

TRANSDICIPLINARY APPROACH TO MAKING SCIENCE-BASED TRANSGENIC PRODUCTS POLICY RECOMMENDATIONS

Pendekatan Transdisiplin untuk Menyusun Saran Kebijakan Produk Rekayasa Genetik Berbasis Ilmu Pengetahuan

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ABSTRAK

Peraturan Pemerintah No. 21 Tahun 2005 Tentang Keamanan Hayati Produk Rekayasa Genetik mensyaratkan bahwa rekomendasi keamanan hayati produk rekayasa genetik harus mempertimbangkan aspek agama, etika, sosial budaya dan estetika serta didasarkan atas prinsip kehati-hatian dan menggunakan ilmu pengetahuan dan statistik yang sah. Tulisan ini menggunakan kerangka yang dikembangkan oleh Choi (2005) sebagai bahan untuk mempelajari proses perumusan rekomendasi berdasarkan prinsip ilmu pengetahuan. Dua konsep dasar digunakan sebagai pemicu pemikiran, yaitu: pertama, konsep rekomendasi berdasarkan ilmu pengetahuan yang sah dan kedua, konsep tanaman transgenik atau produk rekayasa genetik (PRG). Rekomendasi berdasarkan ilmu pengetahuan mengandung makna bahwa ilmu pengetahuan digunakan sebagai sumber pengetahuan untuk merumuskan rekomendasi; dan, konsep transgenik memberikan inspirasi bahwa teknologi baru melahirkan sesuatu yang pada masa lalu merupakan hal yang tidak mungkin ada sekarang menjadi realita. Dengan memanfaatkan proses dan keilmuan transdisiplin diperkirakan akan dihasilkan rekomendasi kebijakan tentang keamanan hayati produk rekayasa genetik yang lebih baik. Kesimpulan umum yang dapat ditarik dari tulisan ini adalah diperlukannya peningkatan kapasitas kelembagaan dalam rangka peningkatan kemampuan menerapkan ilmu pengetahuan dan teknologi sebagai metode yang sah dalam proses perumusan rekomendasi kebijakan di bidang produk rekayasa genetik dengan menerapkan metode pendekatan keilmuan transdisiplin dan prinsip kehati-hatian.

Kata kunci : *keamanan hayati, produk rekayasa genetik, transdisiplin, tanaman transgenik*

ABSTRACT

The Government Regulation No. 21, 2005 of biosafety for genetically engineered products considers aspects of religions, ethics and aesthetics in its policy recommendations and produces recommendations based on the precautionary principle and justifiable scientific methods. The formula developed by Choi (2005) was provided as an example of a science-based policy recommendation making process. Since solving a certain problem

cannot be done without regarding the possible emergence of new problems, a transdisciplinary knowledge-based recommendation making will provide better outcome. The general conclusion is that we need to develop our institutional capacity in order to be able to apply a method of policy recommendation making process in the format of transdisciplinary approach to making science-based transgenic products policy recommendations.

Key words : *biosafety, genetically engineered products, transdisciplinary, transgenic crops*

INTRODUCTION

When physics describes light in seven different colors, as the colors of the rainbow, people realize that light color is neither white nor bright. We have learned that science provides explanation by evidence. Moreover, when thinking about why European eating culture includes the use of plates, forks, spoons, knives and other utensils while Chinese eating culture uses chopsticks and other different utensils, people will think that those differences are not a part of science. They are a part of culture.

However, people also think that science is a part of culture. The origin of science is started from a tradition of asking questions. In a culture where questioning is prohibited, science will not thrive. Science is also a derivation of philosophy. When a philosophy means love of wisdom or love of knowledge then we will see that in a society when love of wisdom or love of knowledge is the foundation of daily life, science will grow.

When we talk about agriculture, we observe a more than 7000 year evolution. People will agree that before community members defined themselves as farmers, they used to be hunters and gatherers that moved to *swidden* (slash and burn) agriculture. Of course, they developed sciences and technologies from which we continue to benefit, starting all the way from selections of domesticated animals, plants, and microorganisms up to building modern and complicated infrastructures and how to serve our food. Food and agriculture have determined our civilization. These facts demonstrate that our ancestors gave us one of the most valuable things in the world.

At the end of the 20th century, more precisely in 1996, the world proclaimed that a new revolution in agriculture had started. The new revolution was to mean the beginning of human actions in application of science and technology to change the characteristics of an organism. According to scientists and technologists this can be accomplished by using a technique of recombining DNAs from two or more different kinds of organisms. The result is usually called Genetically Modified Organism (GMO).

Since 1996, application of GMOs was not in a small area of field experiments. Indeed, GMOs had been planted on about 1.7 million hectares. What comparatively was the size of area planted by GMO crops in 2010? All over the world, GMO crops were about 148 million hectares in 2010. We observed that within about 15 years the world of agriculture had planted land areas 87 times larger than since GMO's beginning.

What is the world opinion regarding the above trend? What are the meanings of that trend? The world is one. But, there are varieties of views among the world's inhabitants.

In terms of GMOs, the world divides itself into two opposing viewpoints. The sources of differences are differences in ideology, philosophy, beliefs or even their interests. When the sources are ideology, philosophy, beliefs or interests, then the reasons behind the different points of view are not scientific because they are very subjective. For example, when we ask someone why they don't like to eat fish, the answers would be very subjective. The choice here is not a matter of benefit-cost ratio consideration. Benefit-cost ratio, of course, is important but not the only scientific reason behind a choice. Choice is a more complicated process and science can be used or applied in all aspects of human understanding in order to help people to be able to make a better choice.

Therefore, the position of a science based policy-making process in making recommendations for GMOs plays a crucial role in increasing institutional learning capacity. This paper was inspired by two concepts: firstly, a science based recommendation and, secondly, transgenic crops or GMOs. A science based recommendation means that science is used as the method of making recommendations; and, transgenic is inspired by that which in the past was impossible is now feasible through newly developed science and technology. However, we also acknowledge that sometimes when one problem was solved by a new means such as infectious diseases being cured by antibiotics, new problems emerged because the diseases now are becoming antibiotic resistance. This means that solving a certain problem cannot be done without regarding the possible emergence of new problems. It is thought that through a multidisciplinary problem solving research a transdisciplinary knowledge base can be developed for making better recommendations (Johnson, 1986). I propose that our subject of analysis is not transgenic crops *per se* but its risks whether those which are only perceived, or believed to be an integral part of the created GMOs.

TWO BASES CREATE DIFFERENT POSSIBLE RULES

A substantial equivalent criterion views that risks associated with GMOs are represented by deviation in characteristics between the created crops and the common conventionally accepted crops. If the characteristics of both are not

different from the conventional crop reference with respect to the environment and health, then GMOs can be recommended to be released to markets.

On the other hand, precautionary principle guides suggest that risks should be avoided by using certain rules. Science is accustomed to guidelines for establishing rules that should also be followed in doing GMOs risk assessment. So, here we can say that a certain recommendation is safe according to certain rules.

Which one is the more scientifically based recommendation making procedure: precautionary principle or substantial equivalence criterion, given the case of making recommendations for GMOs?

I propose that we cannot answer the above question by using no explicit philosophical research methodology as our methodological foundation because certain philosophical or methodology attaches itself into how that methodology sees the real world. For example, normativism values such as rightness/wrongness and goodness/badness are a part of reality, so values are a subject of science. On the other hand, for positivism, values are only in the knowing mind, so values are not the subject matter of science. For positivists, science only deals with value-free positivistic knowledge. Positivists when dealing with values usually develop a conditional normativism methodological orientation; namely they only assume that values are a part of the real world. Another commonly used methodological orientation in policy making analysis is pragmatism which says that value-free positivistic knowledge and knowledge about values are always interdependent.

Scientific methods are methods that are developed according to certain rules that will be elaborated in the following section. What I would like to propose now is that all different methodological orientations described above can use the same or different scientific methods depending on what the problems are to be solved. On the other hand, problem definition cannot be independent of what one believes to be true, and the latter is dependent on the methodological orientations one holds. So, science is not independent from judgment (Tompson, 2003). Otherwise stated, it means that a scientist of one field of study cannot claim that the truth is only him or herself-finding.

So, what is the truth? The truth is evolving, as we learn from the cases of Copernicus or Columbus. It means we cannot wait until having the complete truth in order to make decisions because to have complete truth by itself is impossible. Making recommendations is a process of using science; it is not making science. Therefore, the test of objectivity in using or implementing science is not with its scientific soundness only but also its recommendation workability to solve a certain problem being faced. We must also understand that a problem being solved is also evolving. This means we have to be ready to develop a system of anticipation for any recommendation delivered by government.

Conflicting views are usually generated by conflicting interests held by the parties involved. In purely economic choice, conflict of interest is usually resolved by price mechanism through the process of the supply-demand mechanism. In the case of non-marketed goods such as risks in association with genetically engineered products, the world comes with a very intensive regulatory framework.

Ramessar *et al.* (2009) characterized the distinctive features between the two centers of developed western countries' basic thought frameworks in dealing with transgenic products. While the first group follows substantial equivalence criterion as used by the US, the second group applies the precautionary approach as used by the EU's foundation. He described the distinctive features as follows: "Basically, the US comparative approach seeks to determine whether a GM product has the same risk as its non-GM contemporary, whereas the EU precautionary approach assumes that a GM product is inherently hazardous and requires tests to be carried out to demonstrate safety".

The precautionary approach is incorporated into the decision procedures of the Cartagena Protocol. According to the Cartagena Protocol precautionary principle takes the position that risks are embodied in biotechnology crops and certain developed standard operating procedures should be followed to evaluate whether a recommendation can be released for developing genetically engineered products from their conception up to their commercialization, including monitoring and evaluation.

Antofie and Sand (2009) by reviewing published political statements, strategy and existing legislation at EU predicted that the European Union will accept modern biotechnology in the near future. Their prediction was in line with the development of utilization of modern biotechnology products and services in other developed countries over the past 15 years. This situation has influenced the European Union view of biotechnology. One of the most important impacts on the philosophy of thinking, at least from a scientific point of view that is generally agreed upon now, is that "the lack of scientific evidence should not be a barrier against the commercialization (WTO-TBT agreement) of these products and that biotech research should be continuously developed (Antofie and Sand, 2009).

Antofie and Sand (2009) also showed that at the European Union level, genetically modified plants are considered by the Council Decision of December 2008 as a "subject of public controversy because their advantages for society in general and for agriculture in particular are disputed".

Based on Antofie and Sand (2009), the following were the most important changes in European Union policies: (1) EU has adopted a comprehensive legal framework for the authorization of GMOs; (2) at the EU political level it is recognized that GMOs give rise to public debates, including the scientific community; and (3) that is necessary to look at improvement of the implementation of this legal framework in order to better meet the objectives of

the EU legislation, i.e., that as scientific research generates more quality findings, policy makers will make better decisions. However, numerous underlying obstacles exist (p.1).

INDONESIA LAWS AND REGULATIONS IN TRANSGENIC PRODUCTS

As a part of the international community, Indonesia has been playing an active role in international affairs. Indonesia became a party of both the Convention on Biological Diversity and Cartagena Protocol. Indonesia's ratification of the Cartagena Protocol was legalized by "*Undang-Undang Republik Indonesia Nomor 21 Tahun 2004 tentang Pengesahan* Cartagena Protocol on Biosafety at the Convention on Biological Diversity". For Indonesia it took four years from adoption to ratification of the Cartagena Protocol to the enactment of Law No. 21, 2004.

Based on Law No. 21 mentioned above, the government of Indonesia enacted "*Peraturan Pemerintah* (Government Regulation) *Republik Indonesia Nomor 21 Tahun 2005 Tentang Keamanan Hayati Produk Rekayasa Genetik*", which was signed by Presiden Susilo Bambang Yudhoyono, May 19, 2005.

In Government Regulation No. 21, 2005 cited earlier, it is mentioned in Chapter V, Part I, Article 14, Article 15, Article 16, and 17, among others, the roles, tasks and functions of the Biosafety Commission of Genetically Engineered Products (CGEP) (*Komisi Keamanan Hayati Produk Rekayasa Genetik/ KKHPRG*) as an institution that has a specific task to support the cases of transgenic products in Indonesia. The CGEP/KKHPRG was established by "*Peraturan Presiden* (President Regulation) *Republik Indonesia Nomor 39 Tahun 2010 tentang Komisi Keamanan Hayati Produk Rekayasa Genetik*" which was enacted by President Susilo Bambang Yudhoyono on June 15, 2010.

Indonesia now has the laws, government regulations and the organizations that have functional tasks and obligations to implement a part of a regulatory framework in Indonesia. Major tasks of the CGEP are: (1) to provide a recommendation of biosafety to the Minister of Environment, authorized Minister and to the Head of Non-Ministerial Bodies; (2) to give a certificate of environmental biosafety, food safety and feed safety to the Minister of Environment, authorized Minister and to the Head of Non-Ministerial Bodies; (3) to give suggestions and considerations to the Minister of Environment, authorized Minister and to the Head of Non-Ministerial Bodies in inaction of environmental impact monitoring, risks management and withdrawal of GMO from its distribution; and (4) to assist the Minister of Environment, and authorized Minister and to the Head of Non-Ministerial Bodies in conducting inspection to the entry

and utilization of GMO as well as inspection and proving to the truthfulness of the report on the existence of negative impact of a GMO.

According to the President Regulation, the CGEP has the following functions in relation with GMOs, namely: (1) Formulation for guidelines preparation for environmental biosafety, food safety, and/or feed safety as well as monitoring GMO utilization; (2) Conduct an assessment and/or technical evaluation on a proposal of environmental safety, food safety, and/or feed safety for the purpose of releasing and/or distributing GMO; (3) Informing the general public about implementation of environmental safety, food safety, and/or feed safety through the GMO Clearing Office (GMO CO); (4) Information management on environmental safety management, food safety, and/or feed safety by GMO-CO; (5) Provide a recommendation for releasing and/or distribution of GMO Products either from overseas or from domestic entities; (6) Provide a suggestion on how to control and to manage if GMO's negative impacts occur; (7) Examination and proving evidence on report of occurrence of GMO negative impacts; (8) Conduct cooperation and consultation with variety of institutions in Indonesia or in other countries in the areas of environmental safety, food safety, and/or feed safety; (9) Conduct evaluation and verification of environmental safety, food safety, and/or feed safety of GMO; (10) Provide recommendation in determining guidelines for impact monitoring and risks management of GMO; and (11) Provide recommendation in determining a procedure for withdrawal of GMO.

The following are examples of values statements which are contained in Government Regulation No. 21, 2005:

1) Statement of Goal (Article 2: (1)):

The goal of this Government Regulation is to create environmental safety, food and/or feed safety of a GEP as well as its utilization in agriculture, fisheries, forestry, industry, environment, and non-pharmaceutical health. Here we see that environmental safety, food and/or feed safety of genetically engineered crops are good things to be attained.

2) Statement of Objective (Article 2: (2)):

The objective of this Government Regulation is to increase efficiency and effectiveness of genetically engineered products for the welfare of the people based upon health and management of biological resources principles, consumer protection, certainty of law and certainty of business. Here we learn that increased efficiency and effectiveness of genetically engineered crops are good to be reached.

3) Statement of Approach (Article 3):

This Government Regulation uses the precautionary approach in order to create environmental safety, food and/or feed safety which are based upon justified scientific methods as well as taking consideration of rules of religions,

ethics, sociocultural aspects and aesthetics. Here we are guided by the principle that using the precautionary approach is a right thing to do and thus should be implemented as a basic principle for making recommendations.

The scope of subjects that is regulated by the Government Regulation No. 21 includes:

- a) Type and requirement of genetically engineered products
- b) Research and development of genetically engineered products
- c) Entering genetically engineered products from overseas
- d) Assessment, release and distribution and utilization of genetically engineered products
- e) Inspection and control of genetically engineered products
- f) Institution, and
- g) Funding

Here we learn that Government Regulation No. 21 assumes that factors other than items a) through g) above are not important or can be neglected.

Government Regulation No. 21 provides explanation of Article 3, namely a more elaborated description of the precautionary approach. According to this regulation, a precautionary approach is an approach in a decision making process in order to avoid the possibility of significant negative impacts on the environments and human health, even before the conclusive scientific evidence about those impacts emerge. In this Government Regulation a precautionary approach is implemented within the rules that before any a genetically engineered products can be utilized the environmental risks assessment and management, food and/or feed should be conducted prior to its utilization using justified scientific methods and considering sociological, economic and ethical factors in order to warrant that risks of utilizing a genetically engineered products on the environments and human health can be accepted based upon the enacted available rules and regulations. Considerations from rules of religion, ethics, sociocultural, among others, genetic resources that are transformed into a new crop or food or feed must have no contradiction with religious rules of certain religions, form or phenotype of a genetically engineered products must be identical with its parents and corresponds to the present esthetics.

Let us further elaborate on the approach used in Government Regulation No. 21, 2005: A precautionary approach is an approach within the context of the existence of risks and uncertainties in:

- a decision making process (1), in order to avoid (2) the possibility of significant negative impacts (3)

- to the environment (4) and human health (5), even before the conclusive scientific evidence about those impacts that emerge (6) before any genetically engineered products can utilize the environmental risks assessment (7) and environmental risks management (8), food (9) and/or feed safety (10) should be conducted prior to its utilization (11) using justified scientific methods (12), and considering sociological (13), economic (14) and ethical (15) factors in order to warrant (16) that risks of utilizing genetically engineered products on the environment and human health can be accepted (17) based upon the enacted available rules and regulations (18), considerations from rules of religion (19), ethics (20), and sociocultural aspects (21).

The first output from agencies that have roles to give policy input to the Government of Indonesia is the output of the Biosafety Commission for Genetically Engineered Products. Based upon the description presented above we learn that the goals, objectives, and basic principles that guide the means to achieve the goals and objectives require a substantial amount of information and high capabilities of institutions to collect, ~~to~~ select, ~~to~~ analyze and ~~to~~ use data and information of the whole process of making policy recommendations. It is mandated to all of us to develop comprehensive systems of risk assessment that can fulfill all tasks and functions dictated by laws and regulations.

PROCESS OF SCIENCE-BASED RECOMMENDATION MAKING: Toward Transdisciplinary-Based Recommendation Making

In this Section I brought an example of a science-based policy making framework in the area of public health as provided by Choi (2005). Choi classified 12 essentials or basic elements of science-based policy that are grouped into three classes of broader elements: (a) knowledge generation (credible design, accurate data, sound analysis, and comprehensive synthesis); (b) knowledge exchange (relevant content, appropriate translation, timely dissemination, and modulated release); and (c) knowledge up-take (accessible information, readable message, motivated user, and rewarding outcome) (p.1), as shown in Table 1.

According to Choi (2005), “a systematic framework can be used to describe the key components that link science to policy reveals issues and solutions related to science-based decision making.” Choi defined policy to include not only legislation but also “prudence or wisdom in the management of affairs” and “a definite course or method of action selected from among alternatives in light of given conditions to guide and determine present and future decisions”.

Science-based policy involves producing high-quality scientific evidence, building bridges between the producers and users of scientific evidence and

incorporating scientific evidence into an applied policy and practice. In the process of knowledge generation, there are four aspects that should be attained, namely a credible design to facilitate study or analysis, collecting accurate data, developing sound analysis and doing comprehensive synthesis. However, doing all of them right is not an easy job.

Table 1. Three Areas and Twelve Essentials of Science-based Policy

Areas		
Knowledge Generation	Knowledge Exchange	Knowledge Uptake
1. Credible design	1. Relevant content	1. Accessible information
2. Accurate data	2. Appropriate translation	2. Readable message
3. Sound analysis	3. Timely dissemination	3. Motivated user
4. Comprehensive synthesis	4. Modulated release	4. Rewarding outcome
Produce:	Resulted in:	Knowledge utilization will be better in the sense of:
1. Value-free positivistic knowledge	Knowledge exchange or transaction will enrich:	1. Efficiency and effectiveness of risk analysis, risks management and risks control;
2. Value knowledge	1. Better understanding of the subject	2. Sustainability in production and natural resources and environmental systems
3. Interdependent of 1 and 2	2. Better definition and formulation of the problem	3. Capabilities of a society as a whole will be improved.
Prescriptive knowledge	3. Improved capacity in making and understanding and implementing recommendations	
The subject matter is risk and uncertainties	4. Better vision and anticipation of the next generation problem and possible solutions.	
Disciplinary sciences produce disciplinary knowledge		
Transdisciplinary Sciences produce transdisciplinary recommendations.		

Source: Modified based on Choi (2005).

Choi (2005) mentioned that “evidence for policy decisions should be generated from scientific research based on high-quality study designs”. We share that different purposes of knowledge generation call for different study designs. Experimental studies such as clinical trials and field trials provide strong evidence; community trials and observational studies such as cohort studies and case-control studies provide moderate evidence; other observational studies such as historical cohort studies, cross-sectional studies, and ecological studies provide weak evidence; and case reports and news reports provide minimal evidence (Choi, 2005).

Choi (2005) reminded us that even when scientific evidence is produced from adequately designed studies, current knowledge generation can be hindered by a *false-positive research cycle*. Choi used the case of “cellular telephone use and brain tumors” as an example. The conclusion is still inconclusive, despite multiple studies that have been done and the widespread attention given to the topic. It is because of a false-positive research cycle. The case was induced by a situation when one or more researchers obtained “positive results” are more likely to be published in a journal compared to, for example, 95 studies saying that there was no correlation between cellular telephone and brain tumors (editor's bias). The false-positive studies will make the topic even more urgent in the research community, and the false-positive research cycle begins again as more studies are designed to assess the problem. “Through this biased process, researchers can often “prove” something out of nothing” (Choi, 2005).

A transdisciplinary approach will help to check the likelihood of a false-positive research cycle happening through a variety of mechanisms.

The quality, quantity and sufficiency of data will determine quality of a study. Biased data will make biased conclusions. Bias might be started when we start to build a model of our study. “Even laboratory tests cannot guarantee the accuracy of a study's data”. For example, many physicians use four different types of laboratory tests to diagnose leukemia (routine morphology testing, electron microscopy, cell surface marker identification, and cancer cytogenetics), and the four test results often seem contradictory. Choi (2005) mentioned that out of 109 instances of bias that were found in scientific research (literature review, 4; study design, 31; study execution, 3; data collection, 46; analysis, 15; interpretation, 7; publication, 3), most of the instances of bias were found in the data collection phase of research (46 of 109, or 42%, of the total instances).

Further analysis of knowledge generation, knowledge exchange and knowledge uptake or knowledge utilization can be explored from other literature. This paper emphasized our attention that a science-based recommendation making process is essential in applying the tasks that were mandated by the government's laws and regulations in the area of utilization of genetically engineered products in Indonesia. Policy making recommendation is not a job of science *per se*. It is, in part, using science to develop “instruments” of avoiding or minimizing the risks that are believed to be in association with genetically engineered products. No single discipline can claim the truth, nor can any single discipline understand full knowledge of one-subject matter. Therefore, the only option available for us to develop our learning capacity in facing a hard choice is by applying a mechanism that provides broader opportunities in making a better choice process. A multidisciplinary team of scientists and experts will find transdisciplinary knowledge to be a better base for making transgenic recommendations. A formula developed by Choi (2005) as expressed in Table 2 can be enriched for our guidance to develop a science-based policy recommendation in the transgenic area. In Table 3 I cite a Table from Falck-Zepeda (2009) to ensure that it is not

only Indonesia that incorporated socioeconomic aspects, national laws and regulations in dealing with genetically engineered products, but also, among others, India, the Philippines, Argentina and Brazil.

Table 2. Twelve Recommendations for the Future of Science-based Policy

Area	Essential	Recommendation
Knowledge generation	Credible design	Use high-quality study designs and apply a systematic approach in research to prevent the false-positive research cycle
	Accurate data	Apply existing methods and develop new methods for reducing bias and increasing data accuracy obtained from scientific research.
	Sound analysis	Apply sound analysis methods to produce high-quality results from scientific research.
	Comprehensive Analysis	
Knowledge exchange	Relevant content	Apply existing methods and develop new methods to extract relevant content from existing information.
	Appropriate translation	Develop new techniques for information translation, and simplify the science–user interface.
	Timely dissemination	Develop innovative ways to disseminate information in a timely way.
	Modulated release	Create new methods for organizing the release of prioritized information
Knowledge uptake	Accessible information	Invent new ways to market health information and make it more accessible.
	Readable message	Produce information in a readable, understandable format that is relevant to the audience.
	Motivated user	Educate and motivate policymakers so that they actively seek out scientific evidence to make decisions.
	Rewarding outcome	Develop new ways to effectively show how using science to make decisions is beneficial.

Source: Choi (2005).

Table 3. Countries Considering Socioeconomic Variables in Their Regulations of Transgenic Products

Country	Party CBD/CPB ^a	CFT/CO ^b	Language of relevant text considering socio-economic considerations	Relevant law and regulations for socio-economic considerations
Argentina	Y/N	Y/Y	Decision on the convenience of the commercialization of the genetically modified material over its impact on markets, in charge of the National Market Directorate, so as to avoid potential negative impacts on Argentinean exports.	Resolution n°656/92 of SAGyP and Resolutions n°39/03 and n°57/03 SAGPyA
Brazil	Y/Y	Y/Y	Article 48, Paragraph 1. The National Biosafety Council—CNBS shall: II—analyze, upon request by CTNBio, in the context of convenience, socio-economic opportunity and national interest, requests to grant license on the commercial use of GMO and GMO derivatives.	Decree NO. 5,591, of November 23, 2005
Honduras	Y/Y	Y/Y	Socio-economic considerations will be conducted through partial studies that should include different social and economic impacts.	Honduras draft policy
Kenya	Y/Y	Y/N	“in reaching a final decision, the Authority shall take into account ... (e) socio-economic consideration arising from the impact of the GMO on the environment.”	Kenya draft policy
Uganda	Y/Y	Y/N	“no approval shall be given unless the GMO will not have adverse socio-economic impacts.”	Uganda draft regulations of 2005
Nigeria	Y/Y	N/N	The decision-making procedures shall take into consideration risk assessment, which involves scientific, socio-economic, cultural and ethical considerations.	Nigeria National Biosafety Framework, 2005

R.S. Africa	Y/Y	Y/Y	“The Council may in performing its function in terms of sub regulation (8), consider the socio-economic impact that the introduction of a genetically modified organism may have on a community living in the vicinity of such introduction.”	GMO Act 1997 (Act No. 15 of 1997)
Philippines	Y/Y	Y/Y	“Socio-economic, cultural and ethical considerations. Impacts on small farmers, indigenous people, women, small and medium enterprises, and the domestic scientific community to be taken in to account.”	Executive Order 514 (EO514)
Indonesia	Y/Y	Y/Y	“The utilization of GEAP originating from both domestic and foreign products must pay attention to and take into consideration the religious, ethical, socio-cultural and esthetical norms.”	Regulation 21 of 2005
India	Y/Y	Y/Y	India's biosafety system provides for evaluation of the economic benefits of LMOs through systematic evaluation of agronomic performance.	Not included or mandated by the Environmental Act or Biosafety Guidelines
USA	N/N	Y/Y	Voluntary/additional information	None
Canada	Y/N	Y/Y	Voluntary/additional information	None
EU	Y/Y	Y/Y	European Commission requires preparing a report on the socio-economic impact of GM crops every three years. Definition of socio-economic considerations is unclear in current legislation and associated guidelines, no provision for a risk-benefit analysis.	None
Note: Compilation by author from National Biosafety Frameworks, laws and regulations posted at the Biosafety Clearinghouse (<u>Convention on Biological Diversity, 2008</u>).				
^a CBD/CPB=Party to the Convention on Biological Diversity/Cartagena Protocol on Biosafety				
^b CFT=Conducted confined field trials, CO=Has made approval for commercialization				
^{a,b} Y=Yes, N=No				

Source: Falck-Zepeda (2009).

CLOSING REMARKS

Indonesia's laws and regulations apply a comprehensive and a complex formulation in dealing with genetically engineered products. It is explicitly stated that the policy in dealing with genetically engineered products considers aspects of religions, ethics and aesthetics in its policy recommendation and the way to develop policy recommendations should be based on justifiable scientific methods and using the precautionary principle. We can view that the above process is both a part of developing a new culture and how culture affects the laws and regulations as they apply in one or more cultural groups.

This paper developed a framework of thought in order to fulfill the tasks given by the laws and regulations in Indonesia. The formula developed by Choi (2005) was provided as an example of a science-based policy recommendation making process. The general conclusion is that we need to develop our institutional capacity in order to be able to apply a method of policy recommendation making process such as provided by Choi (2005).

We learned that we need to develop a multidisciplinary organization to be able to reach a higher likelihood for having transdisciplinary policy recommendations for transgenic products.

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