SBSTTA 26 Biosafety AI's

A policy perspective

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Scope of the presentation

- Overview of topics under discussion per AI
- Historical context
- General advice for negotiators

- In depth technical context during next presentation and round of questions

SBSTTA Biosafety Agenda Items

AI 3: Monitoring Framework – Target 17

AI 5: Synthetic Biology

AI 7: Detection & Identification

AI 6: Risk Assessment & Risk Management

SBSTTA Biosafety Agenda Items

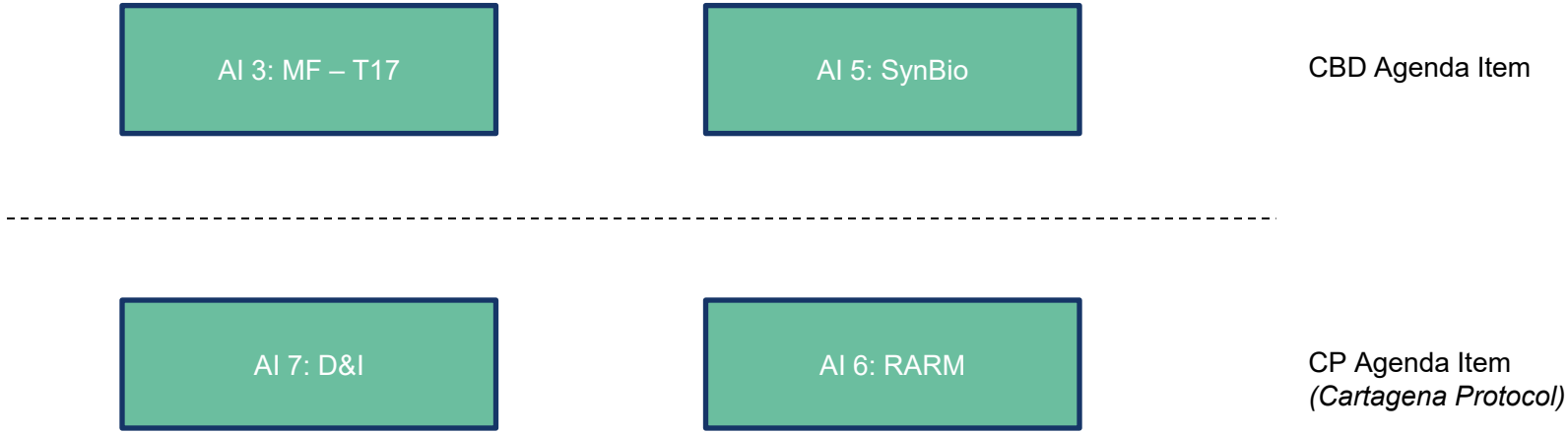
AI 3: MF – T17

AI 5: SynBio

AI 7: D&I

AI 6: RARM

SBSTTA Biosafety Agenda Items



SBSTTA Biosafety Agenda Items

AI 3: MF – T17

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SBSTTA Biosafety Agenda Items

AI 3: MF – T17

AI 5: SynBio

***Establish**, **strengthen capacity** for, and **implement** in all countries **biosafety measures** as set out in **Article 8(g)** of the Convention on Biological Diversity and **measures** for the **handling of biotechnology and distribution of its benefits** as set out in **Article 19** of the Convention.*

AI 7: D&I

AI 6: RARM

Convention Text

Art. 8g. Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health;

Art. 19. *(paraphrased)*

1. provide for the effective participation in biotechnological research activities
2. take all practicable measures to promote and advance priority access
3. basis of the Cartagena Protocol
4. obligation to submit information on use and safety regulations of LMOs

Target 17 - Context

- Difficult negotiation context
  - History
  - Lots of brackets
  - Duality of the target + overlap
- Unclear how MF will be dealt with at SBSTTA 26

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SynBio – Context

- ‘Broad and regular horizon scanning’
  - Consider its outcomes (not the content!)
  - Consider its continuation
  - Consider its process
- Work on capacity building (CBD SEC & Parties)

- Work was done via call for information, Online Forum and mAHTEG *(multidisciplinary Ad Hoc Technical Expert Group)*

SynBio – Advice

- Sensitive AI – hope for the best, prepare for the worst
- Products of SynBio vs LMOs
- Let the volume not deter you

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D&I - Context

- Originates from D&I of unauthorized LMOs → Broader now
- Main aspects of D&I discussions:
  - Training Manual on the D&I of LMOs in the Context of the CP
  - Network of Laboratories
  - Capacity Building

Handling, Transport, Packaging & Identification (Art. 18)

- (…) each Party shall take necessary measures to require that LMO's (…) are handled, packaged and transported under conditions of safety (…).
- Via documentation
  - Food & feed – "may contain LMOs" label, contact point, intended use
  - Contained use: label, contact point, safety requirements
  - Intentional introduction: label, identity & relevant traits, safety requirements, contact point, (if appropriate) contact info importer/exporter and declaration product is in conformity with the Protocol

Illegal Transboundary Movements (Art. 25)

- 1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.
- 2. Party of origin responsible for disposing of illegal LMO…
- 3. …and report to the BCH

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Risk assessment (Art. 15 & Annex III)

- General principles
  - Science-based
  - Based on precautionary principle
  - Comparative approach
  - Case-by-case
- Steps
  - Identification of characteristics with potential adverse effects
  - Evaluate the likelihood these adverse effects take place, the consequences if they do and the overall risk by combining this.
  - A recommendation whether the risk is acceptable and/or possible management strategies & monitoring plans

Risk assessment (Art. 15 & Annex III)

- Points to consider
  - Recipient organism, Donor organism, Vector
  - Characteristics of the modification
  - LMO and differences with recipient organism
  - Detection and identification methods
  - Intended use
  - Receiving environment

Risk management (Art. 16)

- 1. The Parties shall (…) establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.
- Measures take into account
  - Necessary extent to prevent adverse effects
  - Possibility of transboundary movements
  - An appropriate period of observation
  - Inter-Party cooperation on identifying adverse effects and treatment

RARM - Context

- Two important topics
  - Development of guidance on risk assessment
  - Taking stock of new topics to develop guidance for
- Current focus is LMOs with modified gene drives, with special focus on mosquitos
- **Important** – Guidance itself not open for negotiation
  - Peer-review?

In general

- Read the documents
- Value in each negotiators profile
- SBSTTA is not the final station of text

- ‘History is written by those that show up’

Thank you for your attention!

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