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China – Law Firms

China's Regulation Of Pesticides

John D. Connor, Jr.
and Jeffrey Li

McKENNA LONG & ALDRIDGE LLP

After the United States, China is the second largest producer of pesticides. China's steps to improve IP protection,¹ its growing domestic and export agricultural market, lower manufacturing costs and recent efforts to harmonize its pesticide regulatory system have prompted U.S. and multinational pesticide companies to assess China's pesticide market. Even if a company chooses not to enter China's pesticide market and face approximately 2,500 Chinese pesticide manufacturers, a company outside China that sources intermediates or pesticides from plants in China must confirm the registration status of the pesticide in China because, as explained below, production in China triggers the pesticide registration requirement. This article reviews China's regulation of pesticides.

China's Institute For Control Of Agrochemicals Of The Ministry Of Agriculture ("ICAMA")

The manufacture and sale of agricultural pesticides in China is regulated by the Institute for the Control of Agrochemicals of the Ministry of Agriculture ("ICAMA") established in 1963 by the Ministry of Agriculture ("MOA"). ICAMA has approximately 100 staff members who work in eleven divisions, including registration, bioassay, quality control, residue, biotech and environmental and import and export divisions. In addition to ICAMA's regulation of pesticides at the national level, pesticides are regulated under a federated program at the province, city and county levels. ICAMA's responsibilities include implementing regulations, issuing pesticide registration guidelines, reviewing and approving pesticide advertising, inspecting markets that sell pesticides, supervising pesticide quality, conducting efficacy and residue trials, and training technicians and administrators of the provinces. ICAMA is headed by a Director and at present two deputy directors.

China's Pesticide Laws And Regulations

China's principal law governing pesticides is called the *Regulation on Pesticide Administration* ("RPA") issued on May 8, 1997, by the State Council and amended on November 29, 2001, to address requirements of China's admission to WTO. On April 27, 1999, MOA adopted *Implementations for RPA* and amended these regulations in July 2002 and 2004. In 2001, MOA

John D. Connor, Jr. is a Partner in the Washington, DC office of McKenna Long & Aldridge LLP, practicing in the area of pesticide, chemical and environmental regulation. Jeffrey Li is an Associate in the Washington, DC office of the firm, specializing in the area of regulatory, trade and business law. He assists U.S. companies that desire to do business in China. Mr. Li holds a Chinese law degree and is a member of the New York bar (not admitted in DC). The authors wish to thank Mr. Ye Jiming, Deputy Director, Institute for Control of Agrochemicals, Ministry of Agriculture, Beijing, for his assistance on this article.



John D. Connor, Jr.

adopted *Data Requirements of the Pesticide Registration*. ICAMA has also issued regulations on product quality and pesticide advertising.

The RPA, Article 2, defines "pesticide" as any chemical, biological or natural substance used for preventing, destroying or controlling disease, pests, weeds and other harmful organisms inimical to agriculture and forestry and for regulating the growth of plants and insects. While Article 2 defines a pesticide as any substance used to control a pest inimical to agriculture and forestry, the Article also includes within the definition pesticides used "for different purposes and in different places," for example, pesticides to control non-agricultural pests.

Registering Pesticide Manufacturing Plants And Pesticide Products

In China, a company must obtain a license to produce pesticides. Pesticides produced at a licensed facility must meet national, trade or business product quality standards. In addition to holding a license to produce pesticides, a company that produces pesticides must register its pesticide products with ICAMA. It is unlawful in China to either produce or import a pesticide unless the product is first registered. In the U.S., under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), it is unlawful to sell or distribute a pesticide unless the pesticide is registered with the U.S. EPA. (7 U.S.C. § 136a.) Because FIFRA regulates the sale and distribution of a pesticide, a company may produce and sell for export only an unregistered pesticide as long as the producer complies with the Act's foreign purchaser acknowledgement requirements. (7 U.S.C. § 136o.) In contrast, in China a producer of a pesticide intended for export only must register the pesticide. Thus, a U.S. company that sources a pesticide from China should take steps to assure that the product is registered with ICAMA even if the pesticide is not sold in the country.

China's RPA provides for three stages of pesticide registration: the field test, the temporary registration and the formal ('full') registration stage. A field trial registration permits the developer of a pesticide to collect efficacy, residue and environmental data from study plots less than 10 hectares. As local soil and weather conditions may influence the results of these studies, as with many countries, field studies must be conducted in China. The applicant for a field permit must submit product



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chemistry, acute toxicity data on the formulated and technical product, as well as residue and environmental toxicology studies from other countries. Domestic companies file applications for field and temporary registrations with the local provincial or municipal institutes for control of agrochemicals ("ICA's"). Foreign manufacturers file their applications with ICAMA. Products with a field stage registration may not be distributed for sale.

A temporary registration permits larger field or sales trials within a specified area or use under special conditions. The temporary registration is renewable annually up to a maximum of four years. The application for temporary registration to conduct residue trials must include oncogenicity, developmental toxicity and mutagenicity data, as well as residue studies showing residues below an established maximum residue limit ("MRL"). Pesticides with a temporary registration may be distributed for sale.

Foreign and domestic companies both submit applications for full registrations to ICAMA. The applicant for full registration must submit data on product identity, manufacturing, product chemistry, efficacy, residues, environmental fate, ecological effects and the proposed label. Some older pesticides have passed the four year maximum provisional registration period but have not been fully registered. ICAMA is coordinating a voluntary, cost-sharing program to help manufacturers to support full registration for older products. Only products provisionally registered before July 23, 1999, are eligible for this program. ICAMA may extend provisional registration until December 31, 2008.

Under the RPA, pesticide data for a new active ingredient are "protected" for a period of six years from the date of initial full registration. Protected data may not be disclosed or relied upon by ICAMA to support another registration. A follow-on applicant must still conduct its own field trials.

Maximum Residue Limits ("MRL's") In China

In China, ICAMA establishes maximum residue limits ("MRL's") for active ingredients and crop uses registered in China. ICAMA looks to MRL's set by EPA, the Codex Alimentarius Commission ("CAC") and other countries. China's General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) inspects imported commodities

for pesticide residue levels against a domestic MRL or in the absence of a domestic MRL, a tolerance set by CAC or the commodity's country of origin.

ICAMA's Future Initiatives

ICAMA, as well as China's State Food and Drug Administration (SFDA) and its State Environmental Protection Agency ("SEPA"), is taking steps to integrate China's analytical, environmental and toxicological testing laboratories into OECD and EPA GLP standards system to assist in the acceptance of China's data outside of the country. In March, 2005, U.S. EPA and China ICAMA signed a letter of intent on China's development of GLP standards for testing laboratories and the mutual acceptance of data between the two countries. The U.S./China letter of intent calls for GLP training and certification of Chinese laboratories leading to the mutual acceptance of data between EPA and China. Additional future initiatives of ICAMA include harmonization of pesticide data requirements, including maximum residue limits and pesticide data reviews, strengthening protection of intellectual property, and increasing cooperation and exchange of information with pesticide regulators in the west.

China's Regulation Of Disinfectants And Sanitizers

In the U.S., EPA regulates traditional pesticides and disinfectants – pesticides used to control microorganisms, including pathogens. In China, the Ministry of Health ("MOH") regulates the manufacture or distribution of disinfectants in accordance with the *Food and Health Law of China, Disinfection Administrative Measures and Disinfectant Products Application and Acceptance Regulations*. A company must hold two permits to make and sell a disinfectant: a manufacturing permit (called 'Disinfectant Products Manufacturer Permit') for the manufacturing facility and a product permit (called 'Product Health Permit') for each disinfectant product manufactured at the facility and sold by the manufacturer. A disinfectant distributor must obtain a copy of the manufacturer's manufacturing permit and its product permit before purchasing from the producer. To import a disinfectant product into China, the foreign manufacturer does not need a manufacturing permit but must obtain a product permit. An applicant for a disinfectant product permit must submit toxicology, product chemistry and efficacy data. Studies must be conducted at an MOH-authorized laboratory, and while EPA data may be referenced, it will not be accepted by MOH. A panel of experts at MOH's evaluation committee meets and acts on product applications quarterly.

Conclusion

Increasingly China's regulation of pesticide will assume more and more attributes of other regulatory pesticide systems: data harmonization, data protection, uniformed labeling and the safety assessment of older pesticides. This integration and harmonization of China's regulatory system will assist in opening China's pesticide market to foreign investment and assist China's growth and participation in international markets.

¹ Chemical and Engineering News, page 25 (September 19, 2005).

Please email the authors at jconnerjr@mckennalong.com and jli@mckennalong.com with questions about this article.