

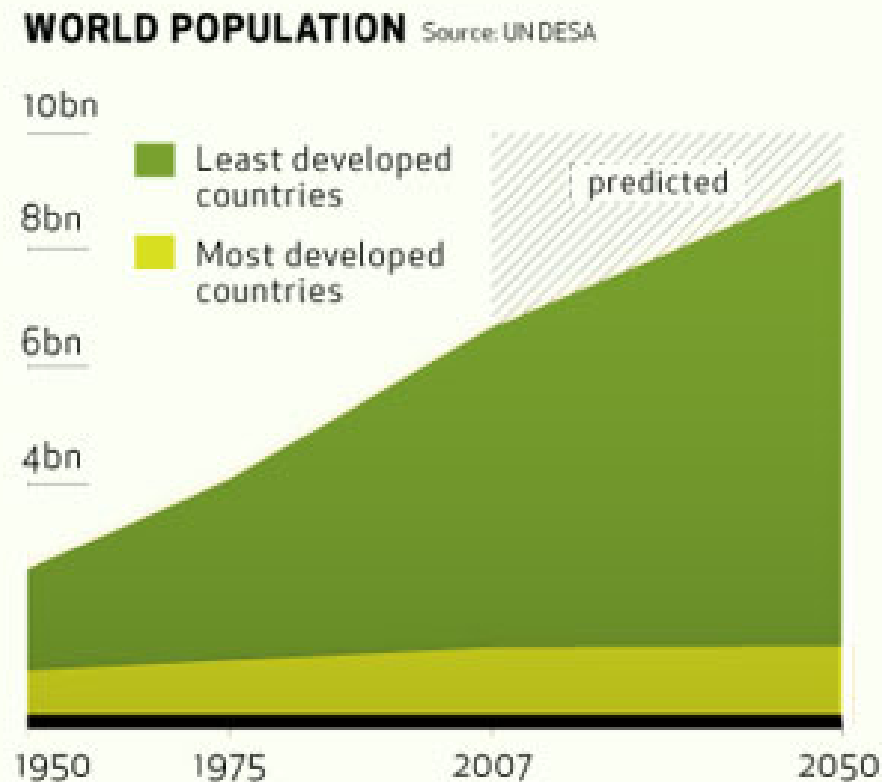


Ensuring Safe, Abundant Crops for a Growing World Population



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**

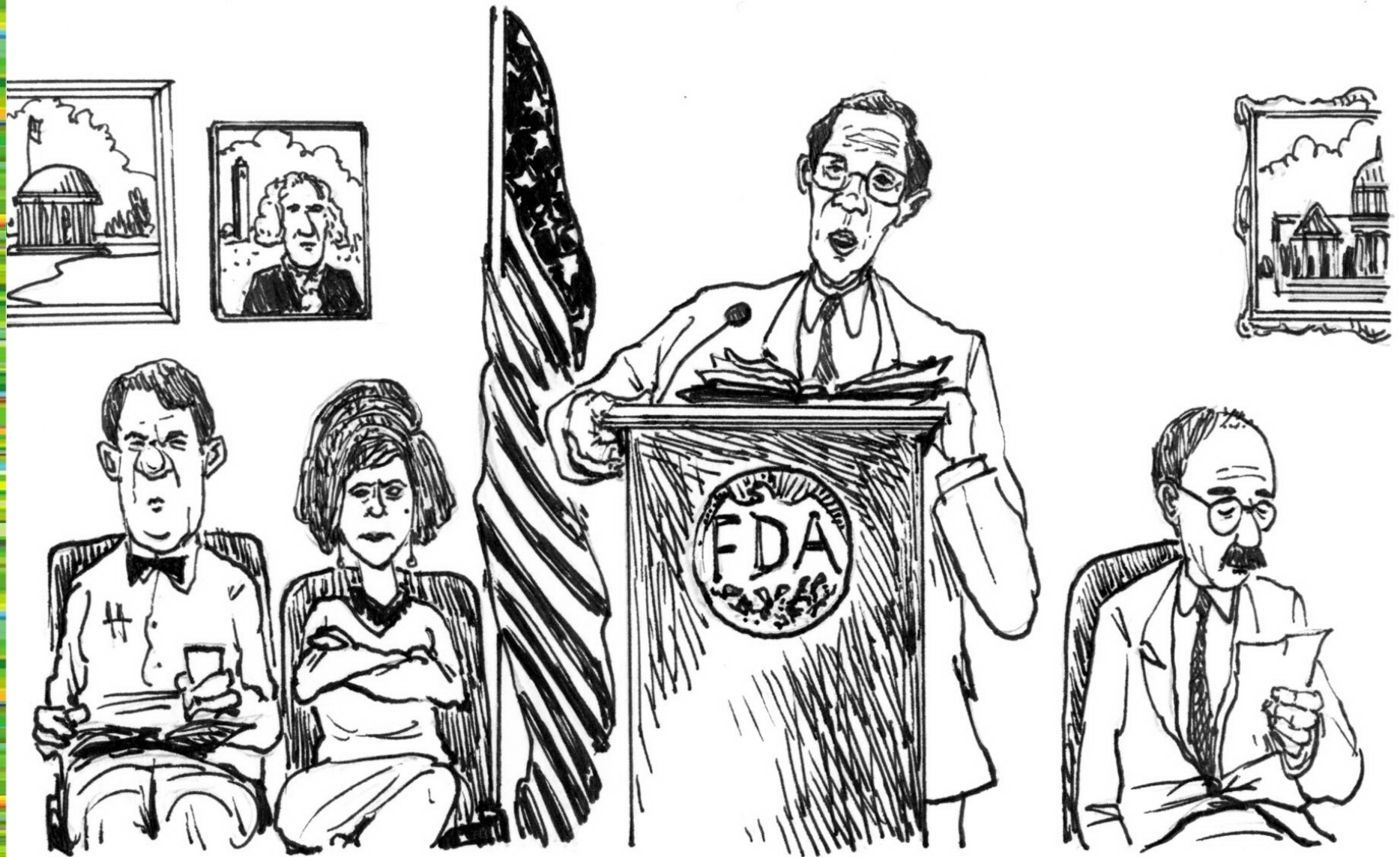
World Bank estimates that in India, fruit and vegetable post-harvest losses amount to 40% of total production.



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).

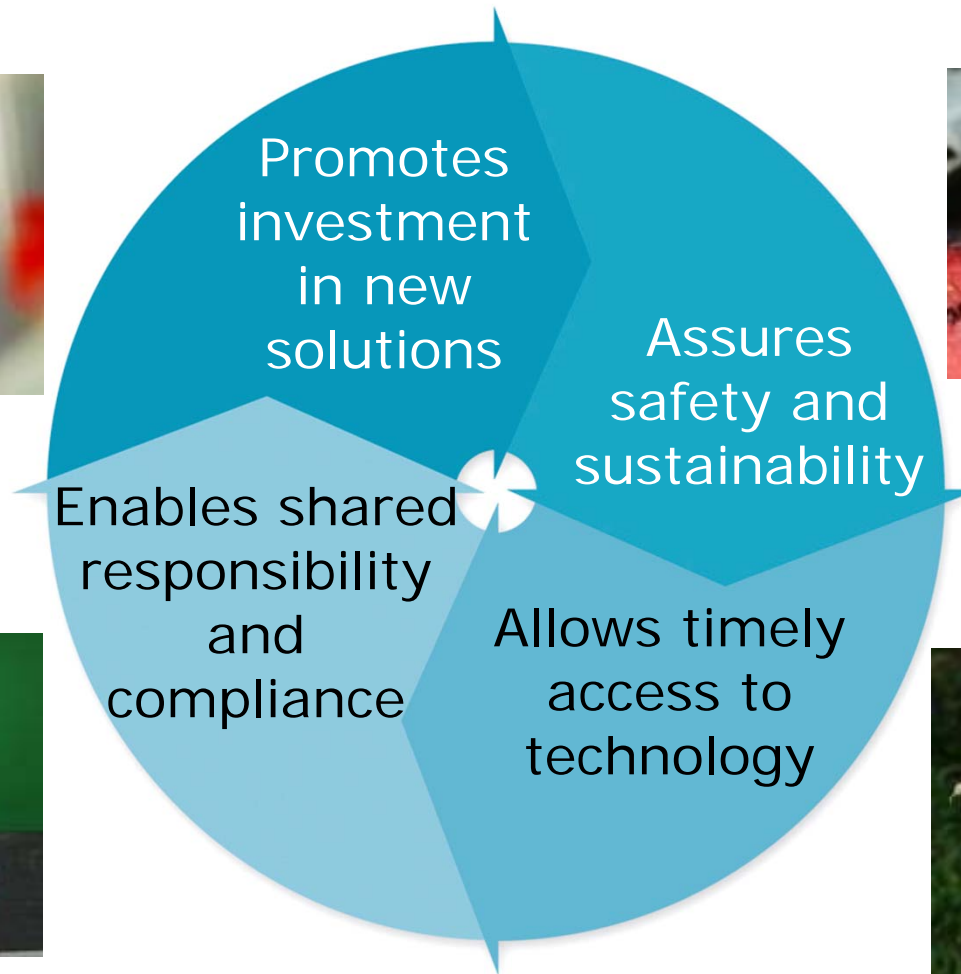


Crop Protection Regulation

- 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



Global Regulatory System Challenges



Complex



Not predictable

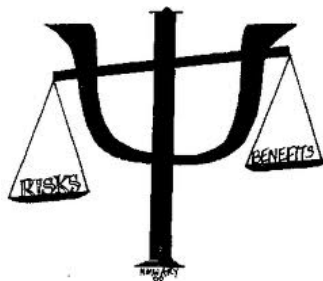


Investment uncertainty



Increasing R&D costs

Lack of risk/benefit analysis

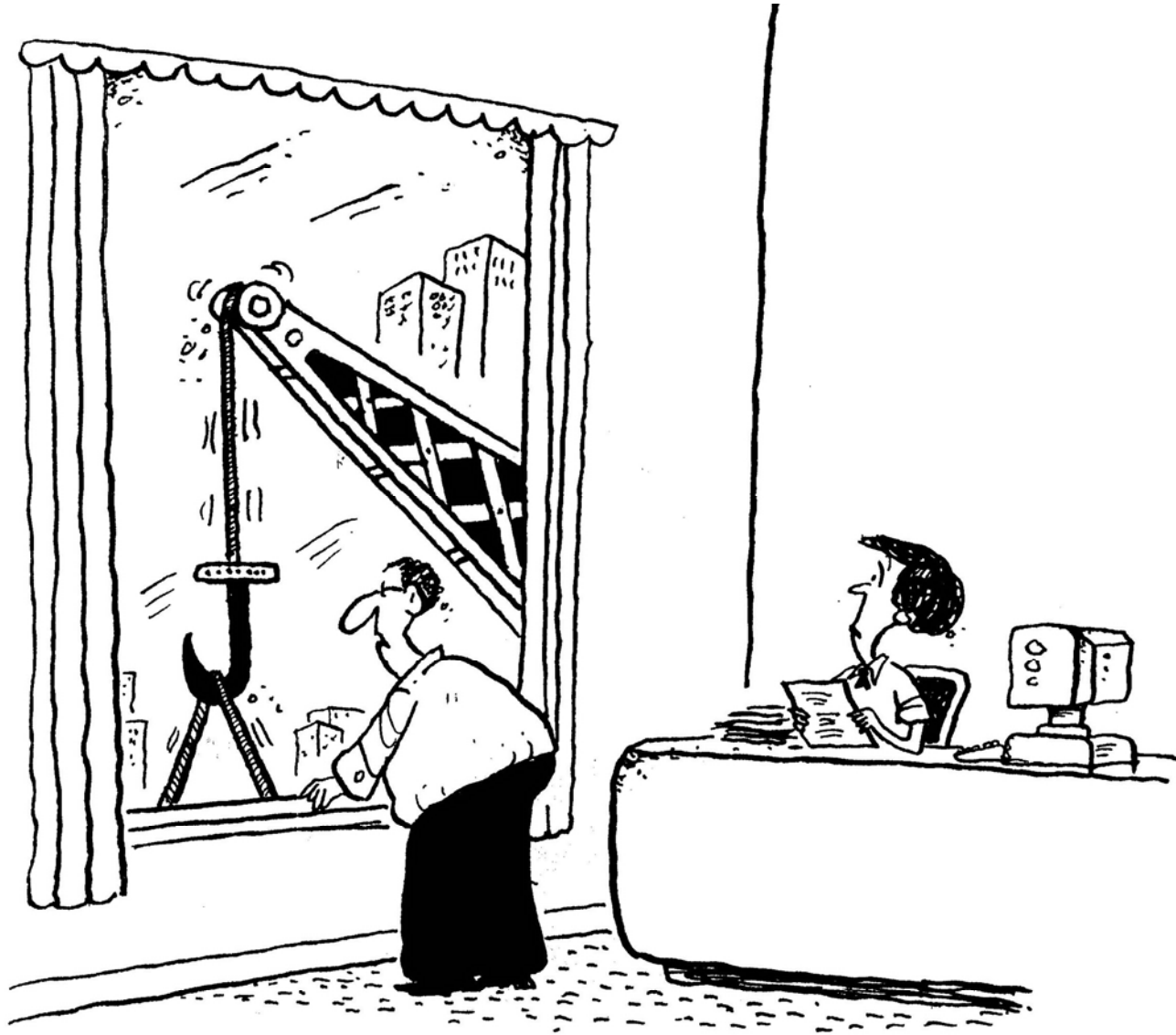


Trade barriers



Lack of Harmonization





DAVE CARPENTER...

" 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



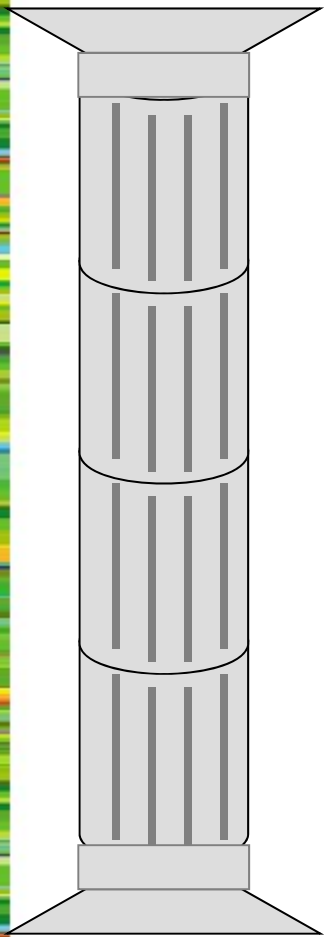
PoR: Societal Expectations

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



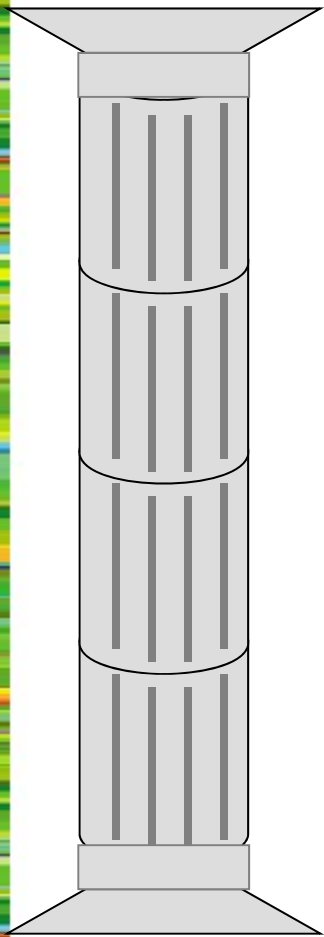
PoR: Recognised Regulatory Principles



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.



PoR: Recognised Regulatory Principles



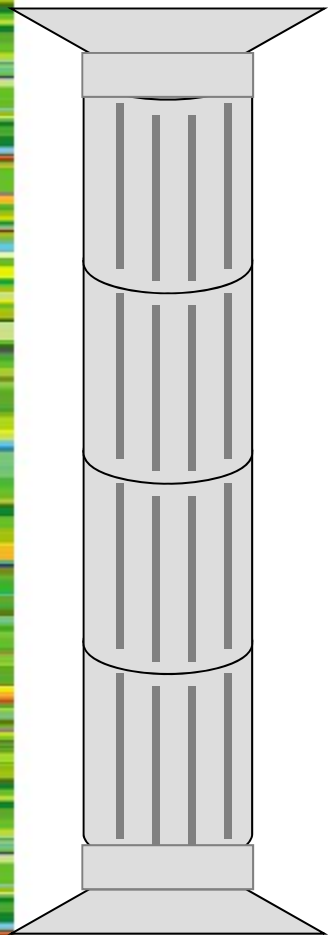
3. **Harmonise internationally** wherever possible, while taking into account local needs and conditions.

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.



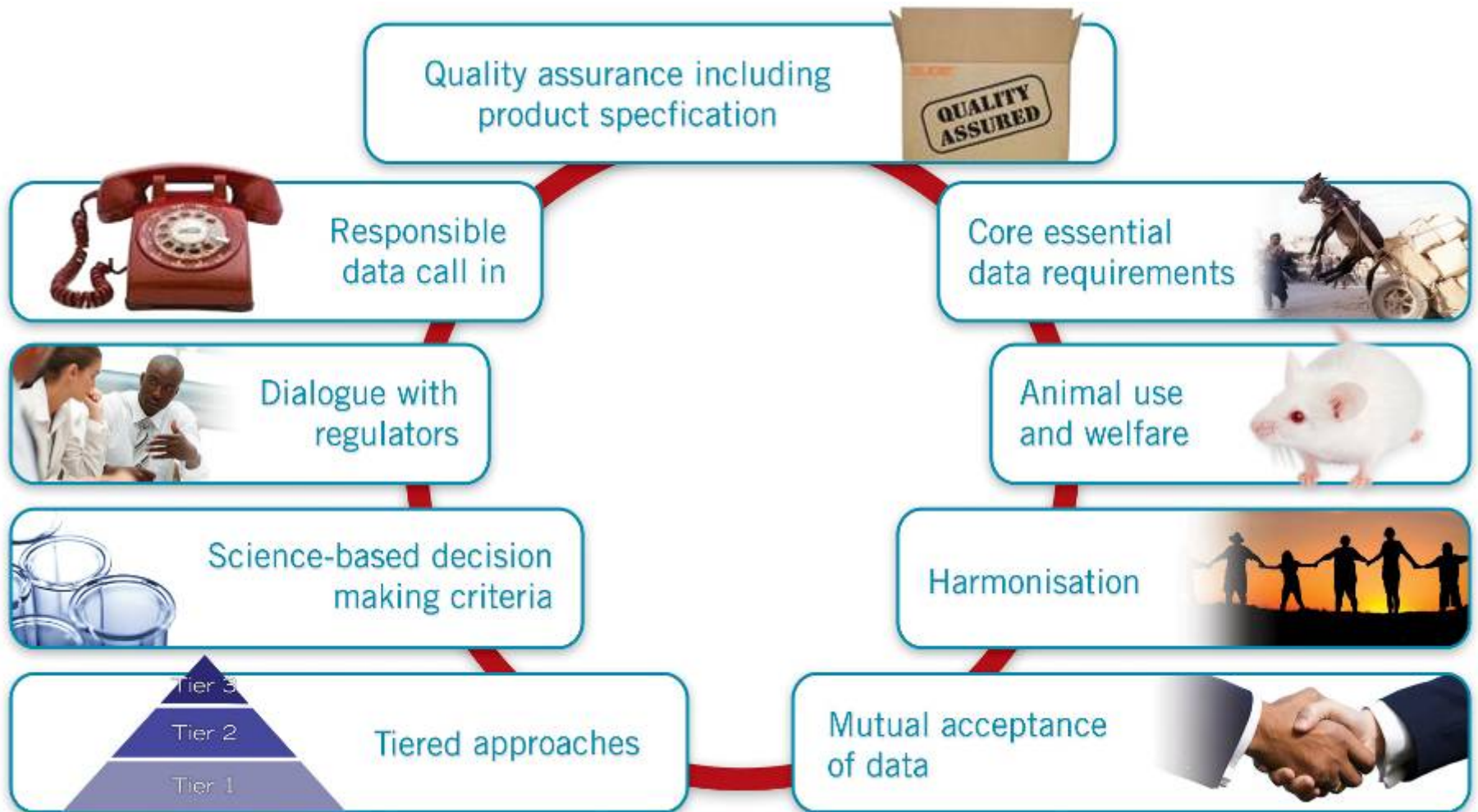
PoR: Recognised Regulatory Principles



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



Gap Analysis Using PoR

Assessed
regulatory
systems
against
PoR



Identified
gaps and
excesses

Systems initially analyzed:

Argentina

Kenya

Bolivia

India

Central America

Morocco

Dominican Republic

Paraguay

Chile

Peru

Colombia

South Africa

Ecuador

Uruguay

Egypt

USA

European Union

Venezuela



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

