éléphant vert

LET'S CULTIVATE A FERTILE FUTURE !

Post-Harvest Pesticides: Regulation in Europe and Beyond

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May 2025

SANDRO FRATI

Education:

Master in Food Technology (University of Torino, Italy)

PhD in Agricultural Entomology (University of Bologna, Italy)

Working in crop protection

2006 – 2013 academia
Evaluation of biocontrol and integrated strategies in pre- and post-harvest
Morphological and molecular identification of pest and diseases
Evaluation of new crop varieties

Since 2013 private sector
Efficacy trials
Product development
Business development

Based in Antwerp, Belgium

ÉLÉPHANT VERT IN A NUTSHELL

Key elements

- Founded in 2012
- Agri biologicals pure-player
- 40+ countries Europe, Africa and globally expanding
- 800 employees
- 80M€ sales
- Dynamic +25% p.a. growth

2 Brands

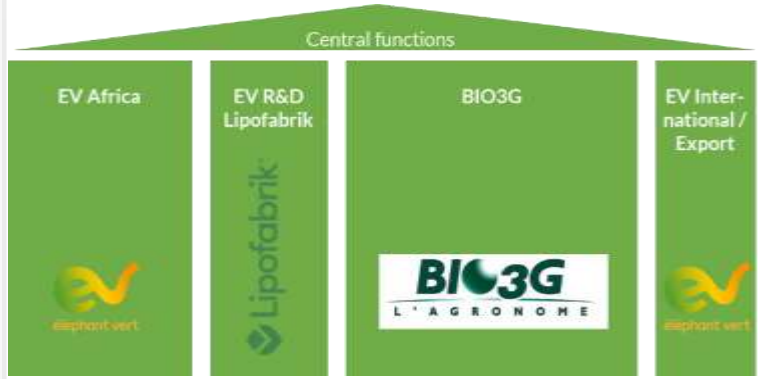
Worldwide

France, Switzerland, Belgium & expanding in EU

25 years
Direct sales
8% French market

3 Product ranges

4 Divisions



A FAST AND TARGETED DEVELOPMENT

2012

CREATION OF ÉLÉPHANT VERT SA

2014

Launch of **production sites** in Morocco and Mali

2015

Creation of **Éléphant Vert France**

2016

Creation of the Éléphant Vert **Senegal**

Launch of the **microorganisms production site**

2017

Acquisition of the assets of **Xurian** Environnement: bacteria production tool, products and approvals

Creation of the Elephant Vert **Ivory Coast**

Acquisition of **Kenya Biologics Ltd. in Kenya and Tanzania**

2018

Acquisition of **Biofertil composting platform in Ivory Coast**

Acquisition of the **majority stake in BIO3G group** providing the group with **its own salesforce in France, Switzerland, Belgium**

2019

Registration of the 1st proprietary biocontrol product **Novacrid®,**

2021

New **general management**

New strategy « **To become a product specialist in biosolutions for worldwide agriculture** »

2022

Acquisition of the French start-up Lipofabrik specialized in lipopeptides

2023

Installation of **2 fermenters of 4m³** at Lipofabrik

Launch of new foliar biostimulant **Novastim**

2024

100% takeover of BIO3G

Diversified range of biosolutions on sale and a rich pipeline

Organic fertilizers

A wide range of
- Organic fertilizers
- Enriched with amino acids, trace elements etc.

Enriching & improving soil
Increasing yields

Biostimulants

Non-microbial

Seaweed extracts, algae complex
- Econitrate®
- Vitality®

Microbial and microbial-based

Pseudomonas putida
- Ovalis rhizofertil® – Xurian®

Bacillus subtilis metabolites
- Novastim®

Biocontrols

Microbials

- Virus-based: Helitec®
- Fungal-based: Novacrid®

+ various microbial-based development candidates across indications

Natural substances

Development candidates

Post-Harvest losses and control

- Increased attention from consumer for healthy food and sustainable environment
- Globalization, every fruit has to be available year-round / no seasonality
- Longer storage and transport
- About 1/3 of food production is wasted, mostly in post-harvest
- Estimation of losses (Sawicka, 2019):

– $ 680 billion per year in industrialized countries

– $ 310 billion per year in developing countries

- Current mainstream strategy: post-harvest application of synthetic pesticides

Key traits of Post-Harvest Pesticides

Pesticides applied after harvest

Examples: fungicides, insecticides, sprout inhibitors, ethylene inhibitors

Used on grains, fruits, vegetables

Ensure food safety

Extend shelf-life

Support trade and reduce wastes

Application methods #1

Drenching

Produce is immersed or sprayed with a high-volume solution, allowing even distribution of the pesticide over the surface.

Drip Application

Controlled application through a drip system, usually during storage or packing, allowing slow and steady pesticide delivery.

Fogging (Aerosol or Thermal)

The pesticide is dispersed into fine droplets or vapor, covering stored produce in enclosed spaces (e.g., warehouses).

Fumigation

Use of volatile chemicals in gas form to penetrate deep into storage areas and produce; commonly used against insects or molds.

Spraying

Direct application of the pesticide solution using handheld or automated sprayers, often on sorting/packing lines.

Application methods #2

Wax Coating with Incorporated Pesticide

Pesticide is mixed with wax or coating solution and applied to fruits (e.g., citrus) to protect and extend shelf life.

Dip Treatment (Immersion)

Produce is submerged in a tank of pesticide solution for a specified time to ensure full surface contact.

Brush Application

Product is brushed onto produce surfaces, often in combination with wax application for fruits.

Electrostatic Spraying

Uses electrically charged droplets to achieve uniform pesticide coverage with lower volume, often in packhouses.

Gas-Phase Treatments

Used for substances like ethylene inhibitors or sprout suppressants (e.g., chlorpropham in potatoes) via gas release in storage.

Purposes of registration of PPP (including post-harvest)

Different procedures / strategies. E.g. Europe, US, Brazil, Asia.

Goals are the same!

- ✓ **Ensure Consumer Safety** - Protect public health by setting safe residue limits and requiring toxicological evaluation.
- ✓ **Guarantee Food Quality and Integrity** - Maintain produce freshness, prevent spoilage, and reduce contamination during storage and transport.
- ✓ **Protect the Environment** - Limit environmental impact from pesticide use, including air, water, and non-target species.
- ✓ **Facilitate Fair Trade** - Harmonize standards (e.g., MRLs) to reduce trade barriers and align with international guidelines (e.g., Codex).
- ✓ **Promote Efficacy and Proper Use** - Ensure products work as intended and are applied correctly to avoid resistance and overuse.
- ✓ **Support Agricultural Productivity** - Allow tools that reduce post-harvest losses and help farmers meet market standards.
- ✓ **Encourage Innovation and Safer Alternatives** - Foster development of newer, lower-risk technologies and active substances.

The EU approach, core principles

Precautionary Principle

Regulatory decisions favor caution when scientific evidence is uncertain, prioritizing human and environmental safety.

Dual Authorization System

Active substances: Assessed and approved at the **EU level** by EFSA.
Plant protection products (formulations): Authorized at the **Member State level**, based on zonal and mutual recognition principles.

Main Legal Framework

Governed by **Regulation (EC) No 1107/2009**, which sets rules for the placing of plant protection products on the market.

Complemented by related regulations on **MRLs (Reg. EC No 396/2005)** and **data requirements**.

Today there is **no separate procedure for PH PPP**

Registration in the EU, step-by-step

Step 1: Active Substance Approval

Submission of a comprehensive dossier to a Rapporteur Member State (RMS) and EFSA.
EFSA conducts a scientific risk assessment (toxicology, residues, environmental impact).
European Commission and Member States vote on EU-wide approval.

Step 2: Product Authorization

Based on an already approved active substance.
Application submitted to one zonal authority (interzonal for PH products, as treatment usually happens indoors).
→ Zonal Evaluation: Focused on local agronomic, climatic, and usage conditions.
→ Mutual Recognition: Other countries in the zone may accept the authorization with limited review.

Step 3: Data Requirements

Must include data on:

- Residues (including post-harvest trials)
- Toxicology (short-term and long-term exposure)
- Efficacy (demonstrating the product works on target pests/diseases)
- Physico-chemical properties, storage stability, operator exposure, etc.

Comparison with other systems

- USA
- Brazil
- Asia: China, Japan, India

USA

Responsible Authority:	**U.S. Environmental Protection Agency (EPA)** under the **Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).**
Unified Process:	EPA reviews both **active ingredients** and **formulated products**—no separate national vs. state-level system for core approvals.
Risk-Benefit Standard:	Products may be approved if the **benefits outweigh the risks** to human health and the environment.
Residue Tolerances (MRLs):	Set under the **Federal Food, Drug, and Cosmetic Act (FFDCA)** by the EPA in collaboration with the **FDA.** Required for each crop and use pattern; tolerances must be met for the product to be sold.
Data Requirements:	Include studies on **toxicology**, **residue chemistry**, **environmental fate**, **ecotoxicology** **Efficacy** part is very limited Post-harvest uses may have reduced data needs if exposure is limited.

Brazil

Responsible Authorities (Three-Agency System):	**MAPA** (Ministry of Agriculture): evaluates agronomic efficacy. **ANVISA** (Health Surveillance Agency): evaluates toxicology and human health risks. **IBAMA** (Environment Agency): evaluates environmental impact.
Simultaneous Review:	All three agencies review the same dossier in parallel, streamlining the process.
Applicable Legislation:	Governed by **Federal Law No. 7.802/1989** and **Decree No. 4.074/2002**. New pesticide law reforms are under discussion to further modernize the system.
Post-Harvest Uses Included:	Evaluated similarly to field uses, but with specific focus on **residue behavior during storage** and **food safety**.
Data Requirements:	Include **residue trials**, **toxicological studies**, **efficacy data**, and **environmental fate** studies. Data from other countries may be accepted if scientifically justified.
MRLs and Food Safety:	ANVISA sets MRLs; often aligned with **Codex** or adapted to national consumption data.

Some key Asian countries

Country	Regulatory Authority	Post-Harvest Focus	Key Notes
China	ICAMA (MOA)	Similar to field use, with storage residue focus	GLP data increasingly required; Codex MRL misalignments
India	CIBRC	Requires local trials, residue data	Simpler process; potential backlog; limited Codex alignment
Japan	MAFF	Strict residue control, storage stability required	Data-heavy; zero-tolerance policy; aligned with OECD

Expected timelines for registration

European Union: 5–7 years (active substance + product authorization)

United States (EPA): 2–4 years for new active substances; shorter for amendments

Brazil: 2–4 years (MAPA, ANVISA, IBAMA joint review)

China: 3–5 years (can vary depending on data availability and product type)

India: 2–3 years (Central Insecticides Board and Registration Committee)

Japan: 3–5 years (MAFF reviews with detailed data requirements)

Importance of MRL (Maximum Residue Limit) #1

Consumer Safety	Ensure that pesticide residues in food are within scientifically acceptable levels for human health.
Regulatory Compliance	Products must comply with MRLs to be legally sold in domestic and export markets.
Trade Facilitation	Harmonized or aligned MRLs reduce **trade barriers** and **rejections at borders**, especially for exporters.
Risk Communication	MRLs act as a **clear, measurable standard** for regulators, producers, and consumers.
Basis for Monitoring and Enforcement	Authorities use MRLs to check if food samples comply during inspections and market surveillance.
Encourages Good Agricultural Practices (GAP)	MRLs are derived based on GAP, encouraging growers and packers to apply pesticides correctly and responsibly.
Post-Harvest Specific Impact	Post-harvest treatments directly affect residue levels at the point of consumption; strict control is essential.
Varies by Jurisdiction	MRLs differ between countries (e.g. EU, USA, Codex, Japan), requiring **careful alignment in international trade**.

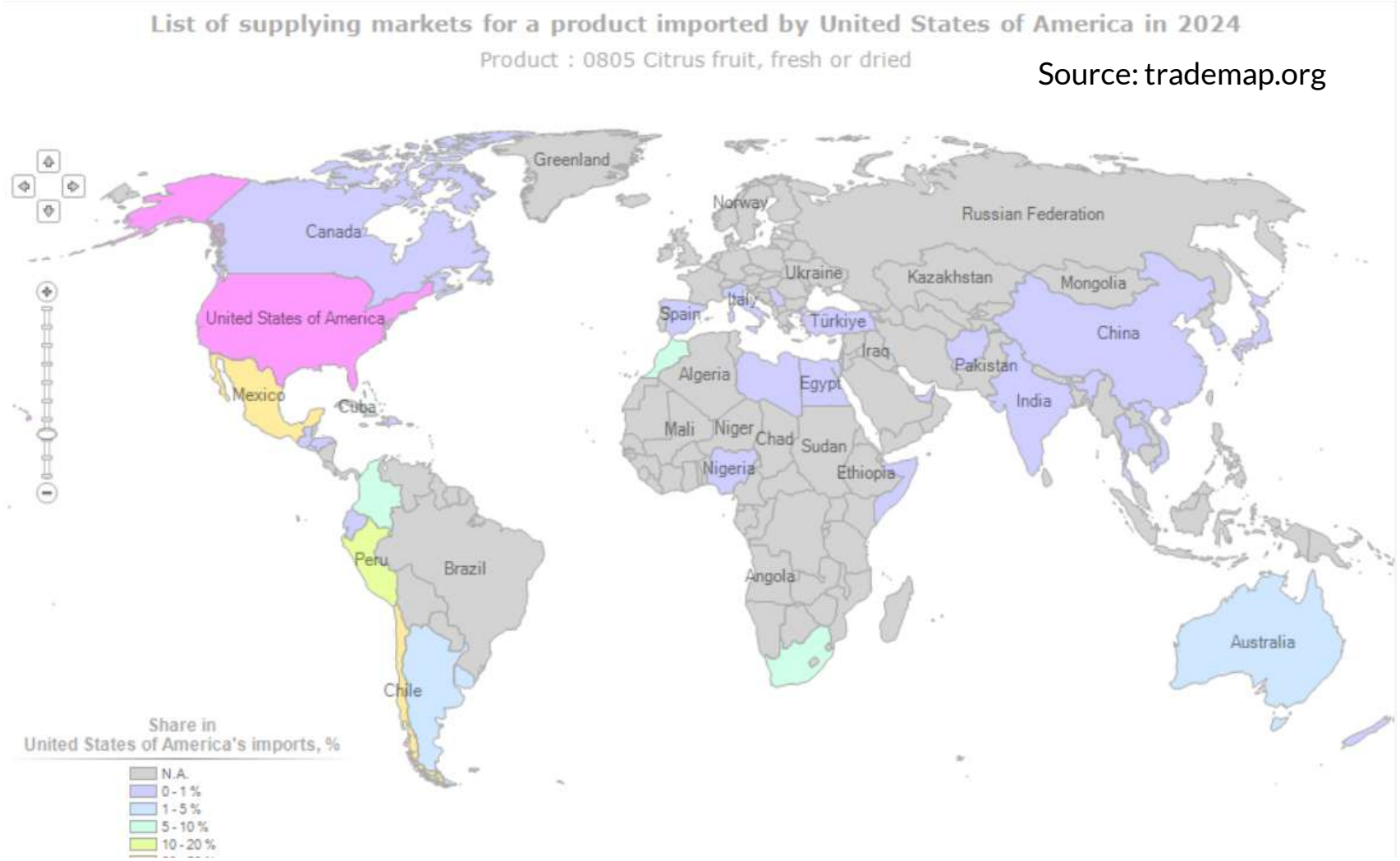
Importance of MRL (Maximum Residue Limit) #2

Critical for Market Access: MRLs determine whether treated produce can be legally sold in domestic and export markets.

Trade-Driven Sensitivity: Post-harvest treatments often leave detectable residues, making MRLs a key compliance factor in international trade.

- **EU**: Very strict and precautionary approach; default MRL = 0.01 mg/kg if not specifically set. Often limits availability of post-harvest products.
- **US (EPA)**: MRLs (called tolerances) are more pragmatic, set based on risk assessments with greater flexibility.
- **Brazil**: Tends to follow Codex MRLs or set national ones; faster and often more tolerant than the EU.
- **China**: MRLs expanding rapidly; not always aligned with Codex or exporting countries, leading to trade risks.
- **India**: MRLs are often outdated and inconsistently enforced; harmonization with Codex is ongoing.
- **Japan**: Very comprehensive and specific MRL list; zero-tolerance policy applies where no MRL is set, similar to the EU.

Importance of MRL (Maximum Residue Limit) #3



Source: trademap.org

Fruit travels a lot! MRL must comply with the regulation at destination

Post-Harvest Registration Challenges #1

Challenge/Impact	Description
Residue Behavior during Storage	Lack of consistent data on residue decline over time; variations in storage and transport conditions.
Diverse Use Patterns	Multiple application methods create complex residue profiles; different practices affect residue stability.
Geographic Variability	Regional variations affect pesticide behavior, requiring localized studies.
Regulatory Variability	Different MRL standards across jurisdictions complicate international trade and harmonization.
Lack of Efficacy Data	Limited data on the efficacy of post-harvest products under real conditions.
Environmental Impact	Environmental safety concerns persist even for post-harvest products.
Duration & Cost of Approval	Lengthy approval processes (3-7 years) and high costs of studies are significant barriers.
Public Perception	Concerns over chemical residues lead to regulatory scrutiny and consumer backlash.
Market Access	Compliance with MRLs opens global markets; non-compliance limits exports.
Competitive Advantage	Navigating regulations fast-tracks market entry and leadership.
Cost Implications	High registration and compliance costs reduce profitability.
Innovation	Stringent processes can hinder new product development.

Post-Harvest Registration Challenges #2

Challenge/Impact	Description
Agricultural Practices	Industry demand for sustainable pesticides drives global practices.
Supply Chain	Regulatory delays can disrupt supply chains, especially exports.
Consumer Trust	Strong compliance builds trust and strengthens brand reputation.
Barriers to Entry	New entrants face challenges with complex regulatory systems.
Reduced Availability of Tools	Regulatory burdens limit access to effective post-harvest pesticide tools, hindering pest management.
Harder Market Entry for SMEs	Small and medium enterprises face higher costs and complexity, limiting their ability to compete.
MRL Discrepancies Cause Trade Issues	Inconsistent MRLs between countries lead to **trade barriers** and **rejections** at international borders.

To summarize – what could be improved?

Streamlined Approvals	Simplify and harmonize the registration process across regions to reduce regulatory complexity.
Shorter Timeframes	Set realistic but faster evaluation timelines to speed up market access and innovation.
More Support for Minor Uses	Introduce incentives, subsidies, or simplified procedures for **low-volume or niche crops** and **post-harvest treatments**.
Codex Alignment	Increase alignment with **Codex Alimentarius MRLs** to reduce trade barriers and improve international consistency.
International Mutual Recognition	Promote **cross-border recognition** of risk assessments and data to avoid duplication.
Adapted Data Requirements for Post-Harvest Uses	Tailor data requirements (e.g., residue trials, efficacy) to the specific nature of **post-harvest applications**.
Digitalization and Transparency	Use digital platforms to improve transparency, tracking, and communication during the approval process.
Public–Private Collaboration	Foster collaboration between **regulators, industry, and academia** to streamline innovation and compliance.
Training and Regulatory Support	Provide better guidance, especially for **SMEs** and **developing countries**, to navigate registration processes.

Thank you for your attention!
Any questions?

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Rejoignez-nous !