GMO's – Risks, Assessment and Mitigation

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Outline

- Sources of risks
  - *Modification Risks*
  - *Production Risks*
  - *Market Risks*
- Risk Assessment
- Mitigating Risks
  - *Prevention*
  - *Contingency planning*
  - *Liability*

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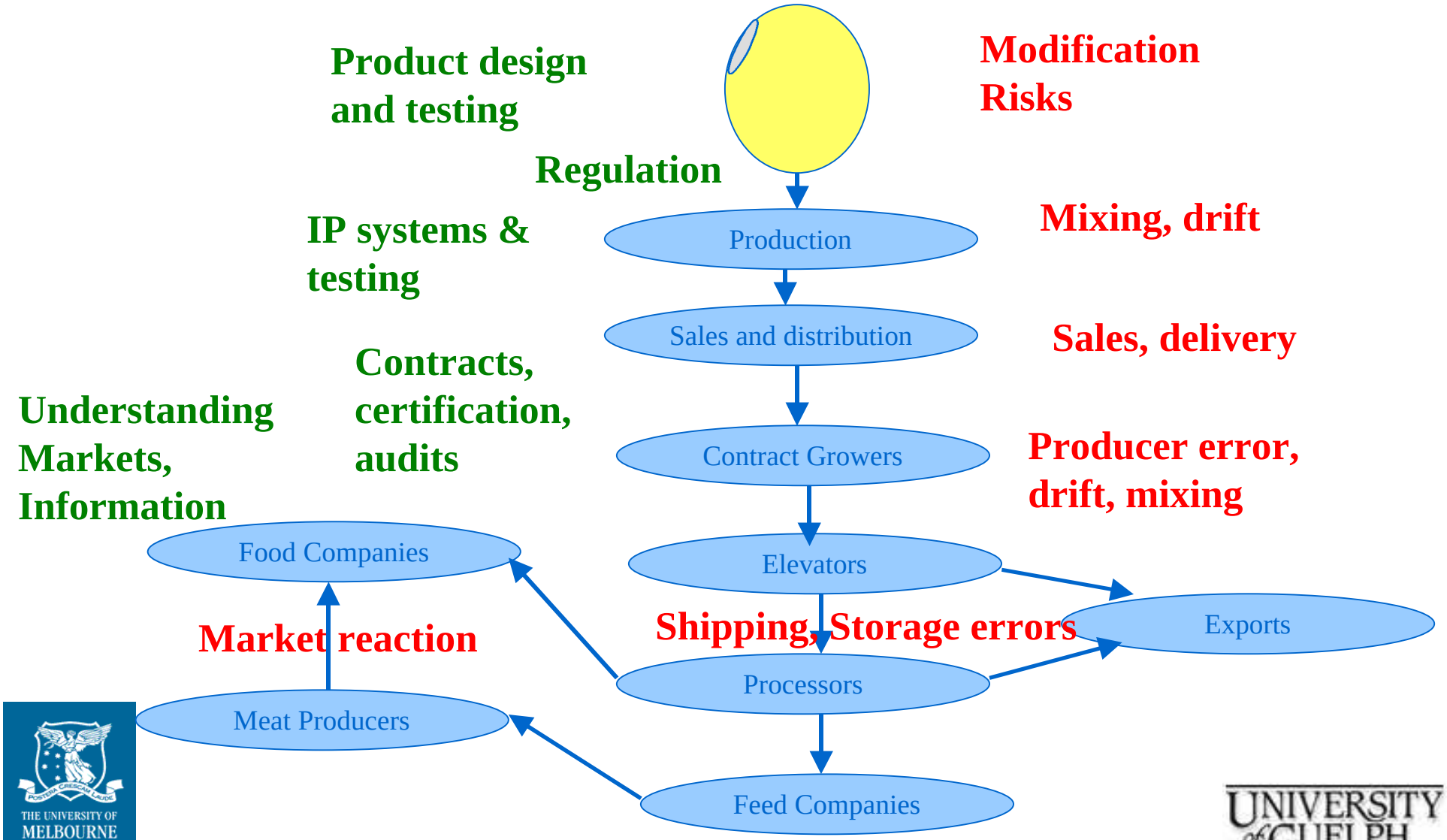
Grain Supply Chains and Risk

Components of a Dynamic Marketing System



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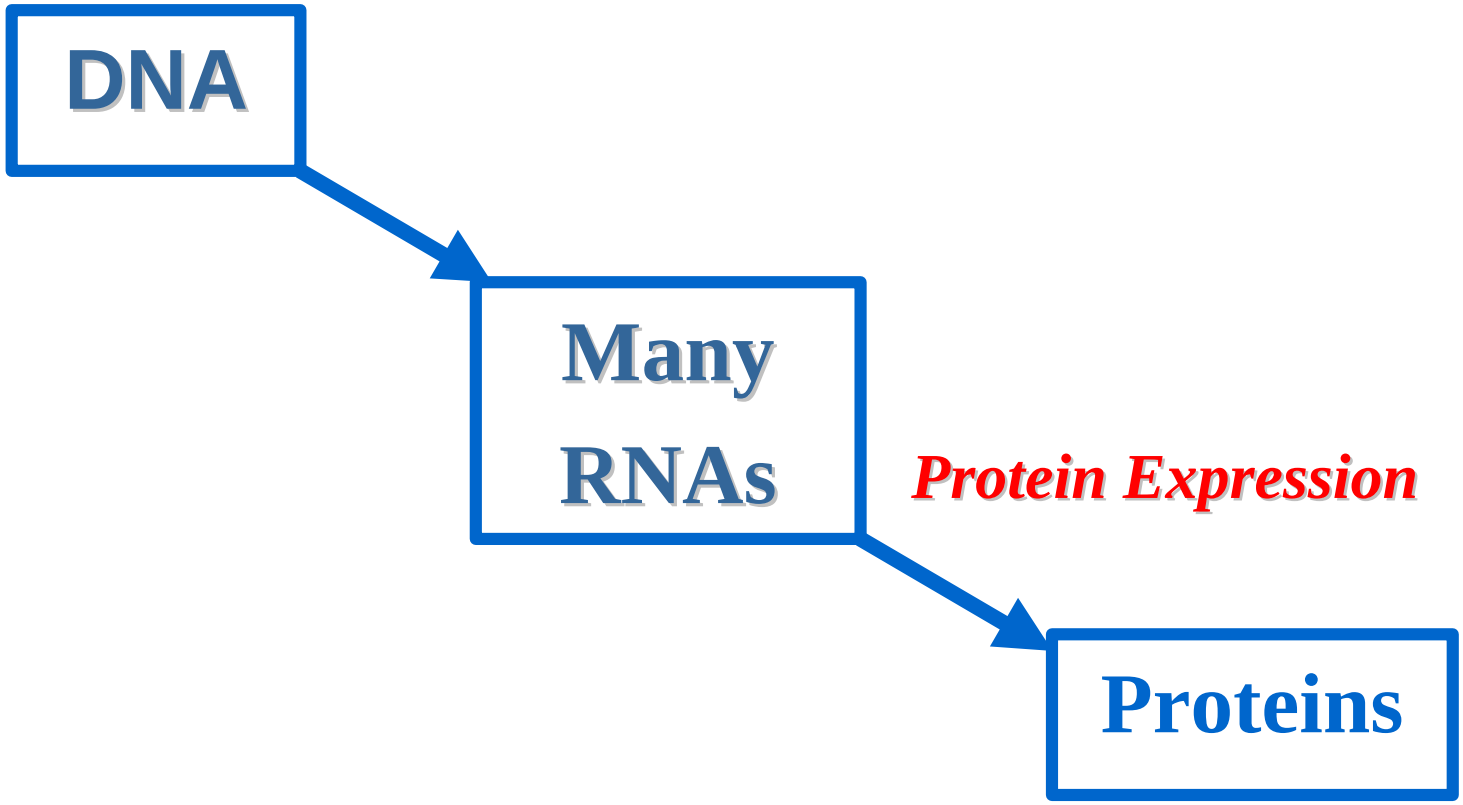
Modification Risks

The Science of Biotechnology



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Source of Modification

- Transgenic Modifications
  - *Inserting genes from one organism into another*
- Modifications within the same species
  - *Turning genes off or on*
  - *Adding duplicate genes to enhance protein production*
  - *Altering the gene and thus the protein produced*

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The Science of Biotechnology

- Alter the proteins – alter the plant
  - *Herbicide resistance*
  - *Insecticide production*
- First Generation - Input Traits
- Final Product is ***"Substantially Equivalent"*** to non-GMO crops

- Opportunities and Benefits - perceived as going to producers and seed companies

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Genetic Modifications in Plants

- Second Generation- Output Traits
- Crops are different from non-GMO crops
  - *Production of selected proteins/fibres*
    - Interlukin expression in tobacco
- Multiple traits add new risks in terms of potential interaction of newly introduced proteins.

- Opportunities and Benefits - more broadly based to include processors and consumers

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Types of Modification Risk

- Health Risks – controlled through regulation
  - *Real risks – potential allergens*
- Environmental Risks - transference

- Industry risk relates to ability to meet health regulations
- Approval process for new varieties
  - *Non EU approved varieties*
  - *Varieties not approved for other jurisdictions*

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Modification Risk Experience

- 1999 – non EU approved varieties grown in N. America – *Approval Risk*
  - *Industry had to identify outlets for those varieties distinct from EU destined product*
  - *Irksome but overall cost not significant*
- 2000 - Starlink – *Health risk*
  - *Potential allergen in found in food products*
  - *Many products pulled from shelves*
  - *Recipes reformulated to avoid yellow corn*
  - *Cost to Aventis may be up to $1 B*
- 2000 – non-approved varieties in EU

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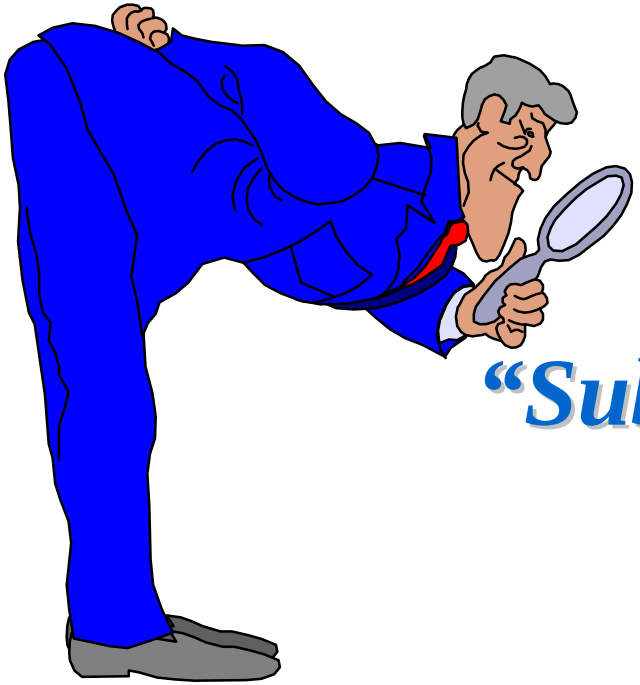
Market Risks

Consumer Reaction to GMOs



"Substantially Equivalent"

Really Means

"Somewhat Different"

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- If the products were really the same why could companies patent them
- They did not like the differences and could see no advantages for them
- Many consumers rejected GMOs, particularly in the European Union

As Consumers Decided
EU Retail Chains Reacted

- Regulatory distinction
  - approved versus non-approved varieties
- Consumer distinction – less sophisticated
  - GMO versus non-GMO
- Retail chain distinction followed consumers
  - GMO versus non-GMO
  - Extending from food products made with GMOs to meat and eggs from animals fed GMOs

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And Governments Followed

- EU
  - *Three year moratorium on GMO approvals*
  - *Number of varieties approved for importing*
  - *Establishing labelling requirements*
- Japan
  - *GMO free or labelling of GMO products*
  - *Establishing labelling regulations*
- Australia and New Zealand
  - *Also committed to labelling regulation*
- United States and Canada
  - *Pressure for labelling is increasing*

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What do Canadian Consumers Think - Pollara and Earnscliffe 2000

1515 telephone surveys & 8 focus groups

Purpose:

- To benchmark sentiment on biotechnology issues
- To assess relative strength of public opinion drivers

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Pollara and Earnscliffe Findings

- Awareness and understanding of biotechnology remain relatively low
  - *Levels of entrenched negative attitudes are low*
- Presume must be benefits, but fair amount of internal tension (esp. as life forms crossed)
  - *Growing conviction to seek out information -- strong support for labelling of GM foods*
- Want to believe that products on store shelves are safe but know little about regulatory process

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Agricultural Business is Reacting

- Establishment of segregated non-GMO supply chains
- Major consumer education initiatives
  - *$50M public relations campaign*
  - *Many smaller initiatives*
- More research into the impacts of GMOs and reducing risks

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Production Risks

Function of

1. Production environment
   - *System characteristics and capabilities*
2. Technology
   - *Biotechnology*
   - *Information technology*
   - *Testing technology*

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Production Environment Comparison

	Agbiotech	**Pharmabiotech**
Production Environment	Global, small scale, natural, long time frame	Global, large scale controlled production
Production Personnel	Numerous, external, varied skill levels	Internal, more highly trained
Process control	Variable and poorly defined, product focused QC	High, process focused Quality Control
Regulation	Low, internal	High, external

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Process Control

- Starlink has only been the most dramatic demonstration that in many instances process capabilities cannot meet product requirements
  - *Lack of information to growers and elevators*
  - *Inadequate segregation capabilities*
  - *Many staff not trained in segregation methods or needs*

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Minimising GMO Risks

- Prevention
  - *Understanding products*
  - *Understanding markets*
  - *Identity preservation*
- Contingency Response Planning
- Liability Protection

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Prevention

- Understanding Products
  - *Health risks*
  - *Environmental risks*
  - *Regulatory requirements*
- Understanding markets
  - *Requirements, tolerances, approvals*
  - *Level of care*

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Managing Production
GMO Market Realities

- GMO and non-GMO markets distinct
- Markets for specific output trait crops will be distinct
- Many customers expect information and a choice

- If the markets are distinct then production should be distinct as well

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Managing Production

- Many different individuals/organisations producing and handling grain through the supply chain
- Cannot duplicate control found in pharmaceuticals but it does provide a model
- Solution – Identity Preserved Production

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Prevention
Identity Preserved Production (IPP)

- Maintain product identity from seeds through production, processing to consumption
- Driven by
  - *Plant breeding needs*
  - *Food safety*
  - *Need for GMO free assurance*
  - *Capturing output trait value*

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IPP System Requirements

1. Procedures and Protocols

2. Tests for verifying product identity

3. Certification and external audits to assure customers that protocols are being followed

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1. Procedures and Protocols

- Systems for identifying and segregating products
- Procedures defining production and handling protocols
  - *Turnover procedures and documentation*
  - *Contracts and agreements*
  - *Paper trail for products*

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Traceability documentation

- There are several subsystems to the Identity Preservation information system
  - *Seed production*
  - *Seed dealer/distribution*
  - *Producer/Commercial production*
  - *Storage and Handling*
  - *Distribution*
- Ultimately these will be all web based to allow controlled access from different locations

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2. GMO Testing

Why Test for GMOs?

- Regulatory Requirements
  - *non-approved vs approved varieties in E.U.*
  - *labelling requirements*
- Customer Requirements
  - *Export markets*
    - Labelling requirements for companies
    - Premiums for non-GMOs
  - *Organic Markets*
  - *Quality Trait GMOs*
    - Premiums for high value GMOs

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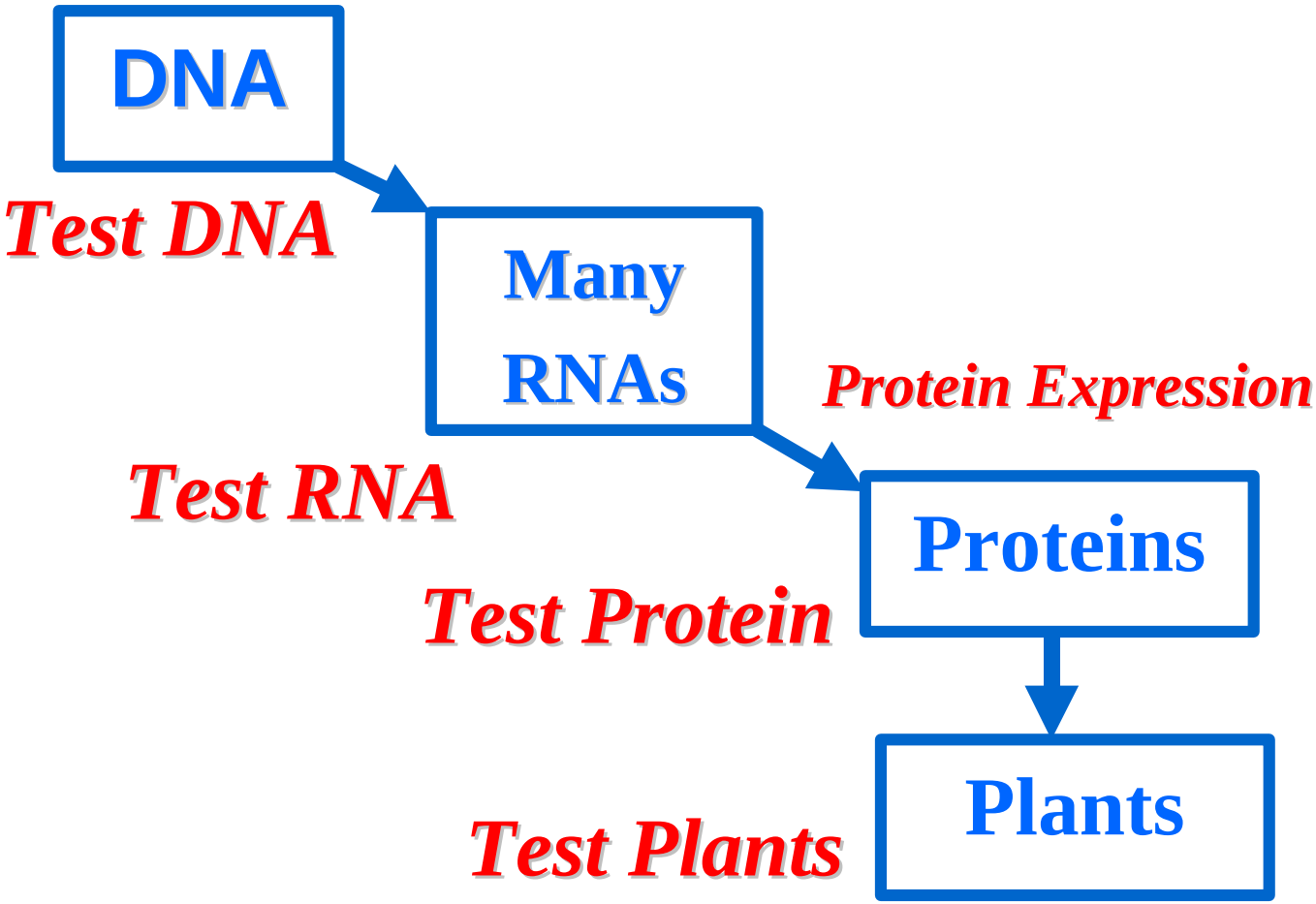
What Can Be Tested?



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GMO Testing

- Testing Plants
  - *Seed growout tests, spraying plants*
  - *Slow, not quantitative*
- Testing Proteins – Elisa, SDI strip tests
  - *Inexpensive and quick*
  - *Test for only one protein at a time*
  - *In some plants the protein is not in the seeds*
  - *Not quantitative*

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GMO Testing - DNA

- Genetic Identity – PCR tests
  - *Exact identification but may have false positives*
  - *Quantitative within limits*
  - *Tests for approved vs non-approved*
  - *Expensive*
  - *Requires special skills usually in offsite, independent labs*

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Certification

- Certification of the *PROCESS* for handling GMOs
- Includes external audits to assure customers that protocols are being followed
- GMO certification - CERT ID, SGS
- SQF 2000 moving in that direction
- ISO 9000, HACCP could include GMOs

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Successful IP System Needs

- Coordination with suppliers
  - *setting system objectives and tolerances*
  - *understanding costs and constraints*
- Training for both staff and suppliers
- Documentation and discipline

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Contingency Response

- Types of events with response defined for each case
  - *Procedural discrepancy*
  - *Field test failure*
  - *Shipping sample failure*
  - *Customer sample failure*
  - *Customer product failure*

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Event Coverage

- Liability Insurance – general coverage
- Non-GMO contamination insurance
- Liability exposure and assignment

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GMOs and the Future

- Turbulence ahead
- May be years before the issues settle and the true value of GMOs is known
- Quality traits will help create acceptance
- Ultimately there will be many different crops with many different supply chains
- The ability to segregate will provide a marketing/trade advantage

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