Second Conference on Biotechnology for Asian Development

Regional Cooperation for Ensuring Access and Capacity Building

Organized by

RIS
Research and Information System for the
Non-Aligned and Other Developing Countries

in collaboration with

CII
Confederation of Indian Industry

IUCN
Regional Biodiversity Programme-Asia

with Support from

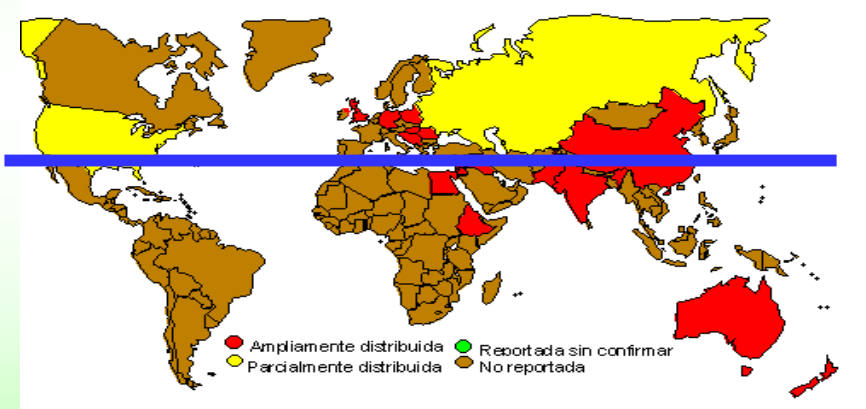
United Nations Educational,
Scientific and Cultural Organization, Paris

Department of Biotechnology
Government of India, New Delhi

7-8 April 2004 at India Habitat Centre, New Delhi

Traceability, labeling and biosafety management

Key Issues and impact on developing countries of Asia



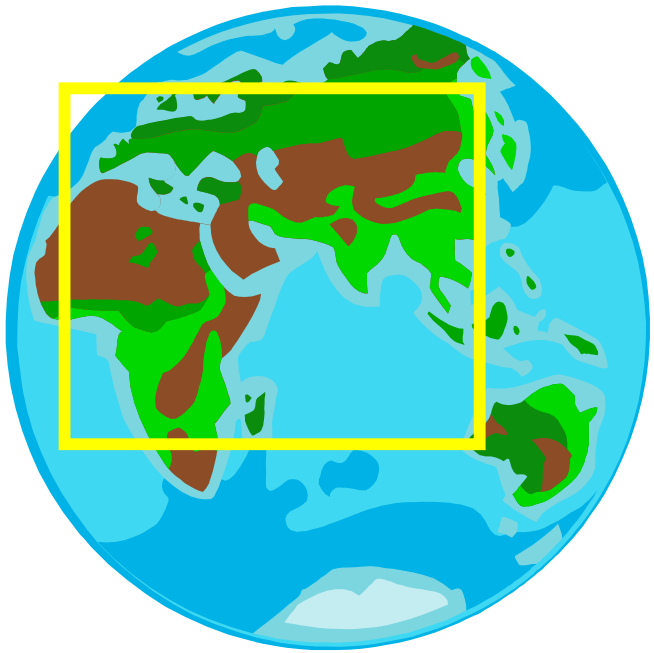
S.R.RAO

In the European Union (EU), consumer distrust of GM crops has prompted governments to develop regulations mandating food products containing GMOs to be labeled as such. Tougher EU standards are in the works that could require companies to provide proof that the GMO content of their products is less than one percent if they want to market food or animal feed as "GMO free."

"Traceability

These so-called "traceability" standards would require tracking products from the farm to the fork so that if any co-mingling is discovered, its point of entry in the process can be more easily identified.

Europe/Africa Regional Labeling Requirements



- EU
  - Mandatory label for foods with detectable DNA or protein, 1% threshold since 1997
  - New proposals for traceability, process-based labeling of food and feed at a 0.9% threshold
- Switzerland
  - Mandatory label for foods with detectable DNA, 1% threshold, 0.2% non-GM threshold
- Africa
  - South Africa: Mandatory label based on substantial equivalence- like US
  - Ethiopia: Mandatory label on all products
  - Algeria & Morocco: ban importation of GM products

EU Biotech Proposals: Status update

- **Member States agreed Common Position in March ’03. Parliament accepted with some amendments July 3, 2003**
- **Expected to become applicable early 200**

Main aspects:

- **Process-based labeling approach (e.g. this would mean soybean oil being labeled**
- **Labeling above 0.9% threshold**
- **Traceability means biotech events must be identified at each stage in the chain**
- **Applies to all products on the EU market**
- **Two year review period**

Asia Pacific Regional Labeling Requirements

- **China** Mandatory label for foods derived from GM, 1% threshold, not applicable when GM ingredient is used to produce a finished food product
- **Hong Kong** Mandatory label, 5% threshold
- **Japan** Mandatory label, 5% by weight/top 3 ingredients; 1% threshold for unapproved varieties in feed, 0% for food
- **Philippines** Mandatory label, 5% threshold
- **Russia** Mandatory label for foods with detectable DNA or protein, 5% threshold, exclusive negative list
- **Korea** Mandatory label, 3% threshold, top 5 ingredients
- **Taiwan** Mandatory label, 5% threshold
- **Thailand** Mandatory label, 5% threshold by weight/top 3 ingredients

Asia Pacific regional labeling requirements

- **Australia**
  - **Mandatory label, 1% threshold**
- **New Zealand**
  - **Mandatory label, 1% threshold**
- **Tasmania**
  - **Ban on all biotech products**

Latin America Regional Labeling Requirements

- **Argentina**
  - **No label required, voluntary labels allowed**
- **Brazil**
  - **Mandatory process-based label for all foods, additives and feeds, meats, 1% threshold**
- **Chile**
  - **Mandatory label, process-based, 2%, not yet implemented**

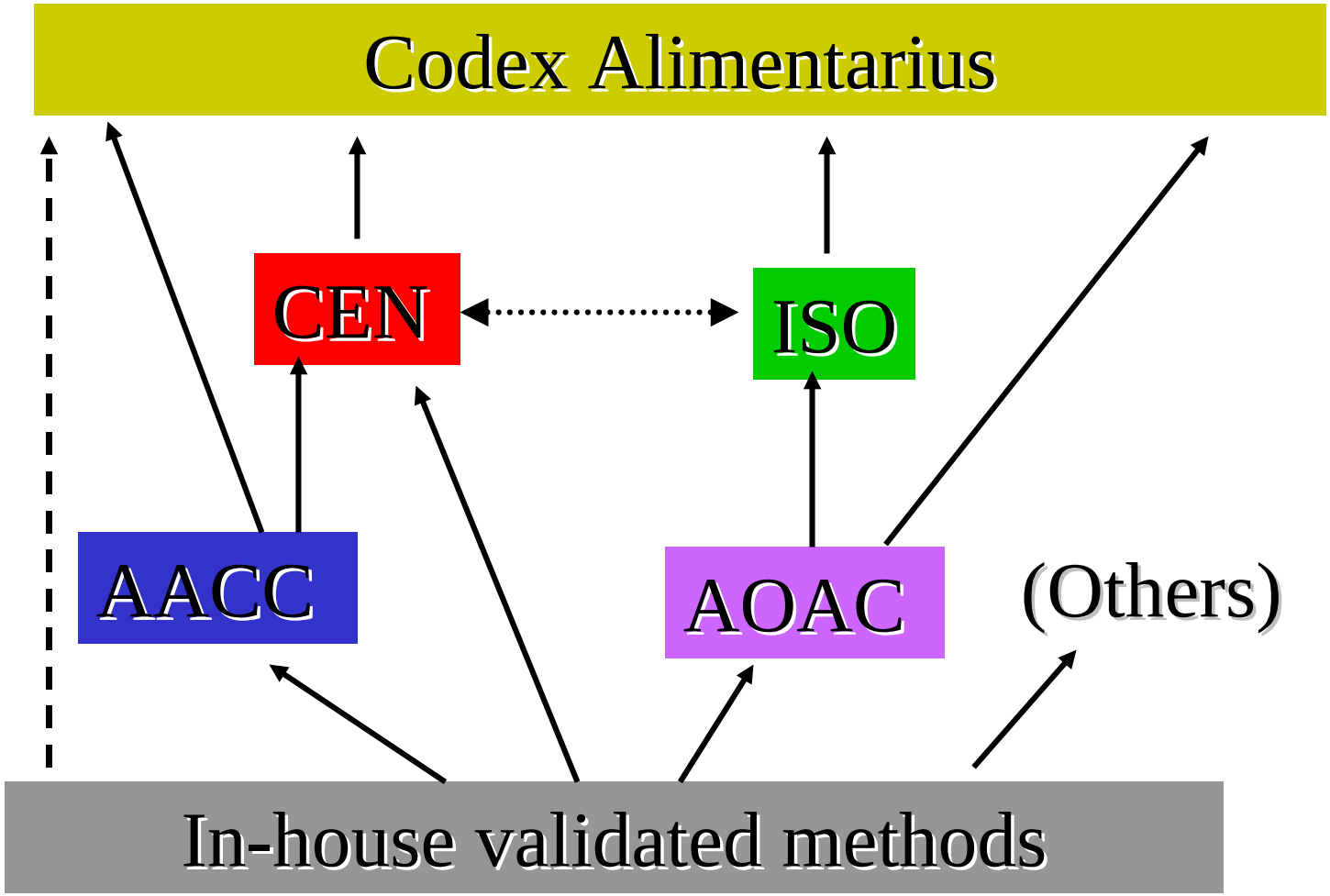
North American Regional Labeling Requirements

- **Canada**
  - No label required, voluntary labels under review
- **Mexico**
  - Under development
- **US**
  - No label required for substantially equivalent events, voluntary labels under review

The Issue

- Need for standardized methods to test for ag biotech products is multi-faceted:
  - Research and development
  - Seed quality
  - Biotech trait presence in conventional seed
  - Compliance with country specific thresholds for grain, feed and food labeling regulations
  - Testing for unapproved events
  - Identity preservation and support of consumer choice labeling

Coordination of Standardization Initiatives



Publicly available methods for Commercial Products

	ELISA	LF Assay	PCR	Ref. Mat.
RR Soybean (40-3-2)	Yes*	Yes	Yes*	JRC, SDI
YieldGard Corn (MON 810)	Yes*	Yes	AACC 4Q01	JRC, SDI
Roundup Ready Corn (GA21)	No	No	JRC 1Q02	JRC 1Q02
Maximizer Corn (BT176)	Yes	Yes	Yes*	JRC
Liberty Link Corn (T25)	Yes	Yes	Yes	NA
YieldGard (Bt11)	Yes	Yes	Yes*	JRC
Roundup Ready Corn (NK603)	Yes 4Q01	Yes 3Q01	NA (2003)	NA (2003)
NewLeaf, NewLeaf +, New Leaf Y Potato	Yes	Yes-leaf	Yes	Yes
RR Canola (RT73)	Yes	Yes	Yes	NA
RR Wheat (MON 71800)	NA (2002)	NA (2002)	NA (2002)	NA (2003)
RR Sugarbeet (77)	NA (2002)	NA (2002)	NA (2002)	Syngenta

JRC = Joint Research Centre

NA, Not available

*Externally validated

Challenges for Standardization of Methods

- DNA: sample prep, extraction, matrix, primer design, simple, multiplex, quantitative PCR, micro-array, ref gene, ref materials, units…
- In-house performance validation agreement
- Protein: multiple antibodies/kits, extraction, matrix influence, cross-product recognition, variability of protein expression, stable peptides, ref materials…

Challenges for Standardization of Methods

- Sampling control plans
- Acceptable values of Performance criteria for validation
- Compatibility (DNA and/or protein-based detection…)
- Decision trees (qualitative *vs* quantitative testing…)
- Ingredient *vs* final food product analyses
- Capability of dynamic ranges to satisfy the thresholds
- Negative lists *vs* advances of the methods
- Definition, generation and certification of reference standards
- Consensus methods
- Significance of zero tolerance

Challenges for Certified Reference Materials

- Source of material (fixed cultivar, DNA…)
- Type (seeds, genomic DNA, plasmids…)
- Correlation between units (weight / number) and type
- Absolute purity not guaranteed
- Are ingredient / final product reference materials useful and feasible? (variability of processing and makeup…)
- Strict production conditions required – particle size, homogeneity, stability

Detection Methods

- Detection methods cross-cut threshold issues in seed, grain, food, labeling.
- Inconsistent testing of seeds, plants, grain and processed ingredients cause disruptions to trade
- Valid detection methods for agbiotech traits are needed for implementation of and compliance with regulations, seed quality control, grain channeling and identity preservation of grain.

UK MAFF PCR Proficiency Studies

Comparison of Laboratories with “satisfactory” Z-scores

i.e. between -2 and +2 for GM Soya for Rounds 1, 2, 3 &4

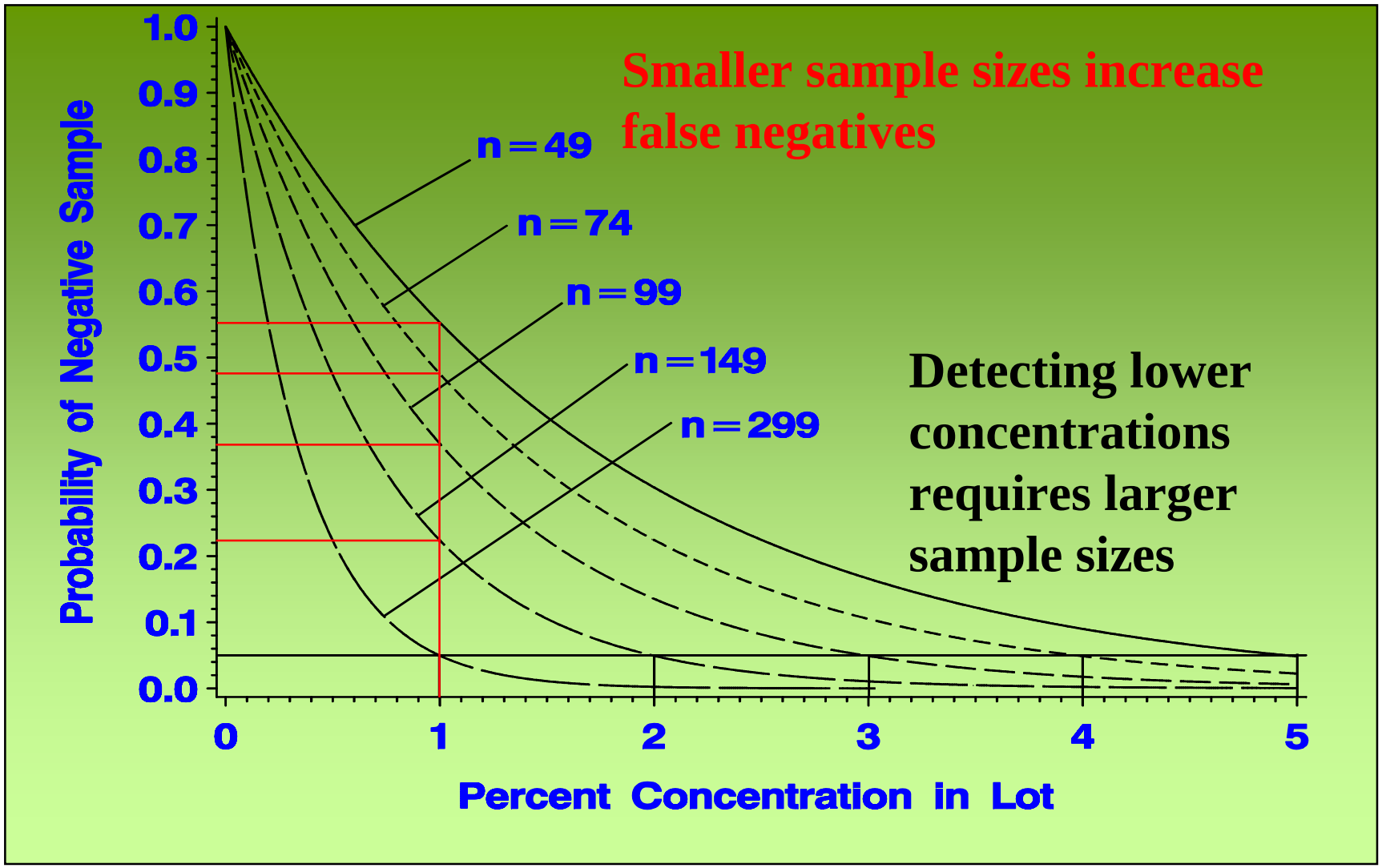
Report	GMO 1	GMO 2	GMO 3	GMO 4
Date	December 1999	January 2000	February 2000	April 2000
Round	1	2	3	4
Test Material	Soya/Wheat (1:49) Flour	Soya/Wheat (1:49) Flour	Soya/Wheat (1:49) Flour	Soya/Wheat (1:49) Flour
Assigned Value (%GM Soya/Soya)	2.21	0.48	0.22	1.84
Target SD	0.25	0.25	0.25	0.25
Labs w/ satisfactory performance	42% (8/19)	89% (17/19)	71% (15/21)	56% (15/27)

Source: IFR report to Participants in MAFF (JFSSG) GMO Proficiency Testing Scheme,Dated April 4, 2000

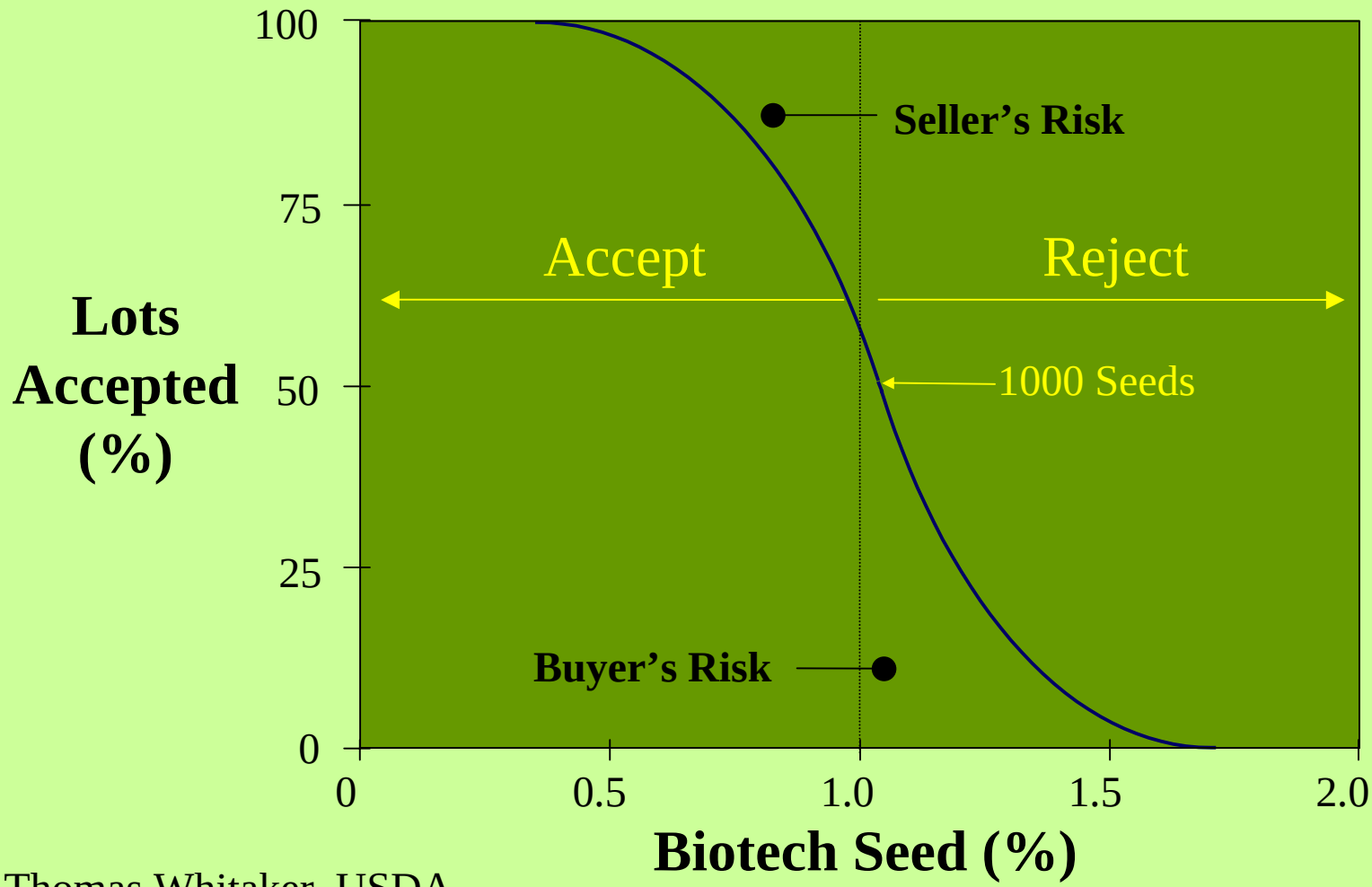
Threshold Testing

- Unapproved Events, GM-Free, non-GM, Zero Tolerance
  - Even a single GM particle is unacceptable
  - The higher the sensitivity the better
- Approved Events
  - Some level of GM is acceptable
  - Detection below threshold is Seller's Risk
  - Negative detection above the threshold is Buyer's Risk
  - Design threshold sampling schemes to address both Buyer's and Seller's risk

The Effect of Sample Size



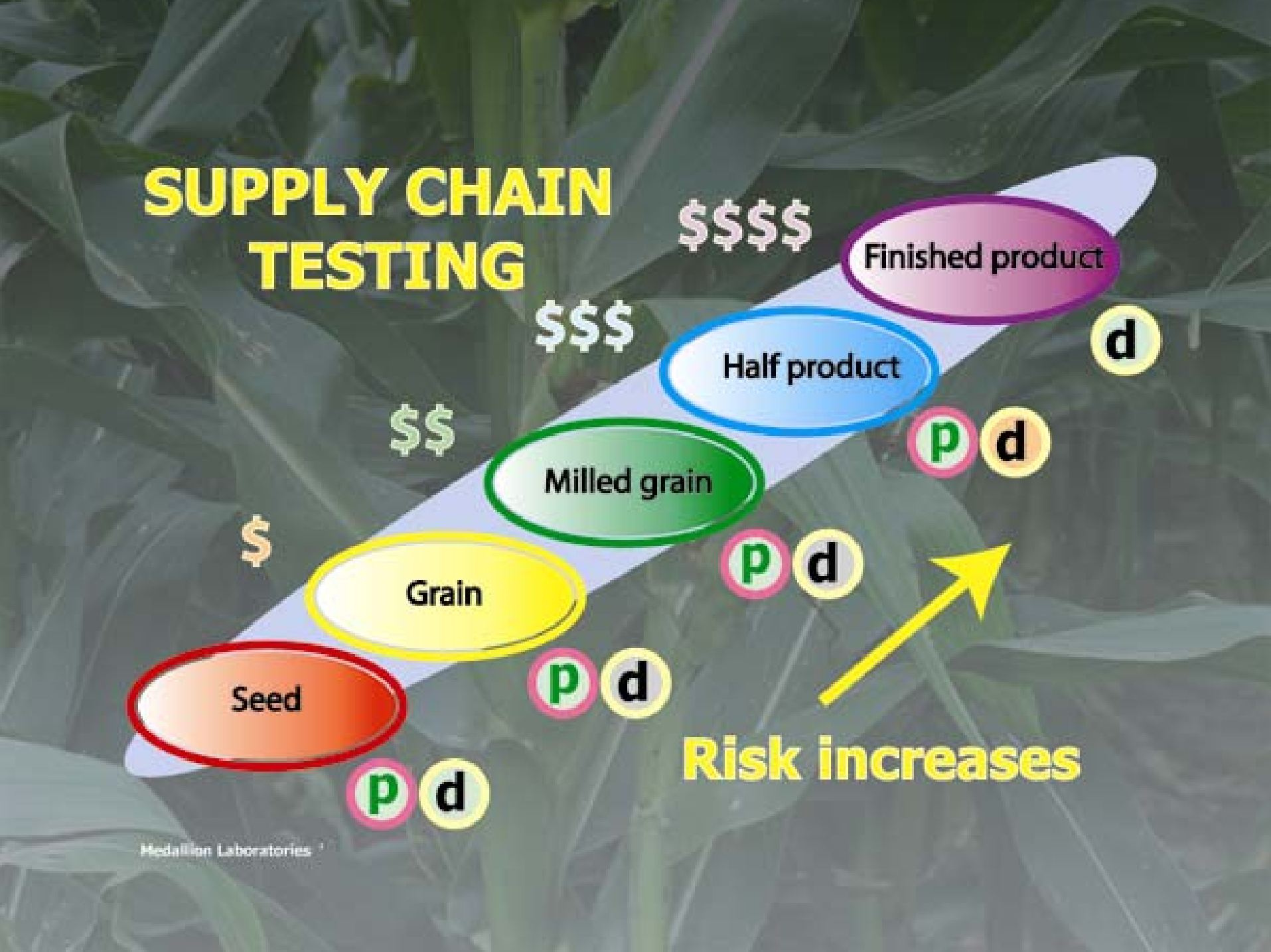
Buyer's and Seller's Risk



Thomas Whitaker, USDA

U.S./Japan StarLink Corn Protocol

- Japan set Zero Tolerance for StarLink
- (3) Samples of 800 kernels
  - All 3 samples must be negative
  - Detects 1 positive in 2400 kernels
- 95% Probability of detecting 0.125%
- 99% Probability of detecting 0.19%
- 21.3% Probability of detecting 0.01%


SUPPLY CHAIN TESTING
$
$$
$$$
$$$$
Seed
Grain
Milled grain
Half product
Finished product
p
d
Risk increases
Medallion Laboratories

Many developing countries do not have the necessary infrastructure to meet strict EU requirements for labelling and traceability of GM crops. Additionally, there is concern that even planting GM crops only for domestic use might jeopardise an export market for non-GM crops.Regulators have not paid enough attention to the impact of traceability thresholds on agriculture in developing countries

Detection of GM food components and ingredients becomes costly, difficult and unreliable when GM-DNA or protein occurs at very low levels, and impossible in ingredients that do not contain such DNA or protein. Reliance on a traceable audit trail is not only expensive but also opens the floodgates to fraudulent labeling

Developing countries cannot afford cost increases in either domestic food production or in export food products, especially in the light of negligible premiums being paid for non-GM food.

CONTRASTING AGRICULTURE SCENARIO

	USA	INDIA
No of farm families	0.9m	105M
Average size of farm	200 Ha	< 2ha
Share in workforce	<2%	>64%
Contribution to GDP	1.7%	26%

The real loss

in the trade dispute between North America and the EU will be the resource-poor, small-scale farmers in developing countries. Most of these developing countries have agriculture-based economies and any impediment to export opportunities will impact negatively on national economies as a whole

Why Labeling Policy?

Labeling is often used to deliver information to consumers on characteristics of products that they are not able to evaluate. Economists refer to this type of characteristic as a credence attribute Whether a product is produced with the use of biotechnology or genetic engineering is frequently difficult or impossible for the consumer to judge. Labeling can transform such a credence characteristic into a search attribute that consumers can learn about by inspecting the product ís package (Caswell, 2000).

CODEX AILMENTARIUS COMMISSION

Three options

Option 1

When a food or food ingredient obtained through modern biotechnology (is no longer equivalent to)/ (or differs significantly from the corresponding existing food or food ingredient as regards to composition or nutrition value or intended use the characteristics or properties which make it different from the corresponding existing food or food ingredient should be clearly defined in the labeling plus allergen , health warning etc

Option 2

The following foods or food ingredients obtained through modern biotechnology as defined in shall be declared to describe method of of production - obtained from genetically modified / engineered organism or produced but not containing GM/E organisms if they contain protein or DNA (threshold level) and no longer equivalent, + allergen, nutritional labeling, etc

When it is not possible to provide information on allergen through labeling the food should not be marketed

Alternative suggestion

Comprehensive labelling : GMO+ production from+ conten with threshhold + all others of 1 & 2 and detailed ingredients/ composition

Elements Of GMO Labeling Policy.

Policy Questions *Some Policy Option*

☺**How are genetic engineering, genetic modification, or biotechnology defined?** *Broadly By specific techniqueused*

☺**Is program voluntary or mandatory?**

Voluntary for non-GMO and/or GMO
Mandatory for GMO /Mandatory for GMO and non-GMO

☺**Which products are covered by the policy?**

All food products/Only key food products/Only certain food categories

☺**Which ingredients are covered?**

All ingredients/Only most important ingredients/All ingredients except preservatives, additives, etc.

☺**When are labeling requirements triggered?**

X ingredients areGM Important characteristics are altered

☺**How are products made from animals fed with GM inputs handled?**

Labeling required if feed is GM/
Labeling not required if feed is GM

How are restaurant, take-out, bulk, and institutional foods handled?

Included in labeling requirements
Excluded from labeling requirements

What label statements must/can be made?

Does contain GMOs (genetically modified)
May contain GMOs (may be genetically modified)
Non-GMO
Does not contain GMOs

How are companies required to verify GM status?

Self-certification by seller is acceptable
Testing
Third-party certification

Can non-GMO labeling be used on products where there are no GM alternatives?

Yes
No

Whether I need to label ?

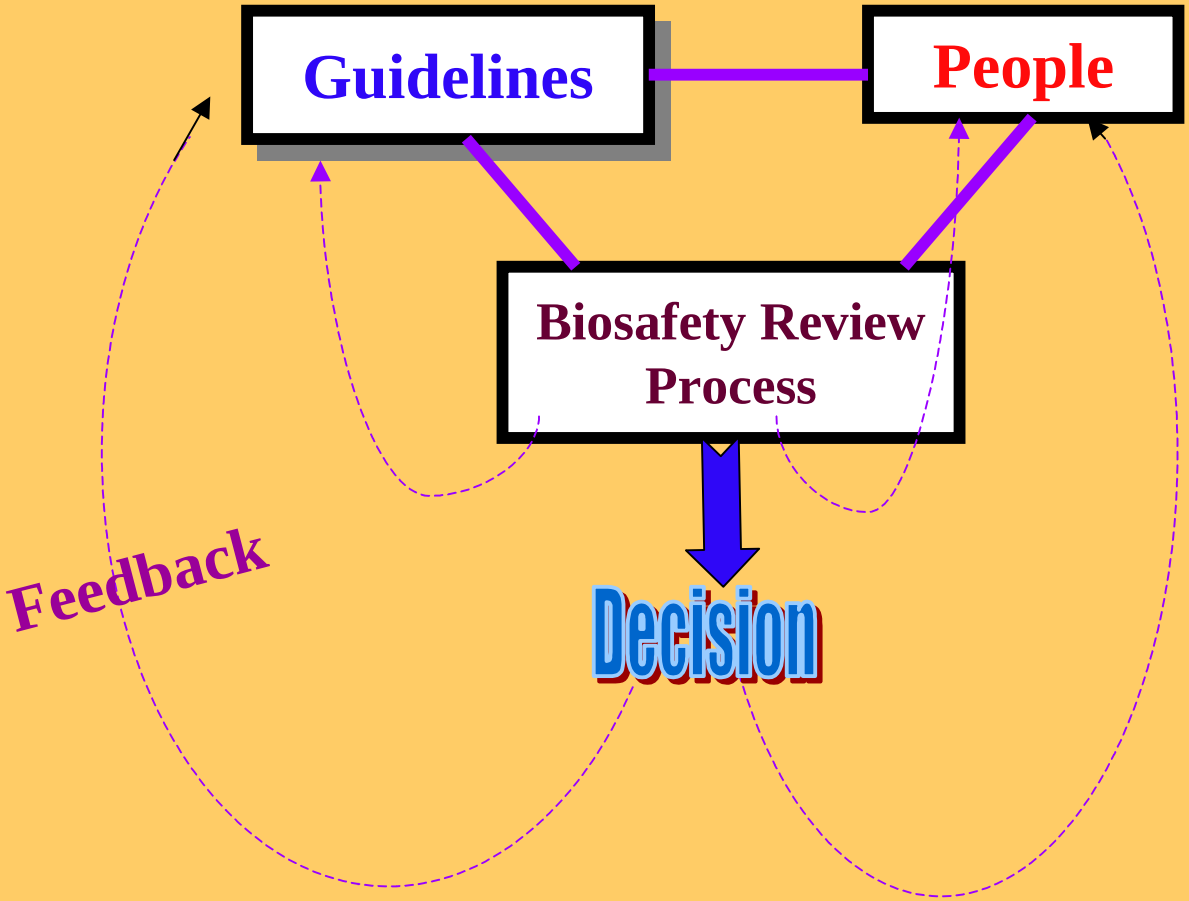
Then

how?

What?

for whom?

A Biosafety System

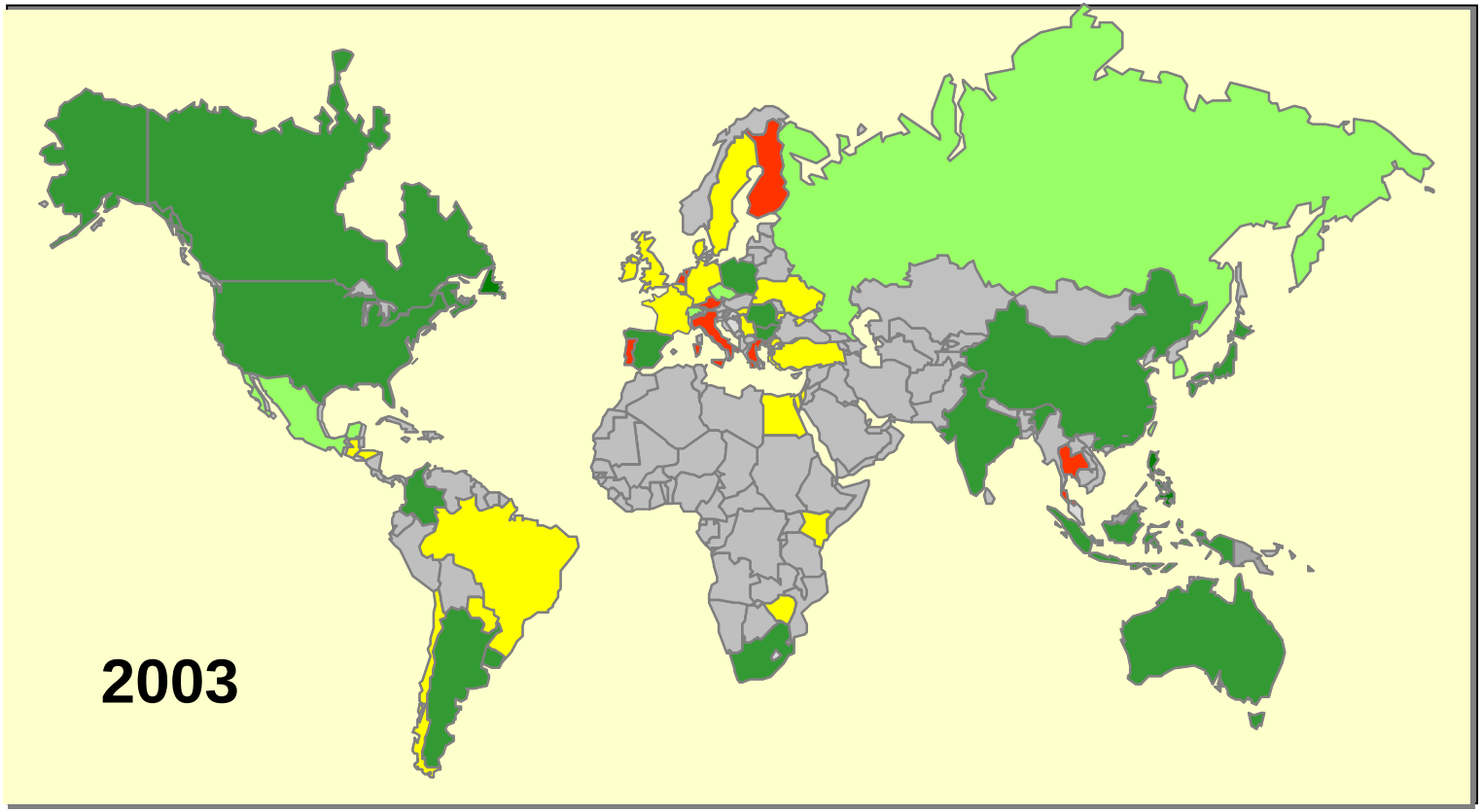


General Conclusions by National and International Scientific Organizations (FAO / WHO / OECD / ILSI)

- Food from biotech crops are not inherently less safe than those developed by conventional breeding
- Types of risks for food from biotech crops are of the same nature as those from conventional breeding
- Same food safety assessment principles and standards apply (“reasonable certainty of no harm”)
- Substantial equivalence confirmed as the most appropriate approach

Regulatory systems and capacity continue to advance world wide

Benefits are realized where approvals are granted



Stages in Research Development and Comm… …ic Plants

Period years	Stages		
3-5			
2-3	…genicity and environmental impact	R…	
1-2	Large scale field tr… …th All India Coor… ICAR/SA…	…tic Engi… (GEAC) , MOEF	
1-2	Vari… …elease Bree…s-foundation-ce…tification of seeds	Seed act for notification or certification, and Plant Variety Protection Min. Agriculture, GOI	0.25-0.50
<1	Farmer	Labeling, Consumer forum	
7-10	Consumer	Labeling, Consumer forum	2.25-4.5

7-10 years

US$ 1- 3 million depending upon the case, stage where the work starts minus capital

BIOTECH AND BIOSAFETY STATUS IN SOUTH ASIA

Biosafety status in SAARC region

Regulations or guidelines prepared/being prepared for approval by parliament

Bangladesh,Bhutan, Maldives Nepal, Sri Lanka

Prepared and bill is before parliament for approval

Pakistan

Biosafety guidelines since 1990 under EPA act and Bt cotton commercialised from March 2002 and sevral crops in pipeline

India

Developing new Biotechnology in not cheap, however. Most current research is being carried out by private sector companies and in the developed world

Distribution of Total R&D Expenditure in Science and Technology

	Percentage	
	Public	Private
India	95	05
Mexico	88	12
Indonesia	96	04
Zimbabwe	86	14
USA	30	70
Switzerland	26	74

In most of the developing countries public sector invests in research and development. Private sector investment is beginning to increase due to Globalisation and reforms in some of them

Capacity of Biotechnology Strengths and Opportunities in Developing Countries

High capacity

India, China, and Singapore

Medium capacity

Malaysia, Thailand, Vietnam, Indonesia, and Philippines

Low capacity

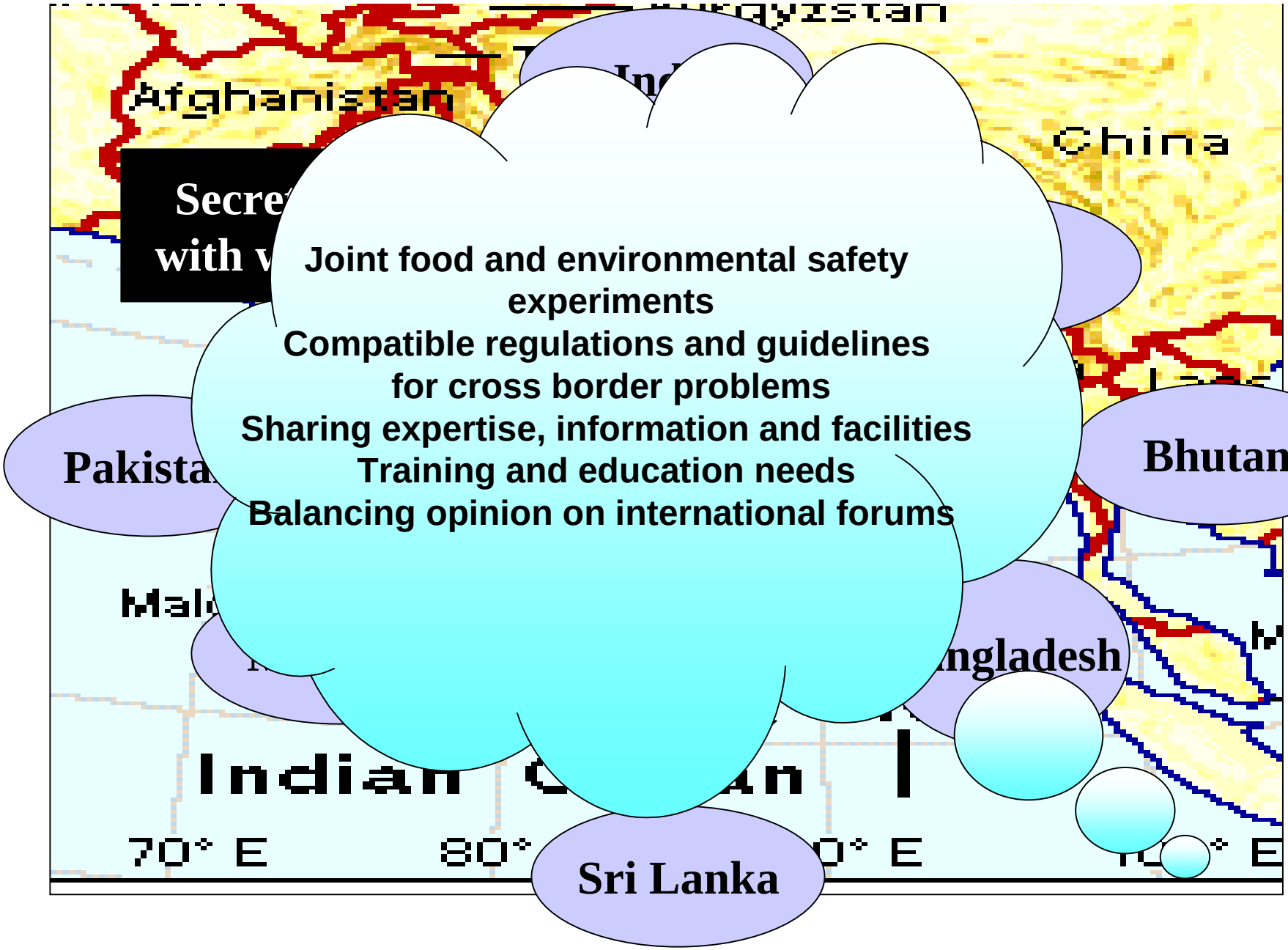
Pakistan, Bangladesh,Nepal Sri Lanka, Nepal, Maldives Brunei, Cambodia, Laos, Myanmar

The issues to be addressed therefore for DCs are the scientific capacity that will be needed to ensure the safety of new foods derived from biotechnology, including human resources for research, laboratory testing, safety evaluation, and monitoring and enforcement;

new policies, guidelines and regulations related to science that may be required for protecting human health, animal health and environmental health

Develop regional Biosafety cooperation for and conducting experiments and sharing data technical with due respect to national commitees .

Regional Biosafety Cooperation Approach



South south cooperation should therefore be strengthened through creation of an

Interface Oraganisation

TO

- **Assist in capacity building through linkages and cooperation**
- **Open communication channels for exchange of information**
- **Facilitate technology access, assessment, transfer and commercialisation**
- **Arrange collaboration between public and private sectors regionally and globally**
- **Facilitate contacts for foreign direct investment and venture capital**
- **Organise regional/international workshops , conference for public awareness**

Asia Cooperation Dialogue (ACD) launched in June 2002 in Thailand, India has been identified as prime mover for in biotechnology initiating regional cooperation among 22 ACD countries.

Regional Biosafety Considerations

Harmonization of procedures/protocols for conducting biosafety experiments on LMOs/GMOs and products thereof among countries.

Identifying indicators for generation of minimum acceptable data on risk assessment and risk management on LMOs/GMOs.

Generation of biosafety data jointly and severally by member countries wherever agro-climatic conditions are similar and the data acceptable.

Regional Biosafety Considerations

Access to infrastructure facilities among countries for generation of biosafety data.

Training and imparting expertise on biosafety among the countries particularly for biosafety regulators.

Exchange programmes for sharing of expertise on conduct of experiments with LMOs/GMOs in contained and open environment.

ACD Biotechnology Consortium may evolve a common stand on the labelling and traceability of products derived from LMOs/GMOs.

If not, continues ……

Dilemma of hunger and malnutrition

Dilemma of hunger and malnutrition

Collaboration & Partnerships

TECHNOLOGY

WTO

CODEX

CBD

TRIPS

PVP

PBR Treaties

conventions

Proponents ⟷ Opponents