

Dec 15th, 2022

Pesticide Regulation in China

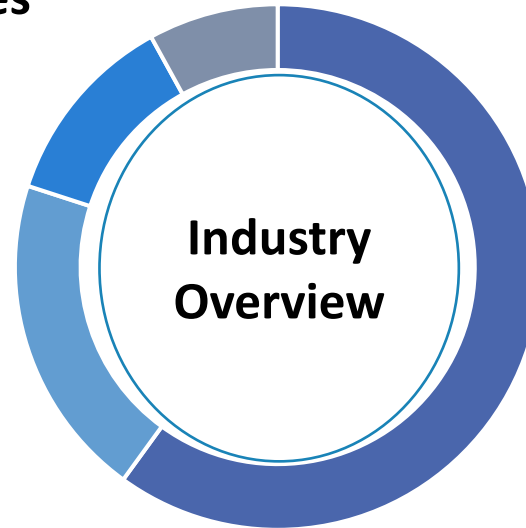
Name: Yolanda Zhang
Affiliation: CIRS Agrochemical Division

Agenda

- 01** | Pesticide Industry in China
- 02** | Pesticide Registration in China
- 03** | Pesticide Production Permit
- 04** | Pesticide Import & Export Management
- 05** | New Regulation and Policy Changes

Overview

1,700+ Pesticide manufactures
700+ big companies



700+ Active Ingredients
40,000 products registered

1,900+ Registration holders
1,800+ Local Companies
120+ oversea companies

2/3 Pesticide Export
Export to 188 countries



What pesticides?

How to register pesticides in China?

Pesticide Definition (1)

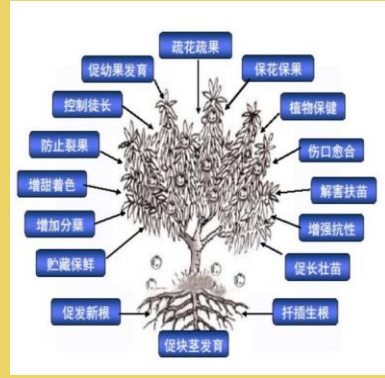
Means a **substance** or **mixture** or other preparation of one or more substances derived from **chemical synthesis**, or originating from **biological** and other **natural sources**, used to prevent or control diseases, pest insects, weeds or other living beings harmful to agriculture and forestry,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



Pesticide Definition(2)

Include various types used for the following purposes and locations:

- (1) To prevent or control diseases, pest insects (including insects, ticks, and mites), weeds, rodents, mollusks, and other organisms harmful to agriculture and forestry;
- (2) To prevent or control diseases, pest 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 or control organisms harmful to **dams, railways, ports, airports, buildings** and other sites.



Authority



Division of Plantation
Management

省农业农村厅

Provincial Department of
Agriculture and Rural Affairs



Institute Control of Agrochemicals,
Ministry of Agriculture

Applicant

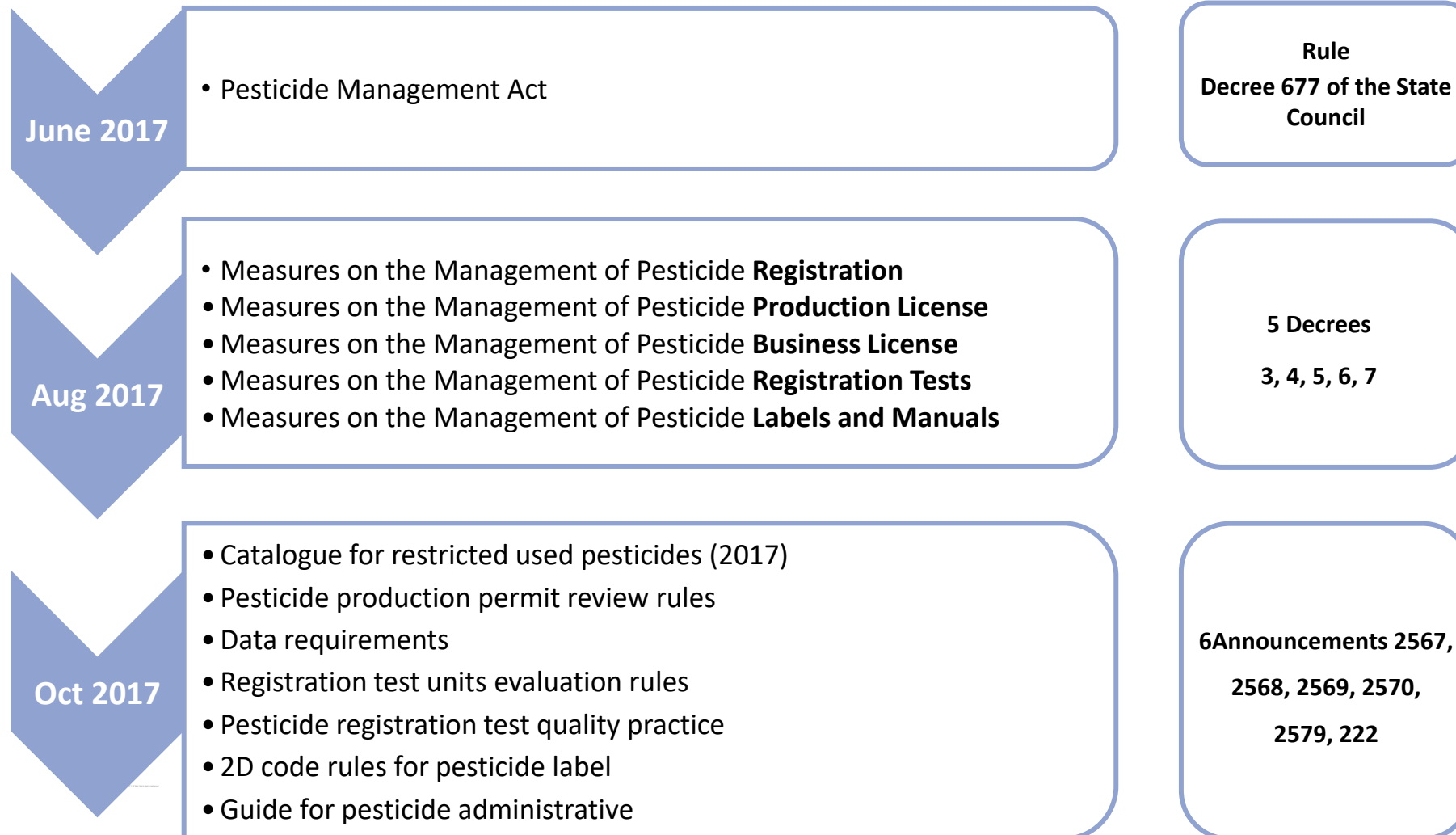


- Domestic companies
- Have production permit

- Foreign companies
- Enterprises export agrochemicals to China

- Domestic developers
- Developers of new agrochemicals in China

Regulation System

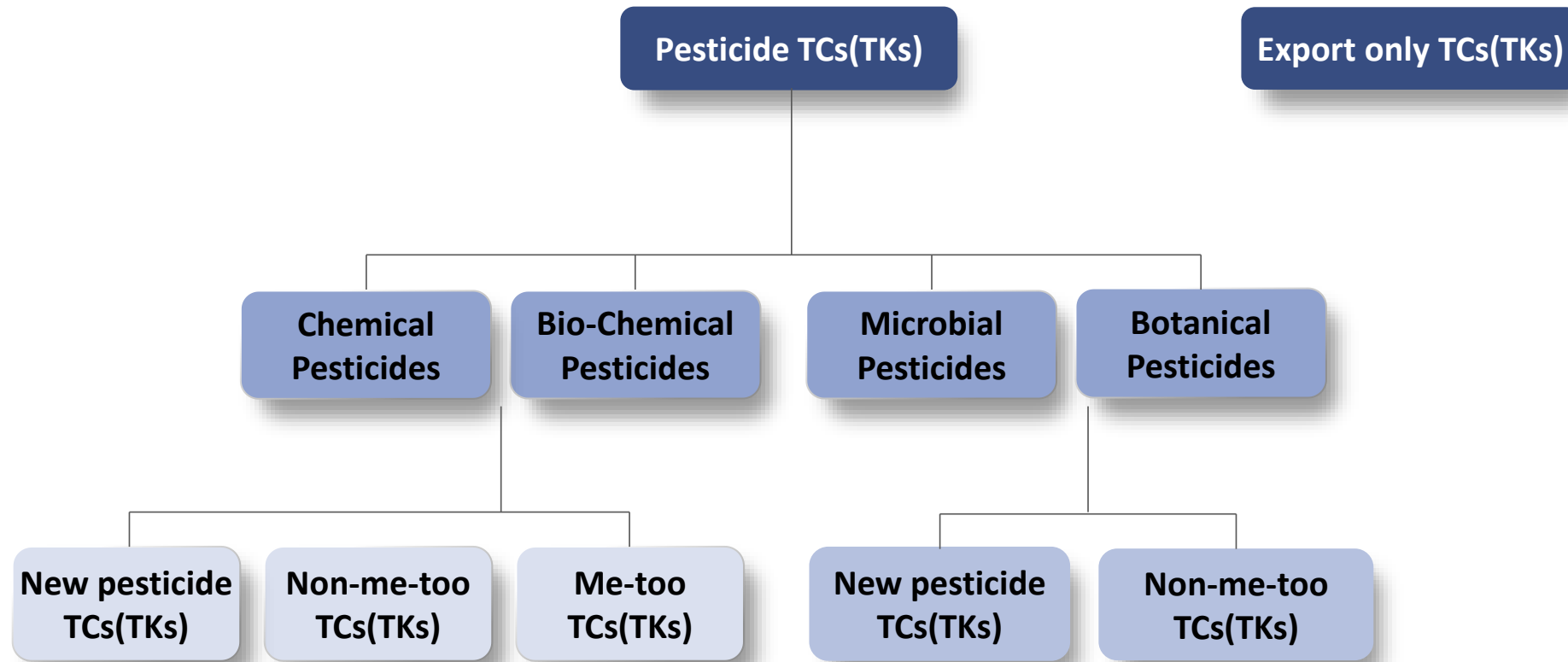


Pesticide Application Category

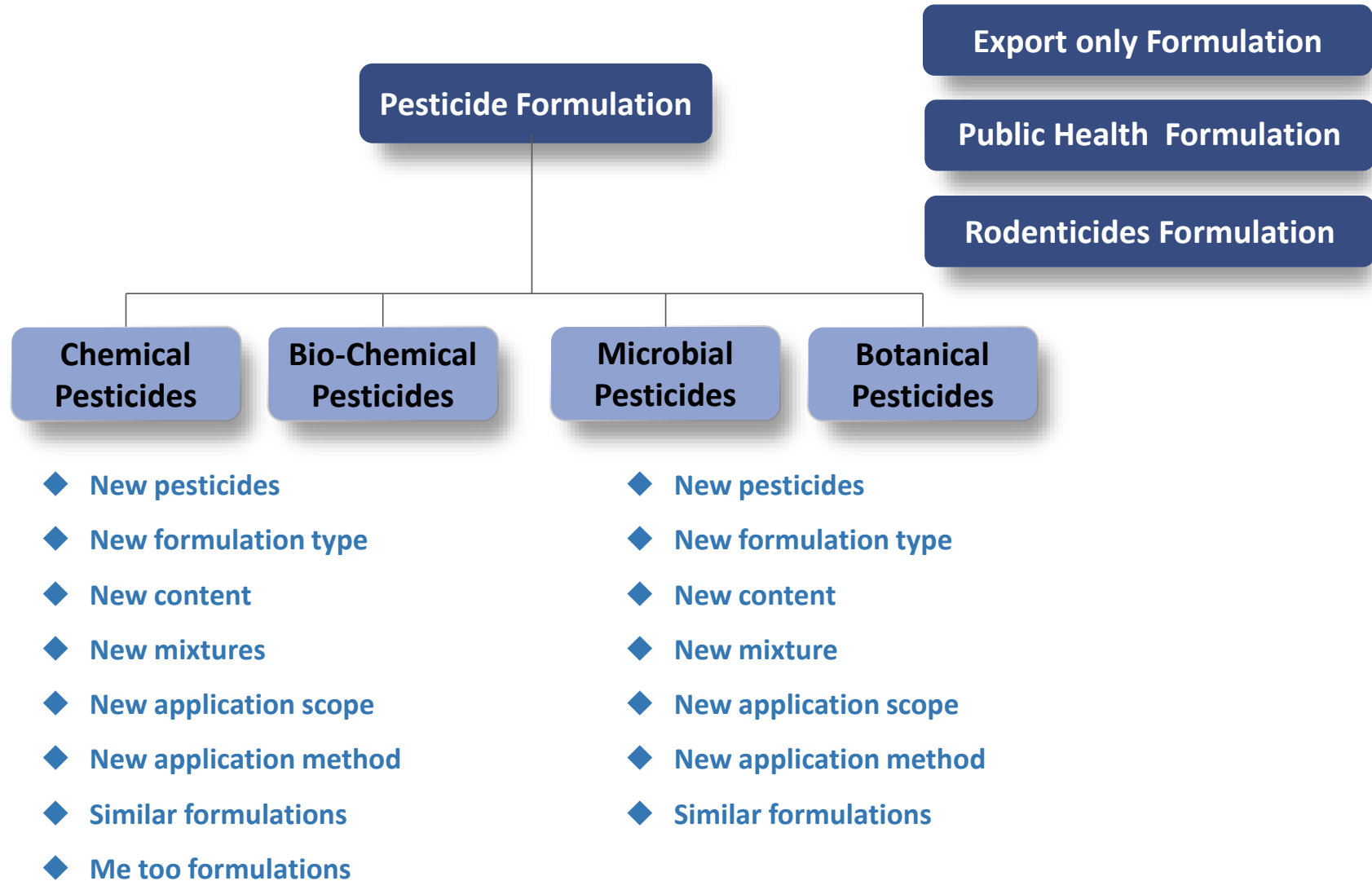
Pesticide TCs(TKs)

Pesticide Formulations

Pesticide TCs (TKs) Application Category



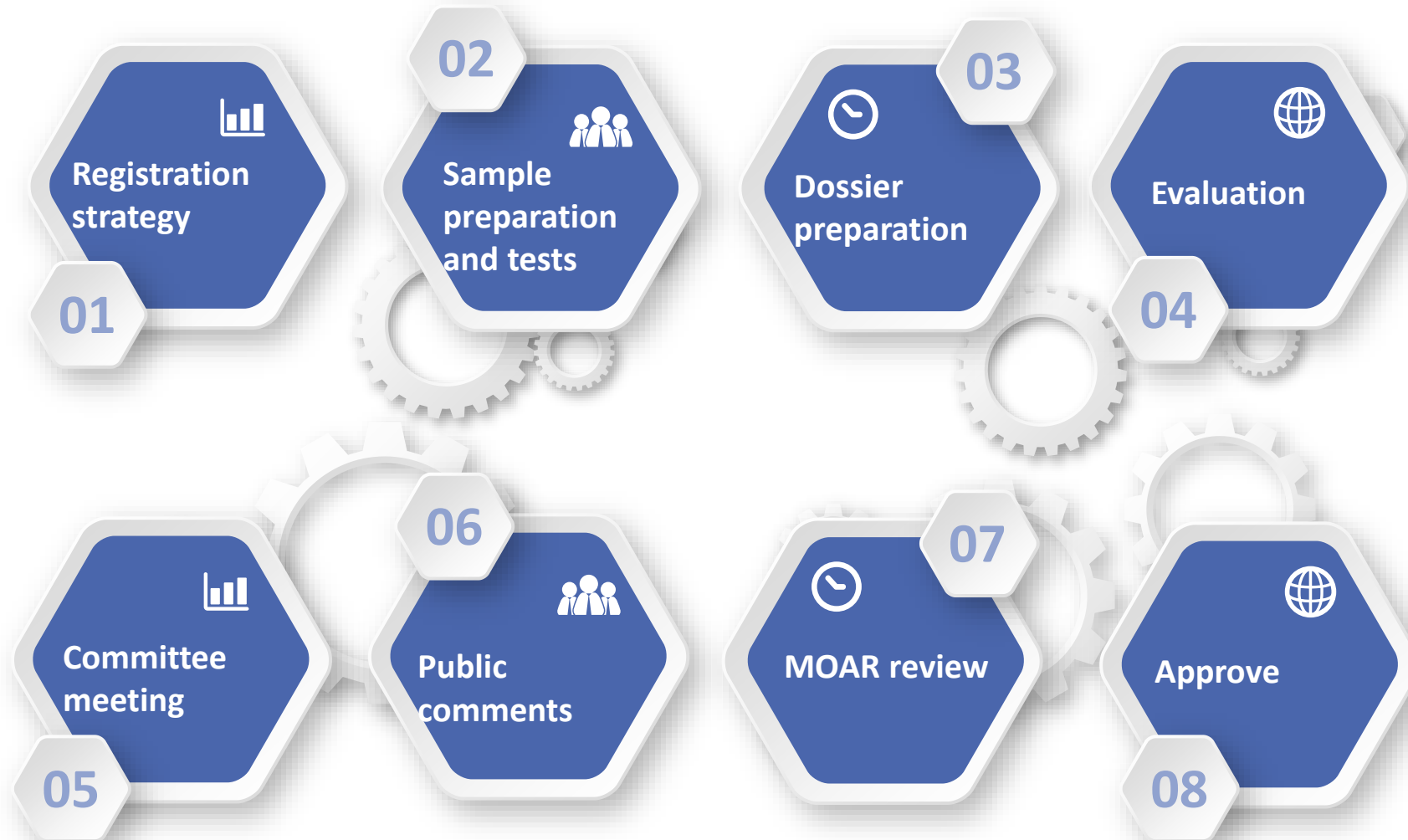
Pesticide Formulations Application Category



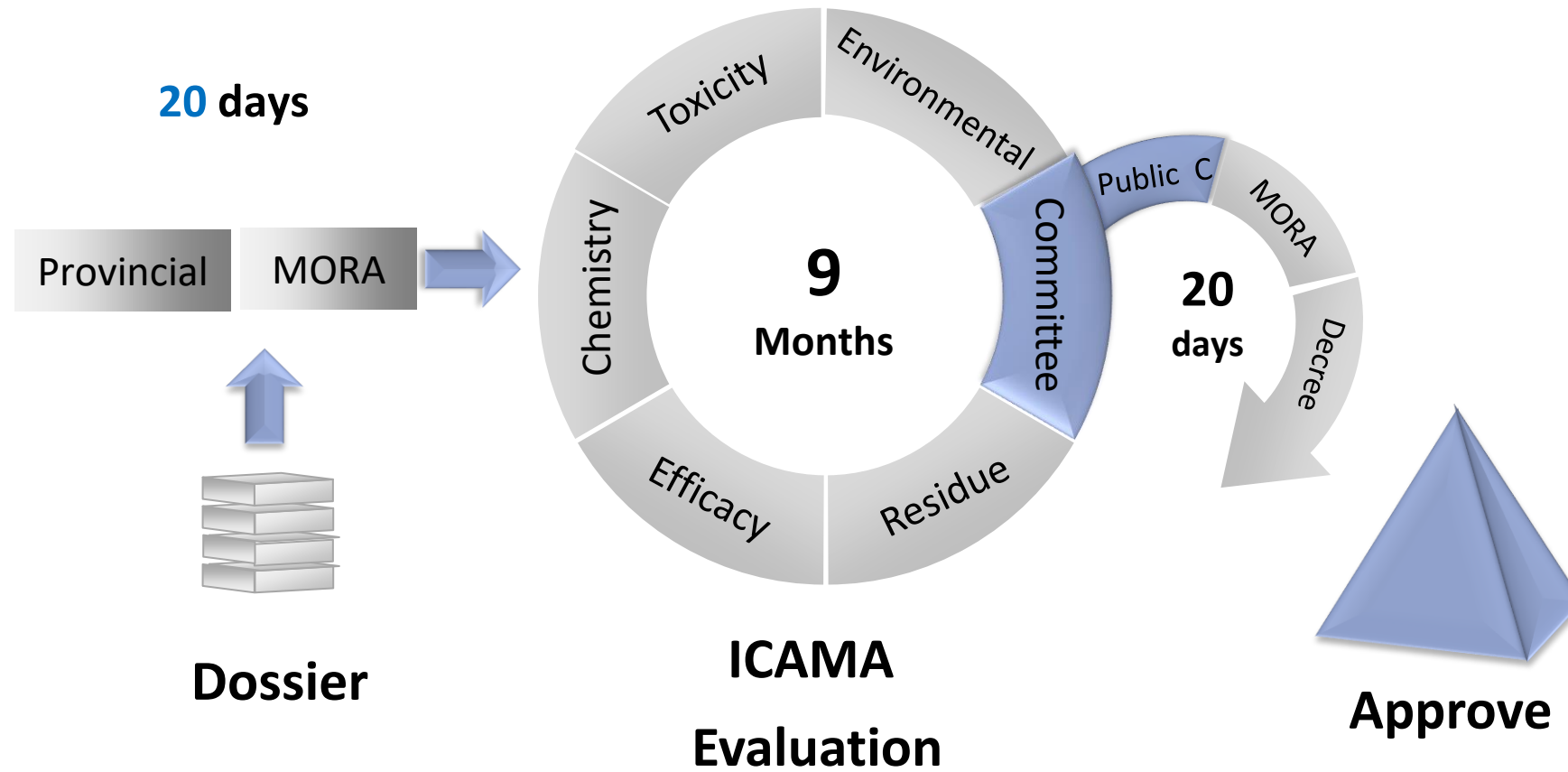
Renewal of Registration

- Registration is valid for 5 years.
- An application for renewal shall be made ninety days before the expiration of the validity period.

Pesticide Registration Process

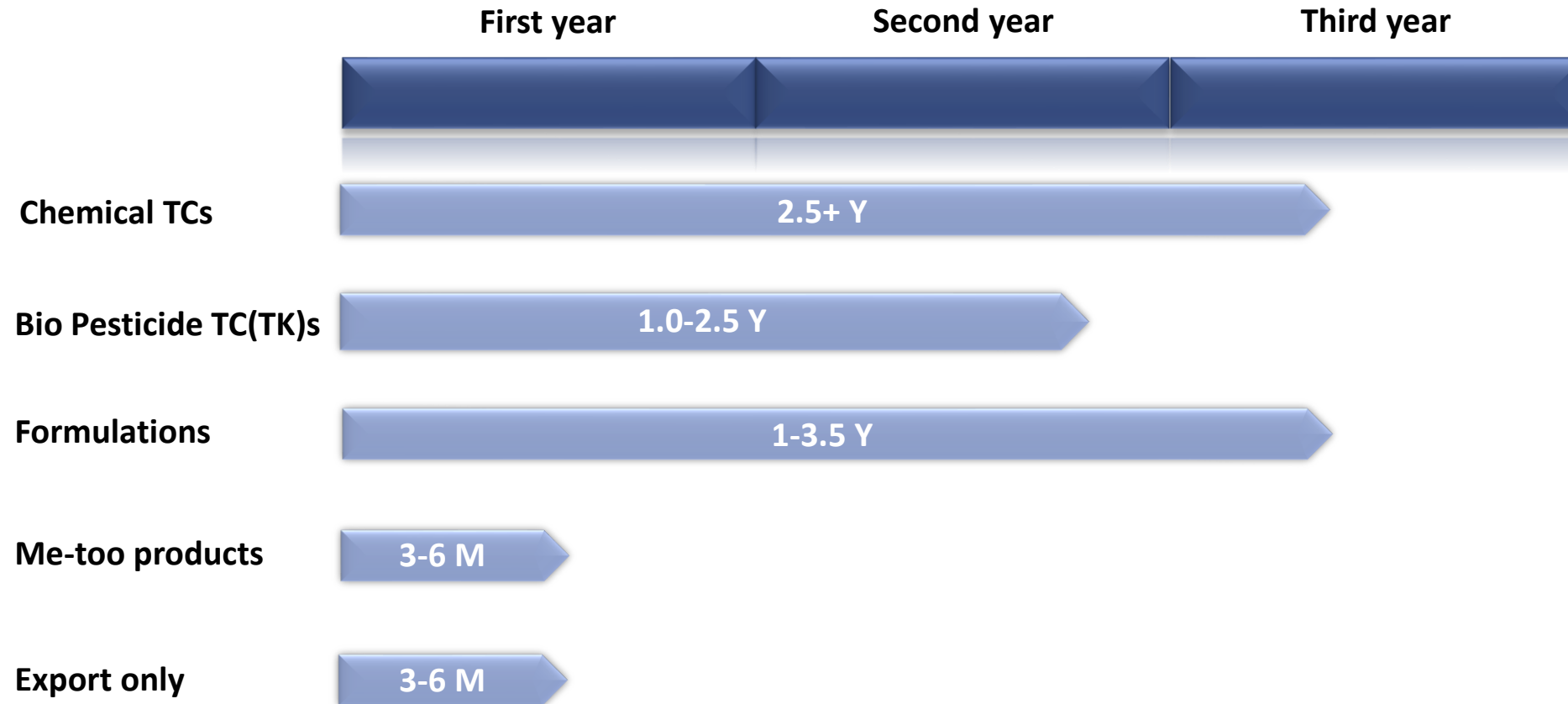


Pesticide Evaluation Process



- Bio-pesticides have a green evaluation process.
- Renewal: 3 months
- Change of registration: 6 months

Pesticide Registration Trail Timelines



Generic Pesticide Technical Material Registration Data Requirements/cost/ timeline in China

Data requirement	After Nov 2017	
	Non-Me-too TCs(TKs)	Me-too TCs(TKs)
Product Chemical	√	√
Toxicity	Whole data package √	/
Eco-tox	Whole data package √	/
E-Fate	/	/
Total estimated Cost	5,000,000RMB ±	300,000RMB ±
Study time	2-2.5 years	3-6 months
Evaluation time	11 months	11 months

Generic Pesticide Formulation Registration Data Requirements/cost/ timeline in China

Data requirement	After Nov 2017	
	Similar Products	Same (Me-too) Products
Product Chemical	√ PCF Quality test 2 years shelf-life studies	√ PCF Quality test
Toxicity	6 packs	/
Efficacy	1 year 3/4/5 locations	/
Eco-tox	5 studies	/
Total estimated Cost (1 crop)	250,000RMB ±	40,000RMB ±
Study time	2-2.5 years	3-6 months
Evaluation time	11 months	11 months

Pesticide Production Permit

Pesticide Production Permit

How is pesticide production managed in China?

Regulation

Article 17

The State applies a pesticide production permit system. Pesticide production enterprises shall meet the following requirements and apply to the competent agricultural departments of the people's governments of provinces, autonomous regions and municipalities directly under the Central Government for pesticide production licenses in accordance with the provisions of the competent agricultural department under the State Council.

Authority

省农业农村厅

Provincial Department of Agriculture
and Rural Affairs

Pesticide Tolling and Repacking



Domestic Companies

Product registration

Within production scope



Entrusting companies

Tollers

Tolling TCs

Tolling formulations

Repacking formulations

Foreign Companies

Product Registration

Within the production license scope



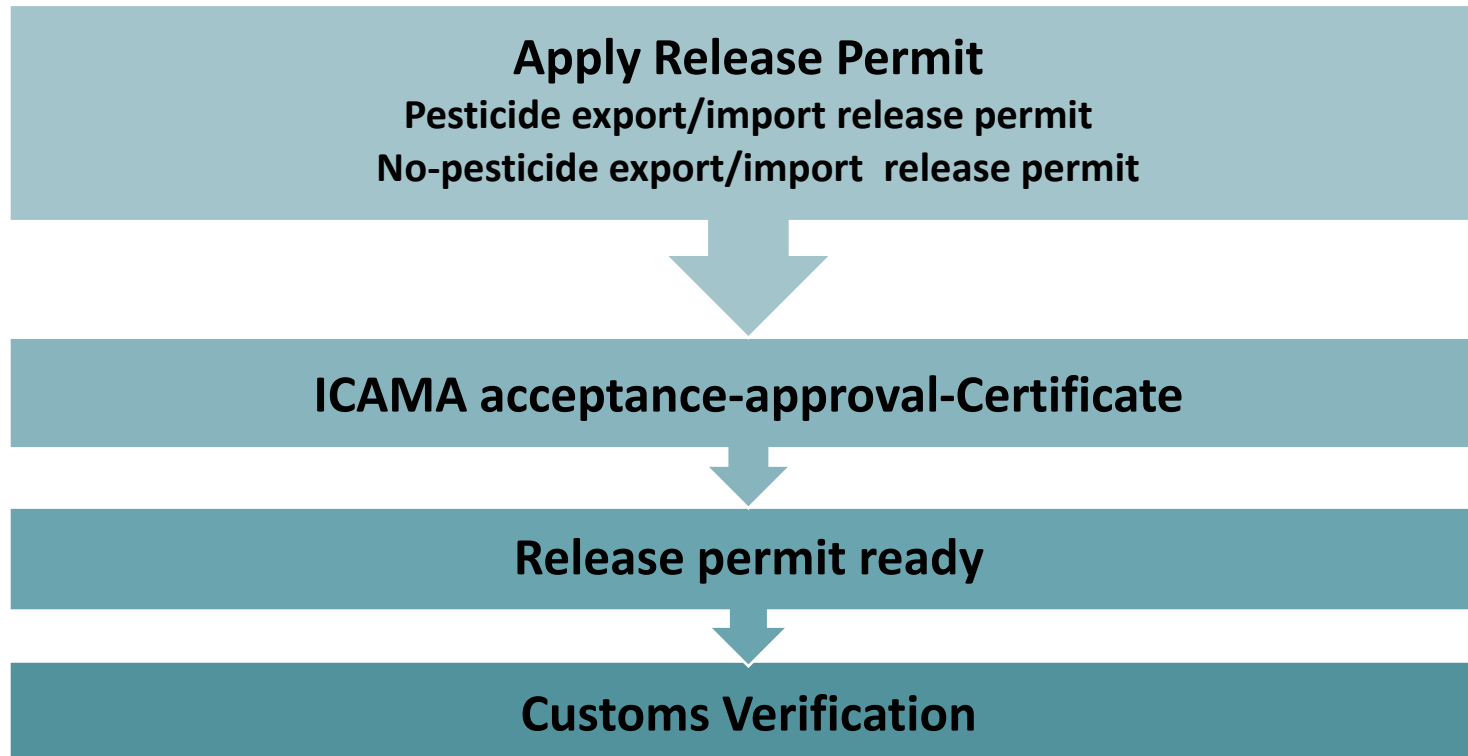
Pesticide Import & Export Management

It is prohibited to import & export pesticides without pesticide registration certificate.

Pesticide Import & Export Management



Import/export pesticides included in the “Pesticide Management Directory of China” need to apply release permit.



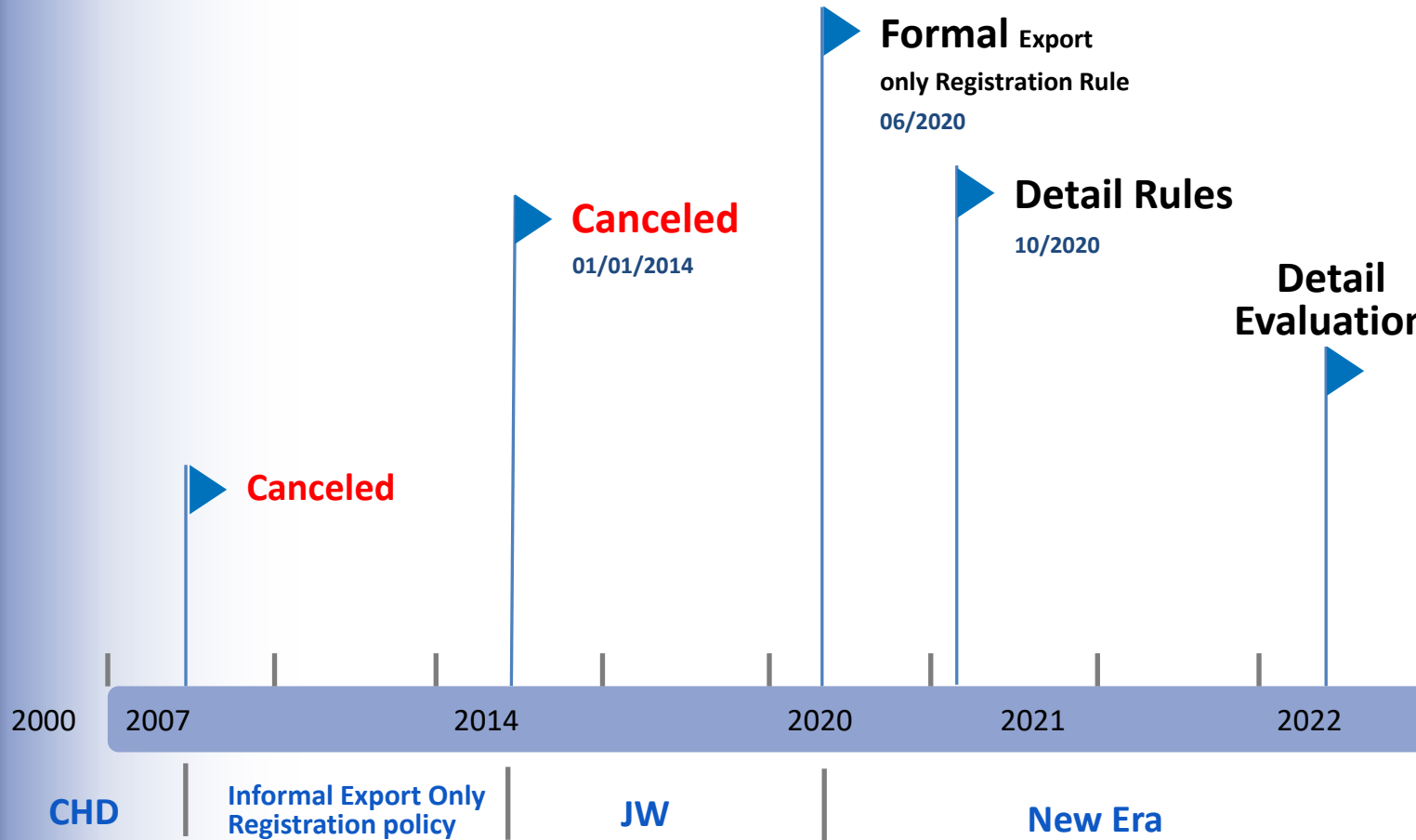
New Regulation and Policy Changes

Mutual Acceptance of Data (MAD) of GLP Studies

- From January 1, 2021, pesticide registration test reports completed by overseas GLP laboratories are no longer accepted in China.
- Not sure if this will change in the future.



Export Only Registration



- After one company has obtained new active ingredient export-only registration, other companies couldn't apply for export-only registration for the same new AI.
- Toxicological data of new pesticide technical literature summary also accepted:
JMPR, EFSA, EPA

Our services



We provide one-stop solutions to help you comply with pesticide regulation in China

Our **services** include:

- Pesticide registration;
- Export-only registration;
- Pesticide registration legislation and policy survey;
- Registration budget, cost control and registration strategy;
- Data evaluation and gap analysis;
- Testing coordination;
- Product safety assessment report(environment/health/dietary);
- Dossier preparation and submission;
- Import and export customs release certificate;
- Renewal of pesticide registration certificate;
- Advice and training on pesticide production permit.



Thank You!

“ *Your Seamless Extension in
Global Regulatory Compliance.* ”



IDEON Science Park, Beta 5.
Scheelevägen 17,
223 63 Lund, Sweden



compliance@gpcregulatory.com



+ 46 (0) 46 211 46 15



www.gpcgateway.com



GPC

Global Product Compliance

2022-12-20

©Global Product Compliance – GPC Group