

Strategies for effective and efficient regulatory compliance

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A new paradigm

- Ag-research has traditionally been lightly regulated
- The advent of biotechnology changed that
- The influence of globalisation on trade in agricultural products

Biotech and GM crops

- Genetic engineering created a fundamental change in governance
- It also became a lightning rod for societal concerns about modern agricultural methods in general

It should be easy...

- Biotech is about living organisms, and about food, environment and health.
- Most people are interested in food and health
- Familiarity is a key component of trust
- Biotechnology can use real life examples close to the audience to create messages

Yet it is not...

- Biotech is seen as alien, unnatural and potentially dangerous
- The connection with what we already know about food and health and the environment has been severed

→ Biotech is seen as « fundamentally different »

Can public R&D in biotech succeed?

- Most biotech projects arise out of molecular biology research
- Working in a regulated field environment takes them far outside their comfort zone
- Two most frequent reactions:
 - “Oh dear, let’s get out of this mess...”
 - “The regulations don’t apply to me (us)...”
- Result:
 - poor track record for biotech **delivery**

Can it be solved?

Making it work

- There are three possible strategies:
 - Create and apply excellence in compliance with the rules;
 - Create the information to change the rules
 - Ignore the rules
- Only the first 2 are practical options!
- Yet most public projects currently act as if they apply the third

Awareness: the first strategic requirement!

Regulatory excellence is not enough

- Biosafety and regulatory compliances are essential for acceptance of GM crops
- Yet it is not sufficient:
 - Acceptance is as much a matter of trust and confidence
 - Confidence depends critically on good communication

A successful regulatory strategy is as much a matter of communication as of compliance!

Every GM crop project has to:

- Generate awareness and expectations management from both practitioners and funding donors
- Provide resources to integrate regulatory cost in project planning

Every GM crop project has to:

- Recognise that in biotechnology regulatory approval is **always** the time limiting factor in project execution and technology delivery!
- Recognise that regulatory compliance starts **at day 0**, not when the first application has to be written;
 - Training of specialised staff!
 - Access to outside regulatory expertise

Regulations is about more than regulations!

- Make sure that all stakeholders are aware of the opportunities and the challenges
- Identify champions to support the project and create “customer pull”
- Keep policy makers, farmers, the public aware and informed

Develop alliances to support/promote science based solutions for the problems of African agriculture!

Thank you!