

Overview of China pesticide registration regulation




Tinting Guo





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A photograph of a wheat field at sunset. The left side of the image shows the wheat in detail, while the right side is a white overlay with text. The text is in a dark, sans-serif font and is centered vertically on the white background.

CN pesticide regulatory system and policy

Chinese pesticide regulatory system

- On May 8, 1997: Regulation on Pesticides Administration.
- New act is issued on April, 2017, implemented on June 1, 2017 ; the regulation contain 8 parts including registration, production, business, usage, management etc..
- 5 related management measures including registration, production, business, tests, labels etc..
- MARA (MoA): Ministry of Agriculture and Rural Affairs
<http://www.moa.gov.cn/>
- ICAMA: The Institute for the Control of Agrochemicals, Ministry of Agriculture

<http://www.chinapesticide.gov.cn/>

Chinese pesticide regulatory system

Total number of pesticide registrations and new registrations in recent 10 years

| Year | Enterprise quantity | Product quantity |
|-------------|---------------------|------------------|
| 2011 | 2328 | 26218 |
| 2012 | 2320 | 27273 |
| 2013 | 2286 | 29737 |
| 2014 | 2243 | 31813 |
| 2015 | 2232 | 34315 |
| 2016 | 2218 | 35604 |
| 2017 | 2206 | 38247 |
| 2018 | 2129 | 41518 |
| 2019 | 1943 | 41229 |
| 2020 | 1909 | 41885 |

Chinese pesticide regulatory system

- Total number of registered enterprises (up to 31st December 2020)

| Enterprise quantity | Local | Oversea | Total |
|--------------------------|-------|---------|-------|
| Enterprise Number | 1786 | 123 | 1909 |
| Including: TC enterprise | 673 | 77 | 750 |
| Formulation enterprise | 1696 | 108 | 1804 |

Chinese pesticide regulatory system

Status of Pesticide Registration

- Sum of pesticide registration number: (up to December 31, 2020)
- Total number of registrations: 41,885
- Active ingredients: 714

Chinese pesticide regulatory system

Pesticide definition

To prevent or control diseases, pests, weeds, rodents, mollusks and other organisms harmful to **agriculture and forestry**

To prevent or control diseases, pests, rodents and other organisms harmful to **storehouses and processing sites**

To regulate the growth of plants and insects

Pesticide



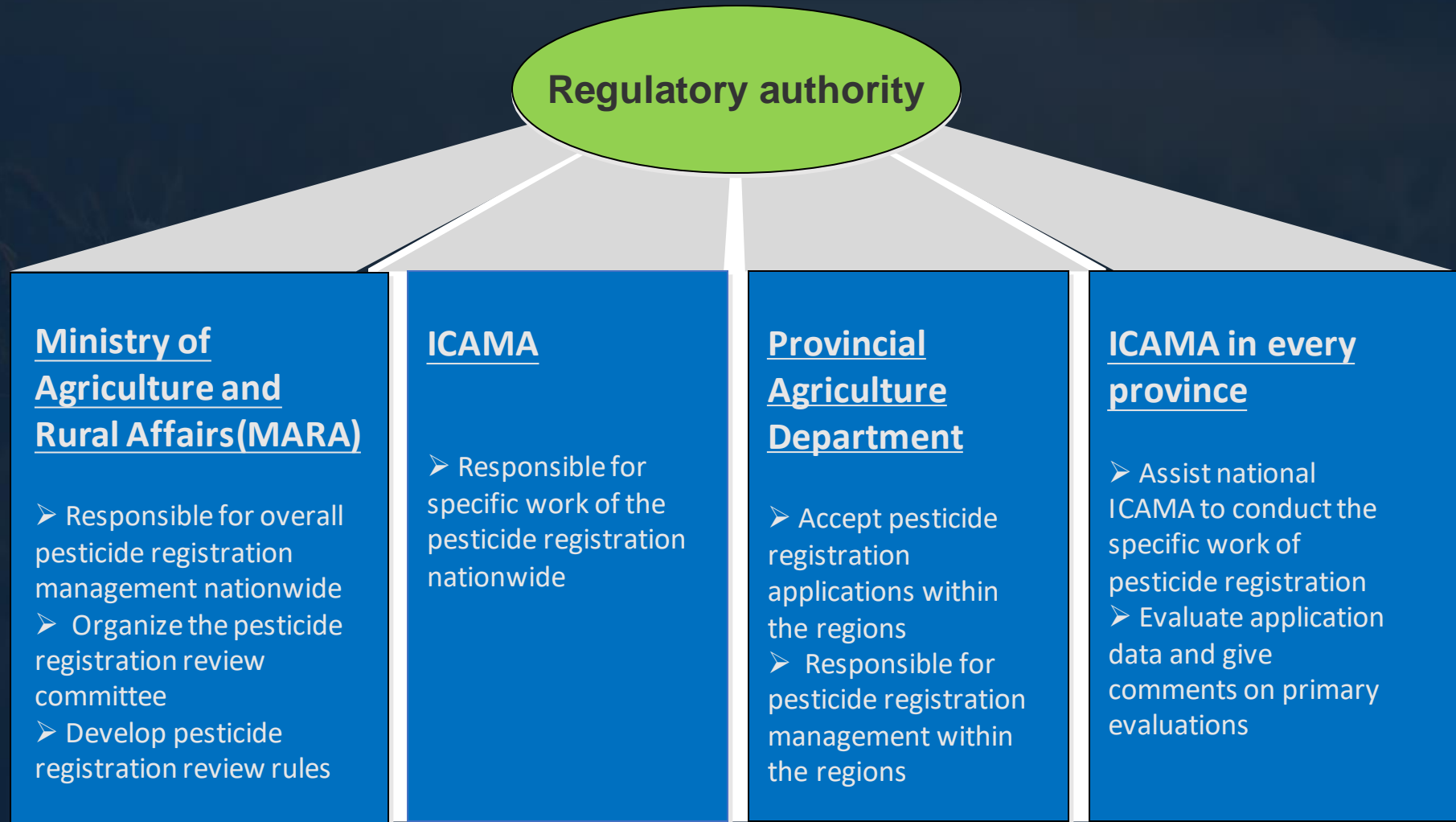
A substance or mixture or other preparation of one or more substances derived from chemical synthesis, or originating from biological and other natural sources, used to **prevent or control diseases, pest insects, weeds or other living beings harmful to agriculture and forestry**, and to purposely **regulate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

To be used as preservatives in agricultural or forestry products

To prevent or control mosquitoes, flies, cockroaches, rodents and other harmful organisms

To prevent or control organisms harmful to dykes and dams, railways, ports, airports, buildings and other sites

Chinese pesticide regulatory system Regulatory authority



Chinese pesticide regulatory system

Registration Operation Process

Provincial agricultural sector

➤ **20 working days** give comments on the preliminary review and report result to ICAMA.

ICAMA

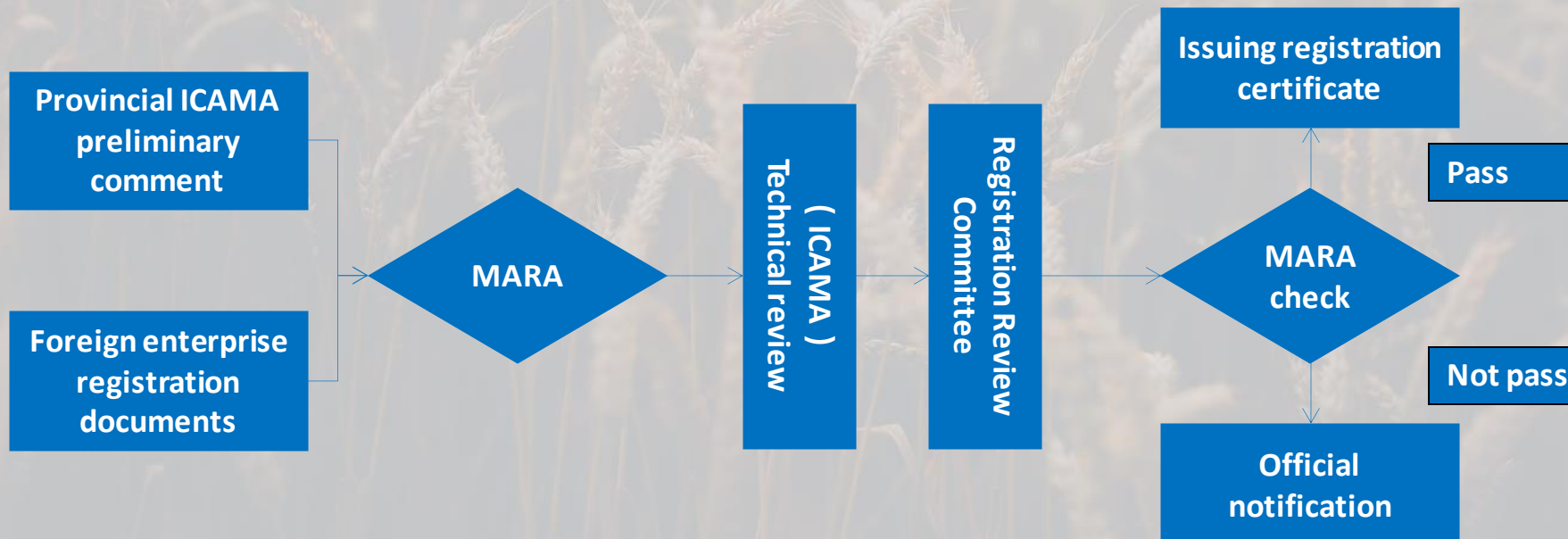
- Accept dossier and preliminary evaluation comments from provincial department
- Conduct technical evaluation within **9 months**

Pesticide Registration Review Committee

- The experts of committee give review comments according to the registration review rules

MARA

- MARA would make final decision within **20 working days** after receive review comments of Review Committee



Chinese pesticide regulatory system

Registration



Duration for test arrangement and review:

TC: 4 years

Formulation:
3.5 years.

Renew registration



Duration for review:

3 months.

Label extension registration



Duration for test arrangement and review:

9+6 months.

Other change



Duration for review:

3 months.

Chinese pesticide registration policy

- State Council Decree 677: Regulations on the Control of Agrochemicals(New Act)
 - Published on March 16, 2017; Took effect on June 1, 2017.
- MoA Decree 3, 2017: Pesticide Registration Management Measures
 - Published on June 21, 2017; Took effect on Aug 1, 2017.
- No. 2569 Announcement: Pesticide Registration data requirement
 - Published on Sep 13, 2017; Took effect on Nov 1, 2017.
- Review criteria
 - Unpublished



Key points of pesticide registration management measures

Key points of regulations on the Control of Agrochemicals and Pesticide Registration Management Measures

➤ Mutual acceptance data issue

A registration test report shall be issued by the registration test agency approved by the Ministry of Agriculture, or issued by a relevant overseas laboratory **under the mutual recognition** agreement between the relevant departments of government, provided that the efficacy, residue, environment and other tests closely related to environmental conditions.

➤ Toxicity tests for main mets

Since Sep 2020, when new AI products apply for registration, applicants need to submit three types of toxicity tests for all the main metabolites :

- Acute toxicity test (oral only)
- Mutagenic test (three in vitro tests)
- 90 days subchronic oral toxicity test

Key points of regulations on the Control of Agrochemicals and Pesticide Registration Management Measures

➤ Radiolabeled metabolism tests

Since 2020, ICAMA required new pesticides applicants submit soil aerobic metabolism, soil anaerobic metabolism and water and sediment metabolism study reports with radioactive markers.

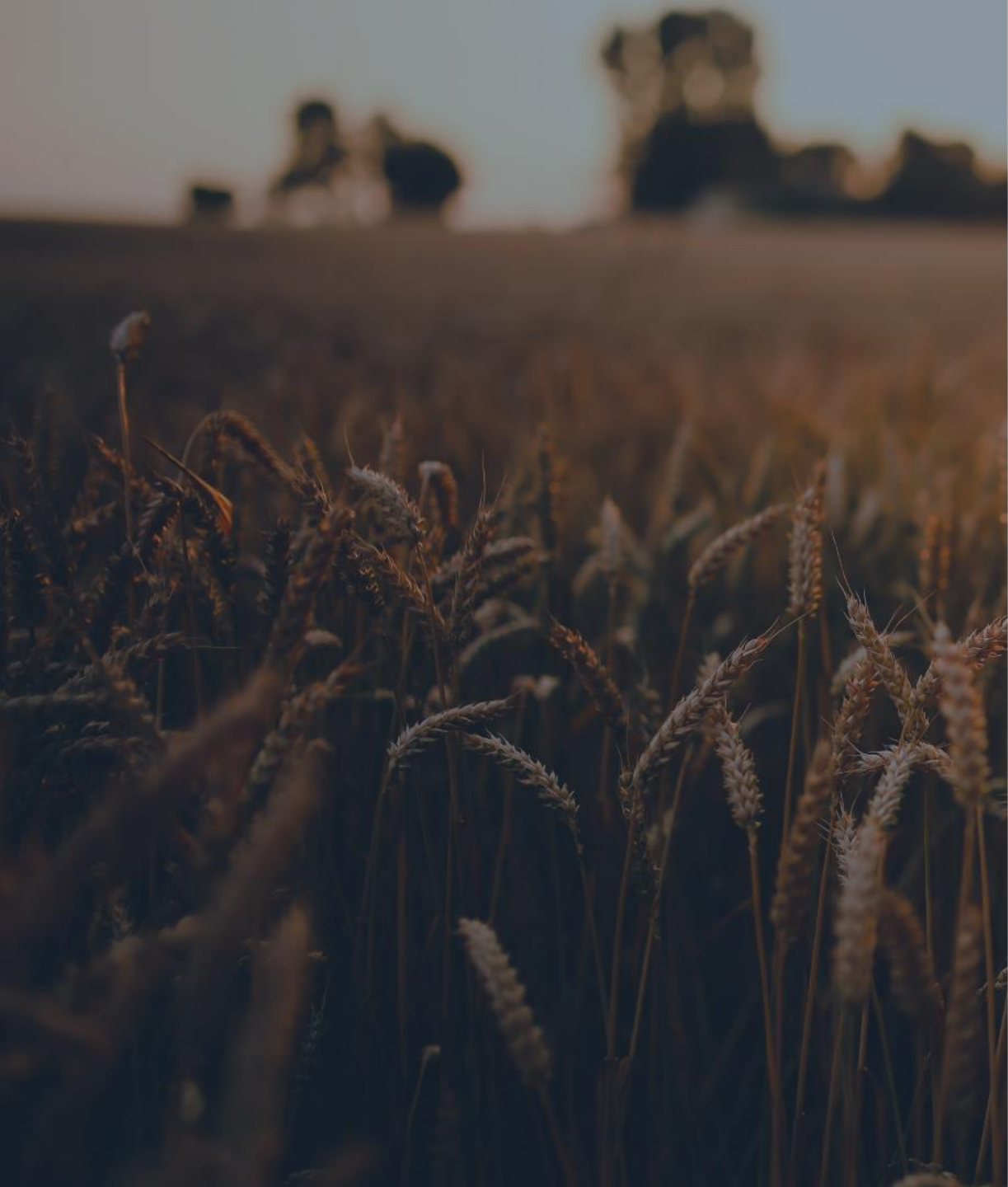
➤ Registration applicant types

- Manufacture: a domestic enterprise holding a pesticide production permit.
- Enterprise exporting pesticides to China: an enterprise exporting the pesticides produced overseas to China.
- New pesticide developer: a Chinese citizen, legal person or other organization applying for a new pesticide registration.

Key points of regulations

Control of Agrochemicals and Pesticide Registration Management Measures

- Authorization
 - The complete registration data consistent with the registration data requirements and owned independently by the pesticide registration certificate holder may be used by other applicants if so authorized.
- Transfer
 - New pesticide developers which already got registration certificate may transfer new pesticide registration dossier to the other companies; **a pesticide manufacturer** who already got registration certificate may transfer registration dossier to **a pesticide manufacturer** with corresponding production capabilities.
 - MoA **shall cancel the previous pesticide registration certificate** and publish the fact.
- Tolling
 - Only apply to Pesticide production enterprise(**domestic enterprise**)



Key points of registration approval



Key points of registration approval - Product safety

- TC(TK) with three causes (carcinogenic, teratogenic, mutagenic), delayed neurotoxicity and pathogenic microbial pesticide are not allowed to register.
- Skin irritation, eye irritation and sensitization:
 - For Homecare product directly used on skin, such as mosquito repellent liquid, mosquito repellent cream, mosquito repellent milk :
 - With skin irritation more than moderate (including moderate) will not allowed to register.
 - Do not accept strong eye irritation product. Moderate eye irritation product is allowed to register.
 - Mild or higher sensitization cannot be registered.

Key points of registration approval - Product safety

- Skin irritation, eye irritation and sensitization:
 - For non-household products:
 - Eyes and skin corrosive is unacceptable. Moderate and strong irritation is acceptable. In the event of corrosion, the formulation manufacturer shall verify with the TC manufacturer the eye and skin irritation test reports. If TC and formulation are both corrosive, the case should be discussed on review committee. If the TC is non-corrosive and the formulation is corrosive, it cannot be registered.

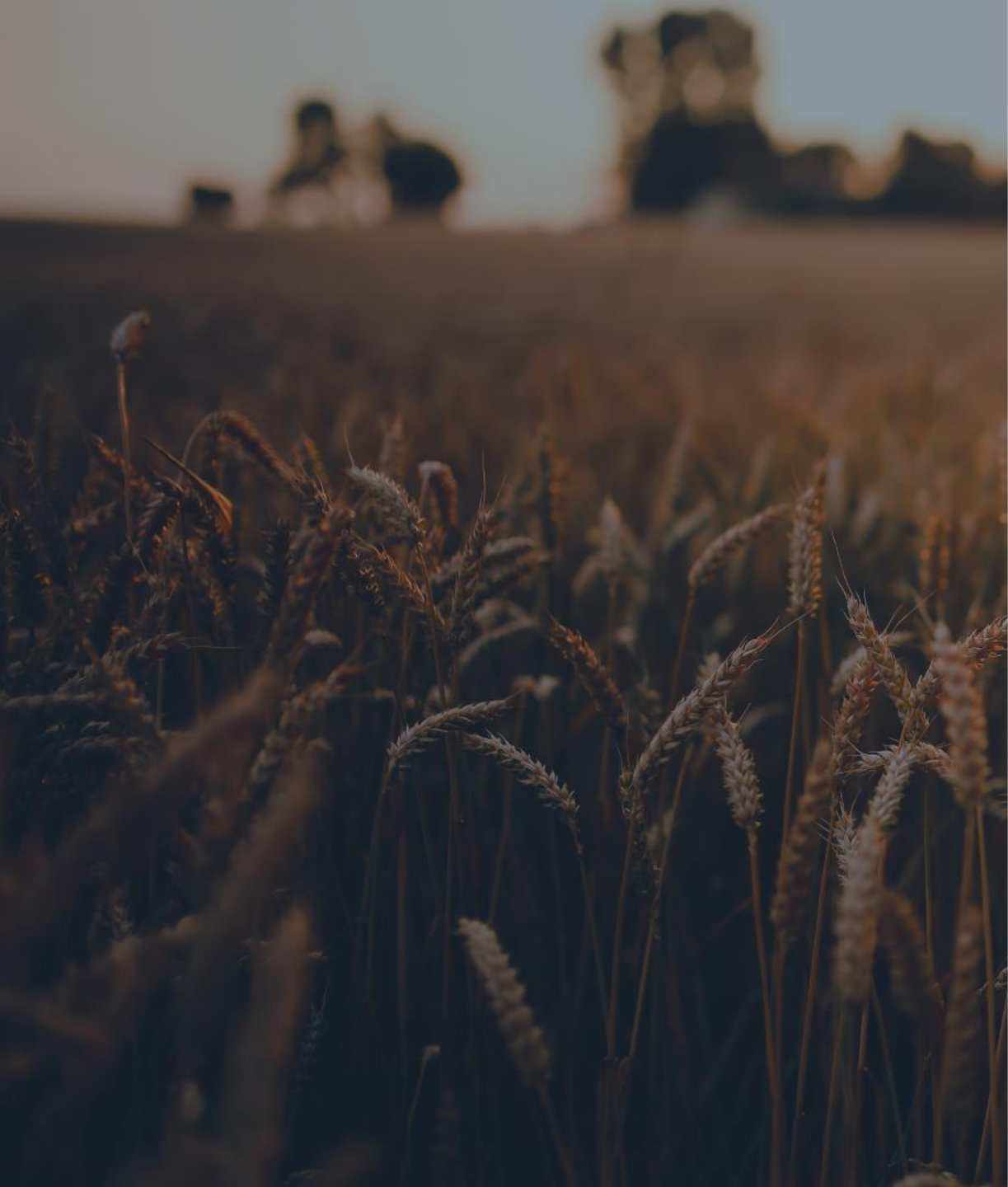
Key points of registration approval

- Content setting should meet the requirements
 - The interval of AI content and ratio of the same AI and formulation type should meet the requirements
 - The AI content of EC, ME and WP formulation type products should not be lower than that of registered products.

- If low-toxic microbial pesticides and chemical information substances TC(TK) or other types of substances TC(TK) which can waive some tests, the waived test reports required for registration of TC(TK) should be completed with formulation sample.
 - Amino oligosaccharide, chitosan, lentinan, oligosaccharide, Polyolefin sugar are excepted.

Key points of registration approval

- Unreasonable mixing will not be approved, such as:
 - Indoor dose response report is inconsistent with drug properties
 - Agriculture and forestry use pesticides are not synergistic
 - Mixture with the same mode of action.
- Mixtures with the same AI and application scope but different ratio applied by the same applicant would not be approved, provided that:
 - Mixed preparations with the same AI ratio and different total contents are excluded
 - Different scope of application is also excluded



Data requirement

Pesticide registration data requirement

Data requirements general was published on Sep 13th, 2017, and took effect on Nov 1st, 2017. In addition to Data Requirements, there are 14 attachments.

1 Data Requirements on Pesticide Registration

Appendix 1 — Data Requirements for Pesticide TC (TK) Registration and the Detailed List

Appendix 2 — Data Requirements for Pesticide Formulation Registration and the Detailed List

Appendix 3 — Data Requirements for Public Health Pesticide Formulation Registration and the Detailed List

Appendix 4 — Data Requirements for Rodenticide Formulation Registration and the Detailed List

Appendix 5 — Data Requirements for Registration Alteration and the Detailed List

Appendix 6 — Data Requirements for Registration of Pesticides Used for Featured Minor Crops

Appendix 7 — Guideline on Field Efficacy Trial Plots Required for Pesticide Registration

Appendix 8 — Classification of Crops Used in Residue Test for Pesticide Registration

Appendix 9 — Residue Test Point Requirements for Pesticide Registration

Appendix 10 — Me-too Pesticide Identification Rules

Appendix 11 — Pesticide Naming Principle

Appendix 12 — Principle for Deciding Contents of Active Ingredients in Pesticide Products

Appendix 13 — Quality Specifications of Pesticide Formulations in Various Formulation Types and Their Physical and Chemical Properties

Appendix 14 — Pesticide Toxicity Grading Standards

Comparison of new / old data requirements (New TC for chemical pesticide)

| Documents list | | Item | |
|---|---|--|---|
| | | Old | New |
| General documents | Applicant certification documents | Not need | Need. (1) Pesticide producer: copies of production license, business license, uniform social credit code, etc. affixed with common seals; (2) New pesticide developer: statement about the application for pesticide registration; (3) Overseas enterprise: identity certificates, statement about registration and use status in the country or region concerned, and statement about any office established in China; (4) Others. |
| Product chemistry | Identification of active ingredients and other restrictive components | Only active ingredient identification information | Identification of active ingredients, safeners, stabilizers, synergists and other restrictive components |
| | Other restrictive components contents | Not need | If there are safeners, stabilizers, synergists and other restrictive components, tolerance level is needed. |
| Toxicity | Sub-chronic (acute) percutaneous, inhalation toxicity test data | Not need | Need |
| | Teratogenicity test data | Submit data about teratogenicity test of one type of mammal, preferably rats. | Submit data about teratogenicity test of two types of mammals, preferably rats and rabbits |
| | Chronic toxicity and carcinogenicity test data | Submit data about carcinogenicity test of one type of rodents, preferably rats. | Submit data about carcinogenicity test of two types of rodents, preferably rats and mice. |
| | Endocrine disrupting effect test data | Not need | Provide as needed. If the chronic toxicity or reproductive toxicity test shows that the product is toxic to the endocrine system, provide the test report on endocrine disrupting effect. |
| Environment | In-water pesticide analysis method and validation | Not need | Need. Include AI and main metabolites analysis method and validation. |
| | In-soil pesticide analysis method and validation | Not need | Need. Include AI and main metabolites analysis method and validation. |
| | Bird reproduction test data | Not need | Need. |
| | Fish early stage toxicity test data | Not need | Need. |
| | Daphnia magna reproduction test data | Not need | Need. |
| | Aquatic plant toxicity test data | Not need | Applicable to herbicides only. |
| | Bee larvae developmental toxicity test data | Not need | Applicable to insect growth modifiers only |
| | Bee semi-field test data | Not need | Provide as needed. If the primary risk assessment shows that the risk posed by the pesticide to bees is unacceptable, provide the bee semi-field test data about a representative formulation. |
| | Silkworm chronic toxicity test data | Not need | Applicable to insect growth modifiers only |
| | Predatory natural enemy acute toxicity test data | Not need | Need. Provide the acute toxicity test data about at least one type of predatory natural enemy |
| Earthworm reproductive toxicity test data | Not need | Provide as needed. Provide earthworm reproductive toxicity test data about TC or a representative formulation under any of the following circumstances: (1) The predicated environmental concentration (PEC) > 0.1 × earthworm acute LC50; (2) Other data show that there is a potential chronic toxicity risk to earthworms. | |

Comparison of new / old data requirements (New formulation for chemical pesticide)

| Documents list | | Item | |
|----------------------|---|--------------------------|--|
| | | Old | New |
| General documents | Applicant certification documents | Not need | Need. (1) Pesticide producer: copies of production license, business license, uniform social credit code, etc. affixed with common seals; (2) New pesticide developer: statement about the application for pesticide registration; (3) Overseas enterprise: identity certificates, statement about registration and use status in the country or region concerned, and statement about any office established in China; (4) Others. |
| | Summary of risk assessment | Not need | Need. Summary of product risk assessment in the aspects of diet, occupational health, environment, etc. |
| | Summary of benefit analysis | Not need | Need. Summary of the analysis on the economic, social and environmental benefits of the product. |
| Product chemistry | Other restrictive components contents | Not need | If there are safeners, stabilizers, synergists and other restrictive components, tolerance level is needed. |
| Toxicity | Health risk assessment report | Not need | Need. A pesticide user health risk assessment report should be submitted. |
| Efficacy | Resistance risk assessment | Not need | Need. |
| | Substitutability analysis and benefit analysis report | Not need | Need. Purpose and use method of the product applying for registration, and its adaptability to the current condition of agricultural production; use cost of the product applying for registration, and expected economic loss that can be recovered and influence on the income of growers; analysis of comparison with existing registered products or chemicals commonly used during production; effect on the resistance management of existing registered products; possibility of substituting pesticides with a higher risk. |
| Residue | Data of plant metabolism test | Provide as needed | Need. (1) At least one type of crops is selected from five types of crops, including: tuber, leaf, fruit, oil plant and grain to do metabolism tests. If the data indicates this pesticide has the same metabolic pathways in three types of crops, no other metabolism tests are required. Otherwise the data of the metabolism tests of all of the five types of crops should be submitted; (2) If the pesticide can be used only in one type of the crops, reasons should be provided and the data of the metabolism test of this type of crops should be submitted (for concrete requirements, please refer to the Guidelines for Crop Metabolism Test of Pesticides). |
| | Data of animal metabolism test | Not need | If needed. Data of livestock and poultry metabolism test of radioactively labeled pesticides. |
| | Data of pesticide residue storage stability test | Provide as needed | Need. (1) Submit the data for the stability of active ingredient matrix and metabolites with toxicological significance when they are stored in the corresponding substrate (for concrete requirements, please refer to the Guidelines for Pesticide Residue Storage Stability Test); (2) The data should cover the period from sampling to sample testing. |
| | Data of pesticide residue test in processed agricultural products | Not need | Provide as needed. (1) Data of changes of active ingredient matrix and metabolites with toxicological significance during processing of agricultural products; (2) Limited to the agricultural products whose pesticide residue quantity may increase after processing, such as representative crops: oil plants: soybean, peanut and rapeseed; fruit: citrus and apple (for concrete requirements, please refer to the Guidelines for Pesticide Residue Test in Processed Agricultural Products); (3) If there is queried data, its source should be stated, and the data for comparison with Chinese agricultural product processing technology should be submitted. |
| | Dietary risk assessment report | Not need | Need. |
| Environmental impact | Data of predator acute toxicity test | Not need | Need. |
| | Environmental risk assessment report | Not need | Need. |

Key point of registration data requirement

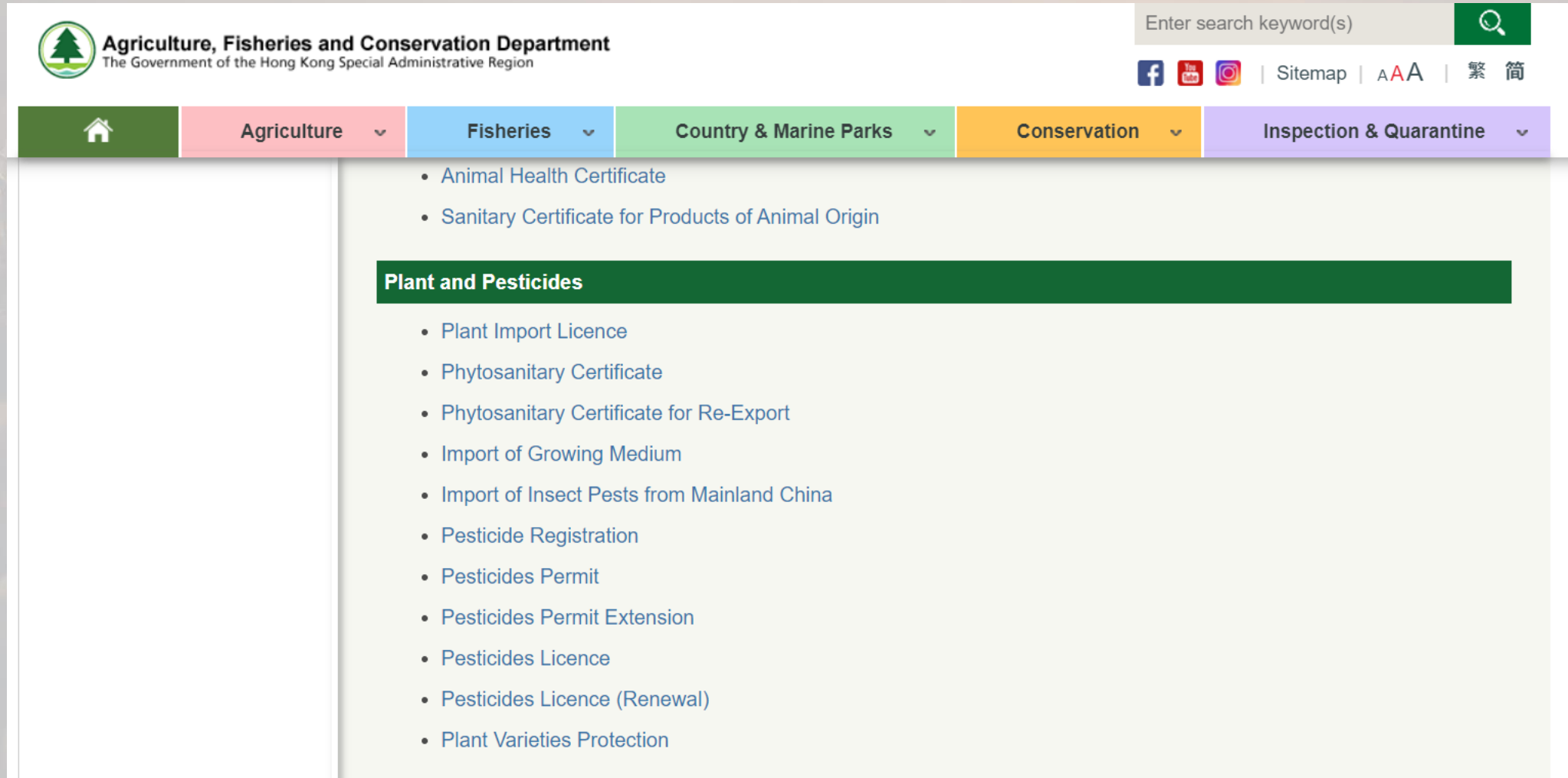
- Health/environmental/dietary risk assessment
- Resistance risk dossier
- More strict requirement for metabolites eco-tox studies
- Metabolites toxicity studies
- Radio labeled metabolism studies
- Residue of processed agricultural products
- Plant/animal metabolism test



Hongkong China pesticide registration


Hongkong China pesticide regulatory system

HK AFCD website:



The screenshot shows the website of the Agriculture, Fisheries and Conservation Department (AFCD) of the Government of the Hong Kong Special Administrative Region. The header includes the department's logo and name, a search bar, and social media icons for Facebook, YouTube, and Instagram. A navigation menu is located below the header, with tabs for Home, Agriculture, Fisheries, Country & Marine Parks, Conservation, and Inspection & Quarantine. The 'Inspection & Quarantine' tab is selected, displaying a list of services including Animal Health Certificate, Sanitary Certificate for Products of Animal Origin, and a section for Plant and Pesticides. The Plant and Pesticides section lists various services such as Plant Import Licence, Phytosanitary Certificate, and Pesticide Registration.

Agriculture, Fisheries and Conservation Department
The Government of the Hong Kong Special Administrative Region

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- [Animal Health Certificate](#)
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Plant and Pesticides

- [Plant Import Licence](#)
- [Phytosanitary Certificate](#)
- [Phytosanitary Certificate for Re-Export](#)
- [Import of Growing Medium](#)
- [Import of Insect Pests from Mainland China](#)
- [Pesticide Registration](#)
- [Pesticides Permit](#)
- [Pesticides Permit Extension](#)
- [Pesticides Licence](#)
- [Pesticides Licence \(Renewal\)](#)
- [Plant Varieties Protection](#)

Hongkong China pesticide regulatory system

- The handling of pesticides in Hong Kong is regulated by the Pesticides Ordinance (Cap. 133) (the Ordinance). The Pesticides (Amendment) Ordinance 2013 commences operation on 27 January 2014.
- Control of pesticides is effected through:
 - registration of pesticides (including their active ingredients and control of inert ingredients);
 - licensing of pesticide traders and manufacturers;
 - requirement for a permit to trade, manufacture, possess, or use any scheduled pesticide or any other unregistered pesticide; and
 - minimum requirements for labeling and bottling of pesticides.

Hongkong China pesticide regulatory system

- Only pesticides that have been registered in Hong Kong may be distributed and used in Hong Kong with a **Pesticides License**. The Pesticides Register detail information includes the active ingredient(s), concentration limit and formulation type. All the information above is listed in Pesticides Register list. Products do not have to be registered as long as they contain the registered active ingredient and conform to the specified maximum concentration of active ingredient(s) and permitted formulation type which listed in the Pesticides Register list.
- The Pesticides Register list is in two parts. Pesticides registered in [Part I](#) are ready-for-use domestic pesticides and those in [Part II](#) are all other pesticides.

Hongkong China pesticide regulatory system

Hongkong China pesticide regulatory system

- Registered product:
License (License renewal)
- Unregistered product:
Permit (Permit extension)
- Need not register if there is already same registered product with the same AI and same formulation type and same or higher AI concentration.

Hongkong China pesticide registration data requirement

- Summary
- Specification and test method validation
- Acute toxicity study full reports.
- Efficacy report and residue data

Thank you for your attention!

