

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 ( $6 \times 10^7$  cells or  $3.2 \times 10^7$  cfu) which was the highest dose deliverable. In an additional study, the minimum lethal dose was shown to be higher than  $6 \times 10^7$  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, *Pseudozyma flocculosa* does not exhibit any mammalian 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.

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## 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

individual discharge points and provide for the evaluation of the performance of BMPs and this alternate permitting strategy in PADEP's efforts to address AMD. This set of BMPs has been used in many successful re-mining projects in Pennsylvania to prevent acid mine drainage and reclaim lands that have been harmed by past mining practices. The proposed XL project would provide for a test of this approach in up to eight watersheds with significant AMD pollution.

**DATES:** The period for submission of comments ends on September 13, 2000.

**ADDRESSEES:** All comments on the draft Final Project Agreement should be sent to: Steven Donohue, EPA Region III, 1650 Arch Street, Philadelphia, PA 19103-2029. Comments may also be faxed to Mr. Donohue at (215) 814-2783. Comments may also be received via electronic mail sent to: donohue.steve@epa.gov.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the draft Final Project Agreement or a Fact Sheet, contact: Steven Donohue, EPA Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103-2029, or Ted Cochin, Office of Environmental Policy Innovation, U.S. EPA, 1200 Pennsylvania Avenue NW (1802), Washington, DC 20460. The FPA and related documents are also available via the Internet at the following location: <http://www.epa.gov/ProjectXL>. Questions to EPA regarding the documents can be directed to Steven Donohue at (215) 814-3215 or Ted Cochin at (202) 260-0880. To be included on the Coal Re-mining and Reclamation Project XL mailing list for information about future public meetings, XL progress reports and other mailings from PADEP on the XL project, contact Michael Smith, District Mining Manager, Hawk Run District Mining Office, Empire Road, P.O. Box 209, Hawk Run, Pennsylvania 16840-0209. For information on all other aspects of the XL Program contact Christopher Knopes at the following address: Office of Policy, Economics and Innovation, United States Environmental Protection Agency, 1200 Pennsylvania Avenue NW (1802), Washington, DC 20460. Additional information on Project XL, including documents referenced in this notice, other EPA policy documents related to Project XL, regional XL contacts, application information, and descriptions of existing XL projects and proposals, is available via the Internet at <http://www.epa.gov/ProjectXL>.

Dated: August 24, 2000.

**Elizabeth A. Shaw,**  
Director, Office of Environmental Policy  
Innovation.  
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**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-00675; FRL-6740-7]

### Pesticides; Harmonization of Treated Seed Policies and Requirements in Canada and the United States; Notice of Availability

**AGENCY:** Environmental Protection  
Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This document announces the availability of a discussion paper that provides information on how pesticide seed treatment products are currently regulated in both Canada and the United States and reviews the degree of harmonization in pesticide regulation in the two countries. The discussion paper on treated seed contributes to the initiatives of the North American Free Trade Agreement (NAFTA) Technical Working Group (TWG) on Pesticides. The NAFTA TWG on Pesticides aims to develop a harmonized approach to the regulation of pesticides in Canada, Mexico, and the United States, while maintaining current high levels of protection of public health and the environment and supporting the principles of sustainable pest management. Canada has also made this harmonization document available for comment through its regulatory processes.

**DATES:** Comments, identified by docket control number OPP-00675, must be received on or before October 16, 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. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-00675 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** Jean M. Frane, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5944; e-mail address: [frane.jean@epa.gov](mailto:frane.jean@epa.gov).

**SUPPLEMENTARY INFORMATION:**

## I. General Information

### A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to persons who produce seed treatment pesticides, or who use such products, both in the United States and Canada. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

### 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," "Regulations and Proposed Rules," 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/>.

To access information about the NAFTA TWG on Pesticides, go directly to the Home Page at <http://www.epa.gov/oppfeed1/international>, and select "NAFTA Technical Working Group (TWG)." The concurrent Canadian Regulatory Proposal is available on their homepage at <http://www.hc-sc.gc.ca>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-00675. 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