Policy & regulatory issues, needs & concerns of developing countries, and future trends

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Regulatory issues
At different stages (e.g., soybean):

Seed → Cultivation → Storage & transport → Processing & marketing

Illustration sources: USDA ARS, SCAFCO, Live Mint
Regulatory issues

Seed:
• Possible causes
  • Accidental cross-hybridization
  • Other causes
• Regulatory
  • Seed purity requirements (generic)
  • Living modified organisms (CBD)
  • Ongoing discussions on GMO thresholds
Regulatory issues

Cultivation, processing, marketing:

- Possible causes
  - Cross-pollination, residual seed in field
  - Other causes

- Regulatory
  - Living modified organisms (viable)
  - Phytosanitary (generic, viable)
  - Codex alimentarius LLP guidance
Regulatory issues

Codex alimentarius LLP guidance
- No specific definition of LLP
- Safety assessment:
  - Similar data requirements
    - Comparative assessment
    - Toxicity, allergenicity & nutrition
  - More restricted possibly for:
    - Molecular data
- Recommendation for data repository
  - Detection and safety assessments
Regulatory issues

Outcomes of FAO survey

- Detection and regulatory systems
  - Full-fledged in some countries
  - Incomplete in others, yet:
    - Keeping track of developments
    - Experience with field trials
    - Focus on labeling and traceability
    - Analytical facilities in line with CBD
- Different approaches towards stacks

Illustration sources: European Commission
Policy issues

Examples of proposed LLP policies

- Zero-tolerance (European Union)
  - Technical zero (0.1%)
  - Varieties commercialized elsewhere

- Action levels (Canada)
  - Generic level (0.1 or 0.2%)
  - Safety assessment according to Codex

- Flexible stringency (USA)
  - No thresholds
  - Based on risk and familiarity
Policy issues

Possible approaches

- Zero-tolerance
  - Technical issues (confirmation)
  - High costs
- Low LLP thresholds
  - Technical issues (identity, confirmation)
  - Forecasted increase in incidents
- Case-by-case
  - Consider risk and exposure
Policy issues

Additional options

- Cooperation in risk assessment
- Example: Vietnam
  - Expedited approval
  - If approved & assessed in 5 developed countries
  - Also pertains to LLPs

Illustration sources: IAEA
Needs and concerns

Developing countries
- LLPs/AP probably not less
- Policy challenges
  - Specific regulations and policies
  - Analytical facilities
  - Staff for biosafety & detection
  - Access to information
  - Segregation of production systems
  - Decision-making in urgent cases
    • For example, food aid

Illustration sources: Commission International
Future trends

Factors
- Increasing GMO production/trade
- Expanding diversity of traits
- Enhanced techniques for crop modification
  - Increased number of experimental crops
- Asymmetric approvals
  - Focused on specific markets only
- Further refinement of detection methods
- Novel plant breeding techniques
  - Different regulatory approaches
Thank you!

Any questions?

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