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MANAGEMENT OF PUBLIC HEALTH INSECTICIDES IN CHINA

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Background of Chinese Public Health Insecticide Industry

Chemical control is the most important element in the integrated approach to control of vectors and pests of public health. Correctly used, insecticides play an important global role in the prevention and control of the vector-pestiferous diseases such as malaria, dengue, dysentery, cholera and typhoid fever, which affect the health and well-being of millions of people worldwide and are an impediment to social and economic development.

There are 1138 produces with 92 varieties and 2319 formulated products of public health insecticides PHI, (Table 1). Rich-d-transallethrin was the most applied insecticide, followed by prallethrin, tetramethrin, permethrin and cypermethrin. More than 67 kinds of formulations were used in China, and aerosol is the most commonly used formulation in China. In 2004, the production value reached 750 million dollars (Table 2). Now, China is the big producer and consumer of PHI in the world.

Table 1. Formulation Registration of PHI in China (2003 and 2004).

Formulation	2003		2004	
	Products registered	Percentage	Products registered	Percentage
Aerosol	565	28.8	680	29.3
Mat	527	26.9	609	26.3
Electric mat	140	7.1	147	6.3
Electric liquid	92	4.7	86	3.7
Bait	94	4.8	91	3.9
Technical material	105	5.3	120	5.2
Aqueous SC	37	1.9	46	2
Emulsifiable concentrate EC	34	1.7	39	1.7
Wettable powder WP	34	1.7	36	1.5
Micro-emulsion ME	1	0.05	13	0.6
Moth-proofer	40	2	62	2.7
Repellents	55	2.8	72	3.1
Others	238	12.1	318	13.7
Total	1962	-	2319	-

Table 2. Statistics of Production of PHI in China (2003 and 2004).

Formulation	2003			2004		
	Production (million)	Value (million dollar)	%	Production (million)	Value (million dollar)	%
Aerosol	150 (cans)	1,500	30.0	232 (cans)	2,300	38.3
Mat	27 (boxes)	2,430	48.6	28 (boxes)	2,520	42.0
Electric mat	54 (boxes)	400	16.0	50.6 (boxes)	370	6.2
Electric liquid	10 (bottles)	100	2.0	18.8 (bottles)	188	3.1
Repellent floral water	-	100	2.0	-	100	1.7
Moth-proffer	50 (tons)	55	1.1	56 (tons)	62	1.0
Others	-	500	10	-	500	8.3
Total	-	5,085	-	-	6,040	-

Public Health Insecticide Management

The management objective is to protect society from the adverse effects of PHI without denying access to the benefits of their use. Registration enables authorities to exercise control over quality, use levels, claims, labeling, packaging, advertising, and disposal of PHI, thus ensuring that the interests of end-users are properly protected. The registration legislation must provide a system that protects both the interest of the public and the rights of manufacturers. Government agencies and various sectors of the community have different responsibilities under any PHI registration and control scheme. As part of pesticide, management of PHI has been same as those in agriculture and forestry in rules and regulations, management agencies, registration and market supervision.

Rules and Regulations

The rules and regulations of PHI have been more authoritative and orderly since 1997. The principal rule of pesticide management in China is Regulation on Pesticide Administration that was issued on May 8, 1997 by the State Council. The Regulation regulated the pesticide registration, namely, all the pesticides produced in China or imported to China must be granted for registration. The Regulation also required production permission management which means the pesticide production in China must obtain production license or approval document. On November 29, 2001, the Regulation was revised to meet the requirements of entering WTO. There also are some laws and rules concerning pesticide management, such as Product Quality Law, Standardization Law, Advertisement Law, Regulation on Hazardous Chemicals Management, etc. Up to now China has formed a systematic legal system of pesticide management, which is the legal basis of ruling by the laws.

Low toxic ingredients were recommended according to theWorld Health Organization. In Regulation on Pesticide Administration, there is a special chapter about registration of PHI. Some ingredients including chlorpyrifos, diazinon, and plifenate were forbidden in China. And some special regulations, such as Notice on limiting the registration of fenobucarb as public health insecticide, have been lain down.

Management Agencies

According to the Regulation, agriculture administration departments are responsible for the pesticide registration, supervision and management in the whole country. However, the administrative and technical experts from the following ministries constitute the Evaluation and Adjudication Board of Pesticide Registration: Ministry of Agriculture (MOA); Ministry of Health (MOH); State Environmental Protection Administration (SEPA); National Development and Reform Commission (NDARC); General Administration of Quality Supervision Inspection and Quarantine (GAQSIQ); All-China Federation of Supply and Marketing Cooperatives (AFSMC); State Administration for Industry and Commerce (SAIC); Customs.

Production and Marketing

The State practices a licensing system for pesticide production. The National Development and Reform Commission is responsible for issuing the Production licences and approval documents. Besides the MOA, GAQSIQ is also involved in the pesticide product quality supervision. The pesticide advertisements are inspected by MOA and SAIC.

ICAMA

ICAMA was established in 1963, directly led by Ministry of Agriculture of PRC, which is responsible for the detailed affairs of pesticide registration and management of the whole country with the following principal responsibilities: pesticide registration, quality inspection, biology test, residue test, market supervision, information service, technical exchange, foreign cooperation and consultation.

There are 11 divisions in ICAMA, including General Office, Registration Division, Bioassay Division, Quality Control Division, Residue Control Division, Supervision Division, Information Resource Division, Planning and Financial Division, Administrative Division, Consultation and Service Center, and Biotech and Environmental Center. In Registration Division, Bioassay Division, Quality Control Division, Residue Control Division, and Biotech and Environmental Center, there are persons specially assigned for PHI. There are about 100 staff, and over 90 percent of them are professional personnel. It owns laboratories of more than 4,000 square meter, which are well equipped with advanced instruments, such as HPLC-MS, GC-MS, etc, and are capable to do various tests of pesticide. And there is the best simulation lab of insecticides of China in the Biotech and Environmental Center. ICAMA is also the National Center for the Pesticide Quality and Supervision and Test.

Local ICAs

At present, every province, municipality directly under the Central Government and autonomous administration regions has established Institutes for the Control of Agrochemicals (ICA) which are responsible for primary evaluation of pesticide registration and other detailed affairs of market supervision and management, conducting tests and judgments on pesticide quality, efficacy and residue, training and instructing pesticide enterprises. Institutes for control of agrochemicals have been formed in many cities and countries, which are responsible for detailed matters concerning pesticide market supervision and management in their administration areas. Up to now, the total personnel engaging in pesticide management has reached 30,000.

Registration

There are three stages of PHI registration in China: efficacy trial, temporary registration and full registration. Efficacy trial stage. When applying for registration of a PHI, the applicator of the PHI shall submit an application for efficacy trial, which may only be carried out after the application is approved. In this stage, application table and product abstraction (including production chemical, efficacy, toxicology and registrations in other countries) in double would be prepared. Temporary registration stage. After the efficacy trial, for the PHIs that need to go through trial demonstration, or need to be placed on trial sale and those need to be used under special circumstances, the manufacturer would apply for temporary registration, and the field trial demonstration and trial sale may only be carried out within the specified area after a Temporary PHI Registration Certificate is issued by MOA. Full registration stage. The manufacturer of PHI that have been proven through efficacy trial demonstration and trial sale to be ready for commercial distribution would apply for full registration, and the production and distribution thereof may only be started after a PHI Registration Certificate is issued by MOA.

Application and Evaluation Procedures

In China, the first step of application for PHI registration is efficacy trial. After that and completion of data preparation, the application for temporary registration can be made, which must be renewed every year and when completion of all relative experiment and data, full registration can be applied for after the period of validity of temporary registration. Application and evaluation of efficacy trial. The domestic companies can apply for the field trial to the provincial ICAs and the application should be finally evaluated and approved by ICAMA. The overseas companies can directly apply for it to ICAMA. The evaluation normally should be finished in one month. Application and approval of temporary registration. The application for temporary registration by domestic companies must be first evaluated by provincial ICAs. Only those applications passing the first evaluation could be submitted to ICAMA for final evaluation. However, overseas companies can directly apply for temporary registration to ICAMA. The evaluation normally will last three months. Application

and approval of full registration. The corporations directly apply for full registration to ICAMA and the latter submit data of new PHI products to Evaluation and Adjudication Board of PHI Registration for evaluation, and finally, the registration will be issued by MOA. The procedure will last one year.

Data Requirements of PHI Registration

Data Requirements of PHI Registration was issued by MOA and other departments in 1982, and revised in 1988, 1992, and 2001. Now the revised version in 2001 is operative. The Requirements was established according to the features of PHI production, sales and use in China and with the reference of PHI registration data requirements of FAO and some developed countries. The basic technical data of PHI registration include data on product specification, efficacy, toxicity and environment, production technology, label, and relative documents and certificates.

Registration Classification

The PHIs are classified into general PHIs and special PHIs and different data requirements are set up for them according to their properties and functions. Special PHIs include PHI, rodenticide, bio-chemical PHIs, microbial PHI, botanical PHI, natural enemy, and GMO. For example, it is required to carry out bioassay of silkworm in toxicology in China. Data requirement is also modified according to new formulation, 'Me-too' products, and new use scope and application methods. The above classification embodies the scientism and rationality of registration requirements and protects the intellectual property rights.

Protection of Registration Data

The unpublicized trial data and other data are strictly protected for 6 years, which are acquired and submitted by applicators that obtained the first registration of PHIs with new compounds. The registration agencies cannot disclose the data without owner's permission. In addition, other applicators cannot use the data of the first applicators without their permission. After 6 years of the first registration, some efficacy, toxicity, and environment data of the Me-too product registration could be omitted or reduced.

To meet the requirements of PHI international trade and reinforce the safety management, we are revising the data requirements again and hopefully it will be issued soon. To strengthen PHI safety management, fulfill the related international conventions such as PIC and POPs, and protect human health and environment, China also regulates the registration of PHI export sine 1999. It is necessary to apply for PHI Export Registration Certificate, which can help the Customs verify the registration of the exported products. Production and Export of POPs products are severely prohibited, and export of PIC products only can be approved with the permit of the importing countries. PHI Free Sales Certificate should be produced if necessary to verify the registration of the exported products in China.

Market Supervision and Management

To maintain a normal order of PHI market, PHI management agencies and administrations of industry and commerce at all levels usually supervise the PHI market and execute the law, inspect and handle illegal cases of production, distribution and use of the PHIs. All the relative departments of the agricultural sector are involved in inspection of PHI quality and do quality check of over 5,000 samples from market every year. The inspection of residue is strengthened recently to guarantee the safety of crop products.

PHI Registration Management in China

PHI management is a systematic program based on science and technology. It includes inspection and management of product quality, safety and efficacy, packaging, transportation, storage and use. The concerned departments established all kinds of standards and guidelines and other technical norms to regulate and instruct PHI production, use and management. The development of society, economy and technology led to stricter requirements for registration and management to improve safety and quality of PHI product. Some measures that will be carried out in future include: improving the laws, rules and technical standards; strengthening safety management and transferring management emphasis; raising data requirements and internationalizing registration management; and, improved administrative systems and reinforcing services.

Internationalization of PHI Registration

With the globalization of the world economy and China's entering WTO, international trade of PHIs increases rapidly, that produces new requirements for the internationalization of PHI registration. Internationalization of PHI registration is currently an imperative subject for PHI management departments and PHI industry all

over the world. To reduce unnecessary repeated experiments and save human resources, alleviate the burden of corporations, accelerate admittance speed of PHI products in the world and increase the whole efficiency of PHI management, all the countries should unify and harmonize PHI registration. However, today there are three problems in the internationalization of PHI registration management: 1) The experiments and registrations in different counties can not be recognized or referred to each other; 2) Data requirements of different countries are not completely identical; 3) Harmonization, and communication of technology and management about registration are not popular.

Establishment and Mutual Recognition of GLP Laboratories

All the countries certify and accredit their own laboratories for registration trials, however, because of the different standards and requirements and lack of communication and negotiation among countries, these qualified can't be mutually recognized. Therefore it is very important to strengthen the uniform certification and muti-accreditation of the laboratories of countries. GLP laboratories are gradually accepted in the world, so that all the countries should establish their own GLP laboratories and accredit each other. China has established the industry standards of GLP Laboratory Guidelines that will be issued and implemented in the near future. China begins to certify GLP laboratories for registration. We hope to cooperate with other countries to establish GLP laboratories and make mutually accreditation.

Consistency of Data Requirement of Registration

The precondition of mutual recognition of registration is the consistency of data requirement. At present, data requirements of different countries are basically consistent in the principle, structure and requirement and only some technical data are different. Therefore, data requirements of registration of all the countries should be harmonized and unified in order to achieve consistent registration requirements and mutual recognition; or it is feasible to establish a basic requirement which is internationally recognized and accepted by most countries, then on the basis of the basic requirement, each country establishes its additional reasonable registration according to its own conditions so as to accelerate registration internationalization.

China is internationalizing its PHI registration and trying to meet the standards and requirements of the developed countries. Now the data requirements of toxicity, environment, registration of the Me-too products and data protect policy and other aspects have been in line with international standards. However, China does not pursue highest standards and requirements blindly. On the contrary, it scientifically and reasonably establishes registration data requirements suitable for most companies with the purpose of safety guarantee. China is ready to harmonize and implement consistent data requirements with other countries in order to promote the internationalization of registration.

Harmonization of Registration Evaluation

With the development of free trade, it is more popular for a PHI product to be applied for registration in several countries at same time. At present the evaluation results in different countries cannot be referred to each other, which results in the repeated evaluation and low efficiency. Therefore, it is necessary for relative countries to strengthen the harmonization and communication of the evaluation.

Communication of Information and Technology

PHI management departments in countries should establish a long-term system for the communication information and technology of PHI management. Conferences and training courses should be held regularly to exchange experience and lessons, study and resolve the problems, unify and harmonize management and accelerate the internationalization of PHI management.