Ensuring Safe, Abundant Crops for a Growing World Population
Our Challenges

• **Global population** to exceed 9 billion by 2050, with most growth occurring in developing countries
Our Challenges

• Population growth will require at least 50% increase in calorie demand

• Only 5-10% more land globally can go into agricultural production

• Climate change and water shortages
Our Solutions

• **Improve yields**
  Without fungicides, yields of most fruits and vegetables would fall by 50-90%, making them unaffordable to many.

• **Help reduce waste**
  World Bank estimates that in India, fruit and vegetable post-harvest losses amount to 40% of total production.
Our Solutions

• Society expects benefits of crop protection with minimal risks! This is done with:

  • Stewardship
    • Training farmers and handlers
    • Integrated Pest Management, etc.

  • Innovation
    • New products and active ingredients

• Regulation
We’ve heard that laughter is the best medicine, so beginning Monday we’ll be regulating it.
Crop Protection Regulation

• Crop protection products are **essential to agricultural production**. But regulation of them key to ensure appropriate use and minimize environmental impact.

• Regulation should result in **societal trust, confidence and benefits** (i.e., safe, reliable food supply).
Crop Protection Regulation

- Under International Code of Conduct, governments have responsibility to regulate crop protection products in their countries.

- Crop protection regulations vary enormously worldwide due to social and political priorities and economic development.
Benefits of Effective Regulation

- Promotes investment in new solutions
- Assures safety and sustainability
- Enables shared responsibility and compliance
- Allows timely access to technology
Global Regulatory System Challenges

- Complex
- Not predictable
- Investment uncertainty
- Increasing R&D costs
- Lack of risk/benefit analysis
- Trade barriers
- Lack of Harmonization
"IT LOOKS LIKE THEY'RE BRINGING IN THE NEW REGULATIONS MANUAL."
Principles of Regulation (PoR)

Three components:

• Meeting **societal expectations** of crop protection regulation

• **Recognized principles** for effective regulation of crop protection products

• Identified **best practices** for effective registration of crop protection products
PoR: Societal Expectations

Regulations should be:

- **Protective** with clear goals
- **Implementable** with clear procedures
- **Informed** based on scientific evidence
- **Enabling** to allow access to technology
- **Enforceable** for accountability
PoR: Recognised Regulatory Principles

1. Compile **sound policy framework** to ensure high standards of product use and protection for human health and environment.

2. Use **quality data and ensure transparency** in regulatory process, while protecting confidential business information and intellectual property.
3. **Harmonise internationally** 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.
PoR: Recognised Regulatory Principles

6. Set up **compliance monitoring** system and active response process to manage adverse incidents.

7. Ensure that **modern standards** are applied to all products in market.

8. Assess **impact of major changes** to or revisions of regulations.
PoR: Registration Best Practices

- Quality assurance including product specification
- Responsible data call in
- Dialogue with regulators
- Science-based decision making criteria
- Tiered approaches
- Core essential data requirements
- Animal use and welfare
- Harmonisation
- Mutual acceptance of data
Gap Analysis Using PoR

Assessed regulatory systems against PoR

Identified gaps and excesses

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<th>Systems initially analyzed:</th>
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Gap Analysis Results

Areas identified for improvement:

• **Registration process**
  - Mutual acceptance
  - IP Provisions
  - Transparency
  - Timescales

• **Approval process**
  - Risk assessment
  - Risk/benefit judgment
  - Stewardship
Evaluating Regulation

Review your own regulatory process and compare to PoR

Identify gaps and excesses

Consider new approaches in spirit of continuous improvement
Ideal Outcomes

- Universal adoption of recognised principles for effective registration of crop protection products and application of best practices.

- Application of universal approaches to assessment of crop protection products and their uses.

- Regulation is critical and should be both stimulant and safeguard for introduction of crop protection products.
Bottom Line

- Our world faces huge challenges and agriculture is at heart of them.
- Crop protection technology is vital part of solution to these challenges.

Thank you for your kind attention