FOOD AND DRUGS SUPERVISORY AGENCY REGULATION

NUMBER 6 YEAR 2018

ON

SUPERVISION OF GENETICALLY MODIFIED FOOD

BY THE GRACE OF GOD ALMIGHTY,

HEAD OF FOOD AND DRUGS SUPERVISORY AGENCY

Considering :

a. that to implement the provisions of Article 14 paragraph (5) of the Government Regulation Number 28 Year 2004 on the Safety, Quality, and Nutrition of Food and Article 7, Article 20 paragraph (4), and Article 27 paragraph (6) of the Government Regulation Number 21 Year 2005 on Bio-safety of Genetically Modified Products, it is required to regulate the safety assessment on the genetically modified food;

b. that several provisions in the Regulation of the Head of Food and Drugs Supervisory Agency Number HK.03.1.23.03.12.1563 Year 2012 on the Guidelines of Safety Review of Genetically Modified Food as amended by the Regulation of the Head of Food and Drugs Supervisory Agency Number HK.03.1.23.03.12.1564 Year 2012 on Supervision of Genetically Modified Product Labeling, it is necessary to adapt to the advanced knowledge and technology;

c. that upon the consideration as referred to in letter a and letter be, it is necessary to stipulate Regulation of Food and Drugs Supervisory Agency on the Supervision of Genetically Modified Food.

In view of :

1. Laws Number 8 Year 1999 on Consumer Protection (State Gazette of the Republic of Indonesia Year 1999 Number 42, Supplement to the State Gazette of the Republic of Indonesia Number 3821);
2. Laws Number 21 Year 2004 on the Legalization of Cartagena Protocol on Biosafety to the Convention on Biological Diversity (State Gazette

of the Republic of Indonesia Year 2004 Number 88, Supplement to the State Gazette of the Republic of Indonesia Number 4414);

3. Laws Number 36 Year 2009 on Health (State Gazette of the Republic of Indonesia Year 2009 Number 144, Supplement to the State Gazette of the Republic of Indonesia Number 5063);
4. Laws Number 18 Year 2012 on Food (State Gazette of the Republic of Indonesia Year 2012 Number 227, Supplement to the State Gazette of the Republic of Indonesia Number 5360);
5. Government Regulation Number 69 Year 1999 on Food Label and Advertising (State Gazette of the Republic of Indonesia Year 1999 Number 131, Supplement to the State Gazette of the Republic of Indonesia Number 3867);
6. Government Regulation Number 28 Year 2004 on Food Safety, Quality and Nutrition (State Gazette of the Republic of Indonesia Year 2004 Number 107, Supplement to the State Gazette of the Republic of Indonesia Number 4424);
7. Government Regulation Number 21 Year 2005 on Biosafety of Genetically Modified Product (State Gazette of the Republic of Indonesia Year 2005 Number 44, Supplement to the State Gazette of the Republic of Indonesia Number 4498);
8. Presidential Regulation Number 39 Year 2010 on the Biosafety Committee of Genetically Modified Product as amended by Presidential Regulation Number 53 Year 2014.
9. Presidential Regulation Number 80 Year 2017 on Food and Drugs Supervisory Agency (State Gazette of the Republic of Indonesia Year 2017 Number 180);
10. Regulation of Food and Drugs Supervisory Agency Number 26 Year 2017 on the Organization and Working Procedures of Food and Drugs Supervisory Agency (State Gazette …);

To Stipulate : REGULATION OF FOOD AND DRUGS SUPERVISORY AGENCY ON THE SUPERVISION OF GENETICALLY MODIFIED FOOD

CHAPTER I

GENERAL PROVISIONS

Article 1

In this Agency Regulation, what is meant by:

1. Food is anything originated from bio-product of agriculture, plantation, forestry, fishery, waters, either processed or not, serving as food or drink for human consumption that include additional materials, raw materials, and other materials used in the process of preparing, processing, and/or making of food or drink.
2. Processed food are food or drink resulting from the process of particular ways or methods, with or without additional materials.
3. Genetically Modified Food are food that are produced and/or use raw materials, additives, and/or other materials resulting from genetically modified products.
4. Genetically Modified Product or Organism resulting from modification, hereinafter referred to as GMP, is living organism, its parts, and/or the processed product having new genetic structures from the application of modern biotechnology.
5. Biosafety Commission of Genetically Modified Product, hereinafter referred to as BC GMP, is the commission in charge of providing recommendation to the authorized Minister and the Chairmen of Non-Ministry Government Institutions authorized in drafting and establishing the policies as well as publishing biosafety certificate of GMP.
6. Food Additives, hereinafter referred to as FA, are the materials added to the Food to change the properties or forms of the Food.
7. Processing Aid is the material, excluding the tools, which is not commonly consumed as Food, used in Food processing to fulfill the particular aim of technology and shall not leave any residue to the final product. However, in inevitable condition, the residue or the derivation in the final product shall not pose any risk to the health as well as having technological function.
8. Food Label, hereinafter referred to as Label, is every information on the Food in the form of pictures, writing, combination of both, or any other form attached on the Food, inserted in, attached on, or be the part of Food packaging.

9. Food Business Actor is every individual working on one or more Food agribusiness sub-systems, namely production input supplier, production process, processing, marketing, trade, and supports.
10. Every Individual is an individual or a corporate, both legal entities and non-legal entities.
11. Agency Head refers to the Head of Food and Drugs Supervisory Agency.

CHAPTER II

GENERAL

Article 2

(1) The Agency Regulation shall be effective for GMP Food produced in the country or imported.
(2) GMP Food as referred to in paragraph (1) shall be:
    a. raw maerials;
    b. FA;
    c. Processing Aids, and
    d. Processed Food.

Article 3

Food Business Actor who produce and/or import GMP Food for trade shall be obliged to fulfill the requirements of Food Safety, Quality, and Nutrition in accordance with the provisions of laws and regulations.

CHAPTER III

SAFETY REQUIREMENTS OF GMP FOOD

Article 4

(1) Other than fulfilling the requirements of Food Safety, Quality, and Nutrition as referred to in Article 3, Food Business Actor who produces and/or import GMP Food to be distributed in Indonesia shall hold the approval of GMP Food Safety.
(2) GMP Food safety approval as referred to in paragraph (1) shall be given to the Head after receiving the recommendation from BC GMP.

(3) GMP Food Safety approval as referred to in paragraph (2) shall be declared as GMP Food Safety Certificate.

(4) Recommendation of BC GMP as referred to in paragraph (2) shall be given after GMP Food safety assessment.

(5) The Assessment as referred to in paragraph (4) shall be conducted in accordance with the guidelines of GMP Food safety assessment as listed in Attachment I which is inseparable part of this Agency Regulation.

Article 5

(1) Other than the provisions as referred to in Article 4, Food Business Actor holding the certificate of GMP Food Safety shall be obliged to submit:
   a. GMP Food samples
   b. counterpart samples; and
   c. documents consisting of:
      1. valid detection method
      2. primary sequence information; and
      3. location information to obtain Certified Reference Material, if any.

(2) GMP Food sample, counterpart, and the documents as referred to in paragraph (1) shall be submitted in no later than 6 (six) months after the certificate of GMP Food Safety as referred to in Article 4 paragraph (3) is issued.

(3) GMP Food sample, counterpart, and the documents as referred to in paragraph (2) shall be submitted in the form as listed in Appendix III, which becomes inseparable part of the Agency Regulation.

(4) If necessary, the Head shall assign the holder of GMP Food Safety certificate to re-submit the sample of GMP Food and the counterpart as referred to in paragraph (1) letter a and b.

Article 6

Food Business Actor who produce and/or import Processed Food containing GMP Food, shall use GMP Food approved by the GMP Food safety.

Article 7

(1) The provisions as referred to in Article 4 paragraph (1) does not apply to the Processing Aids of GMP which does not contain GMP deoxyribonucleic acid/DNA and/or GMP Protein.

(2) Assessment on GMP deoxyribonucleic acid/DNA and/or GMP Protein in GMP Processing Aids shall be conducted following the procedures as listed in Appendix II which becomes the inseparable part of this Agency Regulation.

CHAPTER IV

GMP FOOD LABEL

Article 8

(1) Food Business Actor who produce GMP Food in the country and/or import GMP Food to be traded in the form of retail packaging shall include the Label in accordance with the provisions of laws and regulations.
(2) Other than including the Label as referred to in paragraph (1), Food Business Actor shall include the information of GMP Food on the Label.
(3) The information of GMP Food as referred to in paragraph (2) shall be written "GENETICALLY MODIFIED PRODUCT"
(4) The writing as referred to in paragraph (3) shall be effective for GMP Food containing one raw material listed on the name of the Food type on the main part of the Label.
(5) In the event that GMP Food is the raw material used in the Processed Food, the writing as referred to in paragraph (3) shall be listed after the name of GMP Food on the list materials being used.
(6) The provisions as referred to in paragraph (2) shall not apply to oil, fat, sugar, starch, and GMP Food that have been purified and cannot be identified as containing GMP Protein.

Article 9

(1) The obligation to include the information on GMP Food as referred to in Article 8 paragraph (2) shall be carried out to GMP Food containing at least 3 (three) percent of GMP deoxyrybonucleric acid/DNA
(2) In the event that the Processed Food contains more than 1 (one) GMP Food, the percentage of GMP deoxyribonucleic acid/DNA as referred to in paragraph (1) shall be calculated for each GMP Food.
(3) The concentration of GMP deoxyribonucleic acid DNA shall be proven with the accredited results of laboratory testing.

CHAPTER V

SANCTION

Article 10

(1) Every individual violating the provisions of Article 3, Article 4 paragraph (1), Article 5 paragraph (1), Article 6, Article 8 paragraph (1), and Article paragraph (2), shall be the subject of administration sanction in the form of:
   a. written warning;
   b. fines;
   c. temporary cessation of any activities, production, and/or distribution;
   d. withdrawal of the Food from distribution by the producer; and/or
   e. license revocation.

(2) The sanction as referred to in paragraph (1) shall be carried out in accordance with the provisions of laws and regulations.

CHAPTER VI

TRANSITIONAL PROVISIONS

Article 11

GMP Food distributed before the Agency Regulation comes into effect shall adapt to the provisions of the Agency Regulation no later than 12 (twelve) months after the enactment of the Regulation.

CHAPTER VII

CLOSING PROVISIONS

Article 12

On the day the Agency Regulation becomes effective:

1. The Regulation of the Head of Food and Drugs Supervisory Agency Number H.K.03.1.23.03.12.1563 Year 2012 on the Guidelines of Genetically Modified Food Safety Assessment as amended by the Regulation of the Head od Food and Drugs Supervisory Agency Number HK.03.1.23.03.12.1563 Year 2012 on the Guidelines of Genetically Modified Product Safety Assessment; and

2. The Regulation of the Head of Food and Drugs Supervisory Agency Number HK.03.1.23.03.12.1564 Year 2012 on the Genetically Modified Product Food Labeling Supervision;

   are revoked and declared no longer effective.

Article 13

The Agency Regulation shall come into effect on the day of the stipulation.

For public cognizance, this Agency Regulation shall be announced by publishing it in the State Gazette of the Republic of Indonesia.

Stipulated in Jakarta

HEAD OF FOOD AND DRUGS
SUPERVISORY AGENCY

[signed][stamped]

PENNY K.LUKITO

Enacted in Jakarta

On …

DIRECTORATE GENERAL

LAWS AND REGULATION

MINISTRY OF LAW AND HUMAN RIGHTS

REPUBLIC OF INDONESIA

WIDODO EKATJAHJANA

STATE GAZETTE OF THE REPUBLIC OF INDONESIA YEAR … NUMBER….