

**GUIDELINE FOR TAKING SECURITY ACTION OVER  
THE OBJECT) IN THE SUPERVISION OF DRUGS AND FOOD  
CIRCULATION AT THE PRODUCTION, DISTRIBUTION,  
AND PROVISION OF DRUGS AND FOOD  
(Regulation of the Head of Drugs and Food Supervisory Body of R.I.  
Number 3 Year 2016, dated February 23, 2016)**

WITH THE BLESSING OF THE ONE AND ONLY GOD  
THE HEAD OF DRUGS AND FOOD SUPERVISORY BODY  
OF THE REPUBLIC OF INDONESIA

Considering:

- a. Whereas, in certain situation and condition that needs further clarification and confirmation on supervision of drug and food circulation at the production, distribution, and provision of drug and food, Object of Security Action action is needed;
- b. Whereas, based on the consideration referred to in letter a and provide certainty of the law on the Officer and/or owner of facilities for production, distribution, and provision of drug and food, it is necessary to stipulate Regulation of the Head of Drug and Food Supervisory Body concerning Guideline for Exercising Object of Security Action action on the supervision of Drug and Food Circulation at the Facilities of Production, Distribution, and Provision of Drug and Food ;

In view of:

1. Law Number 5 Year 1997, concerning Psycotrophics (Statute Book of the Republic of Indonesia Year 1997 Number 10, Supplement to Statute Book of the Republic of Indonesia Number 3671);
2. Law Number 35 Year 2009, concerning Narcotics (Statute Book of the Republic of Indonesia Year 2009 Number 143, Supplement to Statute Book of the Republic of Indonesia Number 5062);

3. Law Number 36 Year 2009, concerning Health (Statute Book of the Republic of Indonesia Year 2009 Number 144, Supplement to Statute Book of the Republic of Indonesia Number 5063);
4. Law Number 18 Year 2012, concerning Food (Statute Book of the Republic of Indonesia Year 2012 Number 227, Supplement to Statute Book of the Republic of Indonesia Number 5360);
5. Government Regulation Number 72 Year 1998, concerning Safeguarding Pharmaceutical Preparation and Health Appartus (Statute Book of the Republic of Indonesia Year 1998 Number 138, Supplement to Statute Book of the Republic of Indonesia Number 3781);
6. Government Regulation Number 28 Year 2004, concerning Security, Quality and Food Nutrient (Statute Book of the Republic of Indonesia Year 2004 Number 107, Supplement to Statute Book of the Republic of Indonesia Number 4244);
7. Government Regulation Number 51 Year 2009, concerning Pharmaceutical Work (Statute Book of the Republic of Indonesia Year 2009 Number 124, Supplement to Statute Book of the Republic of Indonesia Number 5044);
8. Government Regulation Number 44 Year 2010 concerning Prekursor Farmasi (Statute Book of the Republic of Indonesia Year 2010 Number 60, Supplement to Statute Book of the Republic of Indonesia Number 5126);
9. Government Regulation Number 40 Year 2013, concerning Implementation of Law Number 35 Year 2009, concerning Narcotics (Statute Book of the Republic of Indonesia Year 2013 Number 96, Supplement to Statute Book of the Republic of Indonesia Number 5419);
10. Presidential Decree Number 103 Year 2001, concerning Capacity, Duty, Function, Authority, Organizational Structure, and Work Procedure of Non-Department Government Institution as amended several times and lately amended by Presidential Regulation Number 3 Year 2013;

11. Presidential Decree Number 110 Year 2001, concerning Organizational Unit and Duty of Echelon I of Non-Department Government Institution as amended several times and lately amended by Presidential Regulation Number 4 Year 2013;
12. Regulation of the Minister of Health Number 167/Kab/B.VII/72, concerning Drugs Retail Trader as amended by Decision of the Minister of Health Number 1331/Menkes/SK/X/2002;
13. Regulation of the Minister of Health Number 922/Menkes/Per/X/1993, concerning Terms and Conditions and Procedure for Granting License for Pharmaceutical License as amended by Decision of the Minister of Health Number 1332/MENKES/SK/X/2002;
14. Regulation of the Minister of Health Number 1799/Menkes/Per/XII/2010, concerning Pharmaceutical Industry as amended by Regulation of the Minister of Health Number 16 Year 2013 (State Gazette Republic of Indonesia Year 2013 Number 442);
15. Regulation of the Minister of Health Number 1148/MENKES/PER/VI/2011, concerning Pharmaceutical Wholesale Trader (State Gazette Republic of Indonesia Year 2011 Number 370) as amended by Regulation of the Minister of Health Number 34 Year 2014 (State Gazette Republic of Indonesia Year 2014 Number 1097);
16. Regulation of the Minister of Health Number 006 Year 2012, concerning Industry and Traditional Herbal Business (State Gazette Republic of Indonesia Year 2012 Number 225);
17. Decision of the Head of Drug and Food Supervisory Body Number 02001/SK/KBPOM Year 2001, concerning Organization and Work Procedure of Drug and Food Supervisory Body as amended by Decision of the Head of Drug and Food Supervisory Body Number HK.00.05.21.4231 Year 2004;
18. Regulation of the Head of Drug and Food Supervisory Body Number 14 Year 2014, concerning Organization and Work Procedure of Technical Operating Unit within the Drug and Food Supervisory Body (State Gazette Republic of Indonesia Year 2014 Number 1714);

## D E C I D E S:

To stipulate:

REGULATION OF THE HEAD OF DRUG AND FOOD SUPERVISORY BODY CONCERNING GUIDELINE TAKING SECURITY ACTION OVER THE OBJECT IN THE SUPERVISION OF CIRCULATION OF DRUG AND FOOD WITHIN THE FACILITIES OF PRODUCTION, DISTRIBUTION AND SERVICE PROVISION OF DRUG AND FOOD .

## CHAPTER I

## GENERAL PROVISION

## Article 1

What is meant in this Regulation by:

1. Drug and Food shall be medicinal stuff, traditional herbal medicine, cosmetics, health supplement, and processed food.
2. Facilities for Production, Distribution, and Service Provision of Drug and Food, hereinafter referred to as Facilities or place where production, distribution, and/or delivery of medicine, medicinal stuff, traditional herbal medicine, health supplement, and/or processed food.
3. Object of Security Action action shall be action taken by Officer of Drug and Food Supervisory Body, including Officer of Technical Operating Unit within the Drug and Food Supervisory Body to conduct inventory, sampling, for laboratory test, and/or sealing, in supervising circulation of Drug and Food, including basic material and/or packing material.
4. Officer of Drug and Food Supervisory Body, including Officer of Technical Operating Unit of Drug and Food Supervisory Body , hereinafter referred to as civil servant employee of Drug and Food Supervisory Body, assigned the duty to exercise supervision on circulation of Drug and Food based on Assignment Letter.

## CHAPTER II

## OBJECT OF SECURITY ACTION ACTION

## Article 2

- (1) If the Officer in exercising supervision on circulation of Drug and Food at the Facilities finds out any Drug

and Food, including basic material and/or packing stuff, that is alleged to have failed to comply with the standard / requirement of security, benefit, quality, marking, and/or information, whereby the Officer is authorized to take Object of Security Action action.

- (2) The Object of Security Action actions referred to in paragraph (1) shall cover:
- a. inventory;
  - b. sampling for laboratory test and/or verification of marking / labeling;and/or
  - c. sealing.
- (3) Minutes on the Action of Object of Security Action as referred to in paragraph (2) must be drawn-up and must be signed by the Officer and the owner of Drug and Food as referred to in Article 2 paragraph (1).
- (4) In the absence of the owner of Drug and Food referred to in paragraph (3) at the location of the Facilities concerned, Minutes on Action Object of Security Action must be signed by the Person in-Charge of the Drug and Food.
- (5) If the owner and/or Person in-Charge referred to in paragraph (4) refuses to sign the Minutes on Object of Security Action, Minutes of Refusal to Sign must be issued.

### Article 3

The Owner referred to in Article 2 paragraph (3) and/or the Person in-Charge as referred to in Article 2 paragraph (4), shall be responsible for the intactness of the seal and the volume of Drug and Food that have been inventoried and/or the sampling to be tested by laboratory and/or verification of marking / labeling conducted during the Action of Object of Security Action.

### Article 4

Within 15 (fifteen) working days as of the date the Minutes on Action of Object of Security Action is signed, the Officer shall be obliged to determine the status Drug and Food which sampling for laboratory test has been conducted and/or verification of marking / labelling as referred to in Article 2 paragraph (2) letter b.

CHAPTER III  
SEAL DETACHMENT

Article 5

- (1) If the laboratory result and/or verification of marking/labeling over the Drug and Food complies with the standard / requirements and/or provisions in the statutory regulation, then within seven (7) working days at the latest as of the date of report on the result of laboratory test and/or verification is issued and received the seal over the Object of Security Action must be detached.
- (2) The detachment of the Object of Security Action as referred to in paragraph (1) must be drawn-up in Minutes of Seal Detachment.

Article 6

- (1) If the result of laboratory test and/or verification of the marking / labelling of Drug and Food fails to comply with the standard / requirement and/or the provisions in the statutory regulation, follow-up action must be taken in line with the provisions in the statutory regulation.
- (2) If the result of laboratory test verification of the marking / ;labeling fails to comply with the standard / requirement and/or the provisions in the statutory regulation indicates initial evidence of existence of criminal act on Drug and Food, immediate investigation must be conducted in line with the provisions in the statutory regulation.

CHAPTER IV  
FORMAT OF MINUTES OF SECURITY ACTION

Article 7

Example of format of Minutes of Security Action referred to in:

- a. Article 2 paragraph (3);
- b. Article 2 paragraph (5); and
- c. Article 5 paragraph (2);

shall be as specified in the Attachment constituting inseparable part of this Regulation.

CHAPTER V

CLOSING PROVISION

Article 8

This Regulation of the Head of Body takes effect on the date it is enacted.

For public cognizance, this Regulation of the Head of Body shall be announced by placing it in the State Gazette of the Republic of Indonesia.

Stipulated in Jakarta

Dated February 23, 2016

HEAD OF DRUG AND FOOD SUPERVISORY BODY  
OF THE REPUBLIC OF INDONESIA,

sgd.

ROY A. SPARRINGA

Enacted in Jakarta

Dated March 8, 2016

DIRECTOR GENERAL OF STATUTORY REGULATION  
OF THE MINISTRY OF LAW AND HUMAN RIGHTS  
OF REPUBLIC OF INDONESIA,

sgd.

WIDODO EKATJAHJANA

STATE GAZETTE REPUBLIC OF INDONESIA

YEAR 2016 NUMBER 373

## ATTACHMENT I

**FORMAT OF MINUTES OF ACTION OF OBJECT OF SECURITY ACTION**  
**MINUTES OF OBJECT OF SECURITY ACTION**

On this day, dated ....., (...), of the month of ....., Year 2000, at ..... hours I:

(Name of Team Leader) Rank ..., NIP ..., as of Officer in-charge of Drug and Food of Supervisory Body /Balai Besar/Balai POM at ..., jointly with:

1	Name: ...	Rank: ...	NIP: ...	Title: ...
2	Name: ...	Rank: ...	NIP: ...	Title: ...

Respectively is assigned the duty in the same office, by virtue of Assignment Letter ..... Number ... dated ..... has exercised Seal Opening at the Facilities at Jalan ....., by:

- a. inventory action (List attached);
- b. sampling for laboratory test and/or verification of marking / labelling (List attached); and/or
- c. sealing.

The Object Security Action referred to above has been approved / disapproved by the Owner / Person in-Charge.

Name :  
 Resident Identity Card Number :  
 Place / Date of Birth :  
 Citizenship :  
 Religion :  
 Occupation :  
 Address :

Witnessed by:

1. Name :  
 Occupation :  
 Address :

2. Name :  
Occupation :  
Address :

IN WITNESS WHEREOF, this Minutes on Object Security Action is drawn up solemnly on oath by Title, and closed and signed in ....., on ....., ....., Year 2000 ...

Owner / Person in-Charge

Officer

Witnesses,

- 1.
- 2.

HEAD OF DRUG AND FOOD SUPERVISORY BODY  
OF THE REPUBLIC OF INDONESIA,

sgd.

Dr. ROY A. SPARRINGA, M.App.Sc

ATTACHMENT II

FORMAT OF MINUTES ON REFUSAL TO SIGNING  
MINUTES ON REFUSAL TO SIGNING

On this day..... .., dated ..... .. (...), month of .., Year 2000, at ..... hours,  
I, (Name Team Leader)

Rank ..., NIP ..., as Officer in charge of Drug and Food Supervisory Body / Balai Besar/Balai POM di ..., jointly with

1	Name: ...	Rank: ...	NIP: ...	Title: ...
2	Name: ...	Rank: ...	NIP: ...	Title: ...

Respectively is assigned the duty in the same office, by virtue of Assignment Letter Number ....., dated ....., stating that Security Action at Object at the Facilities at Jalan ..... has been conducted and Minutes of Object Security Action, and applied for approval from the Owner / Person in-charge of the Facilities, but the person concerned refused to grant approval.

IN WITNESS WHEREOF, this Minutes on Object Security Action is drawn up solemnly on oath by Title, and closed and signed in ....., on ....., ....., Year 2000 ...

Owner / Person in-Charge

Officer

Witnesses,

- 1.
- 2.

HEAD OF DRUG AND FOOD SUPERVISORY BODY  
OF THE REPUBLIC OF INDONESIA,

sgd.

Dr. ROY A. SPARRINGA, M.App.Sc

ATTACHMENT III

to be continued

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