

Data Requirements and Challenges of Biopesticide Registration in China

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- Definition of Biopesticides in China
- Biopesticide Registration Status in China
- Data Requirements for Biopesticide Registration
- Biopesticide Registration Process
- Main Challenges of Biopesticide Registration in China
- Estimated Cost for Biopesticide Registration in China



Definition of Biopesticides in China

1

Biochemical Pesticides

- ❑ They do not have direct toxicity to the target but have only special effects such as regulating growth, interfering with mating or luring;
- ❑ They are natural compounds. If they are synthetic, their structure should be the same as that of natural compounds (differences in the proportion of isomers are allowed).

2

Microbial Pesticides

It refers to pesticides with bacteria, fungi, viruses, protozoa or genetically modified microorganisms as active ingredients.

3

Botanical Pesticides

It refers to pesticides whose active ingredients are directly derived from plants.

Definition of Biopesticides in China

There is no specific definition of biopesticide in China. It includes the following three categories.



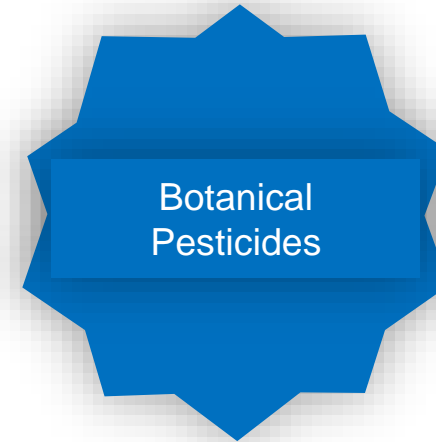
Biochemical Pesticide

- 1 Chemical pheromones
- 2 Natural plant growth regulator
- 3 Natural insect growth regulator
- 4 Natural plant anti inducer
- 5 Other biochemical pesticides



Microbial Pesticide

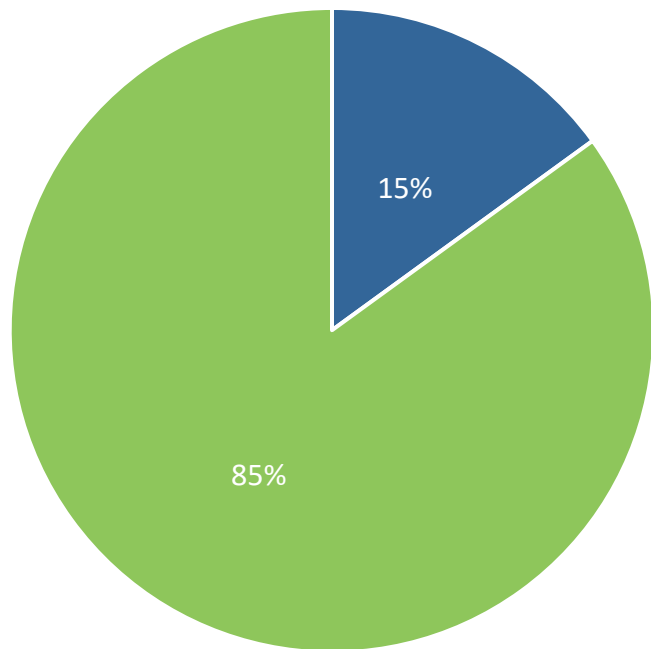
- 1 Bacteria
- 2 fungus
- 3 Oomycetes
- 4 virus
- 5 other



Botanical Pesticides

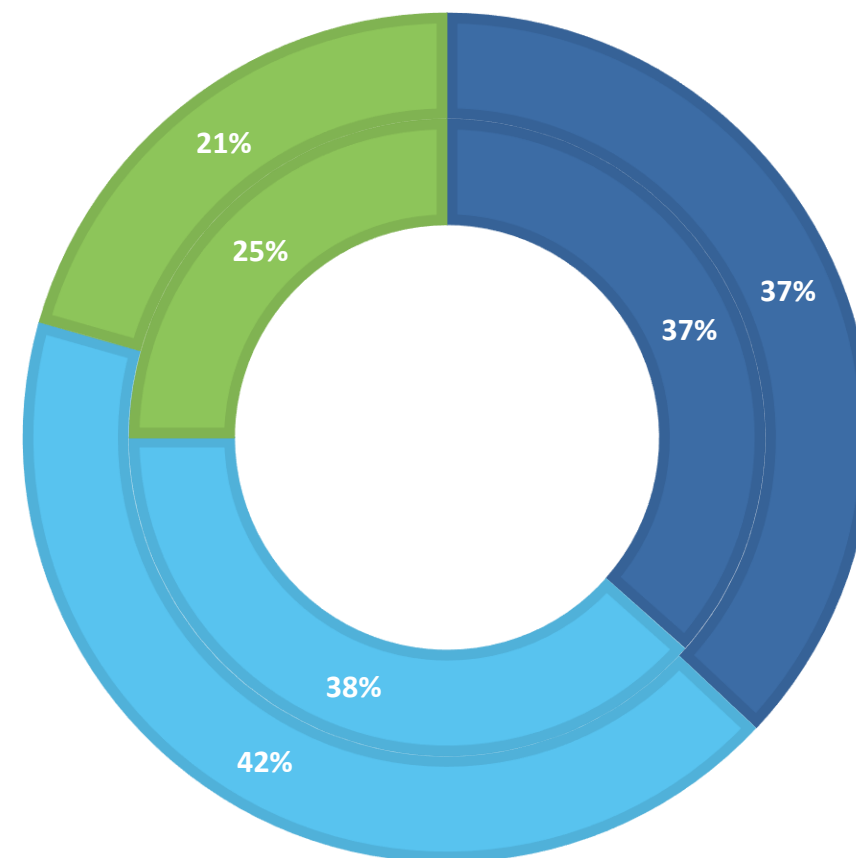
Biopesticide Registration Status in China - 2021

■ Microbial ■ Biochemical ■ Botanical



■ Biopesticide ■ Chemical

Active Ingredient Percentage



There are about 110 products (exclude antibiotics).
Accounting for 3.6% of total pesticide products.

Registration Status of Biochemical Pesticides – Chemical

Pheromones

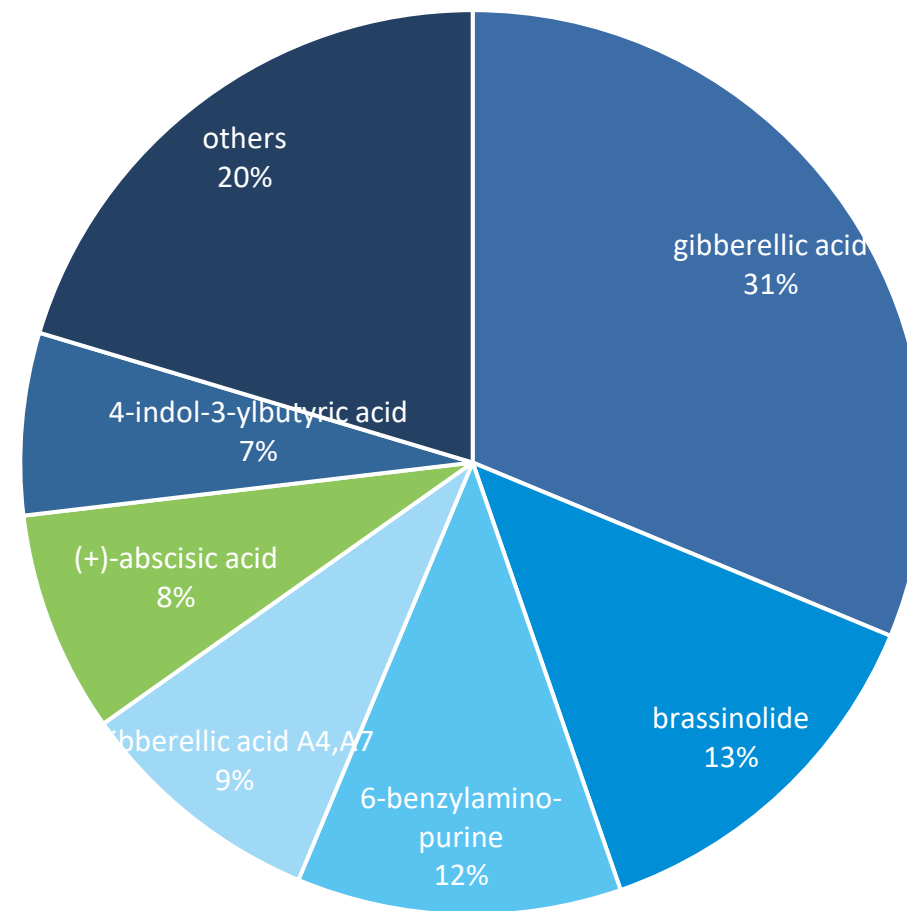
Product name	Active ingredient	Technical	Formulation
Pear small sex pheromone	z-8-dodecen-1-ol z-8-dodecen-1-y acetate E-8-dodecen-1-ylacetate	2	4
/	Z-8-dodecenol	1	/
/	E-8-dodecen-1-ylacetate	1	/
/	z-8-dodecen-1-y acetate	1	/
Sex attractant of striped rice stemborer (<i>Chilo suppressalis</i>)	Z-13-octadecene aldehyde Z-11-hexadecenal Z-9-hexadecenal	0	3
Sex pheromone of green stink bug	(2E)-2-hexen-1-y1 butyrate (2E)-4-oxo-2-hexenal	0	1
Sex pheromone of <i>Spodoptera litura</i>	Z 9 trans 11 tetradecane acetate Z 9 trans 12 tetradecane acetate	0	1
Sex pheromone of Apple bark moth	8,10-dodecadienol	0	1
Meadow moth	Z-9-tetradecane acetate Z-7-dodecene acetate Z-11-hexadecene acetate	0	1



Registration Status of Biochemical Pesticides - Natural Plant Growth Regulators

Active ingredient	Number of TGAI
Gibberellic acid	20
brassinolide	9
6-benzylamino-purine	8
Gibberellic acid A4 + A7	4
(+)-abscisic acid	3
4-indol-3-ylbutyric acid	10
14 hydroxybrassinosterol	3
Adenine	5
Triacontanol	2
Hydroxyene adenine	4
28 high brassinolide	2
28 Epibrassinolide	1
Indoleacetic acid	3
Furfuryl aminopurine	1
Iron dihydroporphyrin	1
Allantoin	1
ascorbic acid	0
22;23;24 Epibrassinolide	0

Number of Formulations



- gibberellic acid
- brassinolide
- 6-benzylamino-purine
- gibberellic acid A4,A7
- (+)-abscisic acid
- 4-indol-3-ylbutyric acid
- others

Registration Status of Biochemical Pesticides - Others

other

cholecalciferol

plant activator protein

harpin protein

BLAD

Natural plant inducer

oligosaccharins

chitosan

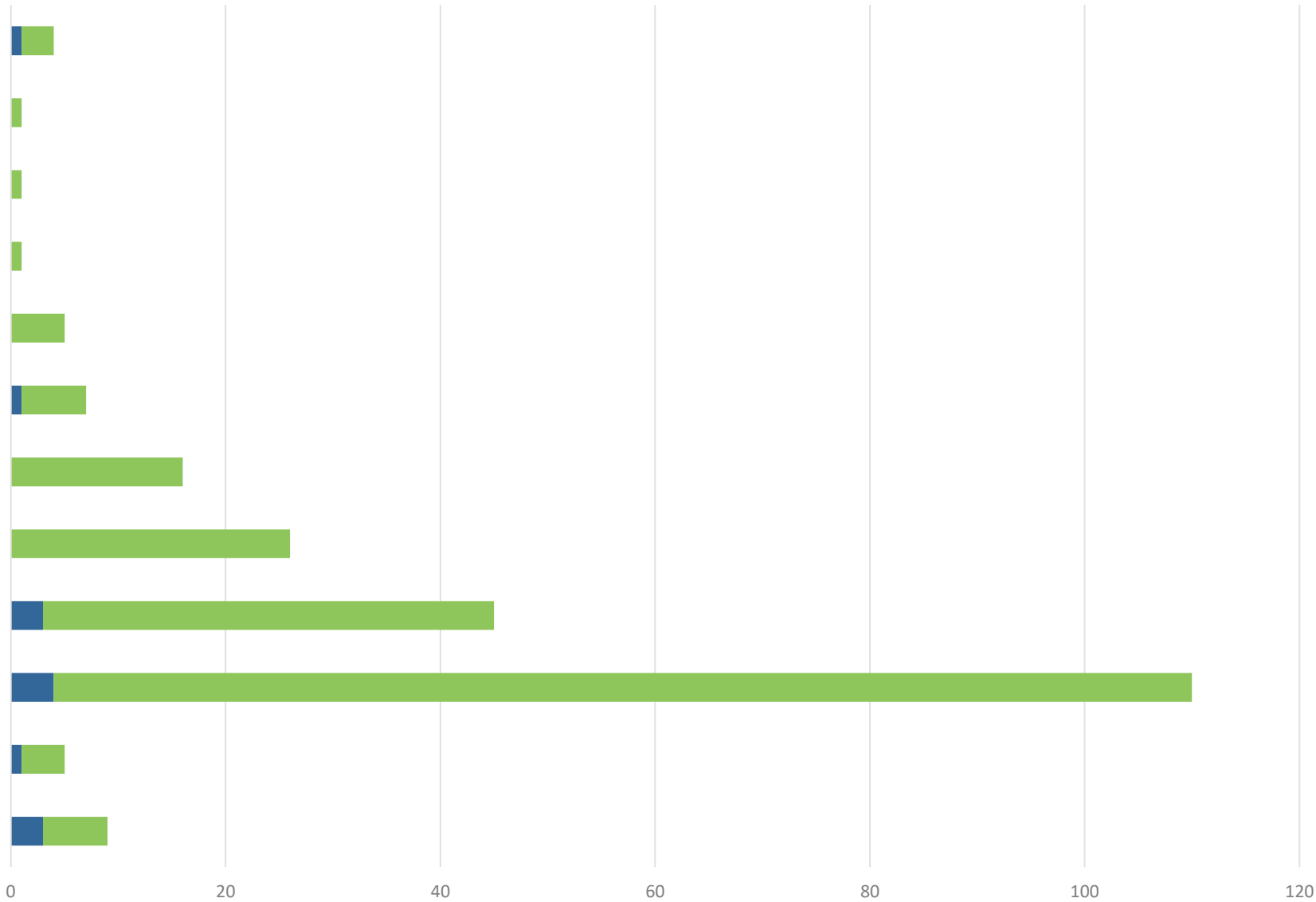
fungous proteoglycan

oligosaccharins

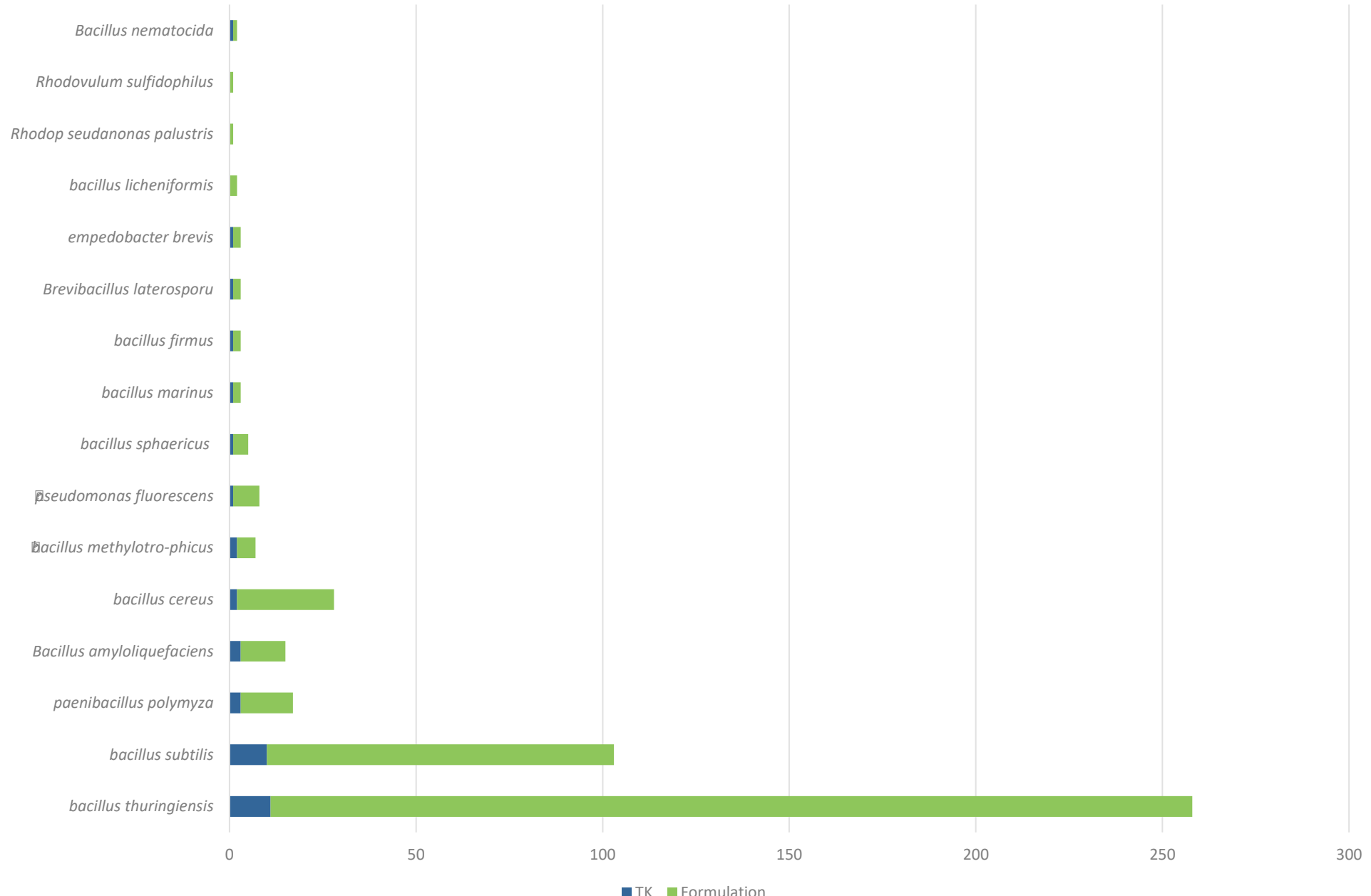
S-Methoprene

Natural insect growth regulator

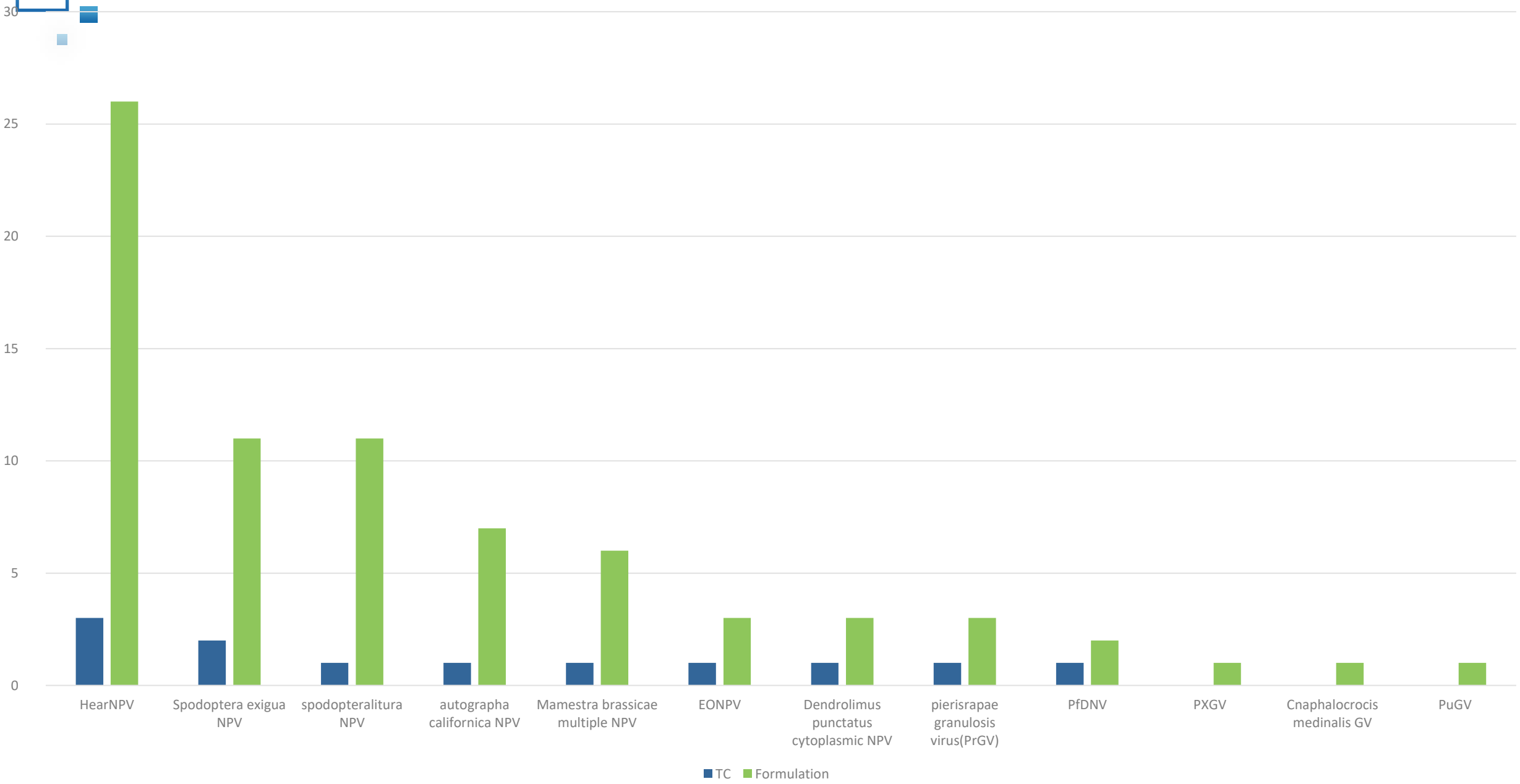
muscalure



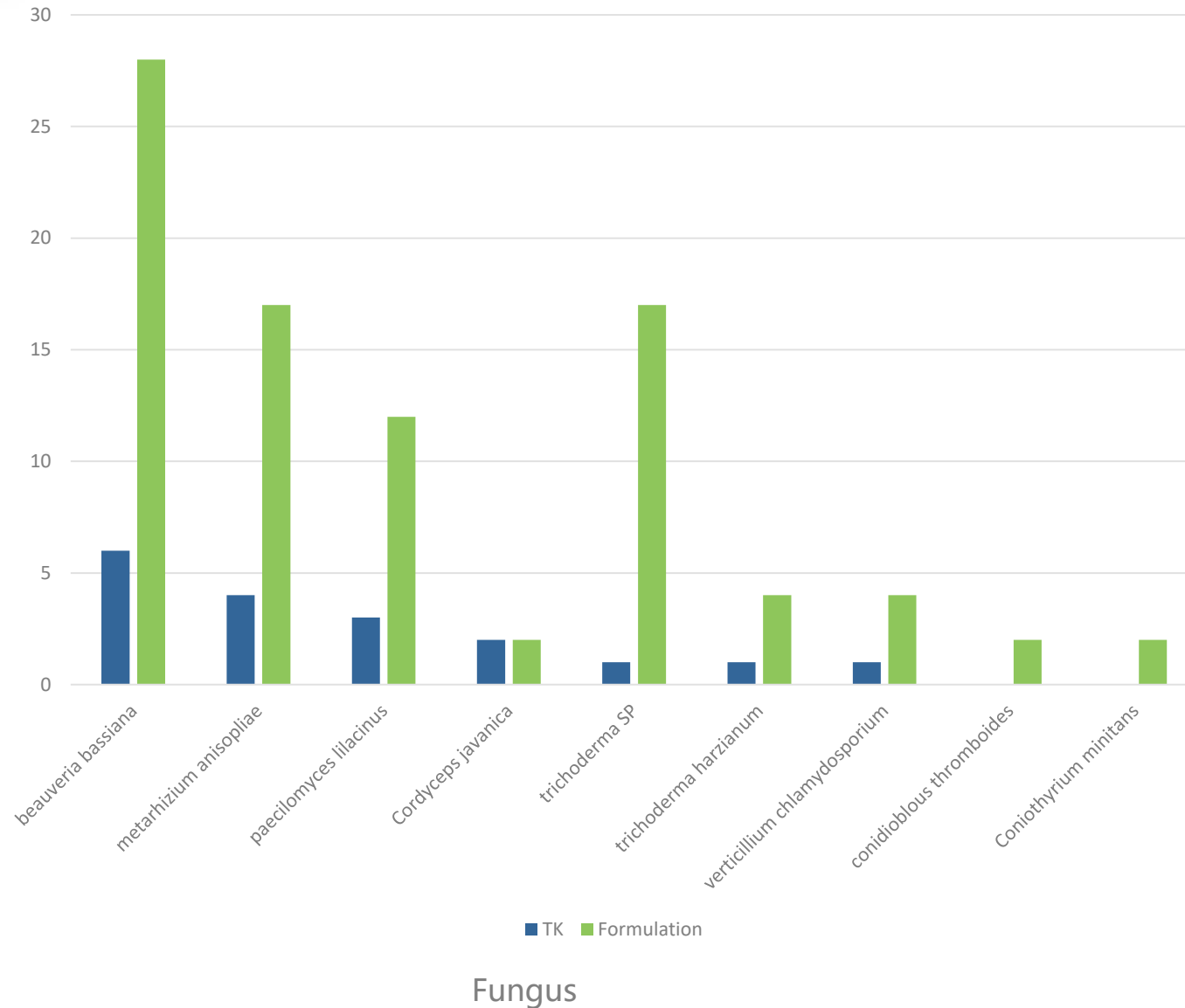
Microbial Pesticide Registration Status - Bacteria



Microbial Pesticide Registration Status - Virus



Status of Microbial Pesticide Registration - Others

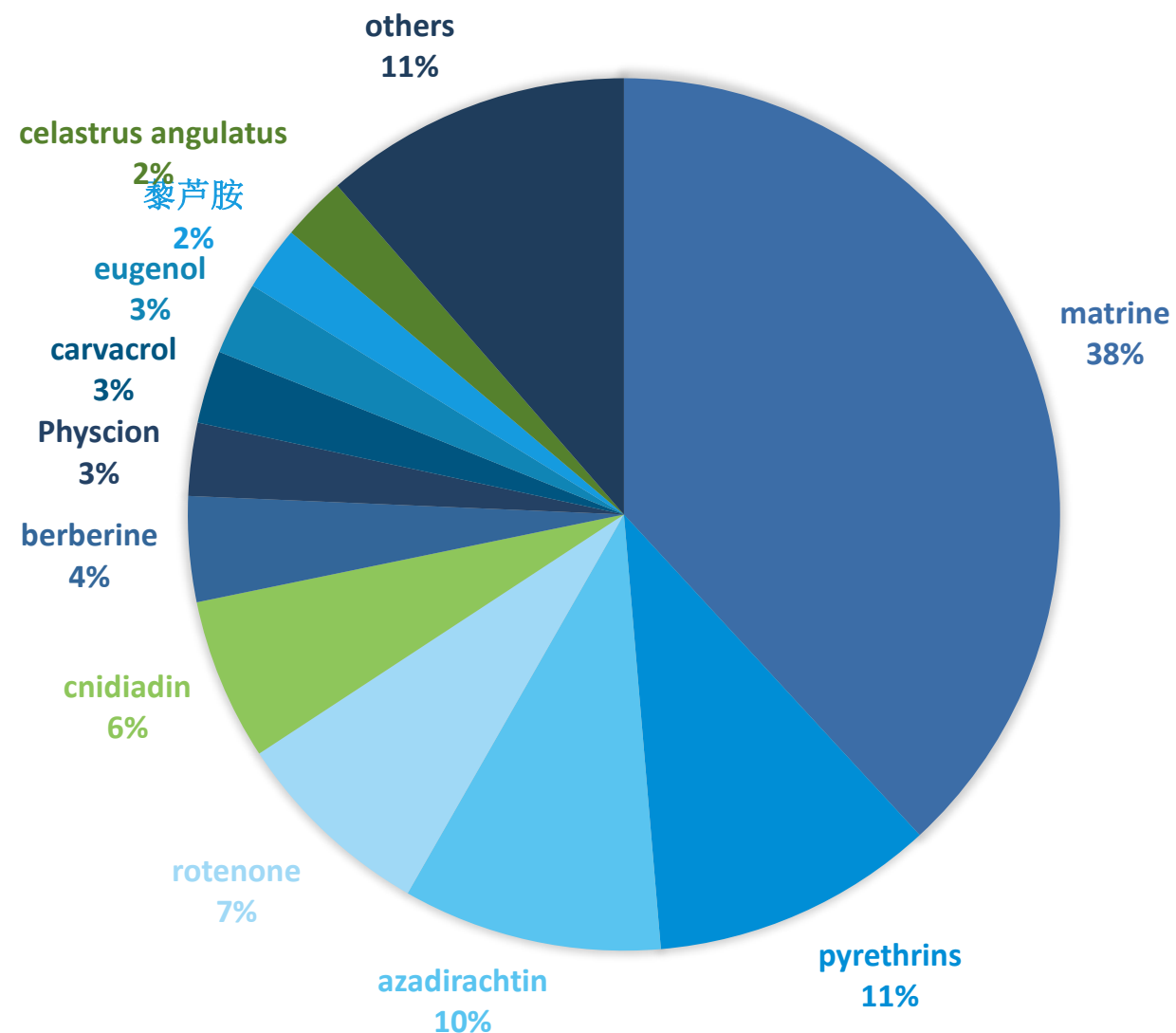


Oligomale Pythium	Oomycetes	1
nosema locustae	protozoan	2
Bacillus thuringiensis	Genetically modified bacteria	1

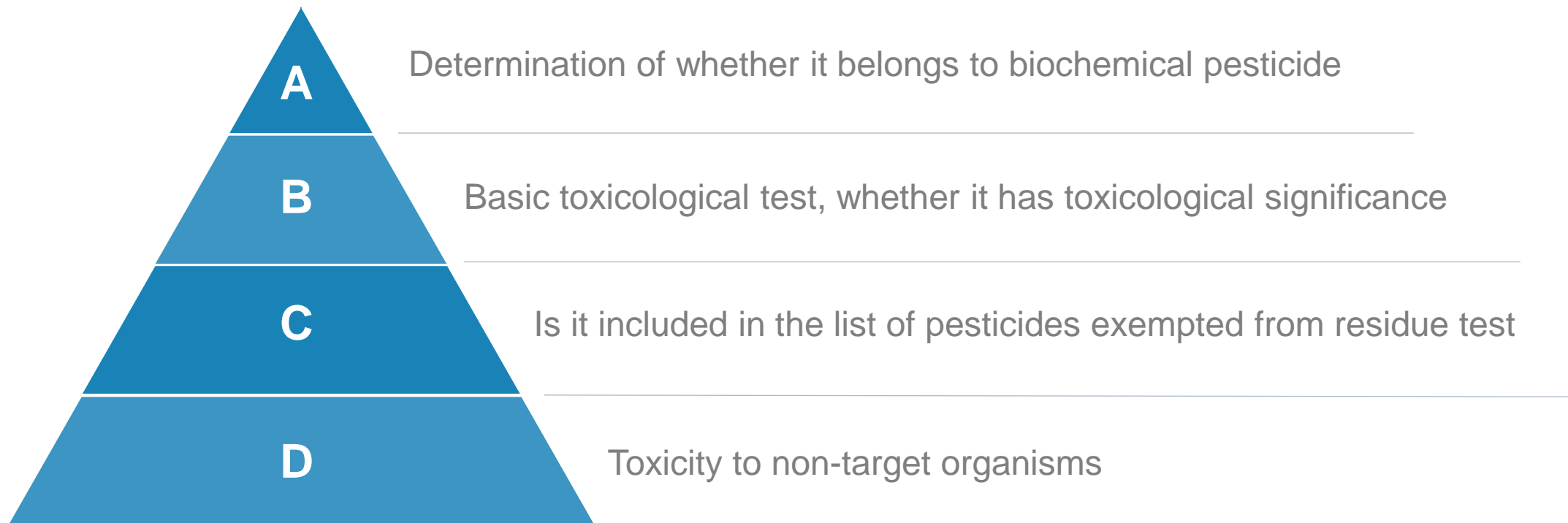
Registration Status of Botanical Pesticides

Active ingredient	Number of TC	Active ingredient	Number of TC
Matrine	5	d-limonene	2
Pyrethrin	4	Eucalyptus oil essence	1
Azadirachtin	3	Allicin	1
rotenone	2	Wolf toxin	1
Osthol	2	Triptolide a	1
berberine	1	Curcumol	1
Emodin methyl ether	2	Steroenol	1
Carvacrol	2	Luowei	1
Eugenol	0	Terpene alcohol	1
Verapamil	1	Pentadecanoic acid	1
Celastrus angustifolia	1	Acetophenone	1
other	15	Star anise oil	0
nicotine	1	Tea saponin	0
Allyl isothiocyanate	2		

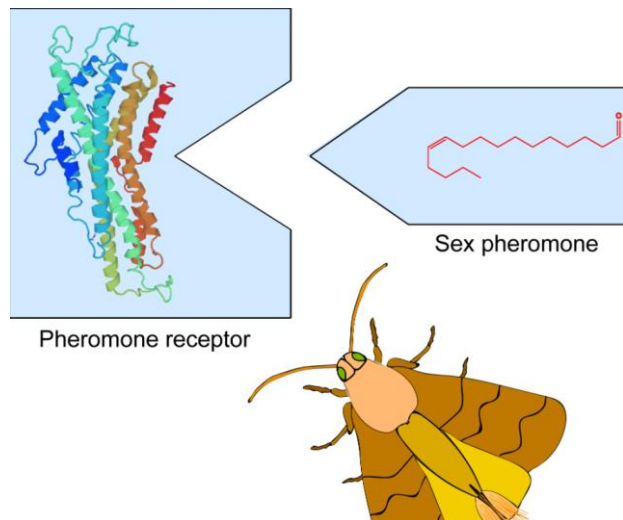
Formulation



Key Points of Biochemical Pesticide Registration Evaluation



Basic Principles of Biochemical Pesticide Registration



1

Agricultural antibiotic pesticides are the same as chemical pesticides.

2

Synthetic biochemical pesticides are treated as chemical pesticides.

3

In principle, it is not allowed to register the new pesticide TK, except for the original active ingredients that cannot be applied for due to material characteristics.

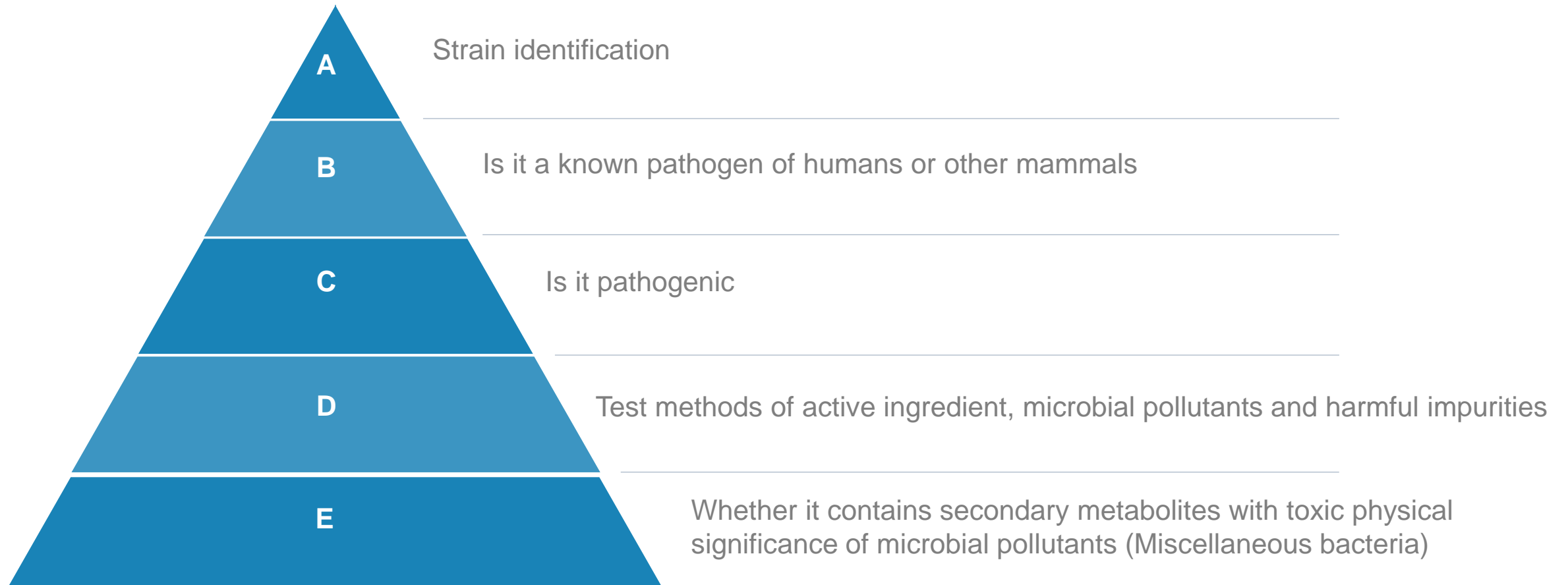
4

For low toxic (micro toxic) pheromones/fermented natural plant growth regulators and polysaccharide pesticides, the registration of TC (TK) can be exempted.

However, the TC dossier completed with fermentation broth and extract of processed formulation shall be submitted.



Key Points of Safety Evaluation of Microbial Pesticides



Basic Principles of Microbial Pesticide Registration



1

Microbial pesticides only have TK.

2

In principle, microbial new pesticides should be registered with the TK and formulation in the same time.

3

If microbial pesticide strains are different from registered pesticides, they shall be submitted for registration according to the new pesticide registration requirements.

4

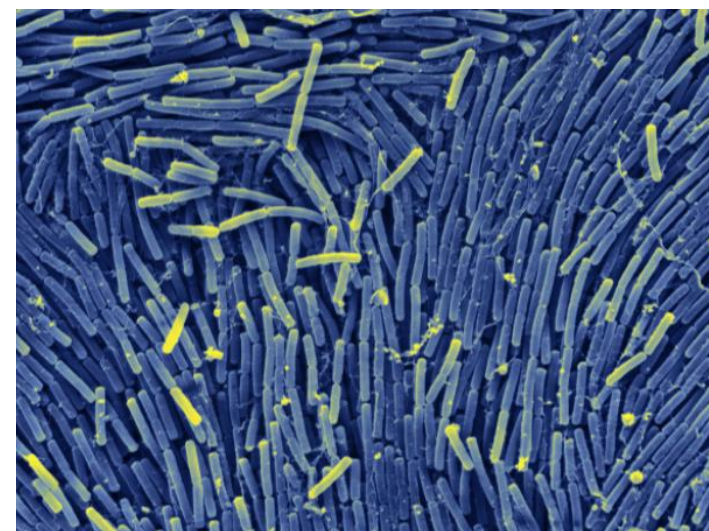
Microbial pesticide TK does not have me-too product.

5

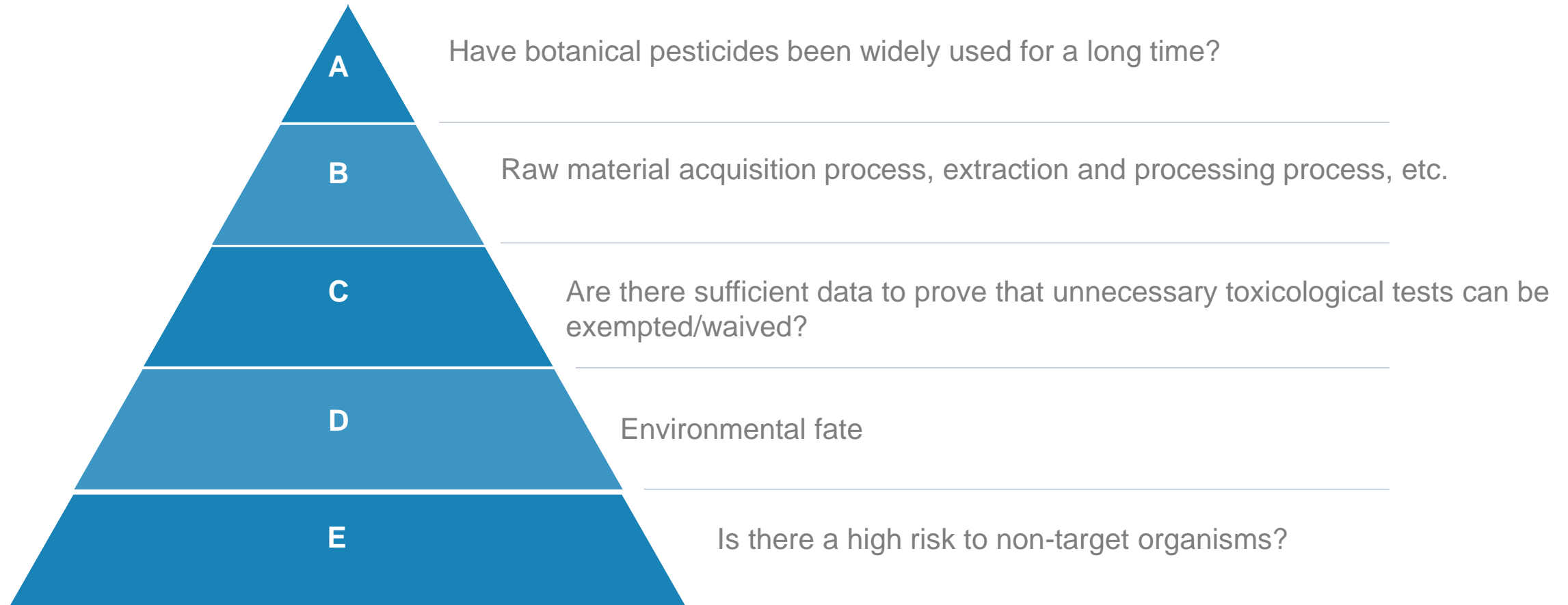
If the microbial pesticide TK is low toxicity or slight toxicity, TK registration can be exempted.

6

In principle, it is not allowed to mix chemical pesticides with microbial pesticides.



Key Points of Safety Evaluation of Botanical Pesticides



Basic Principles of Registration of Botanical Pesticides



1

Botanical pesticides are mainly TK and registered TC under special circumstances.

2

In principle, it is not agreed to exempt the TK registration of botanical pesticides, and the special circumstances shall be considered by the pesticide registration review committee.

3

The botanical pesticide TC(TK) does not have me-too product.

4

In principle, the registration of mixed products of chemical pesticides and botanical pesticides is not approved.



Full version is available free of charge upon request. (agrochem@cirs-group.com)

A wide-angle photograph of a majestic mountain range with snow-capped peaks under a clear blue sky. The mountains are rugged and layered, with some peaks appearing more prominent than others. The overall scene is serene and grand.

Thanks

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