

Global Perspective on Agrochemical regulations – status and way forward

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North America



GPC Global Product Compliance | **AUXILIFE** | **RRMA** REGULATORY REPRESENTATIVES & MANAGERS ASSOCIATION | **AMERICAN PESTICIDE** CHEMICAL

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Agrochemical Webinar Series:
**EPA Pesticide Registration and Data
Compensation - A Case Study of Prothioconazole**

January 27
10:00 - 11:00 CET
14:30 - 15:30 IST

North America – US Legal Framework

- The **Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)** provides for federal regulation of pesticide distribution, sale, and use.
- **The Office of Pesticide Programs (OPP)** regulates the use of all pesticides and establishes maximum levels for pesticide residues in food.

- The **Food Quality Protection Act (FQPA)** requires that a pesticide poses a "reasonable certainty of no harm" before it can be registered for use on food or feed. Focus on
 - aggregate exposure
 - cumulative effects
 - sensitive sub-populations
 - endocrine disruptive effects

- The **Endangered Species Act (ESA)** requires that pesticides will not likely jeopardize the continued existence of any listed species or destroy or adversely modify any critical habitat for those species.

North America – US EDSP

- The **Federal Food, Drug and Cosmetic Act** require from EPA *“to develop a screening program...to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.”*
- In 2009, EPA announced the **Endocrine Disruptor Screening Program (EDSP)** Tier 1 battery of assays and test guidelines (protocols).
- *In vitro* and *in vivo* screening assays were developed, standardized and validated to identify the potential to interact with the estrogen, androgen or thyroid (E, A or T) hormonal systems.

North America – Canada

Regulatory authority

- **Pest Management Regulatory Agency Canada (PMRA)** under the umbrella of the Ministry of Health
 - Review all the data (including the raw data)
 - Determine if the product is acceptable for use in Canada
 - Compare its results with regulatory counterparts in other countries (USA and members of the European Union)
- Data requirements for registration of pesticides are structured in **Data Codes (DACO)** that are available on the website of pesticide section of **Canada.ca**.
- All studies must be carried out in accordance with **OECD test guidelines** under **OECD GLP**.

Central and South America



The banner features a scenic landscape of rolling green hills and yellow fields under a blue sky with mountains in the background. At the top right, there are logos for GPC (Global Product Excellence), AUXILIFE, RRMA (Regulatory Representatives & Managers Association), and CHINERGI. The text 'Join Us!' is written in white on the right side of the banner.

Agrochemical Webinar Series:

Agrochemical Regulations in Brazil, Argentina, Columbia & Paraguay

January 20
10:30 - 11:30 CET
15:00 - 16:00 IST

Central America – Mexico

- Mexico has a comprehensive regulatory framework in place.
- The three most relevant authorities are mentioned on the panel.

<p>Federal Commission for the Protection against Sanitary Risks (COFEPRIS), authorized to regulate and control human health risks and the use, import, export, application and disposal of hazardous pesticides.</p>	<p>Secretary for Environment and Natural Resources (SEMARNAT) is responsible for implementation of regulations that protects soil and water resources and environmental risk assessment.</p>	<p>National Service of Agrifood Health, Safety and Quality (SENASICA), a decentralized body of the Secretary for Agriculture, is responsible for protection of agriculture, cattle and fishery, for certification of risk reduction systems, for biological efficacy, pesticides residues (MRLs) and for selection of pesticides in the case of emergency.</p>
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- While **COFEPRIS** is ultimately responsible for granting the registration, in practice it is bound by the veto power of **SEMARNAT** and **SENASICA**.
- Contentious positions regularly lead to delays of registrations.

Central America – OIRSA

- The **International Regional Organisation for Plant and Animal Health** (Organismo Internacional Regional de Sanidad Agropecuaria, **OIRSA**), is an intergovernmental organization that provides technical assistance to the ministries and departments of agriculture and livestock.
- Member states:
Belize, the Dominican Republic, Guatemala, Honduras, Nicaragua, Panama, El Salvador, Mexico and Costa Rica.
- Among other objectives OIRSA promotes
 - adoption of common policies on animal health, plant health, food safety and quarantine services
 - harmonization of the legislation on agricultural health and quarantine services.

Central America – Similar Registration Process

- Registration process is an administrative act.
 - Data generated for a registration in the USA fulfill data requirements.
- Pesticidal product has to be registered in country of origin.
 - Product label has to be submitted stamped by the authorities of the country of origin.
- Codex MRLs to support trade of commodities.

Central America – Caribbean Islands

- Caribbean countries work together in the **Coordinating Group of Pesticide Control Boards of the Caribbean (CGPC)**.
- **Jamaica** plays a leading role.
- Requirements and process is similar to the one of the Central American countries.
- **Cuba's** contact point is the Central Pesticide Registry of the Department of Plant Health.



Source: Pesticide Control Authority, Jamaica

South America

- **Brazil** and **Argentina** dominate South America in terms of consumption of pesticides followed by **Colombia**.
- A dedicated webinar will introduce the regulations in these three countries.
- **Bolivia, Colombia, Ecuador, Peru** are **working together in the Andean Community of Nations (CAN)** with the objective to align policies.
- Hence, policies that regulate the use pesticides are similar in CAN countries.

South America – Chile

- Ministry of Health is the authority for the registration of household pesticides while pesticides of agricultural use is governed by **SAG (Servicio Agrícola y Ganadero)**, which is an **agency of the Ministry of Agriculture**.
- Foreign companies that want to market pesticidal products must appoint a Chilean partner/technical director who can be contacted by SAG at any time.
- This Technical Director cannot work for more than one company in this area.
- To date, SAG hasn't granted registration based on equivalence.

Australia & New Zealand



The banner features a photograph of a vast, green vineyard under a blue sky with scattered clouds. The rows of grapevines stretch across the landscape, creating a strong sense of perspective. In the top right corner, there are several logos: GPC (Global Product Compliance), AUXILIFE, RRMA (Regulatory Representatives & Managers Association), and a logo for the Americas region. The text 'Join Us!' is written in a white, italicized font in the lower right area of the image.

Agrochemical Webinar Series:
Exporting pesticides to Australia and New Zealand? Compliance Overview and Strategies

March 10
10:30 - 11:30 CET
15:00 - 16:00 IST

Australia

Regulatory authority

- **Australian Pesticides and Veterinary Medicines Authority (APVMA)**
- A dedicated webinar will introduce the regulatory process in Australia and New Zealand.
- Registration holders are obliged to report adverse findings in the field of toxicology, environmental incidences, crop safety, lack of efficacy.
- Other scientific information or reviews from other regulatory bodies may be reviewed by APVMA experts.
- Consequently, products may be called for review that may result in label changes or even cancellation of approval.

New Zealand

Regulatory authority

- **Agricultural Compounds and Veterinary Medicines (ACVM)**

- Import or manufacture of agricultural chemicals that are applied directly to plants, must be registered prior to sell or use.
- Clear guidance on data requirements and registration process is available on ACVM website.

Asia

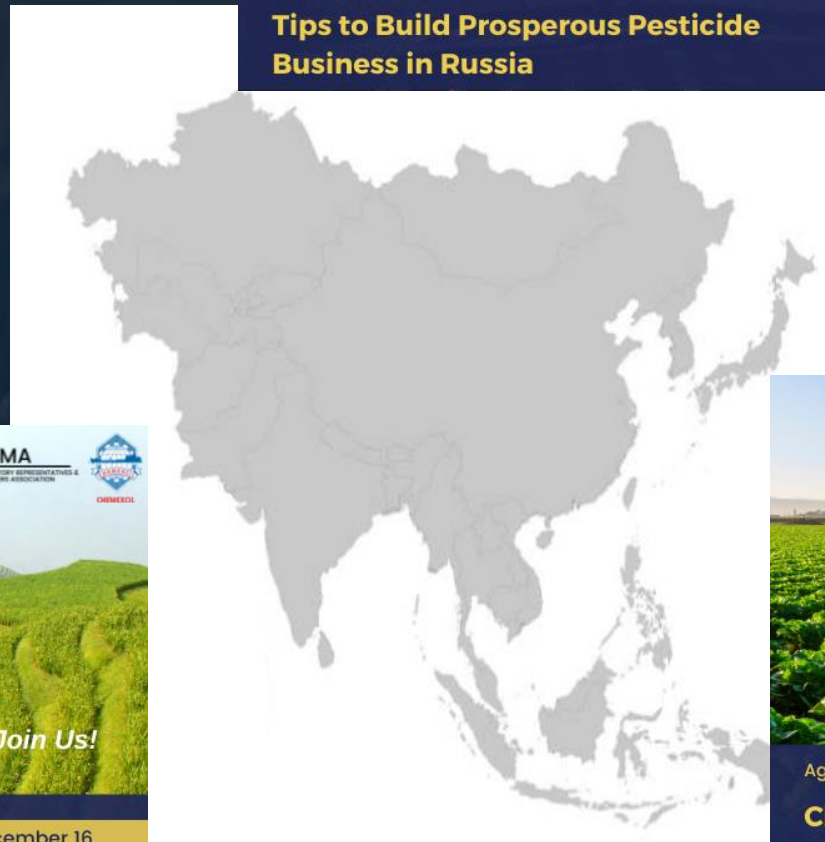


Agrochemical Webinar Series:

Tips to Build Prosperous Pesticide Business in Russia

March 3

10:30 – 11:30 CET
15:00 – 16:00 IST



Agrochemical Webinar Series:

Agrochemical Compliance in South East Asia countries: Vietnam, Indonesia, Philippines & Cambodia

December 16

10:30 – 11:30 CET
15:00 – 16:00 IST



Agrochemical Webinar Series:

China Pesticide Registration Updates

December 9

10:00 – 11:00 CET
14:30 – 15:30 IST

Asia – Japan

- The Agricultural Chemicals Regulation Act was revised in 2018.
- Major changes
 - re-evaluation of registered products every 15 years
 - setting of Acute Reference Dose (ARfD)
 - registration of generic products on basis of TGAI equivalence
- Amendment of Act in 2019
 - Risk assessment of pesticide operators based on Acceptable Operator Exposure Level (AOEL) and Acute Acceptable Operator Exposure Level (AAOEL).
 - Risk assessment for vascular plants and birds
 - Risk assessment on honey-bees and colony development

Asia – Republic of Korea

- The authority is Rural Development Administration (RDA).
- The Pesticide Management Act of 1953 has regularly amended.
- Test guidelines (TG) were harmonized with OECD TG series.
- Risk assessment schemes were adapted from Europe and the USA.
- For instance
 - Modified EUROPOEM is used for operator exposure assessment
 - Dietary risk assessment for consumer was established with two methods, namely MOE approach for non-carcinogen and Q1* approach for carcinogen pesticides.

Asia – Taiwan

- The testing requirements for registration are similar to the ones in OECD countries.
- Particular focus on import tolerances (import MRL) as Taiwan is an importer of fresh fruits and vegetables for other Asian countries, Australia and the US.
- Applications go to the Taiwan Food and Drug Authority for review that is also reviewed by Food Sanitation Safety and Nutrition Advisory Committee.

Asia – Turkey

- Authority: Ministry of Food, Agriculture and Livestock
 - Applicant for registering a pesticide must be a certified applicant, usually a Turkish citizen.
- Three registration categories
 1. New active ingredient in formulation (data on human health and environment, residues on food, at least 2 bioefficacy trials from 2 regions in Turkey)
 2. Label extension (2 bioefficacy trials from 2 regions in Turkey)
 3. Same formulation type and the same percentage of the same active ingredients as the registered product. It should have the same biological effect to the same pests as registered product.
 4. The active ingredient has to be out of patent protection.

Africa



Agrochemical Webinar Series:

Compliance Overview of Agrochemical Regulations in South Africa

February 10

10:30 - 11:30 CET
15:00 - 16:00 IST



Agrochemical Webinar Series:

Recent Updates on Agrochemical Regulations in Kenya and Morocco

February 24

10:30 - 11:30 CET
15:00 - 16:00 IST

Africa – CILSS

- **CILSS (Permanent Committee of Sahel Countries)**
 - Egypt
 - Nigeria
- **Sahel Committee of Pesticides (CSP)** grants approval of pesticides.
- Registration requirements and list of approved products are posted on the website
(<http://insah.cilss.int/index.php/csp/>)

Member states



Africa – Egypt

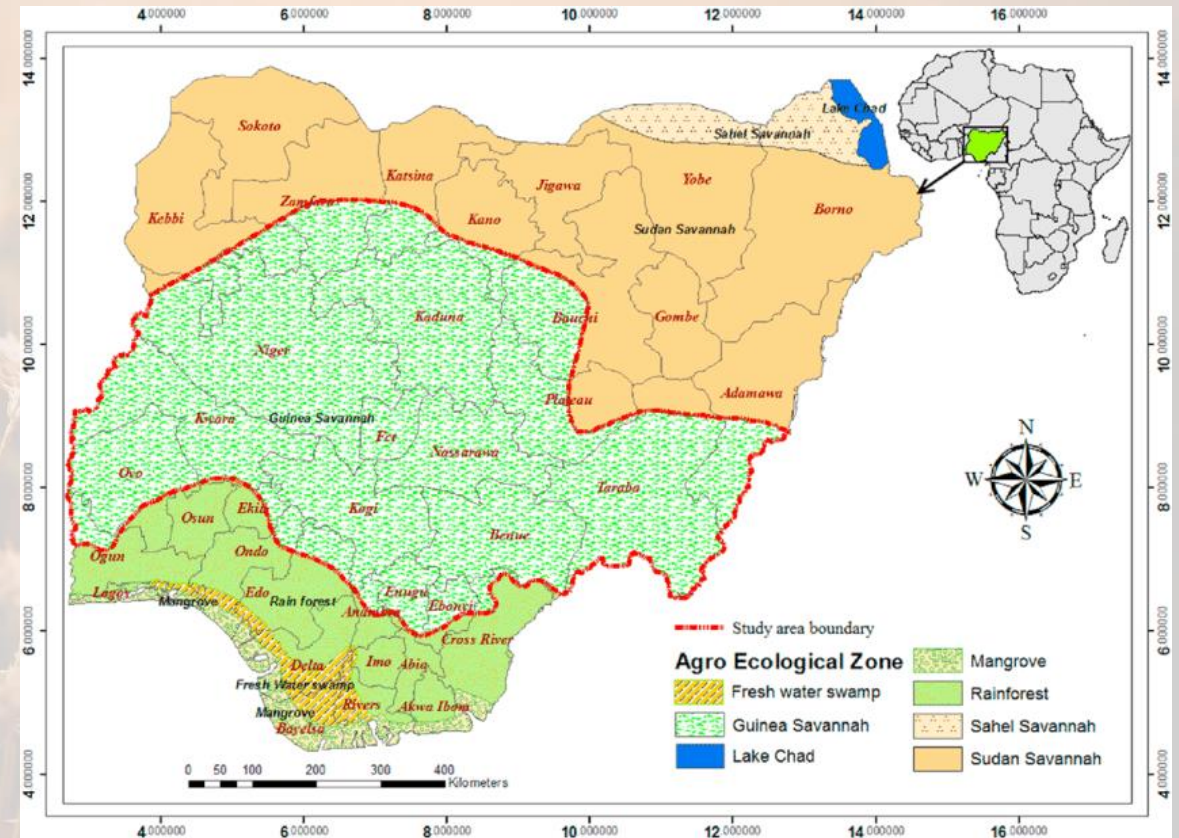
- The **Agricultural Pesticide Committee (APC)** grant registrations
 - The **Central Agricultural Pesticide Laboratory (CAPL)** and APC consult Codex Alimentarius, the EU, and the U.S. EPA in the process of setting MRLs.
 - All licenses for pesticides are valid for six years and are re-evaluated every three years.
- CAPL test efficacy of a pesticide against the target pests according to label claim.
 - The testing takes around 3 years.
 - New product require similar data packages as the one for the EU or USA.

Africa – Nigeria (1)

- The **National Agency for Food and Drug Administration and Control (NAFDAC)** grants registrations.
- The efficacy of a pesticide for the intended use has to be demonstrated in trials for two cropping seasons and two different agro-climatic regions. The assessment is monitored and conducted by the Agency at approved research institutes.

Africa – Nigeria (2)

- Agro-climatic zone in Nigeria.
- The farming sector of this West African country employs about 70 percent of the entire country's labor force.
- Agriculture has been happening across all ecoregions from the forest zone of southern Nigeria (root and tree crops), to the forest-savanna of the center (mainly root), to the semiarid northern Nigeria (grains).



Source: adapted from Illoje, 2001

Europe



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Agrochemical Webinar Series:

**What you need to know about
Agrochemical Regulations in EU and UK**

January 13

10:30 - 11:00 CET

15:00 - 16:00 IST

Europe

- The EU dominates the regulatory environment in Europe.
- Even non-members of the EU such as Ukraine or Serbia tend to adhere to EU standards although their registration processes are less complex than those in the EU.
- After leaving the EU, the UK has been in a transition phase.
- It's unlikely that requirements and criteria will change dramatically.

Europe – the European Union (1)

- Regulation No (EC) 1107/2001 introduced 'cut-off' criteria that apply prior to beginning risk assessments.
- As a consequence, a number of popular products lost market authorization during the re-review process.

Complexity

- Approval of active substances at Commission level in cooperation with Member States.
- Each Member State grants market authorization for use of products.
- The process requires a lot of resources.

Europe – the European Union (2)

- Evolving guidelines
- Revised EFSA guidance document for risk assessment of bees is awaited.
- It will be difficult for insecticides to pass the risk assessment schemes.

Emergency registrations

- Although approval of some active ingredients were revoked their products were allowed for a specific use for one season.

For instance:

- The use of neonicotinoids as coating of sugar beet seeds due to lack of alternatives.

Europe – the European Union (3)

- Sustainable use Directive 2009/128/EC required Member States to reduce the use of pesticides.
- Many Member States stopped registrations for non-agricultural use, for instance the use in parks, public gardens, recreation grounds, schools, health care facilities, nature reserves.

- EU Commission goal is to significantly reduce the use of pesticides in all areas.



Question:

- Will EU farmers have a chance to compete on the world market?

Concluding Remarks

- The regulatory landscape continues to be challenging.
 - Harmonization of some test guidelines has been successful under the OECD umbrella.
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- Regulations will be stricter in the developing world to catch up with global themes such as biodiversity and climate change.
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- I believe that pesticides will continue to play a major role in production of sufficient food for a growing world population.

Thank you.

International Agrochemical Regulations Webinar Series

December 2021
March 2022

