

USA COMMENTS

CHAPTER 6.7.

HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES

General Comment: This chapter is limited in scope and is primarily focused on establishing the prevalence of resistant strains of microorganisms. The OIE may want to consider expanding to include other objectives and methods of surveillance in line with Code Chapter 1.4 .

Article 6.7.1.

Objective

This chapter provides criteria for the:

- 1) development of national antimicrobial resistance surveillance and monitoring programmes,
 - 2) harmonisation of existing national antimicrobial resistance surveillance and monitoring programmes,
- in food producing animals and in products of animal origin intended for human consumption.

Article 6.7.2.

Purpose of surveillance and monitoring

Active (targeted) surveillance and monitoring are **as** core parts of national antimicrobial resistance surveillance programmes. Passive surveillance and monitoring may offer additional information (refer to Chapter 1.4.). Regional cooperation between **all** Member Countries conducting antimicrobial resistance surveillance should be encouraged.

Rationale: Although it is certainly important for Members in close proximity to cooperate, the ability of resistant organisms to rapidly spread between distant locations (via human travel or food trade), highlights the importance of cooperation between *all* Members (and not just regional Members). Also, recommend deleting the word “as” for proper syntax.

Surveillance and monitoring of antimicrobial resistance is necessary to:

- 1) assess and determine the trends and sources of antimicrobial resistance in bacteria;
- 2) detect the emergence of new antimicrobial resistance mechanisms;
- 3) provide the data necessary for conducting *risk analyses* as relevant to animal and human health;
- 4) provide a basis for policy recommendations for animal and human health;
- 5) provide information for evaluating antimicrobial prescribing practices and, for prudent use recommendations;

6) assess and determine effects of actions to combat antimicrobial resistance.

Article 6.7.3.

The development of antimicrobial resistance surveillance and monitoring programmes

1. General aspects

Surveillance of antimicrobial resistance at targeted intervals or ongoing monitoring of the prevalence of resistance in bacteria from *animals*, food, environment and humans, constitutes a critical part of animal health and food safety strategies aimed at limiting the spread of antimicrobial resistance and optimising the choice of *antimicrobial agents* used in therapy.

Monitoring of bacteria from products of animal origin intended for human consumption collected at different steps of the food chain, including processing, packing and retailing, should also be considered.

National antimicrobial resistance monitoring and surveillance programmes should be scientifically based and may include the following components:

- a) statistically based surveys;
- b) sampling and testing of food producing animals on the farm, at live animal markets or at slaughter;

Rationale: Grammar.

- c) an organised sentinel programme, for example targeted sampling of food producing animals, *herds*, *flocks*, and *vectors* (e.g. birds, rodents);
- d) analysis of veterinary practice and diagnostic *laboratory records*;
- e) sampling and testing of food products of animal origin.

2. Sampling strategies

General Comment: Sampling strategies should include non-random sampling and risk-based (targeted) surveillance.

- a) Sampling should be conducted on a statistical basis. The sampling strategy should ensure:
 - the sample is representative of the population of interest;
 - the robustness of the sampling method.
- b) The following criteria are to be considered:
 - sample source such as food producing animal, food, animal feed;
 - animal species;
 - category of *animal* within species such as age group, production type;
 - health status of the *animals* such as healthy, diseased;
 - sample selection such as targeted, systematic random;
 - type of sample (e.g. faecal, carcass, food product);
 - sample size.

3. Sample size

The sample size should be large enough to allow detection of existing and emerging antimicrobial resistance phenotypes.

Sample size estimates for prevalence of antimicrobial resistance in a large population are provided in Table 1 below.

General Comment: Sample size is dependent on the objective of surveillance. Presenting guidelines that are exclusively for the determination of prevalence may mislead readers toward selecting sample sizes based on the table, disregarding their particular objective. The United States would suggest deleting Table 1 and the text preceding it, and rewriting this article to consider, in addition to prevalence, sample size determination for other objectives such as detection, evidence of freedom, etc. Guidelines on the selection of appropriate sampling units should be added.

Table 1. Sample size estimates for prevalence of antimicrobial resistance in a large population

	90% Level of confidence			95% Level of confidence		
Expected prevalence	Desired precision			Desired precision		
	10%	5%	1%	10%	5%	1%
10%	24	97	2,429	35	138	3,445
20%	43	173	4,310	61	246	6,109
30%	57	227	5,650	81	323	8,003
40%	65	260	6,451	92	369	9,135
50%	68	270	6,718	96	384	9,512
60%	65	260	6,451	92	369	9,135
70%	57	227	5,650	81	323	8,003
80%	43	173	4,310	61	246	6,109
90%	24	97	2,429	35	138	3,445

4. Sample sources

Member Countries should examine their livestock production systems on [the](#) basis of available information and assess which sources are likely to contribute most to a potential risk to animal and human health.

Rationale: Grammar

a) Animal feed

Member Countries should consider including animal feed in surveillance and monitoring programmes as they may become contaminated with antimicrobial resistant bacteria, e.g. *Salmonella*.

b) Food producing animals

Categories of food producing animals considered for sampling should be relevant to the country's production system.

c) Food

Member Countries should consider including relevant food products originating from food producing animals in surveillance and monitoring programmes as foodborne transmission is considered to be an important route for the transfer of antimicrobial resistance.

5. Type of sample to be collected

Feed samples should be collected in amounts sufficient for isolation of resistant bacteria of concern (at least 25 g) and should be linked to pathogen surveillance programmes.

Faecal samples should be collected in amounts sufficient for isolation of the resistant bacteria of concern (at least 5 g from bovine and porcine and whole caeca from *poultry*).

Sampling of carcasses at the *abattoir* provides information on *slaughter* practices, *slaughter* hygiene and the level of microbiological contamination and cross-contamination of *meat*. Further sampling of the product at retail sales level may provide additional information on the overall microbiological contamination from *slaughter* to the consumer.

Existing food processing microbiological monitoring, risk-based management and other food safety programmes may provide useful samples for surveillance and monitoring of resistance in the food chain after *slaughter*.

Table 2 provides examples of sampling sources, sample types and monitoring outcomes.

Table 2. Examples of sampling sources, sample types and monitoring outcomes

Source	Sample type	Outcome	Additional information required or additional stratification
Herd or flock of origin	Faecal or bulk milk	Prevalence of resistant bacteria originating from animal populations (of different production types) Relationship resistance – antimicrobial use between resistance and antimicrobial use.	Age categories, production types, etc. Antimicrobial use over time
Abattoir	Faecal	Prevalence of resistant bacteria originating from animals at slaughter	
	Caeca or intestine	As above	
	Carcass	Hygiene, contamination during slaughter	
Processing, packing	Food products	Hygiene, contamination during processing and handling	
Point of sales (Retail)	Food products	Prevalence of resistant bacteria originating from food, exposure data for consumers	
Various origins	Animal feed	Prevalence of resistant bacteria originating from animal feed, exposure data for animals	

Rationale: Improved clarity.

General Comment on Table 2: the “outcomes” listed in the table mostly refer to the determination of prevalence. Outcomes can vary depending on the objective of surveillance and the sample size used.

6. Bacterial isolates

The following categories of bacteria could be monitored:

a) Animal bacterial pathogens relevant to the countries' priorities

Monitoring of antimicrobial resistance in animal pathogens is important, both to:

- i) detect emerging resistance that may pose a concern for animal and human health;
- ii) guide *veterinarians* in their prescribing decisions.

Information on the occurrence of antimicrobial resistance in animal pathogens is in general derived from routine clinical material sent to veterinary diagnostic *laboratories*. These samples, often derived from severe or recurrent clinical cases including therapy failure, may provide biased information.

b) Zoonotic bacteria

i) *Salmonella*

Salmonella should be sampled from animal feed, food producing animals and animal derived food products. For the purpose of consistency and harmonisation, samples should be preferably taken at the *abattoir*.

Surveillance and monitoring programmes may also include bacterial isolates obtained from designated national *laboratories* originating from other sources.

Isolation and identification of bacteria and bacterial strains should follow nationally or internationally standardised procedures.

Serovars of public health importance such as *S. Typhimurium* and *S. Enteritidis* should be included. The inclusion of other relevant serovars will depend on the epidemiological situation in each country.

All *Salmonella* isolates should be serotyped and, where appropriate, phage-typed according to standard methods used at the nationally designated *laboratories*. For those countries that have the capabilities, *Salmonella* could be genotyped using genetic finger-printing methods.

ii) *Campylobacter*

Campylobacter jejuni and *C. coli* should be isolated from food producing animals and associated food products (primarily from *poultry*). Isolation and identification of these bacteria should follow nationally or internationally standardised procedures. *Campylobacter* isolates should be identified to the species level.

iii) Other emerging bacterial pathogens

Other emerging bacterial pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA), *Listeria monocytogenes* or others which are pathogenic to humans, may be included in resistance surveillance and monitoring programmes.

c) Commensal bacteria

E. coli and *enterococci* (*Enterococcus faecium* and *E. faecalis*) may be sampled from animal feed, food producing animals and animal-derived food products.

These bacteria are commonly used in surveillance and monitoring programmes as indicators, providing information on the potential reservoir of antimicrobial resistance genes, which may be transferred to pathogenic bacteria. It is considered that these bacteria should be isolated from healthy *animals*, preferably at the *abattoir*, and be monitored for antimicrobial resistance.

7. Storage of bacterial strains

If possible, isolates should be preserved at least until reporting is completed. Preferably, appropriate isolates should be permanently stored. Bacterial strain collections, established by storage of all isolates from certain years, will provide the possibility of conducting retrospective studies.

8. Antimicrobial susceptibility testing

Clinically important *antimicrobial agents* or classes used in human and veterinary medicine should be included in antimicrobial resistance surveillance programmes. Member Countries should refer to the OIE list of *antimicrobials* of veterinary importance for monitoring purposes. However, the number of tested *antimicrobial agents* may have to be limited according to financial resources.

Appropriately validated antimicrobial susceptibility testing methods should be used in accordance with Guideline 4.4.6: 3.1 of the *Terrestrial Manual*, concerning laboratory methodologies for bacterial antimicrobial susceptibility testing. Antimicrobial susceptibility data should be reported quantitatively (minimum inhibitory concentrations [MICs] or inhibition zone diameters), rather than qualitatively.

9. Recording, storage and interpretation of data

- a) Because of the volume and complexity of the information to be stored and the need to keep these data available for an undetermined period of time, careful consideration should be given to database design.
- b) The storage of raw (primary, non-interpreted) data is essential to allow the evaluation in response to various kinds of questions, including those arising in the future.
- c) Consideration should be given to the technical requirements of computer systems when an exchange of data between different systems (comparability or compatibility of automatic recording of laboratory data and transfer of these data between and within resistance monitoring programmes) is envisaged. Results should be collected in a suitable national database. They should be recorded quantitatively:
 - i) as distributions of MICs in ~~milligrams~~ micrograms per litre;

Rationale: MICs are typically given in micrograms per millilitre, not in milligrams per liter

- ii) or inhibition zone diameters in millimetres.
- d) The information to be recorded should include, where possible, the following aspects:
 - i) sampling programme;
 - ii) sampling date;
 - iii) animal species or type;
 - iv) type of sample;
 - v) purpose of sampling;
 - vi) type of antimicrobial susceptibility testing method used;
 - vii) geographical origin (geographical information system data where available) of *herd, flock or animal*;
 - viii) *animal* factors (e.g. age, condition, health status, identification, sex).
- e) The reporting of *laboratory* data should include the following information:
 - i) identity of *laboratory*,
 - ii) isolation date,
 - iii) reporting date,
 - iv) bacterial species,

and, where relevant, other typing characteristics, such as:

 - v) serotype or serovar,

- vi) phage type,
 - vii) antimicrobial susceptibility result or resistance phenotype,
 - viii) genotype.
- f) The proportion of isolates regarded as resistant should be reported, including the defined interpretive criteria used.
 - g) In the clinical setting, breakpoints are used to categorise bacterial strains as susceptible, intermediate or resistant. These clinical breakpoints may be elaborated on a national basis and may vary between Member Countries.
 - h) The antimicrobial susceptibility testing standards and guidelines used should be recorded.
 - i) For surveillance purposes, use of the microbiological breakpoint (also referred to as epidemiological cut-off point), which is based on the distribution of MICs or inhibition zone diameters of the specific bacterial species tested, is preferred. When using microbiological breakpoints, only the bacterial population with acquired resistance that clearly deviates from the distribution of the normal susceptible population will be designated as resistant.
 - j) Ideally, data should be collected at the individual isolate level, allowing antimicrobial resistance patterns to be recorded.

10. Reference laboratory and annual reports

- a) Member Countries should designate a national reference centre that assumes the responsibility to:
 - i) coordinate the activities related to the antimicrobial resistance surveillance and monitoring programmes;
 - ii) coordinate and collect information from participating surveillance laboratories within the country;
 - iii) produce an annual report on the antimicrobial resistance situation in the country.
- b) The national reference centre should have access to the:
 - i) raw data;
 - ii) complete results of quality assurance and inter-laboratory calibration activities;
 - iii) inter-laboratory proficiency testing results;
 - iv) information on the structure of the monitoring system;
 - v) information on the chosen laboratory methods.

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