REGULATION OF THE DRUG AND FOOD SUPERVISORY AGENCY

NUMBER 9 OF 2025

ON

GUIDELINES FOR THE RISK ASSESSMENT OF SAFETY AND/OR QUALITY OF DRUGS AND DRUG INGREDIENTS

BY THE GRACE OF GOD ALMIGHTY

THE HEAD OF THE DRUG AND FOOD SUPERVISORY AGENCY,

Considering:

a. that in order to ensure that drugs and drug ingredients meet safety and/or quality standards and requirements as well as to improve the competitiveness of the drug and drug ingredient industry, it is necessary to regulate guidelines for the risk assessment of safety and/or quality of drugs and drug ingredients comprehensively;

b. that the safety and/or quality risk assessment of drugs and drug ingredients as referred to in letter a shall be applied to protect the community from drugs and drug ingredients that do not comply with safety and/or quality standards and requirements that are at risk to health;

c. that based on the provisions of Article 3 paragraph (1) letter d of Regulation of the President Number 80 of 2017 on the Drug and Food Supervisory Agency, the Drug and Food Supervisory Agency shall carry out the function of implementing supervision before circulation and supervision during circulation;

d. that based on the considerations as referred to in letter a, letter b, and letter c, it has been deemed necessary to establish Regulation of the Drug and Food Supervisory Agency on Guidelines for the Risk Assessment of Safety and/or Quality of Drugs and Drug Ingredients.

Observing:

1. Regulation of the President Number 80 of 2017 on the Drug and Food Supervisory Agency (State Gazette of the Republic of Indonesia of 2017 Number 180);

2. Regulation of the Drug and Food Supervisory Agency Number 21 of 2020 on the Organization and Work Procedures of the Drug and Food Supervisory Agency (Official Gazette of the Republic of Indonesia of 2020 Number 1002) as amended by Regulation of the Drug and Food Supervisory Agency Number 13 of 2022 on Amendment to Regulation of the Drug and Food Supervisory Agency Number 21 of 2020 on the Organization and Work Procedures of the Drug and Food Supervisory Agency (Official Gazette of the Republic of Indonesia of 2022 Number 629);

3. Regulation of the Drug and Food Supervisory Agency Number 19 of 2023 on the Organization and Work Procedures of the Technical Implementing Unit at the Drug and Food Supervisory Agency (Official Gazette of the Republic of Indonesia of 2023 Number 611) as amended by Regulation of the Drug and Food Supervisory Agency Number 3 of 2025 on Amendment to Regulation of the Drug and Food Supervisory Agency Number 19 of 2023 on the Organization and Work Procedures of the Technical Implementing Unit at the Drug and Food Supervisory Agency (Official Gazette of the Republic of Indonesia of 2025 Number 39).

HAS DECIDED:

To establish:

REGULATION OF THE DRUG AND FOOD SUPERVISORY AGENCY ON GUIDELINES FOR THE RISK ASSESSMENT OF SAFETY AND/OR QUALITY OF DRUGS AND DRUG INGREDIENTS.

Article 1

Under this Regulation of the Agency, the following definitions are employed:

1. Drug is a substance, mix of substances, including biological products, used to influence or investigate a physiological system or pathological state in order to establish diagnosis, prevention, cure, recovery, health improvement, and contraception for humans.
2. Drug Ingredients are efficacious or non-efficacious ingredients used in the processing of drugs with standards and quality as pharmaceutical ingredients.
3. Active Ingredient of Drug is any substance or mixture of substance used in the manufacture of pharmaceutical preparations, and when used in the manufacture of Drug, it will become the active substance of the Drug.
4. Drug Additives, from this point onwards are referred to as Excipients, are substance other than Active Substance of Drug that have been properly evaluated for safety and are included in the drug delivery system to increase the safety and effectiveness of the Drug during storage and use.
5. Nitrosamines are a group of compounds that have the chemical structure of a nitroso functional group that binds to an amine functional group.
6. Nitrosamine Contaminants are Nitrosamine compounds that are unintentionally present and/or undesirable in Drugs and Drug Ingredients derived from the environment or as a result of production processes that can interfere with, harm, and endanger human health.
7. Pharmaceutical Industry is a business entity that has a license in accordance with the provisions of laws and regulations to carry out manufacturing activities of Drugs and Drug Ingredients.
8. Head of Agency is the Head of Drug and Food Supervisory Agency.

Article 2

(1) Safety and/or quality risk assessment of Drugs and Drug Ingredients shall be carried out to ensure that Drugs and/or Drug Ingredients made by Pharmaceutical Industries are in accordance with safety and/or quality standards and requirements.

(2) Drug Ingredients as referred to in paragraph (1) shall include:

a. Active Substance of Drug; and

b. Excipients.

(3) The safety and/or quality risk assessment of Drugs and Drug Ingredients as referred to in paragraph (1) shall be carried out in accordance with the following guidelines:

a. safety and/or quality risk assessment of Drugs and Drug Ingredients against Nitrosamine Contaminants shall be as set out in Appendix I which constitutes an integral part of this Regulation of the Agency;

b. risk assessment of the fulfillment of Excipient quality for Drug production shall be as set out in Appendix II which constitutes an integral part of this Regulation of the Agency y; and

c. risk assessment of microbiological testing of Drug Ingredients for the production of Drugs shall be as set out in Appendix III which constitutes an integral part of this Regulation of the Agency.

(4) Safety and/or quality risk assessment of Drugs and Drug Ingredients shall be carried out for Drugs that do not have a distribution permit and/or Drugs that have a distribution permit from the Head of the Agency.

(5) The safety and/or quality risk assessment of Drugs and Drug Ingredients as referred to in paragraph (3) shall be carried out based on the output/results of the risk management process that considers the suitability of new aspects of knowledge and experience related to risks.

Article 3

(1) Guidelines as referred to in Article 2 paragraph (3) shall be used as a reference for:

a. Pharmaceutical Industries in carrying out:

1. safety and/or quality assessment of Drugs and Drug Ingredients against Nitrosamine Contaminants;

2. risk assessment of the fulfillment of Excipient quality for Drug production; and

3. risk assessment of microbiological testing of Drug Ingredients for Drug production.

b. The Drug and Food Supervisory Agency in evaluating the results of risk assessment carried out by Pharmaceutical Industries in the framework of Drug supervision before circulation and during circulation.

(2) Guidelines for the safety and/or quality assessment of Drugs and Drug Ingredients against Nitrosamine Contaminants as referred to in Article 2 paragraph (3) letter a shall include:

a. information on Nitrosamine Contamination and interim daily intake limits;

b. development of analytical methods and examples of Nitrosamine calculation limits in drugs based on maximum daily dose limits; and

c. stages of the risk assessment.

(3) The guidelines for risk assessment of the fulfilment of excipient quality for Drug production as referred to in Article 2 paragraph (3) letter b shall include:

a. Excipient risk management and categorization team; and

b. risk assessment principles of Excipient.

(4) The guidelines for risk assessment of microbiological testing of Drug Ingredients for the production of Drugs as referred to in Article 2 paragraph (3) letter c shall include the stages of risk assessment of microbiological testing of Drug Ingredients.

Article 4

(1) The safety and/or quality risk assessment of Drugs and Drug Ingredients against Nitrosamine Contaminants as referred to in Article 2 paragraph (3) letter a shall be submitted to the Head of the Agency if the results of assessment indicate the potential presence of Nitrosamine Contaminants in Drugs and/or Drug Ingredients.

(2) The risk assessment of the fulfilment of Excipient quality for Drug production as referred to in Article 2

paragraph (3) letter b must be carried out if the Excipient quality standards and requirements are not completely fulfilled.

(3) The risk assessment of microbiological testing of Drug Ingredients for Drug Production as referred to in Article 2 paragraph (3) letter c shall be carried out for:

a. Drug Ingredients as listed in the compendial that do not require microbial boundary testing on the monograph; and

b. Drug Ingredients that are not listed in the compendial.

(4) The risk assessment of the fulfilment of Excipient quality for Drug production and the risk assessment of microbiological testing of Drug Ingredients for Drug Production as referred to in paragraphs (2) and (3) shall be submitted to the Head of the Agency as a fulfilment of drug registration documents and as part of the implementation of Good Drug Manufacturing Standards.

Article 5

Upon the effective enforcement of this Regulation of the Agency, Regulation of the Drug and Food Supervisory Agency Number 2 of 2023 on Guidelines for the Assessment of Safety and/or Quality of Drugs and Drug Ingredients against Nitrosamine Contaminants (Official Gazette of the Republic of Indonesia of 2023 Number 50), shall be repealed and declared invalid.

Article 6

This Regulation of the Agency comes into force from the date of its promulgation.

For public cognizance, it is hereby ordered that this Regulation of the Agency be promulgated in the Official Gazette of the Republic of Indonesia.

Established in Jakarta,

On 23 April 2025

THE HEAD OF THE DRUG AND FOOD SUPERVISORY AGENCY,

Signed.

TARUNA IKRAR

Promulgated in Jakarta,

On 2 May 2025

THE DIRECTOR GENERAL OF LAWS AND REGULATIONS OF THE MINISTRY OF LAW OF THE REPUBLIC OF INDONESIA,

Signed.

DHAHANA PUTRA

OFFICIAL GAZETTE OF THE REPUBLIC OF INDONESIA OF 2025 NUMBER 297

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