COOPERATIVE INDUSTRY EFFORTS WITH DEVELOPING COUNTRIES TO IMPROVE AGROCHEMICAL REGISTRATION, LABELING AND EDUCATION AND TRAINING PROGRAMS

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ABSTRACT

The agrochemical industry is cooperatively engaged in carrying out education and training activities to eliminate misuse and achieve safety in the use of their products throughout the world. Meaningful and lasting success of these activities will come only after a sound regulatory foundation for the registration, labeling, and use of agrochemicals is established by local governments. This goal is being pursued in Latin America and the Caribbean as a cooperative effort of governments and industry utilizing a consultative process.

The International Group of National Associations of Agrochemical Manufacturers, in 1979, began an intense process of consultations with some Latin American governments. Formal governmental consultations, under the sponsorship of IICA, followed in 1982-83 which included all governments of Latin America and the Caribbean. As a result recommendations were agreed upon among governments for registration requirements, labeling, toxicity categories, and other safety and training considerations. As of 1984, 11 Latin American nations had accepted the recommendations and 7 others were in various stages of the legislative process.

Most Caribbean nations are legally unable to accommodate the recommendations until they establish the prerequisite legislation. IICA is preparing a working document for the governments of the Caribbean to use to establish their own regulations.

An informal consultation between industry and environmental groups to resolve problems associated with the safe use of agrochemicals and the status of the Food and Agriculture Organization (FAO) Draft Code of Conduct on the Distribution and Use of Pesticides are also mentioned.

RESUMEN

La industria agroquímica está cooperativamente envuelta en llevar a cabo actividades de educación y entrenamiento para eliminar el mal uso y obtener seguridad en el uso de sus productos a través del mundo. El éxito duradero y que signifique algo de estas actividades, vendrá solo después de una sólida fundación de regulaciones para la registración, marcar, y el uso de agroquímicos sean establecidas por los gobiernos locales. Esta meta se está tratando de llevar a cabo en latinoamérica y en el Caribe como un esfuerzo de cooperación de gobiernos e industrius utilizando un proceso consultativo.

En 1979, el Grupo Internacional de las Asociaciones Nacionales de Fabricantes Agroquímicos, comenzó un intenso proceso de consultas informales con algunos gobiernos latinoamericanos. Durante 1982-83, consultas formales con los gobiernos fueron auspiciadas por IICA que incluyeron todos los gobiernos de latinoamérica y del Caribe. Como resultado, se acordó entre los gobiernos recomendaciones de requisitos de registración, marcas, categorías de toxicidad, y otras consideraciones de seguridad y entrenamiento. A partir de 1984, 11 naciones han aceptado las recomendaciones y otras 7 están en varias etapas del proceso legislativo.

La mayoría de las naciones del Caribe no pueden legalmente acomodar las recomendaciones hasta que ellas establezcan los pre-requeridas leyes. IICA está preparando un
An international movement to harmonize pesticide registration requirements according to FAO recommendations (FAO 1982) is being successfully implemented in Latin America and the Caribbean as a cooperative effort of governments and industry using the consultative process (GIFAP/WICEM 1984).

As a focal point, there are a few premise statements of obvious facts on plant protection and some lesser known facts about the agro-chemical industry.

(1) Agricultural food and fiber production is the primary industry of man. It serves his basic health and economic needs.

(2) There are no major agricultural crops grown anywhere in the world that are free from pest destruction.

(3) Agrochemicals are the most widely used means of providing immediate and economic plant protection.

(4) All plant protection schemes and materials, natural and synthetic, have inherent limitations for pest control that ultimately determine the extent and nature of their practical use.

In essence, because plant protection is essential to assure food and fiber production worldwide, and since control options are not infinite, any inherent limitations in efficacy, safety, or efficiency for whatever controls are being used (Hollis 1971) must be overcome by correct management in use.

Regarding the agrochemical industry, one of its lesser known features is its size. It is quite small in the United States as well as internationally. In the U.S. it accounts for approximately two percent of the gross sales of the U.S. chemical industry (Hollis 1983). Its total worldwide value in sales in 1984 was 13.8 billion U.S. dollars. Even with recent increases, the total sales value of the worldwide agrochemical industry would still be less than the documented gross sales of some of our U.S. corporations. For instance, the EXXON Corporation reported gross sales for 1984 of 97.3 billion U.S. dollars.

According to Milton Russell (1984), Assistant Administrator for Policy, Planning and Evaluation, EPA, the number of major U.S. pesticide producers declined from approximately 80 companies to 30 companies between 1970-81. The number of compounds screened in relation to the number successfully registered went from 6500/10 in 1967-70 to 82600/11 in 1979. The time from discovery to full registration went from 68 months to 94 months for the same period.

Frawley (1961) cited National Academy of Science figures for 1956 as being three thousand chemicals screened per one marketable product. He approximated the developmental cost, in the 1950's, at almost two million dollars per product. The approximate developmental cost per product reported by some industry members today is in the vicinity of forty million dollars and only one of every 20,000 compounds screened has a possibility of reaching the marketplace. The research and development cost excludes the millions needed to build a plant to produce the product.

The global industrial resource of innovative research and development in plant protection chemistry is shrinking and is considered to be limited now to some 20-40 remaining companies worldwide who still have the financial resources and scientific capabilities
to continue. The evolution of newer plant protection products and their establishment in plant protection field practices takes longer and occurs at a reduced frequency from fewer sources than in the past. If the agrochemical options available for dependable plant protection slowly diminish in light of the need for enhanced productivity and crop diversity to meet the demographer's predictions for the world population in the next 20-30 years, then the potential for a future crisis in plant protection becomes substantive.

It is prerequisite to their continual availability that measures be taken to control the limitations of present and future plant protection products. These limitations are basically safety and misuse. Measures to overcome such limitations are underway within the National Agricultural Chemicals Association (NACA) and through our international organization, The International Group of National Associations of Agrochemical Manufacturers (GIFAP). The strategy followed is the orderly procedure depicted in Figure 1; the Circle of Safety.

For cooperation, there is first the question, how does a regulated industry, regulated more or less in every country, establish a cooperative effort with Government regulators and with non-governmental organizations (NGO). To do this, there are certain conditions that must evolve; the demonstration by the established industry of its scientific

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**Fig. 1. Plant Protection Chemicals—Circle of Safety**
competence and credibility, and the willingness to take the initiative to meet with NGOs, international organizations, and governments in uncompromising forums. Having met these conditions, the agrochemical industry can now announce some of their accomplishments.

Within the framework of NACA, the Association has joined in a forum, the Agricultural Chemicals Dialogue Group (ACDG) with a consortium of environmental and church organizations moderated by the Conservation Foundation. In the past few years, the ACDG has mutually agreed upon and issued voluntary guidelines for industry on advertising (ACDG 1983) and labeling (ACDG 1985) in developing countries.

The NACA International Registration Committee has given industry support through the U.S. Department of State to the FAO Draft Code of Conduct on the Distribution and Use of Pesticides (FAO 1985). The Code had its genesis as a recommendation in the Report of the FAO Consultation on the International Harmonization of Pesticide Registration Requirements held in Rome, Italy (FAO 1982). NACA was present as a member of the GIFAP delegation to the Consultation which supported the Report. GIFAP has since issued position papers indicating support and cooperation on principles reflected in the Code pertaining to hazardous substances export (GIFAP 1983b), good marketing practices in pesticide export (GIFAP 1985a), and options for ensuring quality in stored pesticide products (GIFAP 1985b).

The basic attributes of the Code are that it is voluntary; it is to be observed in countries that are without national laws in regulating pesticide safety or without registration controls prior to marketing; and it involves consideration for shared responsibility for safety measures among government officials, industry, importers and distributors, and users. The Code consists of twelve articles that comprehensively cover the essential regulatory requirements and safety measures set forth in the Report of the October 1982 FAO Consultation (FAO 1982).

The Draft Code was approved by the FAO Committee on Agriculture, comprised of some 94 delegations, in March 1985 and by the FAO Council in June 1985. The Code will be considered by the FAO Commission in November 1985 at which time it will be formally adopted (GIFAP 1985c).

There may be some jurisdiction conflicts and difficulties depending on how some governments conduct their business in agrochemicals. Nevertheless, the potential success of the Code depends most importantly on participating countries and local importers and distributors remaining attentive along with the industry, to carrying out their respective responsibilities as identified in the Code (GIFAP 1985c).

The agrochemical industry demands reasonable and responsible regulation. Industry prefers not to see the Code become a substitute for duly established regulations, but rather that it serve as an interim measure for safety pursuant to the institution of appropriate legislation and regulations in those countries to which the Code is relevant. The GIFAP Latin American Working Group is working cooperatively with the Inter-American Institute for Cooperation in Agriculture (IICA) to bring this about in the Caribbean Region.

Industry’s cooperative efforts with international bodies and the governments they represent is accomplished through participation in GIFAP. The agrochemical industry is one of the few industries that has an international association. It is needed because national associations have no standing outside their borders. GIFAP is recognized as the worldwide representative of the agrochemical industry and is accepted by international bodies such as United Nations organizations and IICA. GIFAP has for some time had official status with FAO. Earlier this year, the Director General of the WHO confirmed the approval of the establishment of official relations between the WHO and GIFAP (GIFAP 1985d). Such industry recognition must be earned over time by the demonstration of competence and credibility.
GIFAP's membership includes over 30 national agrochemical associations which together comprise more than 950 companies. This membership represents, at the international level, more than 90 percent of the world production of agrochemicals. The world distribution of agrochemicals according to end-user sales value in 1981 is shown in Figure 2. This data was presented (GIFAP 1983b), at a UN interagency meeting in the spirit of cooperation, to describe the economic and the health and environmental safety considerations that governments of developing countries should consider before deciding to set up plants to formulate or manufacture agrochemicals.

The member associations of GIFAP have common objectives—to promote crop protection by appropriate use of agrochemicals worldwide and to ensure that the properties and application of these products are in conformity with the needs of agriculture and society; i.e., optimal food and fiber production with minimal hazards for man, animal and environment.

To achieve this, some of GIFAP's aims are:
— To promote the safe and sensible manufacture, handling, packing and transport of agrochemicals by setting, and recommending high standards in conformity with internationally acceptable rules.
— To promote the safe and sensible application of agrochemicals, in conformity with national and international standards and regulations for the protection of the user, the environment, and the consumer.
— To promote harmonization of national and international legislation and regulations concerning control, testing and approval of agrochemicals.

These aims are in consort with the all-inclusive registration and safety guides initiated at the first such FAO Consultation in 1977 and reported final at the 1982 Consultation (FAO 1982). An examination of the Report (FAO 1982) shows, without question, that there are benefits for governments, farmers, consumers, and industry by the institution of the FAO proposals. Meanwhile, the benefits of the FAO proposals remain
latent in the absence of government initiative to implement them. GIFAP recognized this and further recognized that industry is the common denominator in this equation and the party best able to provide the initiative.

Consequently, GIFAP entered into a unique experiment in 1979 whereby discussions on regulatory matters with some governments of Latin America, as a group, were made possible through an informal consultative forum managed and directed by a neutral non-profit organization, the Policy Sciences Center, Inc. (PSC) interested in public policy issues. Public funds from the Charles F. Kettering Foundation, the Rockefeller Brothers Fund, The United Nations Environment Program, and the U.S. Agency for International Development supported the project.

The Consultative Process (GIFAP 1984a), is a strategy for bringing together parties of different persuasions, voluntarily, in a neutral forum so as to: a) encourage communication; b) achieve a better level of mutual understanding of a problem(s) than existed before; and c) reach nonbinding consensus agreements that may lead to the resolution of the problem(s). As such, the Consultative Process is a means of legitimizing essential communications between the regulated industry with its scientific and technological expertise and governments who need information and cooperation.

The PSC project included an on-site evaluation of the status of considerations given to labeling, application, and formulation by governments in eight Latin American countries. The Review Team, lead by Professor Harvey Cromroy, University of Florida, issued a Report (Cromroy et. al. 1981) that was reviewed by all participants. Recommendations were presented and when assembled by PSC (GIFAP 1984a), served as the substance for a final meeting of the Consultation in Key Biscayne, Florida, in 1981. This experiment in the Consultative Process resulted in:

- candid and respectful dialogue on major concerns to both parties;
- provisions for safety information;
- emphasis on product use and application training;
- clear identification, definition, and organization of main issues and problems; and,
- impetus to undertake formal government consultations.

The industry, in complying with a voluntary commitment to the Forum to provide safety information, published guides for the safe handling of pesticides in formulating, etc. (GIFAP 1982), and guides for safe use of pesticides (GIFAP 1983a). Guides pertaining to first aid (GIFAP 1984b) were recently published. All these have been given wide distribution throughout the hemisphere.

The Consultative Process next shifted from unofficial to official government status when the Mexican Government, in applauding the efforts of the Key Biscayne Consultation, took the initiative to hold a “Consultation on the Proper Use of Pesticides in America and the Caribbean” in Mexico City, 1982. The Mexico City Hemispheric Consultation issued proceedings (Direccion 1982) and an official report (GIFAP 1984a) attesting to the essentiality of agrochemicals in food production and recognized problems that need attention. It identified the benefits that would accrue from the harmonization of requirements for registration, labeling, and use. The Report (GIFAP 1984a) recommended that IICA conduct Consultations to harmonize pesticide registration requirements, recognizing the guidelines set forth by the FAO (FAO 1982), in each of the four IICA regions; i.e., the Andean Region; the Central Region including Mexico, Panama, and the Dominican Republic; the Caribbean Region; and the Southern Cone, thus encompassing essentially all the nations of Latin America and the Caribbean. Consultations were held in Cartagena, Colombia, August 1982; San Jose, Costa Rica, April 1983; Port-of-Spain, Trinidad, August 1983; and Santiago, Chile, August 1983. Reports (IICA 1982, 1983a, b, c) were respectively issued and each included recommendations for registration requirements, labeling, toxicity categories, and other safety and training considerations that are universally needed. These were officially approved and signed
by all the government delegates.

An open session was held at the beginning of each Consultation to permit a small GIFAP delegation of experts to present papers (IICA 1982, 1983a, b, c) on registration, labeling, and toxicology requirements. The registration requirements presented included, among other items, suggestions to include information on worker reentry intervals, pre-harvest intervals, and container disposal.

Suggestions for a uniform label format were presented along with the safety idea of adding a precautionary color band commensurate with the toxicity category of a product. The colors, in decreasing order of hazard are: red, yellow, blue, and green. The colors would be standard according to an international color code and would appear at the bottom of the label as a band fifteen percent the height of the label. Toxicology requirements were presented including the suggestion that the WHO classification for toxicity be used. The suggestions of the GIFAP expert delegation were given favorable consideration.

Following completion of all four Consultations, the Director General of IICA prepared a summary report (GIFAP 1984a) of these events for the Inter-American Board of Agriculture. A Resolution (GIFAP 1984a) to accept the regional recommendations and implement them "quickly" was subsequently adopted by all the Ministers and Secretaries of Agriculture in Latin America, the U.S., Canada, and the Caribbean at the October 1983 meeting of the Board in Jamaica.

The status of implementation of the recommendations among the nations of the hemisphere, as of 1984, includes eleven nations in Latin America who have given full acceptance and are implementing the recommendations. Seven remaining nations in Latin America are in various stages of moving through the legislative and regulatory processes to full acceptance and implementation. Most of the Caribbean nations are legally unable to accommodate the recommendations until they establish the prerequisite laws. IICA is translating the new established regulations for the Central Region to serve as a working document for the governments of the Caribbean nations to use to establish their own regulations.

We are closing in on what was thought to be the impossible—the harmonisation of the regulations of agrochemicals throughout the hemisphere. GIFAP and its member associations are sincerely encouraged by these progressive and enlightened moves by the governments of this hemisphere toward the orderly regulation of agrochemicals. The benefits to be derived from having responsible and reasonable national laws and regulations for the proper control and safe use of agrochemicals accrue to all concerned parties: governments, farmers, the public, and the established industry. The benefits include:

- label information and consistent format to meet local needs for correct use and human and environmental safety;
- quality assurance of the product for safety and efficacy reasons;
- proper toxicological considerations for safety of all concerned;
- user education and training for personal and environmental safety reasons; and
- incentives to industry to continue to improve services to local agriculture.

It is not too obvious, but the issue of misuse is addressed throughout these proceedings. Misuse and its attending human and environmental effects does occur and especially in situations of inadequate registration requirements and procedures as they may limit regulatory control. Misuse and its effects are always a matter of concern to the industry and is the main reason we are proponents of sound and enforceable regulations. The legitimate availability of agrochemicals is a main consideration of the FAO Code of Conduct (FAO 1985) and of U.S. requirements as evaluated in Congressional testimony by NACA (NACA 1983).

Meanwhile, developing countries who must import plant protection chemicals and
who do not have a regulatory system and basic registration requirements in place are vulnerable to foreign counterfeiters who fabricate look-a-like agrochemicals which, without quality control, may be contaminated with unknown toxic by-products and perhaps labeled without precautions. There may be no evidence of efficacy. These products may be marketed at attractive cut-rate prices directly or through some exporter who may or may not be interested in following recognized channels of commerce. It is possible that labels as well as containers may be counterfeits of those of an established company. That these activities do occur is verified (Deuse 1984). Developing countries must have the means to evaluate the source and quality of the agrochemicals they import as one primary means of overcoming inadvertent misuse.

The agrochemical industry continues to be cooperatively engaged in carrying out education and training activities. It believes that, while these activities are the mainstays of eliminating misuse and achieving safety, meaningful and lasting success of these activities will come only after a sound regulatory foundation for the registration, labeling, and use of agrochemicals is established by local governments (Figure 1).

REFERENCES CITED

GIFAP. 1988e. The Manufacture and Formulation of Pesticides in Developing Countries. Technical Monograph No. 10. Ibid.
Caribbean Conferences


PLANT PROTECTION CHEMICALS
CIRCLE OF SAFETY

I
Government Registration
- Research Safety Data for Humans and Environment

II
Labeling
- Safe Use Instructions and Precautions for Human and Environmental Safety

III
Education-Training
- Prevent Misuse

Closes the Circle of Safety