REGULATION OF THE MINISTER OF AGRICULTURE

NUMBER: 15/Permentan/OT.140/2/2008

CONCERNING

MONITORING AND SURVEILLANCE GUIDELINES

FOR MICROBIAL RESIDUES AND CONTAMINANTS IN ANIMAL PRODUCTS



[National Emblem of the Republic of Indonesia]

THE MINISTER OF AGRICULTURE OF THE REPUBLIC OF INDONESIA

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MONITORING AND SURVEILLANCE GUIDELINES FOR MICROBIAL RESIDUES AND CONTAMINANTS IN ANIMAL PRODUCTS

BY THE GRACE OF GOD ALMIGHTY

THE MINISTER OF AGRICULTURE,

- Considering: a. whereas, animal products have high value and quality for human's benefit, but they are perishable food and potentially cause hazard to living creature and environment (hazardous food) because they are easily polluted physically, chemically, and biologically, which can cause human health problems so that it is necessary to conduct examination and testing.
 - b. whereas, based on the considerations as abovementioned, and as further implementation of Law Number 32 of 2004 concerning Regional Government and Government Regulation Number 38 of 2007 concerning Division of Governmental Affairs



between the Government, Provincial Governments, and Regency/ City Governments, it is necessary to stipulate Monitoring and Surveillance Guidelines for Microbial Residues and Contaminants in Animal Products by the Regulation of the Minister of Agriculture;

- In view of : 1. Law Number 6 of 1967 concerning Basic

 Provisions for Livestock and Veterinary

 Health (State Gazette of 1967 Number 10,

 Supplement to the State Gazette Number 2824);
 - 2. Law Number 16 of 1992 concerning Animal, Fish and Plant Quarantine (State Gazette of 1992 Number 56, Supplement to the State Gazette Number 3482);
 - 3. Law Number 7 of 1994 concerning
 Ratification of the Agreement Establishing
 the World Trade Organization (State Gazette
 of 1994 Number 57, Supplement to the State
 Gazette Number 3564);
 - 4. Law Number 7 of 1996 Concerning Food (State Gazette of 1996 Number 99, Supplement to the State Gazette Number 3656);
 - 5. Law Number 8 of 1999 Concerning Consumer
 Protection (State Gazette of 1999 Number



- 42, Supplement to the State Gazette Number 3821);
- 6. Law Number 32 of 2004 concerning Regional Government (State Gazette of 2004 Number 125, Supplement to the State Gazette Number 4437), in conjunction with Law Number 8 of 2005 concerning Stipulation of Government Regulation in lieu of Law Number 3 of 2005 concerning Amendment to Law Number 32 of 2004 concerning Regional Government into Law (State Gazette of 2005 Number 108, Supplement to the State Gazette Number 4548);
- 7. Government Regulation Number 15 of 1977
 concerning Rejection, Prevention,
 Eradication, and Treatment of Animal
 Diseases (State Gazette of 1977 Number 20,
 Supplement to the State Gazette Number
 3101);
- 8. Government Regulation Number 22 of 1983 concerning Veterinary Public Health (State Gazette of 1983 Number 28, Supplement to the State Gazette Number 3253);
- 9. Government Regulation Number 78 of 1992 concerning Veterinary Medicines (State



- Gazette of 1992 Number 129, Supplement to the State Gazette Number 3509);
- 10. Government Regulation Number 69 of 1999 concerning Food Label and Advertisement (State Gazette of 1999 Number 54, Supplement to the State Gazette Number 3952);
- 11. Government Regulation Number 82 of 2000 concerning Animal Quarantine (State Gazette of 2000 Number 161, Supplement to the State Gazette Number 4002);
- 12. Government Regulation Number 102 of 2000 concerning Indonesian National Standardization (State Gazette of 2000 Number 199, Supplement to the State Gazette Number 4020);
- 13. Government Regulation Number 49 of 2002 concerning Rates for Services Applicable at the Department of Agriculture, in conjunction with the Government Regulation Number 7 of 2004;
- 14. Government Regulation Number 28 of 2004 concerning Food Safety, Quality and Nutrition (State Gazette of 2004 Number 107, Supplement to the State Gazette Number 4424);



- 15. Government Regulation Number 38 of 2007 concerning Division of Governmental Affairs between the Government, Provincial Governments, and Regency/ City Governments (State Gazette of 2007 Number 82, Supplement to the State Gazette Number 4737);
- 16. Presidential Decree Number 187/M of 2004 concerning Formation of the United Indonesia Cabinet;
- 17. Presidential Regulation Number 9 of 2005 concerning Capacities, Duties, Functions, Composition of Organization and Work Procedures of the State Ministries of the Republic of Indonesia, in conjunction with the Presidential Regulation Number 62 of 2005;
- 18. Presidential Regulation Number 10 of 2005 concerning Organization and Duties of Echelon I of the State Ministries of the Republic of Indonesia;
- 19. Regulation of the Minister of Agriculture

 Number 299/Kpts/OT.140/7/2005 concerning

 Organization and Work Procedures of the

 Department of Agriculture, in conjunction

 with the Regulation of the Minister of



- 20. Regulation of the Minister of Agriculture
 Number 341/Kpts/OT.140/9/2005 concerning
 Completeness of Organization and Work
 Procedures of the Department of
 Agriculture, in conjunction with the
 Regulation of the Minister of Agriculture
 Number 12/Permentan/OT.140/1/2007;
- 21. Regulation of the Minister of Agriculture Number 381/Kpts/OT.140/10/2005 concerning Veterinary Control Certification Guidelines;
- 22. Regulation of the Minister of Agriculture No. 44/Permentan/PD.660/2/2007 concerning Good Veterinary Laboratory Practices;
- 23. Regulation of the Minister of Agriculture No. 45/Permentan/PD.660/2/2007 concerning Guidelines for Classification of Veterinary Public Health Laboratory;
- 24. Regulation of the Minister of Agriculture

 Number 14/Permentan/OT.140/2/2008

 concerning Guidelines for Supervision and

 Testing of Safety and Quality of Animal

 Products;

DECIDED:



To stipulate :

FIRST : Monitoring and Surveillance Guidelines for

Microbial Residues and Contaminants in

Animal Products as set out in the Appendix

shall be as an inseparable part of this

Regulation.

SECOND : Monitoring and Surveillance Guidelines for

Microbial Residues and Contaminants in

Animal Products as referred to in the FIRST

dictum shall be a reference for laboratory

examiners and veterinary public health

supervisors in monitoring and surveillance

of microbial residues and contaminants in

animal products.

THIRD : This regulation shall come into force on

the date of stipulation.

Stipulated in Jakarta

on February 11, 2008

THE MINISTER OF AGRICULTURE,

[signed & sealed]

ANTON APRIYANTONO

COPY of this regulation shall be delivered to:

- 1. Minister of Home Affairs;
- 2. Minister of Finance;



- Minister of Health;
- 4. Minister of Trade;
- 5. Minister of Industry;
- 6. Head of Drug and Food Control Agency;
- 7. Heads of Echelon I in the scope of the Department of Agriculture;
- 8. Governor throughout Indonesia;
- 9. Regents/ Mayors throughout Indonesia;
- 10. Heads of Service serving livestock and/or veterinary health functions of Provinces, Regencies/ Cities throughout Indonesia; and
- 11. Heads of Veterinary Public Health Laboratories throughout Indonesia.



APPENDIX : REGULATION OF THE MINISTER OF AGRICULTURE

NUMBER : 15/Permentan/OT.140/2/2008

DATE : February 11, 2008

MONITORING AND SURVEILLANCE GUIDELINES FOR MICROBIAL RESIDUES AND CONTAMINANTS IN ANIMAL PRODUCTS

CHAPTER I

INTRODUCTION

A. Background

Residues mean the accumulation of medicines or chemicals and/or their metabolites in animal products as a result of the use or contamination of veterinary medicines, hormones, pesticides, and heavy metal contamination in animals and/or animal products either before the production process, in the production process or after the production process.

In the event of consuming any animal products containing residues, it can cause disorder to human, animal and environmental health. Animal products are perishable food and a medium for microbial growth. Animal products can also contain pathogenic microbes derived from sick animals and/or are contaminated from the environment. The number of microbes exceeding the normal threshold or the



existence of pathogenic microbes in animal products can harm human, animal and environmental health.

Microbes can change into resistant in the event that the antimicrobial use is not in compliance with the procedures for their use, or as a result of consuming animal products that contain residues for a long period. It can result in treatment failure and environmental damage.

Therefore, to know the existence of microbial residues and contaminants in animal products, it is necessary to supervise through examination and testing, so that a policy can be determined to prevent microbial residues and contaminants in animal products.

Based on the foregoing matters, monitoring and surveillance are necessary to be conducted before the production process, in the production process, and after the production process, to ensure that any animal products consumed by humans are safe and proper for consumption, or any animal products intended for animals comply with the safety and quality requirements.

B. Purposes and Objectives

1. Purposes

These guidelines are intended as a reference for:

a) examiners in implementing test on monitoring and surveillance of microbial residues and



contaminants in animal products, and taking sample in the surveillance activities of microbial residues and contaminants; and

b) veterinary public health supervisors in taking sample for testing animal products for monitoring.

2. Objectives

These guidelines aim to:

- obtain the valid data of the results of monitoring and surveillance;
- 2) map any events/ degree of microbial residues and contaminants in animal products; and
- 3) provide technical recommendations to policy determinants/ policy makers in realizing guarantee of animal product safety.

C. Scopes

Scopes as regulated in these Guidelines shall include:
Planning Strategies; Microbial Residue and Contaminant
Monitoring; Microbial Residue and Contaminant
Surveillance; and Coordination of Surveillance Result
Supervision.

D. Definitions

In these Guidelines, the following terms shall have meanings assigned to them below:



- Monitoring means monitoring conducted continuously to obtain an estimation of microbial residue and contaminant events.
- 2. Surveillance means observation conducted continuously to obtain the status of microbial residue and contaminant events in a population (animal group).
- 3. Residues mean the accumulation of medicines or chemicals and/or their metabolites in animal tissues and organs after the deliberate use of medicines or chemicals for the purpose of prevention/ treatment as feed additives or inadvertently contaminated by those compounds.
- 4. Contaminants mean the entry or event of chemical and/or microbiological hazards, including microbes in animal products and animal feeds, either directly or indirectly that can cause incomplete animal products and animal feeds so that it can harm human, animal and/or environmental health.
- 5. Maximum Limit of Microbial Contaminants, hereinafter referred to as BMCM, means the maximum number of microorganisms/ microbes (cfu/g) whose contents are still permissible in animal products.
- 6. Maximum Limit of Residues, hereinafter referred to as BMR means the maximum residual concentration (mg/ kg or microgram/g) whose contents are still permissible in animal products.



- 7. Examiner means a person having duties to conduct examination and testing of safety and quality of animal products in veterinary public health laboratories.
- 8. Sampling Officer, hereinafter referred to as PPC, means a person having complied with the requirements and is appointed by a competent authority to conduct sampling.
- 9. Veterinary Public Health Supervisor, hereinafter referred to as the Veterinary Public Health Supervisor, means a Civil Servant having a veterinarian educational background who have joined veterinary public health education and training as declared by a certificate of training for veterinary public health supervisor to conduct supervision in the Veterinary Public Health.
- 10. Animal products mean all materials derived from animals that are still fresh and/or have been processed for the purposes of consumption, pharmacoseutics, agriculture, and/or other uses for the fulfillment of human needs and benefits as long as it is still possible to become a transmitting media for animal diseases, especially zoonosis.
- 11. Business actor means any individual or business entity, either in the form of a legal entity or non-legal entity established and domiciled or carrying



- out activities within the legal territory of the Republic of Indonesia, either individually or jointly through an agreement implementing business activities in the animal products.
- 12. Lot means a sample unit in one batch or production unit that is handled in uniform conditions within a certain period of time.
- 13. Random means a statistic-based random sampling.
- 14. Error means determination of the number of samples required in determining the event of a deviation in a population as declared by the percentage of the possibility of deviation.
- 15. Confidence level means the confidence level in determining the number of samples required in determining the event of a deviation in a population as declared by percentage.
- 16. Hazard element means a biological, chemical, parasitic, prion, genetically modified organism (GMO) or physical agent that enters and/or is in animal products and animal feeds potentially cause human, animal and/or environmental health problems.
- 17. Service means the Regional Government agency serving the veterinary public health function in the Province, Regency/ City.

CHAPTER II



PLANNING STRATEGIES

To achieve the expected goals of monitoring and surveillance activities for microbial residues and contaminants in animal products, it is necessary to prepare for a planning strategy including:

- A. Institutions and Agencies as Person-in-charge and Executor.
 - The Directorate General of Livestock as person-incharge of monitoring and surveillance activities for microbial residues and contaminants in animal products.
 - 2. Provincial, regency/ city service as the executor of monitoring and surveillance activities for microbial residues and contaminants in animal products in the regions based on the technical requirements as stipulated in these guidelines.
 - 3. Veterinary public health laboratories that have been accredited or have complied with the technical requirements as stipulated in Good Veterinary Laboratory Practices as the executor of examination and testing in the field based on an assessment conducted by the Assessment Team appointed by the Director General of Livestock.
- B. Monitoring and Surveillance Site



Monitoring and Surveillance Site shall be determined in such a way so that an undesirable duplication does not occur in sampling. Monitoring and surveillance shall be conducted by the Veterinary Public Health Laboratory in accordance with its working area. In determining the site of sampling for the purposes of monitoring and surveillance must consider the following matters:

- 1. populations and animal productions;
- 2. number of animal slaughters;
- 3. animals and their product traffic;
- 4. animal markets and their products;
- 5. level of public consumption against animal products;
- 6. microbial residue and/or contaminant case events;

C. Schedule and time of implementation

The schedule and time of implementation shall be prepared based on the activities to be carried out, which are adjusted to the long term and short term targets.

1. Long term target

The long term target shall determine activities to be carried out for the next 3 (three) to 5 (five) year-period, which can provide an illustration of the possibility of microbial residues and contaminants in animal products during the period.

2. Short term target



The short term target shall determine activities to be carried out for the next 1 (one) year period, which can provide an illustration of the possibility of microbial residues and contaminants in animal products during the 1 (one) year period, accompanied by a plan of evaluation activities at the end of year within the period.

D. Facilities and Infrastructure

Facilities and Infrastructure used for monitoring and surveillance of microbial residues and contaminants in animal products must comply with the requirements of laboratory quality management and the technical requirements of Good Veterinary Laboratory Practices and ISO/ IEC 17025: 2005 concerning Requirements of Testing and Calibration Laboratory Competencies. Besides, the laboratory used must comply with the requirements of Veterinary Public Health laboratory classification.

CHAPTER III

MICROBIAL RESIDUE AND CONTAMINANT MONITORING

Microbial residue and contaminant monitoring activities shall be carried out by the following stages:

A. Sampling

1. Sampling plan.



Sampling plan shall be carried out by considering the following matters:

- a. purposes and objectives of sampling;
- b. types or varieties of animal products whose samples are taken;
- c. size of groups, number of production units, and time of productions;
- d. number of animal slaughters;
- e. packaging, labels, delivery methods, and geographical/ regional boundaries;
- f. nature, condition, and endurance of the sample taken;
- g. level of hazards for the risk of human health problems (critical, major, minor);
- h. agent surveillance, and hospes or transmitting media and their environmental monitoring;
- i. any samples taken should consist of food of animal origin, which is often consumed by people every day;
- j. any samples of animal products produced, imported, and exported in the large amount/ scale and widely distributed,
- k. the availability of competent PPC HR;
- 1. hazard elements that can disturb health;
- m. sensitivity/ concern of consumer and industrial groups to health and safety of animal products;



- n. distribution of microbial residue and contaminant events;
- o. the Acceptable Quality Level/ AQL, and/or Acceptable Level of Protection (ALOP), and based on the statistic theory (statistic probability).

2. Types of Sample

Types of sample can be distinguished based on the place/ origin where the sample is obtained. Based on the place/ origin of the sample obtained, types of sample can be divided into two, primary samples and secondary samples.

- a. Primary samples, any samples taken directly from breeders, RPH/ RPU, production sites, distributors, selling sites or other animal product business units;
- b. Secondary samples, any samples taken at the entry point in the form of animal products of import origin before being released from animal quarantine measures. For the implementation, it should be coordinated with the Agricultural Quarantine Agency.

3. Procedures for Sampling.

Procedures for animal product sampling shall be carried out through the study of critical point



level of each chain of activities from farming at the level of breeders or animal product businesses, productions, animal product processing processes, at the level of distribution through at the selling site of animal products.

This sampling must pay attention to the following:

- a) number of samples to be taken;
- b) handling and shipping in compliance with the nature and types of sample;
- c) ability and availability of human resources, facilities, and valid test materials and test methods in conducting test in the Veterinary Public Health laboratory;
- d) wide range of regions/ territories, such as rural areas, districts, regencies/ cities, provinces, or animal product business areas;
- e) specific events at a site, such as animal product poisoning case;
- f) level of pollution, type and amount of food of animal origin consumed by local people, and consumers' food habit.
- g) amount of test implementation costs.

4. Sampling methods.

Determination of number of samples for testing chemical residues and microbial contaminants in these



guidelines shall use a reference of determination of number of statistic-based samples.

- a) Determination of number of statistic-based samples shall include:
 - 1) Degree of an indirect/ non-biased sample (non-biased method), using the following formula:

 $n = 4 pq/L^2$ if the confidence level is 95% or

 $n = 9 pq/L^2$, if the confidence level is 99%

p: prevalence

q: 1 - p

L: error = desired error

confidence level = trust level

If n > 10% of population 1

$$n_2 = \frac{1}{1/n1 + 1/N}$$

Example:

TPC > BMCM = 60.9%

p = 0.61, q = 1 - p = 0.39,

L = error = error = 0.05

 $n = 4 pq/L^2 = 4x0.61x0.39/0.0025$

= 381 samples (95%)

 $n = 9 pq/L^2 = 9x0.61x0.39/0.0001$

= 856 samples (99%)

2) Degree of a direct/ biased sample (biased method)



- Prevalence (p) = 0.61 and samples taken at least 381 samples.
- Then the deviation = 0.05
- e.g., just take 200 samples, how many deviation (bias):
 - \star 4x0.61x0.39/ $L^2 = 200$
 - $\star L^2 = 0.9516/200 = 0.0048$
 - * L = deviation = 0.069

b) Sampling Methods

Sampling by systematic random sampling is a sampling of animal products that are selected at certain intervals. The number of samples is calculated from the total population divided by the sample size (n = total population/ sample size), using the random number generator to select the first number. Systematic random is highly recommended in the application of sampling in the field because it is simpler and more practical, but it cannot be used for large populations.



Random Number

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10 66 63 13 45 41 18 77 97 10 70 12 36 08 24 76 10 37 01 67 59 45 46 8*
74 64 65 13 48 92 58 99 70 39 18 11 75 99 87 48 15 94 22 43 56 13 24 91
18 02 76 59 22 12 77 31 77 06 25 01 98 97 76 26 27 00 31 32 49 31 10 94
97 19 10 79 T8 35 10 32 23 35 53 32 69 16 44 21 15 44 64 06 35 81 59 0*
50 91 92 01 00 21 74 20 78 13 14 97 80 95 55 71 97 83 98 14 50 00 00 13
73 70 12 12 29 20 01 56 84 45 45 61 13 04 27 96 92 93 06 66 44 03 51 88
66 72 15 57 41 82 13 15 16 39 02 21 67 75 64 21 71 58 86 68 36 32 14 50
10 79 16 94 14 14 27 53 71 09 18 49 48 69 87 51 16 73 72 73 89 89 85 04
81 21 07 60 01 74 74 56 47 94 29 73 90 35 62 86 89 94 49 28 80 13 62 51
73 79 Q8 70 11 CK 44 77 92 76 21 99 GT 80 01 36 23 50 13 41 28 80 22 89
50 27 43 26 35 73 57 81 15 53 50 22 97 13 11 74 23 82 82 39 56 47 64 93
42 70 67 50 67 04 48 60 27 91 20 93 20 47 69 19 77 14 52 11 89 12 77 56
13 99 47 30 23 73 90 64 60 34 45 90 47 17 55 50 75 44 07 37 67 86 60 15
72 22 83 11 07 90 99 39 66 48 96 08 08 17 4 7 57 42 74 93 83 17 39 39 39
NO 13 88 18 10 76 55 23 NO 54 50 66 69 23 O 6 98 38 57 53 89 97 90 35 22
23 53 07 76 91 48 74 34 96 96 27 80 68 36 07 11 78 36 09 60 13 74 34 4*
39 53 16 47 16 80 30 14 17 33 63 06 05 51 20 73 03 00 30 83 06 00 00 83
61 99 16 33 16 79 83 80 14 26 51 28 41 68 41 48 60 39 44 20 25 90 28 53
19 75 97 23 31 43 37 39 61 17 21 21 28 23 57 07 58 59 33 76 16 58 13 63
47 69 92 38 09 26 49 27 54 04 73 68 94 79 09 79 22 39 65 76 82 60 35 63
41 42 90 11 75 51 54 18 28 60 36 21 59 43 51 86 87 51 12 90 02 19 60 63
66 11 53 82 38 11 82 57 85 91 69 51 43 23 0 1 48 45 80 84 02 53 10 43 45
11 67 85 97 89 73 58 11 22 74 64 69 90 80 2 8 10 20 69 24 08 64 69 19 32
65 24 18 74 82 92 70 60 58 34 34 11 10 00 2 7 65 27 32 36 93 98 66 62 72
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- 5. Implementation of Sampling.
 - a) Sampling Officer (PPC).
 - Sampling shall be carried out by trained, skilled, and certified PPC in animal product sampling activities, and shall understand the procedures for sampling, handling, and shipping.
 - b) Equipment and facilities.
 - The implementation of sampling in monitoring and surveillance activities of microbial residues and contaminants is necessary to be equipped with adequate equipment and facilities in accordance



with the purposes of examination and testing conducted, among others as follows:

- 1) work clothes;
- 2) masks;
- 3) headgears;
- 4) shoes;
- 5) eye protections;
- 6) gloves;
- 7) scissors;
- 8) tweezers;
- 9) ice boxes;
- 10) 70% alcohol;
- 11) cotton;
- 12) sample container (in accordance with the type
 of sample and test);
- 13) media transport;
- 14) marking (labels, stationeries, etc.); and
- 15) sample data form.
- c) Sampling point.

Sampling point shall be selected by considering the circulation track of animal products such as:

- 1) production site (livestock farming);
- 2) slaughtering site;
- 3) shelter/ collection, storage, and circulation site;
- 4) animal processing site;



5) selling site.

For milk sampling, it shall be carried out at the livestock/ cage/ milking site, milk collection and processing site.

- d) Instructions for determination of total samples.

 Instructions for determination of total samples of animal products for the purposes of veterinary public health laboratory testing shall refer to Model-1 of this regulation.
- e) Schedule and time of sampling.

 Schedule and time of sampling must be adjusted to the implementation of production activities ranging from farming, processing, packaging, transportation, distribution, and selling of animal products.
- f) Sample data application form.

The sample data application form taken by PPC shall include information as in Model-2 of this regulation, including as follows:

- 1) sample number or code;
- 2) name and address of sample owner;
- 3) type (animal/ species, animal feeds, types of animal samples/ parts taken as samples);
- 4) history/ origin, and identity of sample;
- 5) hour, date, month, and year of sampling for animal products;



- 6) sampling point;
- 7) name of producer of animal products, and/or animal feeds;
- 8) date and or time of production;
- 9) date on which the sample is sent from the business unit/ producer;
- 10) total populations/ slaughters, contents of animal product packaging, production lots;
- 11) additional information, e.g. notes on the use of medicines in breeders, disinfectants, use of preservatives, use of growth promoters in feeds, antioxidants, and antifungal;
- 12) name and address of the PPC institution;
- 13) PPC's signature.

6. Handling of Sample.

In the handling of sample, it must be considered that any samples taken, carried or sent and stored, the condition does not change, so that the content of substance to be tested can be detected as much as possible. Avoid the possibility of contamination or decrease/ loss of substance to be tested.

Any samples taken must comply with the requirements in accordance with the type of testing to be carried out. In addition to sample of animal products (meat, egg, and milk) there are several types of residual



testing to some kinds of sample that are very specific, such as eye cornea, skin behind ears, urine, and certain edible offal, e.g. liver and kidney.

B. Sample testing.

Sample testing shall carried out in the veterinary public health laboratory, in accordance with the region and its competence by considering the time or duration of testing, and method that has been validated or standard method.

The residual testing analysis method and the limit of detection shall be adjusted to the development of science and technology and refer to the Indonesian National Standard (SNI) and or other international agency standards, such as from Office Internationale des Epizooticae/ World Animal Health Organization (OIE/ WAHO) as set out in Model-3 of this regulation.

C. Reporting on Monitoring Test Results.

Reports shall be submitted to the Head of Technical Implementing Unit at the Testing Work Unit in accordance with the domicile of base administrative unit. The examiner in preparing for the report shall at least use the test result report model, such as Model-5 of this regulation. In the event that the reporting of test



results is not accommodated in the reporting model in the appendix, the examiner may use or modify the reporting model specifically.

If based on the report of monitoring test results by the examiner it is unexpectedly known that there are deviations of animal products produced or circulated, then the head of Technical Implementing Unit furthermore shall submit a report to the Head of Livestock Service or Technical Service serving Livestock and/or Veterinary Public Health Function at the domicile of base administration for surveillance to ensure such deviations.

D. Mapping of Monitoring Result.

Mapping of monitoring result of microbial residues and contaminants is required as a follow-up material in the determination of short term, medium, and long term policies by the Head of the Provincial or Regency/ City Service.

Map of monitoring result of microbial residues and contaminants is information on the level of prevalence/microbial residues and or contaminants occur in a Province or Regency/ City, which is furthermore used to conduct surveillance activities and to determine the plan for taking number of samples in the monitoring activities next year.



E. Follow Up on Monitoring Result.

In the event that the monitoring results of microbial residues and contaminants deviate from the determined standards, the examiner at the Veterinary Public Health laboratory must immediately report to the Head of Work Unit at the domicile of base administrative unit. In the event that the Veterinary Public Health Laboratory is domiciled in the Regency/ City Service, the report shall be submitted to the Head of Service in the local Regency/ City. Based on the report, the Head of Service in the Regency/ City shall report to the Regent/ Mayor with a copy delivered to the Head of Local Provincial Service, to carry out surveillance measures through investigation and/or supervision and coaching on the findings of deviation from the monitoring result standard.

In the event that the veterinary public health laboratory is domiciled in the Provincial Service, the deviation report from the monitoring results shall be submitted to the Head of local Provincial Service. Based on the report, the Head of Provincial Service shall carry out a follow-up to the surveillance through investigation and/or supervision and coaching and reports it to the Governor with a copy delivered to the Director General of Livestock, and the Head of Regency/ City Service of origin of the sample.



For the purposes of determining policies and coaching in the safety and quality of animal products, furthermore the Head of Provincial Service shall submit reports to the Governor with a copy to the Director General of Livestock.

In the event that the testing of microbial residue and contaminant monitoring is domiciled in the Technical Implementing Unit of the Directorate General of Livestock, the examiner/ technical manager shall submit a report of the monitoring results to the Head of Work Unit at the Technical Implementing Unit concerned. The Head of Work Unit at the Technical Implementing Unit shall submit a report to the Head of Service in the Province or Regency/ City of origin of the sample with a copy delivered to the Director General of Livestock. In the event that the monitoring results deviate from the microbial residue and contaminant standards, it will be followed up by surveillance activities through surveillance for further policy determination.

CHAPTER IV

SURVEILLANCE OF MICROBIAL RESIDUES AND CONTAMINANTS

Surveillance shall be carried out to obtain certainty and/or scope of the occurrence of deviations from the testing results of monitoring activities of microbial residues and contaminants in animal products.



Surveillance shall be carried out in the event that the findings of test results from monitoring activities deviate from microbial residue and contaminant standards in animal products. The findings of test results are declared deviating if the degree of residual and microbial contents in animal products exceeds the maximum limit threshold (BMR) of residues and/or exceeds the maximum limit of microbial contaminants (BMCM).

Surveillance of microbial residues and contaminants must be carried out in accordance with the stage of sampling for the purposes of testing in the veterinary public health laboratory. The stage of sampling must be taken, in order to ensure the occurrence of microbial residue and contaminant deviations in animal products. Those stages shall include:

A. Sampling

Sampling of animal products in the context of surveillance shall be carried out by the PPC from the laboratory of examiner at the request of government agencies, business actors, or individuals who require testing of animal products to ensure deviations over the monitoring test results conducted by the veterinary public health laboratory for animal products produced and circulated in the community.

B. Sample Testing



Sample testing shall be carried out by animal product testing officers using standard methods or other validated testing methods.

- testing of animal product samples for the purposes of surveillance must comply with the following requirements;
- any samples of animal products shall be taken and delivered by the PPC, based on standard procedures for sampling;
- 3. to guarantee the fulfillment of requirements for safety and quality of animal products produced or circulated, any business actors or individuals who engage in the production and circulation of animal products shall send samples of their animal products for testing without through PPC;
- 4. any samples of animal products as referred to in letters a and b will be immediately tested by the veterinary public health Laboratory, in the event that they have been accompanied by an identity letter of sample at least containing information as set out in appendix 2 to this regulation;
- 5. Particularly for animal products originating from abroad (import), in addition to fulfilling the requirements in letters a, b, and c, they shall be accompanied by a certificate of health of animal



products, certificate of origin of animal products, and certificate of analysis of animal products.

Testing of samples of animal products shall not be carried out, in the event that the animal products sent for testing do not comply with the requirements as referred to in letters a, b, c, and d. Furthermore, those samples of animal products will be returned or destroyed. Any samples of animal products that have complied with the requirements shall be immediately tested and the results shall be sent to the sample sender and to the PPC as materials for supervision and coaching carried out by the relevant Provincial/ Regency/ City Service.

C. Reporting on Surveillance Test Results

The examiner must prepare and submit a report of the surveillance results that have been carried out to the head of Technical Implementing Unit at the Animal Product Testing Work Unit in accordance with the domicile of base administrative unit. The report of the surveillance results by examiners shall use a form as set out in Model-4 of this regulation.

Furthermore, the Head of Technical Implementing Unit shall submit the report of test results to his respective superiors and business actors or individuals as sample senders.



D. Follow Up on Surveillance Results

Follow-up on surveillance results shall be carried out by the veterinary public health supervisor at the work unit and/or any technical agencies serving livestock and/or veterinary public health functions at the center and regions in accordance with their responsibilities and authorities and domiciles of base administration, based on the report of test results as received from the testing laboratory.

The follow-up on the surveillance results is required by the Work Unit and or any technical agencies serving livestock and/or veterinary public health functions at the center and regions in accordance with their responsibilities and authorities and domiciles of base administration, for the purposes of coaching and supervision, as follows:

1. Any veterinary public health supervisors whose domiciles of their base administrative units in provinces shall report and may recommend to the Head of Service in the province to make a written warning to any business actors of animal products that they produce and/or circulate, so that they immediately withdraw animal products and/or improve the safety and quality of their animal products that they produce and/or circulate.



- 2. Based on the recommendations of veterinary public health supervisors, the Head of Provincial Service shall make a written warning with a copy delivered to the local Governor, the Director General of Livestock, and the Head of Regency/ City Service in accordance with the site where deviations are found, and any competent authority issuing business/ production license.
- 3. Any veterinary public health supervisors whose domiciles of their base administrative units in Regencies/ Cities shall report and may recommend to the Head of Service in the Regency/ City to make a written warning to any business actors of animal products that they produce and/or circulate, so that they immediately withdraw animal products and/or improve the safety and quality of their animal products that they produce and/or circulate.
- 4. Based on the recommendations of Veterinary Public Health supervisors, the Head of Regency/ City Service shall make a written warning with a copy delivered to the Regent/ Mayor, the Head of Provincial Service in accordance with the site where deviations are found, and any competent authority issuing business/ production license.
- 5. Any Veterinary Public Health Supervisors whose domiciles of their base administrative units at the



center shall report and may recommend to the Director General of Livestock to:

- a. give a written warning to any business actors who produce and/or circulate animal products, so that they immediately improve the safety and quality of animal products produced and temporarily withdraw animal products that have been circulated for at least 3 (three) calendar days;
- b. recommend to any competent authority who give business licenses to suspend their business activities temporarily;
- c. recommend to any competent authority who give business licenses to revoke their business licenses.

The report of the surveillance results by the Veterinary Public Health Supervisor to the Director General of Livestock with its copy shall be submitted to the Heads of Province and Regency/ City Services and any competent authority issuing business licenses.

CHAPTER V

COORDINATION OF SURVEILLANCE RESULT SUPERVISION.

The Head of Provincial/ Regency/ City Services shall coordinate in supervising the surveillance results of microbial residues and contaminants by taking early preventive



measure steps from residues or diseases derived from animal products (foodborne disease and foodborne zoonosis) by the following manner:

- Developing and fostering an Animal Product Protection
 Program System through activities of:
 - a. coaching from production or in the livestock.
 - b. determination of sanitary requirements during transportation.
 - c. coaching in the processing of animal products.
 - d. evaluating microbial residues and contaminants in foods of animal origin.
- Conducting training for employees of animal origin food business units concerning understanding the importance of sanitation and hygiene.
- 3. Harmonizing between managers and employees of animal origin food business units so that they agree to guarantee the safety of animal product quality by the principle of "food hygiene".
- 4. Enforcing an effective supervision to pests, such as rodents and insects (pest control) potentially causing microbial contamination in the business unit of animal products.
- 5. Building consumer care by providing knowledge on:
 - a. basic sanitation and practical measures, such as washing hand and wearing clean equipment.



- b. methods of storing, handling, and supplying good animal products.
- c. care to residual hazards, and microbial contaminants.
- 6. Developing the role of Veterinary Medics and Paramedics in addition to the appointed Veterinary Public Health Supervisors by:
 - a. maintaining the livestock to be free from any diseases and environmental hygiene and the proper use of veterinary medicines.
 - b. confirming laboratory for supervision of safety and quality of animal products.
 - c. assisting training and management of animal product business units and its employees to care about sanitation-hygiene.
 - d. training/ assisting community's knowledge on residues and animal product safety and environmental hygiene that can cause any diseases of food origin and zoonosis including the preventive method.
 - f. if it is deemed necessary, it can take legal actions in accordance with the applicable laws and regulations.
- 7. Building the role of Medics and Paramedics by:
 - a. confirming laboratory to the suspect of illness or poisoning sourced from animal products.
 - b. reporting if any extraordinary events to any competent authorities and relevant agencies.



- c. requesting information to a patient being suspected of illness or poisoning sourced from animal products that require treatment.
- d. building community concern to the prevention of cause of diseases or poisoning sourced from animal products including preventive efforts.
- 8. Building the Role of Veterinary Public Supervisors in supervising Safety and Quality of Animal Products by:
 - a. notifying local medical officers on the existence of victims from diseases or food poisoning sourced from animal products.
 - b. reporting cases of food poisoning sourced from animal products to any competent authorities and relevant agencies.
 - c. sending samples to the testing laboratory at the nearest veterinary public health division or other reference laboratories as needed.
 - d. emphasizing producers/ business units of animal products to increase sanitation supervision.
 - e. taking preventive and supervisory measures, and if it is deemed necessary, it may take legal actions (justice).
- 9. Building the role of Examiners or Researchers by:
 - a. developing cooperation of technical health and veterinary epidemiology.



- b. building community's knowledge on hygiene and sanitation.
- c. developing testing techniques and methods.
- d. developing isolation, identification, and characterization techniques of pathogenic microbes.

CHAPTER VI

CLOSING

- A. The veterinary public health laboratory in conducting monitoring and surveillance of microbial residues and contaminants shall be based on the principles of integration, coordination, and synchronization between the veterinary public health laboratories in compliance with their respective responsibilities and functions by referring to these guidelines.
- B. These guidelines are dynamic and will be re-adjusted in the event of any change and development of technology and community's needs.

THE MINISTER OF AGRICULTURE,

[signed & sealed]

ANTON APRIYANTONO



Instructions for determination of total animal product sampling

No.	Commodity	Instructions for	Total minimum				
	Name of the second	sampling	required for sample				
I.	Mammal meat A. Intact or half carcasses, the weight unit is normally 10 kg or more.	Take the diaphragm meat, add meat of neck part from each animal.	500 g 500 g after the leather and bone are discarded.				
	B. Small carcasses (such as rabbit)	Take the back leg or intact carcasses on each animal.	500 g 500 g after the bone is discarded.				
	C. Fresh/ frozen part 1. the minimum weight is 0.5 kg outside bone.	1 (one) unit	500 g				
	2. the weight is less than 0.5 kg.	The unit taken may comply with the test requirements.	500 g after the bone is discarded.				
	D. Form of bulk is frozen.	Cut in crossways or intact.	500 g				
	E. The package is retail or ready to sell unit.	Take 1 unit or some units to comply with the test requirements.	500 g after the bone is discarded.				
II.	Mammal fat						
	A. Sample of big animal slaughtered.	Take fat in the kidney, fat between leather or abdominal cavity from each animal.	500 g				
	B. Sample of small animal slaughtered.	Take fat between leather or abdominal cavity from each animal.	500 g				
	C. Bulk of tissue fat	Take a piece from 3 importation sites into container.	500 g				
III.	Mammal offal						
	A. Liver	Take intact or a piece of liver	400 – 500 g				
	B. Kidney	Take one of kidney and it must be from one species of animal.	250 – 500 g				
	C. Heart	Take intact or a piece of heart	400 – 500 g				
	D. Other parts of offal	Taken from one species. Cut in crossways in the event that it is in the bulk.	500 g				



IV.	Poultry Meat						
	A. Intact carcasses of 2 – 3 kg (such as duck, etc.)	Take wings, legs, or other parts.	500 g after the leather and bone are discarded.				
	B. Poultry carcasses of 0,5 – 2 kg	Take wings, legs, or other parts from 2- 3 poultries, depending on the size.	500 g after the leather and bone are discarded.				
	C. Intact carcasses < 0.5 kg (such as quail, dove)	Take at least 6 intact carcasses.	500 g				
	D. Fresh/ frozen 1. big packaging 2. small packaging	Take one unit. Take a number of units sufficiently.	500 g without leather & bone				
٧.	Poultry fat						
	A. Sample when being slaughtered.	Take abdominal fat from 3-6 poultries.	50 – 100 g of fat				
	B. Form of Bulk	Take from 3 sites of container.	500 g				
VI.	Poultry offal						
	A. Liver	Take 6 intact livers.	250 – 500 g				
	B. Other frozen/ fresh offal	Take from 6 poultries, if it is frozen, take a half container.	250 – 300 g				
VII.	Milk						
	Raw, pasteurized, UHT & sterilized milk		500 ml				
	Evaporating milk		500 ml				
	Powder milk/ milk fat		500 g				
	Cream		200 ml				
	Butter/ Oil butter		200 g				
	Yoghurt		500 g				
	Cheese	200 g					
	Ice cream		500 ml				
	Sweet condensed milk		500 ml				
VIII	Egg and its products						
	Egg liquid and frozen egg	The liquid is taken of 0.25 liter or in the container of 0.5 liter.	500 g				
	Powder egg	Take per container of 0.5 kg minimum of 2 units per sub-sample shall be carried out in an aseptic manner.	500 g				
	Egg retail packaging with eggshell	For each 15 packaging, 2 dozens of eggs shall be taken. If it is more than 15 packaging, 1 dozen shall be taken from 15 random	500 g or ten eggs				



		samples of their multiple.	
	Commercial packaging of eggshell		500 g or ten eggs
IX	Urine	Take 1 unit or more units to comply with the test requirements.	5 ml/ sample
X	Feces	Take 1 unit or more units to comply with the test requirements.	5 ml/ sample
XI	Bile	Take 1 unit or more units to comply with the test requirements.	5 ml/ sample
XII	Serum	Take 1 unit or more units to comply with the test requirements.	5 ml/ sample



Application form of sample identity (Reference Letter of Sample)

Data from samples taken by the PPC or the veterinary public health supervising officer must be equipped with the following information:

- a. sample number/ code;
- b. name and address of sample owner;
- c. type (animal/ species, types of animal samples/ parts
 taken as samples);
- d. history/ origin, and identity of sample;
- e. date, month, and year and time of sampling;
- f. location, site, and sampling point (breeders, RPH/ RPA, processing business units)
- g. name of producer of animal products;
- h. date of production;
- i. date as sent from the business unit/ producer;
- j. total contents;
- k. additional information, e.g. notes on the use of veterinary medicines in breeders, disinfectant used, use of preservatives, use of growth promoters in feeds, antioxidants, and antifungal;
- 1. name and address of the sampling officer;
- m. the sampling officer's signature.



Analysis Methods for Animal Product Residual Detection

Group	Analysis Methods	Detection Limit (degree)
Veterinary medicine residues	HPLC-DAD (UV) or HPLC-FLD,	ng/g (ppb)
	GC-MS, GC-ECD, LC-MS, bio-	
	assays	
Hormone residues	6C-HRMS, GC-MS, LC-MS, bio-	ng/g (ppb)
	assays	
Heavy metal	ICP-MS	ng/g (ppb)
Nitrate	Anion exchange HPLC	µg/g (ppb)
Bacterial toxin	LC-MS, bio-assays	ng/g (ppb);
		pg/g (ppt)
Mycotoxin	LC-MS	ng/g (ppb)
Phytotoxin	HPLC-DAD, LC-MS	mg/g (ppm); ng/g (ppb)
Fish toxin	LC-MS, HPLC, bio-assays	ng/g (ppb)
Polychlorinated biphenyls	GC-ECD, GC-MS	ng/g (ppb)
Dioxins and dioxin - like	HRGC-HRMS, bio-assays	ng/g (ppb)
compounds		
Pesticide		
Polycyclic aromatic	GC-ECD, GC-MS, LC-MS	ng/g (ppb)
hydrocarbons		
Acrylamide	HPLC-DAD (UV) or FLD, GC-	ng/g (ppb)
	MS, LC-MS (in development)	
Chemicals released from	LC-MS ICP-MS, GC-MS	ng/g (ppb)
packaging materials		ng/g (ppb)

Notes:

GC-ECD = Gas Chromatography-Electron Capture Detector

GC-HRMS = Gas Chromatography-High Resolution Mass

Spectrometry

GC-MS = Gas Chromatography-Mass Spectrometry

HPLC = High Performance Liquid Chromatography



HPLC-DAD (UV) = High Performance Liquid Chromatography-Diode Array

Detector (Ultra Violet)

HPLC-FLD = High Performance Liquid Chromatography

Fluorescence Detector

HRGC-HRMS = High Resolution Gas Chromatography- High Resolution

Mass Spectrometry

ICP-MS = Inductively Coupled Plasma- Mass Spectrometry

LC-MS = Liquid Chromatography-Mass Spectrometry



Model-4

Test Result Report Form in the context of monitoring and surveillance of microbial residues and contaminants

LABORATORY NAME

REPORT OF TEST RESULTS OF MICROBIAL CONTAMINANTS

MONITORING AND SURV	EILLANCE		RPH	
OF MICROBIAL CONTAMI	NANTS			
			RPU Import/ Export (0	Country)
			Miscellaneous	,
Date of Taking	:	l ahr	oratory Letter No.	
Example of Recommendation	:		of Receipt	
Letter No.		Date	of Neceipt	
Example of Owner	:	Con	dition of Sample	1
Types of Animal and Types	:	Exar	mined By	:
of Sample				

Reference		TEST RESULTS												
Letter of	1	2	3	4	5	6	7	8	9	10	11	12	13	
Sample No.														

Notes: - Give mark (P) for Positive test result, mark (N) for Negative test result

- Give mark (√) for testing to:



	1 = Total Plate Count	6 = Campolybacter spp./ C. jejuni	11 = Streptococus
	2 = Coliform	7 = Y. enterocolitica	12 = etc., such as Anthrax
	3 = E. Coli/ E. Coli O157	8 = L. monocytogones	
	4 = S. Aureus	9 = CI. monocytogenes	
	5 = Salmonella spp./ S.	10 = Yeast & Moulds	
	enteritidis		
	4		

Signature of Sample Sender	:	Signature of Examiner/	:	10.70
		Reporter		
Name	:	Name	:	
Address	:	Address	:	
Date of delivery	:	Date	:	



LABORATORY NAME

REPORT OF TEST RESULTS OF RESIDUES

MONITORING AND SURV	EILLANCE	RPH	
OF RESIDUES		RPU Import/ Export (C	Country)
Date of Taking	:	Laboratory Letter No.	:
Example of Recommendation	:	Date of Receipt	:
Letter No.			
Example of Owner	;	Condition of Sample	1
Types of Animal and Types	†	Examined By	:
of Sample			
No. Reference		TEST RESULTS	

No.	Reference		TEST RESULTS											
	Letter of Sample No.	Penicillin	Tetracycline	Aminogycloside	Macrolide	Sulfonamide	Beta	Miscellaneous						

Notes: - Give mark (P) for Positive test result, mark (N) for Negative test result - Give mark ($\sqrt{}$) for testing to:

Signature of Sample Sender : | Signature of Examiner/ | : |

Signature of Sample Sender : Signature of Examiner/ : Reporter

Name : Name : Address : Date of delivery : Date



Model-5

Example of Form of Report of Microbial Residue and Contaminant Monitoring

REPORT OF TEST RESULTS OF ANIMAL PRODUCTS TO MICROBIAL RESIDUES AND CONTAMINANTS

Lab

Year :

No.	Province	Regency/ City			Microbial Contaminants									Re	sidues				Preservative						
			Animal	Туре	Total				Test Resu	It (>BMCM)				Total			Test	Result (>	BMCM)				Posi	Positive	
						TPC	E. Coli	Colifo	Staphau reus	Salmonell	Campy lobacter				PC	TC	AG	ML				Total	Formali		
									1000		100000														
1	Riau	Pekan baru City	Chicken	Meat	15	2	1	0	4	0				12	3	1	3	0				5	2		
2	West Sumatera	Padang City	Chicken	Egg	-	-	-	-	-	-				40	22	3	7	1				-	-		
	50 Kota Regency		Buffalo	Milk	20	12	2	0	3	0				-		-	-	-				-	-		
				Liver	10	6	1	0	4	0				10	3	1	0	0				-	-		
				Offal	5	3	0	1	2	0				-	-	-	-	-				6	4		
				Process		-			-	-				14	3	0	1	0				14	0		
		TOTAL	L	ed Meat	50	23	4	1		 		0	0	76	31	5	11	1		-	0	25	6	0	

The test results are presented

Bukittinggi, Month 2007

in number.

Person-in-charge of Testing

NIP.

I, **Eko Tjahyadi**, **Sworn & Certified Translator and team**, hereby declare that this document is an English translation of a document prepared in Indonesian language. In translating this document an attempt has been made to translate as literally as possible without jeopardizing the overall continuity of the text. However differences may occur in translation and if they do the original text has precedence in law.

