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西村あさひ法律事務所

General Food Safety Regulations in Indonesia (Vol. 2): Genetic Engineering, Packaging, Labelling, and Advertising

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Author:
E-mail Noriaki Machida
E-mail Ikang Dharyanto
E-mail Made Grazia Valyana Ustriyana

1. Introduction

Indonesia has several laws that regulate food safety. In the previous issue of this newsletter, we identified the key laws governing food safety in Indonesia, and also discussed the regulation of food additives, insecticides and novel foods.

In continuance of our first article on "**General Food Safety Regulation in Indonesia**", in this article, we will focus on the regulation of genetic engineering of food, along with the regulation of manufacturing, packaging, labelling and advertisement of food in Indonesia.

2. Genome Editing and Genetic Modification

In Indonesia, there (still) are no comprehensive regulations on genetically engineered products ("**GMP**"); however, Government Regulation No. 21 of 2005 on Biological Safety of Genetic Engineering Products ("**GR No. 21**") remains the most relevant.[1]

According to Law No. 18, as lastly amended by the Government Regulation in Lieu of Law No. 2 of 2022 on Job Creation ("**Perppu No. 2**") ("**Law No. 18**") in conjunction with GR No. 21, "genetic engineering of food" is a process that involves transferring genes (trait carriers) from one biological type to another different or similar biological type to obtain a new type capable of producing superior "Food Products,"[2] known as GMP,[3] which also includes food products produced or using raw materials, food additives or other materials resulting from genetic engineering processes.

Based on GR No. 21, there are several types of GMP, as follows:

a. animal GMP, animal products GMP, and products of the processing thereof;
b. fish GMP, fish products GMP, and products of the processing thereof;
c. plants GMP, plant products GMP, and products of the processing thereof; and

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1 See our previous newsletter on the basic provisions on Genetically Engineered Food Products under Law No. 18.

2 Anything that comes from biological sources of agricultural, plantation, forestry, fishery, animal farming, waters (*perairan*), and water (*air*) products, whether processed or unprocessed which is designated as food or beverage for human consumption, including food additives, food raw materials, and other materials used in the preparation, processing and/or production of food or beverages.

3 Law No. 18, Article 1.33.

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d. microorganisms GMP, microorganism products GMP, and products of the processing thereof.

GMP Requirements

GR No. 21 provides that GMP from domestic or foreign countries, analyzed or assessed before they are released or circulated in Indonesia, must be completed with basic information indicating that the products have met conditions of environmental safety, food safety, or GMP safety, as is appropriate.

The basic information indicating fulfillment of environmental safety, as set forth above, involves, amongst others, the following:

a. description and purpose of utilization;
b. expected genetic and phenotypic changes must be detectable;
c. clear identity on taxonomy, physiology, and reproduction of GMP;
d. organisms used as sources of genes must be indicated clearly and comprehensively;
e. the applied genetic engineering methods must follow the standard procedure that can be held accountable scientifically;
f. characteristics of the applicable GMP molecules must be described clearly;
g. expression of genes transformed to GMP must be stable; and
h. destruction methods applied in case of deviation.

While the basic information indicating fulfillment of requirements for food and GMP safety, as set forth above, consist of, amongst others:

a. the applied genetic engineering methods must follow a standard procedure that can be held accountable scientifically;
b. a GMP's nutritional content must be substantially proportional to that of similar non-GMP;
c. content of toxic, anti-nutrient compounds causing allergy in GMP must be substantially proportional to that of similar non-GMP;
d. content of carbohydrate, protein, ash, fat, fiber, amino acid, fatty acid, mineral, and vitamin in GMP must be must substantially proportional to that of similar non-GMP;
e. the protein contained in the gene must not cause allergy; and
f. the destruction methods applied in case of deviation.

GMP Research and Development

Based on GR No. 21, every person who carries out GMP research and development must prevent and/or solve the negative impact of its activities on human health and on the environment and the GMP analysis during the research and development process must be conducted at the laboratory, limited analysis facility and/or limited analysis field.

Before GMP generated by research and development are proposed to be released and/or circulated, an efficacy test must be conducted and it must meet biological safety conditions.

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Introduction of GMP from Foreign Countries

Every person who will introduce similar GMP from a foreign country for the first time must submit an application to the authorized minister (namely the Minister of Environment ("**MOE**")) or to the head of the authorized Non-Departmental Government Institutions ("*Lembaga Pemerintahan Non Departemen/* "**LPND**")).

The application for introduction of GMP must be completed and accompanied by a document certifying that the conditions of environmental safety, food safety, and/or GMP safety have been met.

Other than meeting the provisions above, the introduction of GMP from foreign countries also must be complemented by:

a. a certificate of free trade of GMP in the country of origin; and
b. documents of risk analysis and handling from all authorized institutions where risk analyses were conducted.

Assessment, Release and Circulation of GMP

Based on GR No. 21, assessment of GMP must be conducted before the GMP is released and circulated in the territory of Indonesia.

The assessment shall be conducted based on the written proposal submitted by the applicant to the MOE or the head of the authorized LPND and after receiving the application, the MOE or the head of the authorized LPND, within a period of no later than 14 (fourteen) days, shall submit recommendation of biological safety of PRG to the Minister of the Environment or the Head of Commission for Biological Safety of Genetic Engineering Products (*Komisi Keamanan Hayati Produk Rekayasa Genetik* / "**KKH**[4]*"*).

In the framework of giving of the recommendation of biological safety of GMP, the MOE, or head of the authorized LPND shall assign KKH for assessment which shall be performed no later than 14 (fourteen) days since receipt of letter of assignment.

If the assessment is related to technical evaluation, KKH shall assign the Technical Team for Biological Safety of GMP ("**TTKH**"[5]) to assess the related technical documents and carry out further analysis, as necessary. The analysis of the technical documents shall be done no later than 56 (fifty-six) days since receipt of the letter of assignment from KKH.

Upon receiving the results of the technical evaluation and analysis, KKH, through the Agency for Clearance of Biological Safety of Genetic Engineering Products ("**BKKH**[6]"), shall announce, within no later than 15 (fifteen) days, the receipt of the application, process, and summary of the results of the analysis at a place accessible by the public for 60 (sixty) days to give the public an opportunity to submit their responses. If, within such

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4 KKH is defined as a commission having the duty to give recommendation to the MOE, and head of LPND authorized to arrange and determine policies and to issue certificate of biological safety of GMP.

5 TTKH is defined as a team assigned to assist KKH in conducting technical evaluation and analysis into biological safety and worthiness of consumption of GMP.

6 BKKH is defined as an instrument of KKH having the function as means of communication between KKH and stakeholders.

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time, the public does not submit any responses, the public is deemed not to object to the KKH recommendation and, afterward, the KKH shall submit their recommendation of environmental safety to the MOE, as well as their recommendation of food safety and/or GMP safety to the MOE or the head of the authorized LPND.

Only GMP which have obtained a biological safety recommendation from the MOE or the head of the authorized LPND can be released[7] and circulated[8] within the territory of Indonesia.

3. Food Manufacturing Process and Packaging

The general principle under Indonesian law is that any person producing food for trade is required to apply food processing procedures that prevent the decline of nutritional value and wasting of raw materials. These food processing procedures are implemented gradually based on food type as well as the business type and scale of food production.

Food production processes also must comply with the Food Sanitation procedures determined by Law No. 18. Food Sanitation procedures must be implemented in manner that renders food safe for consumption and maintains such character throughout the activity or process of food production, storage, transport and/or distribution.

The Food Sanitation requirements include as follows:

a. avoidance of the use of materials that can threaten food safety along the food supply chain;
b. Food Contaminant[9] compliance;
c. process control along the food supply chain;
d. material traceability system implementation; and
e. prevention of decrease or loss of nutritional content.

In addition to the above requirement, any person who produces food must also comply with the food packaging requirements aimed at preventing food spoilage and decomposition, protecting food products from contamination, and eliminating foodborne pathogens.[10]

4. Food Labeling

Pursuant to Government Regulation No. 86 of 2019 on Food Safety ("**GR No. 86**"), any person who packs food must observe, among other things, protocols targeting protection of food from contaminants and suitable labelling. "Food labelling" is defined under GR No. 86 as any information concerning food in the form of

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7 "Release" is defined as a statement of recognition that can be distributed after the associated matter/item is determined to meet the requirements pursuant to the applicable laws.

8 Circulation is defined as one or more activities in the framework of commodities distribution to the public, either for trade or not.

9 GR No. 86 (as defined below) defines "Food Contaminant" as material incidentally or undesirably in food that comes from the environment or as a result of a process in the food supply chain and includes, among others, biological contaminants, chemical and heavy metals contaminant, mycotoxins, radioactive substances, and other chemical contaminants, residues of pesticides and veterinary medicines and other substances that can disrupt, harm, or endanger human health.

10 See our previous newsletter on the summary of establishment of food packaging standards under the prevailing regulations.

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pictures, writing, combinations of both or other shapes which are put on, put into, stuck to, or constitute part of food packages. As briefly discussed in our previous newsletter, food business operators must ensure such labels are on and/or part of food packages, and the labels shall be written or printed by using the Indonesian language, Arabic figures and Latin letters.

Further details on food labeling requirements are provided under Government Regulation No. 69 of 1999 on Food Labels and Advertising ("**GR No. 69**"), and specifically for processed food under (a) Head of BPOM Regulation No. 31 of 208 on the Processed Food Labelling as amended by Head of BPOM Regulation No. 20 of 2021 on the Amendment ("**BPOM Reg 20**") and (b) Head of BPOM Regulation No. 26 of 2021 on Nutritional Value Information on Processed Food Label ("**BPOM Reg 26**").

Format requirements

As mentioned above, the details in labels shall be written or printed in the Indonesian language, using Arabic figures and Latin letters. The letters and figures contained in labels shall be clear and easy to read, and shall be of a proportional manner with the surface area of the Label. The use of backgrounds, in the form of pictures, colors and/or other decoration that may obscure the writing in the main part of the label, is prohibited.

With regards to processed food,[11] BPOM Reg 20 specifically regulates that the writing of the Label shall be equal to or greater than the lowercase "o" in Arial typeface with the minimum size of 1 mm (Arial 6 points), while the information of the product names and warnings must be made with the minimum size of 2 mm.

Country of origin

If food is imported from outside Indonesia, in addition to the name and address of the foreign manufacturer, the name and address of the importing party shall be declared on the label.

Content requirements

The main part of labels contain at least the following information, which must be arranged in an orderly, not crowded, manner, and clearly placed in an easily readable position. This part must be placed on the side of packages of Food which allow the public to easily see, observe and/or read it:

a. Name of the product;

   The product name of processed food includes the accurate nature and/or the condition of such food. In addition, the label can include a trade name as well.

b. Net weight or net content; and

   Under GR No. 69, all food sold must contain the measurement markings as follows:

   i. measurement of content for liquid food;
   ii. measurement of weight for solid food; and
   iii. measurement of content or weight for semi-solid or thick food.

[11] Namely, food or beverages resulting from processing by certain means or methods with or without additives.

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c. Name and address of the producer or importer of the food into Indonesia,

   For local products, the producer's name and address should be included. As for imported food, the label must include the importer's name and address. In case the distributor is different from the importer, the distributor's name and address also must be included.

In addition to the above, the following information may be required or included in the label:

a. Information on ingredients used;

   This information shall be included as a list of ingredients, in the order starting from the ingredient which has the largest proportion, except vitamins, minerals and other natural supplements. Groups of food additives shall be mentioned on labels of food containing food additives.

b. Date of expiration;

   The date, month and year of expiration information should be clearly mentioned and preceded by the term "*baik digunakan sebelum*" (best before).

c. Information on nutrition content; and

   Information on the nutrition content of food shall be contained in labels of the food, which are:

   a. accompanied by statements that the food contains vitamins, minerals and or other kinds of nutrition supplements; or
   b. required on the basis of provisions of laws in force in the fields of food quality and nutrition, to supplement vitamins, minerals and/or other kinds of food nutrition.

   Further details on nutrition labeling can be seen in '5. Nutrition Labeling' below.

d. *Halal* for those required.

   GR No. 69 requires anyone producing or importing packed food into the territory of Indonesia for trading and declaring that the said food is permissible for Moslems, shall be responsible for the accuracy of the statement and put the information or word "*Halal*" on the labels, which shall constitute an inseparable part of labels.[12]

For processed food, BPOM Reg 20 provides that the label for processed food must at least include the following information:

a. product name;

b. list of materials used, which shall include raw materials and food additives;

   For food additives, the label must incorporate the following information: (i) the wording "*bahan tambahan pangan*", (ii) the name of the relevant food additive category, (iii) the name of the relevant food additive type, and (iv) the

[12] See also our previous newsletter on this matter.

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maximum amounts food additives that are used in the processed food.

c. net weight or net contents;

d. name and address of the producing or importing party;

e. halal for those required;

   Processed food imported to Indonesia for retain trading is required to include *Halal* information in its label after obtaining a *Halal* certificate. Article 32(3) of BPOM Reg 20 explicitly confirms that non-halal food products (i.e., food products containing non-halal ingredients) are exempted from the halal certification requirement. This means that they can still be sold and distributed in Indonesia.

f. production date and code;

g. expiry date;

h. distribution license (*izin edar*) number; and

i. origin of certain Food ingredients.

   Information about the origin of certain food ingredients includes:

   i. Origin of animal-sourced or plant-sourced ingredients; and

   Animal-sourced or plant-sourced ingredients should be labeled with the animal/plant type followed by the origin of the ingredient.

   Processed food containing ingredients derived from pork is obligatory to include a special sign with the words "*mengandung babi*" (containing pork) and a picture of a pig.

   ii. Food produced through a special process (including genetically engineered food and irradiated food).

If the processed food is intended for sale and processed as "other food," the label must contain information on (a), (c), (d), (f) and (g) above. The labels of food products involving further processing must include an appropriate disclaimer, such as "not for retail sale," "not for repackaging," "only for hotels, restaurants, and catering needs," or by using similar meaning sentences.

In addition, information on allergens and warnings on alcoholic beverages and dairy products must also be included, if applicable. Processed food shall include nutrition claims and health claims, as relevant, and also may include other claims on the label. There also are specific warning requirements for food additives which contain polyol and comparison claims (e.g., if the labels compare the quality of nutrient content with another product, such as "special", "premium", "gold", "platinum", "extra", "plus (+)", "advanced", or other similar words) which shall be accompanied by an asterisk ("*") and the explanation of the asterisk, such as whether that information makes any difference or a comparison to similar products, if needed.

Mandatory warnings and advisory statements

The following are major warning and advisory statements required by GR No. 69:

a. The words "Irradiated Food" (*Pangan Radiasi*) must be included on labels of food that is subject to irradiation treatment. In the case of food not allowed to be irradiated again, the words "Not to be Re-Irradiated" also must be included.
b. The words "Genetically Engineered Food" (*Pangan Rekayasa Genetika*) shall be written on the labels of food resulting from genetic engineering.

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In addition, Article 38 of GR No. 69 also requires that information on labels for processed food for infants, children below five, pregnant or breast-feeding mothers, people on special diets, the elderly and those who suffer from specific diseases must contain information on the allocation, method of use and/or other necessary instructions including any health impact of the food to human health.

Violations and sanctions

Based on Law No. 18 in conjunction with GR No. 86, trading food that is not in accordance with the Food Safety and Quality claims written on the labeling is prohibited. Further in relation to labelling requirements, the following activities may be considered an offence:[13]

a. trading Food that is not in accordance with the food safety and quality claims written on the labeling;
b. erasing, retracting, covering, changing label, relabeling and/or exchanging expiry date, month and year on distributed food; and
c. providing information and statements that are false and/or misleading on the label.

5. Nutrition Labeling

As explained briefly in '4. Food Labeling' above, information on nutrition also is required in certain food labelling.

Nutritional value information on processed food

Under BPOM Reg 20, processed food shall include nutrition claims and health claims. Information regarding nutritional or non-nutritional content must be stated on the label in the form of Nutritional Value Information (*Informasi Nilai Gizi* or "**ING**") which is further regulated under BPOM Reg 26. The ING should be in the form of a table for one serving size, containing:

a. Serving amounts;
b. Number of servings per package;
c. Type and amount of nutrient content;
   Type of nutrient includes total energy, total fat, saturated fat, protein, total carbohydrates, sugar and salt (sodium).
d. Type and amount of non-toxic substances;
e. Recommended Nutritional Adequacy Rate for the Indonesian Community (*Angka Kecukupan Gizi yang Dianjurkan untuk Masyarakat Indonesia*, known as AKG) percentage; and
f. Applicable footnotes.

6. Health Claims and Nutrition Claims

Based on GR No. 69, Food that contains vitamins, minerals and or other kinds of nutrition supplements must state the presence of such products on the label of the food. Nutrition content and health claims are regulated by Head of BPOM Regulation No. 1 of 2022 on the Supervision of Claim on Processed Food Label and Advertisement ("**BPOM Reg 1/2022**").

[13] See our previous newsletter for the possible administrative or criminal liabilities for such offence.

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BPOM Reg 1/2022 defines 'nutrient/non-nutrient claims' as all forms of descriptions that state, indicate or imply that food has certain nutrient/non-nutrient characteristics including, among other things, energy value and protein, fat and carbohydrate content, and vitamin and mineral content. Nutrient/non-nutrient claims include:

a. nutrient/non-nutrient content claims;
b. comparative claims on nutrient/non-nutrient;
c. claims on no addition of sugar;
d. claims on no addition of salt;
e. lactose claims; and
f. gluten claims.

Details of requirements for each claim are include in the Attachments of BPOM Reg 1/2022.

Meanwhile, 'health claims' shall be all forms of descriptions that state, suggest or imply that there is a relation between food or food constituent materials and health. Health claims include functional claims on nutrient/non-nutrients which must state at least the source, disease risk reduction claims which can only be included after obtaining approval from the Head of BPOM, and glycemic claims which are proven by a clinical test.

Credence claims (e.g., organic, natural, fresh)

Organic

Organic food is regulated under the Head of BPOM Regulation No. 1 of 2017 on the Supervision of Organic Processed Food ("**BPOM Reg 1/2017**"). Processed food that already meets the requirements of organic processed food as stipulated in the Organic Process Food Regulation can be described as "Organic" and use the organic logo on the label and in advertising. The "Organic" wording shall be placed after the name of the food.

The minimum content of organic food in Organic Processed Food set out in BPOM Reg 1/2017 is 95% of the total weight or volume, excluding water and salt, with a maximum content of non-organic food of 5% of the total weight or volume, excluding water and salt. "Water and salt" in this regulation is water and salt added during food processing, which may be in the form of sodium chloride or calcium chloride.

Organic processed food and materials used for the manufacture of organic processed food are prohibited from being subjected to irradiation treatment and/or to be derived from genetically engineered products. However, BPOM Reg 1/2017 allows the addition of allowed food additives or excipient into organic processed food as listed in the Attachment to this regulation.

Organic processed food produced or imported to be distributed in Indonesian territory shall be evidenced by an organic certificate issued by an Organic Certification Agency.

Fresh

GR No. 69 stipulates that labels of food that is made of semi-finished materials or finished materials, is prohibited to contain information or statements that the food is made of "fresh" materials. Similarly, BPOM

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Reg 20 prohibits intermediate processed food or other processed food labels to include “fresh” in the wording of its label.

7. Labelling of Novel Food

There is no specific regulation or definition of “novel food” (*produk baru*) in Indonesia. As discussed briefly in our previous newsletter, “novel food” refers to any food ingredient which is not yet approved by the BPOM. Based on this, any party applying to use the phrase “novel food” in its labelling is encouraged to first consult with the BPOM.

8. Labelling of GMP

See ‘2. Genome Editing and Genetic Modification’ above for further details on GMP. Once approved for release or circulation in Indonesia, the label for GMP shall follow the requirements under GR No. 69.

GR No. 69 requires “Genetically Engineered Food” (*Pangan Rekayasa Genertika*) wording to be included in labels of food resulting from genetic engineering, i.e., GMP. In cases where food or ingredients resultant of genetic engineering are used in certain food products, the label should include such information (on the ingredient itself – not the food product). In addition to inclusion of such wording, the label also may contain a special logo for food resulting from genetic engineering.

9. Food Advertising

Food is treated as one of the special products and goods that directly affect human health and the environment, and as such food advertising is subject to stricter advertising requirements than other, “normal” goods and products in Indonesia.

Under Law No. 18 in conjunction with GR No. 69, all food advertisement must contain information or statements regarding the food that are correct and not misleading, both in the form of the pictures and/or voice statements and/or any other forms, and all persons are prohibited from including information or statements that are incorrect or misleading in food advertisement.

In addition to the above, Law No. 18 and GR No. 69 also contain several rules on food advertisement, as follows:

a. every Food advertisement shall not contravene the norms of decency and the public order;
b. any person stating in the advertisement that the food for trade is halal according to the requirements, must be responsible for its truth;
c. any person stating a claim in the advertisement for food trade is obligated to be responsible for the truth of that claim;
d. anybody producing and/or importing food into the territory of Indonesia for trading shall be prohibited from including untrue and/or misleading statements and/or information in advertisements;
e. publishers, printers, licensees of radio or television broadcasting, agents and/or any medium used for disseminating advertisements shall share responsibility for the contents of untrue advertisements, unless the relevant parties have already taken actions needed to examine the truth of the contents of the relevant advertisements;

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f. for the interest of supervision, publishers, printers, licensees of radio or television broadcasting, agents, and/or any medium used for disseminating advertisements shall be prohibited from keeping in secrecy the identities, names and addresses of advertisers;
g. advertisements shall be prohibited from being made in forms discrediting other food products;
h. advertisements shall be prohibited from merely displaying children below 5 (five) in any form, unless the food is designed for children below 5 (five);
i. advertisements of certain food containing high-grade ingredients which can endanger and/or disturb the growth and/or development of children shall be prohibited from being published through any media specially intended for children;
j. advertisements of food for infants up to 1 (one) year old shall be prohibited from being published in mass media, except in special printed media for health, after securing approval from the Minister of Health, and information that the relevant food is not a substitute for mothers' milk must be contained in the relevant advertisements;
k. statements in any form on benefits of food to health which are contained in advertisements in mass media shall be accompanied by information supporting the statements on the relevant advertisements clearly so as to be easily understood by society;
l. advertisements in mass media stating that a food is designed for people on a special diet shall contain elements supporting the statement;
m. advertisements shall be prohibited from containing information or statements that ta food is a source of superior energy and promptly produces strength;
n. advertisements of food for infants and/or children below five shall contain information on its indication;
o. advertisements of processed food containing materials which can disturb the growth and/or health of children shall contain warnings about the negative impacts of the food on the growth and health of children;
p. advertisements shall be prohibited from containing statements or information that the relevant food can function as a medicine;
q. advertisements for food which is made without or partially uses natural raw materials shall be prohibited from containing statements or information that the relevant food is wholly made of natural raw materials;
r. advertisements of food which is made of semi-finished ingredients or finished ingredients shall be prohibited from containing statements or information that the relevant food is made of fresh materials;
s. advertisements containing statements or information that the food has already been enriched by vitamins, minerals and other nutrition supplements shall not be prohibited, as long as the enrichment is done correctly upon the processing of the food.

GR No. 69 further provides that anybody violating the provisions above shall be subject to administrative sanctions, which include:

a. written warnings;
b. prohibition from distributing food products for a certain period and/or order to withdraw food products from distribution;
c. destroying food if the food is proven to endanger health and human life;
d. discontinuation of production for a certain period;
e. imposition of a fine totaling Rp.50,000,000.00 (fifty million Rupiah) at the maximum, and/or
f. revocation of production or business licenses.

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