

MOVING FORWARD ON AGRICULTURAL
BIOTECHNOLOGY THROUGH CONTINUING
EFFORTS ON REGULATORY COOPERATION IN
APEC

Policy Approaches Document

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Agriculture &
Food Systems
Institute

Karen Hokanson
Senior Scientific Program Manager



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Regulatory Cooperation for Agricultural Biotechnology in APEC



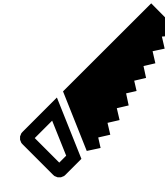
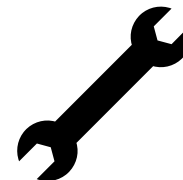
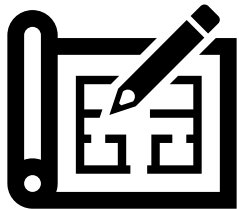
- Section I Introduction
- Section II Benefits
- Section III Approaches
 - Information Sharing
 - Policy Alignment
 - Collaboration on Risk/Safety Assessment
- Section IV Resources and Case Studies
- Section V Future Direction



Section I. Introduction

PURPOSE:

To provide **tools and resources** that will aid APEC member economies in developing, adopting, and implementing policies and best practices that reduce the regulatory burden on products of agricultural biotechnology.



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Section II Potential Benefits

General benefits of regulatory cooperation:

- Increased efficiencies resulting in savings in time and money
- Reduced inefficiencies associated with trade disruptions that can cause economic harm

Benefits to:

- Regulators
- Developers
- Agricultural Traders
- Farmers and Producers
- Consumers

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Section III Approaches to Regulator Cooperation

- Potential **mechanisms** for regulatory cooperation in APEC economies
 - Information Sharing
 - Policy Alignment
 - Collaboration on Risk/Safety Assessment
- What, why, how?
- Feedback from **webinar consultations** with APEC community
 - Information Sharing – May 6, 2024
 - Consistent Policies and Assessments – May 29, 2024
 - Sharing Risk Assessments and Product Approvals – June 17, 2024

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Section III Approaches – Information Sharing



Broadcasting or Direct Communication

- Agency postings of regulatory information
- Biotechnology regulatory-related databases
- Data Sharing/Data Transportability
- Information sharing and capacity building

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Section III Approaches – Policy Alignment

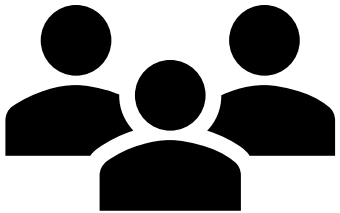
1) High Level Policy Alignment

- Necessary for technical policy alignment
- Already some degree of alignment within APEC member economies

2) Technical Policy Alignment

Mechanisms put in place to accomplish higher level policy

- Administrative procedures
- Scientific/technical procedures
 - Guidance on the conduct of assessments
 - Types of information (data) needed to inform risk/safety assessments
 - Criteria for data acceptance or guidelines for testing
 - Standardized templates for application or data submission



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Section III – Approaches – Collaboration on Risk Assessment



Types of Risk Assessment Collaboration

- 1) Safety Assessment Review
- 2) Parallel Safety Assessment
- 3) Shared Safety Assessment
- 4) Joint Safety Assessments



Section III – Approaches – Collaboration on Risk Assessment

Types of Risk Assessment Collaboration

1) Safety Assessment Review

- One agency shares safety assessment with another for peer-review and comment

2) Parallel Safety Assessment

- Two or more agencies complete their own safety assessment of an application but in a coordinated fashion

3) Shared Safety Assessment

- One lead agency completes a safety assessment, which is then shared with collaborating agencies for peer review and collaborative finalisation

4) Joint Safety Assessment

- Two or more agencies share resources to complete a single safety assessment



Benefits & Challenges of Collaboration on Risk Assessments

Benefits

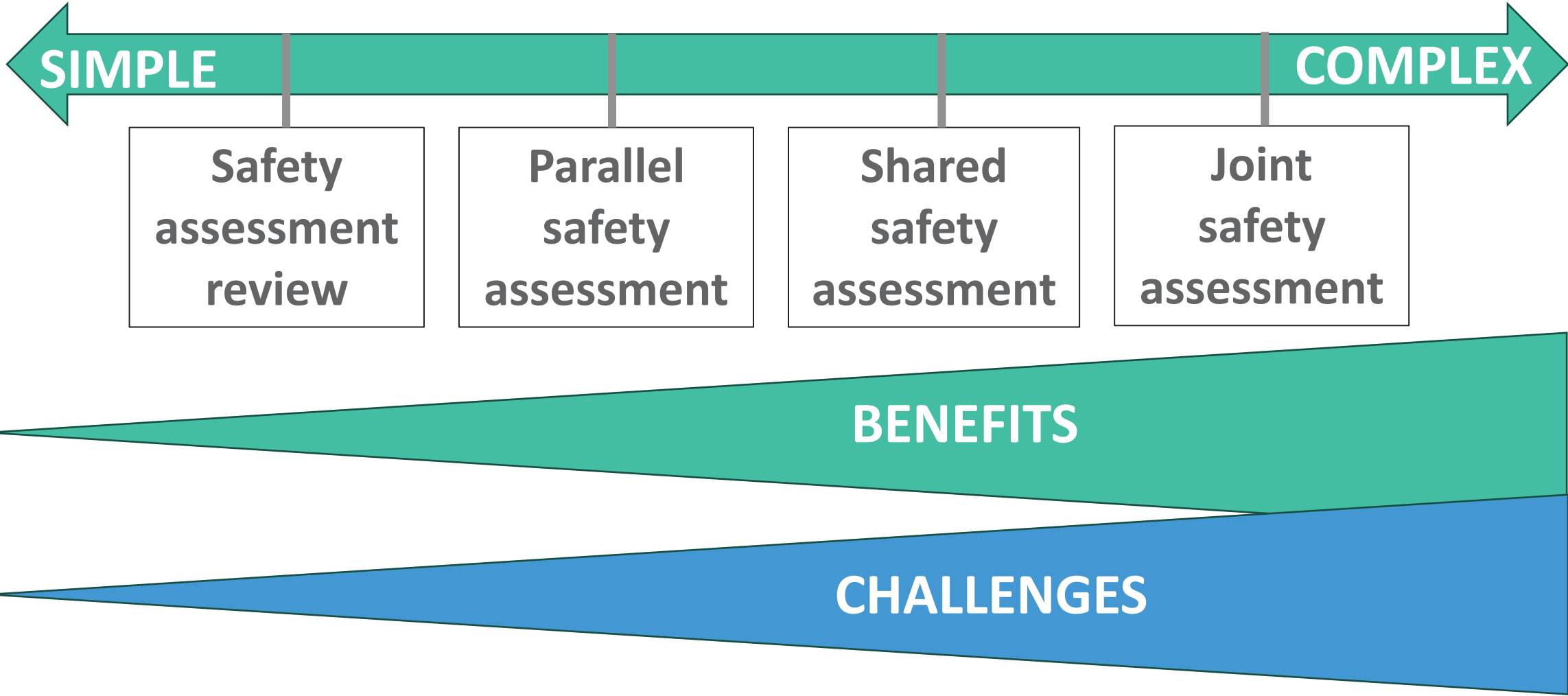
- Reduced regulatory burden and efficiency gains
- Improved synchronization of authorizations
- Mutual capacity building and stronger working relationships among agencies
- A regulatory environment that supports innovation
- Increased public confidence in regulatory decisions

Challenges

- Legal issues, legislative frameworks
- Operational differences between agencies
- Logistical and practical challenges
- Initial demand on resources
- Level of commitment



Benefits vs. Challenges of Collaboration on Risk Assessments



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Case Study Database:

- Name **MERCOSUR/GMC/RES. No. 23/29 (LLP Agreement)**
- Description **An operating mechanism established by a trade bloc...**
- Cooperators **Argentina, Brazil, Paraguay, Uruguay**
- Geography **Argentina, Brazil, Paraguay, Uruguay**
- Mechanism **Policy Alignment**
- Category of Cooperation **Agreement**
- *Keyword Search*

VIEW



CASE STUDY DATABASE

Case Study Database:

- Name
- Description
- Cooperators
- Geography
- Mechanism
- Category of Cooperation
- *Keyword Search*

- Asia Pacific
 - Vietnam
 - South Asia
 - Australia
 - New Zealand
- Global
- North America
 - Canada

DROPDOWNS

- *Information sharing*
- *Policy alignment*
- *Collaboration on Risk Assessment*

- Agreement
- Forum
- Policy



Case studies to date (7)

- **Information Sharing**

- Global Low Level Presence Initiative
- Organization for Economic Cooperation and Development (OECD)

- **Policy Alignment**

- CODEX Alimentarius
- Vietnam's expedited regulatory approval of imported products for direct use

- **Collaboration on Risk Assessment**

- Argentina-Brazil (MOU on mutual recognition of genome-edited traits)
- Health Canada – Australia/New Zealand (FSANZ)
- Mercosur Resolution MERCOSUR/GMC/RES. Nº 23/19 (LLP Agreement – reduce trade disruptions)



(15 resources to date)

Resource Database:

- Name **OECD Consensus Documents**
- Description **...Documents identify information commonly used...**
- Source **Organization for Economic Cooperation (OECD)**
- Source Geography **Global**
- Resource Type **Website**
- Source Type **IGO**
- *Keyword Search*

VIEW

RESOURCE DATABASE



Resource Database:

- Name
- Description
- Source
- Source Geography
- Resource Type
- Source Type
- *Keyword Search*

DROPDOWNS

- Asia
- North America
-United States
- South America
- Global

- IGO
- NGO

- Online Course
- Proceedings Document
- Guideline
- Statement
- Website
- Working Paper

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Consider the outcome of this workshop!



Agriculture &
Food Systems
Institute

foodsystems.org

Thank You



khokanson@foodsystems.org