

Challenges and Opportunities: Developing, Sourcing, and Selling Pesticides in China

China presents U.S. and European producers and marketers of pesticide products with both opportunities and challenges. The opportunities are significant. China's domestic agricultural and non-agricultural pesticide markets are growing dramatically. With the cooperation of U.S. Environmental Protection Agency ("EPA") and the Organisation for Economic Co-operation and Development ("OECD"), China is developing national Good Laboratory Practice standards, which will greatly increase product development opportunities within China itself. Sourcing for export of technical products and for sale in China's domestic market (under joint venture manufacturing plants, wholly owned foreign invested plants or distribution companies or traditional supply contracts to Chinese distributors) will increase. The challenge for U.S. and European companies is to understand the business and regulatory environment in China.

This and future *China Pesticide Bulletins* will help U.S. and European pesticide companies to understand China's growing market for chemical pesticides, biopesticides, antimicrobials, and biotechnology, how pesticides are regulated in China, who are the regulators, and how to do business in China, whether a company is developing, sourcing, manufacturing, or selling pesticides in China.

Registering Pesticides in China

The Institute for the Control of Agrochemicals within the Ministry of Agriculture ("ICAMA") is the national authority that registers and otherwise regulates pesticide products in China. ICAMA was established in 1963. In addition to registering pesticides, ICAMA controls product quality, conducts bioassays, monitors residues, enforces requirements, and cooperates with other Chinese government agencies, foreign governments, and international organizations. ICAMA currently has a staff of approximately 100.

ICAMA requires the registration of crop and non-crop (household or sanitary) pesticides, including technical and end-use (formulated) products. As discussed below, antimicrobial pesticides, including disinfectants, are registered and regulated by the Ministry of Health. The National Development and Reform Commission regulates pesticide production and the establishment of pesticide-producing facilities.

There are three phases of registration in China: field trial, provisional, and formal. Data requirements for each phase are set forth in Data Requirements for Pesticide Registration originally issued by the Ministry of Agriculture ("MOA") in 1989 and most recently amended in 2001. During late 2004 to spring 2005, ICAMA circulated new amendments to the Data Requirements for public comment. When amended, the Data Requirements will further address "me-too" registrations, export-only products, data protection, and increased data requirements for provisional registrations. MOA expects to adopt the amended Data Requirements before the end of this year.

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ICAMA is taking steps to eliminate expired provisional registrations, which will reduce the number of active pesticide registrations in China. In addition, ICAMA has taken steps to strengthen its protection of data submitted to support pesticide registrations, including the aforementioned changes to the Data Requirements for Pesticide Registration. Data submitted to support the provisional registration of a new active ingredient will receive up to ten years of exclusive-use protection running from the date of first provisional registration, which is renewable each year for a period of up to four consecutive years, after which the provisional registrant must obtain a formal registration. Data submitted to support the formal registration of a new active ingredient will receive a six-year period of exclusive-use protection running from the date of formal registration. The ten-year exclusive-use period for provisional registration data can overlap the six-year exclusive-use period for formal registration data. Follow-on or “me too” applicants always have the option to develop and submit their own data, if they cannot get the consent to cite and rely upon previously filed provisional or final registration data subject to exclusive use by the original data owners.

Registering Antimicrobial Products in China

In China, the Ministry of Health (“MOH”) regulates the production and distribution of disinfectants in accordance with the Food and Health Law of China. On March 28, 2002, the Ministry adopted Disinfection Administrative Measures.

MOH issues two types of permits for producing and selling a disinfectant product: a “Disinfectant Products Manufacturer Permit” for the production facility (“manufacturer permit”) and a “Product Health Permit” for each product produced at the facility and sold by the manufacturer (“health permit”). The distributor of a locally produced disinfectant product does not require a permit but must have copies of the applicable manufacturer and health permits.

To import a disinfectant product into China, the U.S. or European producer does not need a manufacturer permit but must obtain a health permit. The Chinese importer or distributor must have a copy of the health permit to import or distribute the product in China. MOH receives, processes, and approves applications for health permits.

A health permit application consists of one original and eight copies of the following: the application form; studies of the product; product formula; major ingredients and quality assurance/inspection procedures; manufacturing process description and illustration; company quality standards for the product; authorization letter to the Chinese agent; proposed label; approvals to manufacture and sell the product in the importer’s country; any other relevant materials; and a complete set of product samples. Required product testing includes toxicology, product chemistry, and product performance (efficacy). Applicants must use MOH’s official forms and submit Chinese translations of foreign-language application materials. The National Center of Health Inspection within MOH processes and approves health permit applications.

Good Laboratory Practices in China

In March 2005, ICAMA and US EPA signed a letter of intent to develop Good Laboratory Practice (“GLP”) standards in China. The joint letter of intent is a step in the direction of future, mutual acceptance of GLP compliance monitoring programs and test data.

In September 2005, ICAMA and EPA jointly hosted a GLP workshop Hangzhou, China. U.S., German, and Swiss GLP regulators addressed the submission of pesticide registration applications from a GLP perspective, quality assurance, laboratory equipment, training of personnel, testing facility management, standard operating procedures, the conduct of study protocols, study data collection, and multi-site studies. In addition, an advanced course for inspectors was held after the GLP workshop.

China’s development of GLP standards will enable Chinese laboratories to generate internationally accepted pesticide and chemical test data and develop maximum residue levels (“MRLs”) to ensure that pesticide crop residues meet international standards. GLP standards also will permit Chinese and Western companies to increase research and development activities in China.

Phaseout of Highly Toxic Pesticides

In 2002-2003, the Chinese government issued several administrative orders to prohibit or restrict uses

of highly toxic pesticides in China. In April 2002, MOA issued Administrative Order No. 194, under which ICAMA is directed to do the following:

1. Stop accepting new registrations of the following 11 highly toxic pesticides: phorate, omethoate, isocarbophos, terbufos, phosfolan-methyl, sulfotep, isofenphos-methyl, demeton, aldicarb, carbofuran, and methomyl. For existing registrations, ICAMA will gradually reduce uses on certain specific crops.
2. Stop accepting repackaging registrations for the foregoing pesticides and stop renewing provisional registrations.
3. Cancel uses on the following crops: omethoate on cabbage and broccoli; isofenphos-methyl on fruit trees; aldicarb on apple trees; carbofuran on orange trees; phorate on orange trees; and terbufos on sugar cane.

In June 2002, MOA issued Administrative Order No. 199, which does the following:

1. Bans use of the following pesticides in China: HCH, DDT, camphechlor, dibromochloropane, chlordimeform, EDB, nitrofen, aldrin, dieldrin, mercury compounds, arsenide compound, lead compounds, fluoroacetamide, gliftor, tetramine, sodium fluoroacetate, and silatrane.
2. Bans or restricts use of the following pesticides on vegetables, fruit trees, tea trees, and products used in traditional Chinese medicine: methamidophos, parathion-methyl, parathion, monocrotophos, phosphamidon, phorate, isofenphos-methyl, terbufos, phosfolan-methyl, sulfotep, demeton, carbofuran, aldicarb, ethoprophos, phosfolan, coumaphos, fonofos, isazofos, and fenamiphos.
3. Bans the use of dicofol and fenvalerate on tee trees.

In December 2003, MOA issued Administrative Order No. 322, under which MOA will phase out five highly toxic organophosphate pesticides: methamidophos, monocrotophos, methyl parathion, phosphamidon, and parathion ("Five OPs"). These pesticides are being eliminated in three phases, phase one (2004), phase two (2005-2006), and phase three (from 2007 on).

On January 1, 2004, MOA cancelled the registrations of end-use products that contain two or more active ingredients and one of them is among the Five OPs and, on June 30, 2004, prohibited sales of existing stocks of such products. On January 1, 2005, MOA cancelled the registrations of end-use products that contain any one of the Five OPs, excluding end-use product registrations held by technical registrants of the Five OPs. In addition, MOA restricted such technical registrations to use on cotton, rice, corn, and wheat. In phase three, MOA will cancel all remaining registrations of end-use products containing any of the Five OPs and prohibit all agricultural uses of the Five OPs, except for export-only production.

In addition, on April 4, 2006, MOA, the National Development and Reform Commission, the State Administration on Industry and Commerce, and the Administration of Quality Supervision, Inspection and Quarantine jointly issued Administrative Order No. 632 to ensure the complete ban on agricultural use of the Five OPs after January 1, 2007:

1. As of January 1, 2007, the sale and use of the Five OPs will be banned in China. All product registrations and manufacturing approval certificates will be cancelled. Agencies will issue special certificates to manufacturers and exporters of the Five OPs for export-only purposes.
2. Current manufacturers of any of the Five OPs must manage production to avoid over production. After 2006, existing stocks must be destroyed according to applicable hazardous waste disposal regulations.
3. Current retailers and distributors also must manage product stocks to avoid excess inventory. After 2006, existing stocks must be destroyed according to applicable hazardous waste disposal regulations.
4. Farmers and consumers are encouraged to use up any existing stocks of products containing the Five OPs by the end of 2006.

As of January 1, 2007, all agencies and provincial departments will inspect for and enforce against the illegal manufacture, sale, or use of the Five OPs.

Since 2004, registration cancellations have eliminated the production of about 100,000 metric tons of

highly toxic pesticides in China. ICAMA continues to encourage Chinese and international producers to make safer and more effective pesticides to replace older, more toxic compounds.

Sourcing in China

Outsourcing is an important strategy for many companies in the agricultural and specialty chemical sectors. Quality is a major consideration when sourcing anywhere. A purchaser of pesticides from a foreign facility should audit the facility to validate manufacturing processes and capacity, technical expertise, and quality controls, thereby preventing potential quality or supply issues. The purchaser should collect and analyze multiple samples from pilot or commercial production facilities in order to confirm the foreign facility's long-term production capacity. As well, the foreign producer should have the necessary environmental controls to ensure that it will be in business in the future.

Once an acceptable producer is selected, pricing and logistics should be negotiated to ensure consistent production and timely delivery at agreed-upon costs. Language barriers can lead to misunderstandings about scheduling, shipping, and customs issues and interrupt or delay supply. If sourcing in China requires sharing technical knowledge or other intellectual property ("IP"), there are steps a purchaser can take to maximum the protection of manufacturing IP. Recently, foreign firms have been successful in enforcing China's laws protecting IP. Establishing a qualified source in China can be an important strategic move in a competitive marketplace.

News from the Regulators

China Launches MRL Database

On March 1, 2006, ICAMA launched a program to establish a Chinese MRL database in Beijing. The kick-off meeting included experts on residue inspection, risk assessment, and computer technology. The discussion included structure, data source, search, and crop grouping issues for the new database system.

No Foreign Genes Found in Heinz Rice Flour in China

On March 31, 2006, the Agricultural Biotechnology Office of MOA reported that, after thorough sampling and testing, no foreign genes were found in Heinz rice flour for babies in China. The report closed out the high-profile case started by an environmental group's claim that Heinz used bioengineered rice to make its rice flour sold in China. In China, genetically modified rice has not been approved for human consumption, although it has been undergoing final field trials for the past five years and has finished final safety testing in China.

2005 China Pesticide Export Data

China Customs released 2005 pesticide trade data, as follows:

1. Imported 36,739 metric tons, a 33-percent increase over 2004; import value was US\$182 million, a 24-percent increase over 2004;
2. Exported 428,572 metric tons, 9.4-percent increase over 2004; export value was US\$1.4 billion, an 18-percent increase over 2004;
3. Produced 1.04 million metric tons, a 20-percent increase over 2004;
4. Exported 203,500 metric tons of herbicides;
5. Export product volume was number one in the world, at 19.5 percent;
6. Export value was number four in the world, at 9.6 percent.

MOA and Customs Re-issued Pesticide Import and Export Certification Management List

MOA and Chinese Customs issued a new pesticide import and export management list on December 31, 2005 that will be effective as of July 1, 2006. Since 1999, Chinese importers and exporters of pesticides have been required to obtain a certificate from MOA for customs declaration purposes.

Next Five-Year Plan for Chinese Pesticide Industry

On February 27, 2006, ICAMA organized a national pesticide administrative meeting in Beijing. The Vice Minister of MOA stated that ICAMA will try to reach the following goals by the end of 2010: (1) reduce the highly toxic pesticide registration rate by five percent, compared to 2005 figures, to seven percent of all registrations; (2) increase formal registrations to over 80 percent of all registrations; (3) increase the current pass rate of ten percent to over 90 percent in market-selective examinations of product quality; (4) increase the current pass rate of 20 percent to 80 percent for market-selective examinations of product labels; (5) reduce illegal pesticide residues on green agricultural products to under three percent of total volume; (6) increase the current pesticide use efficiency rate by five percent to 35 percent.

Pesticide Enforcement and Restriction on Manufacturers in China

On February 16, 2006, ICAMA cancelled 20 provisional registrations due to the production of adulterated products by 23 Chinese manufacturers. As of July 1, 2006, the National Development and Reform Commission will increase the financial requirements to register a pesticide-producing establishment in China: (1) technical manufacturers, 30 million RMB (US\$3.75 million); (2) formulators, ten million RMB (US\$1.25 million); and (3) rodenticide and sanitary manufacturers, five million RMB (US\$625,000).

R&D and New Pesticides in China

Chinese pesticide companies have developed the following new biopesticides in 2005: nitenpyram, neochamaejasmin, *Tripterygium wilfordii*, and brassinolide. These new biopesticides have passed ICAMA's provisional registration requirements and field trials.

Second Annual China Pesticides Program

CropLife America, McKenna Long & Aldridge LLP, and MTD Ventures, LLC hosted the Second Annual China and Pesticides: New Markets, New Sources Program on June 14, 2006 in Washington, D.C. China offers U.S. companies a growing domestic market for both agricultural and specialty pesticides. The program was devoted to helping attendees understand China and its regulation of pesticide products is essential to U.S. pesticide producers and marketers.

Speakers at this year's Program included Mr. Liu Shao-Ren, Director, Registration Division, ICAMA, Beijing; Mr. Sun Shou-hong, Disinfectant Control Section, MOH, Beijing; Anne Lindsay, Deputy Director, Office of Pesticide Programs, US EPA; and Mr. Zhao Bao-qing, representative of AQSIQ at the Embassy of the Peoples Republic of China in Washington, D.C.

The program included the following topics: China's regulation and registration of agrochemicals; China's regulation of agricultural biotechnology; China's program to reduce production and use of toxic pesticides; China's regulation of imports and exports of food and pesticides; China's regulation of disinfectants; US EPA-China cooperation on pesticides and GLPs; sourcing pesticides and intermediates from China; complying with US EPA and ICAMA requirements; and protecting pesticide registration data and other IP in China.

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