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The registration and labeling of agricultural pesticides for use in Puerto Rico (IR-4 Program)

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The Inter-Regional Research Project, No. 4 (IR-4) is a USDA-CSRS and ARS sponsored program to develop data required by the EPA for pesticide, biorational and drug labels for minor or speciality uses. In Puerto Rico, IR-4 pesticide research efforts have been directed towards determining efficacy, effect on yield, residues and phytotoxicity data to obtain tolerances for the pesticide/crop combinations: ametryn/yam, tanier and cassava; prometryn and metribuzin/pigeon pea; paraquat and glyphosate/acerola; chloramben and paraquat/pigeon pea. Most of the data has resulted in Federal or Special Local Need registrations. Field and residue work has also been completed for fluvalinate and captafol/coffee; methomyl/sugar cane; acephate and esfenvalerate/ pineapple; paraquat/cassava, tanier and yam and; fluzifop-p-butyl, fenamiphos and oxamyl/cooking peppers. With IR-4 collaboration, tolerances and exemptions established for pesticide residues on bananas have been extended to plantains, from sweet potatoes to yam and from peas to pigeon pea. The inclusion of specific crops grown in Puerto Rico and the Caribbean Basin into EPA's crop groupings has also been achieved. Problems affecting tolerance approvals and label development by EPA are discussed.

Keywords: Pesticides; Registration, Puerto Rico

Introduction

General considerations

The use of a pesticide in the United States of America, its territories and possessions, must be registered with the Environmental Protection Agency (EPA) in Washington D.C. Types of pesticide registration such as a full federal label, a label restricted to a state or region and an experimental use permit can be obtained by following the requirements of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as established in Sections 3 and 5 (USEPA 1985). In addition, pesticides can be registered for one year under the following types of exemptions: specific, crisis and quarantine-public health (Section 18 of FIFRA).

The Commonwealth of Puerto Rico, through the Departments of Agriculture and Health, regulates the registration and use of pesticides through the provisions of Acts #49 and #132 (DAPR 1980 and DSPR 1966). Under section 24(c) of FIFRA, the Commonwealth of Puerto Rico can register additional uses of federally registered pesticides to meet special local needs. In 1977-1987, over 45 Special Local Need (SLN) registrations were approved by the Puerto Rico Department of Agriculture.

Pesticide manufacturers allocate human resources, time and funds to research and develop new pesticides registered for major commodities such as grains (wheat, rice, corn), soybean, cotton and tobacco. Experience indicates that about 8 to 10 years and more than US\$ 20M are necessary to fulfill all EPA requirements to obtain the first pesticide registration. Manufacturers will develop data for major uses only when the volume of sales exceeds research and development costs. A minor use of a pesticide is a use on a crop which is limited such that the potential market volume of the agrochemical for that particular use is inherently small. Pesticide needs on tropical crops grown in Puerto Rico and other countries in the Caribbean Basin are usually not addressed by manufacturers, simply because potential sales volume is too small. The IR-4 project was established by the USDA to develop data for securing pesticide labels for minor and specialty crops to aid small farmers in the continental US, Hawaii, Guam, Puerto Rico and the US Virgin Islands.

The Inter-regional Research Project No. 4 (IR-4), "Clearances of Safe Animal Drugs, Biorationals (Microbials and Biochemicals) and Pesticides for Minor or Speciality Uses" is a national agricultural program for the clearance of chemical and biologicals for minor uses on food crops, ornamentals, forages and animals. The IR-4 project was initiated by the State Agricultural Experiment Stations (SAES) in 1963 and is a joint effort of the United States Department of Agriculture (Agricultural Research Service and Cooperative State Research Service), (EPA), the Food and Drug Administration (FDA), SAES, individual researchers, animal drug and pesticide manufacturers, and growers. In 1980-1986, IR-4 completed the data for documenting and obtaining positive action on 485 tolerances or exemptions of pesticides on several commodities.

The program has about \$5 million available from federal and state entities and agricultural experiment stations in four USA regions. The Southern Region includes Puerto Rico, the US Virgin Islands, and 12 other states. The IR-4 regional office is at the University of Florida in Gainesville, Florida and sends data and information to National Headquarters at Rutgers University in New Brunswick, New Jersey.

Procedure for Tolerance for Commodities

Pesticide needs are identified by the Puerto Rico IR-4 Liaison Representative with the help of researchers, specialists and extension agents of the College of Agricultural Sciences of the University of Puerto Rico - Mayaguez Campus; growers; members of state agricultural agencies and grower associations and local representatives of pesticide manufacturers. Once the needs are considered by the administration of the Puerto Rico Agricultural Experiment Station, an IR-4 pesticide clearance request (PCR) is prepared and submitted through the regional office to National Headquarters. Information required for a PCR includes: chemical needed, site/commodity where needed, parts of commodity consumed, reasons for need, alternative treatments, importance of proposed use and proposed labeling (formulation, active ingredient, method of application, directions for use, and others).

Each PCR undergoes careful screening, both at the regional office and at National Headquarters to be sure that it meets certain specific criteria. These include the verification of the need for the pesticide, the chemicals already labeled for the requested pest control but which do not satisfy the need, availability of a full registration on a major commodity for the pesticide selected, whether the manufacturer is unwilling to perform the field research but

willing to support registration, lack of major data gaps in EPA and, verification that there are no other EPA constraints impeding the potential use permit.

A research test protocol is developed by IR-4 to generate performance data (efficacy, residues and effect on yield and quality of the commodity) through two or three years of field work. Pesticide manufacturers, state and IR-4 regional laboratories perform the residue analyses.

All field and laboratory data are developed, compiled and evaluated by the IR-4 regional and main offices. The pesticide tolerance data packaging and proposed label are sent to the manufacturer for comments. Several months later, the final package and tolerance petition is submitted to EPA's Office of Pesticide Programs (OPP). The petition is assessed by several divisions of the EPA-OPP. After approval, either the pesticide manufacturer or a third party applies for a pesticide registration for the selected commodity (NACA 1984).

For the last nine years, efforts in Puerto Rico have been directed to securing tolerances for sub-tropical and tropical crops also grown in other Caribbean Basin countries. Pesticide clearance requests and research test protocols have been developed for pineapple, acerola, mango, avocado, mango, papaya, root and tuber crops (yam, tanier, cassava and arracacha), legumes (pigeon pea), plantain, banana, coffee, sugarcane and vegetables (tomato, pepper, eggplant, pumpkin, etc.).

Results and discussion

Pesticide Clearance Requests, Tolerances and Labels

About 263 pesticide clearance requests have been submitted by Puerto Rico (Table 1). A large number have been for pesticides needed on pineapple (16), mango (14), acerola (7), papaya (6), yam (22), tanier (14), coffee (10), plantain and banana (21), pigeon pea (27), and rice (8). Lack of sufficient research funds and trained personnel to collect performance data and low priority in terms of acreage and farm value have hindered the initiation of most of the required work. It has been difficult to combine work with the US Virgin Islands, Hawaii and Florida, in order to obtain data for pesticide tolerances and to develop the label for crops of common interest.

In spite of the difficulties, tolerances have been obtained and uses approved for the following herbicides: ametryn on yams, tanier, and cassava; prometryn, metribuzin, chloramben and paraquat on pigeon pea; glyphosate and paraquat on acerola; and also for the insecticide methomyl on pigeon pea. Several SLN registrations, following Section 24(c) of FIFRA and Commonwealth requirements, were obtained for pigeon pea, yam, tanier, cassava, and acerola (Table 2). Manufacturers have also secured EPA importation tolerances for several pesticides on pineapple, plantain and banana.

For vegetables, data from Puerto Rico and other states was collected by IR-4, evaluated and submitted to EPA in order to secure the tolerance. After tolerance approval, most of the pesticide manufacturers obtained full or restricted federal labels.

Table 1 Information on Pesticide Clearance Requests Submitted by Puerto Rico

Commodity	Number of Pesticide Clearance Requests
Tropical Fruits	20
Root and Tuber Vegetables	54
Sugarcane	11
Plantains and Bananas	21
Coffee	10
Pigeon Pea	27
Rice	8
Pastures and Forages	8
Solanaceous	45
Cucurbits	35
Others	24
Total	263

Field and residue data have already been completed for fluvalinate and captafol on coffee; methomyl and acephate on sugarcane; ametryn on arracacha; acephate and esfenvalerate on pineapple; paraquat on cassava, tanager and yam; fluzifop-p-butyl, fenamiphos and oxamyl on cooking pepper; chlorothalonil on pigeon pea, and *Bacillus thuringiensis* on pineapple. Label petitions have been sent to manufacturers and EPA. The pesticide clearance requests shown in Table 3 are active IR-4 projects that could be completed within the next five years.

A glance at EPA's approved tolerances for citrus and tropical fruits (FCN 1987) reveals that only a few tolerances are available for tropical crops grown in the Caribbean Basin. The number of tolerances available include only passion fruit (2), acerola (2), guava (17), papaya (17), mango (21), avocado (29), and pineapple (44). The Puerto Rico Department of Agriculture has intensified efforts for crop diversification and emphasized the cultivation of tropical fruits for export. Therefore, efforts should be continued to develop field and residue data on tropical crops grown in Puerto Rico and other countries of the Caribbean Basin. Several pesticide manufacturers have indicated interest in securing tolerances and labels for crops shown in Table 4.

Expansion of tolerances

Although most manufacturers consider pesticides used on most crops grown in the Caribbean Basin and Central America as minor uses, with IR-4 and EPA assistance, Puerto Rico has been successful in expanding tolerances and exemptions for pesticide chemicals in the general category of raw agricultural commodities to the corresponding specific raw agricultural commodity (USEPA, 1985).

After many years of work, Puerto Rico has been successful in applying the rulings of Section 40CFR 180.1(h) for banana to plantain; for sweet potato to yam, and for pea to pigeon pea. More information has been requested by EPA to complete the request to apply the tolerances and exemptions for pepper to bell pepper, cooking pepper and sweet pepper (known in Puerto Rico as ajies dulces). These new rulings will facilitate obtaining the use permit for thiabendazole to

Table 2 Examples of Special Local Needs registered in Puerto Rico

Commodity	Pest/Treatment	Formulation
Pigeon Pea	Weeds/pre-emergence Weeds/pre-emergence Pod borers/foliar sprays Pod borers/dust sprays	Caparol 80W ^{a)} Lexone DF Lannate L Thiodan 4D
Yam, tanager, cassava	Weeds/pre-emergence	Evik 80W
Yam	Nematode/foliar sprays Anthracnose/foliar sprays	Vydate L Benlate 50WP
Acerola	Weeds/post-emergence Weeds/post-emergence	Round-up Gramoxone CL
Avocado	Anthracnose/foliar sprays Root rot/soil drench application	Benlate 50WP Terrazole 4E
Pineapple	Weeds/post-emergence Nematode/foliar sprays Weeds/pre and post Reproduction of planting material	Gramoxone CL ^{a)} Vydate L ^{a)} Karmex 80WP Maintain CP-125
Plantain & Banana	Yellow Sigatoka/foliar sprays Yellow Sigatoka/foliar sprays Yellow Sigatoka/foliar sprays Yellow Sigatoka/foliar sprays Nematodes/spot gun Nematodes and banana weevil/ soil surface application Nematodes and banana weevil/ soil surface application Weeds/post-emergence	3055 Spray Oil Orchex 796 Excel Ortalex Bravo 500 Vydate L Furadan 10G Temik 10G Round-up ^{c)}
Coffee	Weeds/post-emergence Anthracnose/foliar sprays Nematodes, leafminers, scales/soil surface application Weeds/post-emergence	Dowpon M Bravo 500 Furadan 10G Round-up ^{a)}
Rice	Weevil/broadcast application Weeds/pre and post	Furadan 3G & 5G Bolero EC
Sugarcane	Pineapple disease/Seed piece dip <i>Diaprepes abbreviatus</i> / foliar sprays	Benlate 50WP Furadan 4F
Tomato	Insects/foliar sprays	Monitor 4S
Tomato and pepper	Weeds/post-emergence	Gramoxone CL
Cucumber and melon	Insects/foliar sprays	Monitor 4S ^{a)}

a) Registration now included in full or supplemental label

control soil-borne and foliar diseases; methomyl and carbaryl for adult *Diaprepes abbreviatus* control on yam; captan for canker control on pigeon pea; and benomyl for powdery mildew control.

The IR-4 Technical Committee has requested that 40CFR 180.1(h) be amended to define *Annona* and include raw agricultural commodities such as atemoya, cherimoya, sugar apple, sweetsop, soursop, custard apple, ilama, and their hybrids. The establishment of the definition requested would facilitate establishing tolerances or exemptions of pesticides on many similar crops of the genus *Annona*.

Table 3 Pesticide clearance requests to be completed before 1992

Pesticide	Pest	Crop
Acephate	Diaprepes root weevil Pod borer	Yam
Carbaryl	Diaprepes root weevil	Pigeon pea
Oxyfluorfen	Weeds	Pigeon pea
Bacillus thuringiensis	Pod borer	Pigeon pea
Permethrin	Pod borers Various insects	Pigeon pea Mango and papaya
Esfenvalerate	Various insects	Mango and papaya
Metalaxyl	Root rots and blights	Papaya
Fluazifop-p-butyl	Grass weeds (post)	Yam, tanager and cassava Pigeon pea Mango and papaya
Glyphosate	Weeds (post directed)	Pineapple
Methomyl	<i>Diaprepes</i> root weevil	Yam
Fenamiphos	Nematodes	Acerola
Benomyl	Powdery mildew	Peppers
Triadimefon	Powdery mildew	Peppers
Chlorothalonil	Anthracoise	Mango
Chlorothalonil	Rust	Pigeon pea
Thiabendazole	Seed Diseases	Yam

Use of Crop Groupings

The concept of establishing maximum pesticide residues for a group of related crops was first used in 1962 and was significantly modified in 1967 when tolerances for negligible residues were initiated.

Table 4 Potential pesticides for pest control in tropical crops

Formulation	Active Ingredient	Pest	Crop
Spotless 25 WP	Dinixazole	Yellow and Black Sigatoka	Plantain and Banana
Tilt 3.6E	Propiconazole	Yellow and Black Sigatoka	Plantain and Banana
Punch 40EC	Flusilazol	Yellow and Black Sigatoka	Plantain and Banana
		Rust, <i>Mycena citricolor</i> , and Anthracnosis	Coffee Coffee Coffee
Summit EC	Triadimenol	Yellow and Black Sigatoka	Plantain and Banana
Rugby 10G	Butylfos	Nematodes & banana weevil	Plantain and Banana
Goal 2E	Oxyfluorfen	Weeds (Pre & Post)	Rice
Bravo 500	Chlorothalonil	Anthracnose Rust	Mango Pigeon pea
Marshal EC	Carbosulfan	Scales & mites	Mango and Citrus

Since 1969 it had been evident that there was an increasing problem with this system. Throughout the 1970's and early 1980's, EPA explored the possibility of further expanding the 14 crop groupings in order to allow a more extensive use of related crops and to minimize the burden of establishing pesticide residue tolerances. By re-grouping crops in at least 18 categories, pesticide tolerances could be established for all members of the group on the basis of those established for representative commodities within each group.

Puerto Rico submitted a substantial number of comments, suggestions and recommendations through the IR-4 Program and directly to the EPA main office. Arracacha, cassava, celeriac, tanier, taro, and yam were included in the root and tuber vegetables; pigeon pea in the legume vegetables; sweet and cooking pepper in the fruiting vegetables; and citron in the citrus fruit groups.

Problems with tolerance approval and labeling

The EPA is in the process of re-registering about 35,000 pesticide formulations. Because of data gaps for active ingredients, many formulations will not be available for minor and specialty crops. Neither will EPA grant additional tolerances for active ingredients lacking complete toxicological data. Re-registration could become one of the major obstacles in labeling pesticides for use on tropical crops.

Serious problems involving legal, economic, cultural practice and diet aspects are affecting the development of pesticide tolerances and labels for tropical crops in USA, Puerto Rico and other countries (PCR 1986).

After IR-4 secures a tolerance for a pesticide use, some agency or group must apply for a label or it will not be available to the grower. Usually the manufacturer will apply for a label. In rare cases, fear of potential crop injury and resulting liability will stifle interest. EPA may, however, allow a third party (grower, grower group or State Department of Agriculture) to apply for the label.

Up to the present, the acreage of commercial plantings of tropical fruits such as mango, papaya, avocado, passion fruit and others is rather small compared to coffee, plantain and banana. In addition, very few reliable technical publications on cultural practices and processing technology for tropical crops are available. The Puerto Rico Agricultural Experiment Station had publications on technological practices for cultivation and production of sugarcane, pineapple, coffee, vegetables, pigeon pea, papaya, mango, plantain, banana, and root and tuber crops. Some of this information is considered by EPA's Branch of Residue Chemistry and Toxicology for tolerance and use permit requests. The publication "Food and Feed Crops of the United States" needs to be updated and cleared of confusing information regarding cultivation practices as well as edible parts of agricultural commodities (Magness 1971).

The allowable daily intake (ADI) is the maximum theoretical intake of a pesticide through a calculated diet based on maximum residue levels (established tolerances) in all commodities. The registration of a pesticide for numerous crops, such as vegetables, tends to use up the EPA's Allowable Daily Intake for the pesticide of interest (BOA 1987). Pesticide manufacturers are highly reluctant to expend an ADI through a profusion of limited marketing's like root and tuber crops, tropical fruits and others.

The information obtained through IR-4 and the Program's achievements can be useful throughout the entire Caribbean Region. Utilization of this information can significantly decrease health and environmental hazards. Furthermore, it can pave the way for opening new markets for agricultural export crops to the U.S. mainland, Puerto Rico and the Virgin Islands. This will indeed be fitting within the framework of the Caribbean Basin Initiative.

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