CHAPTER 6.7.

HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES

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.

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.

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;

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 intended for human consumption.

2. Sampling strategies

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, non-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.

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

<table>
<thead>
<tr>
<th>Expected prevalence</th>
<th>90% Level of confidence</th>
<th>95% Level of confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Desired precision</td>
<td>Desired precision</td>
</tr>
<tr>
<td></td>
<td>10%</td>
<td>5%</td>
</tr>
<tr>
<td>10%</td>
<td>24</td>
<td>97</td>
</tr>
<tr>
<td>20%</td>
<td>43</td>
<td>173</td>
</tr>
<tr>
<td>30%</td>
<td>57</td>
<td>227</td>
</tr>
<tr>
<td>40%</td>
<td>65</td>
<td>260</td>
</tr>
<tr>
<td>50%</td>
<td>68</td>
<td>270</td>
</tr>
<tr>
<td>60%</td>
<td>65</td>
<td>260</td>
</tr>
<tr>
<td>70%</td>
<td>57</td>
<td>227</td>
</tr>
<tr>
<td>80%</td>
<td>43</td>
<td>173</td>
</tr>
<tr>
<td>90%</td>
<td>24</td>
<td>97</td>
</tr>
</tbody>
</table>
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.

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 of animal origin intended for human consumption 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**

<table>
<thead>
<tr>
<th>Source</th>
<th>Sample Type</th>
<th>Outcome</th>
<th>Additional information required or additional stratification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herd or flock of origin</td>
<td>Faecal, faeces or</td>
<td>Prevalence of resistant bacteria</td>
<td>Age categories, production types, etc.</td>
</tr>
<tr>
<td></td>
<td>bulk milk</td>
<td>originating from animal populations of different production types</td>
<td>and antimicrobial use</td>
</tr>
<tr>
<td>Abattoir(cells merged)</td>
<td>Faecal, caeca or</td>
<td>Prevalence of resistant bacteria</td>
<td></td>
</tr>
<tr>
<td></td>
<td>caeca or intestine</td>
<td>originating from animals at slaughter</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Carcass</td>
<td>Hygiene, contamination during</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>slaughter</td>
<td></td>
</tr>
<tr>
<td>Processing, packing</td>
<td>Food products</td>
<td>Hygiene, contamination during</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>processing and handling</td>
<td></td>
</tr>
<tr>
<td>Point of sale (Retail)</td>
<td>Food products</td>
<td>Prevalence of resistant bacteria</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>originating from food, exposure</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>data for consumers</td>
<td></td>
</tr>
<tr>
<td>Various origins</td>
<td>Animal feed</td>
<td>Prevalence of resistant bacteria</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>originating from animal feed,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>exposure data for animals</td>
<td></td>
</tr>
</tbody>
</table>
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 laboratorie. 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 laboratorie 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 laboratorie. 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 of animal origin intended for human consumption.

   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 1.1.6. 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 micrograms per millilitre, milligrams per litre;

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 and production 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.

---------------------

- Text deleted.