GUEST EDITORIAL

Robert Eric Holm, born 1940, Executive Director, IR-4 Program, Rutgers U./Cook College, North Brunswick, NJ. B.Sc. in Agricultural Sciences (1962), M.Sc. (1964) and Ph.D. (1969) in Biochemistry and Plant Physiology, all at Purdue U. 1969-78 Senior Research Associate, Diamond Shamrock Corporation, Painesville, OH. 1978-81, Research Manager, Mobil Chemical, Edison, NJ. 1981-87. Director Agrichemical Sciences, Rhône-Poulenc, Monmouth Junction, NJ. 1987-91, Director Field Research and Product Development, Rhône-Poulenc, Research Triangle Park, NC. 1991-98, Vice President Research and Development, Valent U.S.A. Corporation, Walnut Creek, CA, 1998-, Executive Director, IR-4 Program. *Other activities*: Presentations on minor crop agriculture (approximately 50/year) to universities, commodity groups, agrichemical companies, etc. *Special interests*: Development of strategic partnerships with crop protection industry and regulatory agencies (EPA, etc.). Use of biological agents and reduced risk chemistries for minor crop protection.

The IR-4 Program: Meeting the U.S. Minor Crop Pest Control Challenge

In the past 15 years, formidable challenges have arisen to the availability of crop pest control tools for minor or specialty crop growers in the U.S. The Federal Insecticide, Fungicide and Rodenticide Act of 1988 (FIFRA '88) and the Food Quality Protection Act (FQPA) of 1996 enacted new sets of regulatory requirements on chemicals used to control pests on all crops grown in the U.S. The passage of FQPA brought about dire predictions regarding the future lack of availability of crop protection products for minor crop growers due to increased regulatory requirements for chemical risk assessment.

The Interregional Project Number 4 or IR-4 Program committed to address the minor use challenges of FIFRA '88 and the FQPA as it has since its formation in 1963 as a unique partnership between the land grant university system (state agricultural colleges/universities) and the United States Department of Agriculture (USDA). Two USDA agencies, the Agricultural Research Service (ARS) which is the intramural research arm, and the Cooperative States Research, Extension and Education Service (CSREES), which, among many functions, provides support for agricultural research in the states, are the major funding participants in this partnership. A detailed history of the IR-4 Program can be found in a recent book chapter by Markle, Baron and Holm (5).

IR-4's response to FIFRA '88 was to make a detailed evaluation of the vulnerable minor crop chemicals whose uses would not be supported by registrants and a prioritization of those most critical needs to address over a 10-year period. A goal was set to reregister 1000 minor use clearances during that period. This was aggressively pursued and resulted in over

700 clearances for key minor crop needs being granted by the Environmental Protection Agency (EPA). However, the target was not pursued to its intended completion by the IR-4 Project Management Committee (PMC), which is the governing/management body for the program due to a shift in strategy in the mid-1990's. A 1995 Strategic Plan noted the development of many new chemistries and biological materials by the crop protection industry and started a shift from product defense to the registration of new products, especially those classified as Reduced Risk by the EPA. After FQPA was passed, Reduced Risk/safer chemistry products passing the test were deemed to be most likely to pass the hurdles set by new legislation. In 1996, prior to the passage of FQPA, only 13% of IR-4's projects involved Reduced Risk chemistries. That number jumped to 38% in 1997, the year after FQPA passage, and has averaged over 80% for the past four (2000 to 2003) years (3). This emphasis on Reduced Risk/safer chemistries and biopesticides has made IR-4 a very acceptable regulatory partner for the EPA and other regulatory agencies such as California's Department of Pesticide Regulation (CDPR) and Canada's Pest Management Regulatory Agency (PMRA).

IR-4's successes with the regulatory agencies would not have been possible without the cooperation of the crop protection industry. Developing a partnership with individual companies involves considerable effort on behalf of both IR-4 and the companies' senior management and their technical staffs. This has been especially true in recent years with the numerous consolidations, mergers, product divestments, licensing agreements and other reorganizations (4). IR-4's vast network of university and government researchers, commodity groups and individual growers provides an ongoing and continually updated list of unmet minor crop pest control needs which are prioritized annually at Food Use Workshops attended by all stakeholders (3). These needs are matched with new chemistry and biopesticide activity spectra of the industry's latest technologies.

IR-4's goal is to partner with registrants at the earliest time possible after they make a commercial decision on a new product to discuss potential minor crop opportunities. A number of company/product specific examples such as Arvesta/fenhexamid and iodomethane; BASF/pyraclostrobin, boscalid and BAS 516; Bayer CropSciences/imidacloprid and thiacloprid; Dow AgroSciences/spinosad, tebufenozide, methoxyfenozide, quinoxyfen and zoxamide; Gowan/halosulfuron; and Syngenta/azoxystrobin, cyprodinil, fludioxonil, mesotrione, thiamethoxam and others, can be found in an Agrow Report (3). It is interesting to note that, on the EPA's 2003 Work Plan for New Chemicals, IR-4 is listed as the initial submitter for quinoxyfen's first U.S. registration along with being a joint submitter on spiroxamine and thiacloprid from Bayer CropSciences (2). The tracking of new biological products and traditional chemistries can be found on IR-4's website under New Pest Control Products/Transitional Solution List (1).

The relationship between IR-4 and the EPA has always been positive, but it has been elevated since 1999 through a partnership centered on the EPA/IR-4 Technical Working Group (TWG). The TWG, which meets four times a year, has expanded since 2001 to include CDPR and PMRA. The meetings involve the EPA and IR-4 in technical discussions on ways and means to enhance the regulatory review and efficiencies of IR-4 submitted minor crop registration packages. Some of the innovative approaches developed by the TWG include electronic submission of the registration packages and providing data summaries (Data Evaluation Records) to speed the EPA's regulatory review. IR-4 has also negotiated proposals with the EPA on new Reduced Risk/safer chemistries like azoxy-

strobin and spinosad to make maximum use of the major crop residue data available from the registrants, IR-4's minor crop residue data and the crop grouping concept pioneered by IR-4 and the EPA in Food and Feed Crops in the U.S. (6). By using such surrogate data and reduced data requirements for certain low dietary consumption crops, the end result was the EPA's approval of over 160 spinosad minor crop uses and 120 azoxystrobin minor crop clearances in 2001. This resulted in a savings to IR-4 of over $1,000,000 in field and laboratory analytical expenses compared to the cost of conducting all of the required studies. Recently, IR-4 has facilitated a joint review or workshare program between the EPA and CDPR which has resulted in CDPR conducting 10% of EPA's and 20% of IR-4's minor crop petition reviews since 2001 with considerable savings of time and personnel costs. Before this joint review, a federal EPA approval required a subsequent CDPR review prior to California approval, resulting in up to a year before the new use was available to California minor crop growers. Since California produces over $14 billion of the $40 billion U.S minor crop value at the grower level, these time-savings and earlier product availability are critical. In 2002, PMRA completed its first joint review of an IR-4 petition with the EPA. It is hoped that PMRA will be able to continue and expand this program in the coming years – based on the significant funding initiative by the Canadian government in 2002 – in order to address trade irritant and new product availability issues for Canadian minor crop growers. IR-4 is greatly expanding its cooperative residue program in Canada in 2003 working with Agriculture and Agri-Food Canada as well as commodity groups such as the Canadian Horticultural Council.

The results from the crop protection industry and regulatory partnerships have been impressive. IR-4 averaged 100 new minor crop clearances per year pre-FQPA (from 1984 to 1996). The past 3 years (2000–2002) have resulted in more minor crop clearances (1669) than in the 15 years prior to FQPA. Since its inception in 1963, IR-4 has obtained over 6500 food crop clearances, over 9900 ornamental and non-food crop clearances and over 300 new biopesticide clearances. Based on these past successes and current strong partnerships, IR-4 has a bright future in the coming years in addressing the crop protection needs of U.S minor crop growers.

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Acronymns and their meanings

CDPR = California Department of Pesticide Regulation

CSREES = Cooperative State Research, Extension and Education Service

FIFRA = Federal Insecticide, Fungicide and Rodenticide Act, 1988

FQPA = Food Quality Protection Act, 1996

PMC = Project Management Committee, IR-4

PMRA = (Canadian) Pest Management Regulatory Agency

TWG = Technical Working Group EPA/IR-4

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