Principles of Regulation
Benchmark Questionnaire

CropLife INTERNATIONAL

Background

The world faces formidable challenges to increase food production for an ever-growing population with land and water scarcity and the effects of climate change. Innovative technology is a critical factor in enabling agriculture to grow more food on less land in a sustainable way. This includes safeguarding natural resources such as soil fertility, water supply, wildlife habitats and biodiversity.

Crop protection products are vital for efficient and sustainable use of natural resources as they equip farmers with tools for pest control, increased crop yields, better quality produce, and less burdensome and energy-consuming work practices. While such innovations are to be encouraged, standards need to be ensured, with best farmer practices and consumer safety in mind. Regulation is therefore a critical part of the solution; it should provide incentives for innovation, but also safeguard against unacceptable risks.

Principles of Regulation

While the International Code of Conduct on the Distribution and Use of Pesticides acts as a reference point for globally accepted standards of pesticide management, regulations and regulatory processes vary widely from country to country. This calls for a common approach and sensible harmonisation for global benefit. There are a number of common principles applied to legislation and regulation in a variety of disciplines. Many are reflected in crop protection regulations around the world. CropLife International analysed these regulatory systems which, resulted in the assembly of Principles of Regulation (PoR).

The PoR provide guidance on recognised and universally applicable regulatory principles and best practices. At the heart of sound decision-making are high standards, good processes and risk-benefit analysis associated with the use of a crop protection product. The PoR provide a common reference point for the continuous improvement and development of crop protection regulatory systems worldwide. They invite reflection or reassessment of national or regional regulatory systems and provide a starting point for countries seeking to develop regulations or build capacity.

Benchmark Questionnaire

The key regulatory principles and best registration practices have been compiled into the following list of questions and can be used to assess existing levels of adoption. The provisions should be rated accordingly:

1 = poor/non-existent adoption or significant improvement required
2 = limited adoption or not well enforced or improvement required
3 = good/satisfactory adoption, but some scope for improvement
4 = very good, no need for improvement

Please note: Improvement should be interpreted as meaning the need for better provision, whether insufficient or excessive.

While the questionnaire calls for scoring (1-4 without decimal points), the primary purpose of it is to foster discussion on what should be improved, with what priority and how, rather than merely assess the current situation. The result of the discussion should be captured in the comment column for future reference. The assessment and discussion on improvements should concentrate on actual practices.

	SUBJECT/PROVISION	RATING	COMMENT
1	**Regulatory policy/framework covers:**		
1.1	A defined purpose that is to benefit from technologies (pesticides) without any unacceptable risks		
1.2	Informed decision-making based on information and evidence		
1.3	Promotion of transparency and harmonisation		
1.4	Recognition of animal welfare		
1.5	Periodic review of all approved products		
1.6	Impact assessment for major changes		
2	**Registration processes ensure:**		
2.1	Transparent and well-defined processes		
2.2	Regulators are competent		
2.3	Dialogue occurs between registrant and authorities		
2.4	Mutual acceptance is practiced (where relevant and appropriate)		
2.5	Data requirements are defined		
2.6	Timescales are defined and acceptable		
2.7	Fee structure is defined and equitably applied		
2.8	FAO Code of Conduct principles are applied		
3	**Data requirements include:**		
3.1	Active ingredient specification		
3.2	Formulated product specification		
3.3	Analytical methods		
3.4	Clear definition of the use pattern (bio-efficacy data)		
3.5	Toxicology data		
3.6	Operator exposure data		
3.7	Crop residues data		
3.8	Consumer risk assessment		
3.9	Environmental fate data		
3.10	Ecotoxicology data		
3.11	Environmental risk assessment		
3.12	Clearly defined and predictable requirements		
3.13	A tiered approach to data requirements and risk assessment		
4	**Intellectual property aspects cover:**		
4.1	Respect for patents		
4.2	Requiring applicants to supply test reports		
4.3	Requiring applicants to supply letters of access to data not included in the submission, but needed for evaluation		
4.4	Confidential business information not accessible to third parties		
4.5	A data compensation scheme where relevant		
5	**Review process ensures:**		
5.1	Weight-of-evidence approach is used		
5.2	Science-based analysis of risks and benefits		
6	**Approval process ensures:**		
6.1	Decisions based on sound science		
6.2	Balanced risk/benefit judgements made		
6.3	Right of appeal is part of process		
6.4	Labels are clear, reflect conditions of approval and include appropriate GHS elements		
6.5	Limited political interference		
7	**Post-registration ensures:**		
7.1	Monitoring of compliance with registrations		
7.2	Illegal imports are controlled		
7.3	Stewardship is valued		
7.4	Appropriate management of adverse incidents		

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