

# Exploring the Scope and Purpose of the Risk Assessment

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# What is the Purpose/Goal of the Risk Assessment?

- Decide whether to pursue a particular product or continue conducting research
- Identify all potential risks for the purpose of designing risk mitigation/management strategy
- **Comply with regulatory requirements**

# What issues are included in the risk assessment?

- Stage of development
  - Containment in the laboratory
  - Production in an enclosed facility
  - Release into the environment
- Environmental issues – release into the environment
- Food safety issues
- Worker and human health concerns

# Only risks or also benefits?

- Many products might have risks, but they also could have benefits (which outweigh the risks)
- Environmental versus food safety
- What about the cost of not implementing the technology

# Is the product safe?

- “Safety” is a relative term
- What is your comparator?
- GE organisms – compared to safety of conventional counterparts that already have a history of safe use (which does not mean that they have no risks or impacts)

Nice to Know

V.

Need to Know

Product

V.

Process

# Other considerations

- Harmonization of risk assessment procedures and standards -- consensus can be helpful
  - Data needed; issues to be addressed; risk assessment process
  - Codex Alimentarius, OECD, etc.
- Transparency
  - What do you know (the facts)
  - What are you assuming and the basis for the assumptions
- Public Sector risk assessment research
- Public engagement



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