International Workshop on Harmonization of GMO Detection and Analysis For Central and South America
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ASEAN Network of GM Food Testing Laboratories

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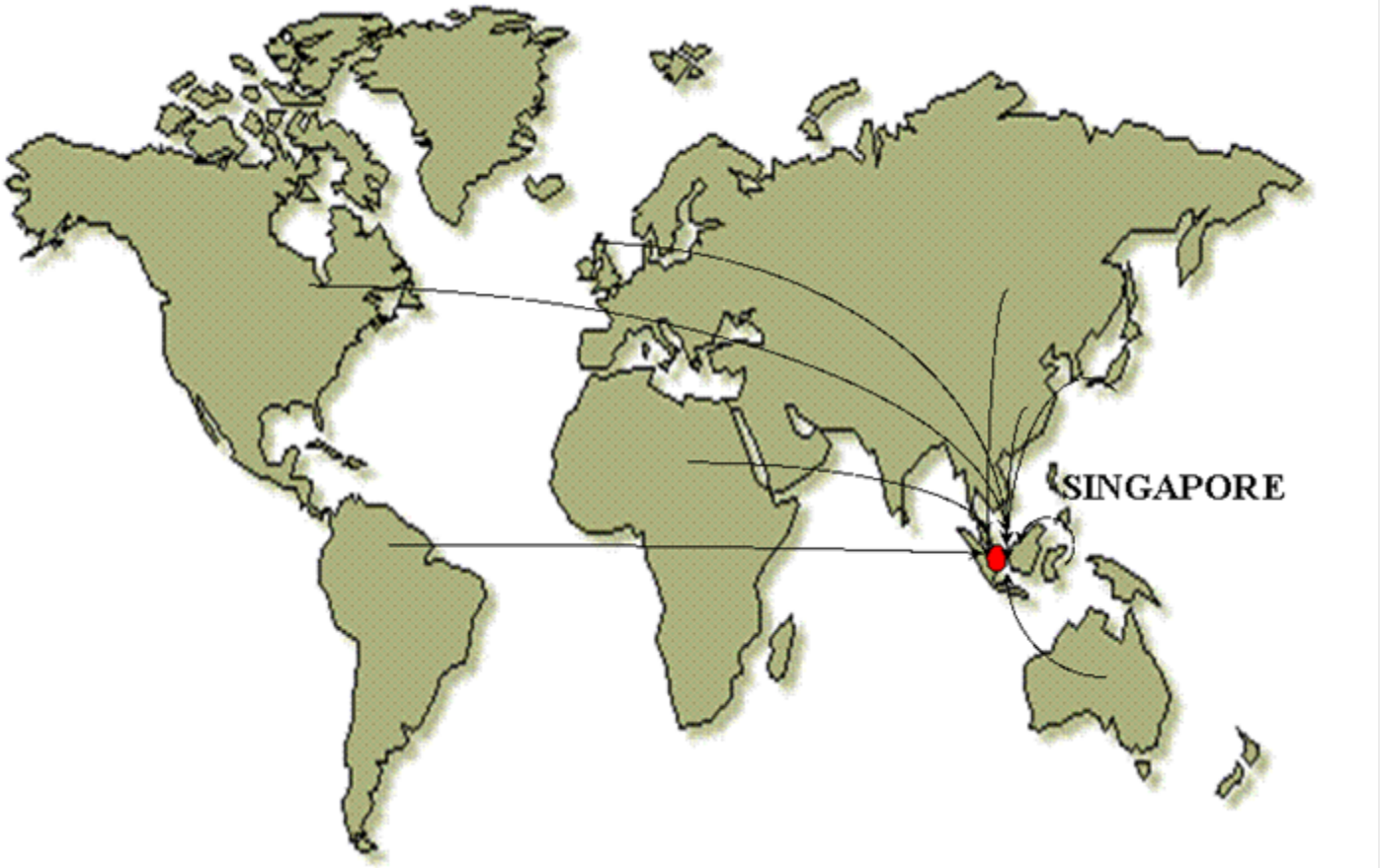
Presentation Outline

- Introduction to ASEAN
- Regulatory framework for GM food in ASEAN
- ASEAN Network of GM Food Testing Laboratories
  - Role and aims
  - Work Prorities
  - Issues and challenges

ASEAN Member States

- The Association of Southeast Asian Nations (ASEAN)
  - established on 8 August 1967 in Bangkok by the five original Member Countries, namely, Indonesia, Malaysia, Philippines, Singapore, and Thailand
- Brunei Darussalam joined in 1984
- Vietnam in 1995
- Lao PDR and Myanmar in 1997
- Cambodia in 1999

ASEAN Member States


SINGAPORE

ASEAN Member States

The ASEAN Declaration states that the aims and purposes of the Association are:

- To accelerate economic growth, social progress and cultural development in the region
- To promote regional peace and stability through abiding respect for justice and the rule of law in the relationship among countries in the region and adherence to the principles of the United Nations Charter

GMO regulatory system: Indonesia

- Law no. 7/1996 (Article 13): R*egulations on the obligation to inspect the GM food*
- 1998 : Guideline for risk assessment for genetically modified plant, animal, fish, and microorganism
- Government regulation no. 69/1999: R*egulation on labeling of the GM food*
- Government regulation no. 28/2004 regulate food safety of food product derived from GMO
- Government regulation no. 21/2005: a revised version of Joint decree of 4 Ministries (1999) and national focal point is the State Ministry of Environment
- Drafting guideline on food safety assessment: to guide the assessment on the food safety

GMO regulatory system: Malaysia

NATIONAL BIOTECHNOLOGY POLICY

- Launched on 28 April 2005
- Biotechnology as the engine of growth for knowledge based economy in the country
- A guideline for conducive environment for R&D and industry growth through leveraging on country′ s existing strength and capabilities
- Proactive in biosafety issues
  - GMAC, National Guidelines, Biosafety Bill and signatory to the Cartagena Protocol on Biosafety
- Currently efforts directed to promote and increase public awareness, both on biotechnology and biosafety legislation
- Biosafety Act (Act 678) in 2007: monitor activities relating to living modified organisms and products of such organisms
- GMO Lab under Dept of Chemistry - designated as EC-ASEAN Reference Laboratory for GMO testing in June 2004

GMO regulatory system: Philippines

Bureau of Plant Industry (BPI) is the agency that regulates GM crops:

- Importation for contained use
- Importation for direct use as food, feed and processing (FFP)
- Field trials
- Commercial release

- developed a biotech website to maintain transparency in biotech regulations, and for the public to have easy access for the information pertaining to GM applications and its status.

- 48 events approved for food, feed and processing (corn soybean, canola, cotton, potato, sugarbeet, alfalfa)

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GMO regulatory system: Thailand

- Department of Agriculture (DOA), Ministry of Agriculture and Co-operatives
  - controls importation / exportation of plants and plant materials as well as GMOs

- Food and Drug Administrative (FDA), Ministry of Public Health
  - makes rules for additives and new foodstuffs including GM food and food derived from GMO; also concerned with the labeling of food
  - Labeling threshold - 5% (for soya & maize)

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GMO regulatory system: Vietnam

Ministry of Agriculture and Rural Development

- Regulates GM field trials and market release

Ministry of Health:

- Regulates bio-safety of food products and GM food testing

- Regulations for GMF labelling: GM products imported for food to have food safety certificate or equivalent

- Currently drafting regulations for mandatory labeling threshold of 5%

GMO regulatory system: Brunei

- No legislation specific on GMOs foods, requirement to comply with the existing Brunei food legislations under Public Health (Food) Act, 1998 and Public Health (Food) Regulation, 2000

- Draft National Biosafety Framework for Brunei Darussalam to establish National Authority of Genetic Modification (NAGM)

- No GMO testing laboratory established yet

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GMO regulatory system: Myanmar

- Development of National Biosafety Framework (NBF) in progress
- Food and Drug Administration (Ministry of Health) responsible for GM food testing

GMO regulatory system: Singapore

- Genetic Modification Advisory Committee (GMAC)
  - set up under the Ministry of Trade & Industry in 1999
  - oversees and advises on R&D, production, use and handling of GMOs
  - ensures public safety while allowing for the commercial use of GMOs and GMO-derived products, in harmonization with international and regional standards
  - provides scientifically sound information to create public awareness on GMO and GMO-related issues

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GMO regulatory system: Singapore

GMAC Guidelines

- Singapore Guidelines for Release of Agriculture-Related GMOs (released Aug 1999)
- Singapore Biosafety Guidelines for Research on GMOs (May 2006)

Regulatory Authority for Food

Agri-food and Veterinary Authority of Singapore (AVA)

- Importation and sale of foods, including GM foods

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Singapore's Regulatory Laboratory for Testing GM Foods

AVA's Veterinary Public Health Laboratory

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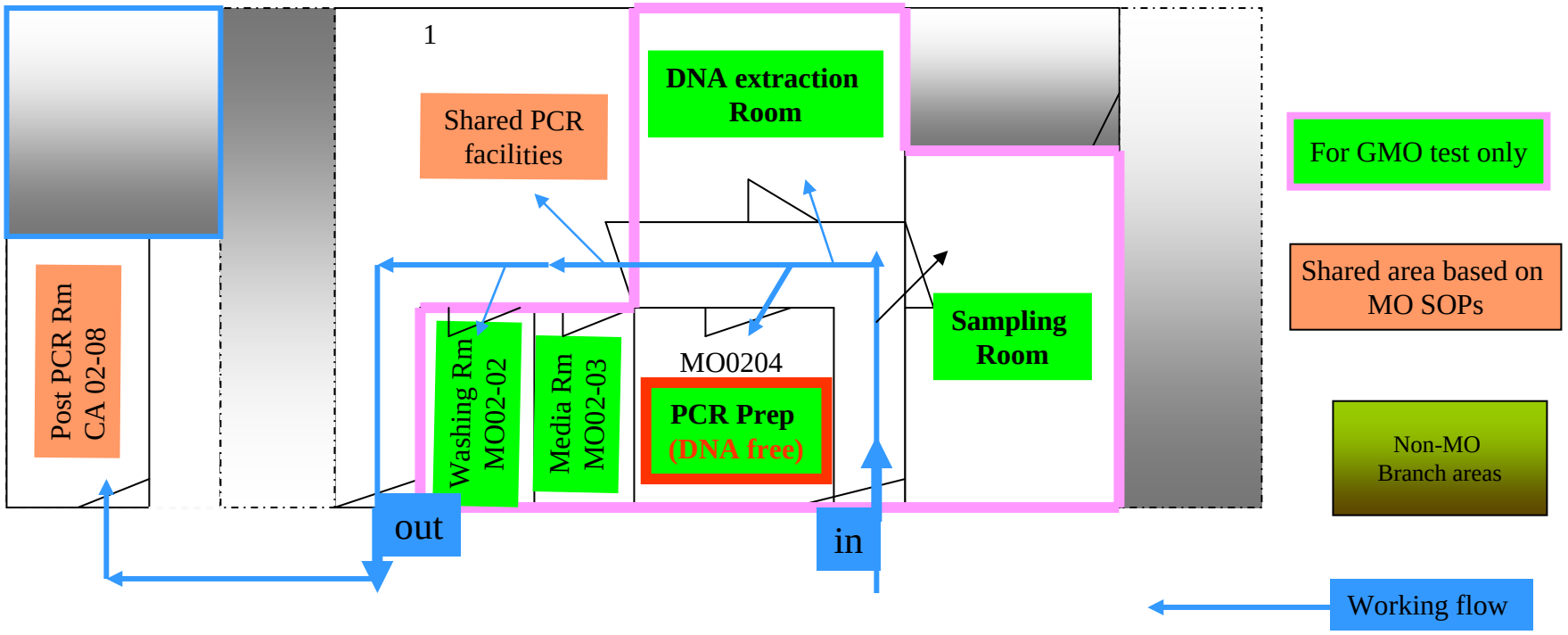
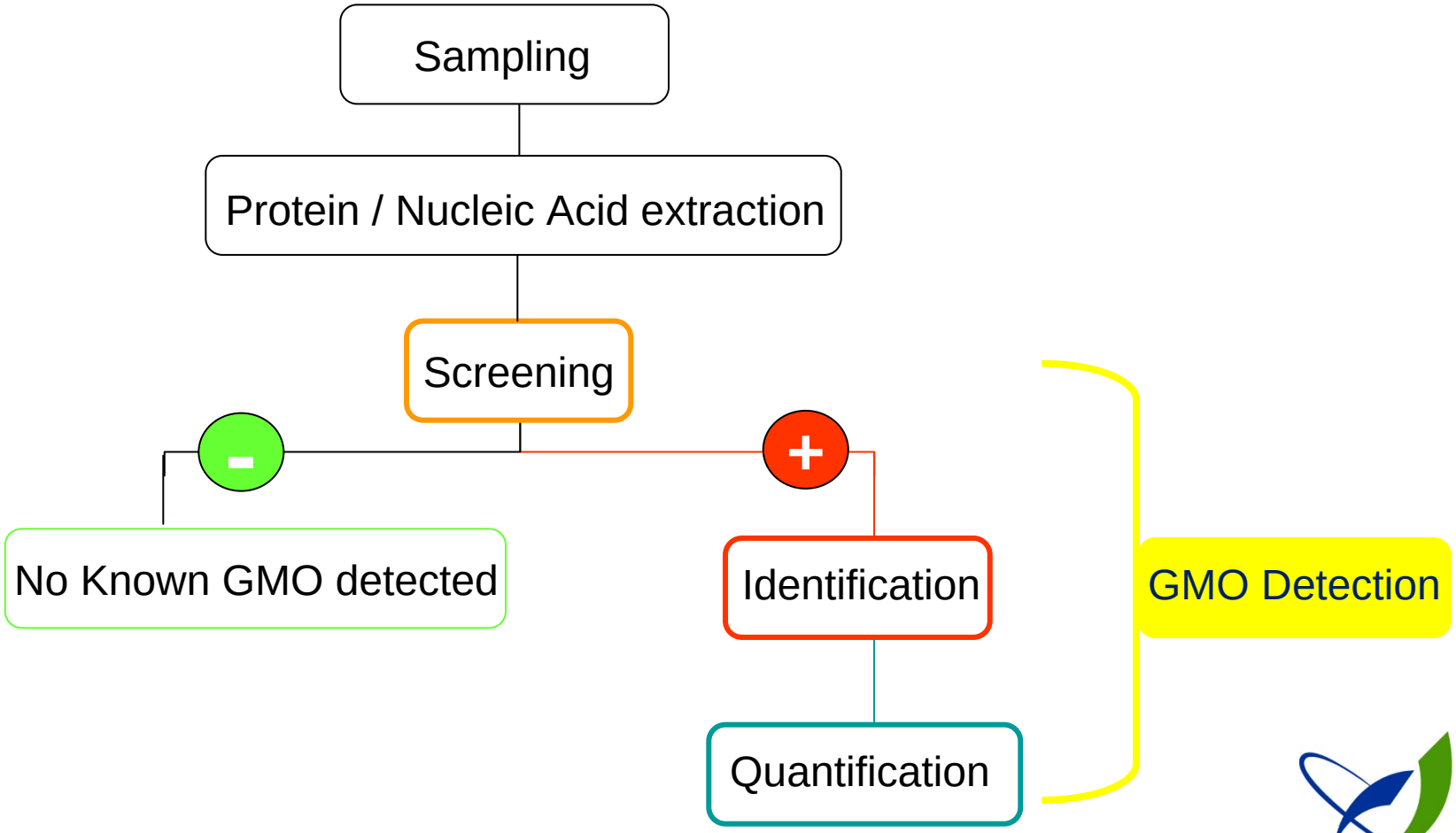
AVA's GM Food Testing Laboratory : Segregated lab working areas



AVA's GM Food Testing Approach (Overview)



GM Food Detection Capabilities

- Mainly DNA-based PCR analysis
- GMO marker screening
  - CaMV 35S promoter, NOS terminator, nptII selection marker, P35S:BAR
- Event / Construct specific qualitative detection
  - GM Maize (CBH351, T25, Bt 10)
  - GM Rice (LLrice 62, LLrice 601, Bt rice)
- Event / Construct specific quantitative detection
  - RR Soya, GM Maize events (Bt11, Bt 176, Mon810, Mon863, GA21, NK603, TC1507)
  - EH92-527- potato, RT73 canola

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Laboratory Quality Assurance

- **ISO/IEC 17025 Accreditation**
  - Singapore Accreditation Council-Singapore
  - Laboratory Accreditation Scheme (SAC-SINGLAS)
  - 48 detection methods accredited

- **Inter-laboratory Proficiency Schemes**
  - UK GeMMA Proficiency Program
  - USDA/GIPSA Proficiency Program
  - EC-ASEAN Proficiency Program

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ASEAN GMO Testing Network

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ASEAN GMO Testing Network: Genesis

- 1999: ASEAN Harmonized Guidelines on the Release of Agricultural Related GMOs

- 2004: ASEAN GMO Food Testing Network established by ASEAN Ministers on Agriculture and Forestry at its 25th Meeting

Singapore designated as the Lead Country of the network

To share and leverage on each others' resources and expertise to build up GM food testing capabilities

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ASEAN GMO Testing Network: Scope and objectives

As a regional cooperation platform for regulatory and scientific exchanges on issues related to GM food analyses

To contribute effectively towards harmonization and standardization of methodologies for sampling, detection, identification and quantification of GM foods in ASEAN

Enhancing collaboration and capacity building activities within and outside ASEAN

Annual meeting organised on rotational basis among ASEAN member countries

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BADAN POM
ASEAN MEETING GENETICALLY MODIFIED
OD TESTING NETWORK

Main Priorities for ASEAN GM Food Testing Network

(a) Information exchanges on regional and international developments in GMO analytical issues

- Methods of detection/quantification
- Reference materials
- Method validation and proficiency testing
- Performance criteria for testing methods

(b) Establishing a regional framework for method validation and proficiency testing alignment with international criteria

(c) Establishing a depository of GM reference materials

(d) Establishing a molecular registry of genetic manipulation for GMOs

(e) Updating listing of GMO testing labs and capabilities in AMCs
- services for AMCs without testing capabilities

(f) Organizing training and capacity building to address technical need within AMCs

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Technical issues and challenges

- Detection of unapproved events
- Lack of reference materials for GMO detection
- Detection of stacked events
- Analysis of highly processed food
- Production of plasmid DNA as alternative source of reference material
- Development of detection methods for GM crops developed in Asian Countries
- Practical approach for screening unauthorized GM crops
- Practical approach for estimation of MU for GMO quantitative analysis
- Detection of transgenic animals

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For further information

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Thank You