HOW TO DESIGN GENETICALLY MODIFIED FOOD LABELING REGULATION IN INDONESIA - TAKING SCIENCE, TRADE LAW AND INDONESIAN DEMANDS SERIOUSLY

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Abstract
The paper critically evaluates the current Indonesian genetically modified (GM) food labeling regime as it is embedded in the international trade law and policy system. This research proposes a GM food labeling regulation for Indonesia based on the socio-economic demands of Indonesia on the one hand and the demands of international trade law and policy on the other. It answers the following research questions: What are the legislative requirements for labelling of genetically modified organisms (GMOS) according to Indonesian law? How should Indonesian law on GM food labelling be designed to meet the interests of its peoples and provide access to foreign markets? We highlight the major weaknesses of the Indonesian GM food labelling law from the perspective chosen in this paper, such as the dependence on regulation from bigger trading blocs, lack of consideration for the socio-economic characteristics of Indonesia, and a low level of compliance. To overcome these shortcomings, we propose a novel GM food labeling regulation for Indonesia that is based on the concept of Food Safety Objective/Appropriate Level of Protection (FSO/ALOP) applicable to developing countries.

Keywords: genetically modified food, labeling regulation, food safety objective. Appropriate level of protection, international trade law

Abstrak
Bagian pertama artikel ini mengevaluasi secara kritis terhadap rezim peraturan label pada pangan rekayasa genetika (PRG) berdasarkan prinsip-prinsip yang berlaku dalam hukum perdagangan internasional dan sistem kebijakan. Riset ini ditujukan untuk menjadi usulan terhadap perubahan peraturan label pada PRG berdasarkan kebutuhan social-ekonomi di Indonesia di satu sisi dan juga berdasarkan prinsip-prinsip hukum perdagangan internasional di sisi lainnya. Pertanyaan riset akan berfokus pada bagaimana peraturan label pada PRG harus disusun berdasarkan ketentuan penyusunan peraturan yang ada di Indonesia dan bagaimana peraturan label pada PRG dapat disesuaikan dengan kebutuhan konsumen di Indonesia dan juga memberikan akses pasar bagi negara lain. Penelitian kami berikan pada kelemahan yang terdapat pada peraturan label PRG yang berlaku saat ini, seperti ketergantungan pada peraturan serupa dari negara-negara atau komunitas negara yang merupakan rekan perdagangan utama, ketidaksesuaian peraturan tersebut dengan kebutuhan social-ekonomi konsumen di Indonesia, dan rendahnya tingkat kepatuhan pelaku usaha. Upaya yang dapat dilakukan untuk mengatasi kelemahan tersebut adalah dengan mengajukan usulan perubahan terhadap peraturan yang berlaku saat ini yang berdasarkan konsep Food Safety Objective/Appropriate Level of Protection (FSO/ALOP) bagi negara-negara berkembang.

Kata kunci: pangan rekayasa genetika, peraturan label, tujuan keamanan pangan, tingkat perlindungan yang dianggap layak, hukum perdagangan internasional

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I. INTRODUCTION

Genetically modified (GM) food labelling in Indonesia is inspired by Japanese GM food regulation, which is a hybrid of the regulations found in the European Union (EU) and the United States of America (USA). The ineffective implementation of this regulation in Indonesian markets endorses a general criticism towards the effectiveness of such legal transplants, especially legal transplants from developed to developing countries. Taking this criticism seriously, this research proposes a GM labeling regulation for Indonesia which aims to balance the socio-economic demands of Indonesia with the demands of international trade law and policy. We thereby seek to answer the following research questions:

1) What are the legislative requirements for labelling of GMOs according to Indonesian law?

2) How should Indonesian law on GMO labelling be designed to meet the interests of its peoples and provide access to foreign markets?

In attempting to answer the two questions above, this paper does not take a specific stance on if and how GM products should be labeled. Rather, to answer the first research question, we apply a doctrinal analysis of the Indonesian law on genetically modified organisms (GMO) labelling. To test its effectiveness, we apply the criticisms generally found in academic literatures concerning such regulatory approaches to Indonesian regulations. We take into consideration Indonesia’s interest to design laws enabling export of its products, while also simultaneously satisfying the demands of the Indonesian people. Based on the doctrinal analysis and criticisms provided concerning the existing law on GMO labelling, we then apply the FSO/ALOP approach applicable to developing countries to structurally analyse and recommend an improved labelling regime based on science, societal demands and international trade law. Where scientific insights as a normative basis are absent, this paper employs a functional comparative legal analysis to determine the missing data. This approach is in line with the requirements of the FSO/ALOP framework for developing countries as discussed elsewhere by the authors. This paper ends with policy recommendations on how to improve the GM labeling regulation in Indonesia.
II. GM FOOD REGULATORY FRAMEWORK IN INDONESIA AND ITS PITFALLS IN THE CONTEXT OF INTERNATIONAL TRADE LAW AND POLICY

This section highlights the key features of GM food regulation in the Indonesian regulatory framework and evaluates its effectivity with regards to the enforcement of international trade law and policy.

A. The Indonesian legal framework for GM foods

GM food regulation is part of Law No. 18 of 2012 on Food (hereafter Food Law). The Food Law has been established in the form of a horizontal legislation, comparable to the EU’s General Food Law. This means that it applies, in principle, horizontally to all actors engaged in the food industry. Article 67 para. (1) Food Law stipulates that food safety needs to be implemented to ensure and maintain “(food) to be safe, hygienic, excellent, nutritious and free from conflict with religion, belief and culture.” Article 68 para. (1) Food Law requires Federal government and regional government to “guarantee the implementation of Food Safety at every stage of the food chain in an integrated manner”. According to Article 68 para. (2) Food Law, an implementing regulation of the central government should further substantiate this division of competences. Sadly, the establishment of such implementing regulation has been pending since 2013. To date, the responsibility for food safety is shared between government authorities and food business actors. This is evident from the provision of Article 68 (3) Food Law “Farmers, Fishermen, Fish Farmers and Food Businesses are required to implement the norm, standard, procedure and criteria of Food Safety as intended in paragraph (2).”

While these general provisions apply to the whole Indonesian food market, Article 69 Food Law sets out seven additional specific food safety chapters. Chapter Four is dedicated specifically to the regulation of the safety of GM food. Article 1 (33) Food Law defines GM food as “Food Genetic Engineering is a process that involves the transfer of gene from one biological type to another biological type that is different or the same to obtain a new type that is able to produce Food products that are superior.” Such GM foods are, according to Article 77 (1) and Article 77 (2) Food Law, subject to pre-market approval: “Everyone is prohibited from producing Food obtained from genetically engineered process that has not obtained Food Safety approval before distributed” and “Everyone who carry out Food Production process or activity is prohibited from using raw materials, Food additives and/or other materials produced from genetically engineered process that has not obtained Food Safety approval before distributed.” Article 79 (1) Food Law then defines the shared responsibility for the enforcement of these regulations between business actors and the government agencies: “Everyone that violates the provision as intended in Article 77 paragraph (1) and (2) is subject to administrative sanction.”

Subjecting GM foods to pre-market approval is regularly viewed as the adoption of a precautionary approach to GM foods, although such a view are nevertheless also subject to a number of criticisms. Such an interpretation is in line with the regulations

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8 Indonesia, Undang-Undang tentang Pangan (Law regarding Food), UU No. 18 Tahun 2012, LN No. 227 Tahun 2012 (Law Number 18 Year 2012, SG No. 227 Year 2012).
11 See: Kai Purnhagen, “The EU’s Precautionary Principle in Food Law is an Information Tool,” European
in the Biosafety Protocol of Cartagena, which has been ratified by Indonesia since 2004. This protocol binds Indonesia with international law to follow a precautionary approach in the area of biosafety. Within the Indonesian legal system, the application of the precautionary approach to the regulation of GMOs is expressed in Article 3 of the Government Regulation No. 21 Year 2005 on Biosafety of Genetically Modified Product\textsuperscript{12} (hereafter Government Regulation). The Government Regulation also defines enforcement activities by assigning and framing the responsibilities of enforcement authorities: the Ministry of Agriculture is responsible for the authorization of feed safety approval and commercialization of GM feeds, whereas the National Agency of Drug and Food Control (NADFC) is responsible for the authorization of food safety approval and commercialization of GM foods.

Subsequent to authorization, the labeling regulations for conventional food applies similarly to GM foods (Government of Indonesia, 1999). However, Article 35 of Government Regulation No 69 Year 1999 on Food Labelling and Advertisement (hereafter the Food Labeling Regulation)\textsuperscript{13} specifies that GM food must be additionally labeled as “Pangan Rekayasa Genetika” (“Genetically Modified Food”). Furthermore, and at times confusingly, the Head of NADFC Decree No. HK.03.1.23.03.12.1564 of 2012\textsuperscript{14} (hereinafter Decree), concerning the regulation of GM food labeling remains effective. The Decree is based on the previous food law regime and was enacted only a few months before the enactment of the current, then new, Food Law. While the Decree regulates more specific provisions than the current Food Law, the relationship between the Decree and the Food Law is unclear.

Until further clarity is provided by the Indonesian regulator, one may hence resort to the general legal principle \textit{lex specialis derogat legi generali}. In this respect, the Decree shall be the law which will be applied primarily regarding to GM food labeling. Only when no specific provisions can be referred to in the Decree, the Food Law will then be referred to. The Decree applies to all GM foods, except for GM foods that have undergone a strict refining process that no GMO protein can be identified in the end product. These requirements cover both domestic and imported products, and both pre-package and non-pre-package GM foods. Furthermore, the Decree also provides more specific labeling requirements based on a threshold level of GM ingredients in the product. The threshold level is 5% per ingredient, which means the labeling requirement shall apply if the food contains more than 5% of GM ingredients on a weight basis. There is no provision about the traceability of GM food or further definition of the threshold level determining an adventitious factor and technical inevitability of GMO content in food. Moreover, the law is silent on labeling of GM feed


\textsuperscript{12} Indonesia, Peraturan Pemerintah tentang Keamanan Hayati Produk Rekayasa Genetik (Government Regulation regarding the Biosafety of Genetically Modified Product), PP No. 21 Tahun 2005, LN No. 44 Tahun 2005 (Government Regulation Number 21 Year 2005, SG No. 44 Year 2005).

\textsuperscript{13} Indonesia, Peraturan Pemerintah tentang Label dan Iklan Pangan (Government Regulation regarding Food Labelling and Advertisement), PP No. 69 Tahun 1999, LN No. 131 Tahun 1999 (Government Regulation Number 131 Year 1999, SG No. 131 Year 1999).

\textsuperscript{14} Indonesia, Peraturan Kepala Badan Pengawas Obat dan Makanan tentang Pengawasan Pelabelan Pangan Produk Rekayasa Genetik (Head of National Agency of Drug and Food Control Regulation concerning Genetically Modified Food Product Labelling Supervision), Peraturan Kepala Badan POM No. HK.03.1.23.03.12.1564 Tahun 2012.
or animal-based foods, where the animals were fed with GM feeds.

B. The Indonesian legal framework for GM foods in the context of international trade law and policy

Despite having established GM-food-related regulations as black letter rules in the national legal framework, the implementation of these rules faces a great deal of difficulty in Indonesia. Most developing countries with GM food labeling regulation, which are only a handful, have not implemented their regulations effectively, including Indonesia. The ineffective regulatory implementation in Indonesia is evident in the lack of labeling in practice: GM food is mostly not labeled when it is exposed to consumers. A number of reasons may explain such ineffective legal enforcement, i.e. lack of efficient government supervision, lack of resources and misaligned exercise of government discretion, and poorly defined laws.

Generally, Indonesia regularly applies international standards to determine the appropriate level of protection (ALOP) and design corresponding measures. This approach ensures that Indonesian legislation is compliant with international law as well as being applied and endorsed by food business operators, which arguably saves regulatory implementation costs. However, international standards are largely absent in the context of GM food labeling. In the absence of international standards, businesses have little to no awareness about the need to label food products containing GMO, especially due to the fear of stigmatizing their products and losing customers.

International standards concerning the labeling of GMO are not expected in the near future. However, ongoing debates between the EU and the USA on how to regulate GMO has led into the development of standards in the Codex Alimentarius Commission, arguably one of the major causes for the deadlock in the negotiations on international standards for GM food labeling. It is important to note that free trade agreements (FTA), such as the Comprehensive Economic and Trade Agreement (CETA) and the Trans-Pacific Partnership (TPP), have the potential to fill in the gap. However, in addition to the known hazards that occur when standards set by developed countries are imposed on developing countries, the future of these trade deals becomes even more uncertain ever since the election of the post-Obama

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15 Grue`re and Rao, “Review of International Labeling,”
16 Confidential interviews with officials of the national food and drug authority.
government.

Several studies have investigated the different regulatory approaches to GMO. Gruère and Rao, for example, showed that labeling policies differ according to the nature, scope, coverage-exception, and degree of enforcement. Another study explained the variation in GM food labeling policies and the differences between the EU and the USA. As food regulations in developed countries often have an extraterritorial effect on developing countries, the failure to find consensus between the biggest trading blocs leaves a gap for developing countries, such as Indonesia. In the absence of trading rules, this situation can actually be seen as providing an opportunity for Indonesia to develop its own GM food safety regulation, which responds to the needs of Indonesia and the requirements of international trade law and policy. In the subsequent section, we propose a GM food labeling regulation that may be better equipped to meet these demands.

III. PROPOSAL FOR AN INDONESIAN FOOD LABELING REGULATION BASED ON AN FSO/ALOP-BASED ANALYSIS

This section details the proposal for an Indonesian GM food labeling regulation on the basis of the FSO/ALOP method developed by the authors elsewhere. This approach facilitates the design of a science-based regulation, which accounts for the socio-economic features of Indonesia as well as the requirements of international trade law. The FSO/ALOP concept for developing countries can be applied to design national regulations under the following circumstances:

- the regulation falls under the regime of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement),
- the regulation is preferably not regulated by a recognized international standard, and
- insufficient available data to conduct a regular FSO/ALOP analysis.

GM food labeling regulations are not subject to international standards. Furthermore, Indonesia has neither sufficient available data to conduct a regular FSO/ALOP analysis nor the means to acquire this data. It is not clear, however, whether GM labeling is subject to the SPS regime or the General Agreement on Tariffs and Trade 1994 (TBT Agreement). When viewed in isolation, GM food labeling regulations are
more technical than product-related. One could therefore argue that they are subject to the TBT Agreement. Nonetheless, countries regularly challenge each other’s GM food labeling regulations on a stricter basis, applying the SPS criteria rather than the more flexible provisions of the TBT Agreement.\(^30\) Such a view is also defendable as, according to Annex A.1. of the SPS Agreement, the agreement covers “approval procedures (…) and packaging and labeling requirements directly related to food safety”. Most national regulations relate GM food labeling, correctly or wrongly, to food safety; hence, we may consider the regulation as an SPS measure. Since the GM food labeling in Indonesia meets all the three requirements, the FSO/ALOP concept for developing countries can therefore be applied.

The general framework of the FSO/ALOP (Fig. 1) approach for developing countries consists of evaluating the current ALOP and FSO and determining the new FSO/ALOP. This is followed by the establishment of an effective enforcement system. Determination of the ALOP and FSO requires an effective risk assessment system that accounts for food safety science and available resources which is consistent with the objective of minimizing negative trade effects.\(^31\) In sections 3.1 and 3.2 we employ this approach to evaluate the current FSO/ALOP for GM food labeling in Indonesia as well as determining the new ALOP. In the context of Indonesia, an effective enforcement system is dependent on first improving current regulations. We therefore focus on improvements in the current regulation, although enforcement is briefly addressed in the policy recommendations in section 4.

\[\text{p" approach of FSO/ALOP-based analysis}\]

\[\text{ALOP}\]
\[\text{FSO}\]
\[\text{REGULATION}\]

- EVALUATION OF CURRENT ALOP
- DETERMINATION OF NEW ALOP
- THRESHOLD LEVEL
- IMPROVEMENT
- ENFORCEMENT

A. Evaluation of current ALOP at global level

A benchmark is needed to evaluate the ALOP in the GM food labeling regulations implemented by Indonesia’s trade partners. We use the margin of safety (MOS) formula\(^32\) to evaluate the ALOP based on the threshold level:

\[^{30}\text{Matthew Stilwell, “Protecting GMO Labeling from a WTO Challenge,”} \text{Institute for Agriculture & Trade Policy (IATP), November 7, 2000,}\ \text{https://www.iatp.org/sites/default/files/Protecting_GMO_Labeling_from_a_WTO_Challenge.htm}\]

\[^{31}\text{Wahidin and Purnhagen, “Determining an FSO/ALOP.”}\]

\[^{32}\text{Ibid.}\]
\[ MOS = FSO - H \]

where

- MOS = Margin of safety
- FSO = Food safety objective
- H = Tolerable level of risk

We set the ALOP of the EU as a benchmark, implying that the EU's threshold of 0.9% becomes the FSO. We further set the threshold levels in the respective countries as H, and use them to calculate the MOS. Table 1 shows that the MOS is negative for Japan, Indonesia, and Malaysia, which means that their ALOP is lower than the ALOP of the EU. Among these three countries, Malaysia has the highest ALOP, with Japan and Indonesia sharing a similar ALOP. In contrast, China has a positive value for its MOS, meaning that China has a higher ALOP than the EU. The USA is a special case, since there is no ALOP established realting to GM food labeling.

### Table 1. GM food labeling regulations in Indonesia’s major trade partners

<table>
<thead>
<tr>
<th>Country</th>
<th>Nature</th>
<th>Product/Process as trigger</th>
<th>Scope-Exemption</th>
<th>Benchmark FSO (EU)</th>
<th>Tolerable level of risk (H)</th>
<th>Margin of Safety (MOS)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU</td>
<td>Mandatory</td>
<td>Process</td>
<td>Meat and animal products</td>
<td>0.9%</td>
<td>0.9%</td>
<td>0%</td>
</tr>
<tr>
<td>USA</td>
<td>Voluntary</td>
<td>Product</td>
<td>Not defined</td>
<td>0.9%</td>
<td>Not defined</td>
<td>Not defined</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Mandatory</td>
<td>Product</td>
<td>Refined foods, not always oil,</td>
<td>0.9%</td>
<td>5%</td>
<td>-4.1%</td>
</tr>
<tr>
<td>Japan</td>
<td>Mandatory &amp; voluntary</td>
<td>Product</td>
<td>Outside of the list</td>
<td>0.9%</td>
<td>5%</td>
<td>-4.1%</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Mandatory</td>
<td>Process</td>
<td>Meat raised with GMO grains, refined foods, such as oils and corn syrups</td>
<td>0.9%</td>
<td>3%</td>
<td>-2.9%</td>
</tr>
<tr>
<td>China</td>
<td>Mandatory</td>
<td>Process</td>
<td>Outside of the list</td>
<td>0.9%</td>
<td>0%</td>
<td>0.9%</td>
</tr>
</tbody>
</table>

\*MOS = FSO - H

### B. Determination of a new ALOP and FSO for Indonesia

Based on the evaluation of the current ALOP implemented by Indonesia and its main trade partners, we undertake a comparative analysis of the ALOP of relevant countries to determine a new ALOP for Indonesia. The following countries are included in the analysis: EU, USA, Malaysia, Japan, and China. The EU and the USA represent the benchmark for policies on GM food labeling. Malaysia is one of the closest neighboring countries in the ASEAN region, one of Indonesia's most important trade partners,\(^{33}\) and a member of the TPP. Japan represents a developed country.

with a valuable market and is also an important trade partner for Indonesia. The last country included in the analysis is China, representing one of the biggest consumers of GM foods. We interpret the ALOP of these countries qualitatively, based on the existing threshold in their GM food labeling regulation.

1. European Union

The EU’s ALOP concerning GMO is to “provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market.”\(^{34}\) To achieve this, the EU has implemented, *inter alia*, a co-existence policy of GM and non-GM products, governed by an information paradigm,\(^{35}\) a general authorization procedure, traceability requirements and mandatory GM food labeling mechanism. The EU uses a process-based approach as trigger, meaning that every food containing, consisting of, or produced from GMO shall be labeled as GM food.\(^{36}\) The notion of “produced from” means that even if the end product no longer contains or consists of GMO, the food may still have to be labeled as GM food. The traceability system is managed by transmitting information in writing among operators along the supply chain of GM food.\(^{37}\) Furthermore, in a situation where the operators avoid using GM foods, there remains a possibility of adventitious or technically unavoidable minute traces of them in conventional foods. In this situation, the EU has established a threshold level of 0.9% for authorized GM foods and 0% for non-authorized GM foods. Hence, during the authorization procedure, the applicant has to provide sufficient evidence that they have undertaken appropriate measures to avoid the adventitious or technically unavoidable presence of GM content in their products at all stages of the supply chain. Operators along the supply chain have to keep records and are subject to strict liability in the event of an unauthorized increase in the threshold level. Both the threshold level of 0.9% for authorized GM foods and the notion of adventitious and technically unavoidable traces are inseparable requirements of the mandatory labeling in the EU.

These strict requirements have affected the production and import of GM foods in the EU.\(^{38}\) The EU produces only a small amount of GM foods and the use of GM ingredients for human consumption is also limited as food business operators in the EU avoid using GM ingredients in their products. Thus, only a handful of GM food products exist in the EU market. The EU remains one of the biggest importers of GM soybean in the world, importing around 15% of worldwide soybean import.\(^{39}\) However, this GM soybean is used for animal feed and not for human consumption. Additionally, as cultivation of GM crops around the world continues to increase, this leaves the EU in isolation and making it increasingly difficult for importers in the EU.

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\(^{34}\) Regulation No. 1829/2003, art. 1(a), 2003 O.J. (L268) 1, 5 (EC).

\(^{35}\) Kalaitzandonakes, et al., *Coexistence of Genetically Modified*. See also: Purnhagen and Wesseler, “Principle(s) of Co-existence,” pp. 71-85.

\(^{36}\) Regulation No. 1830/2003, art. 4 para. 6, 2003 O.J. (L268) 24, 26 (EC).

\(^{37}\) Regulation No. 1830/2003, art. 4 para. 1-5, 2003 O.J. (L268) 24, 26 (EC).

\(^{38}\) Kai Purnhagen and Justus Wesseler, “The “Honey” Judgment of Bablok and Others versus Freistaat Bayern in the Court of Justice of the European Union: Implications for Coexistence,” in *Coexistence of Genetically Modified*, eds. Kalaitzandonakes, et al., pp. 149-165

to find non-biotech sources for human consumption.40

2. United States of America

The USA is one of the biggest producers and exporters of GM foods in the world. Accordingly, the USA is well advised to adopt a pragmatic approach. At the federal level, there is no specific regulation for the labeling of whether a food product does contain or does not contain GM ingredients or was produced using GM techniques. The Food and Drug Administration (FDA) considers GM food as substantially equivalent to its conventional counterpart. Since there are only few specific GM regulations at federal level, the FDA requires that GM foods must, in principle, meet the same requirements as their conventional counterparts, including safety and labeling requirements.41 The FDA issued a non-binding policy in the form of guidance for industry regarding voluntary GM food labeling on November 2015.42 The guidance does not specifically state any related components of GM food labeling requirements (e.g. threshold level or scope). Rather, it provides guidance on determining if a food product may or may not have GM ingredients is being misbranded. The guidance also reaffirms the application of a product-based approach, with a focus on how to use the products rather than on the genetic engineering techniques used to produce them.43 Moreover, the guidance is aimed at suppressing public pressure to introduce mandatory labeling of GM foods.44 Some States, such as Vermont and Maine, have tried to require labels on foods containing GM ingredients. However, most of them have failed hitherto. Regarding to the Vermont labeling law in particular, the former President Obama signed a bill that overturned it, thus allowing companies to hide the information in the form of a bar code.45 However, section 403 and 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA) have the potential to change the FDA’s policy on the labeling of GM foods.

Section 403 (a) FFDCA states that food shall be deemed misbranded if its labeling is false and misleading in any particular. In addition, Section 403 (j) FFDCA requires each ingredient to be stated on the label by its common and usual name. Thus, if a GM food is significantly different from its traditional counterpart that it becomes no longer appropriate to be called by its common name, then the name of the GM food should be stated differently on the label to avoid misleading the consumer.

Section 201 FFDCA states that food shall be alleged misbranded if the labeling is misleading and fails to reveal material facts. Although there is no definition in the FFDCA for “material”, in the guideline, FDA defines “material” as (1) posing special health risks; (2) misleading the consumer in light of other statements made on the labeling; and (3) if there is a food that is similar to other food and consumers assume it has the same nutritional, organoleptic, and functional characteristic, when in fact it is not true. Hence, GM food is not regarded as “material” that needs to be labeled differently from its traditional counterpart.

41 U.S. Department of Health and Human Services, Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants (2015), pp. 73194-73198
42 Ibid.
43 Lau, “Same Science.”
3. Japan

No GM crops are commercially planted in Japan, including soybean. Soybean for human consumption accounts for only 25% of total imported soybean in Japan, and only non-GM soybean is used for human consumption.46 Most of the non-GM soybean is imported from the USA, Canada, and China.47 Japan uses two categories for the mandatory labeling of GM foods: segregated and non-segregated.48 The difference lies in the segregation between GMO and non-GMO at each stage of production. In addition, there is also an option for the operator to have non-GMO labeling; this option is made on a voluntary basis.49 Moreover, unlike the EU, Japan uses a product-based approach, which places more emphasis on GM foods and the way they are used rather than on the genetic engineering process used to produced them. Thus, the labeling requirement does not apply to products that are produced from GMO which no longer contain or consist of GMO. Japan uses a 5% threshold, a threshold more moderate than the EU.

The GM food labeling requirement is only applied to seven “designated genetically modified agricultural products” and 32 processed foods, which contain the “designated genetically modified agricultural products.”50 Thus, the scope is much more limited than in the EU. Within this list, soybean and soybean-based processed foods are the most prominent.

4. Malaysia

Although Malaysian soybean imports from the USA have been increasing in recent years, this soybean is not intended for human consumption. Food grade soybean accounts for only 25% of total soybean imports in Malaysia.51 The food grade soybean import is non-GM soybean from Canada and is mostly used for the production of soybean drink and tempeh. Moreover, no GM crops have been approved for planting and only a few maize and soybean GM events52 have been authorized for import and commercialization, which results in fewer objects for labeling enforcement.53 The

49 Ibid.
52 GM event is a unique DNA recombination event that took place in one plant cell, which was then used to generate entire transgenic plants. See: GMO-Compassm “GMO Compass,” 2017, http://www.gmo-compass.org/eng/home/
Prime Minister of Malaysia, Badawi pointed out that “while Malaysia is aware that biotechnology holds much promise, we are also concerned that biotechnological products should not pose any threat to the environment, or to human health and safety.”\textsuperscript{54} This statement reflects current Malaysian policy towards GM food, particularly related to the labeling regulation. Malaysia and the EU have the same process-based approach to governing GM food labeling. Furthermore, both countries produce few or no GM foods. Despite these similarities, there are differences with regards to the threshold level, scope of the regulation, and existence of the traceability system. Malaysia has a more moderate 3% threshold level and a narrower scope than the EU. Furthermore, traceability does not exist in the Malaysian GM food labeling regulation.

5. China

Although China has not yet approved any foreign GM crops for commercial cultivation, it is one of the biggest consumers of GM foods and also one of the most ambitious countries in terms of research on GM foods. This unique position provides China with a dilemma regarding the regulation of GM food labeling, especially when the view of the Chinese government is unclear.\textsuperscript{55} On September 2014, the Chinese government released an official statement by President Xi Jinping assuring governmental support for biotechnology research, while at the same time calling for a cautious approach to commercialization.\textsuperscript{56} Similar to the EU, China applies a process-based approach in its GM food labeling regulation.

In terms of labeling, China applies a 0% threshold level, which is stricter than the EU. In contrast to the EU, China has no traceability system in its GM food labeling regime. Moreover, the scope of the regulation is also much more limited than the EU. The scope is based on the list in the Ministry of Agriculture’s catalogue, which makes the GM food labeling regulation seem vague. Similar to the EU, Malaysia, and Japan, the approval for commercial cultivation of GM crops is minimal. The implementation of mandatory GM food labeling is not effective in China, which is reflected in the weak enforcement of the regulation.\textsuperscript{57} Although the 0% threshold level may be appropriate from a risk perspective, this level is not feasible due to technical constraints, such as the capacity for laboratory analysis, weak enforcement from relevant food safety authorities, and low compliance from food business operators.

6. Influence of mega FTA

The USA is by far the biggest producer and exporter of GM crops,\textsuperscript{58} and its GM legislation is fragmented across the Federal and State level. Thus, it is natural for the Federal level in the USA to apply a voluntary and product-based approach to labeling of GM foods, particularly from the perspective of the FDA. In contrast, the

\textsuperscript{54} Ministry of Natural Resources and Environment (NRE) Malaysia, The Biosafety Act of Malaysia: Dispelling the Myths (Putrajayaya: Ministry of NRE, 2008), p. 5


\textsuperscript{56} Ibid.


EU uses a mandatory and processed-based approach. The differences in the GM policies of the USA and EU are not only dependent on the two countries different roles in international trade and different consumer attitudes, but also on the different attitudes towards GM technology held by stakeholder groups in these countries.\textsuperscript{59} Two American biotechnology-based companies, Monsanto and Dupont, potentially influence the determination of GM policies in the USA and its negotiation position in the TPP Agreement. In the TPP context, food business operators have the possibility to challenge the decisions of public officials, such as food safety inspectors, on grounds of the Agreement, arguably with little to no reference to the national legal system. In this sense, Article 7.9 of the TPP text stipulates a “Rapid Response Mechanism” that would give new powers to food business operators.\textsuperscript{60} Hence, food business operators could challenge the decision of a food safety inspector regardless of the existing GM food labeling regulations in other TPP member states.

Indonesia is not yet a member of TPP. It is also unlikely that the TPP will ever be concluded considering the political affinity of the post-Obama government. However, the economic interplay from the negotiations surrounding the Agreement and its potential successors may still influence Indonesia, particularly relating to access to (foreign) markets and transformation of relevant Indonesian laws. Current policies of ASEAN countries related to GM food are divided into four groups:

- Countries that have a GM food labeling regulation and do not produce GM crops (Indonesia, Malaysia, Cambodia and Thailand);
- Countries that have a GM food labeling regulation and produce GM crops (Vietnam);
- Countries that have no GM food labeling regulation and do not produce GM crops (Singapore and Brunei); and
- Countries that have no GM food labeling regulation and produce GM crops (Philippines and Myanmar).

Despite the influence of the USA, the EU is an important market for agricultural products for ASEAN countries, including Indonesia. With the new USA policy of market closure, the EU might even become a more interesting trade partner: The EU has influenced and is likely to increasingly influence the establishment of food safety standards in the region. The increasing importance of the EU market for ASEAN countries may therefore counter the influence of TPP and its potential successor.

7. Consumers’ awareness of GMO and trust in the food safety authority

Compared to other countries, consumers in the EU have a high level of GMO awareness and a low level of trust in the authorities, which is said to lead to a high resistance toward GM foods.\textsuperscript{61} In contrast, consumers in the USA are relatively indifferent to GMO and have a high level of trust in food safety authorities, which


leads to a more permissive behavior toward GM foods. The awareness of most Asian consumers is low, which leads to a neutral and non-opposing attitude toward GM foods. For example, Indonesian consumers have been consuming large amounts of GM soybean in the form of tempeh and tofu, but they are unaware of the GM properties in these foods because they are exempted from the labeling requirement. Thus, they seem to accept GM foods. However, considering the precautionary approach and mitigation of the risk of GM foods, the low awareness of consumers toward their own safety should be anticipated by adopting governmental measures. One of the most prevalent mechanisms to ensure consumer safety is a mandatory standard and labeling mechanism.

8. ALOP Recommendation for Indonesia

The overarching policy of the Indonesian government on agricultural biotechnology is to accept the introduction of biotechnological advancements with a precautionary approach with respect to environmental safety, food safety, and/or feed safety, taking into account scientific evidence, as well as religion, ethical, socio-cultural, and aesthetical norms. This policy implies a mandatory approach to GM food labeling. However, Indonesia also wishes to use the benefits of GMO technology for the welfare of its people. Indonesia therefore applies a 5% threshold level, which is more moderate than the thresholds applied in the EU and China. In contrast to the EU, Indonesia uses a product-based approach as a trigger and has no traceability system within the GM food labeling regulation. The scope of the regulation covering GM laws is similar to the one applicable to EU regulation, although highly refined products are exempted from the labeling requirement. No GM crop is currently approved for commercial cultivation. To date, the NADFC has published 19 Food Safety Approvals for imported GM foods.

Indonesia is increasingly dependent on imported GM crops to meet domestic demand, especially for soybean. Over 70% of all soybean used in Indonesia to produce local favorite foods (e.g. tempeh and tofu) is imported from the USA. However, under the current food law, GM-soybean-based tempeh and tofu are not labeled as GM food, because processed foods that have a shelf-life of less than seven days are exempted from the labeling requirement.

No GM-labeled foods are visible in the market, which indicates that the mandatory GM food labeling regulation is not yet effectively implemented in Indonesia. This is most likely due to a number of reasons: the unwillingness of the NADFC to spend its resources on the control and inspection of GM food, the fact that GM foods are

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never listed within the sampling plan of NADFC, and the low compliance of food businesses. However, beyond these reasons, the main issue is the weak link between the regulation and the food safety management systems of businesses, which could be improved by having an FSO/ALOP-based GM food labeling regulation.

IV. RECOMMENDATIONS

Based on the evaluation of the ALOP and FSO, the influence of mega FTA, and consumers’ awareness of GMO and trust in the food safety authority, we conclude that the enforceability of the Indonesian GM food labeling regulation is dependent on primarily improving the regulation itself. We propose to redesign the GM food labeling regulation in Indonesia based on the following aspects: nature of labeling, threshold level, and scope-exemption.

A. Nature of labeling

More than 64 countries currently implement mandatory GM food labeling regulation.67 This trend is also emerging in the USA, where a few States implement mandatory labeling. In light of this trend, the current mandatory GM food labeling regulation in Indonesia should be maintained in order to lower costs of production to export markets. However, the absence of labeled GM foods in the Indonesian market, due to low compliance from business operators and weak law enforcement from the government, undermines this goal. In this regard, voluntary labeling may be more efficient and may allow consumers to choose non-GMO as a quality property of a product.68

Although the awareness of Indonesian consumers about GM foods is still low, we propose the creation of a voluntary non-GM food labeling pathway that coexists alongside the existing mandatory labeling pathway. The current mandatory labeling pathway has not contributed to increase options of exports because of its ineffective implementation and rather generous threshold level. Voluntary non-GM labeling may therefore be able to fill the gap left by the ineffective implementation of the mandatory labeling pathway. In order to facilitate trade and provide access to major markets, we propose to apply a 0.9% threshold level for voluntary labeling; food containing or consisting of GMO content below this level should be authorized to have “non-GM food” on the label. From the perspective of food businesses, the word “non-GM food” can reduce costs to adjust products to export markets.

B. Threshold level

The enforceability of the threshold level is dependent on the post-market control by the authority, such as screening and event-specific detection methods, and the capacity of the industry to comply with the threshold. Beyond enforceability, however, the ultimate step to improve the GM food labeling regulation is by determining a clear and transparent threshold. The determination of the threshold level is not based on science, as there is no scientific evidence that proves GM food is unsafe for human health nor for the environment; hence, the determination is based on public

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policy. Furthermore, the definition of the threshold level in the current regulation is ambiguous, since it is not clear whether the level is applicable to the content of GM ingredient in the specific ingredient or in the product.

We propose to determine the threshold level as the content of GM ingredient in the product on a weight basis. The current 5% threshold level is sufficient for Indonesia, with regard to economic and food security considerations. If Indonesia applies a more stringent threshold, then this will increase the cost of compliance for food businesses and the cost of enforcement for the government; eventually a more stringent threshold will lead to higher consumer prices, particularly for non-GM food.

C. Scope-exemption

Currently, GM food labeling regulation in Indonesia covers all foods produced from, or using raw materials, food additives, and/or other ingredients that are produced from genetic engineering processes. Moreover, the requirement to place the phrase “GMO food” applies to all listed GM ingredients in the product. Notwithstanding the exemption for refined foods, the coverage is wide. Allocation of the authority’s limited resources for the effective enforcement of GM food labeling is consequently difficult. However, defining the scope in a positive list or catalogue, such as the lists used in Japan and China, may prove to be ill-suited in practice as the list needs to be updated whenever a new GM food is authorized.

We propose to reshape the scope into a more practical one. The scope should be for all locally produced or imported food containing or consisting of GMO that has been authorized by NADFC, with the added provision that foods using GMO with altered characteristic are required to be labeled even when the food does not contain GMO.

A balance is needed between the consumers’ right to complete and accurate information on the one hand, and the risk of information overload for consumers on the other hand. We therefore propose to place the words “genetically modified food” on the label for the three main GM ingredients, which have the biggest share on a weight basis in the overall product. As for exemptions, we propose to place more details on these GM food types:

- Food containing or consisting of GMO in a proportion less than 5% of GM ingredients;
- Foods that are exempted from the labeling requirement, such as defined in the executive order No 69 Year 1999;
- Highly refined foods other than highly refined foods with altered characteristic;
- Food from animals fed with GM animal feed;
- Food produced using GM enzymes; and
- Food produced using genetically modified microorganisms (GMM).

V. CONCLUSION

The ineffective implementation of the GM food labeling regulation in the

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69 Zhu, Roberts, and Wu, “Genetically Modified Food,”
Indonesian market raises a general criticism against the effectiveness of such legal transplants, especially transplants from developed to developing countries. Based on this criticism, this research proposes a GM food labeling regulation for Indonesia which is based on the socio-economic demands of Indonesia on the one hand and the demands of international trade law and policy on the other.

We first illustrate the current GM food labeling system in Indonesia, highlighting its regulatory strengths and weaknesses. We then proceed with employing the FSO/ALOP approach for developing countries\textsuperscript{71} to the Indonesian GM labeling system. Subsequently, we conclude with policy recommendations for an improved design of the GM labeling regulation in Indonesia.

Indonesia has a tendency to comply with Codex standards. Thus, if Codex established an international standard concerning GM food labeling, then this standard would most likely be followed by Indonesia. However, considering the ongoing debate between the EU and the USA, it remains uncertain that a standard will be implemented in the near future. The current GM food labeling regulation is poorly implemented in Indonesia: almost all GM food is not labeled when it is exposed to consumers. Reasons for poor implementation include lack of efficient official controls, lack of resources and misaligned exercise of discretion, and poorly defined laws.

An improved GM food labeling regulation will result in a higher ALOP, and will eventually provide a better link between the public health goal and food safety controls. Hence, we recommend an improvement in the GM food labeling regulation in Indonesia based on these three aspects: nature of labeling, threshold level, and scope-exemption. The application of the FSO/ALOP concept for developing countries to the Indonesian GM food labeling regulation, as outlined in this paper, illustrates how to design future GM food labeling regulations.

\textsuperscript{71}Wahidin and Purnhagen, "Determining an FSO/ALOP."
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