THE ROLE OF PRODUCT STEWARDSHIP AND CO-SHARED RESPONSIBILITY IN THE AGROCHEMICAL INDUSTRY

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EXECUTIVE SUMMARY

Product stewardship concerns industry's conduct as it carries out its activities relative to human and environmental consideration.

The activities carried out in this respect find their substance in the product stewardship philosophy which encompasses the fundamental concern of the established industry for the safety and health of all people who make, distribute, and use its products, and for the integrity of the environment.

It is to be known that the established agrochemical industry does practice product stewardship in numerous ways, but as such it is poorly recognized outside the industry and must be clarified.

The practice of product stewardship by multinational agrochemical companies is not always recognized or appreciated because the companies may not have explicitly defined their activities in product stewardship terms. Corporations take it for granted that the product stewardship activities they carry out are understood, but unfortunately, they are not. In this same vein, their many individual product stewardship activities in less developed countries, and the health and environmental benefits derived from them, are not adequately recorded and are seldom reported or made known. Since little, if anything, is ever known about these commitments and accomplishments, the industry is vulnerable to criticism as being indifferent or uncaring about conditions in the less developed countries.

To ensure the degree of human and environmental protection that society expects, without denying it the benefits of plant protection, is a matter of

co-shared responsibility which must include government, manufacturers, distributors/retailers, and users.

Responsibility for environmental management should not be strictly confined to industry. Environmental management, as a practice, should consider all dimensions of an environmental management situation and therein identify all the parties associated with it. The roles and responsibilities of all the involved parties should be defined and then joined in an overall management program based on carrying out co-shared responsibilities.

Some of the many fundamental product stewardship practices that are carried out by multinational companies as they do business in less developed countries, and areas where co-shared responsibilities are necessary in order that the principles and objectives of product stewardship can be fully realized are:

- provide sufficient information on toxicological and environmental properties of agrochemicals before marketing;
- provide information on physical and chemical properties;
- provide biological evaluation data on efficacy and crop safety;
- encourage governments to provide legal means for ensuring proper registration of agrochemicals;
- encourage governments to act on matters promoting safety throughout the entire system and cooperate in these efforts;
- proper labeling is a joint government/industry responsibility;
- provide for proper packaging materials and encourage proper storage, handling, and disposal; and,
- provide for worker health and environmental safety in carrying out the manufacturing and formulation of agrochemicals.

THE ROLE OF PRODUCT STEWARDSHIP AND CO-SHARED RESPONSIBILITY IN THE AGROCHEMICAL INDUSTRY

Product stewardship is a subject that concerns industry's conduct in carrying out its activities and is the substance on which credibility is based. It does require cooperative action with governments and other involved parties and it does have mechanisms of responsibility. Meanwhile, the established agrochemical industry does practice product stewardship, but it is poorly recognized as such and must be clarified.

The product stewardship philosophy encompasses the fundamental concern of the established industry for the safety and health of all people who make, distribute, and use its products, and for the integrity of the environment.

There are certain features of industry that are relevant to this philosophy and its employment that should first be explained:

1. In implementing the product stewardship philosophy, different companies give different titles to this function. Product stewardship is just one of several titles for the subject. Since it is the function, not the title, that is important, we have chosen the title "Product Stewardship" for this paper. The term does have some history in industry and it fits the subject comfortably.

2. There are considerable differences among corporations as to their organization, structure, and management, as well as products produced. Because of this, the approaches to implementing the Product Stewardship philosophy may be quite different.

3. The continuing practice of product stewardship by multinational agrochemical companies is not clearly recognized because the companies have not explicitly defined their activities in product stewardship

terms. There are a few exceptions. Corporations take it for granted that the product stewardship activities they carry out are understood; unfortunately, they are not. In this same vein, their many product stewardship activities in less developed countries, and the health and environmental benefits derived from them, are not adequately recorded and are seldom reported or made known. Since little, if anything, is ever known about these commitments and accomplishments, the industry is vulnerable to criticism as being indifferent or uncaring about conditions in the less developed countries.

The purpose of this paper is to identify certain fundamental product stewardship practices that are carried out by multinational companies as they do business in less developed countries. Included are those matters wherein government and third party cooperation is necessary in order that the principles and objectives of product stewardship can be carried out.

- Sufficient information on the toxicological and environmental properties of pesticide chemicals and products should be available before they are marketed to ensure that a meaningful assessment of hazard to man and the environment can be carried out.
- Information also should be obtained on the physical and chemical properties and purity of the technical grade material used in the formulations, as well as of the formulated product itself. Analytical methods for such determinations are essential. Therefrom, certain criteria of identity, quality and reasonable performance should be identified.
- Biological evaluation data should be available in order to assess the efficacy and crop safety of pesticides. These data may be obtained in the country or region of use, or in other countries or regions with

similar climatic and agricultural conditions.

° The multinational agrochemical industry, as represented by GIFAP member associations, encourages governments to provide a legal means for ensuring that pesticide products are registered, adequate data are supplied by the applicant, only registered products are offered for sale, and that products are used in a manner consistent with the labeling. Such a registration scheme also should provide for adequate control of the registered pesticide products in respect to their quality, their labels, packages and manner of distribution. Even in those countries where a registration processes is not entirely formalized, GIFAP encourages the governments to provide a primary infra-structure with appropriate training and motivation.

° Pesticides are needed and necessary in developing countries for the production of essential food crops. Therefore, governments and industry must share responsibility for judging competence of users, and making pesticides available to those capable and instructed in proper use, or to those able to read, understand, and follow a label. A responsible multinational agrochemical industry and governments can cooperate in many ways in order to accomplish such objectives. For example:

1) Provide adequate labeling for products in a language appropriate for the importing country;

2) Cooperate in national and regional programs to inform farmers and their technical advisors on the proper and safe handling of pesticide products. A copy of GIFAP's, "Guidelines for the Safe and Effective Use of Pesticides," in keeping with this product stewardship activity, is appended as Attachment 1.

3) Cooperate in training programs, e.g., for aerial and ground applicators on proper mixing, handling and use;

4) Provide instructions for drivers of vehicles, or other carriers, transporting pesticide products as to proper loading principles and how to proceed in case of an accident; and,

5) Cooperate in providing on-site audits, technical information, safe handling data, labeling advice, quality control monitoring and education for distributors, formulators and customers (where appropriate).

° Labeling is the main method of identifying the pesticide product and communicating instructions and advice to all concerned with its handling during transport, storage, use, or disposal. The development of a satisfactory label is considered to be the joint responsibility of industry and government.

° Packaging material should be impervious to and must not affect the contents under a range of conditions. Adequate storage of pesticides is important both for safety and for maintaining the efficacy of a product. Storage conditions should keep containers and contents in good condition.

° Information on methods of safe disposal of surplus products and empty containers should be provided. Disposal methods and necessary precautions will vary depending upon the products, the container and facilities available.

Product stewardship practices for worker safety and environmental controls in the manufacturing and formulating of agrochemicals are conducted by the established industry in their facilities in developed and developing countries. However, there are health, environmental, and economic risks to

less developed countries who may themselves engage in these activities unless they observe the same product stewardship practices employed by the established industries. It requires a high level of expertise and considerable investment if the proper product stewardship practices are to be instituted.

The International Group of National Associations of Agrochemical Manufacturers (GIFAP) addressed this matter in a presentation on, "Key Issues on Establishing Plants in Developing Countries for the Formulation of Agrochemicals." The paper was presented at a United Nations Interagency Conference, including UNIDO, UNEP, FAO, WHO, in June 1983, and is appended as Attachment 2. In describing the required infra-structure of a formulating plant, several product stewardship considerations are included, but are not so identified in the following quotation from the report. Asterisks have been added to identify the product stewardship considerations.

> The (formulating) infra-structure required should include a *quality control laboratory, *a waste disposal unit (incinerator), *an effluent treatment unit (if necessary), *medical facilities, *washing and changing facilities, *a canteen (if necessary) warehousing, a workshop, administration offices, utilities (electricity, steam and air), *a catchment system for contaminated rain and fire water, firm access roads, *firm and impermeable areas for the storage and loading of products, and a building for the formulation and filling units. If this infra-structure is already available then the investment required can be of the order of US$0.5-5 million, depending on the complexity of the process. If only a "green site" is available, then the investment required will be significantly higher.

Product stewardship standards and practices have been published by GIFAP and distributed worldwide. A copy of the GIFAP booklet entitled "Guidelines for the Safe Handling of Pesticides During their Formulation, Packing, Storage and Transport," is appended as Attachment 3.

The effective implementation of the Product Stewardship philosophy in an agrochemical business is embodied in at least two principles: (1) product stewardship should be appropriately carried out by all employees around the world, and (2) when applying product stewardship standards do not attempt to

differentiate between societies in which a company operates, but apply constant standards.

The perceptions that arise when the agrochemical industry is viewed from a distance can indeed be biased in uncertainty. A closer view of the established industry would better reveal that the necessary and appropriate considerations for human and environmental safety are in effect.

Meanwhile, there are other parties that are essential to the process of ensuring safety and maximizing benefits to society that must be recognized and their role identified. The manufacturer's product stewardship practices are not, in and of themselves, the total means to ensuring environmental integrity and human safety. An exception may be in the controlled processes of manufacturing and formulating, and even here government plays a role.

To ensure the degree of human and environmental protection that society expects, without denying it the benefits of plant protection, is a matter of co-shared responsibility which must include government, manufacturers, distributors/retailers, and users.

The nature of these responsibilities, which should be considered universal, are described in part as follows in Section 5.2.1 of a Research Report on Labeling, Application and Formulation, copy appended as Attachment 4.

A. Manufacturer - The prime responsibility rests with the manufacturer who first must be satisfied that the product fulfills the many requirements demanded by the public, and the government authorities charged to watch the public interest. The manufacturer must ensure that there is adequate scientific evidence to support all claims for efficacy and safety.

B. Government - Basically, the responsibility of the government is to protect the unwary from the unscrupulous: prevent unsubstantiated claims; ensure adequate directions for use; highlight precautions and limitations in use; protect the uninitiated from his own ignorance; safeguard reputable manufacturers from spurious claims by disgruntled users; and engender confidence in the system by the general public.

C. Vendor - The responsibility of the sellers and distributors of pesticide products is to make certain that they do not offer products for sale which are not registered and that they do not

promote uses which are not recommended on approved labels.

D. User - The user is responsible for following the directions on the registered label.

Recognition that co-shared responsibility for agrochemical safety among the principals, in this case government and distributors, is essential was demonstrated by the Economic and Social Commission for Asia and the Pacific, Committee on Agricultural Development. A report, dated November 5, 1981, E/ESCAP/AD4/10 (copy appended as Attachment 5), includes a program exemplifying the sharing of responsibility for promoting safety by governments and subsequently distributors. The program includes:

> 3.(a) A pesticide management training programme aimed at retail level agro-pesticides distributors within the ESCAP region. The long-term objective of this training programme is to professionalize the retail-level agro-pesticides distributors with special reference to the safe handling and effective use of agro-pesticides. These distributors are recognized by ARSAP as being an important communication channel to pass on information about proper handling of agro-pesticides to the farmers.

The report further notes that the program was undertaken on a regional basis to include eight nations, thereby indicating the appreciation for and the acceptance of these important co-shared responsibilities.

The fact that achieving human and environmental safety in the use of agrochemicals and maximizing their benefits to society is a co-shared responsibility was also recognized by the FAO in its Report, "Second Government Consultation on International Harmonization of Pesticide Registration Requirements," October 1982. The report, in recommending a Code of Conduct in the distribution and use of pesticides aimed at countries lacking an effective pesticide registration process, states that, "In developing such a Code, the Consultation expressed the view that the Director-General should consider the responsibilities of all people involved in the safe and effective use of pesticides including governments, manufacturers, distributors and users ..."

It is to be realized that, from a practical standpoint, whatever benefits can be derived from such a Code can only be realized by employing the concept of co-shared responsibility among all the parties -- manufacturers, government, distributors, and users.

In summary, responsibility for environmental management should not be strictly confined to industry. Environmental management, as a practice, should also consider all dimensions of an environmental management situation and therein identify all the parties associated with it. The roles and responsibilities of all the involved parties should be defined and then joined in an overall management program based on carrying out co-shared responsibilities.

CONTRIBUTOR

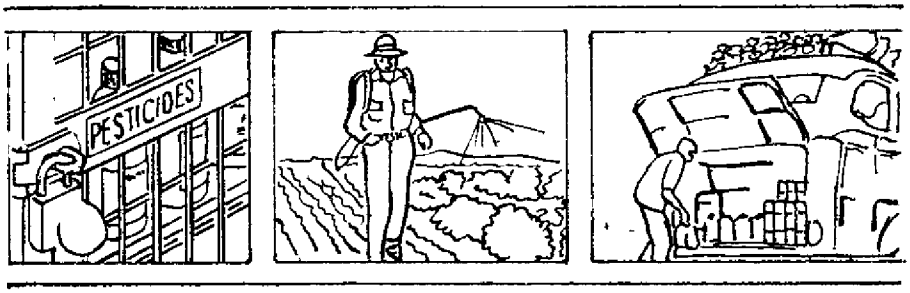
This invited paper is offered as a contribution to the objectives of the November 1984 UNEP World Industry Conference on Environmental Management by the International Group of National Associations of Agrochemical Manufacturers (GIFAP).

June 1984

ATTACHMENT 1

GUIDELINES

for the safe and effective use of pesticides



ATTACHMENT 2

Guidelines

for the safe handling of **pesticides** during their formulation. packing, storage and transport.

GIFAP

GROUPEMENT INTERNATIONAL DES ASSOCIATIONS
NATIONALES DE FABRICANTS DE PRODUITS AGROCHIMIQUES

INTERNATIONAL GROUPOP NATIONAL ASSOCIATIONS
DE MANUFACTURERS OF AGROCHEMICAL PRODUITS

ATTACHMENT 3

(GIFAP paper for presentation at the UN interagency meeting to be held in Geneva from 6-10 June 1983)

KEY ISSUES ON ESTABLISHING PLANTS IN DEVELOPING COUNTRIES FOR THE FORMULATION OF AGROCHEMICALS

INTRODUCTION

The issues involved in the local formulation and packaging* of both chemical and biological pesticides are more complex than might be apparent at first sight.
Developing countries have a special interest because they foresee local production leading to:

- lower foreign currency requirements (for imports)
- possible foreign currency generation (from exports)
- lower prices to farmers
- increased local employment opportunities

However, having a local formulation plant does not necessarily mean that all of the abovementioned aims can be achieved.
This paper has been written to give a better appreciation of the subject of pesticide formulation production. It first details how formulation fits into the overall agrochemical business scene and against this perspective it then details the key issues relating to the establishment of formulation plants in developing countries. Finally it discusses how the Agrochemical Industry has assisted, and can further assist developing countries wishing to set up their own local agrochemical formulation facilities, and some suggestions are made on the role of the UN agencies in this matter.

BACKGROUND

Agrochemical formulation is the stage between the manufacture of the active ingredient (which can be of either a chemical or biological nature) and the marketing of the ready-to-use product. Formulation is the process whereby the active ingredient is put into a form that can be both conveniently and safely applied by the farmer. In essence it involves the physical modifying and/or mixing of the active ingredient with inert ingredients, such as solvents, mineral carriers and surface active agents. It ranges from the production of emulsifiable concentrates by the dissolution of an active ingredient and emulsifier(s) in a solvent, to the production of suspension concentrates by the wet grinding of a suspension of active ingredient and surface active agents in either water or oil.
Active ingredient manufacture is a natural sequential operation for a company that undertakes its own research and development (R & D). It is during the development stage that the manufacturing know-how is generated.

* throughout this paper the word formulation is used to cover both formulation and packaging activities

Formulation know-how is developed at the same time and hence formulation is a natural sequential undertaking for companies that manufacture their own active ingredients.

Investment by industry in agrochemical R & D has the same objective as any other investment, namely, to generate a reasonable return within a reasonable period. Failure to do this would oblige the companies concerned to seek an alternative use for their shareholder's capital.
The size of investment required for an agrochemical R & D programme is now-a-days so large (on average US$30 million per year) that only the major chemical companies can afford it, and even then only if they are successful at discovering, developing, manufacturing and marketing profitable new products. This explains why only some 40 companies worldwide have an innovative agrochemical capability. It is these companies who develop the necessary manufacturing and formulation know-how and who are the prime investors in production plants for new products.
The first plant that a chemical company builds to produce a new active ingredient is the primary plant. Subsequent plants are called secondary plants. Primary plants are virtually always located:

- in one of the world's major agrochemical markets
- close to feedstock
- close to research and development facilities
- where they can share an existing manufacturing location that has the required infra-structure i.e. laboratory, services etc.

From Table 1 it can be seen that the larger part of the world agrochemical market is concentrated in three areas, namely:

	% of world market
North America (USA and Canada)	ca. 35
Western Europe	ca. 20
Japan	12

It is therefore no surprise to find that primary active ingredient plants are almost exclusively located in either North America, Western Europe or (to a lesser extent) Japan. These primary plants are, of necessity, normally designed to produce the major part of the anticipated world requirements of a particular pesticide.
Secondary active ingredient plants are not very common, particularly for proprietary products. This is because of a number of reasons that are beyond the scope of this paper but include the inflexibility of these plants, their high capital cost and the frequent lack of local raw materials and technical resources.
Formulation plants are, however, widely spread around the world, being particularly numerous in those industrialised and developing countries that have a large local agrochemical market and have local availability of raw materials. Flexibility and relatively low capital cost are other key reasons for this proliferation. It should be noted however, that for some biological pesticides instability of the unformulated active ingredients means that formulation must be carried out immediately following production of the active ingredient and therefore the formulation plant needs to be located on the same site as the active ingredient production plant.

Local formulation plants can be divided into several categories and sub-categories, namely:

i) those operated by private enterprise. This includes
   - the manufacturers of the active ingredients (typically major national or multi-national chemical companies), and
   - local independent companies.

ii) those operated by non-profit-making organisations such as farmers cooperatives and local authorities.

A factor to be considered for plants operated by local independent companies and non-profit-making companies is whether the plant is dependent on proprietary products or commodity products. For proprietary products the supplier of the active ingredient must protect his corporate reputation and brand image and therefore before making product and know-how available he will require guarantees from local formulators with respect to safety, industrial hygiene, environmental protection and quality control. In the course of time he will provide the formulator with a regular updating of information relating to matters such as toxicological and analytical developments. For commodity products however, both products and formulation know-how are often freely available and a local formulator will only be obliged to satisfy local legal requirements on safety, quality etc.

KEY ISSUES REGARDING PLANT LOCATION

When deciding whether or not to build a local formulation plant, be it in an industrialised or developing country, there are a number of key issues that must be considered.

JUSTIFICATION

This depends on the standpoint adopted. Private enterprise must be assured of economic viability before committing funds to investment in a plant. At the same time it is highly unlikely that a non-profit-making organisation such as a farmers cooperative or a local authority would contemplate investing capital in a venture that was likely to operate at a loss. In order to make a rational decision the factors that must be analysed and evaluated are as follows:

a) Market volume and potential

A detailed estimate must be made of the local market volume and future potential. This should be accompanied by similar estimates for the selling prices of the formulations to be produced. It is essential that these estimates be as reliable as possible and therefore predictions should be based on as many previous years' figures as can be obtained. Care should be taken not to build in distortions that may have been caused by, for example, unusual climatic conditions. It is also most important in a developing country market environment to take into account any existing and anticipated agricultural development plans or Government policies because these can have a major impact on market direction and rate of change.

Formulation plants, unlike active ingredient plants, are generally reasonably flexible in being able to produce not one specific product but a range of formulations of one type e.g. liquid insecticidal

products containing different active ingredients. This makes them less vulnerable to product changes in the market.

b) Availability of raw materials

A number of key formulation ingredients such as mineral carriers and solvents are locally available in some developing countries and, if they are reasonably priced, this is a major step towards making local formulation an attractive venture. A virtually essential prerequisite is that the product packs must also be locally manufactured because the importation of packaging materials would be a very expensive requirement.
There are countries where the quality of some local ingredients is not high enough or consistent enough for producing formulations having an acceptable minimum quality. Typical problems include impurities in mineral carriers or water in solvents, either of which can lead to decomposition of the active ingredient. If major ingredients need to be imported this can result in locally formulated products costing more than the imported formulations because of freight and packaging costs and the fact that bulk-buying discounts available to high volume central plants are not usually available to low volume local plants.

c) Technical resources

The complexity of a formulation plant depends on the process involved. The commonest type of plant is the liquid blending unit which, although relatively simple still contains items such as flame-proof electrical motors and switchgear, pumps and the filling machine. In addition, items of the plant infra-structure such as the utilities unit and the laboratory require certain technical resources. These resources include:

- design, engineering and construction expertise
- equipment and spare parts supply
- technical service

All of these can of course be imported but this requires foreign currency, it is expensive and it is time consuming. If a developing country already has a chemical or closely related industry in the area of the intended formulation plant it is more likely to have the necessary local technical resources than one that does not. If there is no technological culture or industrial infra-structure in the area of the intended plant, and if the local resources are limited, serious consideration should be given to whether a local formulation venture is worth progressing.

d) Personnel

The key jobs in a formulation plant, for example the plant manager, quality control chemist and maintenance engineer, require a high calibre of staff who have good experience or who have had good training in this type of work. The level of operator in a formulation plant must be good enough to ensure a safe and economic operation. Once again, if a developing country already has its own chemical industry in the area of the intended plant then it may have an adequate reservoir of the right calibre of personnel.

e) Economics

The level of investment required for a formulation plant will depend very much on whether there is an existing site with the necessary infra-structure. The infra-structure required should include a quality control laboratory, a waste disposal unit (incinerator), an effluent treatment unit (if necessary), medical facilities, washing and changing facilities, a canteen (if necessary), warehousing, a workshop, administration offices, utilities (electricity, steam and air), a catchment system for contaminated rain and fire water, firm access roads, firm and impermeable areas for the storage and loading of products, and a building for the formulation and filling units. If this infra-structure is already available then the investment required can be of the order of US$0.5-5 million, depending on the complexity of the process. If only a "green site" is available then the investment required will be significantly higher.

Whether a local formulation venture is being financed and operated by a private enterprise or by a non-profit-making organisation the likely economics of the operation must be evaluated. Such an evaluation requires the making of a cash flow calculation using the estimated figures (over a 5-10 year project life) of sales volume, selling prices, manufacturing costs, working capital costs, financing costs, local taxes and capital investment. From this cash flow calculation various profit indicators can be calculated, such as the internal rate of return, the net present value and the return on investment. Alternatively, the minimum acceptable internal rate of return can be fixed and from that the prices at which the end products should be sold (for example, to members of a cooperative) can be calculated.

GENERAL BUSINESS CONSIDERATIONS

Problems in developing countries that can make investment in local formulation plants unattractive include:

a) Exchange controls

It is not uncommon for certain developing countries to impose exchange controls that can be as severe as preventing the issuing of letters of credit. This can have a disastrous effect on plant production and economic viability if a company is dependent on imported raw materials or spare parts.

b) Extreme changes in exchange rate

A high local rate of inflation against the world's major currencies has been a major problem for a number of developing countries in recent years. This can make local formulation unattractive if key ingredients (including the active ingredient) need to be imported. This is because such imports usually have to be paid for in hard currency around the time of delivery. They are then processed and sold in local currency. In the agrochemical business it is common practice for farmers to pay for products a number of months after taking delivery, and even after harvesting. In the meantime the value of the local currency has been decreasing against the major world currencies but local selling prices have been unable (or not allowed by price controls) to keep pace. This

is particularly the case in countries that occasionally impose maxi-devaluations of their currency.
Such a financial climate is not conducive to attracting investment from private enterprise because it is very difficult to make a reliable estimate of the likely economic viability of a business venture.

c) Profit and dividend remittance

If investment in a local formulation plant is to be made either wholly or in part from outside of a developing country, for example, by a manufacturer of active ingredient, then there should be an assured mechanism for remitting profits or dividends back to the investor.

d) Protection of foreign investment

If a foreign company is considering investing capital in a local formulation venture then it has to be certain that its investment will be protected against such possibilities as nationalization, because experience has shown that compensation, if paid, is rarely adequate.

PROVISION OF KNOW-HOW AND SERVICES

The sort of know-how required for local formulation includes product recipes, processing conditions, product and packaging specifications, analytical methodology and regulatory data. This may be freely available for some commodities but for proprietary products it is the industrial property of the patent holder. The types of services that can be required include process trouble-shooting, safety/quality auditing and training of personnel. Know-how can, of course, be provided to either an independent, a joint-venture or a wholly-owned local company by the developer of the know-how, but guarantees must be given that the know-how will be protected by the local laws of the country from being disclosed to others. A mechanism for the remittance of know-how fees and/or service-fees may be required.

ESSENTIAL SAFETY, HEALTH, ENVIRONMENTAL AND QUALITY REQUIREMENTS

There are a number of aspects related to the formulation of agrochemicals about which there should be no compromise, whether production be in an industrialised or developing country or whether it be carried out by a major or small company. These aspects are:

a) Safety

Like many other chemicals, pesticides and their formulations can be flammable and are sometimes dust explosive. At the same time they can also be toxic to man. Since the production of formulations involves the handling of large quantities of these products special procedures and precautions must be adopted if hazards are to be adequately contained. This requires good management, good plant design, good operational practices and the provision of the necessary equipment and infra-structure.

Aspects specific to safety include, for example, flame-proof electrical equipment for handling flammable liquids, explosion-prevention or -containment equipment for handling explosive dusts and hydrocarbon propellents (for aerosols), fire-fighting equipment that is appropriate for agrochemical fires, and emergency showers and eye wash units. Such facilities are, of course, of little value if they are not well maintained and if there is no experienced and reliable management with well trained and reliable operators.

b) Industrial hygiene and occupational health

Poor industrial hygiene can lead to poor occupational health. Industrial hygiene is particularly important in agrochemical formulation plants because of the toxic nature of some of the products. Key requirements include an effective ventilation system, the avoidance of drips, splashes and spills, the use of clean protective clothing, regular washing and showering, and the prohibition of practices such as eating, drinking and smoking in the plants.
Even with these requirments being enforced there should also be medical surveillance of the operators together with medical facilities for dealing with emergencies. Once again good management, good maintenance and good operational procedures are essential.

c) Environmental protection

During the past few years a number of agrochemical companies have begun to suffer the consequences of having, many years ago, disposed of agrochemicals in land-fill sites. This was generally done with the consent of the authorities. Poor records of where products were dumped, combined with the development of more sensitive analytical techniques and more rigorous ecotoxicological regulations have resulted in these practices becoming either banned or strictly controlled in a number of industrialised countries. This has led to the development of a thriving waste disposal business in these countries, with either private enterprise or the local authorities setting up and operating incinerators. Such facilities are rarely available in developing countries and hence it is a virtual prerequisite when building a new plant in a developing country to also build an effective waste disposal facility. This naturally increases the initial investment cost, particularly if the facility cannot be shared with other adjacent chemical plants.

d) Quality

Agrochemicals are products that are judged by their performance, and hence, if a local market is to be either maintained or hopefully increased, the farmer must be assured that the product he buys will always be of good quality.
Agrochemical quality control begins with checking the quality of the incoming ingredients and packaging materials. Once the product has been formulated it is necessary to determine the active ingredient content and carry out a number of key physical tests such as emulsion stability and suspensibility. When the formulation is packed, the filled pack should be checked for weight/volume packed, container leakage/damage and correct labelling.

All of these tests require specifications containing the appropriate test methods and specification limits. Active ingredient determination usually requires the purchase of rather expensive instruments such as gas chromatographs and/or infra-red spectrophotometers, with the added need for skilled and competent quality control chemists. The determination of the potency of biological insecticide formulations cannot be done by conventional chemical techniques. These are usually tested by bioassay using live insects. Insect-rearing facilities are therefore required and the quality control technician needs to have entomological training.
Because of the risk of degradation, care should be taken not to hold stocks of active ingredient or formulated product for too long in hot climates.

The above-mentioned aspects are of such importance that it would be unwise to contemplate local formulation if any one of them cannot be made to reach the required standard. (Guidance on the standards required for safety, hygiene and environmental control are given in the GIFAP booklet "Guidelines for the safehandling of pesticides during their formulation, packing, storage and trarsport"). It is most important that standards are maintained once operation commences. They should be monitored by having regular audits. If a local company is undertaking formulation of a proprietary product the patent holder will generally make certain demands regarding quality, safety etc. before allowing local formulation of his product. He is obliged to do this in order to protect his corporate reputation and brand image.

CONCLUSIONS

It is apparent from the foregoing that the issues involved in locating agrochemical formulation plants in developing countries are quite complex. Investment in such ventures can be made by either foreign or local private enterprise, or by a non-profit-making organisation such as a farmers cooperative or a local authority. Independent of who makes the investment the venture must:

- be economically viable i.e. profitable from a private enterprise standpoint and (perhaps) able to produce cheaper products from a cooperative standpoint
- have access to good quality and reasonably priced local raw materials and packaging materials, and have access to active ingredients
- have access to competent and experienced local personnel
- have access to local technical resources
- not be handicapped by exchange-control and exchange-rate problems
- have access to know-how and services
- be safe, hygienic and environmentally secure
- produce products of good quality.

THE ROLE OF THE AGROCHEMICAL INDUSTRY IN HELPING DEVELOPING COUNTRIES

The Agrochemical Industry, either as independent companies or through its international association (GIFAP), can help developing countries who wish to undertake local formulation production in the following ways:

a) as independent companies

a major agrochemical company may decide that investment in a formulation plant in a particular developing country would be worthwhile. It would then proceed independently or as a joint venture with a local company. There are many examples where this has already been done in developing countries.

Know-how can be provided to a local venture. This can be:

- product-related know-how that could be provided by individual active ingredient suppliers as part of a product- supply arrangement
- know-how related to process design, plant construction or plant operation that could be provided by individual major agrochemical companies on either a straightforward consultancy basis or linked to a product-supply arrangement

b) as GIFAP

GIFAP has recently taken the initiative of producing the following illustrated booklets which cover the general subjects of safety, hygiene, health and environmental protection:

. "Guidelines for the safehandling of pesticides during their formulation, packing, storage and transport". (1982)
. "Guidelines for the safe and effective use of pesticides". (1983)

The formulation booklet has been printed in both English and Spanish and is proving already very popular with both local agrochemical formulators and the appropriate Government authorities. 20,000 copies of the English edition have already been issued.

Agrochemical experts of member companies of GIFAP have also contributed substantially to the second edition of the UNIDO book "Industrial Production and Formulation of Pesticides in Developing Countries". This edition will be published during 1983 and it contains a comprehensive chapter on local formulation plant ventures called "Key Decision Criteria for Establishing a Local Formulation Plant". Other chapters in the book deal with subjects such as plant design, safety and quality control.

GIFAP also acts, from time to time, as an adviser to UN agencies. For example, GIFAP is presently assisting WHO with the reviewing and finalizing of its document called "Control Technology-Guidelines for the safe formulation, storage and transport of pesticides". GIFAP will also contribute to a forthcoming UNEP Workshop on the incorporation of environmental aspects into pesticide development project planning and implementation.

THE ROLE OF THE INTERNATIONAL AGENCIES IN HELPING DEVELOPING COUNTRIES

GIFAP believes that it is essential for the UN agencies to have a balanced and well coordinated approach when considering the local formulation of pesticides in specific developing countries. In order to avoid duplication of effort and to have harmony of purpose it is GIFAP's opinion that formulation plant feasibility studies would best be carried out by an Interagency Task Force. This Task Force would contain the appropriate specialists from each interested UN agency. It would not sit permanently but would be convened whenever a request for assistance was received from a developing country.

It would naturally be important for developing countries to be made aware of the existence of the Task Force. They should also be asked to make clear their specific motives when requesting the help of the Task Force.

However, in addition to undertaking feasibiity studies for new formulation plants in specific developing countries where there is either no or insufficient formulation capacity GIFAP firmly believes that the UN agencies should also make a concerted effort to improve the standards of safety, hygiene, environmental protection, quality and efficiency in those formulation plants that already exist in many developing countries.

GIFAP would be willing to contribute to Interagency Task Group meetings in an observer capacity.

TABLE 1: The world's major agrochemical markets (excluding public health outlets)

Country	Estimated 1981 sales value (US$ million)	% of world market
1. USA	4,200	32.3
2. Japan	1,560	12.0
3. France	965	7.4
4. Brazil	875	6.7
5. Soviet Union	545	4.2
6. United Kingdom	470	3.6
7. West Germany	468	3.6
8. Italy	410	3.2
9. Canada	340	2.6
10. Hungary	275	2.1
11. India	245	1.9
12. Spain	240	1.8
13. Mexico	235	1.8
14. Austrialia	225	1.7
15. South Korea	160	1.2
16. South Africa	150	1.2
17. East Germany	130	1.0
18. Indonesia	120	0.9
19. Netherlands	110	0.8
Total	11,723	90.3
World Market	13,000	100

Note: No reliable figure is available for China

Information taken from: Wood Mackenzie and Co., Agrochemical Service, October 1982

Attachment 4

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IMPROVING THE SAFE USE OF AGRICULTURAL CHEMICALS IN LATIN AMERICA:

A RESEARCH REPORT ON LABELING, APPLICATION AND FORMULATION.

by: Dr. Harvey L. Cromroy

Dr. Lawrence O. Roth

Mr. Kenneth J. May

The Policy Sciences Center, Inc.
New York, New York.
December 22, 1980

With the support of the
Charles F. Kettering Foundation,
the Rockefeller Brothers Fund,
and the U. S. Agency for
International Development

A Note to the Reader:

This report is a part of a broader project directed by the Policy Sciences Center. The project is a consultative process between governments in Latin America and the international chemical industry, to improve the safe-use of agricultural chemicals.

In the first half of the project, which ended in February, 1979, it was agreed by both government and industry participants that the priority was to improve safe use in three areas: labeling, application and formulation.

At that time, it was also agreed that background research would be done, to be followed by an exchange of position papers, and a final meeting to seek a consensus on action.

This half of the project was funded by the Charles F. Kettering Foundation, the Rockefeller Brothers Fund and the United States Agency for International Development.

It was in this context that the Center commissioned these independent research reports. Research on labeling was commissioned from Dr. Harvey L. Cromroy (University of Florida); research on application from Dr. Lawrence O. Roth (Oklahoma State University) and research on formulation from Mr. Kenneth J. May (International Business Consultant). Dr. Cromroy wrote the general introduction, conclusion and edited the overall report.

5.2.1 Gonzalez (39) noted that agricultural development in Latin America is characterized by a steady expansion of the cultivated area with impressive developments in the production of food crops which have occurred in some countries. Two excellent examples are Columbia's rice production which increased from less than 400,000 metric tons in the late 1950's to over a million tons in recent years and Brazil's soybean production which went from less than 200,000 tons in the late 1950's to 7 million tons in 1974 and currently ranks Brazil as the third largest producer of soybeans in the world. Pesticides have played a significant role in the intensification of agricultural production in Latin America, and it can be anticipated that the ever-increasing demand for food in the region will coincide with an increase in the amounts of pesticides used. The regulation of pesticides is to provide society with maximum protection from adverse effects while not denying it access to benefits. The registration requirements establish the manner in which a pesticide may be marketed and used. Registration implies a number of different controls among which evaluation is the most important. The assessment of a pesticide for registration purposes requires that extensive scientific information be developed by the manufacturer on all aspects of the product, its properties and performance. Legislation for pesticide registration must provide a system under which the public's interest and the manufacturer's rights are protected. There are four levels of responsibility associated with pesticide registration. These are as follows:

A. Manufacturer - The prime responsibility rests with the manufacturer who first must be satisfied that the product fulfills the many requirements demanded by the public, and the government authorities charged to watch the public interest. The manufacturer must ensure that there is adequate scientific evidence to support all claims for efficacy and safety (68).

References

(39) Gonzalez, R.H. 1976 Crop Protection in Latin America with special reference to integrated pest control. FAO Plant Protection Bull. vol. 24(3) : 65-75.
(68) Snelson, J.T. 1978. The need for and principles of pesticide registration. FAO Plant Protection Bull. vol. 26 (3): 93-100.

B. Government - Basically, the responsibility of the government is to protect the unwary from the unscrupulous: prevent unsubstantiated claims; ensure adequate directions for use; highlight precautions and limitations in use; protect the uninitiated from his own ignorance; safeguard reputable manufacturers from spurious claims by disgruntled users; and engender confidence in the system by the general public (68).

C. Vendor - The responsibility of the sellers and distributors of pesticide products is to make certain that they do not offer products for sale which are not registered and that they do not promote uses which are not recommended on approved labels.

D. User - The user is responsible for following the directions on the registered label.

5.2.2 Freed and Snelson (35) have pointed out that it would be desirable to the extent possible in keeping with sovereignty and singular needs of individual nations to achieve a degree of international uniformity in requirements for registration of pesticides. The advantages of such a goal is supported by the following reasons:

A. Developing countries with limited resources need technical guidance to set up and administer laws of their own.

B. The active ingredients of pesticides are international commodities developed by relatively few countries with an advanced chemical industry, but they are formulated in many countries and sold in most.

C. Toxicological, biological and environmental research is extremely costly, and meeting the demands of registering authorities now represents the major component of the cost of developing a new pesticide.