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Critics on Policy of Soy-Based Infant Formula in Indonesia: Compared to Australian and New Zealand Food Standards

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ABSTRACT

Background: World Health Organization (WHO) recommends breast milk as sole and the most complete infant food during the first 6 months. However, in certain circumstances, when breastfeeding is not possible, not desired or not advised, infant formulas like those are made of soy can be given to newborns. However, the safety of long-term use soy-based formula has been argued due to the possible adverse effects of phytoestrogen, phytates and aluminum in human body as well as the consequences of agrochemicals residue. Therefore, those problems should be taken into account while developing, reviewing or amending policy of infant formulas. This article reviews the adequacy of soy-based infant formula policy in Indonesia to anticipate issues in SIF consumption.

Methods: Australian and New Zealand Food Standards Code was used to compared to the decree of Indonesian NADFC. The results were described narratively and analyzed from the perspective of the author.

Results: Accordingly, only small aspects of SIF are regulated in Indonesian policy. The use of SPI for SIF in Indonesia is not a compulsory though scientifically another source may trigger diarrhea in newborn baby. No clause related to aluminum content, zinc to copper ratio, isoflavone level, GM soy and pesticide residue found in Indonesian policy.

Conclusion: Apparently, very limited provision regarding SIF has been covered by Indonesian policy. The regulation of SIF marketed and manufactured in Indonesia should be more specific and developed based on recent clinical and epidemiological studies. On the other hand, Indonesia needs a comprehensive system where society may participate in reviewing the laws.

Keywords: soy-based infant formula, food policy, food standards

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1. Introduction

Reviewing its history, soy-based infant formula (SIF) was firstly introduced over a century ago in the United States in 1909 (Westmark, 2017). Health professionals advice the use of this lactose-free milk especially for babies with galactosemia, lactose intolerance and those whose parents were vegan (Bosch, 2011; Vandenplas et al., 2014). Former generation of SIF was based on soy flour and since 1960s and recent modification has been made of soy protein isolate (SPI) to ease digestion. To date, SIF has

been supplemented with essential amino acids, lipids, vitamins and minerals to resemble the nutrient contents of breastmilk. However, the safety of long-term use of SIF has been debated. This issue has been increasingly raised along with the introduction of genetically modified (GM) soybeans in early 1990s.

Despite of its health benefits as therapeutic agents for infants with gastrointestinal issues, many cross-sectional and pure experimental studies have found that natural genistein and daidzein in soybeans may alter human reproductive hormones leading to endocrine disruption. The researchers reported women fed with soy formula in early infancy tend to experience heavy menstrual bleeding, have higher maturation index and unfavorable effects on early menarche compared to those fed with non-SIF (McCarver et al., 2011; Stallings et al., 2017; Upson et al., 2016). On the other hand, exposure of SIF in male infants may suppress their steroidogenic capability leading to the disturbance of sex hormone release (Abo-Elvoud et al., 2019; Chen and Rogan, 2004; Zhu et al., 2016). On top of that, according to Chen and Rogan's study, genistein alone in daily SIF consumption may equal to five contraceptive pills (22-45 mg/L) (Chen and Rogan, 2004; Esch et al., 2016; Yu et al., 2016). As comparison, breastmilk contains 1-10 µg/L isoflavones and the suggested safe level is 3.2 mg/kg (Vandenplas et al., 2014). The fact shows that genistein is accumulated in human body due to frequent feeding hence brings some researchers to a speculation that may lead to the long-term effects for both male and female newborns.

Another conflicting area is related to the effects of phytates in mineral absorption. This antinutrient may impair the absorption of Zn, Ca, P, and Fe in infant's gastrointestinal tract (Vandenplas et al., 2014). Studies reported that soy infant formula contains 1.5% phytates and 1/3 of total phosphorus is phytate-bound (Gomez et al., 2016; Vandenplas et al., 2014). Therefore, soy formula should be supplemented by those micronutrients, otherwise it will increase the risk of infant malnutrition. Regarding the high level of aluminum content (200-700 µg/L) in SIF compared to breastmilk and cow's milk-based formula, another concern about possible risk of aluminum in SIF has been addressed (Burrell and Exley, 2010; Vandenplas et al., 2014; Westmark, 2017). This aluminum exposure, which seems to come from the soybean itself and equipment residues while manufacturing milk formulas, may lead to serious health problems as aluminum can burden infant's gastrointestinal tract and renal functions (Chuchu et al., 2013; Gomez et al., 2016; Redgrove et al., 2019).

The last major focus of SIF's controversial is the agrochemical residues such as benzene, toluene, chloroform, styrene and glyphosate (Westmark, 2017). Therefore, genetically engineered soy is proposed to be the solution of pesticide residue. However, the use of GM soybeans leads to another long discussion about its safety as some researcher found that transgenic soybeans poses a greater risk on health as a result of consuming foreign DNA (Lucht, 2015). Given all those counter arguments, specific food regulation regarding the use of SIF seems to be crucial.

Food regulation is a specific instrument aimed to protect public health and safety. This regulation will vary in every country or even every state. Australia and New Zealand Food Ministerial Forum on Food Regulation, which consists of health and agriculture ministers from the states and territories as well as the Australian and New Zealand governments, has the authority to develop food policy in both countries (FSANZ, 2019b). Under the Australian New Zealand Food Standards Code, the primary production, composition, processing, handling, labelling and safety of food (including those related to soy-based infant formula) in both countries are managed. These standards are enforced by Australian state and territory as well as New Zealand governments through their individual Food Acts. While in Indonesia, food policy making takes place in such complicated political environments led by Indonesian House of Representatives in coordination with president (Blomkamp et al., 2017). Afterwards, relevant regulatory agencies like Ministry of Health, Ministry of Agriculture, Ministry of Maritime Affairs and Fisheries, Ministry of Industry and Trades as well as National Agency for Drug and Food Control of the Republic of Indonesia (NADFC known as BPOM) issued the technical policies. Consequently, food policies in Indonesia may overlap or be missing in some parts. To date, Indonesian government introduced two legal references related to infant formula, namely Health Minister Regu-

lation Number 39 Year 2013 on Infant Formula Milk and Other Baby Products and Decree of NADFC Number 1 Year 2018 on Supervision of Processed Food for Special Nutritional Purposes. However, so far, there has been no review whether or not both policies facilitate the right regulation regarding soy-based infant milk. Therefore, this article may be important to act as policy analysis and evaluation of one part of the food policies in Indonesia. At the end, this paper aims to provide recommendations to Indonesian government to develop specific clauses to guarantee the health and safety of Indonesian future generations who consume soy-based infant milk.

2. Method

Basically, this paper was an analytical perspective of researcher, in which legal materials were used as secondary data. Two relevant legal references, namely Health Minister Regulation Number 39 Year 2013 on Infant Formula Milk and Other Baby Products and Decree of NADFC Number 1 Year 2018 on Supervision of Processed Food for Special Nutritional Purposes were studied intensively and compared to Standard 2.9.1: Infant Formula Products (part of Australian New Zealand Food Standards Code). Google search engine was used to access the Indonesian food policies. Major information regarding the role, plans and programs related food were accessed from NAFDC's official website (www.pom.go.id) while the food policies of Australia and New Zealand were accessed from the Food Standards Australia New Zealand (FSANZ)'s official website (www.foodstandards.gov.au). This study was conducted in April-May 2019. Critics were made according to following guideline questions:

1. How is the model of food policy cycle in Indonesia, Australia and New Zealand?
2. Have the current food policies in Indonesia anticipated issues in SIF consumption?

3. Results

Food regulations in Australia and New Zealand were developed by Food Standards Australia and New Zealand (FSANZ), an independent agency consists of health and agriculture ministers from the states and territories of Australian and New Zealand. FSANZ is responsible for developing and managing standards of food including the primary production, composition, processing, handling, labelling and safety of food manufactured and distributed in both countries. Literally, everyone in Australia and New Zealand may access their food policies and give comments and advices by filling the specific application forms in FSANZ's official website. Later, FSANZ board will evaluate and decide whether or not to accept the advices and change the Food Standard Codes. Then, the changes will be notified to the Australia and New Zealand Ministerial Forum on Food Regulation. The forum has responsibility to reject, adopt and ask FSANZ to review the decisions. On the other hand, anyone who accesses FSANZ's website can easily track the changes in codes and standards. Therefore, they will always be updated to the valid policies. This process is carried out continuously while implementing the food standards.

On the contrary, in Indonesia, the general process of policymaking takes place in a complex political environment. Before becoming an enacted food policy, the draft of policy should be approved by the parliament and the president. Afterwards, relevant regulatory agencies like Ministry of Health, Ministry of Agriculture, Ministry of Maritime Affairs and Fisheries, Ministry of Industry and Trades as well as National Agency for Drug and Food Control of the Republic of Indonesia (NADFC known as BPOM) will issue the technical policies. In terms of SIF regulations, Indonesia has 2 relevant regulations, namely the Health Minister Regulation Number 39 Year 2013 on Infant Formula Milk and Other Baby Products and Decree of NADFC Number 1 Year 2018 on Supervision of Processed Food for Special Nutritional Purposes. The first policy can be accessed from Indonesian Ministry of Health official website while the second policy can be found online under NADFC's Legal Documentation and Information Network (SJDI) System. Moreover, both regulations are present in Indonesian and

English languages. Under the NAFDC's official website, platform to make complaints have been provided and can be accessed by anyone. However, it seems to be too general and mainly used for services dissatisfaction. On top of that, in general, Indonesian people are not aware of the existence of food policies unless they are part of Indonesian political parties, government employee, food industry and scholars. More importantly, most of Indonesian society do not know how to propose the changes of food policy as it is not well informed by the government.

Worldwide, at least 4 major issues have been debated regarding the consumption of SIF in infant. First, the possible adverse effects of phytoestrogen which may alter human reproductive hormones leads to endocrine disruption. Second, the effects of phytates that may impair the absorption of Zn, Ca, P, and Fe in infant's gastrointestinal tract. On the other hand, aluminum residue in SIF formulas may burden infant's gastrointestinal tract and renal functions. Last, the use of transgenic soybeans which is still under debate though genetically engineered soy is proposed to be the solution of pesticide residue. Those problems should be anticipated mainly by developing policy instruments. Table 1 shows comparison between regulations of SIF in Indonesia and Australia-New Zealand. The composition, labelling and marketing of SIF in Australia and New Zealand are regulated in Standard 2.9.1: Infant Formula Products (FSANZ, 2019a). Standard 2.9.1 was developed by Food Regulation Standing Committee in 1993 and the latest version was published in November 2017. While in Indonesia, SIF is specifically regulated in Decree of NADFC Number 1 Year 2018 on Supervision of Processed Food for Special Nutritional Purposes. Accordingly, the use of soy or SPI is not mentioned in the decree of Health Minister though SIF is considered as infant formula milk. Moreover, only small aspects of SIF are regulated in the Decree of NADFC Number 1 Year 2018. For instance, the use of SPI for SIF in Indonesia is not compulsory while vice versa in Australia and New Zealand. However, both Indonesia and Australia-New Zealand have specified the maximum and minimum level of protein isolate in SIF. Likewise, in terms of calcium and phosphor ratio, both countries show quite similar proportion. On the other hand, there is no clause related to aluminum content and zinc to copper ratio in Indonesian policy. Apparently, very limited provision regarding SIF can be found in Indonesia and when regulations are present, they are too general or considered similar as other types of infant formula.

4. Discussion

Food policy model in Australia and New Zealand has been well established. FSANZ as the government agency has the important role in developing and managing food standards in both countries. Moreover, it is clear that their society actively participate to build their food system. By contrast, general process of food policymaking in Indonesia cannot be represented as a cycle like in Australia and New Zealand. Even though the food policy in Indonesia can be found online, public are not well informed about its policy cycle or the process of policymaking and at which stage they can participate to build a better food system. This means policy initiation is not raised from the bottom level. Consequently, common people do not have the chance to review and propose the changes of policy when it is considered irrelevant and needs improvement. Therefore, Indonesian government should build a system where its people can improve their policy literacy and aware of their roles to jointly develop a system to ensure the health of all Indonesians.

Australia and New Zealand have shown good examples, in which their Standard 2.9.1 regarding Infant Formula Products have been frequently reviewed. For instance, SIF marketed in Australia should be made from SPI, which has higher protein digestibility than soya flour. It is likely due to bleak history of soya flour, which has a low protein availability and may cause neonatal diarrhea (Vandenplas et al., 2014; Westmark, 2017). Moreover, Australian Food Regulation Standing Committee particularly assigned 0.1 mg/100 mL as the maximum standard of aluminum in soya infant formula. This level of aluminum was considered to be harmless for normal infant but was not recommended for preterm infants (Chuchu et al., 2013). Likewise, the maximum and minimum level of soy protein isolate, ratio of calcium and phosphor, ratio of zinc and copper as well as GM soy risk analysis were

Table 1. Specific Provision Regarding SIF in Indonesia, Australia and New Zealand

Aspects	Indonesia	Australia and New Zealand
Regulations	Decree of NAFDC Number 1 Year 2018 on Supervision of Processed Food for Special Nutritional Purposes	Australia New Zealand Food Standards Code, Standard 2.9.1: Infant formula products
Source of infant formula	May be made from SPI	SPI is the sole source of SIF
Total protein isolate		
Minimum	2.25 g/100 kcal (0.54 g/100 kJ)	0.45 g/100 kJ
Maximum	3.0 g/100 kcal (0.72 g/100 kJ)	1.4 g/100 kJ
Upper limit reference	none	none
Calcium: Phosphor ratio		
Minimum	1:1	1.2:1
Maximum	2:1	2:1
Zinc: copper ratio	none	max 15:1
Aluminium	not mentioned	max 0.1 mg/100 mL
Isoflavone level	not mentioned	not mentioned not mentioned, but provided in different section, i.e.: Standard 1.5.2 (Food produced using gene technology)
GM soy	not mentioned	
Pesticide residue	not mentioned	not mentioned
Labelling and packaging requirements	Same as other infant formulas	Same as other infant formulas

made based on scientific evidence. In general, this standard was relevantly developed to meet the WHO's standard of infant formula, World Trade Organization agreements and nutrition policies in Australia and New Zealand.

On the other hand, NAFDC has not assigned more specific details of SIF produced and marketed in Indonesia. For instance, Indonesia does not propose the legally required SPI as a sole source of SIF. This means manufacturers may produce SIF from soya flour even though it may lead to neonatal diarrhea and it has a low bioavailability. Fortification of SIF with micronutrients including trace minerals should be a compulsory, otherwise it may increase the risk of malnutrition in newborn baby (Gomez et al., 2016). Moreover, the ratio of zinc and copper in Indonesian SIF are not mentioned. In fact, this is quite important in reconstitution of powdered milk product. Improper ratio may result in trace-element nutrition unbalance (Gomez et al., 2016). Furthermore, certain standard of isoflavone level need to be assigned to prevent the possible effect on reproductive functions (Abo-Elsoud et al., 2019; Chen and Rogan, 2004; Esch et al., 2016; Vandenplas et al., 2014; Yu et al., 2016; Zhu et al., 2016). It is due to the evidences that women fed with soy formula in early infancy tend to experience heavy menstrual bleeding, have higher maturation index and unfavorable effects on early menarche compare to those fed with non-SIF (McCarver et al., 2011; Stallings et al., 2017; Upson et al., 2016). Similarly, in male infants, exposure of SIF may suppress their steroidogenic capability which leads to the disturbance of sex hormone release (Abo-Elsoud et al., 2019; Chen and Rogan, 2004; Zhu et al., 2016).

In addition, the maximum level of aluminum in SIF should be assigned by Indonesian government. Aluminium exposure from soybean and equipment residues in milk factory may lead to serious health problems in infant's gastrointestinal tract and renal functions (Burrell and Exley, 2010; Vandenplas et al., 2014; Westmark, 2017). Furthermore, issues related to GM soy should be anticipated. Those all become an important homework for NAFDC as Indonesian primary agency to assess and formu-

late the national policies. Indonesian NAFDC needs to work together and engage with other relevant ministries, stakeholders including manufacturers, scientists and community to establish a better food regulation and policy system. Hence, in the future, those references should become guidelines for all manufacturers to produce soy-based infant formula and provide adequate information to assist consumers, especially mothers who are not able to breastfeed their babies. On top of that, well-developed food standards will protect the health of Indonesian generation.

5. Conclusion

Indonesian food policies regarding SIF is considered inadequate to protect Indonesian generation who consume SIF. Very limited provisions and clauses regarding 4 major issues of SIF consumptions have been covered by the Decree of NADFC Number 1 Year 2018 on Supervision of Processed Food for Special Nutritional Purposes. On top of that, Indonesian society are not well-informed to the process of policy review and analysis. This brings to the lack of food policy literacy among Indonesian people. Therefore, Indonesia needs a comprehensive system where society may participate in reviewing the laws.

Considering issues about the extrapolating potential long-term effects of isoflavones, phytates, aluminum, pesticide residue and transgenic soy in human body, personally think, Indonesian government should start developing specific regulations of soy infant formula. It could be recommended that certain standard of isoflavone level is set to prevent the possible effect on reproductive function. In terms of phytates issue, it may also be advisable if the fortification of iron, zinc, calcium, and phosphorus in soy infant formula become a compulsory for the milk manufacturers. Furthermore, it may be regulated that SIF is not recommended for preterm infants except certain technologies have been well established to anticipate the adverse effects on premature baby. However, to develop the regulation, it requires further clinical and epidemiological studies and may take a long journey.

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Conflict of Interest

There is no conflict of interest.

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