



# The Principles of Regulation

## CIPAC Symposium

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  - Societal expectations of regulation
4. Use Assessment and RA Concepts
5. Proposals for continuous improvement



# Our world faces huge challenges

Global food security is threatened by:

- the global population set to exceed 8 billion by 2030
- a 50% increase in calorie demand
- only 5-10% more land globally could be made available for agricultural production
- the practical consequences of climate change and water shortages



# Agriculture is at the heart of these challenges

- **GROWING FOOD**

Raising yields and ensuring a secure, reliable food supply

- **CREATING RENEWABLES**

Beyond food, agriculture must provide renewable sources of fuel, fibres and feed

- **SUPPLYING SUSTAINABLY**

Protecting biodiversity, natural habitats and water resources through efficient production



# Crop protection technology is a vital part of the solution

Such challenges require the public and private 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, agriculture and plant science



Promoting investment in new solutions



Assuring safety and sustainability

Shared responsibility and compliance



Timely access to technology



# Regulation of Pesticides

- Pesticides play a unique role in society, but their uses, benefits, and regulation are poorly understood by many
- Under the International Code of Conduct Governments have the overall responsibility to regulate the availability, distribution and use of pesticides 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

Pesticide regulations vary enormously around the world, reflecting the relative importance of agriculture 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

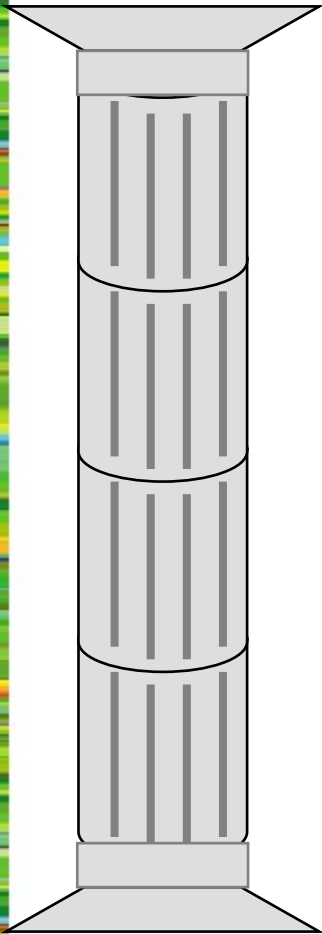


# The Principles of Regulation

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



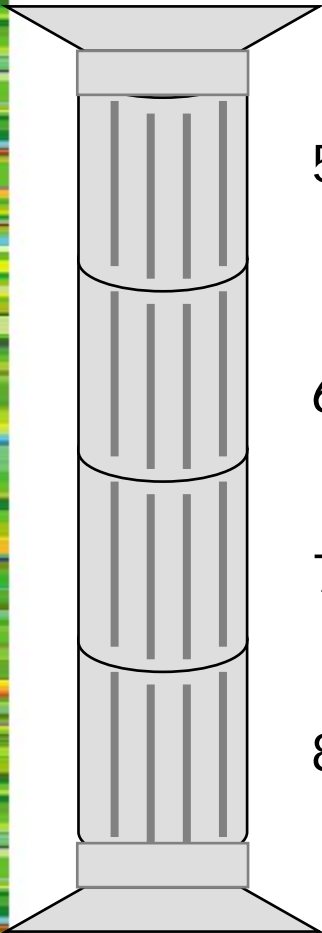
# 8 Key recognised regulatory principles



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



# 1

## Sound policy framework to ensure high standards of use and protection for human health and the environment

- Establishes the core purpose of any pesticide regulation enabling society to benefit from advances in technology whilst ensuring there is no unacceptable risk based on:
  - An evaluation and decision-making process using scientific data for determining acceptability of intended purpose, and for the protection of health and the environment
  - Assessment of the consequences of use including agricultural and socio-economic needs, local conditions and appropriate mitigation measures
  - Determining permitted use(s) and exercise quality control



# 2

## Quality data and transparency of regulatory process, whilst safe-guarding confidential business information and intellectual property

- Ensuring data quality and transparency of the regulatory process
  - establishing type and standard of data is essential in building trust in regulatory decisions
  - visibility of data requirements, guidelines, steps in the process helps to avoid unnecessary duplication and creates greater efficiency
- Confidential business information (CBI) and intellectual property rights must be respected
  - Reasonable periods of protection promote ongoing innovation and protect investment in R&D
  - Clarity on data requirements and access that ensures equal competition and safety standards.



# 4

## Scientific principles and use assessment (risk/benefit)

- An evidence-based approach to understanding the consequences of using a product
  - Data generated to accepted standards
  - Risk-based approach to determine if protection goals are being met and to facilitate risk management
  - An objective and justifiable basis for making decisions that promotes transparency and harmonisation
- An assessment of consequences of use means assessing the risks and the benefits:
  - Characterise the product and assess practical use
  - Decisions that neither deny the grower access to efficacious products nor compromise safety.





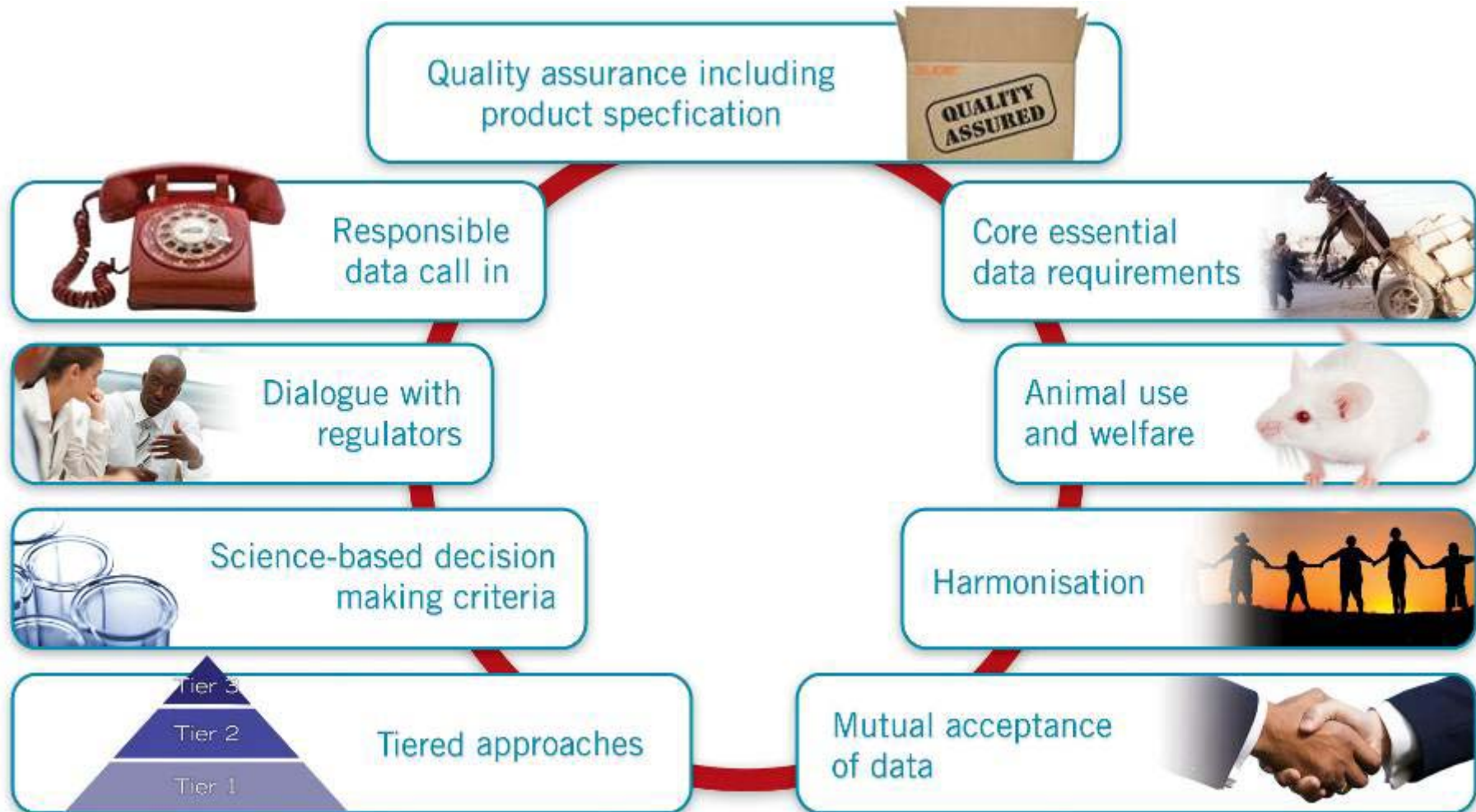
## Impact assessment of major changes to/revisions of regulations

- Changes to a regulation can have unacceptable or unintended consequences which go beyond its original objectives.
- Any significant changes should be assessed for the societal and economic impacts to ensure that in the broadest sense society continues :
  - to be protected from unacceptable risks for human health and for the environment
  - to benefit from advances in agricultural technology





# 9 Best practices for effective registration



# Quality Assurance



- Assurance of the quality of health and safety through compliance with the relevant standards for:
  - the core set of data requirements (eg GLP)
  - identity, purity, composition, performance and stability of the product
  - equivalence to determine that all “similar” pesticide products being marketed correspond in identity, quality, purity and composition to the substances tested, evaluated and cleared for toxicological and environmental acceptability.
- Use internationally recognised standards to help:
  - build and maintain industry, regulators and public confidence in decision-making process
  - facilitate harmonization of data submissions and cooperation between Regulatory Authorities



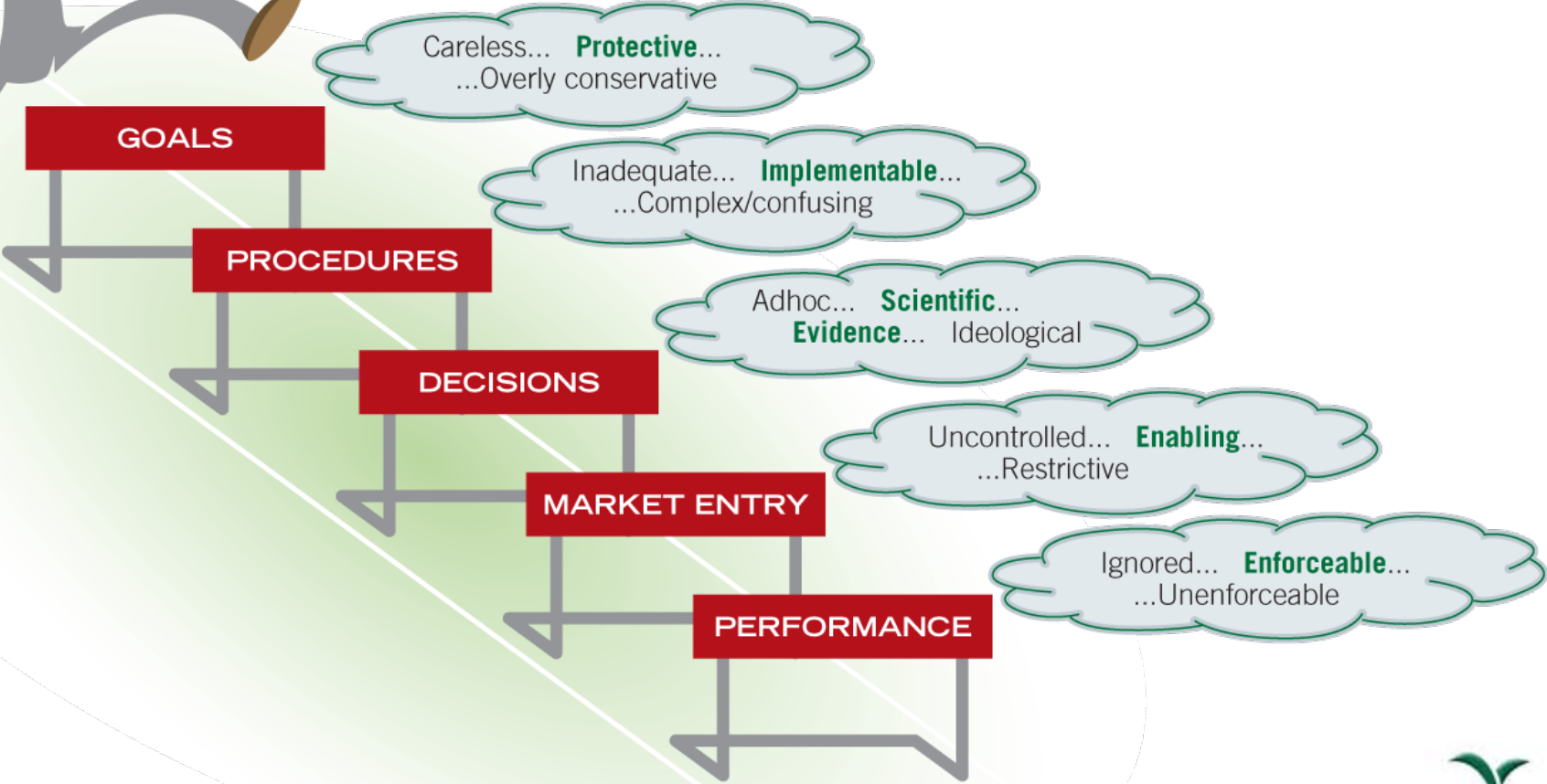
# Core essential data requirements



- A core set of essential data requirements provides a basis for assessing the risk profile for the proposed use of the product
  - eliminates duplicative testing to satisfy slightly different data requirements addressing essentially the same concerns
  - It facilitates harmonization of data requirements and cooperation between Regulatory Authorities
  - Whilst the core data may be the same the risk assessment should reflect any difference in conditions of use
- Creates confidence in the in decision-making process for all stakeholders including industry, regulators and the public



# Societal expectations of regulation



# Analysis of existing regulation using the Principles of Regulation

Assess regulatory process against the Principles of Regulation



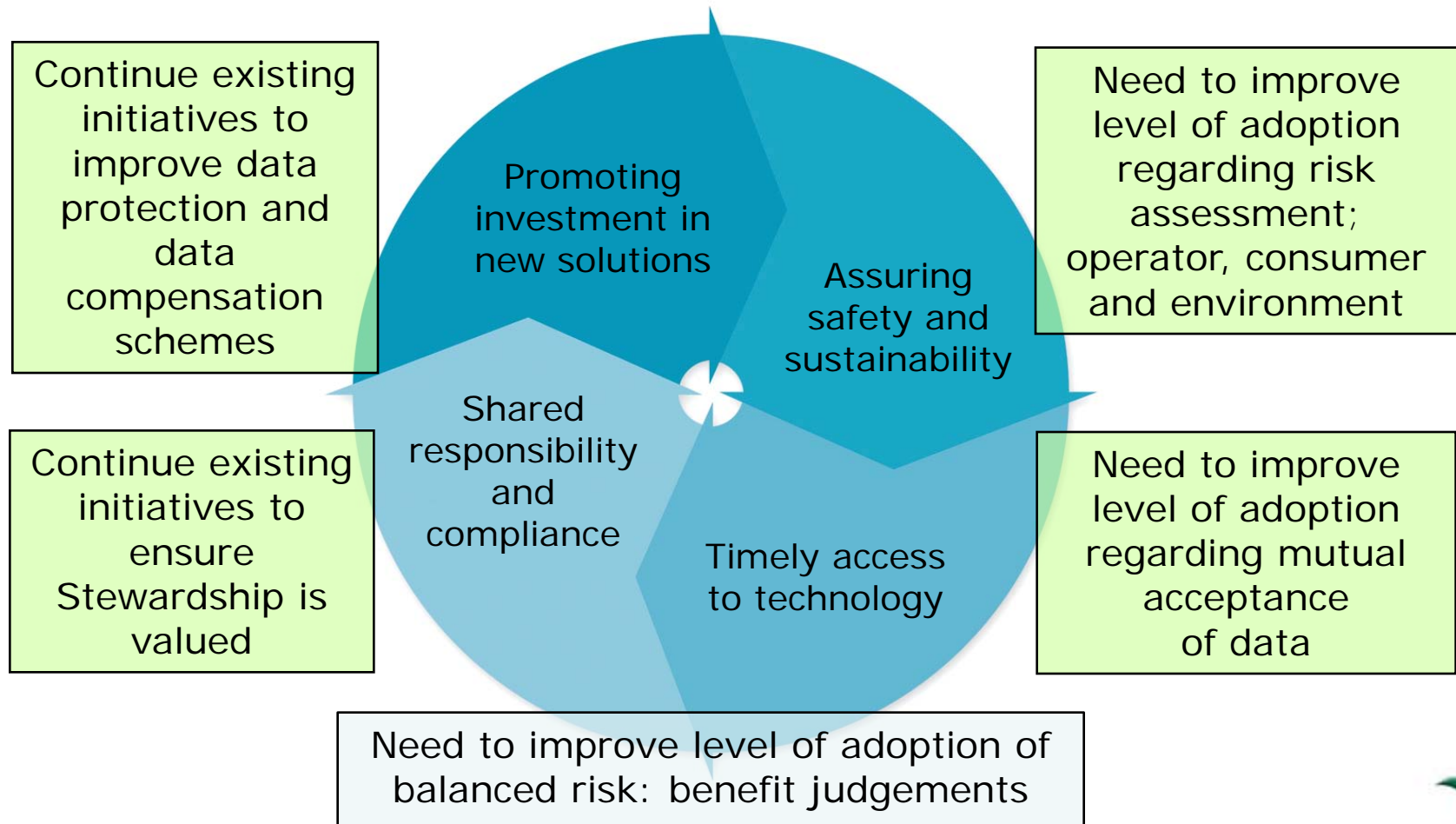
Identify gaps and excesses



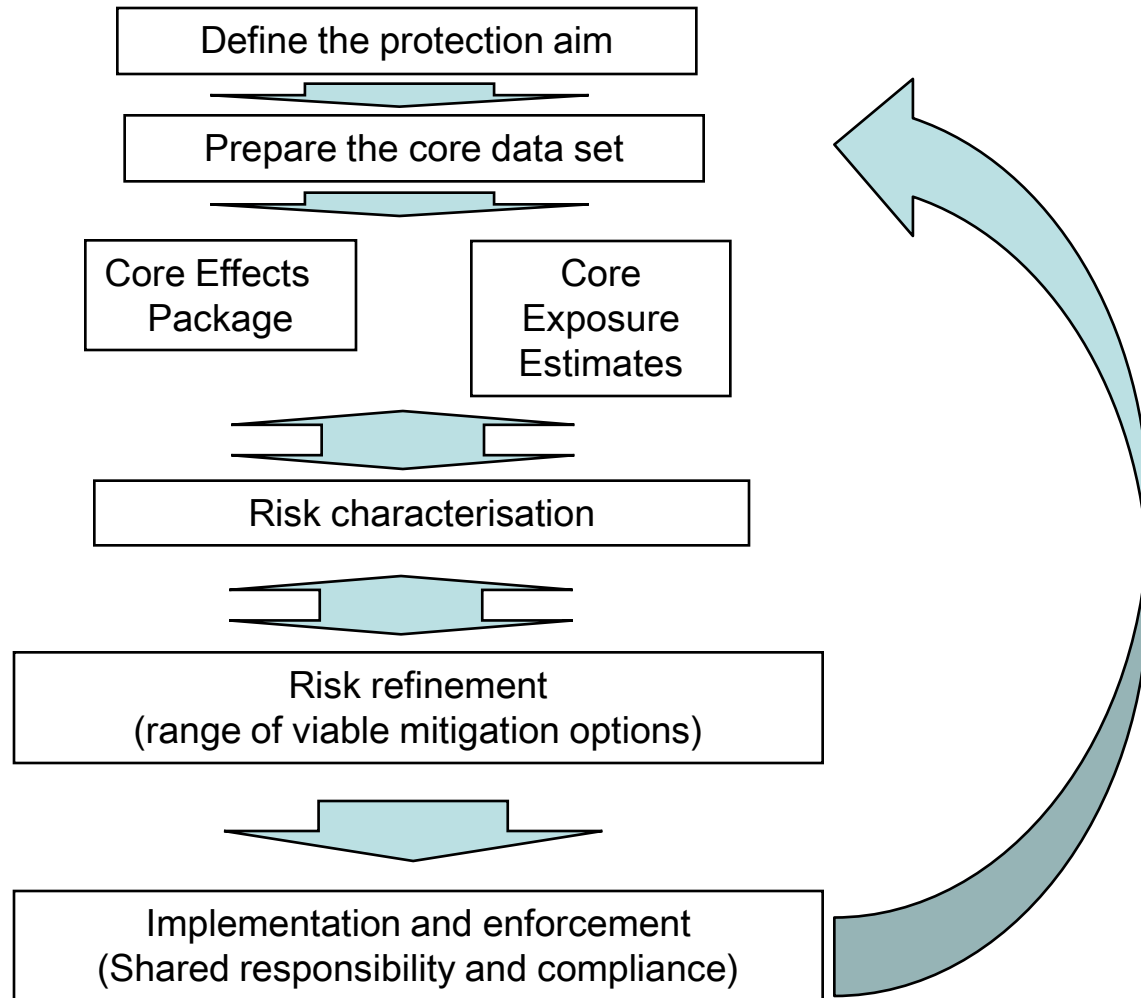
Consider options and approaches in a spirit of continuous improvement



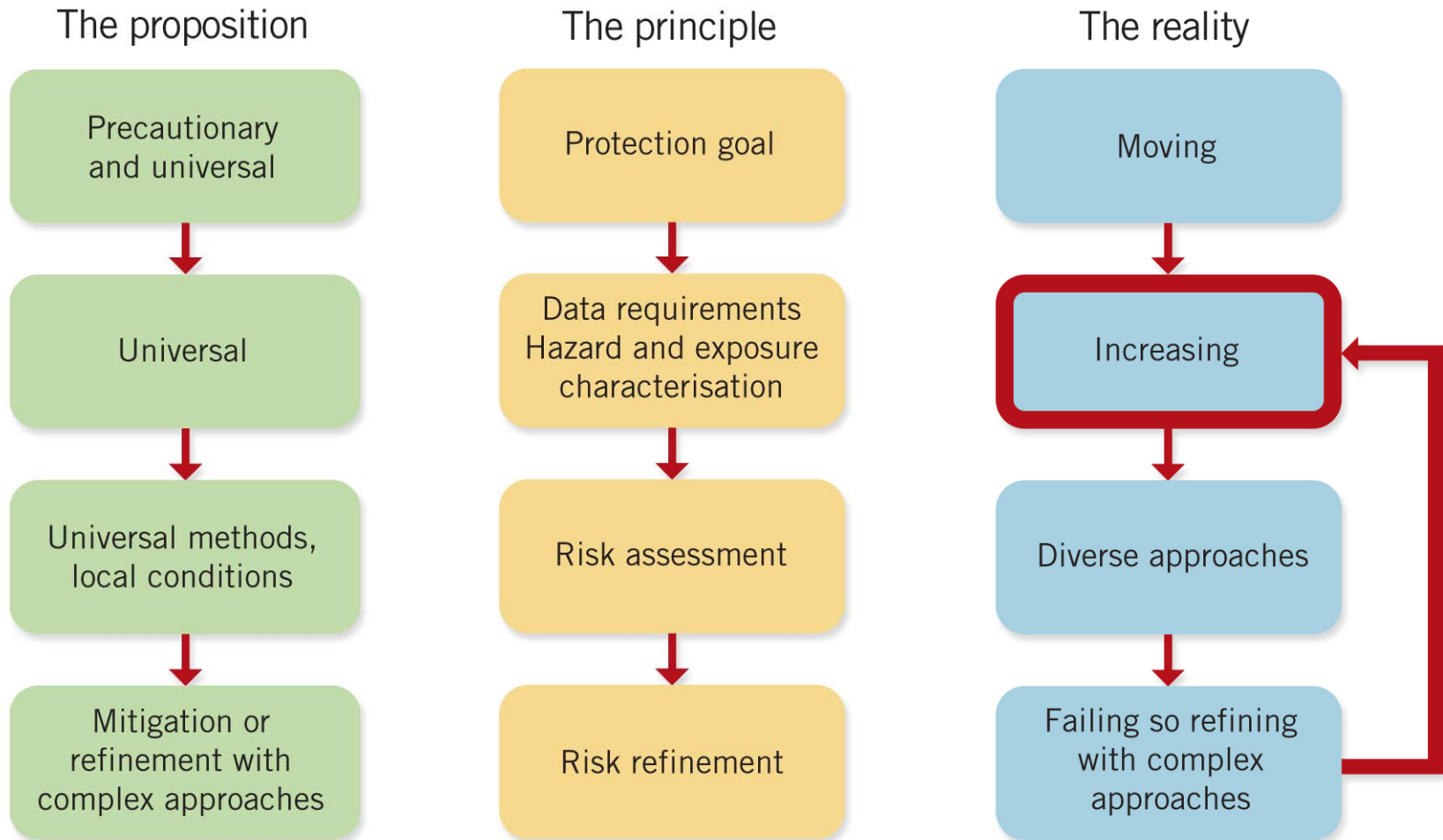
# CropLife analysis of existing regulation in meeting future challenges



# Universal framework for assessing safety of use

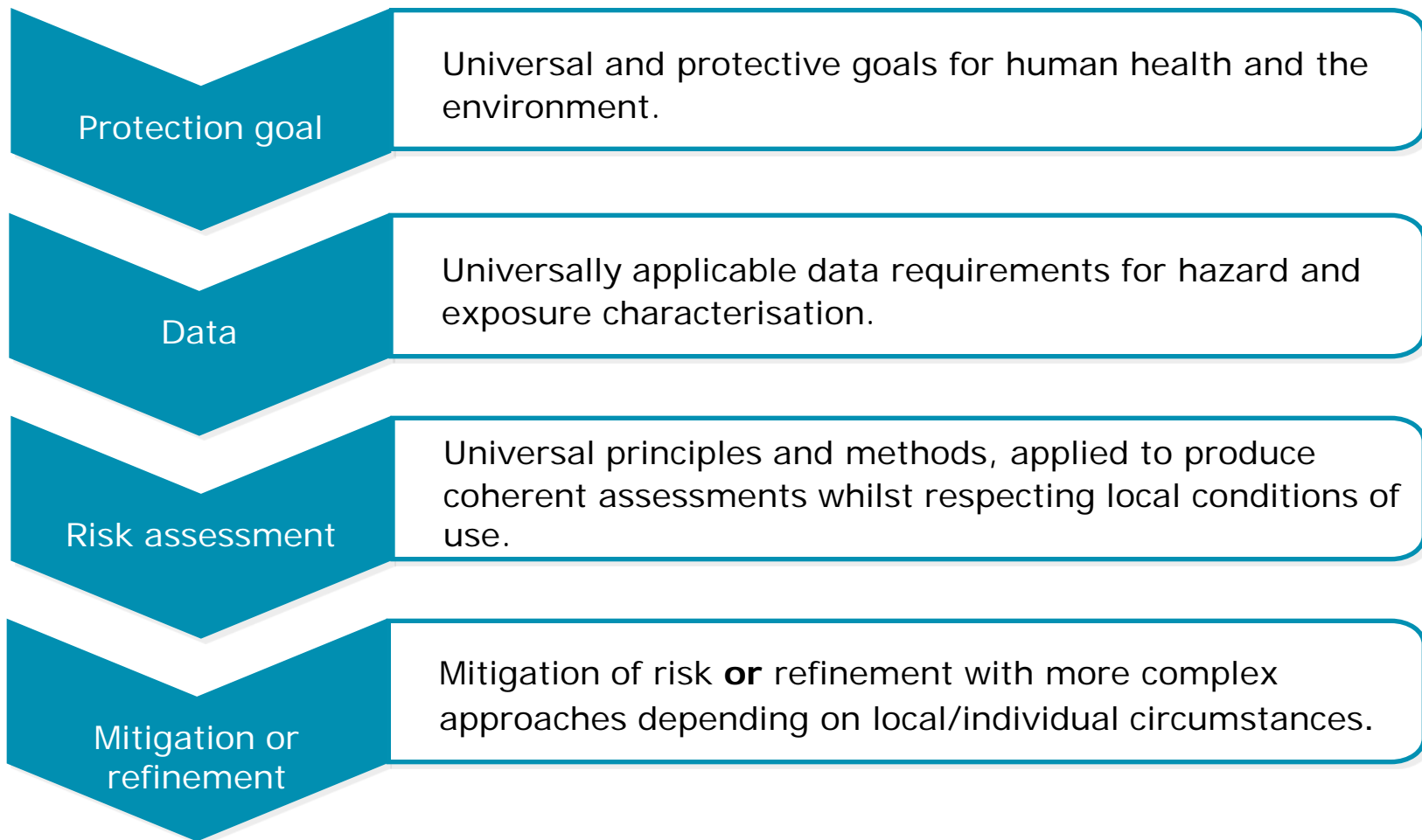


# The complexity factor in risk assessment



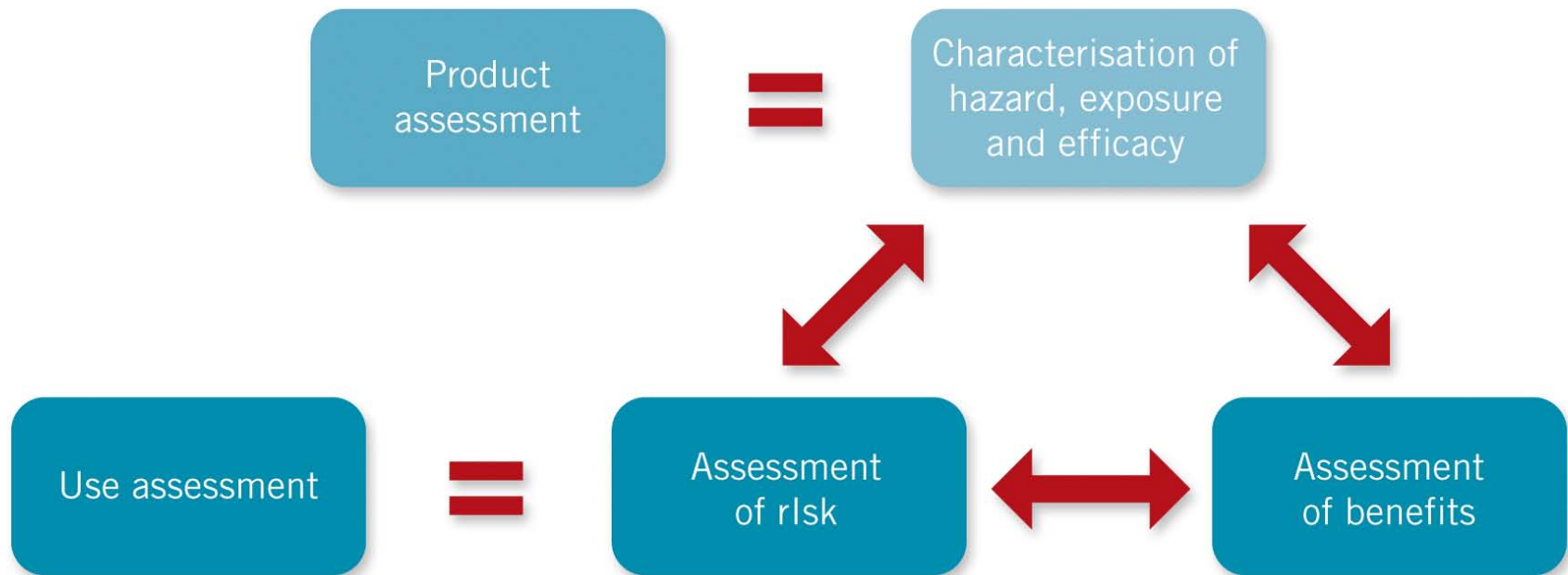


# Key elements of the assessment



# Universal assessment of product and its 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 reflected in independent decisions

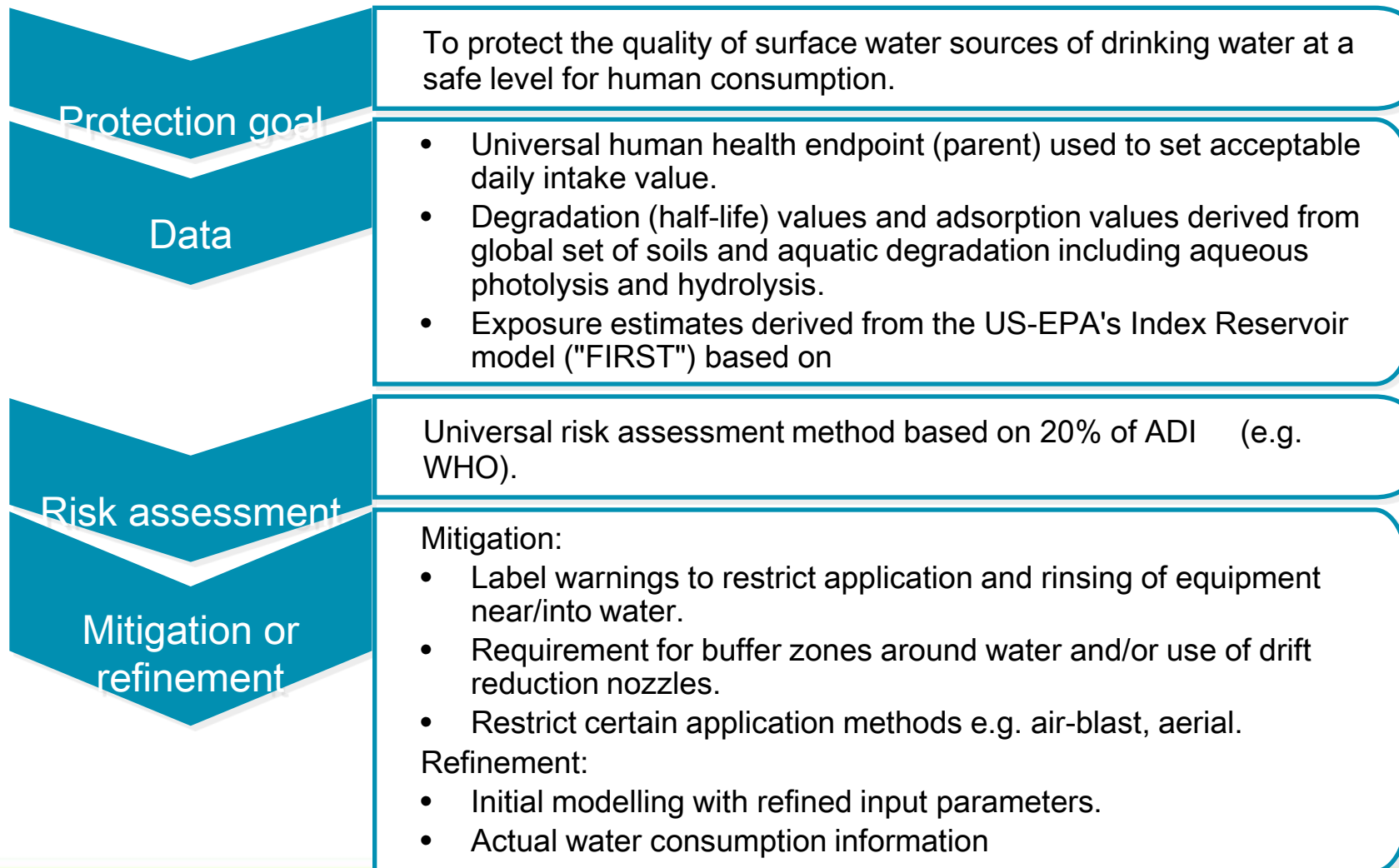


# What is use assessment?

Products	✓	Uses ✗
 		
 		
 <chem>CH3-CH2-OH</chem> 		



# Surface water as drinking water



# Terrestrial organisms



## Protection goal

**Within agricultural land:** to maintain the immediate and long-term viability of the agricultural function of the land.

**In non agricultural land:** to minimise any effects on the viability of populations and preserve the long term (season to season) abundance and diversity of all species.

**Species having special economic, cultural or aesthetic value:** to ensure that there are no significant effects on populations that would damage the viability of the economic, cultural or aesthetic heritage.

## Data

- Characterisation of effects on parameters which influence population dynamics; survival, time to reproduction and offspring production. Based on indicator organisms. One bird species.
- Standard set of exposure calculations tailored to properties of pesticide product and use pattern. Extrapolation of calculations using global data set.



# Terrestrial organisms



- A common approach to uncertainty factors, performing risk calculations and express risk characterisation

## Mitigation:

- Changes to use pattern
- Practices for drift reduction practices including buffer zones between the point of application and the off-crop environment.
- Geographical restrictions including restriction of sensitive areas
- Provision of ecological refuges.

## Refinement:

- Carefully designed studies with clearly defined hypotheses, assessment endpoints and interpretation (acceptability) criteria.



# 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



# CropLife proposition

- Our world faces huge challenges
- Agriculture is at the heart of these challenges
- Crop protection technology is a vital part of the solution
- Regulation is an imperative and should be a stimulant and a safeguard
- The CropLife proposition is for a universal approach to the Principles of Regulation





Thank you for your kind attention



# Back-up Slides

- Principles
- Practices



# 3

## International harmonization wherever possible, but always taking into account local needs and conditions

- In a world where agricultural products are traded globally harmonisation of regulation can:
  - facilitate trade
  - prevent unnecessary duplication and save resources
- Harmonisation should not compromise the ability of countries to make independent decisions in the local context but facilitate:
  - exchange of information leading to a greater common understanding and sharing of best practices
  - building of trust in regulatory decisions



# 5

## Responsibilities of each party throughout the production and supply chains as well as commitments to responsible action

- Effective regulation requires 2 major elements:
  - the setting of quality and safety standards including establishing the conditions for use, storage and disposal
  - responsible adherence on these standards and conditions in practice
- Responsibility resides with a range of government bodies, industries and public sector organisations and requires
  - appropriateness of standards and conditions
  - dissemination of information
  - active stewardship



# 6

## Compliance monitoring system and an active response process to manage adverse incidents

- Compliance monitoring is an essential part of ensuring adherence to the standards and conditions of approval:
  - post-registration surveillance or monitoring studies helps to better understand the in-use situation and the potential for improvements
- A system of monitoring and active response requires:
  - collaboration between the responsible authority, the industry, the users and other relevant health or environmental organisations



# 7

## Process to ensure that modern standards are applied to all products in the market

- Modern standards can be maintained by:
  - a re-registration process for the periodic review of pesticides and/or
  - special reviews or data call-in when indicated necessary by scientific evidence or risk indicates that regulatory action is needed
- Maintaining modern standards for all products means that:
  - no applicant benefits from or is disadvantaged by having a more or less updated approval (equal treatment ensures fair competition in the market place)



# Quality Assurance



- Assurance of the quality of health and safety through compliance with the relevant standards for:
  - the core set of data requirements (eg GLP)
  - identity, purity, composition, performance and stability of the product
  - equivalence to determine that all “similar” pesticide products being marketed correspond in identity, quality, purity and composition to the substances tested, evaluated and cleared for toxicological and environmental acceptability.
- Use internationally recognised standards to help:
  - build and maintain industry, regulators and public confidence in decision-making process
  - facilitate harmonization of data submissions and cooperation between Regulatory Authorities



# Core essential data requirements



- A core set of essential data requirements provides a basis for assessing the risk profile for the proposed use of the product
  - eliminates duplicative testing to satisfy slightly different data requirements addressing essentially the same concerns
  - It facilitates harmonization of data requirements and cooperation between Regulatory Authorities
  - Whilst the core data may be the same the risk assessment should reflect any difference in conditions of use
- Creates confidence in the in decision-making process for all stakeholders including industry, regulators and the public





# Animal welfare



- The extent of use of laboratory animals should be justified to:
  - ensure that animal welfare is being respected
  - meet societal expectations
  - align with modern scientific understanding and experimental method
- Minimising the use of laboratory animals is facilitated by :
  - a harmonised core set of essential data
  - use of alternative validated testing methods
  - Ensuring data that has a valued output or end point for regulatory decision-making



# Harmonisation



- Harmonisation should focus on establishing a core set of essential data requirements and the assessment approach because it:
  - Allows a product to be assessed based on a commonly understood data set and recognised risk assessment methodology without compromising the ability of countries to make independent decisions in the local context.
- Harmonisation should reflect international accepted good practice because it:
  - Provides a commonly understood basis for exchange of information leading to greater work sharing
  - Helps to build confidence in regulatory decisions



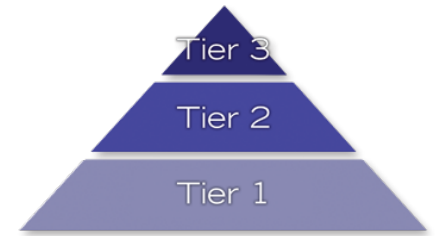
# Mutual acceptance of data



- Mutual acceptance of data is a collaboration between responsible authorities where one makes use of data reviews performed by another.
  - It is facilitated by harmonisation of core essential data requirements and permits more effective and efficient deployment of limited evaluative resources
  - Retains independence of local decision-making
- Collaboration can lead to greater work sharing and mutual recognition:
  - Uses limited resources more effectively
  - enables faster evaluation where reviews are already available
  - Greater uniformity in decision-making



# Tiered approaches



- A tiered approach is a stepwise process which aligns the extent of data required with the degree of risk:
  - starts with an assessment of more limited data set
  - where appropriate takes account of higher tier data or mitigation of use required to demonstrate safe use
- A tiered approach avoids unnecessary generation of higher tier tests which means that:
  - animal use and costs are limited to those which are absolutely necessary to assure safety in use
  - the responsible authority only assess data that is necessary to come to a decision



# Science in decision-making



- Implementing science in decision-making means:
  - Defining protection goals and decision-making criteria
  - Using test methodology that is based on established scientific principles and understanding
  - Using data to understand the characteristics of the product and consequences of its use
- Using a science-based system provides:
  - A sound basis for decision-making based on scientific evidence using risk and benefits evaluations
  - A fair basis for decision-making which facilitates access to new active ingredients and products whilst safeguarding public health and the environment



# Dialogue with regulators



- Dialogue between competent regulators and registrants should be established to assure a greater understanding of:
  - the submitted data package and meeting the protection goals
  - the need for higher tier data or mitigation measures
  - the way forward in the event of any technical or process issues
- This means incorporating effective procedures for dialogue to:
  - avoid delays or misunderstandings
  - achieve greater efficiency and effectiveness in processing a submission



# Responsible data call-in



- Unscheduled review of registered pesticides should be conducted if:
  - it is warranted by new information relevant to actual use practices or health or environmental risks and
  - it is required to maintain an assurance of safety and achieving the protection goals
- This will mean having a process which ensures:
  - regulatory authorities are provided with any new or updated data/information in a timely manner
  - relevant progress in science and technology can be applied through testing methodology and decision criteria
  - equal treatment of all products affected

