World Organisation for Animal Health

Ministry of Agriculture
Republic of Indonesia

In partnership with Canada

# MBT : Strengthening and Sustainability on Biosafety, Biosecurity, and Bioengineering for Health Laboratories in ASEAN

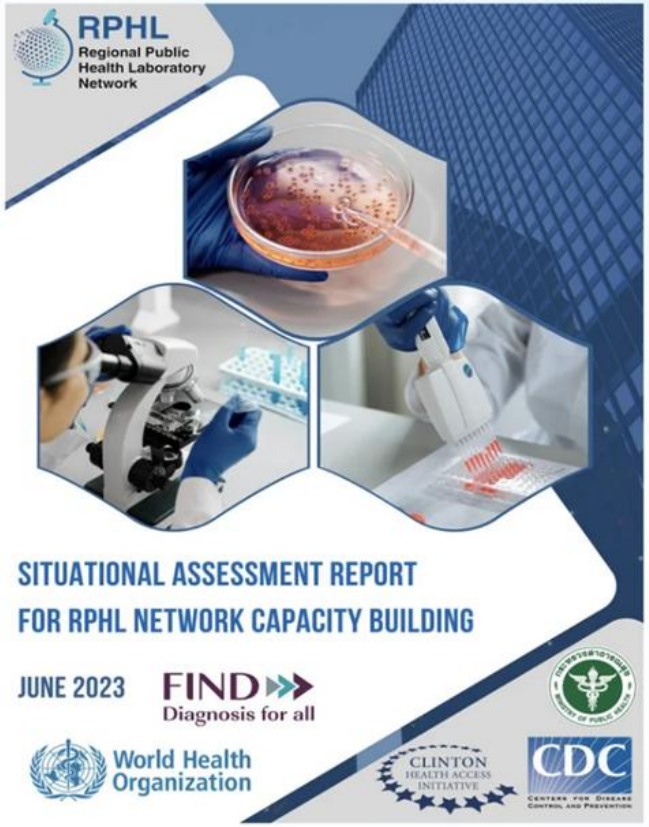
Biothreat reduction: Coordination and Partnership

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# Presentation Outline

- Current ASEAN Laboratory Baseline
- Addressing Bioengineering
- Capacity Building
- The Sustainability Challenge or barriers
- Fostering Regional Networks
- Summary

# Current ASEAN Laboratory Baseline




The result of this assessment will serve as an evidence base for the RPHL Network:

- To develop the workplan on Capacity Building Development to serve the needs of 12-member countries
- To identify strengths as well as opportunities for intervention across the region. Participating member countries include:



SCAN ME!

# Current ASEAN Laboratory Baseline

## Biosafety & Biosecurity Capacity Landscape

Regional Assessment Summary Across 12 RPHL Network Member Countries (June 2023)

### Policy & Governance

83% (10/12) of countries have policies in place. However, **biosecurity legislation** lags significantly in countries like Myanmar, Timor-Leste, and Viet Nam, focusing primarily on biosafety.

### Infrastructure

50% of the network possesses functional **BSL-3 laboratories**. Despite high-level commitment, 42% of countries report poor capacity in the **maintenance and certified use** of Biosafety Cabinets (BSCs).

### Sub-national Gaps

A critical disparity exists; 58% of countries exhibit **poor IPC and waste management** at sub-national levels. 50% lack risk analysis capacity outside central reference laboratories.

# Addressing Bioengineering

## The Laboratory Implementation Gap

### Regulatory Frameworks

Acts like Thailand's Pathogen and Animal Toxins Act (PatAct) dictate high-level safety mandates. However, national regulations do not automatically provide day-to-day bench-side protocols for complex bioengineering diagnostic and research environments.

### Sophisticated Risks

Emerging medical biotechnologies feature complex dual-use risks. Without concrete, validated engineering practices in biological containment (biocontainment), laboratories run the severe risk of localized exposure or accidental environmental release.

# Addressing Bioengineering

## Thailand’s PatAct Legal Pillars

### 1. Scope of Substances

Covers modern biotech products including synthetic biology, GMOs, and bioengineered agents modified from prions or microbes.

### 2. Risk Classification

Classifies pathogens (Groups 1–4) and toxins (Groups 1–3) into Notification, Licensing, or Prohibition pathways.

### 3. Regulated Activities

Strictly controls six essential actions: production, import, export, sale, transit, and possession to guarantee full traceability.

### 4. Safety & Security

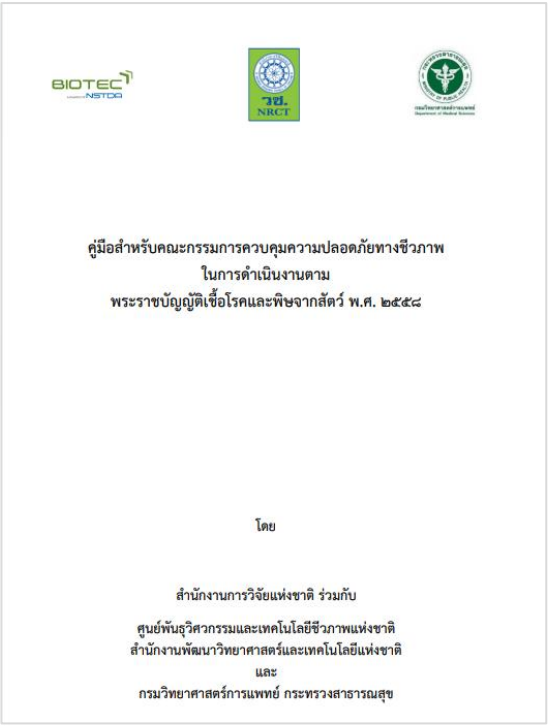
Enforces Biosafety (preventing community containment leaks) and Biosecurity (access control and mandatory personnel training).

### 5. Emergency Powers

Empowers the Minister under Section 6(11) to issue urgent safety regulations protecting public interest from emerging tech.

### 6. Institutional Link

Integrates legal mandates with Institutional Biosafety Committees (IBCs) to screen research for Dual-Use Concerns (DURC).



# Addressing Bioengineering

## Operationalizing Biocontainment & Biorisk Management

Ensuring regional biosafety requires secure, legal pathways for shipping clinical and diagnostic samples across borders.

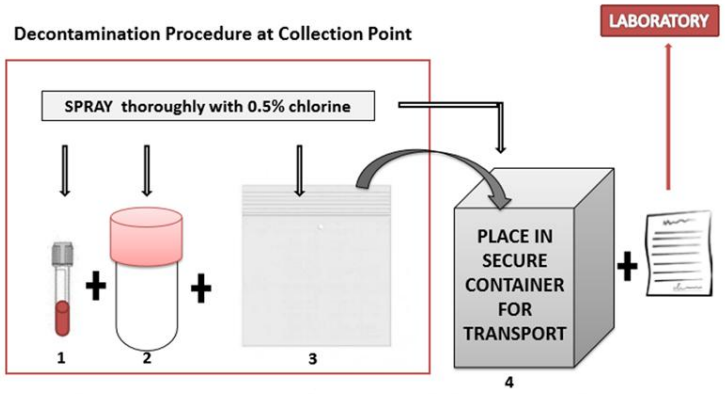
Building on successful Phase 2 initiatives, the MBT project established specialized expertise and practices in specimen referral. This logistical framework directly empowers laboratories to perform safe, compliant sample transport that adheres to the transit restrictions of PatAct.

PPE



Dirty & Clean person

Decontamination




Each step wipe with 0.1% chlorine solution





| Dirty Zone | Clean Zone | Public area |
|---|---|---|
| Primary+ Secondary container | Outer Container | Courier/Public |

# Addressing Bioengineering

## Operationalizing Biocontainment & Biorisk Management

### 1. NSF-Standard BSC Certification

**Primary Containment Quality:** MBT builds local human capacity by training and certifying expert "BSC Certifiers" under the NSF standard. This guarantees Biosafety Cabinets across ASEAN protect laboratory personnel from infectious pathogens at the point of action.

### 2. BSL-3 Engineering Validation

**Secondary Containment Integrity:** Establishing localized, rigorous validation guidelines for BSL-3 laboratories. This measures air handling, directional pressure, and structural engineering to verify high-risk bio-agents cannot escape into the surrounding environment.

# Capacity Building

## 1. Training Models

Transitioning legal biosafety compliance from a checklist to robust operational expertise:

- **Train-the-Trainer:** Empowers local "master trainers" to continuously scale instruction across organizations.
- **Blended Learning:** Combines digital theory with rigorous physical workshops (PPE drills, spill kits).
- **Curriculum Standardization:** Certified training programs with specialized content tailored for biosafety officers and practitioners as prescribed by PatAct 2015.

## 2. Biosafety Associations

Acting as a vital bridge between national regulators and frontline scientific practitioners:

- **Third-Party Verification:** Offers impartial competence evaluations, reducing resource pressure on state agencies.
- **Knowledge Platforms:** Organizes national conferences to dissect risks of emerging genetic engineering.
- **Technical Guidelines:** Co-creates practical operational handbooks to translate statutory text into lab-floor realities.

## 3. One Health Synergies

Expanding and unifying safety networks across public health and veterinary laboratories:

- **Human-Animal Lab Twinning:** Pairs high-resourced national hubs with regional veterinary diagnostics.
- **Cross-Sectoral IBC Reviews:** Integrates public health & animal experts to assess zoonotic and dual-use dangers.
- **Secure Sample Logistics:** Scaling IATA/WHO-compliant transport protocols for safe cross-border shipments.

# The Sustainability Challenge or barriers

## Strategic Sustainability Strengths and Governance by:

- The Power of Legal Mandate: PatAct 2015 transforms biosafety from an optional research activity into a non-negotiable statutory requirement.
- Resource Optimization: Utilizing Regional Training Centers (RTCs) as a shared-resource ecosystem under the One Health Network to achieve economies of scale aligned with NOH Lab Strategy.
- Governance-Led Momentum: Linking domestic operations with international standards (ISO 15190, ISO 35001) through regional networks (e.g., RPHL Network).

## Fluctuating funding Strategic Actions:

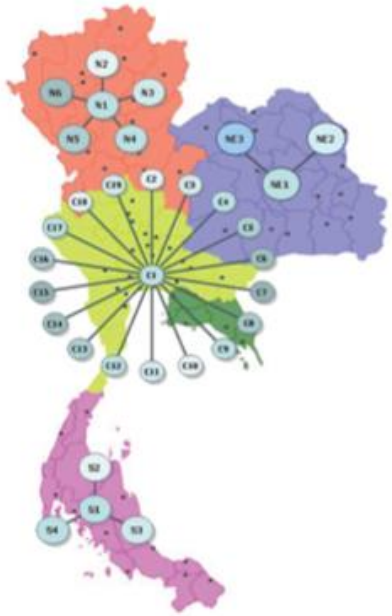
- Mainstreaming: Formally embed bioengineering risk assessment as a permanent Strategic Pillar within the One Health National Laboratory Strategic Plan/IBC approach to secure core national budgets.
- Regulatory-Driven Compliance: Mandate that all domestic research grants (via PMU-B, NRCT) automatically allocate a percentage of their budget toward biosafety infrastructure and compliance.
- Institutionalized Training: Integrate specialized bioengineering and DURC risk assessment into the mandatory, 3-year refresher training tracks at existing RTCs aligned with country's law and regulations.

# The Sustainability Challenge or barriers

## The Power of Legal Mandate

**Regulatory Leverage on Research Grant by Institutional Biosafety Committee (IBC)**

To assist the safety research practically as shown in the biosafety guideline, the IBC has been established within academic and research institutes.



**N – North Region**
N1 - Chiang Mai University
N2 - Mae Fah Luang University
N3 - Maejo University
N4 - Uttaradit Rajabhat University
N5 - Reserch Institute for Health Science, Chiang Mai University

**NE – North East**
NE1 – Khon Kaen University
NE2 – Suranaree University of Technology
NE3 – Ubon Rajathanee University

**C - Central Region**
C1 – Mahidol University
C2 – Assumption University
C3 – Burapha University
C4 – Chulabhorn Research Institute
C5 – Chulalongkorn university
C6 – Kasetsart University
C7 – King Mongkut's Institute of Technology Ladkrabang
C8 – King Mongkut's University of Technology Thonburi
C9 – National Center for Genetic Engineering and Biotechnology
C10 – Thailand Institute of Scientific and Technological Research
C11 – Rajamangala University of Technology Thanyaburi
C12 – Ramkhamhaeng University
C13 – Rangsit University
C14 – Srinakharinwirot University
C15 – Silapakorn University
C16 – **Thammasat University**
C17-19 - Private Companies

**S - South Region**
S1 – Prince of Songkhla University
S2 – Rajamangala University of Technology Srivijaya Provides
S3 - Thaksin University

IBC network

## Resource Optimization

**NOH Lab Strategy**

แผนกลยุทธ์
การพัฒนาระบบและเสริมสร้างสมรรถนะ
ห้องปฏิบัติการสุขภาพหนึ่งเดียวระดับชาติ
เพื่อความมั่นคงด้านสุขภาพ



NATIONAL ONE HEALTH LABORATORY SYSTEM AND CAPACITY STRENGTHENING STRATEGY FOR HEALTH SECURITY (NOH LAB STRATEGY)

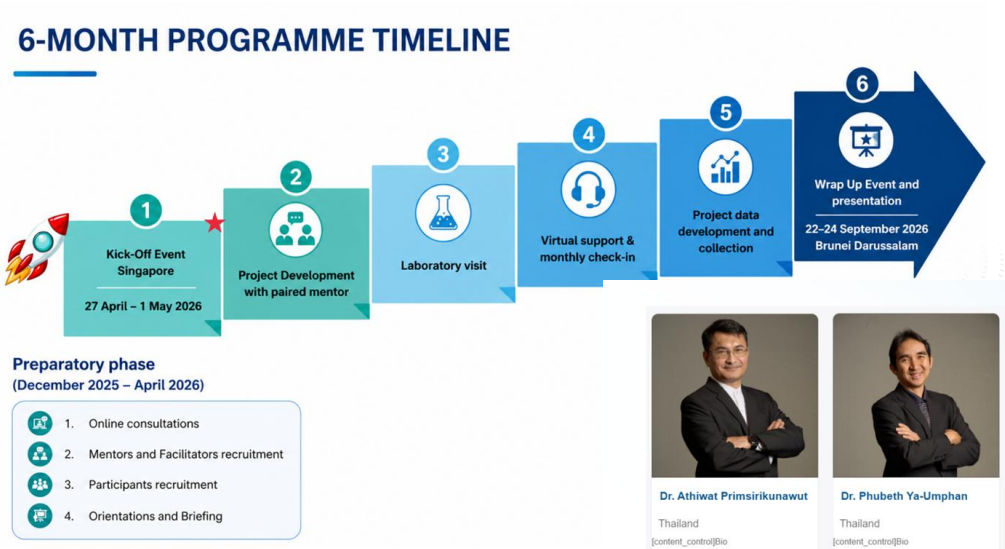
# Fostering Regional Networks

## Platform

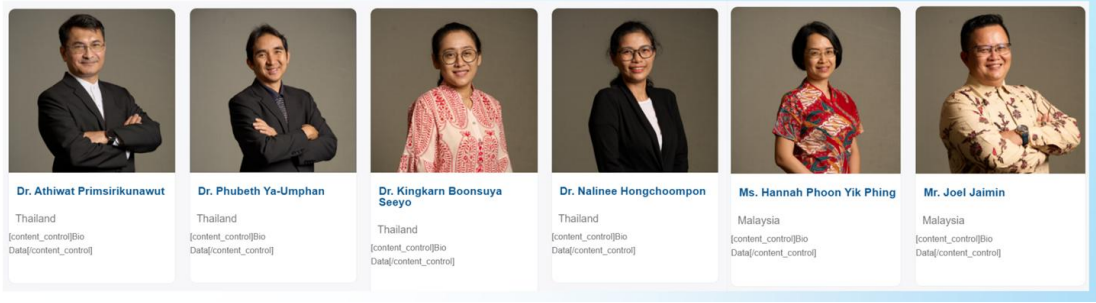
- ☑ Twinning Programme/Peer to Peer: Cohort 1 to Cohort 2
- ☑ Subject Matter of Expert (SME): Biosafety and Biosecurity, Biological Waste Disposal, etc.
- ☑ Knowledge sharing: VC (Market place), Materials, etc.
- ☑ Regional Training Center for ASEAN Laboratory




Twinning Programme




SME



# Fostering Regional Networks

**Regional Training Center**

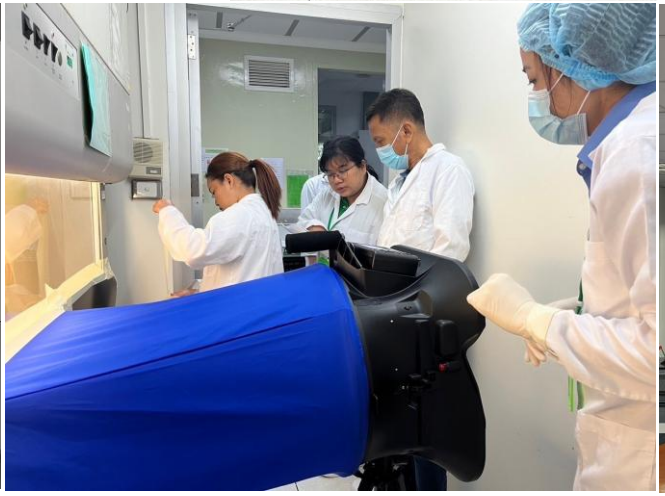
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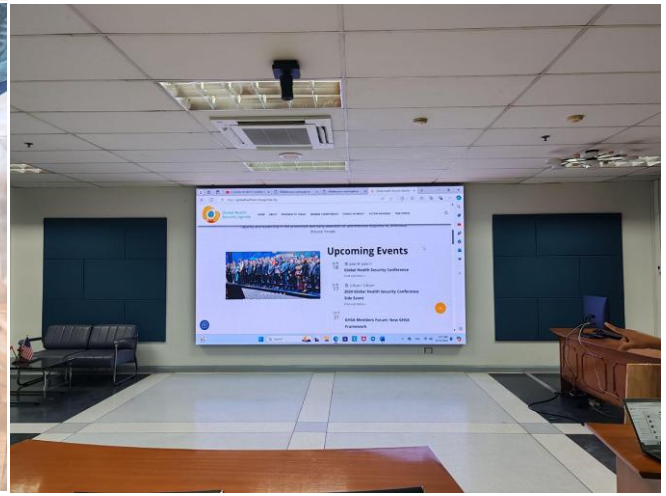




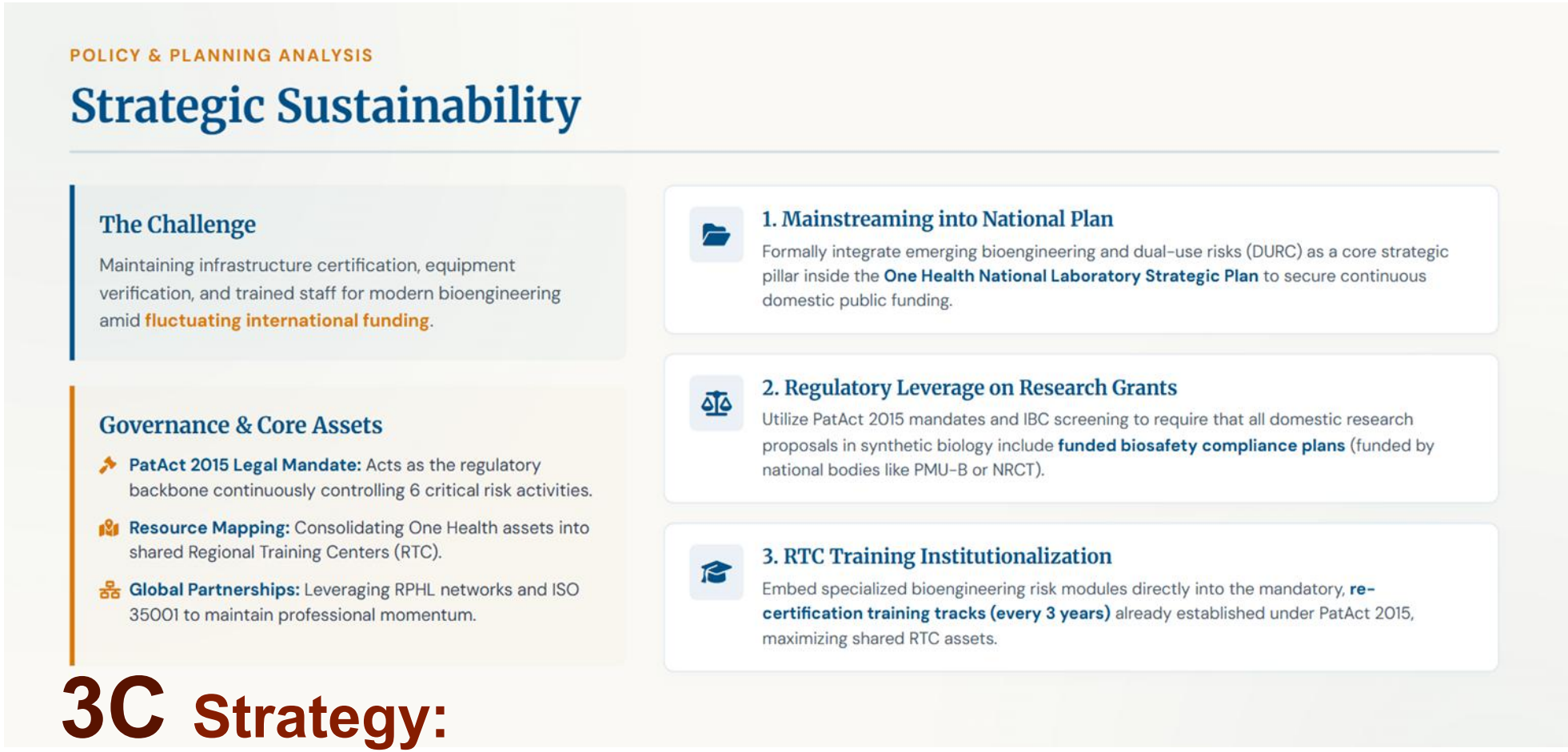






# Summary




"Sustainability is not about finding new grants to replace old ones; it is about embedding safety values and standards directly into routine operations and legal enforcement."

**3C Strategy:**

**Commitment Collaboration Co-Creation**




**Contact:** secretariat@rphlnetwork.org

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# Thank you

Biothreat reduction: Coordination and Partnership

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