

Guide on Pesticide Registration and Regulation in China

Prepared by Hangzhou REACH Technology Group Co., Ltd. (CIRS Group)



Disclaimer:

Guide on Pesticide Registration in China is a resource for companies and individuals who want to have their pesticide products registered for sale in The People's Republic of China. The guide describes the review process of Institute for the Control of Agrochemicals (ICAMA), The Ministry of Agriculture and Rural Affairs (MARA) of the People's Republic of China for registering a pesticide product and its use.





Content

Chapter 1 - Introduce of Pesticide in China3	; -
1.1 Definition of pesticide in China3	
1.2 Pesticide application categories in China6	
Chapter 2 - Pesticide Regulation in China 9) -
2.1Authorities) -
2.2 Pesticide Regulatory Framework in China	
2.3 China Pesticide Technical Specification15	; -
2.4 Contract Research Organizations (CROs)16	<u>,</u>
Chapter 3 - How to Register a Pesticide Product in China18	; -
Chapter 4 - Registration fees23	; -
Chapter 5 - Pesticide Production24	ļ.
5.1 Pesticide Production Supervision Department24	ļ.
5.2 Entry Qualification24	ļ.
5.3 Process on Apply for Pesticide Production License25	; -
5.4 Requirements for Application Materials of Production License 25	; -
5.5 Tolling Pesticide26	<u>,</u>
Chapter 7 - Pesticide Import and Export Requirements27	٠.
Chapter 8 - Pesticide Labeling Requirements28	; -
Chapter 9 - Pesticide Business Management Requirements 29) -
Summary 29) .



Chapter 1 - Introduce of Pesticide in China



Introduction

Welcome to the introduce of pesticide in China. This page is an introductory resource for companies and individuals who wish to sell their pesticide products in China. While this chapter provides the definition of the pesticide related clause and how to determine what type of registration that might apply to your product.

1.1 Definition of pesticide in China

A pesticide

refer to a substance or mixture or other formulation of one or more substances derived from chemical synthesis, or originating from biological and other natural sources, used to prevent or control diseases, insects, weeds or other living beings harmful to agriculture and forestry, and to purposely regulate the growth of plants and insects.

The pesticides mentioned in the preceding paragraph include the following types used for different purposes and places:

- (1) To prevent or control diseases, insects (including insects, ticks, and mites), weeds, rodents, mollusks and other organisms harmful to agriculture and forestry;
- (2) To prevent or control diseases, insects, rodents and other organisms harmful to storehouses and processing sites;
- (3) To regulate the growth of plants and insects;
- (4) To be used as preservatives in agricultural or forestry products;
- (5) To prevent or control mosquitoes, flies, cockroaches, rodents and other harmful organisms;
- (6) To prevent and control harmful organisms endangering rivers, dams, railways, docks, airports, buildings and other places.

New pesticides

refer to pesticides whose active ingredients have not been approved for registration in China, including new pesticide TCs (TKs) and new pesticide formulations.



Active ingredients

refer to particular biologically active chemical structural components or organisms within pesticides.

Technical material (TCs)

refer to products composed of active ingredients and relevant impurities generated from the production process. They may be added with a small amount of addictive as needed.

Technical concentration (TKs)

refer to products composed of active ingredients and relevant impurities generated from the production process. They could contain a small amount of necessary additive and applicable diluent.

Formulations

refer to products in a stable state processed with pesticide TCs (TKs) and applicable adjuvants or processed using the biological fermentation and/or the phytoextraction methods, etc.

Adjuvants

refer to single-component or multi- component substances that are added to a pesticide on top of active ingredients, and that do not have any pesticide activity or function of active ingredients themselves, but can or will help improve the physical and chemical properties of the pesticide.

Impurities and relevant impurities

impurities refer to by-products generated from the pesticide production or storage process; relevant impurities refer to, compared with active ingredients of a pesticide, impurities contained in or generated from the pesticide production or storage process and that are obviously hazardous to humans and the environment, and will poison the crops, cause contamination to or compromise the quality stability of agricultural products or give rise to other adverse effects.

Me-too TCs

refer to TCs applied for registration that have the contents of active ingredients and other main quality specifications no lower than the registered TCs, and the adverse effect of impurities which contain is basically on the same level or lower than the registered ones.

Me-too formulations

refer to formulations applied for registration that have the same content of active ingredients, the same type and content of other restrictive components, the same dosage form, and the same TC as the registered ones, and that do not contain any other adjuvant that will result in significant increase of the product toxicity or environmental risks, and have main quality specifications no lower than those of registered products.

Similar formulations

refer to formulations applied for registration that have a content of active ingredients and a dosage form same as, and other components different from, the registered ones.