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NAPPO Symposium,
“Living Modified Organisms and Plant Health”
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A presentation on eLMO



Elmo Loves You!





Pest Risk Analysis of Living Modified Organisms

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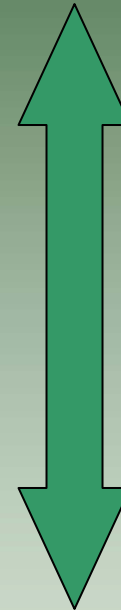
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Pest Risk Analysis (PRA) stages

1. Initiation
2. Pest risk assessment
3. Pest risk management



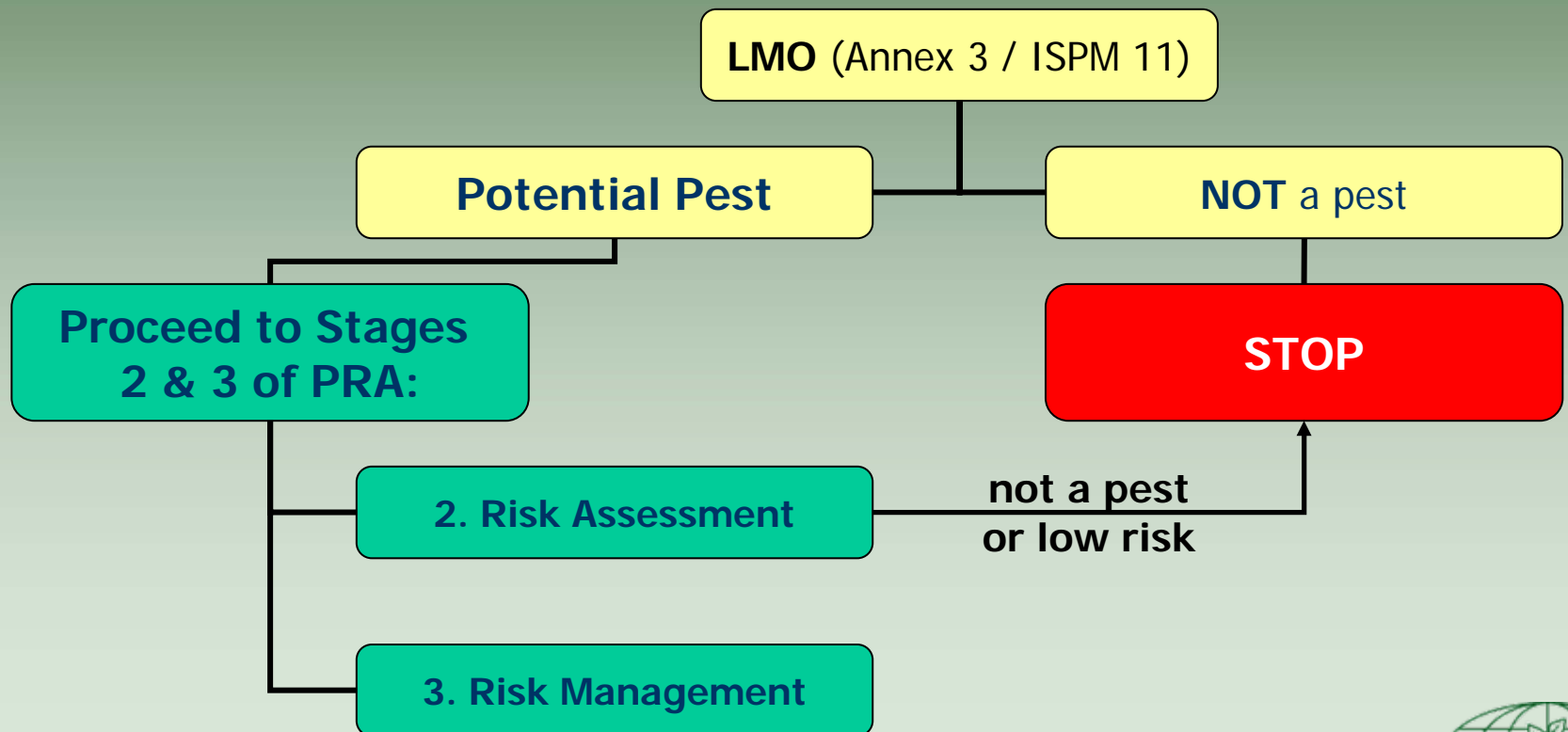
**Risk
communication**

Risk analysis is *science-based* but is NOT science





Stage 1 of PRA: Initiation





In other words, for LMOs

- **Pre-screening if an LMO is a possible pest (Refer to Annex 3 of ISPM 11).**
 - **If an LMO is NOT found to be a pest, PRA is not needed.**
 - **If an LMO is found to be a pest, proceed to next stages of a regular PRA process (Refer to ISPMs 2 & 11).**





Potential risks may result from:

- Changes in adaptive characteristics
- Adverse effects of gene flow or gene transfer
- Adverse effects on non-target organisms
- Genotypic and phenotypic instability

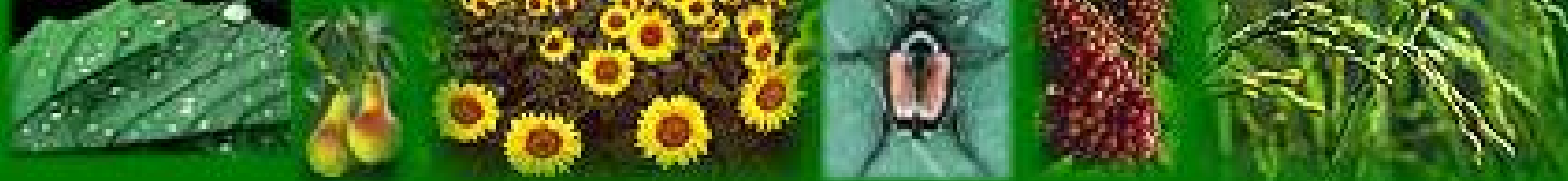




Factors that may lead to the conclusion that an LMO does not require further evaluation:

- Similar organisms previously assessed
- LMO contained and not be released
- Evidence from research that LMO is unlikely to be a pest
- Experience in other countries.

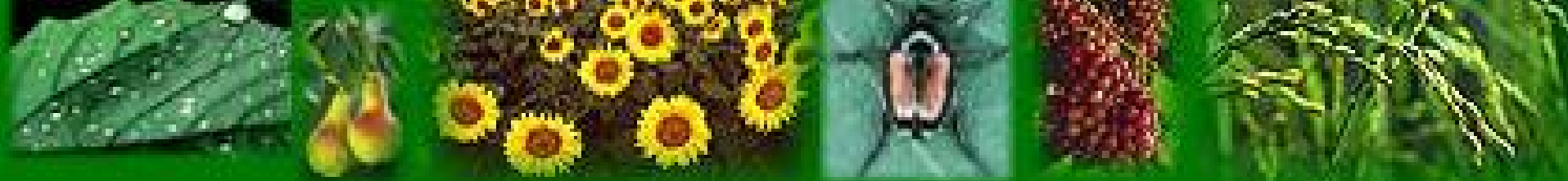




Evidence based factors that indicate pest potential:

- Field, research, or laboratory data indicating possible risk
- Characteristics similar to known pest
- PRAs for similar organisms (including LMOs) indicate a pest potential
- Experience in other countries.





Uncertainty related factors that may justify PRA:

- Lack of knowledge about specific modification(s)
- Credibility of information
- Insufficient data



Photo: The Guardian





Stage 2 of PRA: Risk assessment – In general...

- What can go wrong? (hazard)
- How can it happen? (probability)
- How likely is it? (probability)
- What are the consequences? (magnitude)
- Incorporates uncertainty



Overview of pest risk assessment

1. Categorization of individual pests
2. Assessment of the probability of introduction and spread
3. Assessment of the potential economic consequences of the introduction and spread

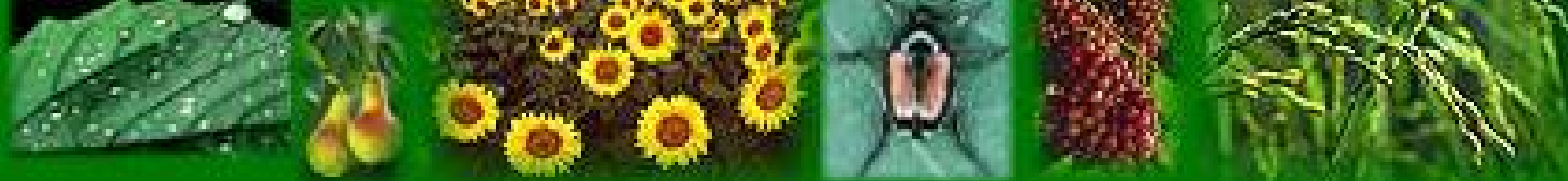




Step 1. Categorization

- The process for determining if the LMO is a pest that has the potential to cause economic harm (including environmental harm)
 - Identification of the organism and characteristics (e.g. nature of the genetic modification)
 - Presence in the PRA area
 - Potential for establishment and spread





Step 2. Probability of Introduction and Spread:

- Present in the pathway
- Escapes detection
- Survives transit
- Arrives to a favorable location
- Overcomes resistance of environment
- Comes into contact with host
- Able to reproduce and spread





Step 3. Possible Consequences

- Direct economic
 - Indirect economic
 - Environmental
 - Other:
 - Political
 - Social
 - Aesthetic
-
- Detailed guidance is in ISPM No. 11 (2004)





Uncertainty and Variability

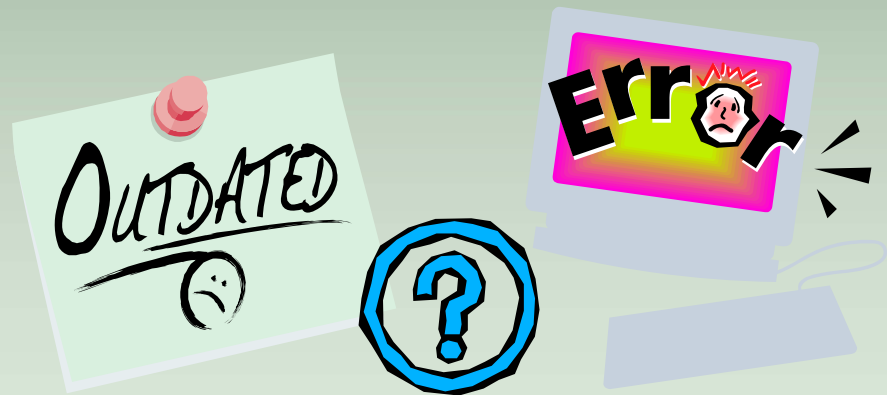
- Variability (a fact of life):
 - Differences in target population and pathogenicity
 - More data may not reduce variability
- Uncertainty (what don't we know):
 - Gaps in knowledge
 - Conflicting information
- Additional data CAN reduce uncertainty

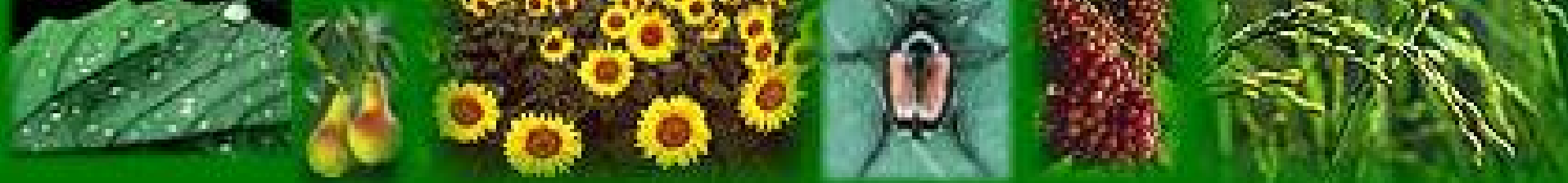




Recognizing Uncertainty

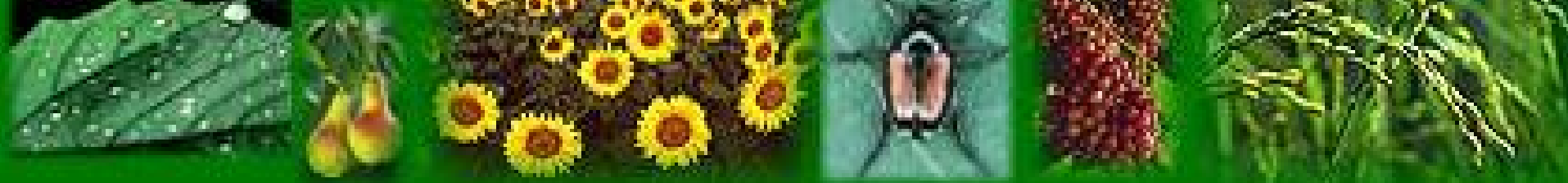
- Natural variability
- Missing information
- Vague information
- Conflicting information
- Dated information
- Incorrect methods
- Errors





Characterizing Uncertainty (in assessment stage)

- Methods:
 - Weighted factors, categories, formulas
 - Narrative explanations for individual risk factors
 - General summary of overall uncertainty
- Should communicate:
 - Quality
 - Quantity
 - Rationale and response (in Stage 3 Risk Management)



Transparency in Assessment (conclusion)

- Documentation
- Identify processes/methods
- Link evidence to conclusions and decisions
- Describe uncertainty
- Identify data gaps; areas for additional research



Stage 3 of PRA: Risk Management

- Risk management should be consistent with a country's appropriate level of protection
- Appropriate level of protection
 - “acceptable level of risk”
 - The level of protection deemed appropriate by a WTO member in establishing a...phytosanitary measure to protect ...plant life or health ...must take into account relevant economic factors.





Risk Management Options

- Requirements related to use and distribution
- Procedures for the provision of information
 - tracing systems,
 - documentation systems,
 - identity preservation systems
- Reduce probability LMO pose risk to other crops
 - management of systems and traits
 - control of reproductive ability or alternate hosts





Impacts of measures

- Measures should be evaluated for:
 - Efficacy
 - Cost / benefit
 - Impact on existing regulations
 - Commercial impact
 - Social impact
 - Environmental impact





Addressing Uncertainty during Management Stage

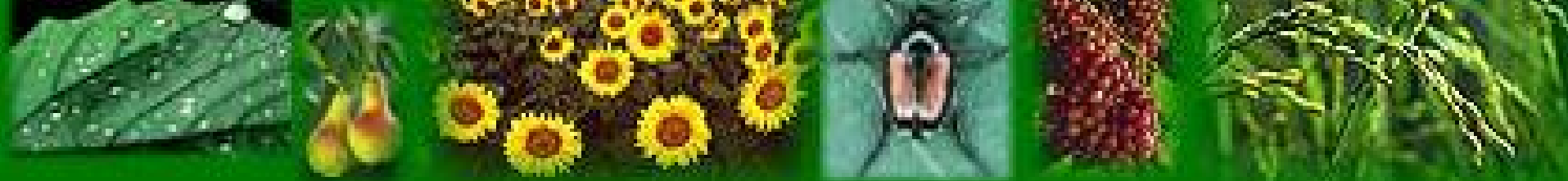
- Characterize Uncertainty
 - Identify
 - Quantify (qualitatively or quantitatively)
- Information gaps
 - Identify
 - Quantify
 - Communicate priority needs



Redundancy

- Redundancy is adding measures or adding strength to measures:
 - To compensate for uncertainty
 - As a safeguard for lack of experience
 - No less stringent measure is available
- Redundancy may be a type of provisional measure and therefore requires technical justification to be maintained





Phytosanitary Certificates and other Compliance Measures

- Information on Phytosanitary Certificates regarding LMOs that are identified as pests should only be related to phytosanitary measures (see ISPM No. 12: Guidelines for phytosanitary certificates).





Contact details

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