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**Regulations: Procedures for Authorization and Use  
of Agrochemicals in Malaysia  
and Some Selected Developing Countries of Asia (\*\*)**

**ABSTRACT.** — Attempts at intensifying cultivation of food crops have resulted in increased incidence of pests and diseases. Hence for many countries the tendency has been to increase the applications of pesticides in terms of frequency, dosage and types of chemicals. Although the use of pesticides constitutes a major approach by which pest population may be controlled, steps have to be taken to ensure that it does not pose excessive danger to users, consumers and the environment. The Government of Malaysia through its Pesticides Act 1974, makes available provisions for the control of various aspects of pesticides including importation, manufacture, packaging, labelling, transportation, storage, sale and use. Currently the enforcement is still at the early stage of development, covering only the registration, labelling, and advertisement of pesticides. A brief account of authorization and use of agrochemicals as applied to P.R. China, Pakistan and the Philippines is included.

**1. INTRODUCTION**

The strategy adopted by most countries in Asia to increase their production of crop has been based on yield enhancement per unit area. The yield increases that have been recorded have resulted largely from the introduction of high yielding varieties which generally require a higher application of fertilizer. The high genetic vulnerability of most of these improved varieties coupled with the high intensity with which they are being cropped, have tended to bring about an increased incidence of pests and diseases. This is particularly so when application of nitrogen is relatively high and the climate under which these crops are being grown is hot and humid.

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To combat the increasing pest and pathogen problems, most countries resort to the increased use of pesticides. Available information indicates that there is a tendency towards increment in consumption of pesticides in most of the Asian countries. In Malaysia, for instance, estimates made over a period of five (5) years from 1977 to 1981 show an increase in the value of pesticide consumption by about 63 percent (Table 1). A similar pattern is detected in Pakistan and the Philippines, where records indicate that there have been almost a three-fold increase in the former and a two-fold increase for the latter. Tables 2 and 3 tabulate the consumption rate of pesticides in the two countries. Although no precise figures are available to depict the consumption rate of pesticides in P.R. China, indications based on some reports point to a figure of 150-200 thousand tons annually.

While the use of pesticides constitutes the major approach by which pest population may be controlled so as not to exceed the economic threshold level, every step has to be taken and accounted for to ensure that they do not pose excessive danger to users and consumers and would not in the long run be contributory towards the disruption of the ecosystem.

In an attempt to safeguard the usage of pesticides, the various government administrations in both developed and developing countries have drafted rules and regulations by which all activities pertaining to the pesticides industry, from importation to manufacturing, from storage to sale and final utilization and disposal could be effectively regulated and monitored.

This paper highlights to some degree of detail the administration of pesticides as practised in Malaysia, and for the purpose of comparison, a brief account is made of similar administration as found in the People's Republic of China, Pakistan and the Philippines.

## 2. PESTICIDES REGULATION AND USAGE IN MALAYSIA

Perhaps the most appropriate junction to introduce this topic is the establishment of the country's *Pesticides Act of 1974*, which stipulates rules, regulations and conditions pertaining to the pesticides industry. With the enactment of this Act, a Pesticides Board was instituted, with membership consisting of:

- (1) the Director-General of Agriculture;
- (2) the Director of Health Services;
- (3) the Director-General of Chemistry;
- (4) the Director of the Malaysian Agricultural Research and Development Institute;
- (5) the Director of the Rubber Research Institute of Malaysia;
- (6) the Controller of the Standards and Industrial Research Institute of Malaysia;

TABLE 1 - Values of Import, Local Production and Total Supply of Formulated Pesticides, 1977-1981 (*value in thousand \$M*)

Year	Import (C.I.F. value)	Local Production* (wholesale value)	Total Supply (combined value)
1977	42,025	58,897	100,922
1978	44,659	48,288	92,947
1979	71,047	63,772	134,819
1980	86,414	62,837	149,251
1981	101,400	63,200	164,600

Source: Department of Statistics, Malaysia.

\* Wholesale value of herbicides only, comprising 80-90 percent of total production.

TABLE 2 - Pesticide Consumption in Pakistan.

Pesticides	Metric tons of active ingredient		
	(1980-81)	(1981-82)	(1983-84)
I. <i>Insecticides</i>			
(i) Chlorinated hydrocarbons	—	173	332
(ii) Organophosphates	—	659	1,323
(iii) Pyrethroids	—	16	166
(iv) Carbamates	—	123	189
		971	2,010
II. Acaricides	—	—	9
III. Fungicides	—	154	205
IV. Rodenticides	—	1	1
V. Fumigants	—	80	19
VI. Herbicides	—	56	123
	*714	1,262	2,367

\* *Uncategorized.*

TABLE 3 - Sales of Pesticides in the Philippines ('000).

Stock Sales* (Net Distribution Prices)		
	1977	1983
Insecticides	18,941	38,053
Fungicides	8,322	12,121
Herbicides	5,271	11,088
Rodenticides	125	75
Fumigants	95	225
Nematicides	—	3,541
Others	1,138	3,547
<i>Total</i>	<i>33,892</i>	<i>68,650</i>

\* In US\$

- (7) the Director-General of Veterinary Services;
- (8) the Chief Pharmaceutical Chemist of the Ministry responsible for health services;
- (9) the Director-General of Forestry, West Malaysia;
- (10) the Director of Agriculture, Sabah;
- (11) the Director of Agriculture, Sarawak; and
- (12) the Secretary.

The chairmanship is assumed by the Director-General of the Department of Agriculture while a senior officer of the same department is appointed as the Board's Secretary. The primary role of the Board is to draw up and formulate regulations and to oversee their total implementation. It also reviews the situation of the pesticide industry from time to time and makes appropriate changes and amendments to rules and regulations. The technical back-up services required by the Board are provided for by the Department of Agriculture.

The objective of the Act is to provide the public with the supply of safe and effective products, particularly to control the dangers of pesticides to users, the general public, domestic animals, fish and the environment as a whole. In essence activities involved in the enforcement of the Act consist of the following:

- (i) Control of importation and manufacture of pesticides by registration;
- (ii) Control of importation of pesticides for educational or research purpose by means of a permit;
- (iii) Control of manufacture, sale and storage of pesticides by licensing;

- (iv) Control of presence of pesticides in food;
- (v) Reporting of death or injury occasioned by pesticides; and
- (vi) Enforcement, analysis, court proceedings and other general matters.

The following paragraphs provide accounts of the process, conditions and requirement involved (to be involved) in the administration and regulation of pesticides.

## 2.1 *Product Registration*

The Act, as stipulated in Section 7, requires that all pesticides intended to be imported or manufactured within the country be registered. By virtue of this, anyone who wants to import or manufacture pesticides will have to submit his application to the Secretary of the Pesticides Board. A pesticide is evaluated on the basis of its efficacy, chemical and physical properties, formulation, toxicity, residual analysis, safety, product stability, specifications, registration status in other countries and the proposed labelling of the product.

It is therefore imperative that an applicant furnish the Board with all this pertinent information. In terms of efficacy it is mandatory that information be furnished to substantiate the claim made on the effectiveness of the product. For this purpose data based on laboratory and field experiments are required, detailing the design of the experiment, application techniques, observation methods and results.

With regard to pesticide residues, it is required that the applicant provide information on procedures by which residues can be analysed. Information on pre-harvest interval, the amount as well as the nature of residues on food crops at various intervals and recommended maximum residue limits will be required in the near future.

The condition imposed on labelling is that a registered pesticide at a point of sale would have on its container a label approved by the Board. The label should have on it information as to which class of hazard it belongs to, its trade name, formulation, usage and contents. The name and address of the registrant are also required on the label. Table 4 shows the different colours assigned to the various (hazard) classes of pesticides. The product label would have the appropriate colour band printed on it so as to indicate the hazard class of the respective pesticide.

Registration of pesticides is implemented according to the nature of hazards that they pose. Malaysia has adopted the WHO Classification by hazards, whereby pesticides are categorised into four (4) classes, namely, I a, I b, II, III arranged in the order of decreasing toxicity. An additional class is however incorporated, which is designated as IV.

When an application is approved, the pesticide is registered for a period of three (3) years and the applicant is issued the appropriate certificate. A re-registration is required when the three (3) year period expires.

TABLE 4 - Assignment of Colour to the Different Classes of Pesticides.

Class	Colour of Band	Warning Statement
Ia	black	VERY HIGHLY POISONOUS
Ib	red	HIGHLY POISONOUS
II	yellow	POISONOUS
III	blue	HARMFUL
IV	—	—

Immediately after a pesticide is approved for registration or re-registration the information would be published in the Gazette. Similarly for any occurrence of cancellation or deregistration, the details would also be published. Figure I depicts the process of product registration.

Unregistered pesticides may be brought into the country but only for purpose of research and education. As in the case of other pesticides, applicants are obliged to submit application to the Board's Secretary, furnishing the latter with information regarding trade name of pesticide in question, its formulation, percentage of active ingredient, purpose and quantity that is intended to be imported.

Violation of any rule and regulation under the provision is punishable by law.

## 2.2 Control of Manufacture

Section 15 of the Act stipulates provisions for the control of manufacture of pesticides. Although provisions have been made for this purpose, rules and conditions pertaining to it have yet to be drafted.

Currently, approval to establish a factory is the prerogative of the Ministry of Labour, under its Factory and Machinery Act of 1969. Only registered pesticides are allowed to be manufactured.

## 2.3 Sale, Storage and Usage

The Act under Section 15 also stipulates provisions for the sale, storage and use of pesticides. Currently, regulations to cover these provisions are being formulated and it is only a matter of time before they will be enforced. A person intending to store and/or sell pesticides has to submit his application to the Pesticide Board, furnishing information on the size and location of premises where storage and sale are to be operated as well as the category of pesticides in terms of toxicity, i.e., as determined earlier under paragraph 14.

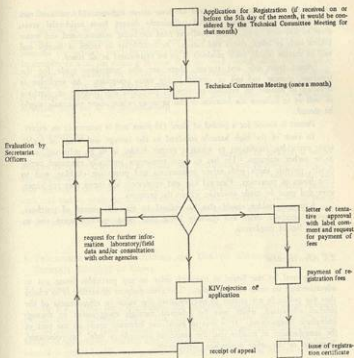


Fig. 1 - Pesticide Registration Process in Malaysia.

When an application is approved, a license would be issued, the validity period of which would be for one (1) year. It is however renewable on application.

In view of the safety hazards posed to handlers and operators of storage and sale premises, certain conditions are being made mandatory to those involved in these activities. Among the conditions that will be imposed is the requirement to have pesticides of classes Ia and Ib, which are very poisonous in nature, stored under lock and key; that pesticides be retailed in their original

containers; transaction to be limited to those above eighteen (18) years of age, and to have the premises located sufficiently distant from residential areas, areas of livestock, areas where food and feed are being manufactured and water bodies such as lakes, rivers and canals. Accountability in terms of receipt and sale of certain highly toxic products is to be maintained at all times.

Apart from sale and storage, there are also provisions made for the purchase, storage and use of certain highly toxic pesticides. An applicant is required to declare his occupation, type of pesticides and purpose of purchase as well as to indicate the location of the premises where these chemicals would be stored.

Permit is issued for a period of three (3) years and is renewable on expiry.

In view of the high hazards involved in the storage and usage of highly toxic pesticides, conditions to which a permit holder is to be subjected, have to be rather stringent. He has to have employees medically examined periodically, provide them with safety instructions and protective clothing, and to limit hours of operation. First-aid kits and respirators are items that are imperative and must be made available within the premises.

A permit holder would also be obliged to maintain record of purchase, quantity received, dates and quantity being used, area operated upon and an updated list of employees.

#### *2.4 Advertisement*

Approval by the Board is required prior to any pesticides being put to advertisement on radio and television. The main purpose of vetting is to ensure that the public is not misled to over-estimate the value or effectiveness of the product advertised, which may be achieved through exaggeration or through unrealistic comparisons. It is also to avoid any inference made on the part of the manufacturer or retailer that the particular pesticide is 'safe', 'nonpoisonous', 'harmless' or any other misleading implications.

#### *2.5 Presence of Pesticides in Food*

The Pesticides Act, 1974, has provision for the control of pesticide residues in food, permitting only the use of certain pesticides in food and allowing the presence of pesticide residues at levels not exceeding the specified quantity.

Although such provisions are found in the Pesticides Act, the control of pesticide residues in food will be regulated under the 1985 Food Regulations, enforced by the Ministry of Health. These regulations will be made effective as of October 1st, 1986. The Pesticides Board will support the enforcement through the provision of laboratory analytical services. The maximum residue limits stipulated are in line with those of the FAO/WHO Codex Alimentarius Commission.



## 2.6 *Death and Injury*

Section 28 of the Act stipulates that all injuries and deaths occurring as a result of fumigation, spraying or any other mode of treatment of plants, premises (or articles, etc.) by using pesticides, be reported to the authority. In compliance with the rules, it is clear that the onus would be on the employer to report any incident of injury or fatality befalling any of his employees. The same is expected of medical practitioners, who during the course of their duty treat injuries or come across fatalities due to pesticides. These provisions, however, have yet to be implemented.

## 2.7 *Enforcement*

For the purpose of enforcement a specified category of officers is authorized to carry out inspections to ensure that regulations and provisions of the Act are followed. Currently, enforcement duties are limited to ascertaining that only registered pesticides are being imported, manufactured, formulated, packed and sold and to verifying their chemical properties. Gradually as the proposed rules and regulations for sale, purchase, storage and use are enforced, the area of coverage would be greatly enhanced.

# 3. PROCEDURES FOR AUTHORIZATION AND USE OF AGROCHEMICALS IN THE PEOPLE'S REPUBLIC OF CHINA

## 3.1 *Current Legislation in P.R. China*

In P.R. China the "Regulations for Pesticide Registration" were enforced on the 1st of October, 1982. The Regulations stipulate that pesticides used for the control of plant diseases, insect pests, weeds and other harmful living beings in agriculture, forestry and animal husbandry, products used for insect control in public health, and growth regulators for plants and insects are within the range of control and must be registered before they can be produced and distributed in the country.

## 3.2 *Product Registration System*

The registration of pesticides under these "Regulations" falls into three categories, i.e., product registration, supplementary registration and temporary registration. Prior to registration, information on physical and chemical properties, specifications and analytical methods, efficacy trials, toxicity test and its effects on environment has to be submitted together with the samples of the pesticide concerned.

The product is evaluated by the "Evaluation Committee on Pesticide Registration". If approved, a registration certificate is issued to the applicant.

Pesticides produced by foreign companies have to be registered to be marketed in China. Additional information would be required for these pesticides. Efficacy and residue trials report, obtained from at least two typical areas in China for at least two years, has to be submitted for consideration.

### *3.3 Control on Handling and Usage in P.R. China*

Control on usage is done through the issuance of "Criteria for Safe Use of Pesticides" in 1981 by the Ministry of Agriculture, China. The "Criteria" regulates the dosage, method, maximum number of applications and pre-harvest intervals for 28 kinds of pesticides on 16 kinds of crops.

In 1982, the "Ministry of Agriculture, Animal Husbandry and Fishery", and the "Public Health Department" revised and issued the "Regulations for Safe Use of Pesticides" on the basis of the original "Instructions on Safe Use of Highly Hazardous Pesticides". In accordance with a comprehensive toxicity evaluation, 85 kinds of commonly used domestic pesticides were classified into three categories, i.e., highly hazardous, moderately hazardous and slightly hazardous. Based on the regulation, 26 highly hazardous pesticides are prohibited from use on vegetables, tea, fruit trees, Chinese medicinal herbs and for public health.

## **4. PROCEDURES FOR AUTHORIZATION AND USE OF AGROCHEMICALS IN PAKISTAN**

### *4.1 Current Legislation in Pakistan*

Under the "Agricultural Pesticides Ordinance 1971", the Federal Government of Pakistan established an "Agricultural Pesticides Technical Advisory Committee" (APTAC), consisting of eighteen (18) members with the Federal Secretary of the "Ministry of Food and Agriculture" as its chairman. The Joint Secretary of the Ministry acts as Vice-chairman and the Plant Protection Advisor and Director as the secretary. Other members are from the government agencies concerned with pesticides.

The committee is responsible for advising the government on legal administrative and technical implications of the "Agricultural Pesticides Ordinance" and the "Rules" associated with it, registration of pesticides and the drawing up of specifications or requirements for registration of pesticides.

The APTAC is empowered to appoint as many sub-committees as it deems necessary for specific purposes for a period of 3 years. At present, there are two (2) standing sub-committees: the "Technical Sub-committee" to advise APTAC on registration, and the Committee on specifications of pesticides.

### *4.2 Product Registration System*

An application for registration of a brand of pesticide has to be made to the "Plant Protection Advisor and Director" on prescribed forms. The applicant is

required to provide detailed data on physical and chemical properties, toxicology, residues, environmental effects, efficacy, etc. The application is to be accompanied by a prescribed fee, a sample of the product formulation, technical material on which the formulation is based and a small reference material of pure active ingredient.

After verification of the claims in the application, the samples are forwarded to the Provincial Governments to conduct, in direct association with the applicant, biological tests for two (2) crop seasons under field conditions. The trial results, after evaluation by the "Technical Sub-committee of APTAC", are presented to APTAC. A registration certificate is issued by the "Department of Plant Protection" on approval by APTAC. The approval is for a period of three (3) years and is renewable on request. The registration is granted by brand name and formulation for particular crops and pests. The common name of the product and name of manufacturer would also appear on the certificate of registration.

Import of BHC, DDT or any mixtures containing BHC or DDT is prohibited. As for other groups of pesticides only those registered in Pakistan can be imported. Generally, not more than 50% of the supply imported is in the form of finished product. For non-systemic granules the entire supply has to be formulated locally. Import of fully finished form is allowed only in the case of highly hazardous systemic granules. In addition to product registration, an importer has to apply for an import license from the Provincial Government.

#### *4.3 Control on Manufacture and Formulations in Pakistan*

No manufacturing or formulation plant for pesticides can be established in the country without government approval. A manufacturer/formulator has to submit a feasibility report of the project to be undertaken. The government would consider the proposal, keeping in view the availability of raw material and prospects of the products to be manufactured.

It is also required that manufacturers of pesticides follow specified rules and regulations so as to maintain high quality products and to protect the well being of factory workers. For this purpose inspectors are employed to check on manufactured products.

### **5. PROCEDURES FOR AUTHORIZATION AND USE OF AGROCHEMICALS IN THE PHILIPPINES**

#### *5.1 Current Legislation in the Philippines*

The "Presidential Decree No. 1144" promulgated on May 30th, 1977 created the "Fertilizer and Pesticide Authority (FPA)" to regulate fertilizers, regulatory functions related to pesticide sale, importation, formulation, distribution, storage, transport and use. The authority implemented the Decree through

the issuance and adoption of the "Rules and Regulations No. 1, Series of 1977" which govern the importation, manufacture, formulation, repacking, distribution, sales, storage and use of pesticides and other agricultural chemicals in the interest of improving agricultural production, protecting public health and enhancing environmental quality.

### 5.2 Product Registration System

Basically, the Philippine registration system integrates all relevant concepts endorsed by the "FAO Ad-Hoc Government Consultation on International Standardization of Pesticide Registration Requirements (1977)" as well as those from other regulatory agencies, notably the "Environmental Protection Agency" in the United States.

Except for the biological efficacy data which must be generated locally, those pertaining to toxicology, residue and effect on environment data from internationally accepted sources may be considered.

For local bio-efficacy tests, herbicide trials must be conducted during two seasons replicated in two locations. For insecticides and fungicides, however, one season trial replicated in at least two locations would suffice. All tests in support of registration must be covered with a duly approved "Experimental Use Permit".

FPA has categorized pesticides into commodity and proprietary compounds. Proprietary compounds are those that are still protected by original patents, obtained at the country of origin, while commodity compounds are those whose original patents have already expired. Proprietary pesticides must be supported by full documentation including chronic, sub-chronic and long-term toxicity studies, while commodity products may be registered with minimal data requirements. The system works on the assumption that commodity compounds have been in the market for a long time and any adverse effects would have been noted earlier. Registration is required for each source or supplier of pesticides.

FPA relies heavily on the technical advice of a panel of consultants which constitute the "Pesticide Technical Advisory Committee (PTAC)". The PTAC brings together highly experienced technical experts in the field of pesticide management, toxicology, pharmacology, pesticide chemistry, entomology, weed science and plant pathology, whose main responsibility is to advise FPA on the technical matters related to pesticide registration.

A special sub-committee on registration under the PTAC undertakes the task of evaluation of all data submitted in support of registration. This sub-committee is composed of two (2) entomologists, two (2) plant pathologists, a nematocide expert, a rodent control expert, two (2) pesticide chemists and two (2) toxicologist/pharmacologists. Recommendations are forwarded to the PTAC which in turn submits them to FPA after another round of deliberations.

Only local companies duly licensed by FPA may apply for product registration. Foreign suppliers or companies registered under the "Security and

Exchange Commission (SEC)" as regional liaison offices are not allowed to register pesticide products. In practice, therefore, the applicant or registrant is normally the distributor or the local subsidiary of a foreign-based pesticide company.

Focus of evaluation will be the label and all claims in the label must be supported by the required data. Label signals and precautionary warnings are based on toxicity categories, which are a modified version of the WHO recommended classification scheme. Labels are colour-coded by product type but this will be changed to reflect level of toxicity. FPA introduced its own concept of phased registration into the system to cater to the need to introduce products into the country at varying stages of market developments.

*Experimental Use Permit (EUP)* — All pesticides to be tested in the Philippines must be covered by an appropriate experimental use permit. Different types of EUPs depending on the degree of market development of the product are issued with corresponding requirements and limitations.

*Conditional registration* is granted to products that have met almost all requirements of registration except for some data which FPA requires companies to submit within an agreed period of normally six months. Products under this type of registration may be marketed subject to certain conditions.

*Full registration* is valid for one year and in cases where additional data may be required, such data will form the basis for a renewal. Normally renewal is granted with no additional requirements.

*Provisional registration* was granted to products marketed before the establishment of FPA.

Product availability is not geared solely to the toxicity category but is restricted to institutional (plantation) use or use by FPA-licensed applicators based upon specific hazards posed by each product and availability of economical substitutes as well as the importance of the product to the potentially restricted segment of agriculture.

### *5.3 Licensing of Handlers in the Philippines*

Section 9, P.H. 1144 and Section 1, Article III of the "Rules and Regulations" stipulate that no person shall engage in the business of importing, manufacturing, formulating, repacking, distribution, storing or selling of pesticides, except under a license issued by the authority pursuant to these regulations. A separate license shall be required for each establishment or place of business subject to these rules, to be conspicuously displayed therein. FPA licenses are issued to all pesticide companies, dealers and pest control operators.

### *5.4 Regulations on Importation in the Philippines*

All pesticides and active ingredients brought into the country must be covered by an appropriate import certificate from FPA.

### 5.5 *Monitoring Programmes in the Philippines*

Various monitoring programmes have been designed to check compliance with the provisions of P.D. 1144, especially those involving licensing and registration requirements, including enforcement on use of restricted pesticides.

As far as residues are concerned, the control of levels in food has not yet been formally established. Preliminary design has been undertaken and necessary regulations and procedures outlined. However, implementation has been slow, pending completion of laboratories, staffing and procurement of necessary supplies.

Random sampling of formulations to check compliance with registered specifications are on-going activities of both FPA and BPI.

### 6. SUMMARY

Clearly, all the countries mentioned in this paper have established rules and regulations to control production, import, handling and use of agropesticides. They differ however to a certain extent in terms of procedures, the differences of which could perhaps be attributed to the differing political stature, socio-economic status and the general agriculture patterns that exist in the respective countries. There is however an area of similarity among them which is manifested by the fact that regulations and enforcement are still in the early stages of development. Complete enforcement has yet to be achieved, particularly in the aspects of usage and environmental protection.

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