Introduction to Pesticide Management Regulation

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I. Overview

- The Pesticide Management Regulation (Revised Draft)
  - adopted by the Executive Meeting of the State Council on 8 February 2017,
  - released by the Xinhua News Agency on 1 April 2017,
  - and put into effect from 1 June, 2017.

- The Pesticide Management Regulation
  - was issued and implemented on 8 May 1997,
  - revised for the first time in November 2001
  - and the current one is the second revision.
• Pesticide Management Regulation is the basic regulation for pesticide management in China, covering the whole process from pesticide trial, registration, production, trade, use, monitoring and evaluation.

• The revision has referred to experience and practices of some developed countries in pesticide management, trying to address current problems and provide more appropriate and effective institutional guarantee. Main principles
  
  – Reduce duplication and overlapping.
  – Streamline administration, delegate power and give play to the role of the market to the extent possible.
# Main structure

66 articles in 8 chapters for the 2017 Version

1. General Principles 6 articles  
2. Pesticide Registration 9 articles  
3. Pesticide Production 8 articles  
4. Pesticide Operation 6 articles  
5. Pesticide Use 10 articles  
6. Supervision 9 articles  
7. Legal Responsibilities 16 articles  
8. Supplementary Rules 2 articles

49 articles in 8 chapters for the 2001 Version

1. General Principles 5 articles  
2. Pesticide Registration 6 articles  
3. Pesticide Production 6 articles  
4. Pesticide Operation 6 articles  
5. Pesticide Use 6 articles  
6. Penalty 8 articles  
7. Supplementary Rules 2 articles  
8. Others 10 articles
The 2017 Version and the 2001 Version are basically the same in the overall structure; both are composed of 8 chapters, but the 2017 Version includes 17 additional articles.

The 2017 Version involves major changes in the management system, qualification requirements of pesticide registration applicants, the composition of National Pesticide Registration Review Committee, the management of pesticide registration trial entities, competent departments of pesticide production, pesticide operation and use management and punishment on illegal behaviors, with more clearly identified legal responsibilities.
II. Main revisions

• Management system
  – The Ministry of Agriculture is responsible for national pesticide management, including pesticide registration, production license, operation license, pesticide use and punishment of illegal behaviors.
  – Agricultural departments at and above the county level are responsible for pesticide management within its jurisdiction.
  – Departments of safety supervision, environment protection and public security are responsible for supervision of safe production, wastes and fire control according to law.

• In terms of administrative licensing,
  – The Ministry of Agriculture is responsible for pesticide management and the management of pesticide registration trial entities.
  – Provincial agricultural departments are responsible for production licensing management.
  – Agricultural departments at and above the country level are responsible for pesticide operation licensing management.
Pesticide registration

- China implements pesticide registration system. Pesticide production enterprises, enterprises exporting pesticides to China and developers of new pesticides could apply for pesticide registration.
  - Add the developers of new pesticides and encourage innovation.
- Protection period for data of new pesticide registration is 6 years.
- ICAMA is responsible for pesticide registration review. Provincial institutes for the control of agrochemicals assist in pesticide registration review within the jurisdiction.
• New pesticide developers could transfer data of registered pesticides.
• Production enterprises could transfer registration data to pesticide production enterprises with corresponding production capacity.
  – Reduce duplicate registration, promote appropriate flow of resources of the pesticide industry, encourage weak enterprises to exit the market in an orderly manner.
• The Regulation identifies that the MOA shall establish National Pesticide Registration Review Committee.
  – Departments of agriculture, forestry, health, environment protection, grain, industrial management shall recommend experts to participate in the Review Committee in personal capacity.
  – Departments of agriculture, forestry, health, environment protection, grain, industry and production safety supervision and management shall send representatives to participate in the Review Committee.
  – The National Food Safety Risk Assessment Expert Committee shall also recommend experts.
• The scope of examination and approval of pesticide registration trials is narrowed down.
  – New pesticide registration trial shall apply for administrative license and the Ministry of Agriculture is responsible for examination and approval;
  – Non-new pesticide registration trial only needs to report for record with provincial agricultural department;
  – Streamline administration and delegate power, reduce examination and approval.

• Focus of trial management is adjusted from efficacy to examination of safety risks of trials and precautionary measures.
• Establish pesticide registration trial entity identification system. Pesticide registration trial shall be undertaken by trial entities identified by the MOA. Registration trial entities shall be responsible for the authenticity of the trial report.

  – Regulate trial behaviors, strengthen supervision on registration trial samples and trial entities and guarantee the authenticity and traceability of data.

  – Conform to international practices and facilitate international data mutual recognition.
• Abolish temporary registration.
  – *Temporary registration has been introduced since 1980s and served as an interim practice to encourage registration and promote industrial development.*

  – *Disadvantages have been gradually shown: incomplete data of toxicology and environment trial, difficult to conduct risk assessment; low threshold and a large mount of homogeneous products.*
• Implement registration renewal. Pesticide registration certificate is valid for 5 years.

• Establish pesticide monitoring and re-evaluation mechanism.
  – *Provincial and above agricultural departments monitor the safety and effectiveness of the use of registered pesticides;*
  – *Registration re-evaluation shall be carried out for pesticides with serious harm or high risks;*
  – *Decisions on restricted or banned use be made according to the review results.*
• Strengthen open government.
  – Approval, issuance and renewal of pesticide registration certificates;
  – Changes of pesticide registration certificates;
  – Product labels authorized by the pesticide registration;
  – Product quality standard number, **maximum residue limits** and inspection methods of pesticide registration.
Pesticide production permit

• Continue to implement pesticide production license system.
  – Harmonize fixed authorization and production license into one pesticide production license; one license for one enterprise.
  – Production scope authorized according to technical products and formulation.
• Provincial agricultural departments are responsible for implementation.
• Conditions of production license are prescribed.
  – Conform to industrial policy.
  – Technology, personnel, factories and other production facilities and pesticide quality management system shall meet requirements.
• Allow commissioned processing and repackaging.
  – *Consignor shall obtain corresponding pesticide registration certificate.*
  – *Consignee shall obtain pesticide production license.*

• Strengthen product label management.
  – *Changing authorized label information arbitrarily and including fake and misleading information in label is forbidden;*
  – *Pesticide name, active ingredient, content and toxicity shall be clearly identified on the label.*
  – *Labels of pesticides of restricted use should carry the words Restricted Use in prominent positions.*
  – *Increase e-traceability information code.*
Pesticide operation license

• Increase pesticide operation license system. Exclusive operation is changed into licensed operation.
  – The operation of public health pesticides is exempted.

• Agricultural departments at and above county level are responsible for implementation.
  – The operation of highly toxic pesticide shall obtain permission for provincial agricultural departments.

• Qualification requirements on operators
  – The operators shall be equipped with professional knowledge of pesticide, pests and disease control, familiar with pesticide management regulations and be able to guide safe and appropriate use of pesticides;
  – The operators shall have operation premise and storage sites that are effectively isolated with other commodities, sources of drinking water and living zones, and be equipped with protective facilities compatible with the pesticides concerned;
  – The operators shall have systems of quality management, account keeping, safety protection, emergency handling and storage management compatible with the pesticide concerned.
• Designated operation of pesticides of restricted use.
  – Highly toxic pesticides and pesticides of which the use is technically demanding.
• Establish incoming goods inspection and purchase and sales account keeping system.
  – Pesticide operators shall keep purchase and sales accounts and faithfully record the information of pesticide name, specification, quantity, production enterprises, purchasers, buyers and data of sales of pesticides purchased and sold.
  – Purchase and sale account shall be maintained for over 2 years.
• Notification system
  – Ask for the situation of pests and diseases and make scientific recommendation of pesticides. Explain use methods correctly.
Pesticides use

- **Strengthen pesticide use guidance and training.**
  - **Agricultural departments at and above the county level shall organize institutions of plant protection, agricultural extension among others to provide free technical training for pesticide users.**
  - **Encourage agricultural research institutes, schools, specialized farmers' cooperatives, supply and sales cooperatives, public service agricultural organizations and specialized staff to provide technology services for pesticide users.**
  - **County-level agricultural departments encourage the establishment of specialized pest and disease prevention and control service organizations to provide guidance, regulation and management of specialized pest and disease prevention and control and formulation and use of pesticide of restricted use, and enhance the level of pest and disease prevention and control.**
Agricultural products production enterprises, food and agricultural products warehousing enterprises, specialized IPM organizations and specialized cooperatives shall establish pesticide use record.

- **The time, location, target of pesticide application, and the name, quantity used and production enterprises of the pesticide shall be recorded.**
- **Use record shall be maintained for over 2 years.**
• Pesticide users are forbidden to use virulent and highly toxic pesticides to prevent and control public health pests, in the production of vegetables, melons and fruits, tea, fungus and traditional Chinese medicines, for the prevention and control of pests and diseases of aquatic plants and in protection zones of sources of drinking water.

• Pesticide users are encouraged to appropriately collect pesticide packages and other wastes; pesticide production enterprises and operators shall recover pesticide wastes and prevent pesticides from polluting the environment and prevent pesticide intoxication accidents.

• Labels of pesticide products for agricultural products for food use shall indicate PHI.
Supervision and management

• County-level agricultural departments shall conduct survey 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.

• Establish accident report system.
  
  – Production enterprises: suspend production, inform operators and users, and report to competent departments.
  
  – Operators: suspend sales, inform producers, suppliers and users, and report to competent departments.
  
  – Users: suspend uses, inform operators and report to agricultural departments.
Increase problem pesticide recall system: if pesticides with serious harm or relatively high risks to agriculture, forestry, human and animal safety, quality and safety of agricultural products and ecological environment are detected, producers, operators and users shall take measures and recall the products in a timely manner.

- **Production enterprises:** suspend production, inform operators and users, report to competent departments and recall products proactively.
- **Operators:** suspend sales, inform producers, suppliers and users, and report to competent departments, and recall products from users.
  - **Users:** suspend uses, inform operators and report to agricultural departments.
  - **Manager:** supervise or order for recall.
Legal responsibilities

• Identify that any person that violates regulations shall be punished correspondingly according to the seriousness of the case. The penalty ranges from order for correction, name off, punishment to criminal sanctions.
  – If agricultural departments at and above county level and their staff fail to exercise supervision and management functions and lead to serious loss or baneful social influence, misuse authority and neglect duty;
  – If members of the Pesticide Registration Review Committee seek illicit profits in pesticide registration review;
    – If the registration trial entity issues fake report of trial for registration, the trial entity for pesticide registration will be disqualified; administrative punishment will be imposed; and its qualification application will not be accepted within 5 years.
• For producers:
  – The sum of fine on the production of pesticides without production license or the production of fake pesticides is no less than 50,000 yuan;
  – The sum of fine on the production of substandard pesticides with production license is no less than 10,000 yuan;
  – For the production of fake pesticides, pesticide production license and relevant pesticide registration certificates shall be revoked;
  – In case of a revocation of pesticide registration certificate, pesticide registration application will not be accepted within 5 years.
Pesticide operation without license

- shall be outlawed,
- and illegal earnings, pesticides of illegal operation, tools and equipment used for illegal operation, etc. shall be confiscated.
- Fine: no less than 5,000 yuan;
- If the case constitutes crime, the violator shall be prosecuted for criminal liability.
• Fake pesticide operation
  – *Order the suspension of operation*;
  – *Confiscate illegal earnings and pesticides, among others*;
  – *Fine: no less than 5,000 yuan*;
  – *May revoke pesticide operation license*;
  – *If the case constitutes crime, the violator shall be prosecuted for criminal liability.*
In any of the following cases, the users shall be ordered for correction and be punished:

- Do not use pesticide according to pesticide label;
- Use of banned pesticides;
- Use virulent and highly toxic pesticides to control public health pests, for the production of vegetables, fruits, tea, fungus and traditional Chinese herbs or for the control of pests and disease of aquatic plants;
- Use pesticides in protection zones of sources of drinking water;
- Use pesticides to intoxicate fish, shrimp, bird and animals;
- Litter pesticides and pesticide packages or clean pesticide application equipment and machines in protection zones of sources of drinking water.
• Rules of sanctions
  – **In case of pesticide production and operation without licenses or the revocation of registration certificates and licenses, the person directly responsible shall be banned from pesticide production and operation activities for 10 years.**
III. Next steps

- According to the authorization to agricultural departments by the Regulation, 21 rules or regulatory documents are to be developed. 10 rules or regulatory documents will be prioritized.
  - Other 11 documents, such as Policy on Pesticide Industry, Review criteria for registration, and so on.
• Focus on the study of issues that require immediate solution in agricultural production and greatly concern pesticide enterprises.
  – Encourage new production R&D policy.
  – Minor crop and bio pesticide registration policy.
  – Phasing out existing highly toxic pesticides.
  – Accelerate the establishment of residue standard system.
  – Accelerate the application of risk assessment technologies in registration.