

# The Principles of Regulation for Vector Control Products

Vector Control Team



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# Human health faces huge challenges

- Risk of disease transmission by insects is increasing - accelerated by climate change and urbanisation
- The world population is set to exceed 8 billion by 2030
- 2.5 billion people at risk of contracting dengue
- > 500 million cases of malaria, >750,000 deaths each year



# Vector Control is at the heart of overcoming these challenges

- **Maximising Benefits of Current Products**

Ensuring best practices for handling, application and use are observed

- **Developing New Products**

An active pipeline of Public Health insecticide active ingredients and products is needed to meet future vector control needs

- **Tackling Insecticide Resistance**

Promoting the use of existing resistant management tools and strategies



# Vector Control is a vital part of the solution

These challenges require the private and public sectors to confront this head on and together

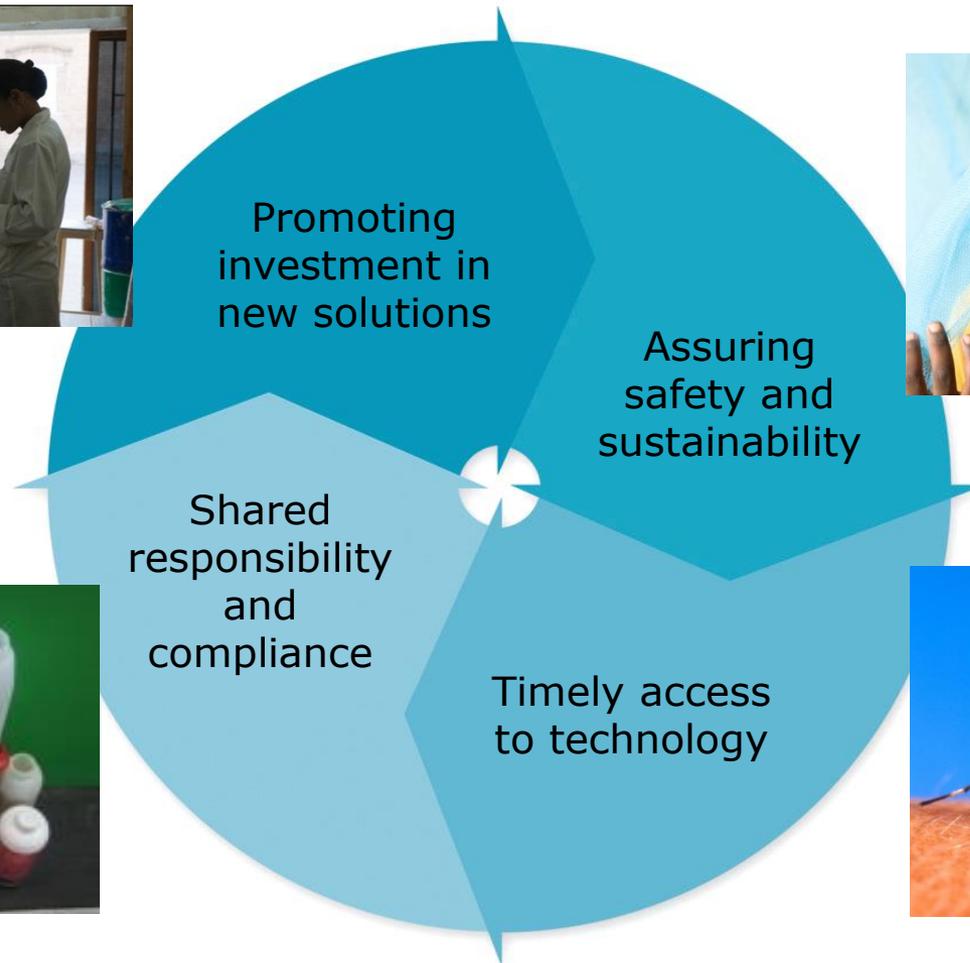


Regulation is key to  
addressing these challenges



# Regulation is an imperative

It should be both a stimulant and a safeguard, working in the service of society, Public Health and Vector Control solutions.



# Regulation of Vector Control Products

- Vector Control products play an important role in society, but their benefits and regulation are poorly understood
- Under the International Code of Conduct Governments have the overall responsibility to regulate the availability, distribution and use of Vector Control products in their countries and to ensure the allocation of adequate resources for this mandate
- Regulation can be the basis for good standards and practices and thus the foundation for societal trust, confidence and capacity building



# A global solution for a global challenge

Regulation of Vector Control products varies enormously around the world, reflecting the importance of healthcare to society, political priorities, and economic development.

So how do we satisfy the needs of our societies and meet the global challenges of the future?

CropLife has looked at the standards and practices in operation today and put together

## **'The Principles of Regulation'**

in support of good regulation globally

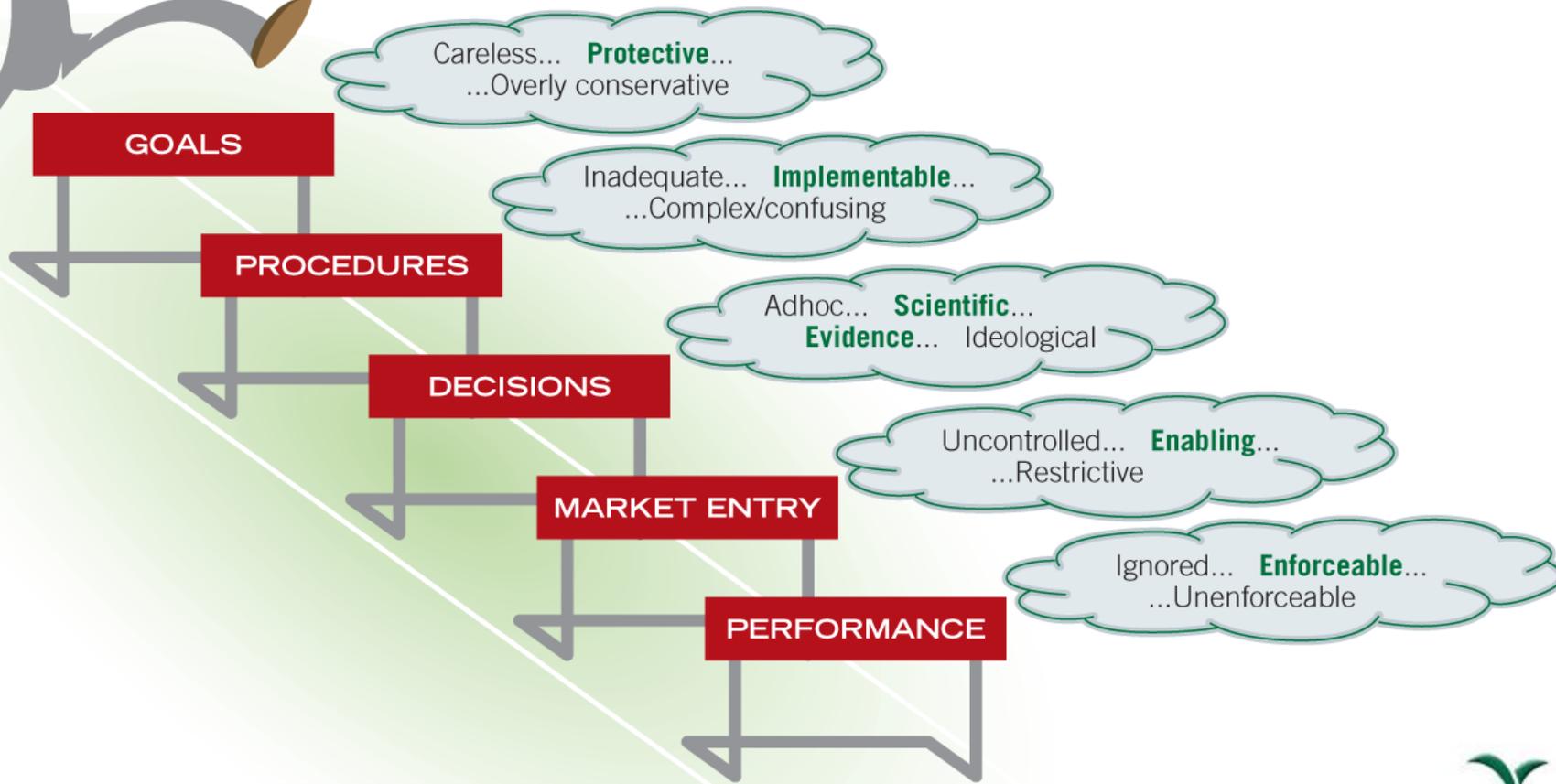


# The Principles of Regulation

- Societal **expectations** of regulation
- Key recognised regulatory **principles**
- Identified best **practices** for effective registration



# Societal expectations of regulation

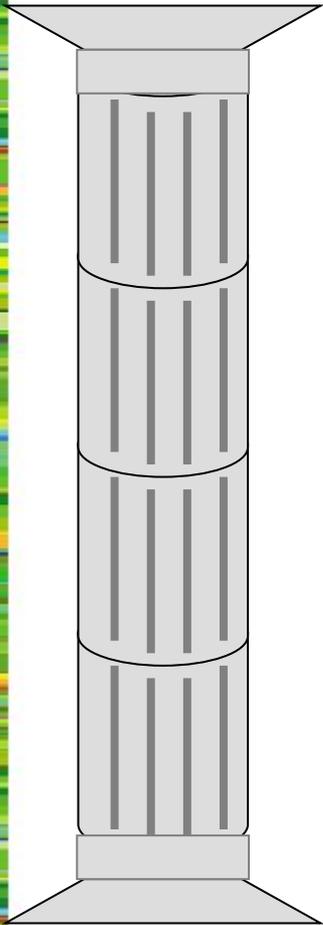


# Societal expectations of regulation

- **Protective** – clear protection goals that form a basis for balanced decisions which assess use (risk and benefits)
- **Implementable** – an understandable process built around a common framework builds trust and creates opportunities for workshare &/or capacity building
- **Informed** – decisions based on evidence using a common framework which extends understanding and capabilities around the world
- **Enabling** – process that allows access to technology whilst meeting protection goals
- **Enforceable** - shared responsibility for post-approval monitoring and compliance



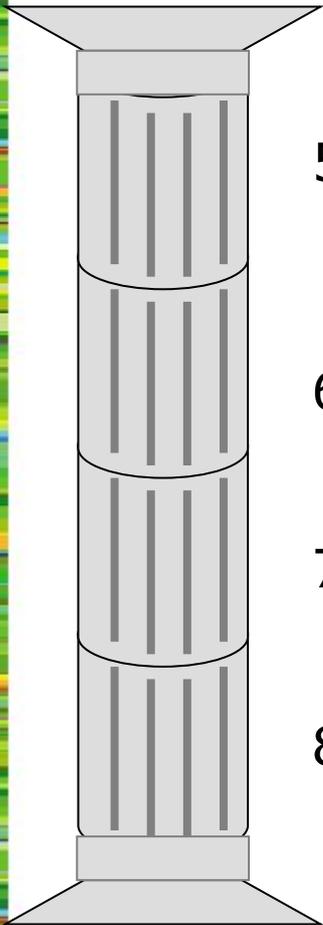
# 8 Key recognised regulatory principles



1. Sound policy framework to ensure high standards of use and protection for human health and the environment
2. Quality data and transparency of regulatory process, whilst providing protection of regulatory data safeguarding confidential business information and intellectual property
3. International harmonization wherever possible, but always taking into account local needs and conditions
4. Scientific principles and use assessment (risk/benefit)



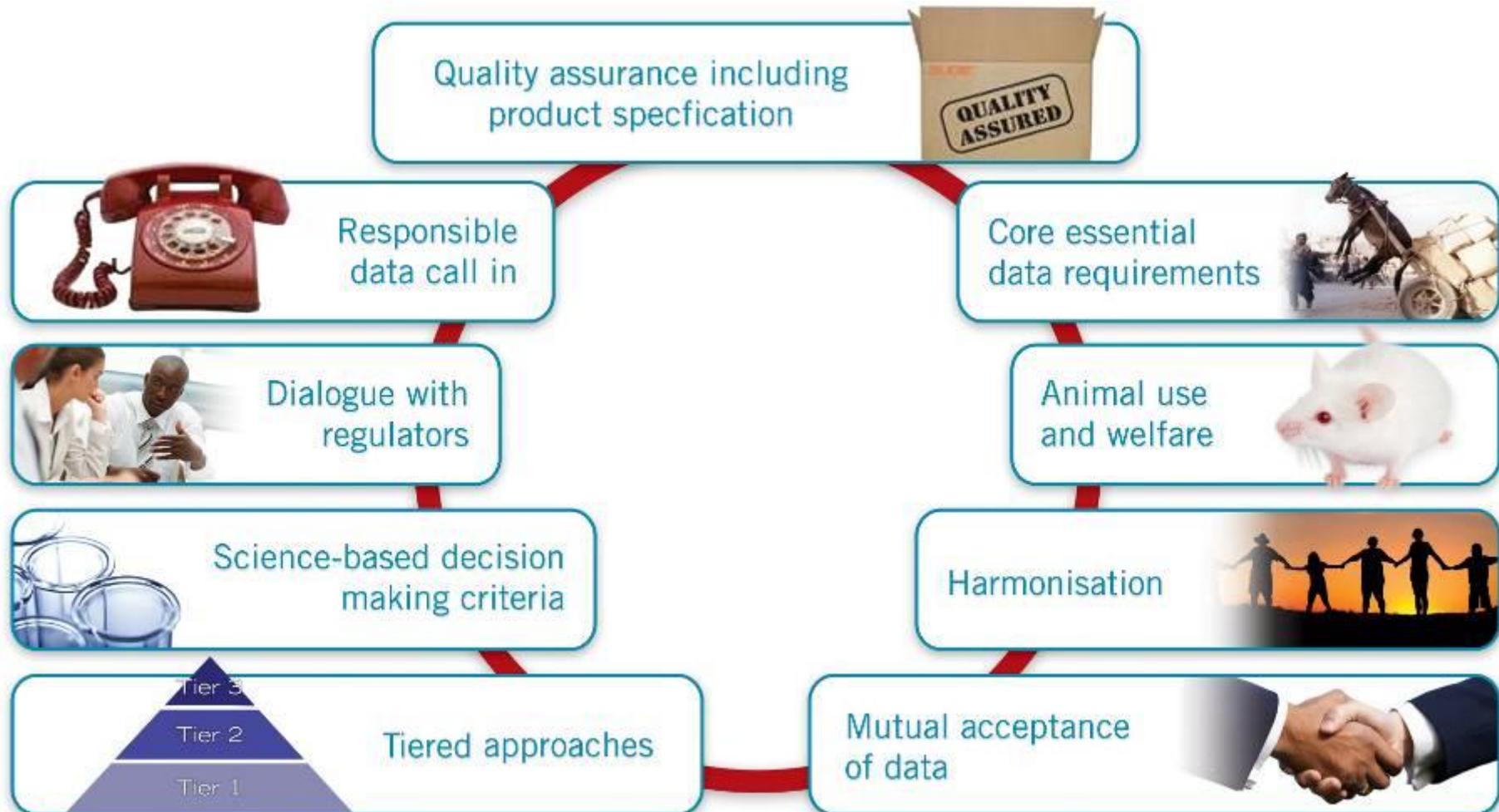
# 8 Key recognised regulatory principles



5. Responsibilities of each party throughout the production and supply chains as well as commitments to responsible action
6. Compliance monitoring system and an active response process to manage adverse incidents
7. Process to ensure that modern standards are applied to all products in the market
8. Impact assessment of major changes to/revisions of regulations

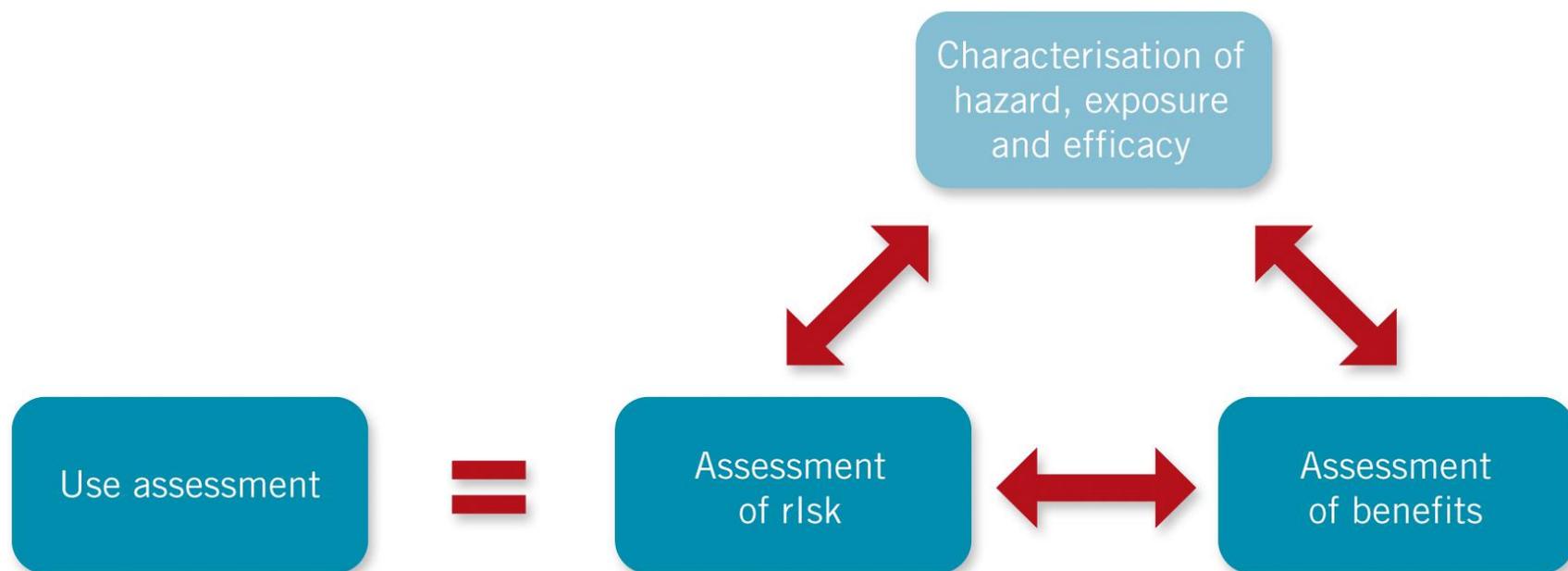


# 9 Best practices for effective registration



# Universal assessment of Vector Control products and their uses

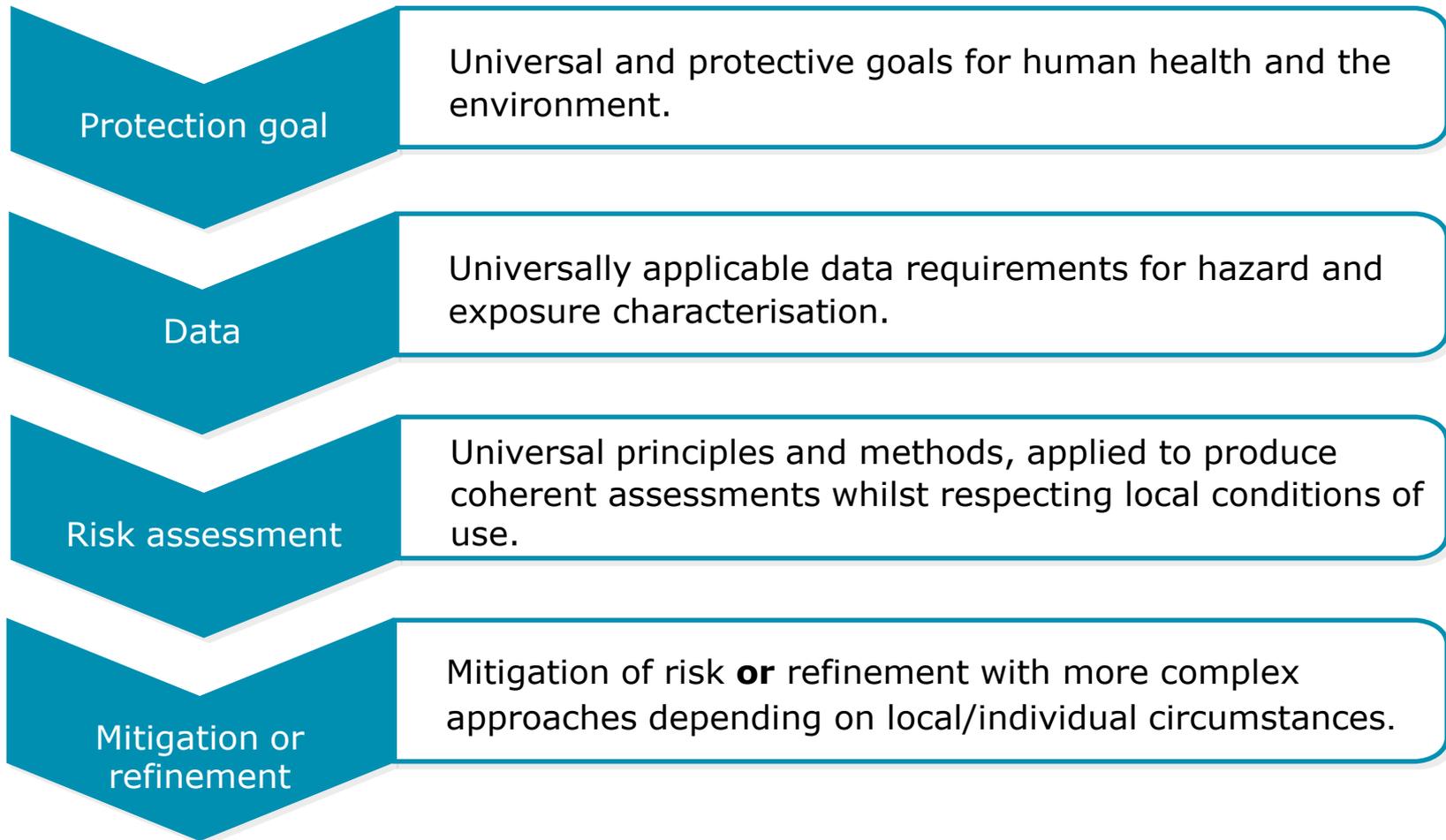
Universal data requirements leading to one consensus view on characterisation of product



Universal approach to assessments to produce coherent outcome.  
Local conditions of use, needs and desired benefits can be reflected in independent decisions



# Key elements of the assessment



# Analysis of existing regulation using the Principles of Regulation

Assess regulatory process against the Principles of Regulation



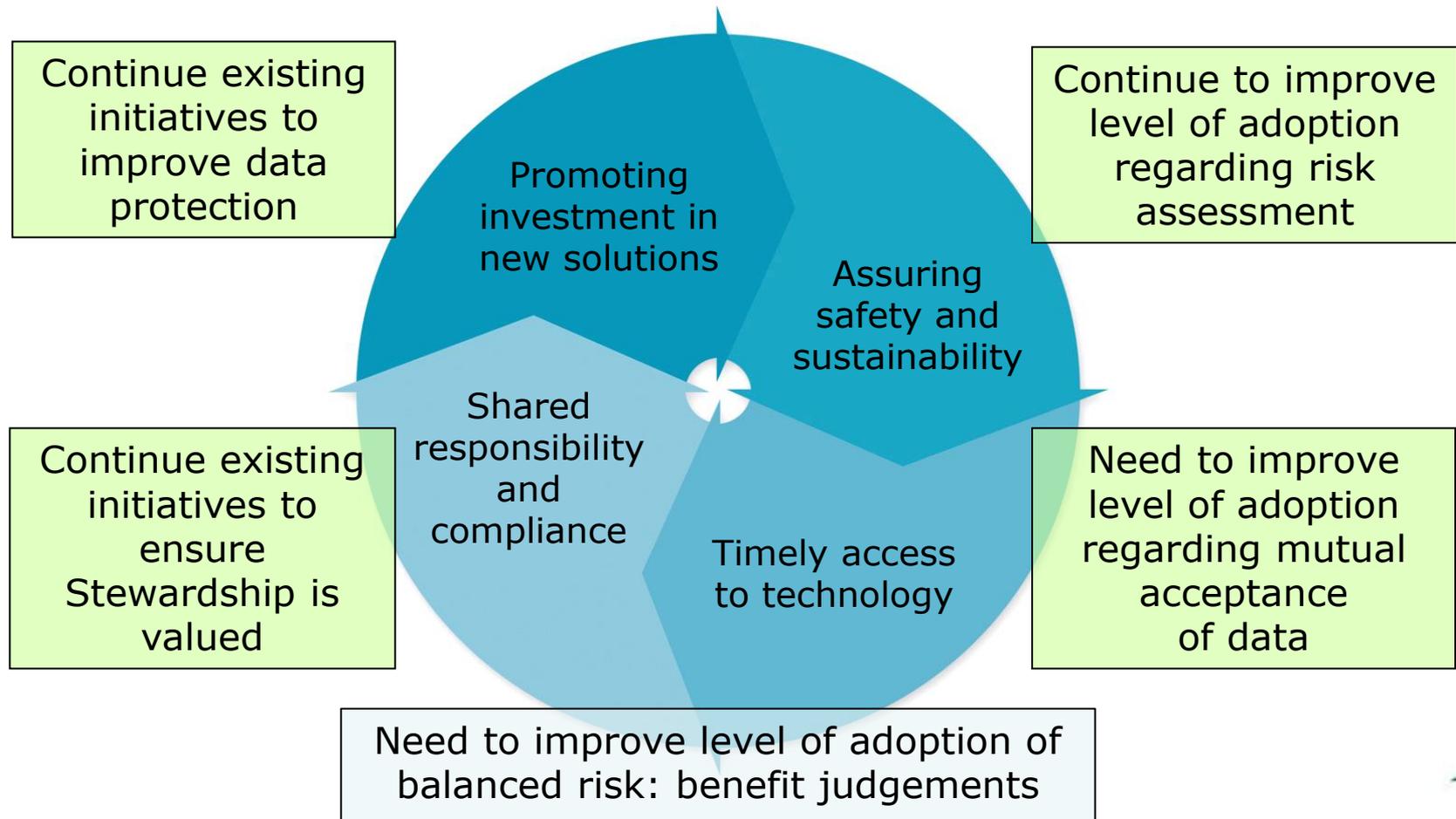
Identify gaps and excesses



Consider options and approaches in a spirit of continuous improvement



# CropLife analysis of existing regulation in meeting future challenges



# Priorities for continuous improvement

- Universal adoption of the key recognised regulatory principles and application of the best practices for effective registration .
- Universally applicable approaches to the assessment of a product and its uses (Use Assessment):
  - Establishing clear protection goals
  - Product characterisation based on essential core data essential
  - Risk assessments using recognised risk assessment principles and local conditions
  - Refinement of risk assessment or risk mitigation
  - Local needs and desired benefits reflected in assessment



# Vector Control - CropLife proposition

- Human health faces huge challenges
- Effective management of Vector borne diseases is at the heart of these challenges
- Effective use of existing Vector Control products and development of new technology is a vital part of the solution
- Regulation is an imperative and should be both a stimulant and a safeguard
- The CropLife proposition is for a universal approach to the Principles of Regulation



Thank you for your kind attention

