

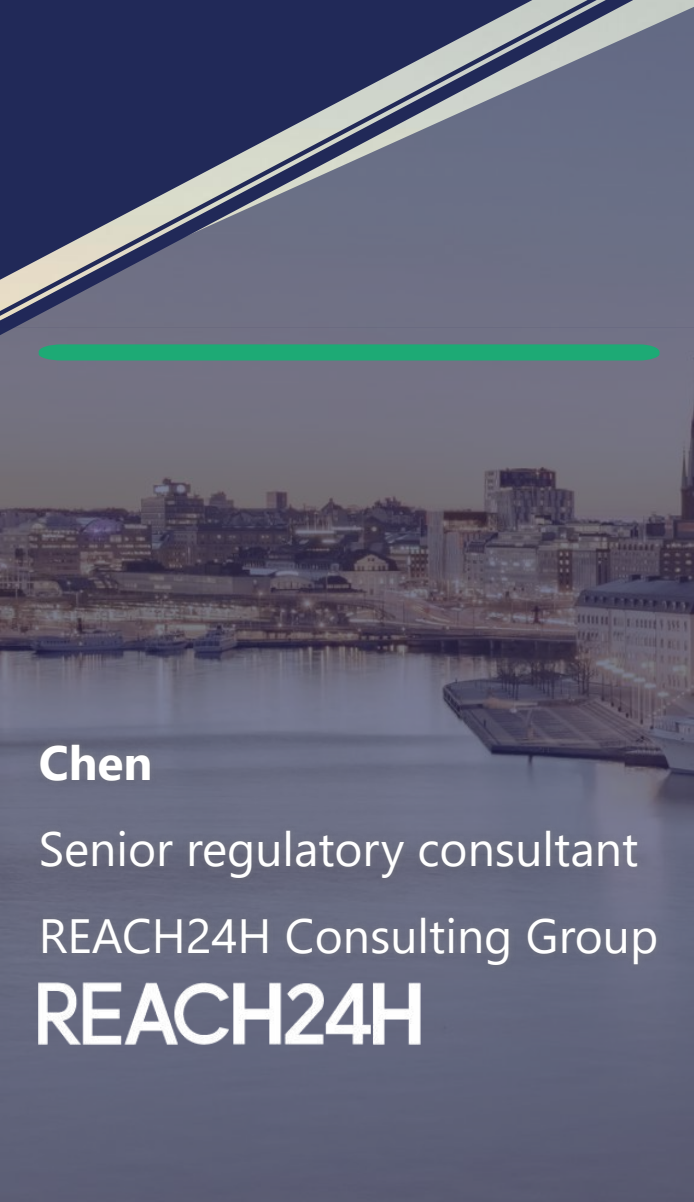
Introduction of New Pesticide Registration in China

Chen

Senior regulatory consultant

REACH24H Consulting Group

REACH24H



Contents

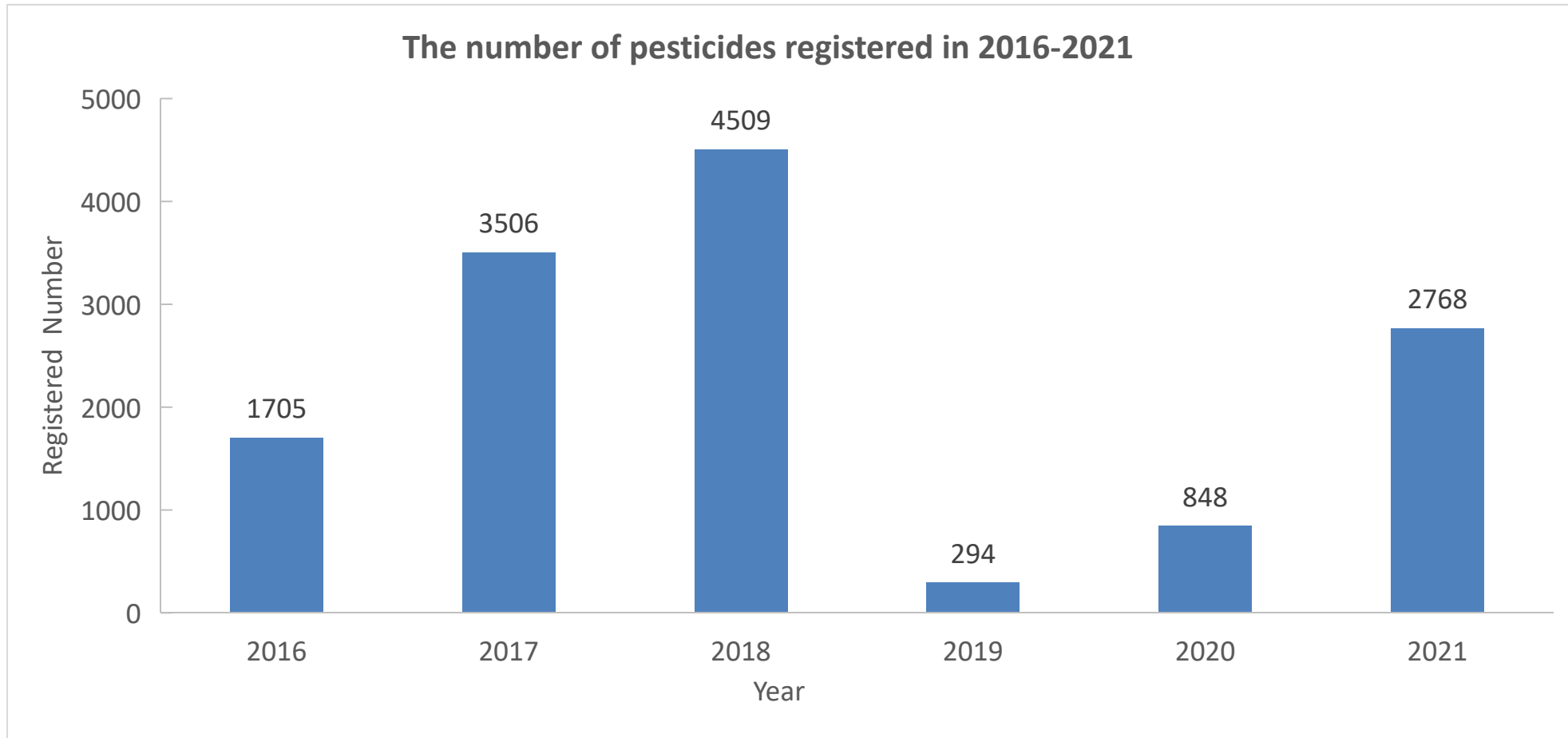
- 01 / Registration Trends on China Pesticide**
- 02 / Introduction of China's New Pesticide Registration**
- 03 / Compliance Strategy Analysis about New Pesticide**
- 04 / The Latest Pesticide Policies & Requirements**

01

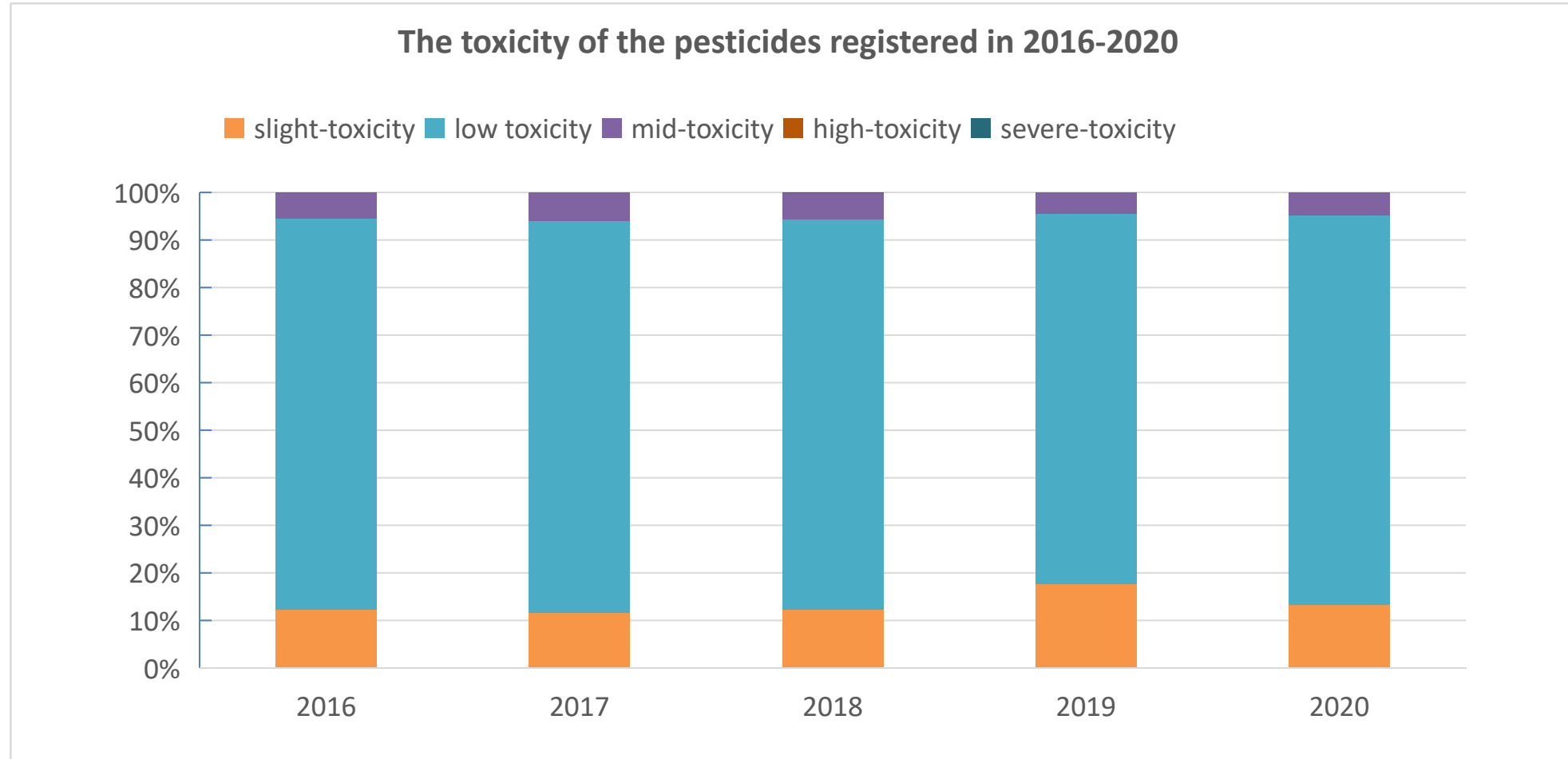
Registration Trends on China Pesticide



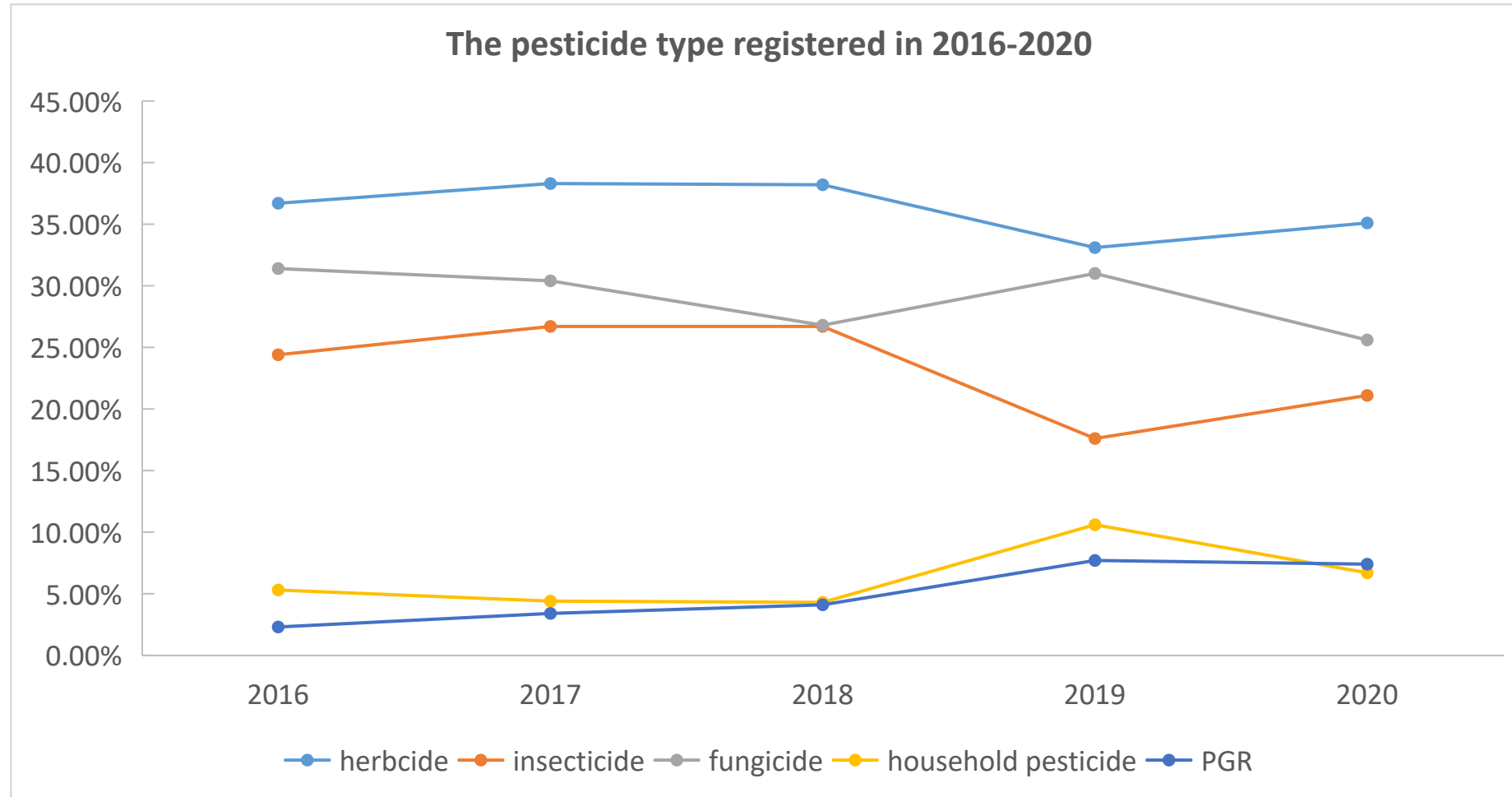
China Pesticide Registration in Recent Years



China Pesticide Registration in Recent Years



China Pesticide Registration in Recent Years



Most Popular Active Ingredients

No.	2016 Year	2017 Year	2018 Year	2019 Year	2020 Year
1	glufosinate-ammonium	glufosinate-ammonium	glufosinate-ammonium	glufosinate-ammonium, glyphosate	cyhalofop-butyl, metamifop
2	pyraclostrobin	pyraclostrobin	dinotefuran	6-benzylamino-purine	thiamethoxam
3	thiamethoxam	thiamethoxam	penoxsulam	glufosinate-ammonium	metamifop
4	difenoconazole	penoxsulam	pyraclostrobin	gibberellic acid	clothianidin
5	florasulam	glyphosate ammonium	cyhalofop-butyl	bispyribac-sodium	pyraclostrobin
6	mesotrione, atrazine	imidacloprid	thiamethoxam	glufosinate-ammonium, fluoroglyphofen-ethyl	glufosinate-ammonium
7	mesotrione	diquat	diquat	pinoxaden	gibberellic acid
8	glyphosate-isopropylammonium	cyhalofop-butyl	clothianidin	(+)-abscisic acid	petroleum oil
9	cyhalofop-butyl	thifluzamide	abamectin	pretilachlor, bensulfuron-methyl	pinoxaden
10	abamectin-aminomethyl	fosthiazate	glyphosate ammonium	prothioconazole	glufosinate-ammonium, glyphosate

New Pesticide Registered

Content/Year	2018 Year	2019 Year	2020 Year	2021 Year
New pesticide	11	9	6	23
Bio-pesticide	3 (27%)	3 (33%)	3 (50%)	18 (78.3%)
Pesticide with slight or low toxicity	10 (91%)	9 (100%)	6 (100%)	22 (95.7%)



02

Introduction of China's New Pesticide Registration



Why are New Pesticides encouraged?

1. Adjust the structure of pesticide products ;
2. Establish a new pesticide innovation pattern--Low risk pesticide, microbial and botanical pesticide.

Policy trends

1. Pesticide resistance is increasing. Need to accelerate pesticide replacement.
2. Serious occurrence of major pests and diseases and the task of prevention and control is heavy.

Pesticide industry

1. New pesticides can help companies increase their benefits;
2. Intellectual property protection helps to promote enterprises to apply for the registration of new pesticides.

Benefit for Enterprises

Definition



Pesticide

A substance or mixture or other preparation of one or more substances derived from chemical synthesis, or originated from biological and other natural sources, used to prevent or control diseases, insects, weeds, rodents or other organisms harmful to agriculture and forestry, and aimed to regulate the growth of plants and insects.



**New
pesticide**

A new pesticide refers to the pesticide that contains any active ingredient not approved and registered in China, including new pesticide TC (TK) and new pesticide formulations.

The Scope of China Pesticide



Agriculture Pesticide



Pesticide in Storehouse



Plant Growth Regulator (PGR)



Preservation



Sanitary Insecticide

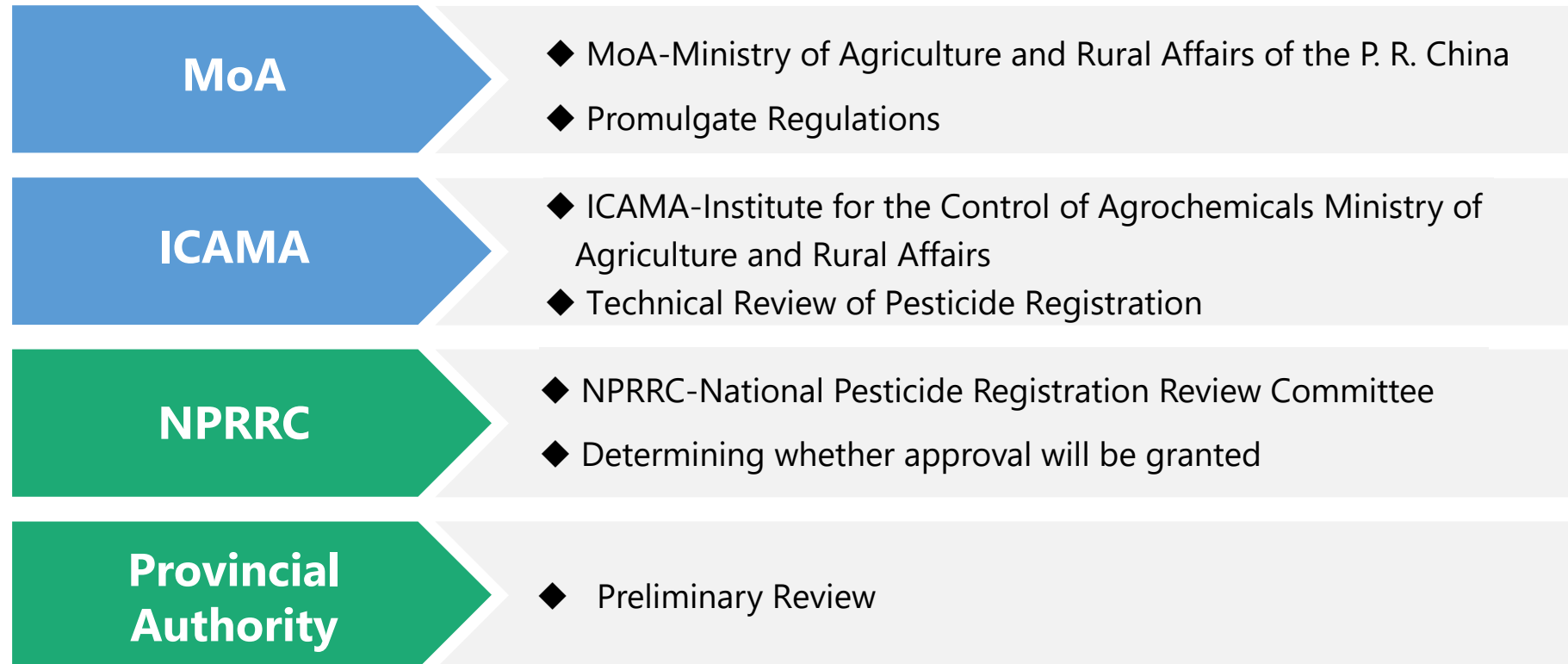


Others

Regulatory System

Categories	Document Name	Effective Date
Main Regulations	Regulation on the Administration of Pesticide	Jun 1 st 2017
	Administrative Measures for the Registration of Pesticide (Revision)	Jan 7 th 2022
	Administrative Measures for Pesticide Registration Tests (Revision)	Jan 7 th 2022
	Administrative Measures for Pesticide Manufacturing License (Revision)	Dec 6 th 2018
	Administrative Measures for Pesticide Business License (Revision)	Dec 6 th 2018
	Administrative Measures for Pesticide Labels and Manuals	Aug 1 st 2017
Subsidiary Regulations	Data Requirement on Pesticide Registration	Nov 1 st 2017
	List of restricted and banned pesticides (2019)	Nov 29 th 2019
	Import and Export Customs Notice for Pesticide (2022 Vision)	Jan 1 st 2022

Competent Authorities



Applicant of New Pesticide

01

Local Manufacturer

- Have pesticide manufacturing license

02

New Pesticide Developer

- Citizens, legal persons or other organizations in China.

03

Oversea Enterprise

- Manufacturers or trade companies
- Have offices in China or entrust intermediary organizations which have the legal person status in China

Data Requirements of New Pesticide

TC/TK



- Product chemistry data
- Toxicity data
- Environmental impact data

Formulation



- Product chemistry data
- Toxicity data
- Efficacy trials
- Residue trials
- Environmental impact data
- Risk assessment

Tests should be carried out at ICAMA-GLP labs or overseas lab under the mutual recognition agreement.

Procedure of New Pesticide Registration



Naming a Chinese common name

1. Apply to standardization committee for a Chinese common name.
2. Add to pesticide database.



Testing

1. Data gap analysis
2. Sample sealed
3. Test recorded
4. Testing reports review



Dossier preparation

1. Test reports and justification
2. Samples



Submission and Evaluation

1. Provincial authority and MoARA
2. NPRRC review



Application for registration of TC and formulation should be submitted simultaneously.

Summary of New Pesticide Registration

Procedure	Note
Applicant	Chinese pesticide manufacturer, Chinese pesticide developers, Overseas enterprises
Pesticide type	New pesticide, including chemical, biochemical, microbial and botanical pesticide
DGA	Phy-Chemical data, toxicology data, efficacy data, residual data, environment data etc.
Naming	Having a Chinese Common Name; Adding to pesticide database
Testing (ICAMA-GLP Lab)	Sample sealed-> test recorded -> test performed (generally 2~3 years)
Dossier	General documents + studies reports; Samples
Evaluation	ICAMA -> NPRRC (about 1 year)

03

Compliance Strategy Analysis about New Pesticide



Special Requirements for New Chemical Pesticide Registration

Data

◆ Product chemistry data

Phy-chemical properties of a.s. is required.

◆ Environment behavior fate data is required.

Data

◆ Residue data

1. Tests about metabolism in plants, metabolism in livestock are required.
2. Residue information in other countries is also required.

◆ Efficacy trials

1. Efficacy trials carried out in large-scales.
2. Monitoring method of field resistance.

Process

- ◆ Naming and adding to the database.
- ◆ To be reviewed and approved by the NPRRC.

Submission

- ◆ TC and formulation should be applied simultaneously.
- ◆ The samples of active substance, TC, formulation, relevant impurities and major metabolites should be submitted to MoA.

Difficulties in New Chemical Pesticide Registration

Cost

- Costs: 10~20 millions
- Time: 3~5 years

Risk assessment

- More strictly
- Refer to the review results of EFSA/EPA/JMPR

Toxicological & metabolic tests

- Toxicity test with relevant impurities and major metabolites.
- Metabolic tests with radioactive substance.
- Special toxicity tests, metabolic and toxicokinetic tests

Compliance Strategy



- Conduct a pre-risk assessment first



- Choose low-toxic and slight-toxic pesticides
- Select bio-pesticide which has been approved in other countries



- Entrust a professional consultant agent to complete the registration progress.

04

The Latest Pesticide Policies & Requirements

A person wearing black gloves is spraying a plant with a yellow pesticide bottle. The background is a blurred field of green plants.

New Pesticide Policies

Green Channel

For products that meet the requirements of the "green channel", priority will be given to the technical review process under the premise of ensuring product quality and safety.

◆ Scope:

1. **Biopesticide and agricultural antibiotics produced by biological fermentation.**
2. **New pesticide which is used to replace the highly toxic pesticides.**
3. Pesticide participating the joint efficacy trial for special minor crops.
4. Other pesticide identified by MoARA.

◆ How to apply

The applicant shall **submit a written application** for "green channel" when applying for the pesticide product registration.

New Pesticide Policies

National Development Plan for Pesticide Industry

- ◆ Control the number of pesticide registrations

Target	2020 Year	2025 Year
Number of pesticide registered	41885	< 45000

- ◆ Promote the development of new chemical pesticide with high efficacy and low risk, and biopesticide.



New Requirements

Toxicity test with relevant impurities and major metabolites

The acute oral toxicity test, mutagenicity test, and sub-chronic oral toxicity test are needed for relevant impurities and major metabolites.

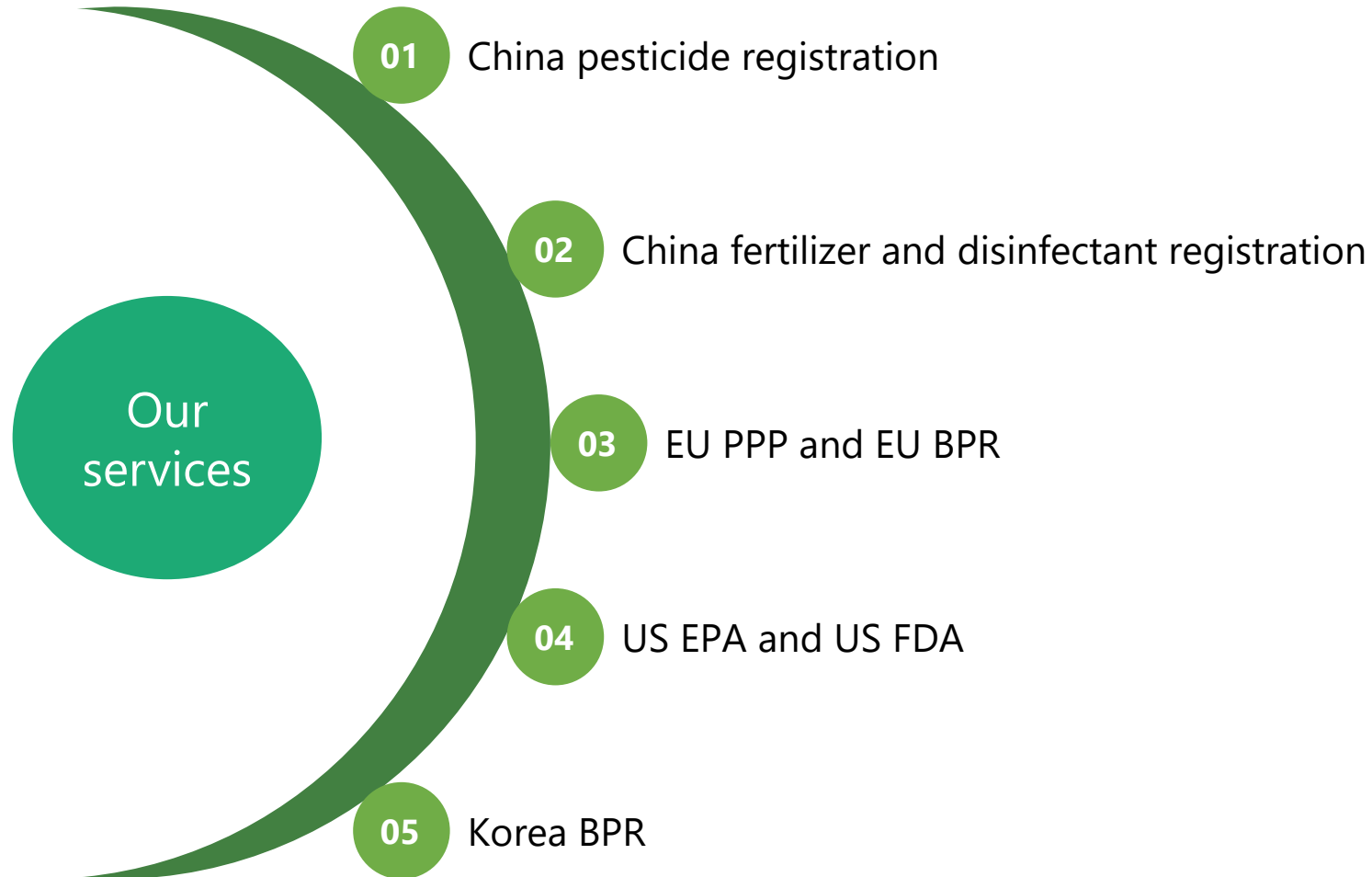
Pesticide ready-mixture

Registration of blended products will not be approved in the following cases:

1. The combined effect on the claimed target is antagonistic.
2. The mechanism of action of the active substance is same.
3. Herbicide mix with other function of pesticide.
4. Chemical pesticide mix with botanical pesticide.

.....

Our Compliance Service



Thank You.

Contact us for global regulatory services



<https://gpcgateway.com/>



Global Product Compliance (GPC)



compliance@gpcregulatory.com



+46 46 2114615



IDEON, Beta 5, Scheelevägen 17, 22363
LUND, SWEDEN