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## Production and Trade of Pesticides (\*\*)

### INTRODUCTION

Forgive me for narrowing the announced contribution on *Production and Trade of Agrochemicals* to that of *Pesticides* only. Also, since this meeting has a focus on *tropical agriculture* I will concentrate on those aspects which are seen as issues in *developing countries* by today's critical public. Key words like "Bhopal" and "Export of dangerous chemicals" show those issues to be part of the general problem of the *transfer of technology* to developing countries.

Since the introduction of pesticides as a tool in agricultural production public attention has shifted from usefulness of the product (i.e., efficacy, crop tolerance) and product quality to residues in food and effects on the environment and finally to user or applicator safety. All these aspects of pesticide usage are now critically reviewed by the competent authorities before they register a product, i.e., officially permit the sale in their country. That registration process itself is the subject of another presentation at this International Meeting.

Safety aspects in production and adequate trade practices of chemicals — not only of pesticides — have recently reached high public attention world-wide. While the regulation of trade practices normally also is the domain of the registration authorities, other authorities are involved in regulating and controlling safety in production.

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## 1. ASPECTS OF PESTICIDE PRODUCTION

### 1.1 *Background*

The production of a pesticide product involves the manufacture of the active ingredient(s), its formulation and packaging. Formulation is the process whereby the active ingredient is put in a form that can be both conveniently and safely applied by the farmer. 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 granules, wettable powders and water dispersible granules to emulsifiable concentrates and suspension concentrates (1). Finally, the product is to be packed into tailor-made containers which correspond to the characteristics of the specific type of formulation involved as well as to the requirements of the prevailing storage, transport and use conditions.

### 1.2 *Review of major pesticide production issues*

In its study entitled "Agriculture: Toward 2000" published in 1979, the Food and Agricultural Organization of the United Nations (FAO) foresees a continued growth in the world-wide use of pesticides to achieve the much needed increase in food production in many parts of the world. It is therefore important to plan that the future needs can be covered by the availability of an adequate supply of products of acceptable quality and price. In regard to assuring that supply by local manufacturing, GIFAP, the international trade association for manufacturers of agrochemicals (2), has reviewed a number of related issues in its document "The Manufacture and Formulation of Pesticides in Developing Countries" (1983). The following review is largely based on this document.

#### 1.2.1 *Present world-wide location of manufacturing plants*

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. Similarly, 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.

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 always located

(1) See: "Catalogue of Pesticide Formulation Types and International Coding Systems", GIFAP Technical Monograph Nr. 2.

(2) GIFAP, Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques, is the international trade association for manufacturers of agrochemicals. GIFAP, Avenue Hansoir 12, 1180 Brussels, Belgium - Telephone: (2) 374.59.82, Telex: 621.20.

- in one of the major world pesticide markets;
- close to feedstocks for the complex chemical intermediates;
- close to R & D facilities;
- where skilled manpower is available;
- where they can share an existing manufacturing location that has the required infrastructure (i.e., power and water supply, effluent treatment, incinerators, etc.).

It is not surprising to find that primary active ingredient plants are almost exclusively located in either North America, Western Europe or (to a lesser extent) Japan, since the world pesticide market is concentrated in these three areas, namely:

	<i>% of world market</i>
North America	ca. 35
Western Europe	ca. 20
Japan	12

Secondary active ingredient plants are not very common, particularly for proprietary products. This is because of a number of reasons, e.g., the high capital cost, the frequent lack of local raw materials and technical resources and the inflexibility of these plants to produce other chemicals than the ones they have originally been designed for. Also, primary plants are normally designed to produce the major part of the anticipated world requirements of a particular pesticide. This of necessity in order to reduce the pay-back time of the immense R & D costs for bringing that pesticide successfully on the market.

However, during the past 15 years pesticide active ingredient manufacture has become quite common in the major agricultural developing countries of the world, i.e., in Brazil, India, Mexico, Indonesia and other countries.

Formulation plants are, however, widely spread around the world, being particularly numerous in those 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 that proliferation of formulation plants.

#### *1.2.2 Reasons for setting up manufacturing plants in developing countries*

Governments, not only of developing countries, have a special interest in local production because they foresee

- lower foreign currency requirements (for imports);
- possible foreign currency generation (from exports);
- lower prices to farmers;
- increased local employment possibilities;
- reduction of dependency of their agricultural production upon other countries.

However, having local production facilities does not mean that all of the above aims can be achieved. A number of aspects need careful consideration before a decision is reached to erect a pesticide manufacturing plant.

### 1.2.3 Aspects to consider before setting up manufacturing plants

Local production plants may be operated by private enterprises (e.g., local independent companies or multinational companies) or by non-profit-making organizations (e.g., farmers' cooperatives, local authorities).

Private enterprise must be assured of economic viability before committing funds to investment in a plant. At the same time it is not likely that a non-profit-making organization would contemplate investing capital in a venture that was likely to operate at a loss. The aspects to be analyzed for reaching a rational decision relate both to active ingredient and formulation plants being more critical for the former. They are as follows:

#### a) *Economics*

A detailed estimate of the market volume and of its future potential must be made. Together with an estimate of the production costs and of the selling prices of the products the economic viability of the project can be judged.

Often serious underloading of plants in developing countries has been experienced. This has resulted in some operations becoming uneconomical and of higher product costs as compared to the imported pesticide.

#### b) *Investment costs*

The level of investment required, e.g., for a formulation plant, will depend very much on whether there is an existing site with the necessary infrastructure. The infrastructure 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 or hot water, and air), a catchment system for contaminated rain and fire water, firm access roads, firm and impermeable areas for storage and loading of products, and a building for the formulation and filling units. If this infrastructure is already available then the investment required can be of the order of US\$ 500,000-5 million, depending on the complexity of the process. If only a "green site" is available then the investment required will be significantly higher.

#### c) *Technical resources*

The resources required 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 plant it is more likely to have the necessary local technical resources than one that does not.

d) *Availability of know-how and skilled manpower*

Careful consideration is to be given to the availability of know-how and skilled manpower for managing and operating at a high standard the following critical areas:

- process safety;
- occupational health;
- environmental protection;
- quality control.

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) *General business considerations*

Exchange controls may be a limiting factor if they are so severe as to virtually make impossible importation of raw materials, equipment or spare parts. A foreign investor certainly will carefully have to evaluate the mechanism for remitting profits or dividends and the safety of his investments against such possibilities as nationalization.

#### 1.2.4 *Future trends in the production of pesticides*

There can be no doubt that the legal environment in industrialized countries and a certain saturation of the pesticide market will lead to a qualitative rather than a continued quantitative growth. Legal requirements in the area of environment protection will result in highly sophisticated production and recycling processes to minimize the generation of waste, in the construction of expensive incinerators for volatile, liquid and solid wastes and in improved effluent treatment systems. Increased awareness of occupational health problems particularly for biologically active chemicals such as pesticides will generate the development and use of closed production and formulation equipment of facilities, reducing to a minimum exposure of operators.

The cost of production and formulation of pesticides will thus increase and require a further concentration of these activities to keep operations economically viable. Most multinational companies as well as some chemical industry associations have developed internal guidelines calling for the realization of equal standards world-wide in respect to human and environmental safety and quality standards. It is a very difficult and sometimes impossible task to transfer improvements of safety standards achieved in headquarters production facilities to those in other countries. There can be no doubt that, in view of the public pressure, multinational companies will make big progress in implementing world-

wide uniform safety standards. Local private or public production facilities will similarly come under pressure to follow the same safety standards. As a consequence of such foreseeable developments it will be increasingly difficult for a non-industrialized country to make decisions for the local production of pesticides and to strike a balance of the wishful degree of independence and its commitment to follow established safety standards.

## 2. ASPECTS OF PESTICIDE TRADE PRACTICES

### 2.1 *Background*

Regulations and controls are needed for the trade in products such as pesticides, which potentially could affect human health or the environment and the end-users of which, the farmers or farm workers, represent a rather large group of individuals with a heterogeneous and often not adequate level of education.

While laws and regulations for the trade in pesticides exist in practically all countries, it is understood that their implementation is by far not realized everywhere. It is because of this situation that the FAO, in consultation with other UN bodies and with delegates from industry and consumer organizations, developed an "International Code of Conduct on the Distribution and Use of Pesticides". This Code was formally accepted by the FAO member countries at their conference in November 1985.

The basic objective of that voluntary Code is to serve as a point of reference in respect to responsible and generally accepted trade practices, particularly in countries which have not yet an adequate infrastructure for regulating and controlling the trade of pesticides. Although the Code clearly speaks of the shared responsibility of many segments of society including governments, industry, trade and international institutions, it requests public and private manufacturers, distributors or traders to comply also under circumstances where governments do not. The pesticide industry fully supports this Code and its international organization GIFAP issued the following statement immediately after acceptance of the Code by the FAO Conference: "GIFAP considers the voluntary Code a practical and reasonable basis for cooperation and shared responsibility between governments, international organizations, manufacturers, distributors and users of pesticides. GIFAP believes that it will be effective in meeting the needs of the developing countries in particular and realistic in its demands on industry. It will help promote the safe and effective use of pesticides and, in turn, help alleviate problems that might result from misuse, especially in countries where there is no or inadequate regulatory infrastructure".

The present format of the Code is a complicated, lengthy and unevenly detailed document with a great number of confusing repetitions as it attempts to cover all different shades of concerns of the many interested parties involved in its elaboration.

The following is an attempt to select and highlight the major issues of the

Code. In doing so, an overview on a set of important aspects of pesticide trade practices will be obtained, which today are under constant vigilance of very critical segment of the public.

## 2.2 *Review of major pesticide trade issues as detailed in the FAO Code*

The Code assigns, through a set of articles, responsibilities to either the government, to the industry or to both. With the term "industry" a very heterogeneous group of public and private enterprises is collectively addressed: local and multinational manufacturers, formulators, distributors, traders, brokers, sellers.

### 2.2.1 *General responsibilities*

#### Governments

*to introduce and implement laws, regulations and controls, i.e., to set up a scheme for the registration of each product before it is allowed to be sold*

Developing or smaller countries do not need an elaborate registration scheme or procedure if they organize themselves to base their granting of sales permits on the decisions reached in other countries with due consideration of their local needs and conditions for the use of the product. However, all countries at least need an efficient control scheme to constantly monitor that only registered products with the prescribed packaging and labelling are on the market. This they can achieve with a thorough control of imports.

*to respect property rights on registration data*

As we will see in reviewing the Code, great expertise is required from industry with respect to the testing of pesticides, the evaluation of the test data and the judgment whether a product can be used safely under specific local circumstances. In fact such expertise can only be generated through long experience in related R&D work. This means that finally the objectives set in the Code can only be realized on the strong shoulders of R&D companies. Since these shoulders have also to bear the ever-increasing risks and costs of generating the huge amount of safety and environmental data for successful registration of their products, the proprietary rights to these registration data have to be adequately protected. This need for protection has found the support of the "Second Government Consultation on Harmonization of Pesticide Registration Requirements" (Rome, October 1982) and GIFAP has issued a related position<sup>(1)</sup>: Firstly, an adequately long *exclusive use period of 15 years* after registration of a pesticide is requested in order to make up for the time of patent protection lost between issuing of the patent and successful registration (about 8 years). Secondly, after

<sup>(1)</sup> See "GIFAP Position Papers on Freedom of Information, Hazardous Substance Export and Product Stewardship", October 1983.

elapse of these 15 years following issuance of a sales permit the registration data can be used by the authorities in favor of other manufacturers interested to produce the compound if the latter a) adhere to the same product quality standards, b) are ready to share equally the costs of any follow-up data developed by the originator which is younger than 10 years, and c) are willing to share equally the costs of any future data needed to defend the product.

While these safeguards would not be prohibitive to responsible competitors they would have some effect to protect from speculative manufacturers and marketers who have not a long-term commitment to the agrochemical industry and to its customers.

#### Industry

*to follow the product up to the end-user in order to find out whether there is a need to make changes in the type of formulation, the package, the labelling or the distribution*

Industry realizes the importance of that aspect particularly in developing countries, and GIFAP has issued a position paper, "GIFAP Principles and Objectives of Product Stewardship and Good Marketing Practices in the Export of Pesticides" (1).

*not to sell products in tropical countries which require uncomfortable protective clothing*

This requirement is an example of many other requirements of the Code which remain a matter of judgment of local circumstances and depend on the benefit of and the need for the product.

#### Governments, industry and interested groups

*to disseminate educational materials to pesticide users, farmers' organizations, agricultural worker unions, etc.*

Responsible members of the agrochemical industry have been providing educational and training services in connection with the safe handling and use of pesticides for quite some time. Besides the activities of individual companies in this sphere, GIFAP has also been involved through the publication and promotion of the following booklets:

— Guidelines for the safe handling of pesticides during their formulation, packing, storage and transport (GIFAP, Brussels, 1982).

— Guidelines for the safe and effective use of pesticides (GIFAP, Brussels, 1983).

— Guidelines for emergency measures in cases of pesticide poisoning (GIFAP, Brussels, 1984).

These booklets, which are accompanied by posters, are also available in slide show form and in various languages. They provide valuable instructions in simple, easy-to-understand language. For illiterate persons, the use of other means of communication such as pictograms is being encouraged. Some agrochemical companies like Shell have been particularly active in the pictogram sphere. Besides



these publications, many of the national member associations of GIFAP (e.g., the Mexican Association) have come up with their own educational material to suit local conditions. All of these activities highlight the importance attached by GIFAP to Educational and Training Programs, though there is a necessity to further build upon this foundation. In recognition of this, GIFAP has already embarked on an expansion of coordinated industry training activities.

### 2.2.2 Responsibility in pesticide testing

The Code details the well known testing requirements and asks industry to comply. This is no real issue for larger or R & D companies as testing data are vigorously required for the registration of their products in industrialized countries. There is practically no development of products solely for developing countries.

#### Governments

*to possess or have access to facilities for controlling the quality of pesticides on sale and for carrying out residue analysis*

This is a very important responsibility of governments. There are some development aid organizations which have programs for setting up or supporting local analytical laboratories and hopefully others will join them in that effort.

#### Industry

*to assure that the quality of the manufactured products complies with the quality declared in the registration submissions*

Again this obligation is standard practice for R & D companies and they would wish that all other manufacturers, formulators and brokers are living up to the same standard. It is therefore important that governments possess or have access to analytical facilities.

*to be responsive to requests of governments for advice and help with analytical methods and for training technical staff in analytical work*

This support had been given in the past on an individual basis by many multinational companies. However, in order to make it effective, all companies operative in a given country should now coordinate and finance that support jointly.

### 2.2.3 Responsibility in reducing health hazards

#### Governments

*to set up poison control centers and operate first aid services*

The need for these services is not only for pesticides but also for other potentially dangerous chemicals with which a country becomes confronted during its economic development. It is hoped that support in this area becomes an objective of development aid programs.

*to supervise that pesticides are separately stored in shops and to regulate the disposal of empty containers and unused product*

The problems in this area are certainly a cause of many avoidable intoxications. In certain countries industry could perhaps be supportive of related government controls.

#### Industry

*to protect the health of operators and the environment in the manufacture or formulation of pesticides*

As described in the preceding chapter on Aspects of Pesticide Production, multinational companies are determined to achieve world-wide a uniform standard of safety. However, the conditions in certain countries may not allow to achieve that goal or may render production/formulation facilities uneconomical.

*to halt the sale of products in circumstances when safe use does not seem possible*

Whilst there can be no doubt that basically this must be the behavior of a responsible company, the determination of a use to be unsafe may often be a matter of judgment. The same comment relates also to the next selected responsibility:

*to reduce hazards by developing adequate formulations and packages*

#### Public sector groups

*to avoid unjustified confusion and alarm amongst the public by considering all available facts and distinguishing between major differences in levels of risk amongst pesticides and uses*

Responsible criticism certainly is helpful in achieving improvements but it has a negative effect if it becomes unrealistic or willingly destructive.

### 2.2.4 Responsibilities in distribution

#### Governments

*to classify the products by their hazard potential considering type of formulation and use (the WHO classification scheme is recommended)*

Uniformity of the classification schemes used in individual countries would much facilitate trade and be helpful in making progress in the safe use of chemicals.

*to regulate availability, i.e., access of users to pesticides in accordance with the level of education of the user groups and if indicated to prohibit the use of dangerous products*

In cases of missing regulatory infrastructures, local industry associations could agree on a description of user groups to which exclusive access to certain dangerous products would be allowed.

*to recognize, when importing food, the good agricultural practice of the export country as a basis for acceptance of pesticide residues*

Some industrialized countries do not allow the import of agricultural produce when it contains residues above their local residue tolerance level, although the level of residues in the offered produce is safe and results from good agricultural practice in the exporting country.

*to prohibit the repackaging, decanting or dispensing of any pesticide in food or beverage containers*

#### Industry

*to assure that the quality of exported and domestically sold pesticides is identical*  
Governments should find ways to exert controls on all imported products.

*to assure that pesticides manufactured by a subsidiary company are of comparable quality with those made by the parent company*

This justified requirement only makes sense when local private or public manufacturers likewise adhere to the quality standards of the originator(s) of the product(s).

*to help authorities in stamping out trading malpractices of importing agencies, local formulators and distributors*

This request implies, as the next one shows, that all local manufacturers, formulators and traders get organized in an association where malpractices of members can be discussed and the necessary measures taken.

*to trade only with reputable traders who should be members of a recognized trade union*

*to train persons who sell pesticides in giving advice on safe and efficient use*

This should apply to all members of the trade.

*to offer packs which suit the needs of small-scale farmers and avoid the risk that resellers will repackage products into unlabelled or inappropriate containers*

Large packs are more economical and often on the market for competitive reasons. If local associations would develop their own related binding regulations, companies often could live up to the requirement.

#### 2.2.5 Responsibilities in exporting/importing

##### Governments of export countries

*to assure that authorities in other countries are informed on actions taken to ban or severely restrict a pesticide*

*to assure that authorities of an importing country are alerted before a first export of a banned or severely restricted pesticide takes place*

#### Governments of import countries

*to set up an infrastructure for handling the information exchange  
to allow or deny the announced import based on its own judgment*

#### Industry

*to give any related information on the properties of the product*

A responsible company always would inform governments on bans or severe restrictions. It is important that this cumbersome information exchange procedure on top of the registration schemes will be limited to products to which the definitions for "banned" and "severely restricted" properly apply.

"banned": A pesticide for which *all registered uses* have been prohibited by final government regulatory action or when requests for all registrations or equivalent action for all uses *have not been granted* because of health or environmental reasons.

"severely restricted": A limited ban — means a pesticide for which *virtually all of its registered uses have been prohibited* by final government regulatory action, but certain specific registered use(s) remain authorized.

### 2.2.6 Responsibilities in packaging, labelling, storage and disposal

#### Governments

*to license premises for packaging and repackaging*

This important responsibility should also include the licensing of distributor or sales shops.

#### Industry

*to follow the FAO Guidelines on Packaging and Storage of Pesticides and those on Good Labelling Practices*

These guidelines rightly require the printing in the local language, advise the use of symbols and request information on the formulation date and storage stability.

### 2.2.7 Responsibilities in advertising

#### Industry

*to follow FAO Guidelines on Good Advertising practice*

*to make no statements which are not capable of technical substantiation*

*to make no claims to safety, such as "safe", "nonpoisonous", "harmless", "non-toxic", etc.*

*to include appropriate warning phrases and symbols*

Interested groups

*to monitor adherence to FAO advertising guidelines*

Industry welcomes the general guidance in advertising, and local associations should monitor the behavior of their members.

CONCLUSIONS

After reviewing some pesticide production aspects and a number of issues of the trade in pesticides selected from the Code it has become evident how difficult and challenging the task for a company is to live up to standards as expected from today's critical public. There is certainly no room for short lived deals of marketeers in this business with potentially dangerous chemicals. The quality of behavior expected can only be existent in companies which have a long-standing tradition in culturing quality and safety awareness based on a broad technical infrastructure and solid scientific background. In fact, even so, a company might finally fail when other companies would constantly not follow standards and take economic advantage in the market. It is therefore indeed important that the behavior of companies is accurately policed by knowledgeable authorities as is the case in industrialised countries or can be judged by other companies or interested groups of the public against mutually agreed standards as contained in the Code. In order to assure compliance, companies preferably have either their own local formulation, packaging, distribution and sales organizations or strongly and durably liaise with local reputable companies.

The weaker the local authorities the greater the need for companies to aggregate in associations for close collaboration to commonly achieve the standards of the Code. Such local industry or trade associations, with the help of the guidance of the Code, could, by self-regulating their behavior, replace missing laws and government controls. The Code does indeed stipulate that manufacturers, formulators and distributors get organized in local manufacturer or trade associations.

As explained above, GIFAP, the world-wide umbrella organization, has already prepared many valuable guidelines and documents to serve its national trade associations in pursuing adherence to the Code.

Considering the high standards expected by the public, pesticide production and trade are not suited for small independent companies or operations. Agriculture and its farmers in developing countries are best served when companies, dedicated to that business, can maintain or extend their technical infrastructure and know-how by allowing them the necessary profits, e.g., through protection of their proprietary rights on data, processes and investments.