

Principles of Regulation

In a world where agriculture faces huge challenges, crop protection products are essential and their regulation must be both a safeguard for society and a stimulant for innovation.

Our Challenges

- The global population will exceed 8 billion by 2030, which will increase calorie demand by 50 percent. Yet only 5 to 10 percent more land globally can be used for agricultural production.
- More food must be produced on existing farmland by increasing crop quantity and quality. Agriculture must also provide renewable sources of fuel, fiber and feed, while protecting natural habitats and resources.

Our Solutions

- Make the latest agricultural technologies available worldwide as countries ensure their appropriate use through sound regulatory systems.
- Establish or improve and harmonise regulations and registrations of crop protection products worldwide for their effective and responsible use.

CROP PROTECTION PRODUCTS allow farmers to control pests, diseases and weeds; increase crop quantity and quality; and engage in less burdensome and energy-consuming work practices. Effective regulation of these products allows them to be continuously improved for maximum effectiveness with minimum impact on the environment and human health.

To close the gaps, CropLife International has assembled Principles of Regulation (PoR), including best practices for crop protection registration and goals to meet societal expectations. The PoR invite reflection or reassessment of national or regional regulatory systems to better benefit society and agriculture. The PoR also provide a starting point for countries seeking to develop a crop protection regulatory system or build capacity.

With these PoR, CropLife International seeks to bring consistency and integrity to crop protection product regulations and registrations worldwide, helping to ensure safe, reliable and abundant crops in the future.



5 Goals to Meet Societal Expectations

- 1 **Set clear protection goals** that are not overly conservative for the proposed product use.
- 2 **Establish implementable procedures** that are neither inadequate nor overly complex.
- 3 **Make informed decision-making** based on sound science and evidence.
- 4 **Enable timely access to products** with the assurance that they can be used safely.
- 5 **Use enforceable performance measures**, such as post-approval compliance monitoring through the shared responsibility of regulators and industry.

8 Principles for an Effective Regulatory System

- 1 Compile a **sound policy framework** to ensure high standards of product use and protection for human health and the environment.
- 2 Use **quality data and ensure transparency** in the regulatory process, while protecting confidential business information and intellectual property.
- 3 **Harmonise international policies** wherever possible, while taking into account local needs and conditions.
- 4 **Conduct use assessment of each product** that is evidence-based using sound scientific principles.
- 5 **Clarify responsibilities** of each party throughout production and supply chains and call for responsible action.
- 6 Set up a **compliance monitoring** system and **active response** process to manage any potential adverse incidents.
- 7 Review crop protection products in the market periodically and ensure that **modern standards** are applied to all products.
- 8 Assess the **impact of major changes** to or revisions of regulation policies to ensure no unacceptable or unintended consequences occur.

9 Best Practices for Registration of Crop Protection Products

- 1 **Define quality assurance standards** and whenever possible, base them on internationally recognized testing guidelines and methods.
- 2 **Assess product safety** with sufficient data to well manage risks. The data should take into account local circumstances.
- 3 **Only use laboratory animals where necessary** in product testing. If animal studies are necessary, state why.
- 4 **Harmonise data requirements and risk assessment approaches** with those that have been internationally accepted.
- 5 **Share data and risk assessment approaches between responsible regulatory bodies** to minimize duplication of efforts and interpretational differences.
- 6 **Take a tiered approach to product assessment** in order to use resources effectively and appropriately.
- 7 **Use clearly defined protection goals, accepted test methodologies and well-established risk assessment procedures** relevant to the intended use of the product.
- 8 **Foster communication** between regulators and registrants.
- 9 Set up a **“data call-in” system** so that new data relevant to the use of products can be requested and registrations reviewed.

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