D. Cumulative Effects

Novartis Crop Protection believes that consideration of a common mechanism of toxicity is not appropriate at this time since there is no information to indicate that toxic effects produced by CGA–329351 would be cumulative with those of any other chemicals.

E. Safety Determination

1. *U.S. population*—i. *Acute risk*. The risk from acute dietary exposure to CGA–329351 is considered to be very low. The NOAEL in a 28-day study was 50 mg/kg, which is 6–fold higher than the chronic NOAEL. Since chronic exposure assessment did not result in any unacceptable exposure for even the most impacted population subgroup, it is anticipated that also the acute exposure will be in an acceptable range. Again, the requested tolerance on rape seed (i.e., canola) was found not to contribute any measurable additional impact on acute exposure to CGA–329351 so that for the general population less than 15% of the acute RfD is utilized.

ii. *Chronic risk*. Under the conservative exposure assumptions of residue levels being at tolerance level, less than 10% of the RfD will be utilized by the U.S. general population. Use on canola does not measurably contribute to this exposure, particularly given that no detectable residues were found even when 3x the use rate was utilized. Therefore, based on the completeness and reliability of the toxicity data supporting this petition, Novartis Crop Protection believes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of CGA–329351 taking into account dietary and non–occupational exposures.

2. *Infants and children*. There is no indication that CGA–329351 interferes with the pre–natal or neo–natal development, even when experimental animals were exposed to very high doses leading to maternal toxicity. Infants and children are not expected to show any particular sensitivity to CGA–329351.

i. *Acute risk*. The risk from acute dietary exposure to CGA–329351 is considered to be very low. The NOAEL in a 28–day study was 50 mg/kg, which is 6–fold higher than the chronic NOAEL. According to our analysis there is no measurable impact of the requested tolerance on the exposure to CGA–329351. The utilization of the acute RfD from the most exposed group is 26% (non–nursing infants).

ii. *Chronic risk*. Calculated on the basis of the TMRC for CGA–329351, utilization of RfD from dietary exposure of children is estimated as: 4.3% for nursing infants, 14% for non–nursing infants, 21% for 1 to 6 year old and 12% for children 7–12 years old.

F. International Tolerances

There are no Codex Maximum residue levels established for CGA–329351.

[FR Doc. 00–22011 Filed 8–29–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–965; FRL–6739–8]

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–965, must be received on or before September 29, 2000.

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

FOR FURTHER INFORMATION CONTACT: By mail: Sharlene Matten, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 605–0514; e-mail address: matten.sharlene@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–965. 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–965 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–965. 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 17, 2000.

Kathleen D. Knox, Acting

Director, Biopesticides and Pollution Prevention 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. 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.

Plant Products Company Ltd.

0F6136

EPA has received a pesticide petition 0F6136 from Plant Products Co. Ltd., f314 Orenda Rd., Brampton, Ontario, Canada L6T 1G1, proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the microbial pesticide *Pseudozyma flocculosa* in or on all raw agricultural commodities (RAC). Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Plant Products Co. Ltd. has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Plant Products Co. Ltd. and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product Name and Proposed Use Practices

The active ingredient *Pseudozyma flocculosa* is formulated into the end use product called Sporodex WP Biological Fungicide. Sporodex is a wettable powder that controls powdery mildew on greenhouse-grown English seedless cucumbers and roses.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues. Pseudozyma flocculosa* is widely distributed as a saprophytic fungal epiphyte and as a

hyperparasite of powdery mildews in Canada, the U.S., and Europe on aerial plant surfaces in field or greenhouse agricultural ecosystems. *Pseudozyma flocculosa* is readily isolated by standard techniques and will grow aerobically on most artificial substrates in liquid and solid fermentations with an optimal pH in the acidic pH range of 4.5–6.8. It assimilates glucose, lactose, maltose, myo-inositol, xylose, ethanol and will grow and sporulate on cellulosic, chitinous, and keratinous natural substrates and is hyperparasitic on powdery mildews.

2. *Magnitude of residue at the time of harvest and method used to determine the residue.* This section is not applicable, as this proposes an exemption from the requirement of a tolerance.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* An analytical method for residues is not applicable, as this proposes an exemption from the requirement of a tolerance.

C. Mammalian Toxicological Profile

No evidence of pathogenicity or infectivity of Sporodex has been demonstrated following acute oral gavage, intraperitoneal and intratracheal challenge studies in rats. No toxicity has been shown following a single oral dose in rats. No toxicity or irritation was observed following a single dermal application in rabbits. Slight toxicity was observed following a single intraperitoneal challenge in rats. However, toxicity observed was due to normal immune response to foreign material deposited in the peritoneal cavity. Toxicity was observed in rats dosed by intratracheal challenge. Mortality was associated with the quantity of test material delivered (6 x 10^7 cells or 3.2 x 10^7 cfu) which was the highest dose deliverable. In an additional study, the minimum lethal dose was shown to be higher than 6 x 10^7 cells, which was the highest dose deliverable. Other signs of toxicity following intracheal challenge were associated with normal immune responses to foreign material in the lung. No reports of human toxicity have been made from those working directly with this microbe for the past 10 years. Conjunctival erythema was seen in five of six rabbits at the 1–scoring, and in two of six rabbits at the 24–hour scoring interval. The highest primary irritation score observed during the study was 1.7 (maximum possible score=110) at the 1–hour scoring interval. No signs of ocular irritation were observed in any rabbits at or following the 48–hour scoring interval. The bioactive compounds produced by *Pseudozyma flocculosa* are not known as genotoxins.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food. Pseudozyma flocculosa* does not exhibit any mammalian toxicity. Therefore, any dietary exposure would not be harmful to humans. Also, *Pseudozyma flocculosa* is a naturally occurring, ubiquitous microorganism indigenous to the United States and Canada.

ii. *Drinking water.* Since, the proposed use is for indoor application in greenhouses only, residues of *Pseudozyma flocculosa* are unlikely to occur in drinking water. Also, *Psuedozyma flocculosa* does not exhibit any mammlian toxicity, therefore any exposure through drinking water would not be harmful to humans.

2. *Non-dietary exposure.* Plant Products Co. Ltd. believes that the potential for non-dietary exposure to the general population, including infants and children, is unlikely as the proposed use sites are primarily agricultural and horticultural and that non-dietary exposures would not be expected to pose any quantifiable risks due to lack of residues of toxicological concern.

E. Cumulative Exposure

Consideration of a common mode of toxicity is not appropriate, given that there is no indication of mammalian toxicity of *Pseudozyma flocculosa* and no information to indicate that toxic effects would be cumulative with any other compounds.

F. Safety Determination

1. *U.S. population.* The lack of toxicity of *Pseudozyma flocculosa* has been demonstrated by the results of acute toxicity testing in mammals in which *Pseudozyma flocculosa* caused no adverse effects when dosed oral and via inhalation. Thus, the aggregate exposure to *Pseudozyma flocculosa* over a lifetime should pose negligible risks to human health.

2. *Infants and children.* Based on the lack of toxicity and low exposure, there is a reasonable certainty that no harm to infants, children, or adults will result from aggregate exposure to *Pseudozyma flocculosa* residues. Exempting *Pseudozyma flocculosa* from the requirement of a tolerance should pose no significant risk to humans or the environment.

G. Existing Tolerances

Plant Products Co. Ltd. has no information to suggest that *Pseudozyma flocculosa* will adversely affect the immune or endocrine systems.

H. International Tolerances

Plant Products Co. Ltd. is not aware of any tolerances, exemptions from tolerance or maximum residue levels issued for *Pseudozyma flocculosa* outside of the U.S.

[FR Doc. 00–22012 Filed 8–29–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6860–6]

Project XL Draft Final Project Agreement: State of Pennsylvania Department of Environmental Protection (PADEP) Coal Remining and Reclamation XL Project

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: EPA is requesting comments on a draft Project XL Final Project Agreement (FPA) for the State of Pennsylvania Department of Environmental Protection (PADEP) Coal Remining and Reclamation XL Project (hereafter ''Coal Remining and Reclamation''). The FPA is a voluntary agreement developed collaboratively by PADEP and the EPA. Project XL, announced in the **Federal Register** on May 23, 1995 (60 FR 27282), gives regulated entities the opportunity to develop alternative strategies that will replace or modify specific regulatory or procedural requirements on the condition that they produce greater environmental benefits.

The Pennsylvania Department of Environmental Protection (PADEP) has proposed a project aimed at improving overall in-stream water quality by reducing acid mine drainage (AMD) and reclaiming scarred lands resulting from abandoned coal mines in Pennsylvania. Under this project, PADEP will explore a new approach to encourage the remining and reclamation of abandoned coal mine sites and provide environmentally responsible incentives for potential reminers.

The proposed approach would be based on compliance with in-stream pollutant concentration limits and implementation of best management practices (''BMPs''), instead of National Pollutant Discharge Elimination System (''NPDES'') numeric effluent limitations measured at individual discharge points. The project will collect data to compare in-stream pollutant concentrations versus the loading from