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POLICY BRIEF

A publication of the Policy Advocacy Group (PAG) of the Department of Science and Technology-
Philippine Council for Agriculture, Aquatic and Natural Resources Research and Development (DOST-PCAARRD)

Development of a Framework for Harmonizing Biosafety Guidelines and Research Protocols on Biosafety in the ASEAN Region

Harmonization can be defined as "the process of standardizing laws, regulations and parties to facilitate the expansion, fairness, and efficiencies in competing in a globalized economy and the sharing of technology for information and dissemination." Harmonization of biosafety guidelines and research protocols was initially conceived as a sectoral strategy in fast-tracking the potential benefits of products derived from modern biotechnology in the Association of Southeast Asian Nations (ASEAN) Region. It is an integral component in the operationalization of ASEAN Economic Community (AEC) Blueprint 2025.

Agribiotechnology is important in expanding food production frontiers and achieving food security in the ASEAN Region. Because of this, a DOST-PCAARRD-funded project on ***Development of a Framework for Harmonizing Biosafety Guidelines and Research Protocols in the ASEAN Region*** assessed the existing biosafety regulatory system and research protocols in the ASEAN Region in order to develop a harmonized system of standards and protocols in the Region.

The study used review of literature, participant observation with face-to-face interactions among ASEAN regulators, and integrated data analysis and synthesis. In the review of literature, assessments were made with the different models and experiences of harmonization primarily focused in Asia, the Asia-Pacific Economic Cooperation (APEC) and ASEAN countries, and to lesser extent, the

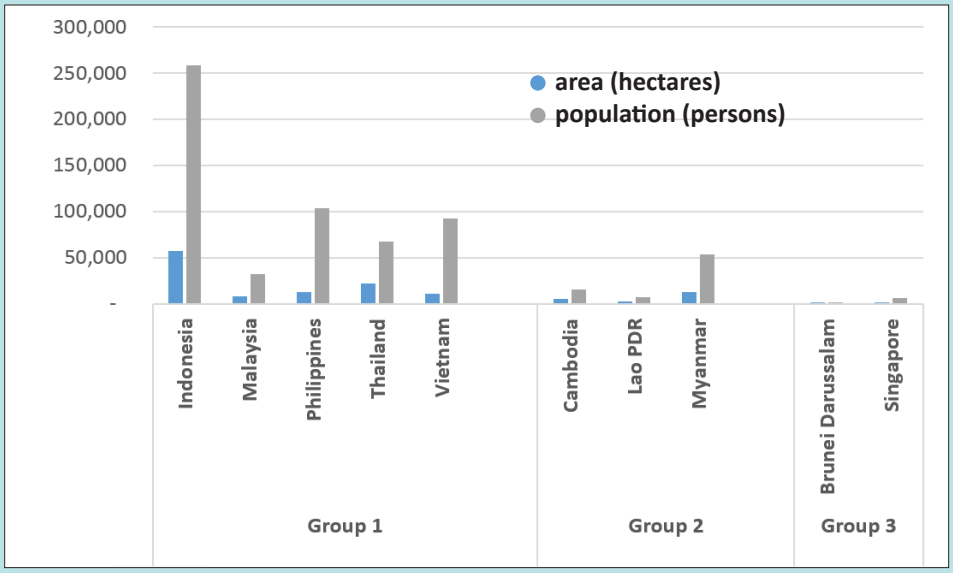
models of Europe and Eastern Africa. It also used the results of the workshop of a select group of regulators officially representing the 10 ASEAN member states (AMS) during the *2017 ASEAN Conference on Harmonization of Biosafety Guidelines and Research Protocols for Agricultural Products Derived from Modern Biotechnology*.

ASEAN AGRIBIOTECHNOLOGY PROFILE

The project came out with an ASEAN agribiotechnology profile of the 10 AMS classified into groups according to their levels of involvement in biosafety management and biotechnology development. Group 1 consists of Indonesia, Malaysia, Philippines, Thailand, and Vietnam, which have biosafety regulatory framework and assessment protocols. Group 2 includes Cambodia, Lao PDR, and Myanmar, which have draft or in-progress regulatory framework and assessment protocols. Lastly, Group 3 consists of Brunei Darussalam and Singapore, which do not have biosafety framework and assessment protocols.

Across the 10 AMS, the rapid growth of population (growing 50% during the past 20 years) coupled with the rising levels of incomes of 4.1% during the same period triggered the rising demand for food. This rising food demand, along with resource constraints and climate change where the AMS are most vulnerable, put the ASEAN Region in a disadvantaged position in sustaining food supplies. This economic setting brings further the strong argument for the region to explore alternative productivity-enhancing technologies, such as products derived from modern biotechnology, as part of the solution in improving the productivity of the agriculture and natural resource sectors.

Fig. 1. Population and agricultural area in the ASEAN, 2017.



Source: ADB (2017)

Uneven biotechnology and biosafety development in region due to the following factors was observed: population size, dependence on agriculture and food demand, technology readiness and capacity for innovation, government support, and public acceptance. These country variances partly explain the low adoption of biotechnology in the Region as a whole.

Population and food demand

Figure 1 shows the population size and agricultural land area of the 10 AMS. There is a descending order of magnitude in terms of population and agricultural land area from Group 1 to Group 3. This exhibits a similar pattern with the involvement of country groups to biotechnology and biosafety development, which was observed to be highest in Group 1 and lowest in Group 3.

Technology readiness and capacity for innovation

Wide divergence was observed in both technology and innovation parameters within and among the three groups (Table 1). The rankings of countries in Group 1 ranged from 46th to 80th for technological readiness and from 22nd to 71st for innovation. Meanwhile, Group 2 rankings were from 97th to 110th for technology readiness and from 81st to 110th for innovation. Finally, Group 3 which consists of Singapore and Brunei Darussalam had rankings of 14th and 60th, respectively for technological readiness and 9th and 80th, respectively for the capacity to innovate.

Singapore obtained the highest ranking in terms of innovation and technology readiness. Cambodia had the lowest score in terms of technology readiness, while Lao PDR ranks last for capacity for innovation; both countries are at the intermediate stage of biotechnology and biosafety development.

Table 1. ASEAN global ranking in terms of technology readiness and innovation.

Country	Technology Readiness	Innovation
Group 1		
Indonesia	80	31
Malaysia	46	22
Philippines	83	65
Thailand	61	50
Vietnam	79	71
Group 2		
Cambodia	97	110
Lao PDR	110	81
Group 3		
Brunei	60	80
Singapore	14	9

Source: WEF (2017)

Table 2. Public expenditures on agricultural R&D, ASEAN.

	Countries	Total Agricultural R&D Spending (million constant 2011 PPP dollars)	Total Agricultural R&D Spending as a Share of AgGDP (%)
Group 1	Indonesia	379	0.1
	Malaysia	592.3	1
	Philippines	133	0.33
	Thailand	171	0.3
	Vietnam	136	0.18
Group 2	Cambodia	22.4	0.2
	Lao PDR	24.2	0.4
	Myanmar	6	0.06
Group 3	Brunei	-	-
	Singapore	-	-
	ASEAN	**1463.9**	**2.57**

Source: SEARCA (2015)

Government support

The extent of government support in agriculture research was uneven across the three country groups. The more advanced group in terms of biotechnology development had the highest research and development (R&D) expenditure and collectively spent a higher portion of their agricultural output for R&D activities. The five countries in Group 1 had an R&D spending on agriculture ranging from US$133 to 592 million (M) while those in Group 2 ranged from only US$6 to 22 M (Table 2).

Group 3 was the least advanced group in biotechnology development as Brunei and Singapore had no data on public expenditure on agricultural R&D, which was possibly due to their extremely low dependence to agriculture.

PILLARS OF HARMONIZATION FRAMEWORK

Three pillars in establishing a framework for harmonizing biosafety guidelines and research protocols on biosafety is proposed. These were: full characterization of the regulatory system, integrated perspective of the biosafety guidelines and genetic modification (GM) introduction, and institutional capacity building.

Pillar 1: Full characterization of the regulatory system

Ten descriptive characteristics of a harmonization framework for biosafety guidelines and research protocols are proposed:

1. Inclusive – is open to all members of the ASEAN
2. Science-based – follows the basic rudiments of science in its decision-making process
3. Comprehensive – covers the different stages of development and introduction of products derived from modern biotechnology
4. Adequate legal authority – includes legal instruments in the assessment process
5. Clear safety standard – makes biosafety the foremost consideration in the assessment standards, which can be domestic or international in nature.

6. Transparent and understandable – makes public access to information a major component of biosafety regulation
7. Participatory – gives the opportunity to give information and comments to the public and regulators on regulations, guidance documents, and specific application before regulatory decisions
8. Flexible and adaptable – is able to adapt to the fast-paced innovations in biotechnology
9. Efficient, workable, and fair – can minimize cost of implementing the regulatory process to ensure safety to humans and the environment; treats stakeholders fairly
10. Predictable – gives key players the ability to execute long-term plans related to development and management of biotechnology products without unexpected costs and legal conflicts

Pillar 2: Integrated perspective on biosafety guidelines, research protocols, and GM introduction and development

For a harmonized framework for biosafety guidelines and research protocols to be sustainable, it must include an integrated perspective on the dynamics of the "biosafety guidelines-research protocols-GM introduction and development continuum." This integrated view is central to the AMS' understanding of their state of GM development and presence of in-country biosafety regulatory framework.

The study developed a matrix for integration of biosafety guidelines and protocols for harmonization. The matrix indicated the three groups of AMS relative to the status of their biosafety guidelines within the context of the different stages of GM introduction in individual ASEAN countries.

There are different stages of GM introduction that require certain compulsory guidelines and specific protocols for specific events. These stages are based on the Cartagena Protocol, a legally binding global protocol that seeks to contribute to ensuring the safe transfer, handling, and use of living modified organisms created through modern biotechnology.

The two basic stages of GM introduction are R&D and commercialization of GM products.

GM R&D starts with the confined and contained use up to field trials. Commercialization on the other hand, includes approval for the introduction of GM products for food, feed, and processing; commercial cultivation/production; and post-commercial monitoring activities.

The individual country domestic guidelines will determine the biosafety protocols given the specific GM events. In addition to domestic biosafety guidelines among AMS, there are additional international guidelines which are acceptable by the Cartagena Protocol at different stages of GM development.
The study classified international Standard Guidelines of GM introduction into four categories: R&D application; food, feed, and processing (FFP); field trials; and commercial propagation.

- **R&D application**. There are at least three guidelines that can be used in the development of protocols for R&D: the National Institute of Health (NIH) guideline for research involving recombinant DNA; good laboratory practices; and biorisk management on laboratory biosafety guidance.
- **Food, feed, and processing**. For the FFP segment of biotechnology level of intervention, there are at least six guidelines to base research protocols:
  - Risk assessment for feeds;
  - General standards for contaminants and toxins in food and feed;
  - Guidance document on Scientific Panel on GMO;
  - Safety assessments arising from GM food/feed;
  - Guidance document on traceability and labelling; and
  - Safety assessment of GMO food and feed.
- **Field trials and commercialization**. Five biosafety protocols and guidelines can be used in the risk assessment of field trials and commercial application. These are:
  - Roadmap for Risk Assessment of Living Modified Organisms;
  - Good Experimental Practices (GEP);
  - European and Mediterranean Plant Protection Organization (EPPO) Standards;
  - United Nations Environmental Programme (UNEP) International Technical Guidelines for Safety in Biotechnology; and
  - Guidance Documents by the Animal and Plant Health Inspection Service (APHIS).

(L–R) Dr. Leonardo A. Gonzales, workshop facilitator of the 2012 ASEAN Conference on Harmonization and President of the Society Towards Reinforcing Inherent. Viability for Enrichment (STRIVE), Inc. ; Dr. Seng Vang, former Chairman of the Sub-committee on Biotechnology (SCB) of the ASEAN COST and Deputy Director of the Cambodian Agricultural Research and Development Institute; and Dr. Reynaldo V. Ebora, Acting Executive Director of PCAARRD and focal person for the ASEAN COST-SCB.

Pillar 3: Institutional capacity building and regional collaboration

A third and a very crucial pillar to be included in the harmonization framework is the need for institutional capacity building at both the individual countries and the region. This aspect was accentuated during the sub-workshop on complementary institutional capacity building during the 2017 ASEAN Harmonization Conference.

Priority areas for biotechnology and biosafety development among AMS were identified and potentials for collaborative support for each were discussed. The plans for collaborative efforts were formulated by assessing which countries in the region are capable of providing support.

Capacity building was identified by the 10 regulator-delegates during the 2017 ASEAN Harmonization Conference. Vietnam, Thailand, Malaysia, and the Philippines were identified as lead countries to extend external efforts in order to foster progress on regional cooperation in capacity building.

As starters, the following activities were identified during the 2017 ASEAN Harmonization Workshop/ Conference.

1. Thailand volunteered to provide a translation of their existing training modules and other information materials on their website.
2. Malaysia was committed to collaborate with other AMS for the development of biosafety training programs. A draft curriculum and concept notes will be prepared by the delegates for approval and request for funding support from the ASEAN-Committee on Science and Technology (COST).
3. Vietnam and Indonesia were willing to provide technical support for trainings on field trials.

Table 3. Presence of regulatory instruments in the different stages of biotechnology development in the ASEAN.

Criteria/Level of GMO Development	Group 1										Grou		
	Indonesia		Malaysia		Philippines		Thailand		Vietnam		Cambodia		Lado
	a	b	a	b	a	b	a	b	a	b	a	b	a
1. R&D													
1.1 Confined and Contained Use	+	+	+	+	+	+	+	+	+	+	-	+	o
1.2. Application for Field Trial	+	+	+	+	+	+	+	+	+	+	-	+	-
2. Commercialization													
2.1 Introduction as Food and Feed													
2.1.1 Locally Produced [c]	+	+	-	-	+	+	-	-	+	+	-	-	-
2.1.2 Imported	+	+	+	+	+	+	+	+	+	+	+	+	o
2.2 Commercial Cultivation/ Production	o	o	-	-	+	+	-	-	+	+	-	-	-
2.3 Post-commercial monitoring	o	o	-	-	+	+	-	-	-	-	-	-	-

Source: SEARCA (2015)

[a] Guidelines.
[b] Legislations.
[c] For homegrown products with high potentials for commercialization i.e., GM Sugarcane in Indonesia; Golden Rice, Bt Eggplant, and GM Papaya in the Philippines; and Golden Rice in Vietnam.

+ Guidelines or legislations are in place.
o Development of guidelines or legislations is in-progress.
- Guidelines or legislations are not yet in place.

4. The Philippines volunteered to establish for the 10 AMS an office that will act as a depository data-sharing facility on biosafety/biotechnology and other information, including the monitoring of the process of developing the ASEAN harmonization initiative.

GAP ANALYSIS

A biotechnology gap analysis was also done to strengthen the commonalities and reconcile the differences among the 10 AMS. The commonalities within groups are strong. For example, in Group 1, almost all of the five countries have strong agribiotechnology interventions in R&D and in commercial imports of GM for FFP (Table 3). These strengths in biosafety regulations and research protocols in Group 1 can be used as a bridging mechanism for the other ASEAN countries who are in Groups 2 and 3.

The implication of the gap analysis was to prioritize the segments of the agribiotechnology levels of development to harness the strengths and reconcile the gaps across the ASEAN as the bases of capacity building, which is the domain of the third pillar of the framework.

POTENTIAL SOCIO-ECONOMIC AND RELATED BENEFITS OF HARMONIZATION

Establishing an effective and efficient regional harmonization of biosafety guidelines and protocols can provide ASEAN member countries opportunities in their pursuit of attaining their goal of sustainable inclusive economic growth and development. Among others, these inclusive opportunities include lower regulatory cost; faster adoption of GM technologies; expansion of ASEAN intra and rest-of-the-world trade in agricultural products; enhancing productivity of the feedgrain-livestock sectors in the

up 2			Group 3			
PDR	Myanmar		Brunei		Singapore	
b	a	b	a	b	a	b
o	-	-	-	-	+	-
-	+	-	-	-	-	-
-	-	-	-	-	-	-
o	+	-	-	-	+	-
-	-	-	-	-	-	-
-	-	-	-	-	-	-

ASEAN Region; and cross-cultural integration for capacity building activities.

Lower regulatory cost

Standardized and regionally harmonized biosafety procedures can reduce cost of biosafety compliance. First, they reduce the cost of routine data and information requirements that can delay biosafety assessments. For example, across the same and similar ecological zones, common standardized science-based protocols can be used, instead of following the repetitive process of data generation and presentation. This can only be achieved, however,

***Bt* corn farmer in the Philippines. Image credit: SEARCA-BIC**

if the regulators understand the procedures and processes and are in agreement to put these processes together on the ground.

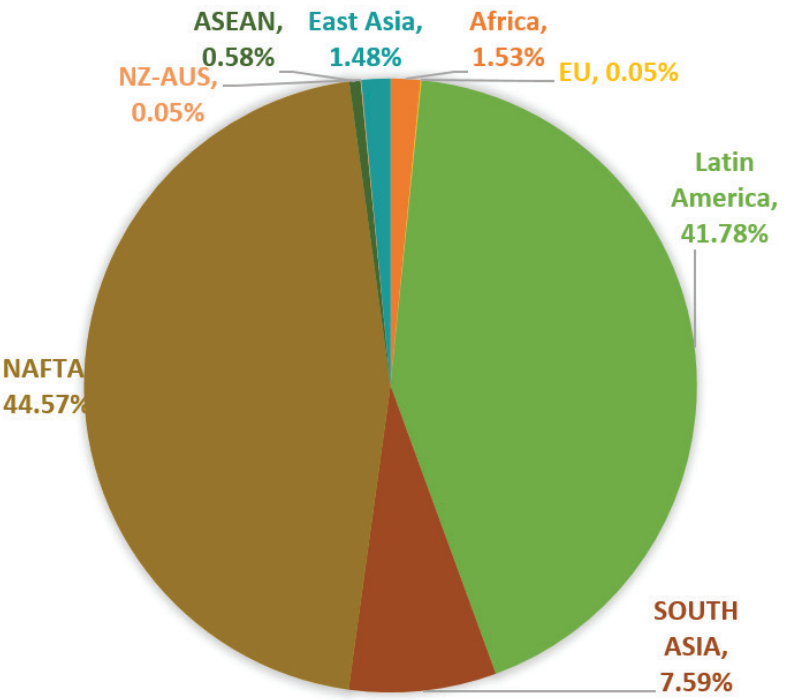
Faster adoption of GM technologies

The potentials for GM crop adoption in the ASEAN region is large, but in 2017, the total share of ASEAN was only a meager 0.58% (Fig. 2). The positive socio-economic benefits of GM crops have been empirically proven globally (Brookes & Barfoot 2016), especially their impact on productivity, farm income, and the environment. Given that these technologies are already available in developed countries, it would be much faster to adopt them in the ASEAN region; with an effective ASEAN harmonized guidelines and protocols.

Expanding ASEAN intra and rest of the world trade in agricultural products

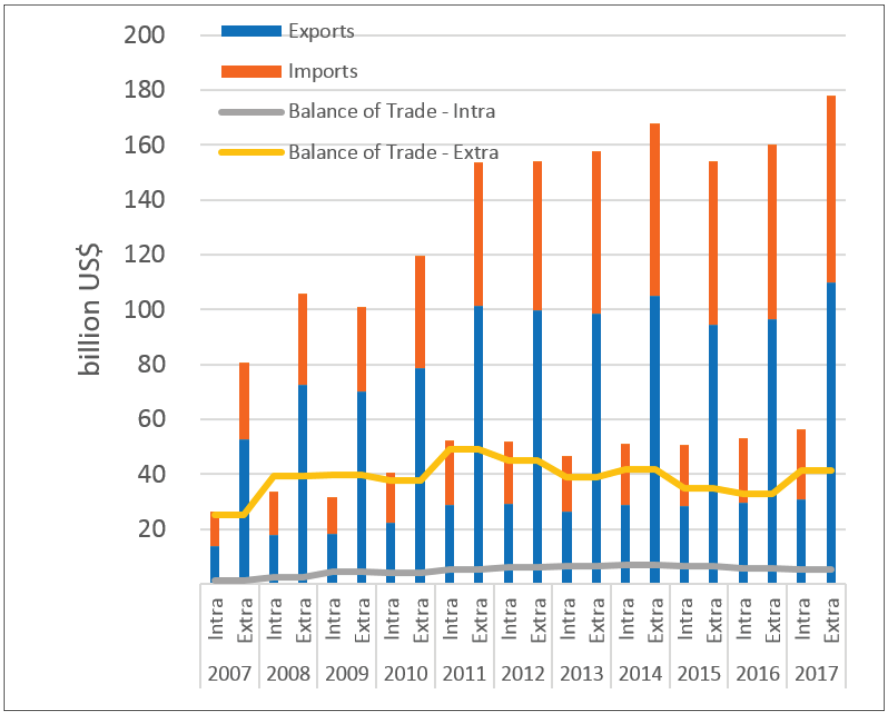
The ASEAN region was a net exporter of food and agricultural feed products both within the ASEAN region and the rest of the world in 2017 (Fig. 3). However, its trade balance with the rest of the world, averaging to US$39.23 billion (B) from 2012 to 2017, had declined in the past 5 years, while ASEAN intra-trade balance, with an average value of US$ 6.15 B, had been constant during the same period. An effective harmonized biosafety guidelines and protocols can trigger commercial adoption of GM food and feed crops that can competitively expand the trade balance of intra-ASEAN and rest of the world trade.

Fig. 2. Regional distribution of GM crop adoption, 2017.



Source: ISAAA (2017)

Fig. 3. ASEAN Trade on Agricultural Goods within the Region and with the rest of the world, 2000–2017.



Source: ASEAN database (2018)

Enhancing the productivity of the feedgrain-livestock sectors

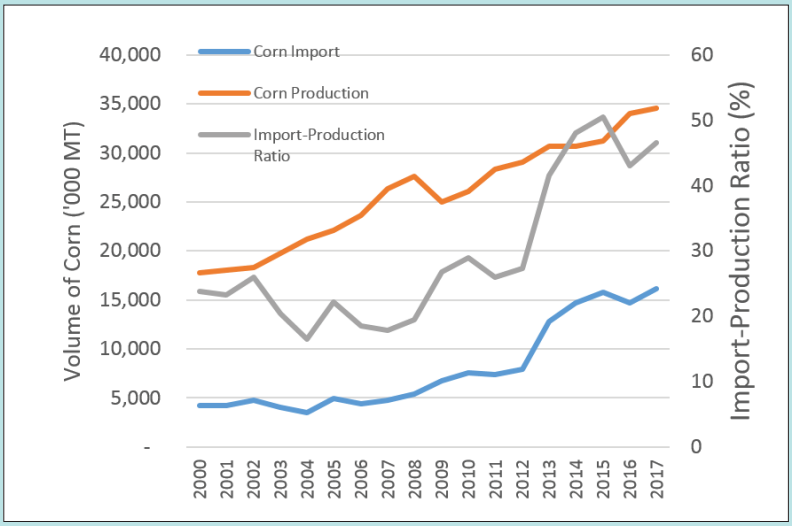
The ASEAN region was a net importer of feed stuff such as corn and soybeans in 2017. The ratio of corn imports to corn production averaged 53% (United States Department of Agriculture (USDA 2017) in the past 5 years (Fig. 4).

Soybean meal imports on the other hand, were way above the domestic production in the region. The import production ratio averaged 398% from 2013 to 2017 according to USDA (Fig. 5).

The combined value of ASEAN corn and soybean meal imports in 2016 was estimated by USDA at US$ 7.972 B (Fig. 6). If the region has an effective harmonized biosafety guidelines and protocols, the region can save foreign exchange through import substitution activities.

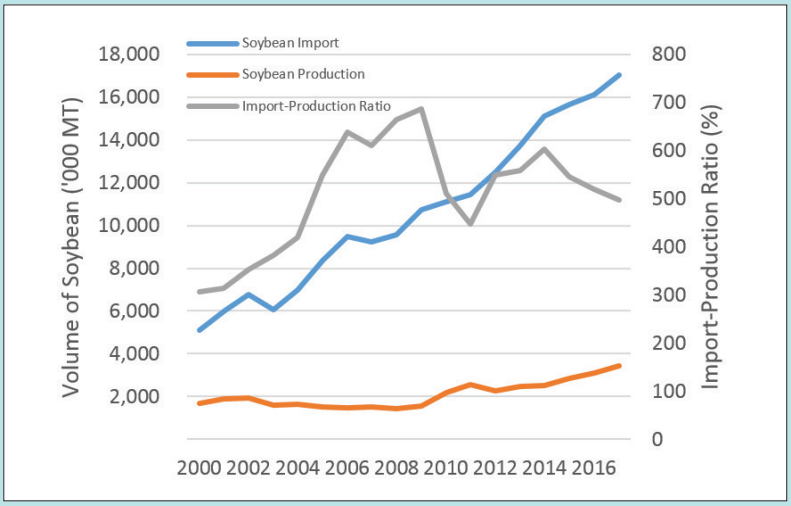
The feedgrain-livestock subsectors are structurally integrated in ASEAN. The intra-trade tariff rates of feed products averaged to zero in contrast to the most favored nation (MFN) tariff of the World Trade Organization (WTO) at 1.27%. Likewise, the tariff rate under MFN for livestock products is 10% while under ASEAN it is only 3% (WTO Database 2017). The integration of the feedgrain-livestock subsector can be an efficient economic activity in the Region given the high productivity and cost efficiency of GM corn production.

Fig. 4. Corn import, production, and import-production ratio, ASEAN: 2000–2017.



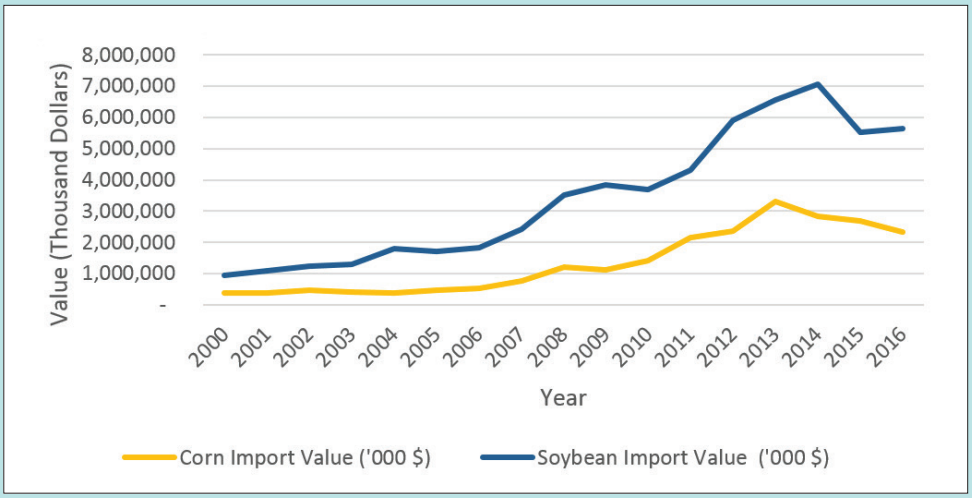
Source: USDA (2017)

Fig. 5. Soybean meal import, production, and import-production ratio, ASEAN: 2000–2017.



Source: USDA (2017)

Fig. 6. Corn and soybean import value, ASEAN, 2000–2016.



Source: IMF (2017) and USDA (2017)

OPERATIONALIZING THE CONCEPTUAL FRAMEWORK OF HARMONIZATION

A flowchart on how to operationalize harmonization in the region is presented in Figure 7**.** It concluded that two priority areas should be entry points: R&D and direct use for FFP.

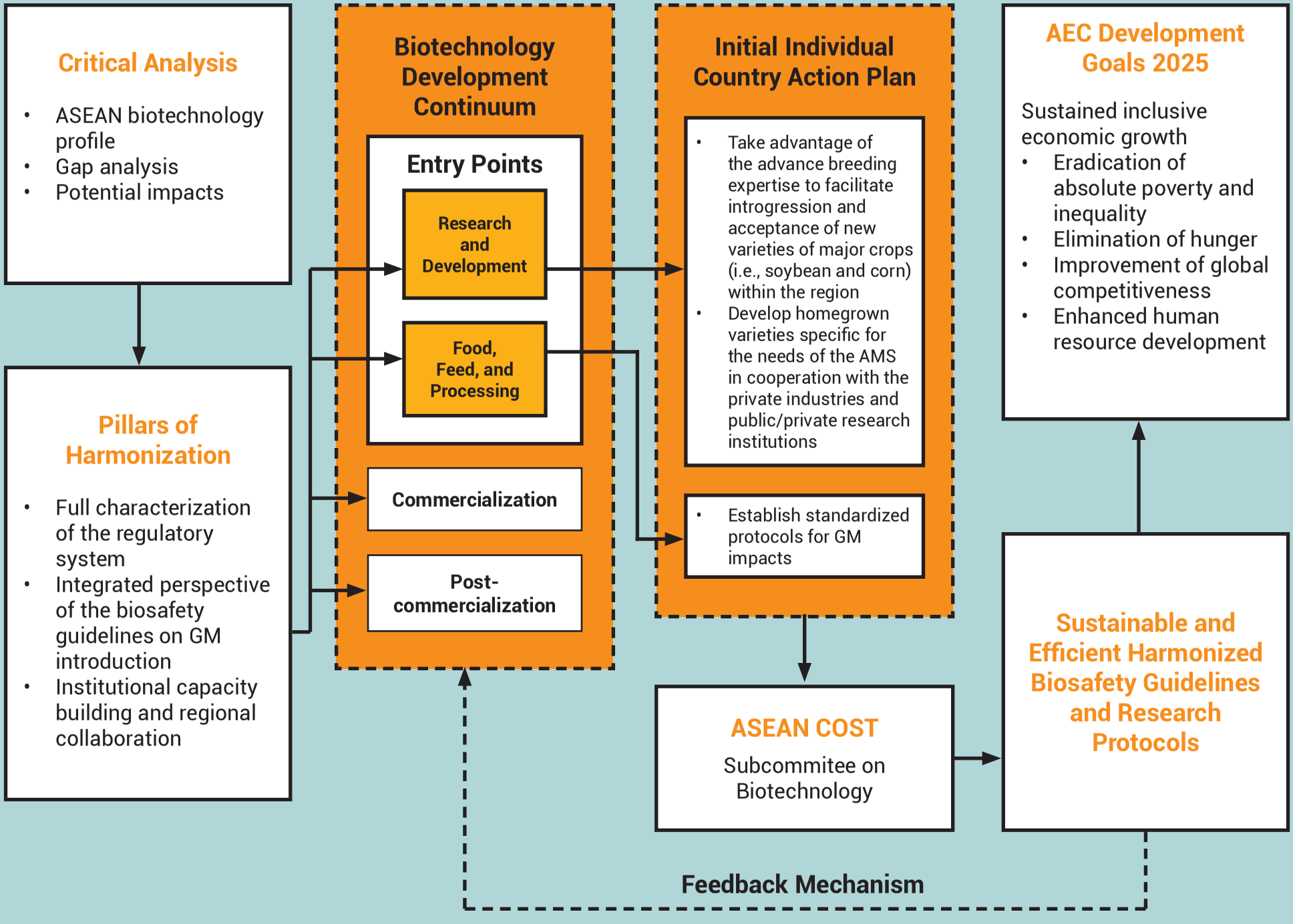
For individual countries, their initial action plan for R&D should be focused on two areas. These are:

1. to take advantage of the advanced breeding expertise to facilitate introgression and acceptance of new varieties of major crops within the region; and
2. to develop homegrown varieties specific for the needs of the AMS in cooperation with the private industries and public/private research institutions.

For direct use as FFP, the priority is the development of standardized protocols for GM imports. Once individual countries have established their standard FFP protocols, these can then be shared by the 10 AMS for harmonization.

Finally, the overriding goals of establishing an operational harmonization framework were those embodied in the AEC Blueprint 2025 in attaining sustained inclusive economic growth (eradication of absolute poverty and inequality, elimination of hunger, improvement of global competitiveness, and enhanced human resource development). The process of attaining these development goals through harmonization is via the institutional mechanism of the ASEAN COST, more specifically SCB.

Fig. 7. Operationalizing the conceptual framework for harmonizing biosafety guidelines and research protocols in the ASEAN region.



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EDITOR'S NOTE

This paper is based on the DOST-PCAARRD and STRIVE Foundation project, "Developing a Framework for Harmonizing Biosafety Guidelines and Research Protocols on Biosafety in the ASEAN Region," under the leadership of Leonardo A. Gonzales.

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POLICY BRIEF highlights DOST-PCAARRD's stance on policy issues on S&T in agriculture, aquatic, and natural resources through the coordination of the *Policy Advocacy Group (PAG)*. The PAG spearheads policy and advocacy related to PCAARRD Medium-term Plan.

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