interval after 3 days for irrigation and after 7 days for weeding and scouting. These use changes have been made to the Curalan EG formulation (EPA Reg. No. 7969–85) as a supplemental label for this registration. The supplemental label will allow use until August 30, 2003.

B. Requests for Voluntary Amendment and Cancellation

Pursuant to FIFRA section 6(f)(1)(A), BASF submitted requests for voluntary cancellation and use amendment of the registrations for vinclozolin. Specifically, BASF requested that EPA immediately amend registration number 7969–85 (Ronilan, Curalan, Touche) to terminate the use of vinclozolin on onions, raspberries, and ornamental plants.

EPA has considered the public comments received as detailed above in section II.A. and the timing of this Notice, and has modified the time frames for use cancellation and existing stocks from that published in the original proposal. These changes are reflected in the following Table 1.

TABLE 1.—TIME FRAME FOR USE CANCELLATION AND EXISTING STOCKS PROVISION

Commodity	Date of Registrant Use Cancellation Request	Last Date for Sale and Distribution of Existing Stocks by Registrant	Last Date for Sale and Distribution of Existing Stocks by Others	Last Date for Legal Use
Onions	July 15, 2000	August 30, 2001	October 15, 2001	December 15, 2001
Raspberries	July 15, 2000	August 30, 2001	October 15, 2001	December 15, 2001
Ornamentals (except conifer seedlings)	July 15, 2000	August 30, 2001	October 15, 2001	December 15, 2001
Conifer seedlings	July 15, 2000	August 30, 2003	October 15, 2003	December 15, 2003
Kiwi	December 31, 2001	December 31, 2002	November 30, 2003	January 30, 2004
Chicory	December 31, 2001	December 31, 2002	November 30, 2003	January 30, 2004
Lettuce	July 15, 2004	July 15, 2005	September 30, 2005	November 30, 2005
Succulent Beans	July 15, 2004	July 15, 2005	September 30, 2005	November 30, 2005

III. Cancellation Order

Pursuant to FIFRA section 6(f)(1)(A), EPA hereby grants the requested voluntary use cancellations and amendments of the registrations for vinclozolin as described in this Notice. Accordingly any distribution, sale, or use of existing stocks of in a manner inconsistent with the terms of this Order or the Existing Stock Provisions in Unit IV of this Notice will be considered a violation of section 12(a)(2)(K) of FIFRA and/or section 12(a)(1)(A) of FIFRA.

IV. Existing Stocks Provision

Pursuant to section 6(f) of FIFRA, EPA is granting the requests for voluntary amendment and cancellation during the appropriate time frames identified in Table 1. For purposes of the cancellation order, the term ''existing stocks'' will be defined, pursuant to EPA's existing stocks policy at (June 26, 1991, 56 FR 29362) (FRL–3846–4), as those stocks of a registered pesticide product which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the amendment or cancellation. Any distribution, sale, or use of existing stocks after the effective date of the cancellation order that is not consistent with the terms of that order will be considered a violation of section 12(a)(2)(K) and/or 12(a)(1)(A) of FIFRA.

The distribution or sale of existing stocks by registrants will not be lawful under FIFRA after the sale and distribution dates for registrants listed in Table 1, except for the purposes of returns and relabeling, shipping such stocks for export consistent with the requirements of section 17 of FIFRA, or for proper disposal. Retailers and distributors may sell or distribute products with previously approved labeling which have been released for shipment until such supplies are exhausted, or until the date specified for ''Sale and Distribution by Others'' as presented Table 1, whichever comes first. End-users may use products with previously approved labeling until such supplies are exhausted or until the last legal use date listed in Table 1, whichever comes first.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: August 10, 2001.

Jack E. Housenger,

Acting Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 01–21200 Filed 8–21–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1035; FRL–6794–6]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–1035, must be received on or before September 21, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1035 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Fungicide Branch, Registration Division (7505C),

Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–7740; e-mail address: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–1035. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1035 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1035. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want To Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

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

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

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

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

of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

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

Dated: August 8, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Syngenta Crop Protection, Inc.

0F6218

EPA has received a pesticide petition (0F6218) from Syngenta Crop Protection, Inc., 410 Swing Road, P.O. Box 18300, Greensboro, North Carolina 27409–8300 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of azoxystrobin (methyl(E)-2-2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl-3- methoxyacrylate) and the Z isomer of azoxystrobin, (methyl(*Z*)-2-2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl-3-methoxyacrylate) in or on the raw agricultural commodities legume vegetables (succulent or dried) group at 3 parts per million (ppm), hops at 50 ppm, grapes at 3 ppm, tomatoes at 2 ppm, and tomato paste at 6 ppm. The proposed tolerance in or on grapes is an increase from the current tolerance of 1.0 ppm, the proposed tolerance in or on tomatoes is an increase from the current tolerance of 0.2 ppm, and the proposed tolerance in or on tomato paste is an increase from the current tolerance of 0.6 ppm. The proposed tolerances on legume vegetables (succulent or dried) group and hops are new. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of azoxystrobin as well as the nature of the residues is adequately understood for purposes of the tolerances. Plant metabolism has been evaluated in four diverse crops, cotton, grapes, wheat and peanuts, which should serve to define the similar metabolism of azoxystrobin in a wide range of crops. Parent azoxystrobin is the major component found in crops. Azoxystrobin does not accumulate in crop seeds or fruits. Metabolism of azoxystrobin in plants is complex with more than 15 metabolites identified. These metabolites are present at low levels, typically much less than 5% of the total recoverable residue (TRR).

2. *Analytical method*. An adequate analytical method, gas chromatography with nitrogen-phosphorus detection (GC-NPD) or in mobile phase by high performance liquid chromatography with ultra-violet detection (HPLC-UV), is available for enforcement purposes with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances. EPA concluded that the method(s) are adequate for enforcement. Analytical methods are also available for analyzing meat, milk, poultry, and eggs, and also underwent successful independent laboratory validations.

3. *Magnitude of residues*. Nineteen residue trials in legume vegetables were carried out in the United States and Canada in 1998 and 1999. Maximum residues of 1.9 ppm resulted from multiple foliar applications. Six residue trials in hops were carried out in the United Kingdom and Germany in 1998 and 1999. Maximum residues were 16 ppm. In the interest of harmonizing United States tolerances with those of Canada and the European Union, representative residue data from Canada and Germany are presented that demonstrate maximum residues of 2.4 ppm in grapes and 1.3 ppm in tomatoes.

B. Toxicological Profile

1. *Acute toxicity*. The acute oral toxicity study in rats of technical azoxystrobin resulted in an LD_{50} of > 5,000 milligrams/kilogram (mg/kg limit test) for both males and females. The acute dermal toxicity study in rats of technical azoxystrobin resulted in an LD_{50} of > 2,000 mg/kg (limit dose). The acute inhalation study of technical azoxystrobin in rats resulted in an LC_{50} of 0.962 milligrams/liter (mg/L) in males and 0.698 mg/L in females. In an acute oral neurotoxicity study in rats dosed once by gavage with 0, 200, 600, or 2,000 mg/kg azoxystrobin, the systemic toxicity no observed adverse effect level (NOAEL) was < 200 mg/kg and the systemic toxicity NOAEL was 200 mg/kg, based on the occurrence of transient diarrhea in both sexes. There was no indication of neurotoxicity at the doses tested.

2. *Genotoxicity*. Azoxystrobin was negative for mutagenicity in the *salmonella/mammalian* activation gene mutation assay, the mouse micronucleus test, and the unscheduled deoxyribonucleic acid (DNA) synthesis in rat hepatocytes/mammalian cells *in vivo/in vitro* procedure study. In the forward mutation study using L5178 mouse lymphoma cells in culture, azoxystrobin tested positive for forward gene mutation at the TK locus. In the *in vitro* human lymphocytes cytogenetics assay of azoxystrobin, there was evidence of a concentration-related induction of chromosomal aberrations over background in the presence of moderate to severe cytotoxicity.

3. *Reproductive and developmental toxicity*. In a prenatal development study in rats gavaged with azoxystrobin at dose levels of 0, 25, 100, or 300 milligrams per kilogram per day (mg/kg/day) during days 7 through 16 of gestation, lethality at the highest dose caused the discontinuation of dosing at that level. The developmental NOAEL was greater than or equal to 100 mg/kg/day and the developmental lowest observed adverse effect level (LOAEL) was > 100 mg/kg/day because no significant adverse developmental effects were observed. In this same study, the maternal NOAEL was not established; the maternal LOAEL was 25 mg/kg/day, based on increased salivation.

In a prenatal developmental study in rabbits gavaged with 0, 50, 150, or 500 mg/kg/day during days 8 through 20 of gestation, the developmental NOAEL was 500 mg/kg/day and the developmental LOAEL was > 500 mg/kg/day because no treatment-related adverse effects on development were seen. The maternal NOAEL was 150 mg/kg/day and the maternal LOAEL was 500 mg/kg/day, based on decreased body weight gain.

In a 2–generation reproduction study, rats were fed 0, 60, 300, or 1,500 ppm of azoxystrobin. The reproductive NOAEL was 32.2 mg/kg/day. The reproductive LOAEL was 165.4 mg/kg/day; reproductive toxicity was

demonstrated as treatment-related reductions in adjusted pup body weights as observed in the F18 and F2 pups dosed at 1,500 ppm (165.4 mg/kg/day).

4. *Subchronic toxicity*. In a 90–day rat feeding study the NOAEL was 20.4 mg/kg/day for males and females. The LOAEL was 211.0 mg/kg/day based on decreased weight gain in both sexes, clinical observations of distended abdomens and reduced body size, and clinical pathology findings attributable to reduced nutritional status.

In a subchronic toxicity study in which azoxystrobin was administered to dogs by capsule for 92 or 93 days, the NOAEL for both males and females was 50 mg/kg/day. The LOAEL was 250 mg/kg/day, based on treatment-related clinical observations and clinical chemistry alterations at this dose.

In a 21–day repeated-dose dermal rat study using azoxystrobin, the NOAEL for both males and females was greater than or equal to 1,000 mg/kg/day (the highest dosing regimen); a LOAEL was, therefore, not determined.

5. *Chronic toxicity and carcinogenicity*. In a 2–year feeding study in rats fed diets containing 0, 60, 300, and 750/1,500 ppm (males/females), the systemic toxicity NOAEL was 18.2 mg/kg/day for males and 22.3 mg/kg/day for females. The systemic toxicity LOAEL for males was 34 mg/kg/day, based on reduced body weights, food consumption, and food efficiency, and bile duct lesions. The systemic toxicity LOAEL for females was 117.1 mg/kg/day, based on reduced body weights. There was no evidence of carcinogenic activity in this study.

In a 1–year feeding study in dogs to which azoxystrobin was fed by capsule at doses of 0, 3, 25, or 200 mg/kg/day, the NOAEL for both males and females was 25 mg/kg/day and the LOAEL was 200 mg/kg/day for both sexes, based on clinical observations, clinical chemistry changes, and liver weight increases that were observed in both sexes.

In a 2–year carcinogenicity feeding study in mice using dosing concentrations of 0, 50, 300, or 2,000 ppm, the systemic toxicity NOAEL was 37.5 mg/kg/day for both males and females. The systemic toxicity LOAEL was 272.4 mg/kg/day for both sexes, based on reduced body weights in both at this dose. There was no evidence of carcinogenicity at the dose levels tested.

According to the new proposed guidelines for Carcinogen Risk Assessment (April 1996), the appropriate descriptor for human carcinogenic potential of azoxystrobin is ''not likely.'' The appropriate subdescriptor is ''has been evaluated in at least two well conducted studies in two appropriate species without demonstrating carcinogenic effects.''

6. *Animal metabolism*. In this study azoxystrobin, unlabeled or with a pyrimidinyl, phenylacrylate, or cyanophenyl label, was administered to rats by gavage as a single or as 14–day repeated doses. Less than 0.5% of the administered dose was detected in the tissues and carcass up to 7 days post-dosing and most of it was in excretion-related organs. There was no evidence of potential for bioaccumulation. The primary route of excretion was via the feces, though 9 to 18% was detected in the urine of the various dose groups. Absorbed azoxystrobin appeared to be extensively metabolized. A metabolic pathway was proposed showing hydrolysis and subsequent glucuronide conjugation as the major biotransformation process.

7. *Metabolite toxicology*. There are no metabolites of concern based on a differential metabolism between plants and animals.

8. *Endocrine disruption*. There is no evidence that azoxystrobin is an endocrine disrupter.

C. Aggregate Exposure

The Agency has concluded from review of available data that there is no acute toxicological endpoint of concern. Therefore, an acute risk assessment is not necessary. For azoxystrobin, only a chronic (noncancer) risk assessment is necessary.

1. *Dietary exposure*. Permanent tolerances have been established (40 CFR 180.507(a)) for the combined residues of azoxystrobin and its Z isomer in or on a variety of raw agricultural commodities at levels ranging from 0.02 ppm on tree nuts to 20.0 ppm on rice hulls. Included in these tolerances are numerous ones for animal commodities, established in conjunction with tolerances for rice and wheat commodities.

i. *Food*. In conducting this chronic dietary risk assessment, Syngenta has made the very conservative assumption that 100% of all commodities having azoxystrobin tolerances or proposed tolerances will contain azoxystrobin residues at the level of the tolerance. Default concentration factors have been removed where data show no concentration of residues (grapes, juice; grapes, raisins; tomatoes, juice; tomatoes, puree; and potatoes, white (dry)). The chronic reference dose (RfD) is 0.18 mg/kg/day, derived from the NOAEL of 18.2 mg/kg/day from the rat chronic toxicity/carcinogenicity feeding study and an uncertainty factor of 100 to allow for interspecies sensitivity and intraspecies variability.

The Novigen DEEM (Dietary Exposure Evaluation Model) system was used for this chronic dietary exposure analysis. The analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1994 through 1996. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of dietary exposure.

The existing azoxystrobin tolerances (published and pending; FIFRA section 18 tolerances were excluded in this analysis because most are included as pending tolerances), result in a theoretical maximum residue contribution (TMRC) that is equivalent to the following percentages of the chronic RfD. Because the 10x safety factor was removed by EPA, the chronic RfD is equal to the PAD (population-adjusted dose). As a result, the exposure given as a percentage of the total allowable is reported as %PAD.

Population Group/ Subgroup	Exposure (mg/kg/ day)	Percent Reference Dose[1] (%Chronic PAD/RfD)
U.S. population	0.033665	18.7
All infants (< 1–year)	0.043793	24.3
Nursing infants (< 1–year)	0.015041	8.4
Non-Nursing infants (< 1–year)	0.052206	29.0
Children (1–6 years old)	0.069628	38.7
Children (7–12 years old)	0.040975	22.8
Hispanics	0.038407	21.3
Non-Hispanic/ non-white/ non-black	0.046447	25.8

Population Group/ Subgroup	Exposure (mg/kg/ day)	Percent Reference Dose[1] (%Chronic PAD/RfD)
Females 13+ (nursing)	0.035904	19.9

[1]Percentage reference dose (% chronic PAD) = exposure x 100% (because RfD=PAD in this case) chronic PAD.

ii. *Drinking water*. There is no established Maximum Concentration Level for residues of azoxystrobin in drinking water. No health advisory levels for azoxystrobin in drinking water have been established. The concentration of azoxystrobin in surface water is based on Generic Estimated Environmental Concentration (GENEEC) modeling and in ground water based on Screening Concentration in Ground Water (SCI-GROW) modeling.

Based on the chronic dietary (food) exposure estimated, chronic drinking water levels of concern (DWLOC) for azoxystrobin were calculated and are summarized in the following table. EPA has estimated that the highest estimated environmental concentration EEC of azoxystrobin in surface water is from the application of azoxystrobin on grapes (39 µg/L). The EEC for ground water is 0.064 µg/L resulting from use on turf. For purposes of risk assessment the maximum EEC for azoxystrobin in drinking water (39 µg/L) should be used for comparison to the back-calculated human health drinking water levels of comparison (DWLOC) for the chronic (noncancer) endpoint. These DWLOCs for various population categories are summarized in the following table.

Group/Subgroup[1]	RfD (mg/kg/day)	TMRC (food) (mg/kg/day)	Maximum Water Exposure[2] (mg/kg/day)	DWLOC[3, 4, 5](g/L)
U.S. population	0.18	0.033665	0.146335	5121.725
Females 13+ (nursing)	0.18	0.035904	0.144096	4322.88
Children (1–6 years old)	0.18	0.069628	0.110372	1103.72

[1] Within each of these categories, the subgroup with the highest food exposure was selected
[2] Maximum chronic water exposure (mg/kg/day) = chronic RfD (mg/kg/day) - food exposure (mg/kg/day)
[3] DWLOC (µg/L) = maximum water exposure (mg/kg/day) X body wt (kg) ÷ (10^{-3} mg/µg) X water consumed daily (L/day)
[4] HED default body weights are: U.S. population, 70 kg; females (13+ years old), 60 kg; infants and children, 10 kg
[5] HED default daily drinking rates are 2 L/day for adults and 1 L/day for children

2. *Non-dietary exposure*. Azoxystrobin is registered for residential use on ornamentals and turf. The Agency evaluated the existing toxicological data base for azoxystrobin and assessed appropriate toxicological endpoints and dose levels of concern that should be assessed for risk assessment purposes. Dermal absorption data indicate that absorption is less than or equal to 4%. No appropriate endpoints were identified for acute dietary or short-term, intermediate-term, and chronic term (noncancer) dermal and inhalation occupational exposure. Therefore, risk assessments are not required for these exposure scenarios.

D. Cumulative Effects

Azoxystrobin is related to the naturally occurring strobilurins. Syngenta concluded that further consideration of a common mechanism of toxicity is not appropriate at this time since there are no data to establish whether a common mechanism exists with any other substance.

E. Safety Determination

The acute safety analysis was not applicable since no suitable toxicological end-point of concern was identified during Agency review of the available data. The short-term and intermediate-term safety assessment also was not applicable, in this case because no indoor and outdoor residential exposure uses are currently registered for azoxystrobin. Therefore, only a chronic analysis was needed.

1. *U.S. population*. The chronic dietary exposure analysis showed that exposure from all existing permanent and proposed tolerances, including those in or on legume vegetables (succulent or dry) group, hops, grape and tomato for the general U.S. population would be 18.7% of the RfD.

2. *Infants and children*. The chronic dietary exposure analysis showed that exposure from all existing permanent and proposed tolerances, including those in or on legume vegetables (succulent or dry) group, hops, grape and tomato for children (1–6 years old), the subgroup with the highest exposure, would be 38.7% of the RfD.

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. 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 interspecies and intraspecies variability. EPA believes that reliable data support using the standard hundredfold margin/factor but 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. The Agency ad hoc FQPA Safety Factor Committee removed the additional 10x safety factor because infants and children are not believed to have an increased sensitivity to azoxystrobin, compared to adults.

Syngenta has considered the potential aggregate exposure from food, water, and non-occupational exposure routes and concludes that aggregate exposure is not expected to exceed 100% of the RfD and that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to azoxystrobin residues.

F. International Tolerances

There are no Codex Maximum Residue Levels established for azoxystrobin.

[FR Doc. 01–21048 Filed 8–21–01; 8:45 am]

BILLING CODE 6560–50–S