9-1-92

BRIEFING MEMORANDUM

SUBJECT: Registration of New Biological Pesticides: Pseudomonas fluorescens strain A506, Pseudomonas fluorescens strain 1629RS, and Pseudomonas syringae strain 742RS

FROM: Anne E. Lindsay, Director
Registration Division (H-7505C)

TO: Douglas D. Campt, Director
Office of Pesticide Programs (H-7501C)

BACKGROUND

On July 15, 1991, Frost Technology Corporation submitted a petition for an exemption from the requirements of a tolerance for residues of the biological pesticides Pseudomonas fluorescens and Pseudomonas syringae in or on all raw agricultural commodities when applied to growing crops as a frost protection agent in accordance with good agricultural practices. Concurrently, applications for the registration of four end-use products containing three strains of the bacteria, singly and in combination, were submitted under the product names Frostban A, B, C, and D. Frostban A contains 23% Pseudomonas fluorescens A506 and 24% each of the other two strains which is equivalent to 11.3×10^{10} colony forming units (CFU) per gram. Each of the following products contains 71% active ingredient (equivalent to 11.3×10^{10} CFU/gm): Frostban B, Pseudomonas fluorescens A506; Frostban C, Pseudomonas syringae 742RS; and Frostban D, Pseudomonas fluorescens 1629RS. An Experimental Use Permit was previously accepted for testing of these products.

The active ingredients in these products are naturally occurring bacterial isolates selected for their ability to compete with and reduce populations of ice-nucleating bacteria on plant surfaces. Pseudomonas fluorescens is ubiquitous in the environment and is a natural component of the microbial flora of soil, water and plants. Pseudomonas syringae is similarly widespread and may commonly be found on the majority of plant surfaces and less commonly in soil and water. These organisms are not generally regarded as human or animal pathogens.

The products are intended to be applied to plants to reduce frost and frost damage to leaves, blossoms and fruit at the rates of 0.33 to 0.44 pounds of product/acre. The products are also intended to be used to aid in the control of fire blight of apples and pears when used in an integrated fire blight control program.

SCIENCE FINDINGS

Summary Science Statement

The results of the data submitted confirm the lack of mammalian toxicity or pathogenicity of the live strains of the bacteria in the Frostban products by oral or inhalation routes of exposure, by intraperitoneal injection or by dermal application.

Requests for waivers of data requirements for avian oral, freshwater fish, freshwater aquatic invertebrate and nontarget insect testing were granted. Nontarget plant testing indicated that the strains of Pseudomonas in these products did not have any adverse effects on the plants tested. Testing of the organisms on honey bees was not submitted. Since the products will be applied during flowering, the honey bee testing will be required as a condition of registration. The organisms in these products will not pose a risk to wild mammalian species or to any endangered species.

Data for environmental fate are not triggered under current requirements for these products since the organisms are naturally occurring species and the results of initial Tier I tests did not indicate the need for additional testing.

Toxicological Characteristics

Acute oral toxicity/pathogenicity test: Results of this test indicated that the combined organisms in these products were not toxic or pathogenic to rats 7 days after exposure to a dosage of 8.4×10^{10} CFU.

Acute intraperitoneal injection test: The test material was not lethal to or significantly toxic to mice when injected in a single intraperitoneal dose of 2.8×10^{8} CFU/animal.

Additional data/information: Testing of various Pseudomonas strains closely related to those contained in these products were conducted. Acute oral and acute inhalation toxicity tests indicated that the strains tested were not lethal or toxic to rats. Primary eye and primary dermal studies in rabbits using closely related organisms showed no significant irritation effects.

Ecological Characteristics

No adverse effects are expected from the use of these products

on avian wildlife, aquatic organisms or nontarget insects because of the lack of demonstrated toxicity of the bacteria on these types of organisms. Additionally, due to the natural occurrence and ubiquitous nature of the organisms and their lack of persistence on the crop plant, these products are not expected to cause a significant impact on these organisms.

In the nontarget plant study which was submitted, no adverse effects on the nontarget plants in the test were demonstrated.

No adverse effects to mammalian systems would be expected because of the lack of toxicity demonstrated in the toxicity testing of the Pseudomonas strains.

No risk to endangered species is expected due to the low toxicity, natural occurrence, ubiquitous nature, lack of phytotoxicity and lack of persistence of the bacteria.

Due to the application of the products during plant flowering, when honey bees are most active, a honey bee test is being required as a condition of registration.

BENEFITS

Some bacteria, which are found naturally on plant surfaces, initiate frost formation by providing a nucleus for ice formation. When such bacteria are present on plant surfaces, frost damage occurs at higher temperatures than when they are absent. The bacteria in these products, when applied to newly emerging plant tissue will displace the ice-nucleating bacteria which might normally occupy that site. Since these bacteria do not initiate ice-nucleation, the plant can withstand temperatures several degrees less before being affected by the frost. This temperature difference would often be sufficient to prevent loss of the crop due to damaging effects of frost on flowers or tender foliage in the spring or may extend the growing season in the fall.

Ice-nucleating bacteria may also be controlled by chemical means. Registration of a biological frost prevention agent would provide a safer alternative to chemical pesticides.

The products are also intended to be used in an integrated fire blight control program on apples and pears. The products will be used in combination with reduced rates of standard antibiotic products currently used for fire blight control. This type of program would reduce exposure to antibiotics and possibly reduce or delay development of antibiotic resistance in humans and animals.

TOLERANCE ASSESSMENT

The petition which was submitted requested a generic exemption for the bacterial species Pseudomonas fluorescens and Pseudomonas

syringae. It was concluded that there are insufficient data to support an exemption from tolerance requirements for all strains of these very common and widespread bacteria at this time. The data are adequate to support an exemption from tolerance requirements for the specific bacterial strains in these products.

An exemption from the requirement of a tolerance is proposed to be established for the residues of Pseudomonas fluorescens strain A506, Pseudomonas fluorescens strain 1629RS, and Pseudomonas syringae strain 742RS in or on all raw agricultural commodities when applied as a frost preventive or biological control agent on growing agricultural crops in accordance with good agricultural practices. Based upon the lack of toxicity and pathogenicity of these organisms in the Tier I mammalian toxicity/pathogenicity studies, an exemption from tolerance requirements is warranted. Additionally, data were submitted to demonstrate that there is a significant population of naturally occurring fluorescent pseudomonads present on washed fresh produce intended to be consumed raw.

SUMMARY OF MAJOR DATA GAPS

The only outstanding data gap for this biological control agent is the requirement for conducting a study to determine the effect of these organisms on honey bees. The study is being required since the products will be applied at flowering when bees are most active. There have been no reports of toxicity to insects caused by these bacteria so the risk posed to honey bees by conditional registration should be minimal. Additionally, the time limit being imposed for completion of this test (9 months) would insure that the study is completed prior to the spring use season for the products. Therefore, a conditional registration would be justified.

RECOMMENDATION

I recommend that you concur with this section 3(c)(7)(C) registration for Pseudomonas fluorescens strains A506 and 1629RS and Pseudomonas syringae strain 742RS.

Concur: [signature]

Do Not Concur: _____

Date: SEP 1 1992

H7505C:C.Grable:cg:8/21/92