

China Pesticide Registration



We prepared this presentation in order to promote better understanding of China Pesticide Registration. Based on our experience, the topics and related information contained within, are specially chosen, to save you time and effort.

Content

Part I	Part II	Part III
Background	Registration	Further More
Authorities Law and Guidance 2011 Reg. Sta. Data Update and news	Scope and Applicants Registration workflow Product Analysis Data Analysis	Duration and Cost SDS and Label Practical tips

Part I

Background

Authorities

Law and Guidance

2011 Reg. Sta. Data

Update and news

Authorities



MOA

The Ministry of Agriculture of the People's Republic of China
www.moa.gov.cn



ICAMA

The Institute for the Control of Agrochemicals under the Ministry of Agriculture (ICAMA)
www.chinapesticide.gov.cn

Three Main Regulations/Guidance

Regulation on Pesticide Administration (RPA)

The State Council

Issued on May 8, 1997 and amended on November 29, 2001

Provisions for the Implementation of the Regulation on Pesticides Administration

Ministry of Agriculture

Issued on April 27, 1999 and amended on July 27, 2002

Data Requirement of Pesticide Registration (DRPR)

Ministry of Agriculture

Issued on April 12, 2001 and revised on December 8, 2007

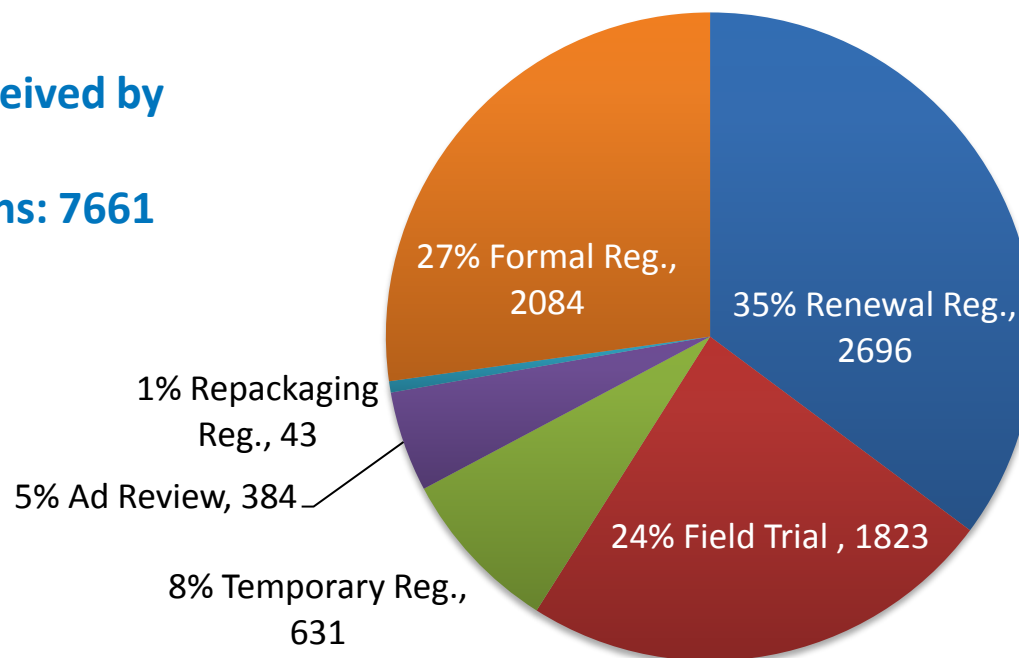
Relevant Law/Guidance

- ✓ Pesticide Advertisement Inspection Measure
 - ✓ Guidance on Pesticide Efficacy Trials
 - ✓ Guidance on Pesticide Environment Safety Test and Evaluation
 - ✓ Guidance on Pesticide Toxicity Tests
 - ✓ Guidance on Pesticide Label and Manual
 - ✓ Guidance on Pesticide Packaging
 - ✓ Guidance of Safety Handling on Pesticide Storage and Transportation
 - ✓ Standards on Pesticide Residue
 - ✓ Standards on Pesticide Products
-



Registration Statistical Data (2011)

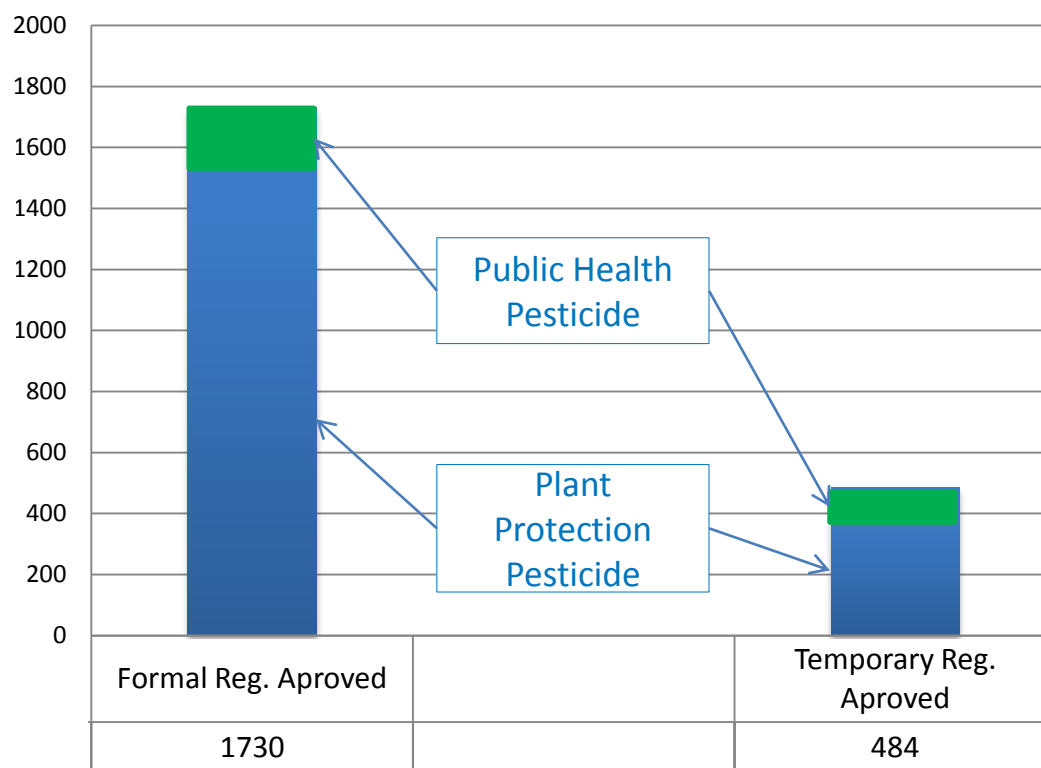
**Applications received by
ICAMA in 2011
Total Applications: 7661**



*Information source: Overview on pesticide registration and management 2011, **Pesticide Science and Administration**, Vo1. 33, ISSN 1002-5480*

Registration Statistical Data (2011)

**2214 Certificates
issued in 2011**



*Information source: Overview on pesticide registration and management 2011, **Pesticide Science and Administration**, Vo1. 33, ISSN 1002-5480*

Updates and News

- I. **Draft Regulation on Pesticide Administration (July 20, 2011)**
 - Temporary registration will be cancelled
 - More articles related to imported pesticides are added

 - II. **Draft Provisions on Data Requirement of Pesticide Registration (April 28, 2011)**
 - Reduced data requirements for low risk pesticide

 - III. **MOA Notice 1586 2011;**
 - List of banned or restricted high toxicity pesticides
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Part II

Registration

Scope and Applicants

Registration workflow

Product Analysis

Data Analysis

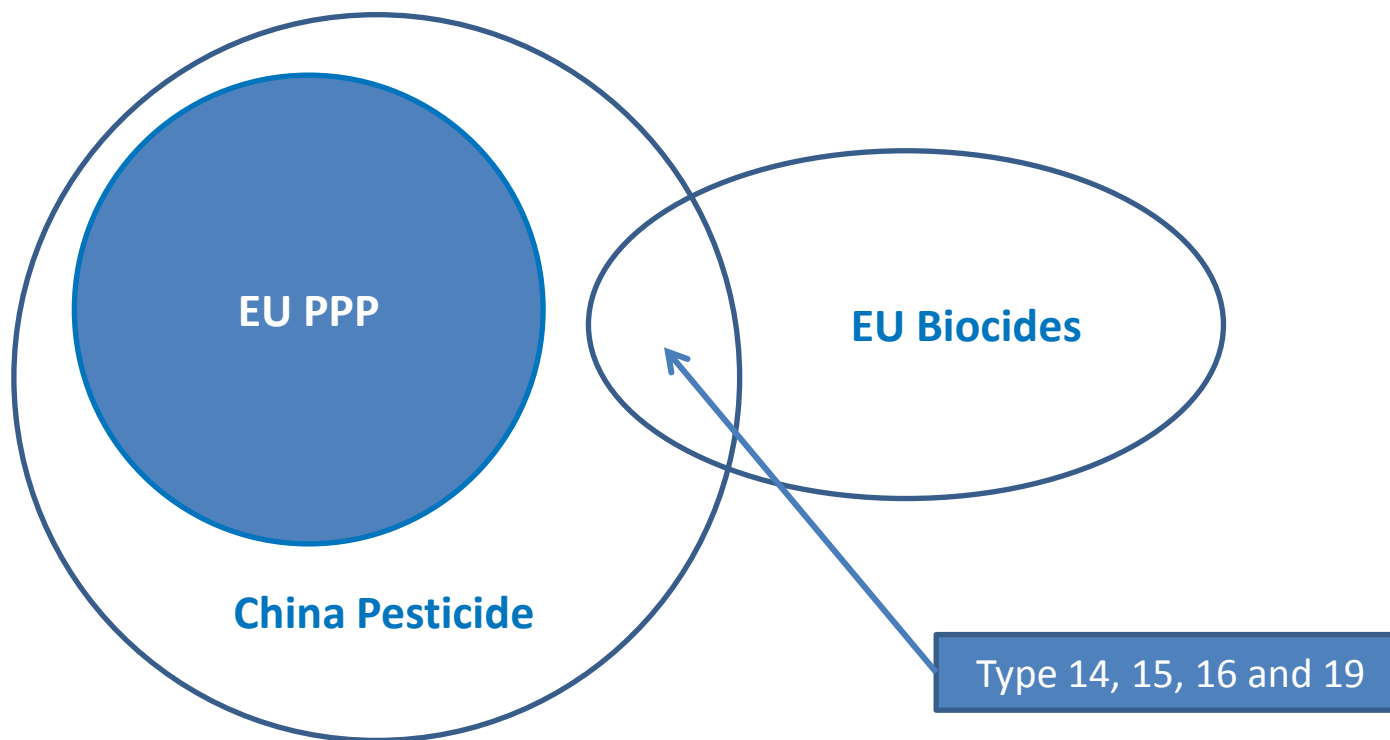


Pesticide Scope

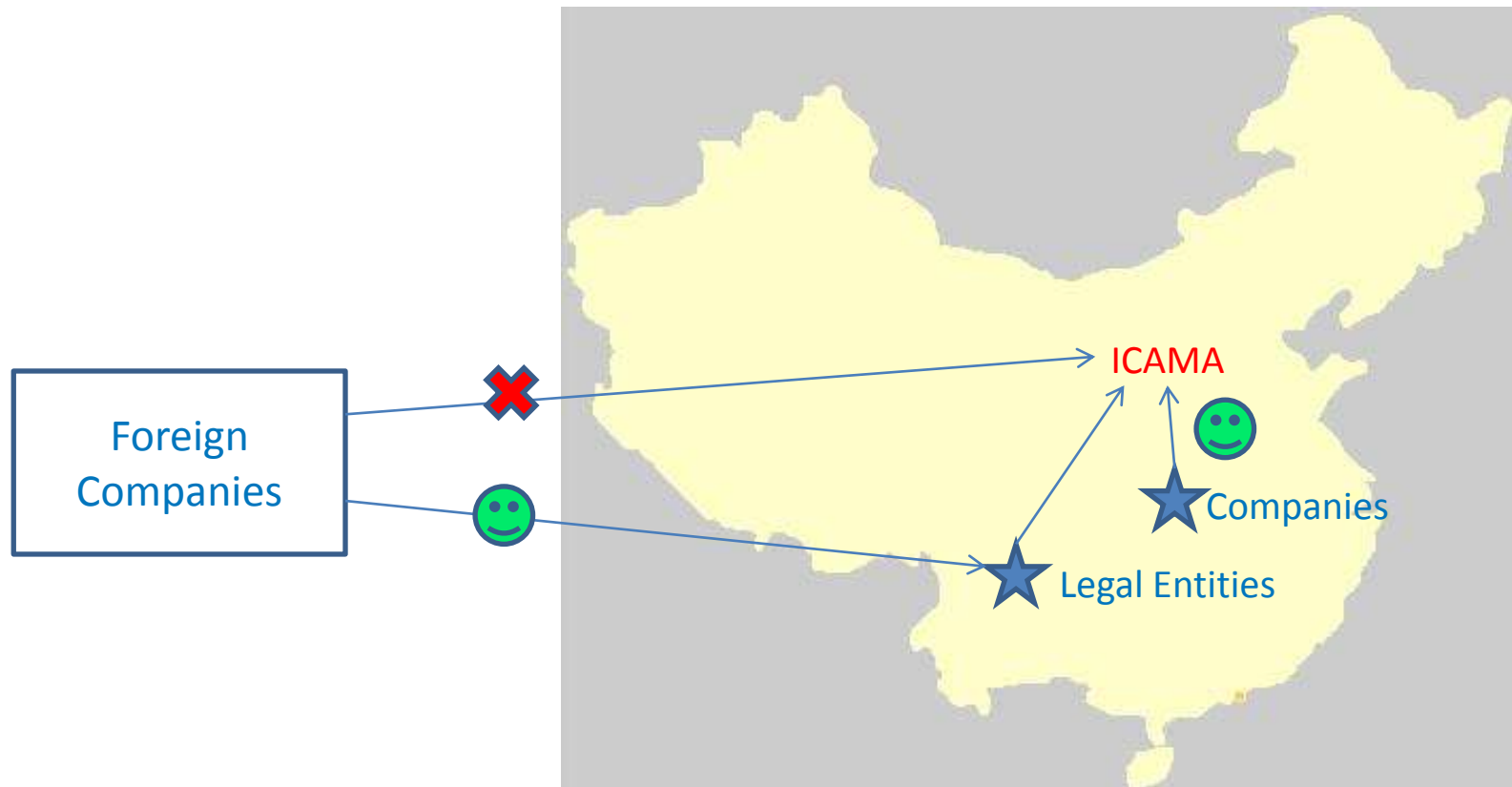
Type	Instance
To control agriculture/forestry pests	Glyphosate, Abamectin
To control storage pests	Methyl bromide
PGR and IGR	NAA, GA, Diflubenzuron
Agricultural or forestry preservative	Prochloraz
Public health pesticide	Tetramethrin
To control pests harmful to other places	Chlorpyrifos

Part II

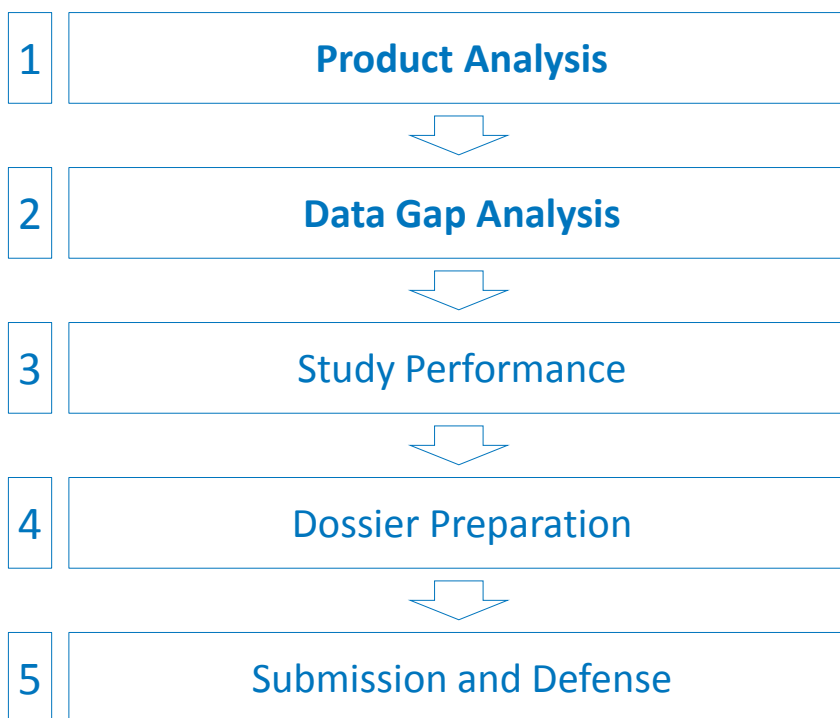
What is the difference between product scope under China Pesticide and EU PPP?



Applicants



Registration Procedures



Product Analysis

Feasibility Analysis

- 1, Regulated or not Regulated
- 2, How many registration and competitors in China
- 3, Market Potential
- 4, Application in China

Product/Registration Type Analysis

- 1, Generic pesticide or special pesticide
 - 2, New Pesticide or Same Pesticide
 - 3, Data Requirement
 - 4, What data can be exempted
-

How to find your expected information from ICAMA's website?

Part II

Registered number
Active ingredients
Registered company



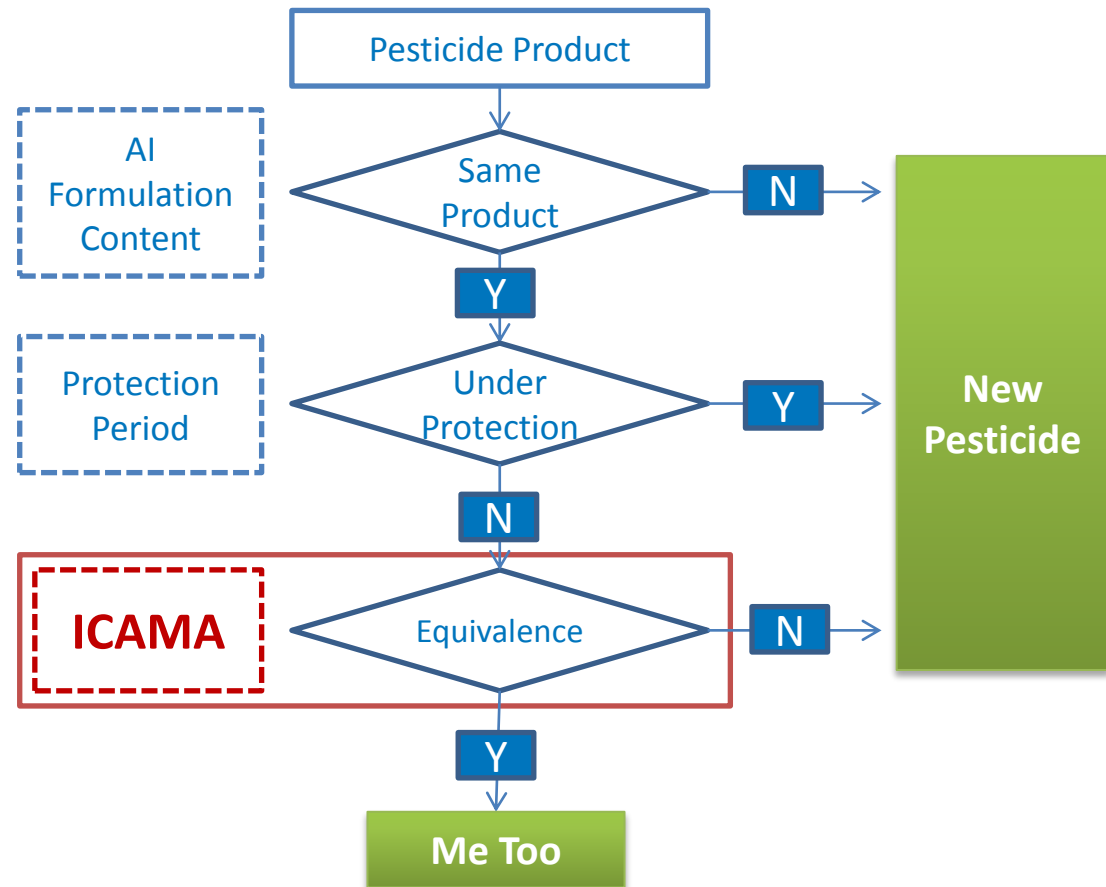
<http://www.icama.org.cn/en/>

Registered Products
Registration process
Label Information
AI
Expired registration
AD overview
Field Trial
Certificate of free sale
...



<http://www.icama.org.cn>

How to determine if a pesticide product can be registered as “Me Too”?



Data Analysis

Purpose:

Avoid unnecessary tests and studies

Tasks:

Data Requirements identification

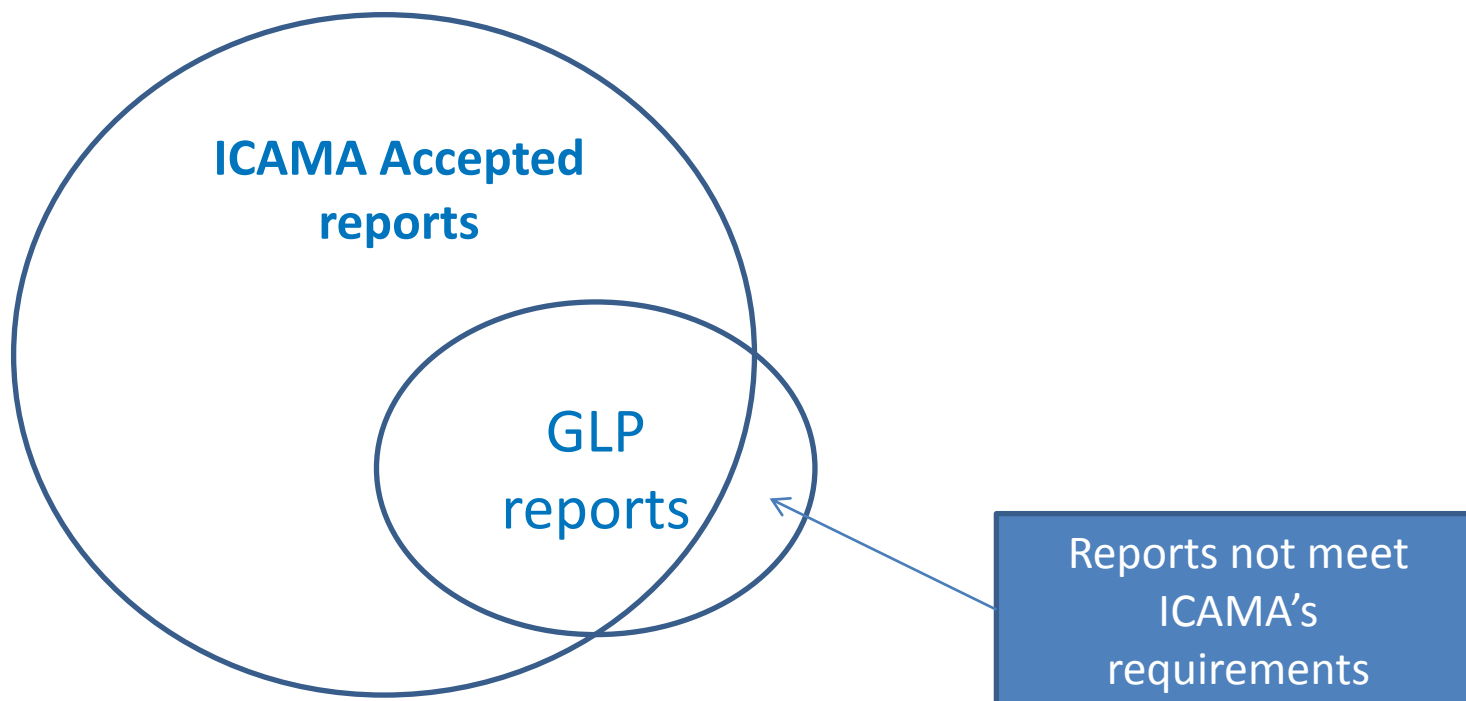
Existing Data Evaluation

Data Gap Identification

Data Collection and Integration Suggestions

Final Assessment

What kinds of study reports can be accepted by ICAMA?



What Are the Data Requirements for New Formulated Products and New Technical Products?

Formulated Products

- ✓ Application form
 - ✓ Pre-analysis of Mode of action
 - ✓ **Lab efficacy and safety test report**
 - ✓ Filed efficacy test ports
 - ✓ Certificate of composition of technical
 - ✓ Product standard
 - ✓ Storage stability test reports (cool, accelerate, and real time tests)
 - ✓ Six pack test reports
 - ✓ **Residue test reports**
 - ✓ Ecotoxicity test reports
 - ✓ Label
 - ✓ MSDS
 - ✓ Integrated information report
-

Part II

Technical Product

- ✓ Application form
 - ✓ Product Summary
 - ✓ Five batch analysis report
 - ✓ Product Standard
 - ✓ Manufacturing process
 - ✓ Six Pack Reports
 - ✓ 90 Days feeding test report
 - ✓ Mutagenicity tests (three tests reports)
 - ✓ Reproduction toxicity report reports
 - ✓ Teratogenic toxicity report
 - ✓ Metabolism in animals
 - ✓ 2years Chronic/carcinogenic toxicity report
 - ✓ People exposure data
 - ✓ Toxicity information of impurities
 - ✓ Neurotoxicity test report
 - ✓ Environmental fate tests
 - ✓ Eco-toxicity test reports
 - ✓ Label
 - ✓ MSDS
 - ✓ Integrated information report
-

Part III

Further More

Duration and Cost

SDS and Label

Practical tips

Duration



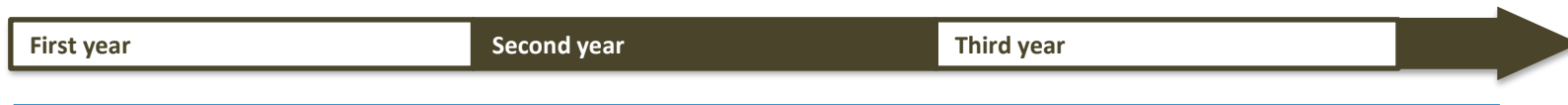
Me Too, 2 years

Duration and work tasks are based on the completeness of existing data/reports.






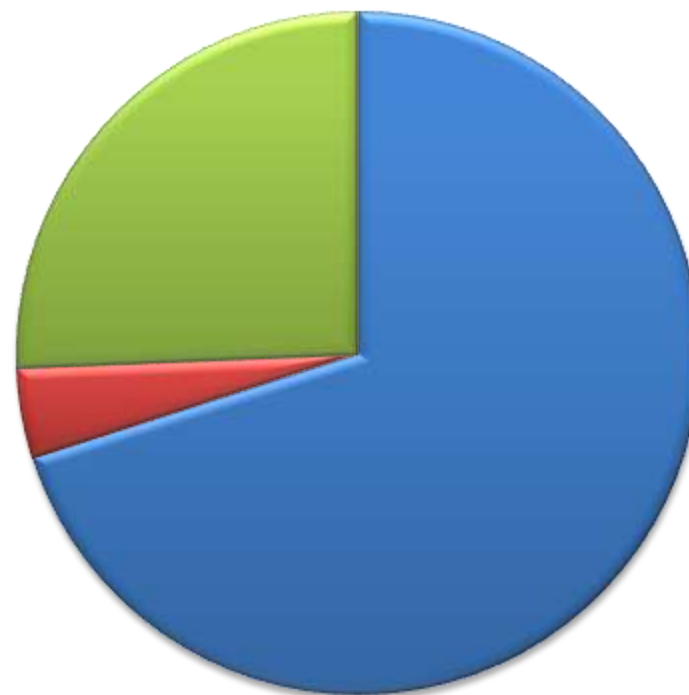
New Pesticide, 2-3 years

Work tasks of study performance will be different due to different product types and the necessary tests. For the best situation, the duration of New Registration should be 25 months.



Cost Analysis

-  Study Performance Cost
60~ 80%
-  Administration Fee.
1-5%
-  Manpower Cost.
20-40%



SDS

- ✓ *Explanations on Pesticide Safety Data Sheet (MSDS)*
 - ✓ 16 titles
 - ✓ In Chinese
-

Label – Technical Product

China Pesticide Label must be prepared according to the *Guidance on pesticide label and manual*. The labels are different for technical material and formulated product.

The diagram illustrates the layout of a pesticide label for a technical product, with the following fields highlighted:

- Registration Certificate Number, Approval Number, Product standard Number:** 农药登记证号: PD20070183, 农药生产许可证(或生产批准文件)号: [redacted], 产品标准号: [redacted]
- AI Name:** 联苯菊酯
- AI Content: 95%:** 有效成分含量: 95%
- Toxic Symbol:** 中等毒 (Medium Toxicity)
- Caution words:** 中等毒
- Registrant Contact info:** [redacted]
- Color Code:** [redacted]
- Feature:** 产品特点: 内吸、熏蒸作用, 杀虫谱广, 用于农作物, 其他场所。
- First Aid:** 中毒急救: 1. 用过的容器... 2. 操作时应做好防护... 3. 万一着火, 泄漏或泼洒, 应用... 4. 万一着火, 泄漏或泼洒, 应用... 5. 万一着火, 泄漏或泼洒, 应用...
- Precaution Symbol:** 注意: 本品仅用于加工农作物... 不得用于... 不得用于... 不得用于...
- Storage and Transport:** 贮存和运输: 本品应贮存于干燥、阴凉、通风、防潮处, 远离火源或热源, 置于儿童接触不到之处, 并加锁。勿与食品、饮料、饲料等其他商品同贮同运, 用过的容器... 处理, 不可做他用, 也不可随意丢弃。
- Shelf life and net content:** 净含量(重量): 毫升(克), 生产日期: 年 月 日 批号: 有效期: 2年



Label – Formulated Products

Trade mark

Direction of use
(different with the
technical material)

川福华 农药登记证号:PD20010583
农药生产许可证(或生产批准文件)号:
产品标准号:

草甘膦异丙胺盐(41%)
有效成分含量:30%
剂型:水剂

使用技术和使用方法:

防治对象	防治对象	推荐用药量	使用方法
水稻	一年生杂草和多年生恶性杂草	250-500毫升/亩	定向喷雾
甘蔗	一年生杂草和多年生恶性杂草	250-500毫升/亩	定向喷雾
柑橘园	一年生和多年生杂草	273-547毫升/亩	定向茎秆喷雾
果园	一年生杂草和多年生恶性杂草	250-500毫升/亩	定向喷雾
剑麻	一年生杂草和多年生恶性杂草	250-500毫升/亩	定向喷雾
林木	一年生杂草和多年生恶性杂草	250-500毫升/亩	定向喷雾
桑树	一年生杂草和多年生恶性杂草	250-500毫升/亩	定向喷雾
橡胶树	一年生杂草和多年生恶性杂草	250-500毫升/亩	定向喷雾

(注:1)全株用前稀释=容量/剂量×15
(2)基药成分量取剂量(毫升/千克)=(制剂含量×10000000-制剂稀释倍数)

1.一年生杂草在生长旺盛期,多年生杂草在开始开花阶段,使用清水将本品稀释后,对杂草茎叶均匀定向喷雾。2.对多年生恶性杂草,在第一次施药一个月后再施药一次,才能达到防除效果。

生产企业名称:四川省乐山市五通桥区
地址:四川省乐山市五通桥区
电话:0833-3360538 传真:0833-3360538

产品性能(用途):
本品是灭生性内吸传导型灭生性除草剂,主要通过抑制植物体内烯醇丙酮基莽草素磷酸合成酶,从而抑制莽草素向苯丙氨酸、酪氨酸及色氨酸的转化,使蛋白质的合成受到干扰导致植物死亡。本品适用于茶叶、甘蔗、剑麻、林木、桑树、橡胶树、果园一年生、多年生杂草的除草。在正常使用技术条件下,对天敌及有益生物较安全。

注意事项:
1.施药时应防止药液漂移到作物茎叶上,以免产生药害; 2.草甘膦与土壤接触立即失去活性,宜作茎叶处理; 3.施药当天用药效果优于低温天气,施药后3-4小时下雨会影响药效,可酌情补喷药液; 4.草甘膦对金属制成的镀锌容器有腐蚀作用,易引起火灾,对金属容器有腐蚀性作用; 5.低温贮存时如有结晶析出,使用时应充分摇动容器使结晶溶解,以保证药效; 6.药液应用清水配置,有沉淀的水会降低药效; 7.使用本品时应穿戴防护用品、面罩和手套等防护用品,避免吸入药液; 施药期间不可吃东西、喝水和吸烟等施药后应及时洗手和洗脸等; 8.清洗施药器具的废水禁止倒入河流、池塘等水源; 9.孕妇及哺乳期妇女避免接触此药; 10.施药后8天内不能翻草、翻耕、放牧等。

中毒急救:
1.对眼睛、皮肤和上呼吸道有刺激作用; 2.尚无特效解毒剂,若摄入量较大,可用土根糖浆洗吐,还可在服用的活性炭泥中加入山梨醇; 3.若不甚沾染皮肤,应用大量清水清洗,若灌入眼睛,应用清水冲洗至少15分钟; 4.送医院对症治疗。

储存和运输:
本品应贮存于干燥、阴凉、干燥、通风处,远离火源或热源,至于儿童触及不到之处,并加锁。勿与食物、饮料、种子、饲料、肥料等同仓储运,用过的容器应妥善处理,不可作他用,也不可随意丢弃。贮运时防止潮湿和日光直射。

净含量(重量): 毫升(克) 生产日期: 年 月 日 批号: 有效期: 3年

除草剂



Practical Tips

Some reasons of Registration Rejection

Not a pesticide
Medical products are not fit for using as pesticide
Mistake in the application form

Notice on the label is not corresponding to the toxicity of the products
Nonconforming label
Incorrectly naming of active ingredient

Risk assessment is needed for products with risk potential to environmental safety
Lack of toxicity studies reports or metabolism studies reports or environmental fate studies reports or residues studies on the registration crops or others data
Mistake or lack of PHI

Residue is out of limits
Mixed formulated products with same mechanism of action
Undefined mechanism of action or field efficacy

Practical Tips

Banned List and Restricted List

Banned List

✓ 23 Pesticide

Restricted List

✓ 19 Pesticide

✓ Some crops applications are restricted

MOA Notice 1586

✓ 15 June, 2011

Notice 1586 list

✓ 22 Pesticides

✓ Oct 31, 2011

✓ Oct 31, 2013

Part III
Banned List

Arsenic	DDT	BHC	Sodium fluoroacetate	Silatrane
Diromoethane	Nitrofen	Thiodaqual	Monocrotophos	Ammonium phosphate
Toxaphene	Aldrin	Fluoroacetamide	Methamidophos	Lead
Dibromochloropropane	Dieldrin	Gliflor	Parathion-methyl	
chlordimeform	Mercurials	Tetramine	parathion	

Restricted List

Omethoate	Thyme	Carbofuran	Fonofos
Dicofol	Isofenphos-methyl,	Aldicarb	Isazofos
fenvalerate	Phosfolan-methyl	Ethoprophos	Fenamiphos
Daminozide	Sulfotep	Phosfolan	Fipronil
Terbufos	Demeton	Coumaphos	

22 pesticides listed in the Notice 1586

Fenamiphos	Cadusafos	Coumaphos	Methomyl	Bromomethane
Zinc Phosphide	Fonfos	Methidathion	Ethoprophos	Endosulfan
Posfolan-Methyl	Omethoate	Thimet	Aldicarb	
Calcium Phosphid	Terbufos	Isofenphos-Methyl	Aluminium Phosphide	
Magnesium Phosphide	Sulfotep	Carbofuran	Isocarbophos	

Workshop

Subject:

1st Workshop on Pesticide Registration in EU and USA – Hangzhou, China

Time:

10-11 April 2012

Address:

Liutong Hotel, Hangzhou, China

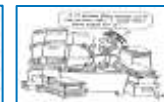
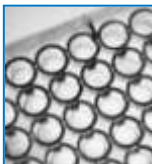
Presenter:

Louis Wyness, Director, Technology Sciences Group Europe (TSGE)

Robert Stewart, Ph.D., Vice President, Technology Sciences Group Inc. (TSG)

Emma Huang, Senior Pesticide Registration Specialist, CIRS China

Thanks for Your Attention



FOR ANY QUERIES/ QUESTIONS, PLEASE DO NOT HESITATE TO
CONTACT: MR. DAVID WAN. Email: david@cirs-reach.com
