerances in § 180.380 and is eliminating § § 185.1850 and 186.1850.

IX. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''Object'' to a tolerance regulation issued by EPA under the new section 408(d) as was provided in the old section 408 and in section 409. However, period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which given the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use its current procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by September 16, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(I). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

X. Public Docket

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number [OPP–300507] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number (insert docket number). Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

XI. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

XII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Parts 180, 185 and 186

Environmental protection, Animal feeds, Administrative practice and procedure, Agricultural commodities, Food additive, Pesticides and pest, Reporting and recordkeeping requirements.

Dated: July 14, 1997.

Stephen L. Johnson,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180—[AMENDED]

1. In part 180:

a. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

b. By revising § 180.380 to read as follows:

§ 180.380 Vinclozolin; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the fungicide 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 food commodities in the table below. There are no U.S. registrations for Belgian endive, cucumbers, grapes, peppers and tomatoes as of (May 30, 1997). The time-limited tolerance will expire and is revoked on the date(s) listed in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Beans, succulent	2.0	10/1/99
Belgian endive, tops	5.0	None
Cucumbers	1.0	None
Grapes	6.0	None
Grape, pomace, dry (as a result of application to grapes)	42.0	None
Kiwifruit	10.0	None
Lettuce, head	10.0	None
Lettuce (leaf)	10.0	None
Onions (dry bulb)	1.0	None
Peppers (bell)	3.0	None
Prunes	75	None
Raisins (as a result of application to grapes)	30	None
Raspberries	10.0	None
Stonefruits	25.0	None
Strawberries	10.0	None
Tomatoes	3.0	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

PART 185—[AMENDED]

2. In part 185:

a. The authority citation continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.1850 [Removed]

b. Section 185.1850 is removed.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation continues to read as follows:

Authority: 21 U.S.C. 342, 348 and 701.

§ 186.1850 [Removed]

b. Section 186.1850 is removed.

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