The Implementation Problems on Application Law Number 33 Year 2014 about Halal Product Guarantee (Study of Medicinal Products)

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ABSTRACT

By the implementation of Law No. 33 year 2014 concerning Halal Product Guarantee, it mandates that any existing products must be halal. The meaning of product is "goods and/or services related to food, beverages, drugs, cosmetics, chemical products, biological products, genetic manipulation products, as well as used things that are worn, used, or utilized by people". Article 4 of the Law stipulated that "Products which entered, circulated and traded in the territory of Indonesia must be halal-certified". By normative side, both articles are clearly stipulated that medicine that was imported, circulated and traded in Indonesian must be guaranteed its halal status. This paper will look at the aspect which aims to find out the problem in the implementation of Law Number 33 year 2014 concerning Halal Product Guarantee and the role of the government in the success of Law Number 33 year 2014 concerning Halal Product Guarantee in Indonesia. Looking at the purpose of the formation of Law No. 33 year 2014 concerning Halal Product Guarantee and the obstacles deal with its implementation, then looking at the extent of the government's role in the success of Law No. 33 year 2014 concerning Halal Product Guarantee in Indonesia. The provisions concerning exemptions related to the use of non-halal medicine in certain conditions are not sufficiently regulated in Law Number 33 year 2014. For this reason, at the Government level, it is necessary to stipulate more detailed and operational rules regarding the provisions regarding medicine and treatment in order to remain related with the provisions of Islamic law, and not to complicate people, and not to be a problem with the provisions in Law No. 33 year 2014 concerning Halal Product Guarantee. Because the reality happened in society is that there are still products contained hazardous substances which will have an impact on health, while the normative rules regarding halal conditions in medicinal products are clearly illustrated in the Qur'an and the Hadith. The provision applies in normal conditions (fi halat al-ikhtiyar). However, in certain situations, it is possible to consume things that are unclean and forbidden, because there is a greater purpose, preventing the occurrence of more fatal dangers, such as disability, serious illness, to death. These abnormal conditions will apply special laws. With the applying of those regulations above, it means all provisions related to the use of drugs must be halal-certified because if it is not halal-certified, then it certainly violates the rules set by the government through Law No. 33 year 2014.

Keywords: Implementation Problems, Law Number 33 Year 2014

INTRODUCTION

Problems with implementing the application of Law No. 33 Year 2014 on Halal product Guarantee and the role of government in the success of law number 33 Year 2014 on Halal product Guarantee in Indonesia, lies in the commitment The Indonesian Government and the great willingness of all Indonesians in which the enactment of Law No. 33 Year 2014 means that the government is prepared with all the
consequences of the products circulating in the territory of Indonesia. As stated in article 4 concerning circulation that products entered, circulated, and traded in the territory of Indonesia shall be certified Halal.

Halal certificate is a written decree (fatwa) of Indonesian Ulema Council (MUI) that clarified the halal food product is in accordance with Islamic law, aims to provide legal certainty to those who consume the food. However, existing regulations still impressed sectoral, partial and inconsistent and not systemic and most fundamental that the halal certification is not an obligation (mandatory) for businesses, but it is voluntary (Sofyan Hasan, 2014).

Speak Halal product, not only in line with food, but also medicine, and cosmetics, financing, and even halal tourism. Data shows the value of the transaction of halal products in the year 2005 is estimated to $2.1 trillion. Demand for halal products increased as the time and population increase Muslims. In 2009 there were about 1.82 billion Muslims in the world, projected in the year 2025 Muslims will cover 30% of the world population. Indonesia itself saves a huge potential in this regard. Has the largest Muslim population in the world (Anton Apriyantono, 2019), and has government support in the form of Halal Product Assurance Act that has been formed along with Institute for Drug and Cosmetic Food Assessment Indonesian Ulema Council. All of this, Indonesia’s biggest challenge is the implementation of technical matters such as regulations that include certification systems, supervision, and coaching. In addition, Indonesia also has no Mutual Recognition Agreement (MRA) with other countries, industrial infrastructure, and ease of access to the raw materials of halal, thoyyib, and relatively inexpensive industries. Health products are also required to have halal certificates such as medicines, biologic products (including blood for transfusions and derivative products derived from blood), vaccines, chemical products, and genetic engineering products used for the treatment of or prevention of disease.

METHODS

Methodology

This writing is research library or library research. Where each research focuses on the discussion using the approach (literature research). Approach in problem solving and discussion will be done by descriptive analysis, which describes and analyzes the data by linking the context of the problem that is being discussed with data. That exist or perhaps with concepts in a particular field that relate to it. Data analysis uses content analysis (content analysis) where conclusions are made from the assessment of data conducted systematically and objectively.

Discovery

In the course of Law No. 33 year 2014 about the Halal Product Guarantee is formed with the intention to guarantee to the religious people to worship and live the doctrine of religion, giving a sense of comfort and protection to the Community, especially those who are Muslims of all food products and used in circulation in the territory of Indonesia for the government very and the role of the Government in this case is still limited to policy/regulation, but in its implementation there is no hard sanction issued as a deterrent effect for producers in violation of the above provisions.

1. The absence of the rules of implementation concerning this law which should have been launched by the government in September 2019
2. Lack of human resources on the provider of the company's Halal product assurance Organizing Agencies of halal Product Guarantee herein after referred to as (BPJPH) because an estimated 1.5 million companies, especially food requires Halal certification
3. The duties, functions, and arrangements of the organization Organizing Agencies
of Halal Product Guarantee are governed in the Presidential regulation. Organizing Agencies of Halal Product Guarantee authorities include:

a. Formulating and establishing Halal Product Guarantee policy
b. Determine the norms, standards, procedures and criteria of Halal Product Guarantee
c. Publish and revoke Halal certificate on foreign products; And
d. Register Halal certificate on foreign products.

In carrying out the authority as intended, Organizing Agencies of Halal Product Guarantee in cooperation with the ministries and/or related institutions, the Institute of Halal Inspectors (LPH), and the Indonesian Ulema Council (MUI). This establishment requires mature technical preparations. This will be difficult because the implementation regulation of Halal Product Guarantee law does not exist.

RESULT AND DISCUSSION

After the issuance of Law No. 33 year 2014 about Halal product guarantee, then solve the problem regarding the product, circulating products in Indonesia, there are some obstacles faced mainly against the product with the type of The drugs in the implementation of the field include:

1. Getting Halal raw materials
   The lack of domestic medicines and vaccine raw materials encourages the pharmaceutical industry to import from other countries. To date, no less than 95 percent of the material originated in China, Korea, India, and the United States. Therefore, some products are difficult to get Halal label from the government and Indonesian Ulema Council. However, it can still be sought while there is a support fund research of raw materials from the government. The reason, to get the perfect formula, requires in-depth research. As such, the halal product is assured because the healthcare industry does not have to import raw materials from other countries.

2. Adequate infrastructure support for the production process
   Article 50 in Law No. 33 year 2014 mentions that the business actors must separate the location, the production process, until the distribution of halal and non halal products. To implement the chapter, it certainly needs a qualified facility. For instance, the development of new infrastructure so that the product manufacture can be distinguished. For large companies, it may be easy to make changes. However, small industries are developing, often experiencing difficulties in funding. Not necessarily, they can build new infrastructure quickly. In fact, on the other hand, the industry should immediately release the products needed by the community.

3. Quality versus Halal raw materials
   Halal label can guarantee the quality of the pharmaceutical product because it should be with the application of this law is not a consideration for the manufacturer of the drug to determine a specific composition reduction in some types of medicines that can reduce the quality Drugs and vaccines. Conversely, the effectiveness of products is more assured if only emphasized on the criteria of safe, qualified, and efficacious. If you still change the formulation or composition, the company must repeat several tests. From the start of the stability test, the preparation performance, the clinic, to the process revalidation. For sure, this action takes a very long time. Meanwhile, the production void of the drug or vaccine has an impact on patient safety.

4. Time and expense constraints to get certified
   Ideally, the halal certification expenditure process is about 3-4 weeks. However, some companies take more time than that. There are constraints of document completeness; products do not
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qualify, until the issue costs. Regarding costs, some of the chapters in Law No. 33 year 2014 do mention it. For instance, article 23 letter C which reveals that halal certificate can be obtained at an affordable cost. Then, in article 44 clause 1-3 also mentioned the issue of certification funding is charged to the business actors. However, for micro enterprises, the expense can be transferred to local government or other institutions. Clearly, it is explained in the general provisions of Law Halal Product Guarantee number 33 year 2014 point 5. That, funding can be borne by the Regional Revenue and Expenditure Budget (APBD), Country Revenue and Expenditure Budget (APBN), social institutions, associations, religious institutions, or communities. (Danur Osda, 2019) Many manufacturers are not yet aware of the importance of halal certificates because these certificates were once voluntary for producers who wish to apply for halal certification. Based on Food and Drug Supervisory Agency data, the number of registered products is as much as 113,515 products, while having had the Halal certificate Indonesian Ulema Council only 41,695 products. This means that only 36.73% of products circulating in Indonesia and have been certified Halal Indonesian Ulema Council. (Chintia Faradina, et.al., 2019)

5. The ignorance of the public to the implementation of this law also applies to products with the type of drugs also does not have a significant impact on the sale of drugs and vaccines, so that the drug manufacturers are still in On the comfort zone

6. The sanctions are unclear as well as the one that is guessing the entrepreneurs still got a fresh breeze.

CONCLUSION

From the above classification can be concluded:

1. The Government must immediately issue a regulation in the form of implementing Committee to implement this legislation in whole and mature

2. The difficulty of procurement of raw materials and seriousness of the manufacturer of drugs-the drug to receive the best solution to implantation of these laws can be applied to the drug products also seems to have not received a warm welcome

Long and expensive administration and bureaucratic into consideration of the lack of interest in producers in halal certification

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