



THINK GLOBALLY, ACT LOCALLY

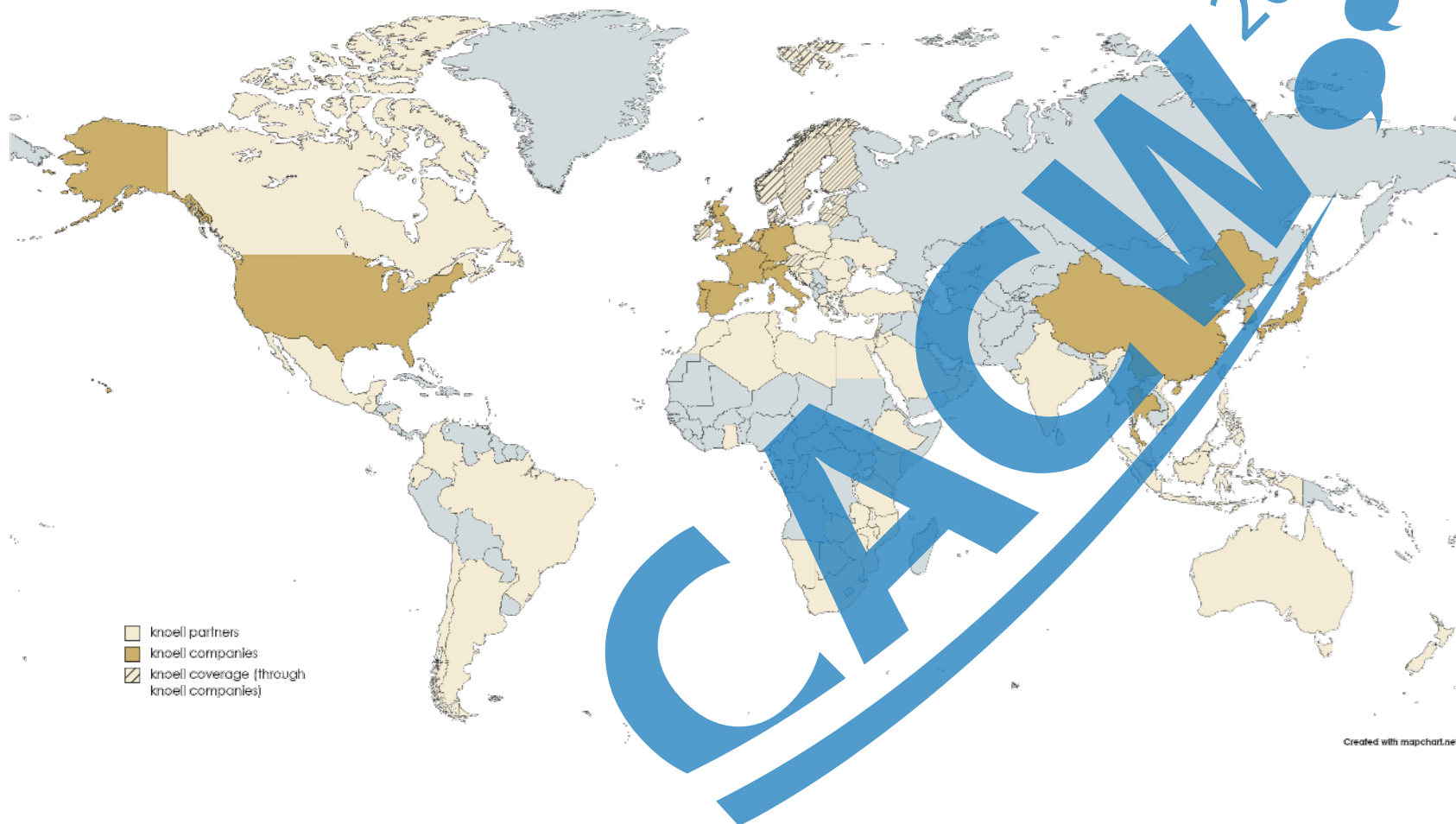
**YOUR GO-TO PARTNER
FOR REGISTRATION
WORLDWIDE**

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Your benefit – our expertise 用我们的专业技术为您服务



		<p>Think globally, act locally 放眼世界, 立足本土</p> <p>Your go-to partner for registration – worldwide 您的全球法规服务合规伙伴</p>	
<p>Leading provider of regulatory services and risk assessments 全球领先的登记服务和风险评估的供应商</p>		<p>> 25 years, privately owned 超过25年行业经验的家族企业</p>	
<p>Global regulatory compliance solutions 全球合规解决方案</p>		<p>Range of critical regulatory areas covered 覆盖所有关键合规领域</p>	
<p>Experts from a variety of scientific disciplines 丰富的来自不同学科的专家库</p>		<p>> 500 experts 超过500位专家 > 30 languages 提供30多种语言服务 > 20 locations on 3 continents 20多家分公司, 覆盖3大洲</p>	
<p>In-country registration and field studies 本土服务: 登记和田间试验</p>		<p>Own companies plus network of cooperation partners 当地分公司+可靠的合作伙伴机制</p>	



Our experts are located in North America, Europe and Asia with partners worldwide.

科奈专家分布在北美、欧洲和亚洲，合作伙伴遍布全球

If a country is not covered by your interest, please contact us. We can make many things possible and are continuously expanding.

如果您感兴趣的~~国家~~未包括在内，请联系我们。我们有大量可靠伙伴/资源助您进入市场。

- service coverage can vary per country due to resources and expertise
- 由于资源和专业知识的不同，服务覆盖范围可能因国家而异。

Regulatory solutions for your key market 为您的产品进入目标市场提供解决方案



We assist you in obtaining and maintaining market access for your portfolio – globally.

我们协助您在全球范围内获得产品市场准入的合规。



ANIMAL HEALTH
动物健康



BIOCIDES
生物杀灭剂



CHEMICALS
化学品



CROP PROTECTION
作物保护



CROP NUTRITION
作物营养



COSMETICS
化妆品



FOOD & FOOD CONTACT MATERIALS
食品和食品接触材料



MEDICAL DEVICES
医疗器械

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More than 500 scientists work globally on projects for substance and product registration. Tailored, multidisciplinary and multilingual teams of experts with years of experience will move your projects forward.

全球有 500 多名技术专家从事活性成分和产品注册领域。将由具有多年经验的专家组成的量身定制、多学科和多语言团队共同推进您的项目。

- Dr Knoell Consult Ltd, Head of Division **Regulatory Affairs Crop Protection, Nutrition & Biologicals**

科奈作物保护、营养和生物防治 全球法规事务负责人

- Head of Division: Sean McCarthy

- Over 25 years' experience gained in consultancy, industry, and government sectors. Working in multiple legislative areas including plant protection, fertilizers, and biocides. Has a proven track record in the strategic development of new products and bringing them to the market.

曾就职于咨询、工业和政府部门工作，拥有超过 25 年的经验。在多个立法领域工作，包括作物保护、营养和生物杀灭剂。在战略开发新产品并将其推向市场方面建树颇丰。

- Degree in Chemistry from the University of London (Royal Holloway), then went on to gain a Doctorate in Organic Chemistry from the University of Sussex. And continued onto post-doctoral research studies at the Université Catholique De Louvain, Belgium.

在伦敦大学(皇家霍洛威学院)获得化学学位，随后又在苏塞克斯大学获得有机化学博士学位。之后在比利时鲁汶天主教大学从事博士后研究。



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Registration of Pesticide Products for Agricultural Use in North Africa – Morocco, Algeria, Tunisia and Egypt 农用农药产品在北非(摩洛哥、阿尔及利亚、 突尼斯和埃及)的注册

China International Agrochemical Conference – CAC 2024

第二十四届中国国际农用化学品及植保展览会

14 March 2024

2024年3月14日

Dr Sean McCarthy

Dr Knoell Consult Ltd

Head of Division Regulatory Affairs Crop Protection, Nutrition & Biologicals

科奈作物保护、营养和生物防治全球法规事务负责人

Market Overview in North Africa北非市场概况

- ▶ **Morocco, Algeria, Tunisia and Egypt** key markets in the North African region for pesticide products for agricultural use
摩洛哥、阿尔及利亚、突尼斯和埃及是北非地区农用农药产品的主要市场。
- ▶ Agriculture is driven by the topographic characteristics of the land and climatic conditions
农业活动受地形特征和气候条件的驱动。
- ▶ Average contribution of the **agricultural sector** to their total gross domestic product (GDP) around 13%
农业部门对其国内生产总值(GDP)的平均贡献约为13%。
- ▶ Up to 50% of the population involved in agriculture
高达50%的人口从事农业生产相关工作。
- ▶ **Pesticide demand** highly dependent on **imports**
农药需求高度依赖进口。
- ▶ **National plans to support agriculture development, sustainable agriculture and irrigation** (Green Morocco Plan (PMV), National Program for Irrigation Water Saving (PNEEI), etc)
支持农业发展、可持续农业和灌溉的国家计划(如摩洛哥的绿色计划(PMV)、国家节水灌溉计划(PNEEI)等)。
- ▶ Egypt is the largest **agrochemical market, in terms of consumption**, valued at US\$350 million, followed by Morocco with \$220 million, Algeria with \$90 million, and Tunisia with \$50 million*
在农药消费方面, 埃及是最大的农化市场, 价值3.5亿美元, 其次是摩洛哥2.2亿美元, 阿尔及利亚9000万美元, 突尼斯5000万美元*。

*SOURCE: Christina Xie (2019).Observation of North African Market: Morocco moves towards environment friendly agrochemicals to support 'Green Moroccan Plan' <https://news.agropages.com/News/Detail-32431.htm>

Market Overview in North Africa北非市场概况

Key Agriculture Figures 主要农业数据	Morocco 摩洛哥 ¹	Tunisia 突尼斯 ²	Algeria 阿尔及利亚 ³	Egypt 埃及 ⁴
Agricultural Land 农业用地	9 million Ha (15%)	5.5 million Ha (32%)	8.5 million Ha (3.6%)	3.3 million Ha (4%)
Irrigated Area 灌溉面积	1.5 million Ha	0.42 million Ha	0.987 million Ha	2.7 million Ha
Number of Farms 农场数量	1.8 million	0.516 million	1.198 million	-
Average Farm Size 农场规模	5 Ha	10.2 Ha	8.6 Ha	-
Farm smaller than 10 Ha 小于10公顷的农场	70%	75%	70%	80%
% of GDP (2017) GDP占比% (2017)	17%	12%	12.3%	11.5%
% of employment (2017) 就业率% (2017)	38.8 %	16%	10.4%	29%
Main Crops 主要农作物	Cereals, Vegetables crops, Strawberries, Grapes, Citrus, Fruit trees 谷物, 蔬菜作物, 草莓, 葡萄, 柑橘, 果树	Olives, Cereals, Stone fruit, Vegetables Crops, Palm trees 橄榄, 谷物, 核果, 蔬菜作物, 棕榈树	Cereals, Vegetables crops, Fruit trees, Potato, Citrus, Palm trees 谷物, 蔬菜作物, 果树, 土豆, 柑橘, 棕榈树	Sugar cane, Sugar beet, Wheat, Rice, Maize, Cereals 甘蔗, 甜菜, 小麦, 大米, 玉米, 谷物
Output value of the agricultural industry in million Euro 农业产值 (百万欧元)	15,370	3,356	14,314	27,127

- 1 from Ministry of agriculture Morocco, ONCA
摩洛哥农业部, ONCA
- 2 from Ministry of agriculture Tunisia, National Statistical Institute (INS)
突尼斯农业部和国家统计局研究所 (INS)
- 3 from Ministry of agriculture Algeria, Office National des statistiques ALGERIE (ONS)
阿尔及利亚农业部和国家统计局办公室 (ONS)
- 4 from Ministry of agriculture Egypt, Egypt Data portal
埃及农业部和埃及数据门户网站

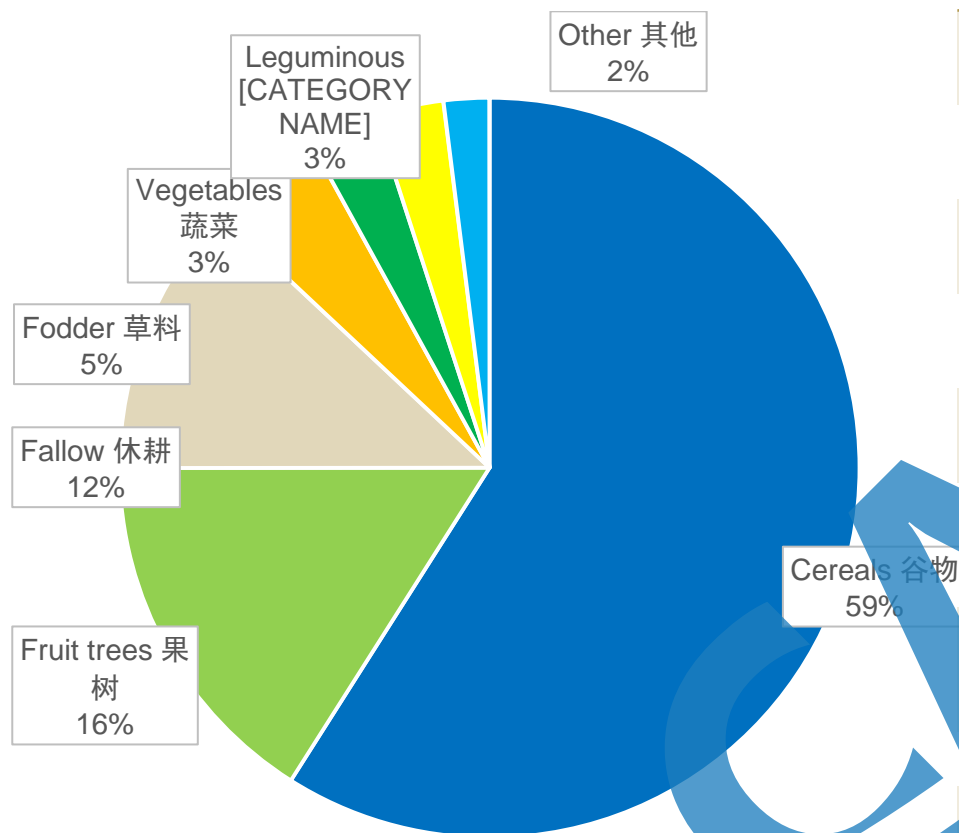
SOURCE: Christina Xie (2019).Observation of North African Market: Morocco moves towards environment friendly agrochemicals to support 'Green Moroccan Plan' <https://news.agropages.com/News/Detail-32431.htm>

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Market Size – Morocco市场规模-摩洛哥

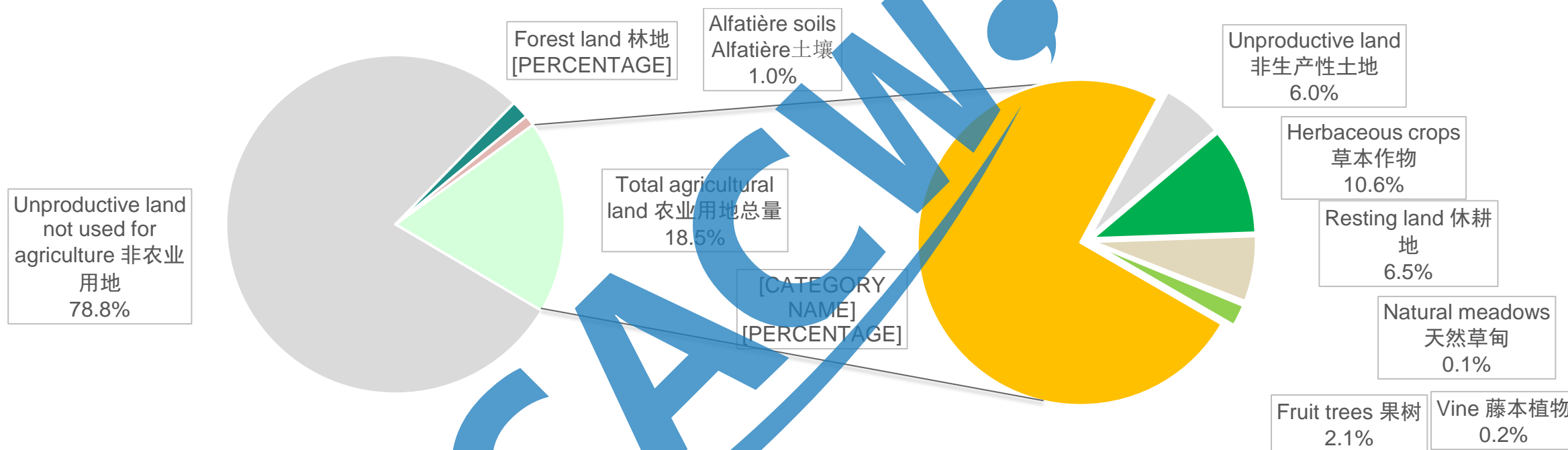
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registration



SOURCE: R. Harbouze, J.-P. Pellissier, J.-P. Rolland, W. Khechimi (2019).
Rapport de synthèse sur l'agriculture au Maroc. [Rapport de recherche]
CIHEAM-IAMM. 2019, pp.104. ffhal-02137637v2

Crop 作物	Cultivated area (ha) 栽培面积 (公顷)	Production (t) 产量 (吨)
Cereals (durum wheat, soft wheat, others) 谷物 (硬粒小麦、软质小麦、其他)	5.300.000	8.000.000
Pulses (broad beans, chickpeas, lentils, peas) 豆类 (蚕豆、鹰嘴豆、小扁豆、豌豆)	385.000	280.000
Sugar crops (sugar beet, sugar cane) 糖作物 (甜菜、甘蔗)	70.600	376.000
Oilseed crops (sunflower) 油料作物 (葵花籽)	44.000	48.000
Vegetables (tomatoes, fresh beans, other) 蔬菜 (番茄、新鲜豆类等)	260.000	7.700.000
Berry fruits (strawberries, raspberries and blueberries) 浆果 (草莓、树莓和蓝莓)	7.166	203.000
Fruit trees (almond, apple, apricot, plum, peach and nectarine) 果树 (杏仁、苹果、杏、李、桃和油桃)	265.000	884.000
Citrus 柑橘	85.000	13.000.000
Olive 橄榄	680.000	2.500.000
Date Palm 椰枣	48.000	90.000
Rice 大米	6.500	50.000
Perfume rose 香水玫瑰	80	2.000
Saffron 藏红花	60	3

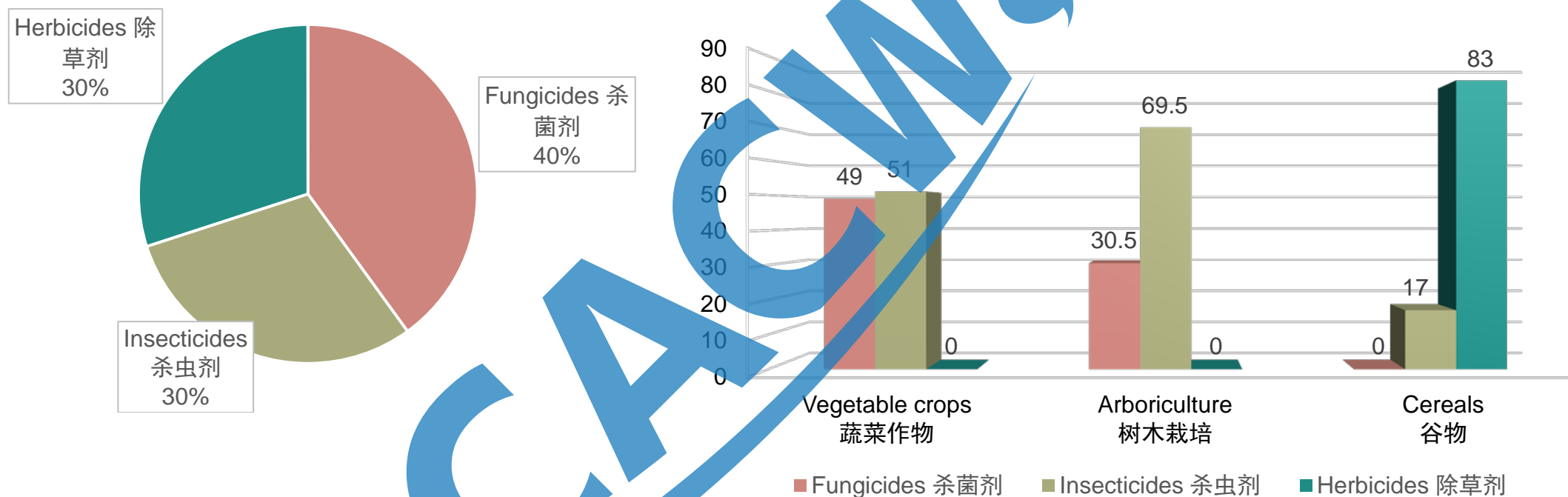


SOURCE: Statistique Agricole 2019. Superficies et Productions Serie "B". July 2021. République Algérienne Démocratique et Populaire, Ministère de l'Agriculture et du Développement Rural, Direction des Statistiques Agricoles et des Systèmes d'Information

Market size – Algeria市场规模-阿尔及利亚

Crop 作物	Cultivated area (ha) 栽培面积 (公顷)	Production (t) 产量 (吨)
Winter cereals (durum wheat, barley, soft wheat, oat, triticale) 冬季谷物 (硬粒小麦、大麦、软质、燕麦、黑小麦)	3.185.647	5.625.990
Spring cereals (maize, sorghum) 春季谷物 (玉米, 高粱)	1.665	7.295
Industrial crops (tomatoes, peanuts, tobacco, other) 经济作物 (番茄、花生、烟草等)	38.018	1.717.818
Pulses (dry broad beans, chickpeas, lentils, dried peas, dry beans, other) 豆类 (干蚕豆、鹰嘴豆、小扁豆、干豌豆、干豆等)	119.217	136.229
Vegetables (potatoes, melons, watermelons, onions, peas, fresh broad beans, tomatoes, peppers, carrots, zucchinis, garlic, fresh beans, cauliflowers, turnips, eggplants, artichokes, cabbages, other) 蔬菜 (土豆、甜瓜、西瓜、洋葱、豌豆、新鲜蚕豆、番茄、辣椒、胡萝卜、西葫芦、大蒜、新鲜豆类、花椰菜、萝卜、茄子、洋蓍、卷心菜等)	533.060	14.670.041
Forage crops 饲料作物	959.841	5.260.891
Citrus (oranges, clementines, lemons, tangerines, pomelos) 柑橘类 (橙子、小甘菊、柠檬、橘子、柚子)	63.744	1.583.493
Vines (table grapes, wine grapes, raisins) 藤本植物 (鲜食葡萄、酿酒葡萄、葡萄干)	61.676	549.833
Stone fruits and pome fruits (almonds, apples, apricots, pears, peaches, plums, pomegranates, cherries, medlars, quinces, carobs, other) 核果类和梨果类水果 (杏仁、苹果、杏子、梨子、桃子、李子、石榴、樱桃、枸杞、温棒、角豆等)	117.681	1.646.053
	Number of trees 树木数量	Production (t) 产量 (吨)
Date palms 椰枣	16.508.912	1.136.025
Olives 橄榄	43.474.114	868.754
Figs 无花果	4.855.726	114.092

SOURCE:
Statistique
Agricole 2019.
Superficies et
Productions
Serie "B". July
2021. République
Algérienne
Démocratique et
Populaire,
Ministère de
l'Agriculture et du
Développement
Rural, Direction
des Statistiques
Agricoles et des
Systèmes
d'Information



SOURCE: Merabet C. & Bouguetaya M.(2022). Rapport Phytosanitaire sur les Pesticides Commercialisés en Algérie. Mémoire en vue de l'obtention du Diplôme de Master. Université Mohamed El Bachir El Ibrahimi B.B.A. Faculté des Sciences de la Nature et de la Vie et des Sciences de la Terre et de l'Univers.

Market Size – Tunisia市场规模-突尼斯

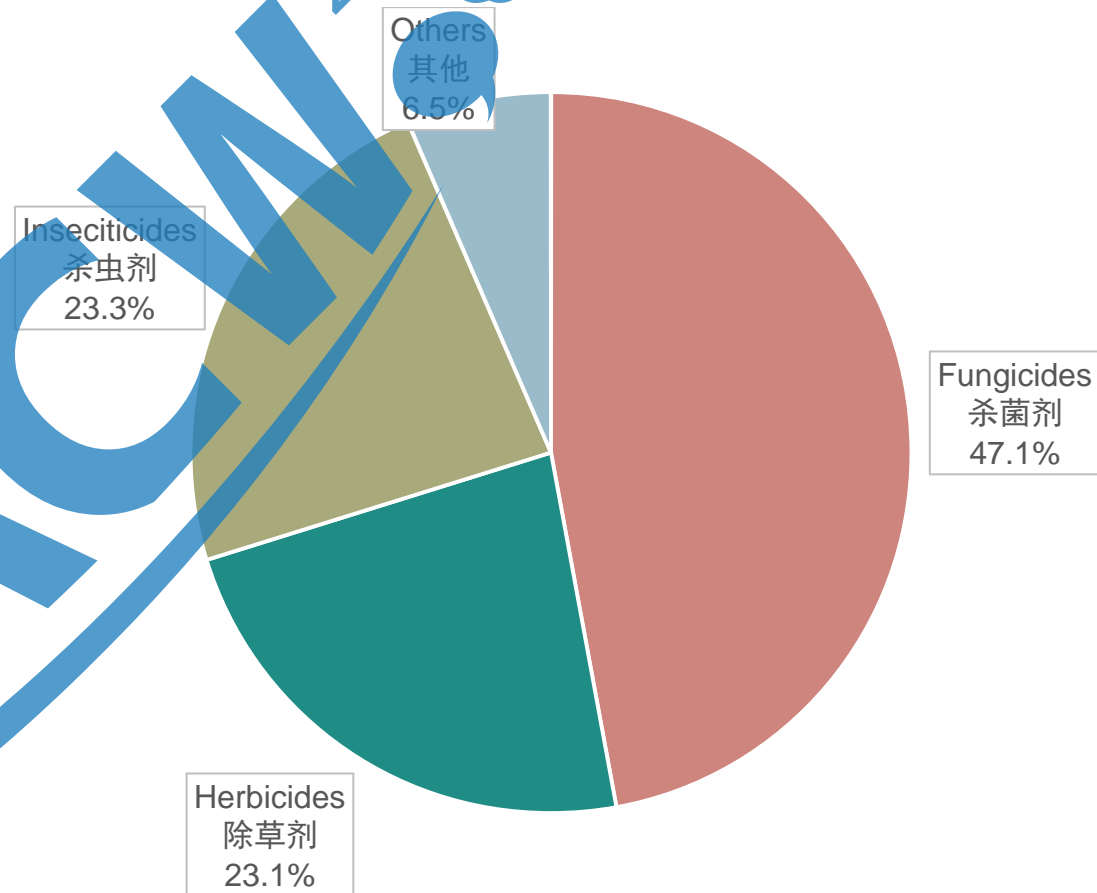
Crop 作物	Cultivated area (ha) 栽培面积 (公顷)	Production (t) 产量 (吨)
Cereals (wheat, barley, triticale) 谷物 (小麦、大麦、黑小麦)	1.320.110	1.534.000
Pulses 豆科	83.000	75.000
Citrus 柑橘	25.120	528.400
Fruit trees (except Citrus) 果树 (柑橘除外)	298.140	3.136.000
Olives 橄榄	1.610.600	2.000.000
Dates 椰枣	45.300	332.000
Vegetable crops (tomatoes, melons, watermelons, onions, peppers, artichokes) 蔬菜作物 (番茄, 甜瓜, 西瓜, 洋葱, 辣椒, 洋蓍)	139.340	4.052.000
Industrial crops 经济作物	18.470	-
Fodder 草料	416.950	5.163.800

SOURCE: Ministère de l'Agriculture. Institut National de la Statistique

Market Size – Tunisia市场规模-突尼斯

	Number of products 产品数量
Fungicides 杀菌剂	462
Herbicides 除草剂	226
Insecticides 杀虫剂	228
Others 其他	64
Total 总计	980

SOURCE: Guidephytosanitaire.tn



Pesticide Registration Overview 农药登记概况

- ▶ **Separate procedure for each North African country** (different legislation and organisation)
每个北非国家都有自己独立的登记流程(不同的法规体系和主管机关)
 - ▶ Registration process and data requirements in general **similar but with specificities at national level** (specific guidelines and forms)
登记流程和数据要求总体上相似, 但每个国家都有具体规定(具体的指导原则和表格)
 - ▶ Registration process and data requirements also **similar for Middle East countries**
中东国家的登记流程和数据要求也相似
- Registration of same/similar pesticide products in EU or other countries facilitates preparation of application for registration in these countries
在欧盟或其他国家登记相同或类似的农药产品, 有利于准备在这些国家登记的申请



Main Basic Requirements for Registration 登记的主要基本要求

- ▶ **Valid registration of the pesticide product in an OECD country and/or country of origin.**
农药产品在经合组织(OECD)国家和/或原产国的有效登记。
- ▶ **Active substance (AS) is not banned/restricted in the specific country** 活性物质 (AS) 在特定国家未被禁用/限制
 - Authorisation in EU does not guarantee the AS is allowed (highly hazardous AS can be problematic)
欧盟的授权并不保证AS是允许的(高度危险的 AS 可能有问题)。
 - Tunisia: AS must be approved at least in one of the following EU, USA, Canada, Australia or Japan
突尼斯: AS 必须至少在欧盟、美国、加拿大、澳大利亚或日本(其中之一)获得批准。
- ▶ **Registration holder: a legal entity (branch) in the country of interest OR an authorized local importer and distributor**
登记持有人: 相关国家的法人实体(分支机构)或当地授权进口商和分销商



Other Important Requirements其他重要要求

- ▶ **Registration of the AS:** not necessary
活性物质(AS)登记:无需
 - Information on the AS is supplied with the registration dossier of the pesticide product
有关 AS 的信息与农药产品的登记档案一起提供。
 - The source of AS must be declared and a Letter of Supply (LoS) (and Letter of Access, LoA) is required
必须申报 AS 的来源, 并提供供货函(LoS) (和准入信, LoA)。
- ▶ **Efficacy trials** (1 season for Morocco & Algeria, 2 seasons for Tunisia & Egypt) **and Phys chem/ PHI (Egypt) determinations to be carried out locally in the specific country**
药效试验(摩洛哥和阿尔及利亚一季, 突尼斯和埃及两季)和物理化学/ PHI(埃及)测定将在特定国家当地进行。
 - Efficacy trials from other countries only as supportive information
其他国家的药效试验仅作为辅助信息。
 - Product samples and analytical standards will be required (import permit)
需要提供产品样本和分析标样(进口许可证)。
- ▶ **Studies for Registration Dossier:**
GLP登记档案试验数据要求:GLP
- ▶ **Legalisation of documents:** necessary for all countries except Morocco
需要合法化(认证和/或公证)的文件:除摩洛哥外, 所有国家均需提供
 - Registration Certificate in the country of origin/OECD country
原产国/经合组织(OECD)国家的登记证书
 - Authorisation Letter
授权书
 - Quality Warranty Certificate
质量保证书



Other Important Requirements 其他重要要求

Submission of application 申请提交:

- Specific periods for each country (not fixed, may depend on the type of pesticide product)
每个国家的具体时间限(不固定, 可能取决于农药产品的类型)
- Physically by local distributor/local company
由当地分销商/当地公司负责具体操作

Communication with CA 与主管机关的沟通:

- Through local distributors or local contacts, direct communication of foreign company with the CA is not possible
通过当地分销商或当地联系人进行沟通, 外国公司无法直接与主管机关进行沟通。

Registration renewal 登记续期:

- Complete dossier for Algeria, Tunisia and Egypt; light dossier for Morocco
阿尔及利亚、突尼斯和埃及需要提交完整的登记档案; 摩洛哥需要提交简化的登记档案;
- Valid registration in OECD country/country of origin
在经合组织(OECD)国家/原产国的有效登记。



► Pesticides for agricultural use (PPPs, fertilizers, some products considered as biocides in EU)

农业用农药(植保产品, 肥料, 欧盟被视为生物杀灭剂的一些产品)

- **Morocco:** Ministry of Agriculture, Fisheries, Rural Development, Water and Forests (<http://www.agriculture.gov.ma/en>) and National Office for Sanitary Safety of Food Products (ONSSA) (<https://www.onssa.gov.ma>)

摩洛哥: 农业、渔业、农村发展、水利和森林部和国家食品安全办公室 (ONSSA)

- **Algeria:** Ministry of Agriculture and Rural Development (<http://madrp.gov.dz/>), Directorate for the Protection of Plants and Technical Inspection (DPVCT), Sub-Directorate for Registrations and Authorisations

阿尔及利亚: 农业农村发展, 植物保护和技术检查局 (DPVCT), 登记和授权分局

- **Tunisia:** Ministry of Agriculture, Water Resources and Fishery (<http://www.agriculture.tn/>), Directorate General for the Protection and Quality Control of Agricultural Products

突尼斯: 农业、水资源和渔业部, 农产品保护和质量控制总局

- **Egypt:** Ministry of Agriculture and its enforcement agency Agricultural Pesticide Committee (APC) (<http://www.apc.gov.eg/EN/>)

埃及: 农业部及其执行机构农业农药委员会 (APC)



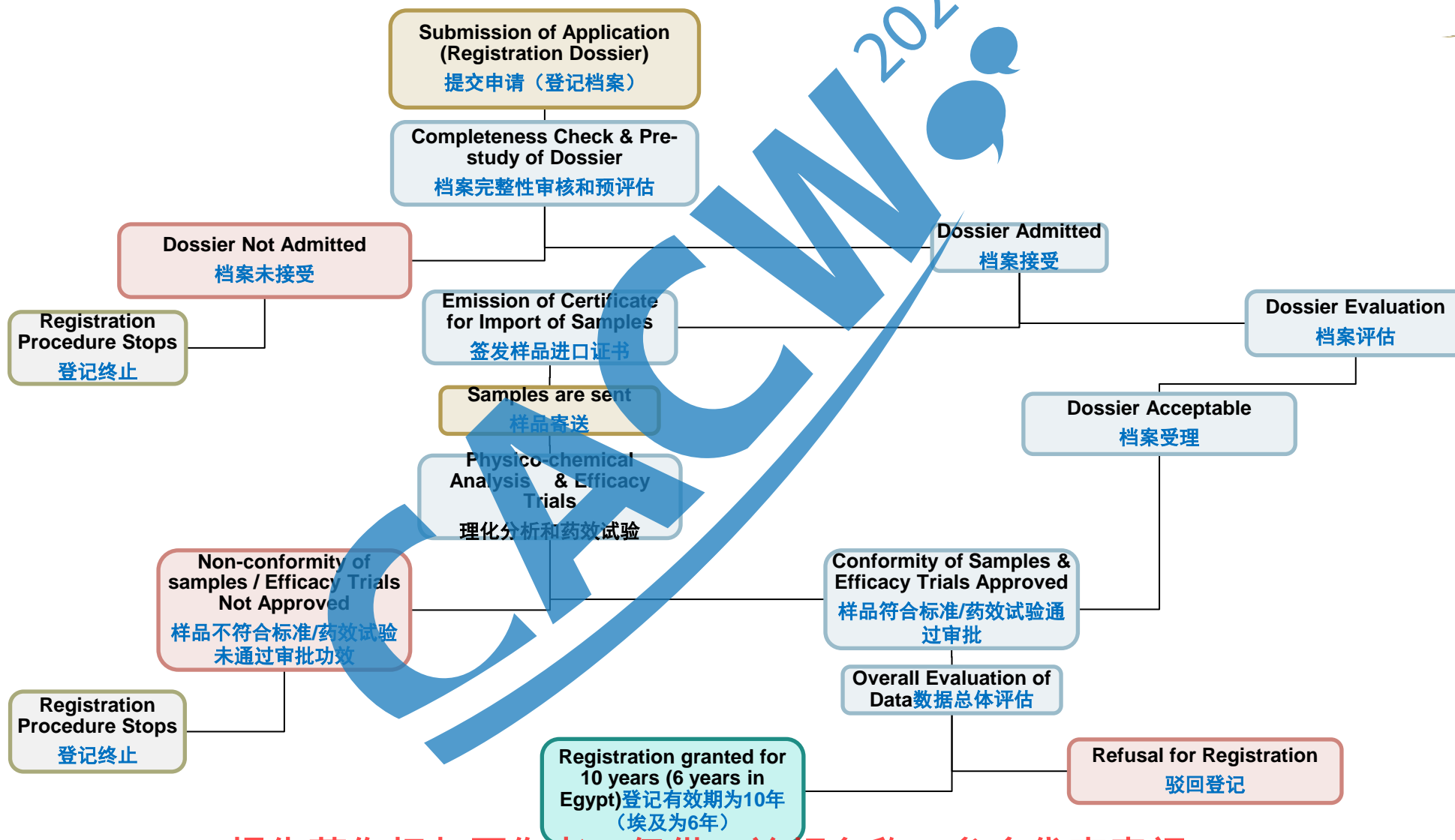
General Registration Process一般登记流程

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registration

Overall procedure ~ 3 years (depends on CA workload)

整个流程 ~ 3 年 (取决于 CA 的工作量)



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I. Active Ingredient Dossier活性成分档案

- Identity of the AS
活性成分的鉴定
- Studies on Physical & Chemical Properties (may require 5-BA)
活性物质的物理和化学性质测试(可能需要5批次报告)
- Other information (mode of action, classification,...)
其他信息(作用模式、分类等)
- Analytical Methods
分析方法
- Studies on Mammalian Toxicology (acute, short-term, long-term, metabolism)
哺乳动物毒理学测试(急性、短期、长期、代谢)
- Studies on Residues
残留测试
- Studies on Fate & Behaviour in the Environment
环境行为测试
- Studies on Ecotoxicology
生态毒理学测试



GLP studies GLP 测试

Summary + Full report to be provided
摘要+报告全文

II. Formulated Product Dossier

制剂产品档案

- Identity of the FP
制剂产品的鉴定
- Studies on Physical and Chemical Properties
物理和化学特性测试
- Data concerning application/use & classification
关于施用/使用和分类的数据
- Analytical Methods
分析方法
- Efficacy data (data from other countries as supportive information)
药效数据(来自其他国家的数据仅作为支持性数据)
- Studies on Toxicology and exposure assessment (operator, worker, bystander)
毒理学和暴露评估(操作者、工人、旁观者)
- Studies on Ecotoxicology (bees & NTA risk assessment for Morocco)
生态毒性学测试(摩洛哥, 蜜蜂和非靶标动物的风险评估)



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Summary + Full report to be provided
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III. Administrative Dossier and Additional Data行政档案和其他数据

- Authorisation Letter授权书
- Valid Certificate of Registration of FP in OECD country/country of origin经合组织(OECD)国家/原产国的有效FP登记证书
- Manufacturing license生产许可证
- LoS for the AS and LoA (if applicable)活性成分的供货函(LoS)和准入信(LoA)(如适用)
- Composition Certificate成分证书
- Certificate of Analysis from independent (GLP) lab分析证书(由独立的GLP实验室提供)
- Product Specifications产品规格
- Proposed (and original) label建议的(和原始的)标签
- Local Efficacy trials当地的药效试验
- Samples of product and analytical standards产品样本和分析标样
- Storage stability study (preferred > 2 years)储存稳定性测试(建议 > 2年)
- SDS安全技术说明书
- Formulated product brochure制剂产品手册
- Information on authorisations granted in other countries其他国家授权信息



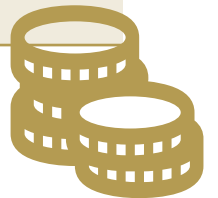
Legalization of some documents may be required (Tunisia, Egypt)
可能需要对某些文件进行合法化(认证和/或公证)
(突尼斯、埃及)

Administrative Fees (example of Morocco)行政费用(以摩洛哥为例)

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Concept 类别	Units 单元	Fee (MAD) 费用(MAD)	Fee (CNY) 费用(CNY)
Evaluation of Registration Dossier 注册档案评估	Product 产品	10 000	7 160
Samples import 样品进口	Product 产品	500	360
Efficacy trials 药效试验	Trial 试验	1 000	716
Analysis for import control of registered product 登记产品的进口管制分析	Import 进口	200-2 500	143-1 792
Renewal 展延	Product 产品	5 000	3 584
Use extension 用途扩展	Use 用途	2 000	1 434
Extension to minor use 扩展到次要用途	Use 用途	500	360

National Office for Sanitary Safety of Food Products (ONSSA) (Jan 2024)
国家食品安全卫生安全办公室(ONSSA) (2024年1月)



报告著作权归原作者, 仅供“论坛名称”参会代表查阅

- **knoell does not provide registration holding services** (only list of local distributors as potential registration holders based on public information).
科奈不提供登记持有服务(仅根据公开信息提供本地分销商名单作为潜在的登记持有人)。
- ▶ **General Global Regulatory Support** for specific product/s and specific country/ies (Q & A)
针对特定产品和特定国家/地区的全球法规支持服务(Q & A)
- ▶ **Consultancy Support** to contact CA and check if a specific product/s require/s registration and which is the CA responsible for the registration
咨询服务:联系主管机关并核实特定产品是否需要登记, 以及登记的具体主管机关
- ▶ **Registrability Analysis** for specific product/s and country (general information on registration process and possible registration pathways, timelines fees & remarks, suggested registration pathway)
特定产品和特定国家的可登记性分析(关于登记流程的一般信息、可能的登记途径、时间线、费用及注意事项, 建议的登记途径)
- ▶ **DGA in support of registration of product/s in a specific country according to national regulations**
数据缺口分析(DGA): 根据特定国家的法规, 支持特定产品在该国登记
- Overview of the data requirements for the registration of the product/s 产品登记所需数据的概述
 - Overview of the regulatory process, information on authority fees and regulatory timelines 登记流程及相关费用的概述
 - Comparison of list of data from client versus data requirements and identify missing data 客户数据与数据要求的比较
 - Identify and recommended major next steps 确定并推荐下一步主要行动

► Dossier Preparation档案编制

- Preparation of the necessary technical and administrative documents for product authorization
为产品授权准备必要的技术和行政文件
- Compilation of all other necessary documents/letter/certificates to be supplied by the client
客户提供的必要文件/信函/证书的汇编
- Communication and coordination with CA (through local partner)
与主管机关的沟通和协调(通过当地合作伙伴)
- Submission to CA (through local partner)
向主管机关提交登记档案(通过当地合作伙伴)
- Post-submission support
提交后的状态追踪和进一步技术支持
- Preparation of product label
产品标签的编制





Thank you for
your attention!

knoell global contact

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