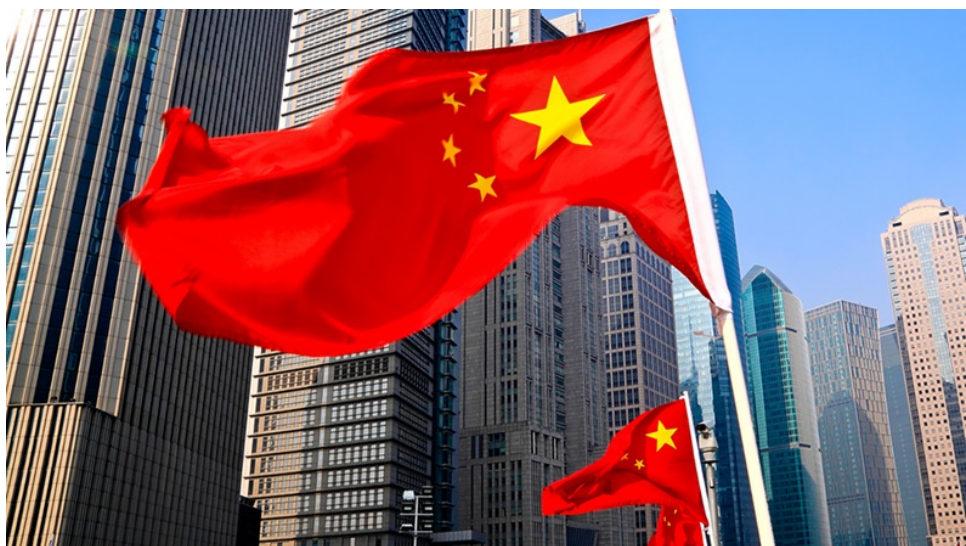


China establishes new pesticide regulations

13 Jun 2017 | **NEWS**

by Agrow Editorial Team |

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A new set of regulations governing pesticides in China became effective on June 1st. The Regulation on Pesticide Administration was released during the 164th executive meeting of the State Council on February 8th. The Regulation contains revised rules that replace the first Regulation promulgated by Decree 126 of the State Council of the People's Republic of China on May 8th 1997.

The Regulation covers the entire process from pesticide trials, registration, production, trade and use to pesticide monitoring, assessment and evaluation. The new edition draws on the advanced pesticide management experience and common practices of developed countries with an aim to provide a suitable and effective guarantee for addressing practical issues in China. The overall principle is to reduce duplication of management, simplify administration processes, empower the provincial level institutes for the control of agrochemicals, and to become more market oriented.

The new pesticide management Regulation is composed of eight chapters with 66 articles, 17 more than the first Regulation. The chapters are: general principles; pesticide registration; pesticide production; pesticide operation; pesticide use; supervision; legal responsibilities; and supplementary rules.

The major changes lie in the qualification of product registration applicants, the members of the national pesticide registration review committee, the management of pesticide registration trial entities, the management of pesticide production, operation and use, and the penalties on illegal activities.

The Regulation lays out the structures of regulatory bodies. The Ministry of Agriculture (MoA) is the only central governmental Ministry to administer national pesticide management, with the duties of pesticide registration, production licences, operation licences, pesticide use and penalties for illegal activities. Agricultural departments, at and above county level, are responsible for pesticide management within their administrative jurisdictions. Departments of safety supervision, environment protection and public security are responsible for safe production, waste management and fire control according to relevant laws, respectively.

In order to encourage innovation, the developers of new active ingredients are entitled to be main registration applicants. The data protection period for a new ai is six years. New ai developers are allowed to transfer the data package of registered pesticides to other qualified applicants. In order to reduce duplicate registration, promote the flow of registration information and encourage the smaller pesticide enterprises to exit the market in an orderly manner, registration certificate holders are allowed to transfer their registration data dossier packages to other pesticide production enterprises with the corresponding production capacity. Furthermore, the new Regulation permits the waiving of residue and environmental studies if the applicant's product(s) use patterns are substantially the same as the registered ones, and a letter of consent is given from previous registrants. It also clearly notes that the Institute for the Control of Agrichemicals, Ministry of Agriculture (ICAMA) is responsible for pesticide registration review. Provincial Institutes for the Control of Agrochemicals (ICA) assist in pesticide registration review within their administrative jurisdictions.

The new Regulation stipulates that the MoA shall organise and establish a National Pesticide Registration Review Committee, which will be composed of qualified professionals from the Ministries of Agriculture, Forestry, Health, Environment Protection, Grain and Industrial Management.

To streamline the administration of field trial permit examination and approval, the new Regulation states that only new ai registrants need apply for field trial permits from the MoA. For off-patent ais, field trials are to be notified to the provincial ICA.

The Regulation also establishes a pesticide registration field trial entity or contractor identification system. Pesticide registration trials shall be performed by trial entities certified by the MoA. The trial entities are expected to be responsible for the authenticity of the trial reports.

The Regulation ends temporary registrations, which were perceived to be giving rise to issues such as incomplete toxicological and environmental data, and a number of registration of the same ais.

Further changes include the implementation of a pesticide registration renewal system with the registration certificate being valid for five years. Re-evaluations are going to be carried out for “high-risk” products.

Product label management has been strengthened under the Regulation. It is forbidden to tamper with the authorised label with fake or misleading information. The product name, ai, content and toxicity should be clearly identified on the label as well as prominent indication of use restrictions. Electronic traceability information codes need to be added to the label.

Pesticide operators are required to keep purchase and sales records for two years. Agricultural production enterprises, food and agricultural products warehousing enterprises, specialised IPM organisations and co-operatives shall also maintain for two years, pesticide use records on time, locations, target pests, product name, quantities, and production enterprises.

National level agricultural departments shall conduct surveys and maintain statistics of pesticide production, sales and use on a regular basis and notify relevant departments in a timely manner. Agricultural departments at and above county level shall fulfill pesticide supervision and management functions.

In case of improprieties related to pesticide production and operating without a licence, a ten-year ban can be imposed or the registration certificates and licences revoked.

Further guidance to the Regulation in the form of 21 supporting rules documents are being developed following the Regulation having come into effect.

In order to address the issues that need immediate solutions, China will initiate a new production R&D policy, minor crop and biopesticide registration policy, establish a residue standard system, and apply risk assessment technologies in registration.

(The article was written by Puguo Zhou, Director General of ICAMA (Institute for the Control of Agrochemicals, Ministry of Agriculture) and Shuyou Han, Agrow Correspondent (China).



