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, and the
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 core parts of national antimicrobial resistance surveillance programmes. Passive surveillance and monitoring may offer additional information (refer to Chapter 1.4.). The OIE encourages cooperation between among all Member Countries conducting antimicrobial resistance surveillance and monitoring 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.

General aspects The development of antimicrobial resistance surveillance and monitoring programmes

1. General aspects

Surveillance of antimicrobial resistance and at targeted intervals or ongoing monitoring of the prevalence of and trends in 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. Animal Feed and the environment should also be considered according to national priorities.
Surveillance or 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.

Annex 12 (contd)

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

- **1a)** statistically based surveys;
- **2b)** sampling and testing of food-producing animals on the farm, at live animal markets or at slaughter;
- **3c)** an organised sentinel programme, for example targeted sampling of food-producing animals, herds, flocks, and vectors (e.g. birds, rodents);
- **4d)** analysis of veterinary practice and diagnostic laboratory records;
- **5e)** sampling and testing of products of animal origin intended for human consumption;
- **6i)** sampling and testing of feed ingredients or feed.

**Article 6.7.4.**

**Sampling**

**12. 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 and meets the objectives of the surveillance;
  - 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 method such as targeted, systematic random, non-random;
  - type of sample (e.g. such as faecal, faeces, caecum, carcass, food product);
  - sample size.

**23. Sample size**

The sample size should be large enough to allow detection or determine prevalence of, or trends in, existing and emerging antimicrobial resistance phenotypes.

The sample should avoid bias and be representative of the animal population, process, product or other unit of interest whilst taking into account the expected prevalence of the bacteria in the sample type, the expected prevalence of the resistance phenotype and the desired level of precision and confidence.

The sample size calculation in Table 1 is should be based on independent samples. However, if there is any clustering at the establishment or animal level, the sample size should be adjusted accordingly. At low levels of expected prevalence, exact methods of sample size calculation should be preferred to approximate.
methods. Samples from which bacteria were not isolated cannot be used in the calculation of prevalence of the resistance phenotype.
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 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>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>62</td>
<td>227</td>
</tr>
<tr>
<td>40%</td>
<td>85</td>
<td>286</td>
</tr>
<tr>
<td>50%</td>
<td>85</td>
<td>286</td>
</tr>
<tr>
<td>60%</td>
<td>65</td>
<td>260</td>
</tr>
<tr>
<td>70%</td>
<td>65</td>
<td>260</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>

### 34. Sample sources (Table 2)

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*.

**a) Food-producing animals**

Categories of food-producing animals considered for sampling should be relevant to the country’s production system. Resource allocation should be guided by criteria such as production volume of the food-producing animal species and the prevalence of resistant bacteria.

**b) Food**

Member Countries should consider including products of animal origin intended for human consumption, produced locally or imported, in surveillance and monitoring programmes, as foodborne transmission is considered to be an important route for the transfer of antimicrobial resistance.

**c) 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*.

**d) Environment**

Member Countries should consider including the environment (the animal-immediate environment or the wider environment) in surveillance and monitoring programmes as the environment of animals can be an important route for transfer or persistence of antimicrobial resistance.
48. Type of sample to be collected (Table 2)

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).

Feed samples representative of the batch should be collected in amounts sufficient for isolation of resistant bacteria of concern (at least 25 g) and should be linked to any pathogen surveillance programmes that may be in place.

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 slaughterhouse/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>
<thead>
<tr>
<th>Source</th>
<th>Type</th>
<th>Output</th>
<th>Additional information required or additional stratification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herd or flock of</td>
<td>Faeces or faeces or</td>
<td>Prevalence of resistant bacteria originating from animal populations</td>
<td>Age categories, production types, etc. Antimicrobial use over</td>
</tr>
<tr>
<td>origin</td>
<td>bulk milk</td>
<td>of different production types</td>
<td>time</td>
</tr>
<tr>
<td>Abattoir</td>
<td>Faeces</td>
<td>Prevalence of resistant bacteria originating from animals at slaughter</td>
<td>As above</td>
</tr>
<tr>
<td>Caeca or intestines</td>
<td>Caeca or intestines</td>
<td>Prevalence of resistant bacteria after carcass dressing, representative of the hygiene, of the process and the contamination during slaughter</td>
<td></td>
</tr>
<tr>
<td>Carcass</td>
<td>Carcass</td>
<td>Prevalence of resistant bacteria after processing, representative of the hygiene, of the process and the contamination during processing and handling</td>
<td></td>
</tr>
<tr>
<td>Processing, packing</td>
<td>Food products</td>
<td>Prevalence of resistant bacteria originating from food, exposure data for consumers</td>
<td></td>
</tr>
<tr>
<td>Point of sale (Retail)</td>
<td>Food products</td>
<td>Prevalence of resistant bacteria originating from animal feed, exposure data for animals</td>
<td></td>
</tr>
<tr>
<td>Various origins</td>
<td>Animal feed</td>
<td>Prevalence of resistant bacteria originating from animal feed, exposure data for animals</td>
<td></td>
</tr>
<tr>
<td>Various origins</td>
<td>Environment</td>
<td>Occurrence of resistant bacteria originating from the animal; immediate or the wider environment</td>
<td></td>
</tr>
</tbody>
</table>
**Article 6.7.5.**  

**Bacteria subjected to surveillance and monitoring**  

6. Bacterial isolates  

The following categories of bacteria could **may be included in surveillance and monitoring programmes monitored:**  

1a) Animal bacterial pathogens relevant to the countries’ priorities  

   a) Surveillance and monitoring of antimicrobial resistance in animal bacterial pathogens is important, both to:  
      
      i) detect emerging resistance that may pose a concern for animal and human health;  
      
      ii) detect changes in susceptibility patterns;  
      
      iii) provide information for risk analysis;  
      
      iv) provide data guide for veterinarians in to inform their prescribing treatment decisions;  
      
      v) provide information for epidemiological studies and trend analysis.  

   b) Information on the occurrence of antimicrobial resistance in animal bacterial pathogens is in general either derived from routine clinical material sent to veterinary diagnostic laboratories or from an active monitoring programme. These samples, often derived from severe or recurrent clinical cases including therapy failure, may provide biased information. Although antimicrobial resistance information provided by diagnostic laboratories is primarily for treatment purposes, it is also useful for identification of novel resistance patterns and can possibly assist in identifying emerging resistance. However, in order to estimate accurately the prevalence of antimicrobial resistance in the bacterial pathogen, in a larger population of animals, an active sampling programme should be implemented.  

   c) To promote a harmonised global approach to the selection of animal bacterial pathogens for inclusion in national surveillance and monitoring programmes, bacteria should be selected using **one or more of the following criteria:**  
      
      i) impact on animal health and welfare;  
      
      ii) implication of antimicrobial resistance in the bacterial pathogen on therapeutic options in veterinary practice;  
      
      iii) impact on food security and on production (economic importance of associated diseases);  
      
      iv) bacterial diseases responsible for the majority of veterinary antimicrobial usage (stratified by usage of different classes or their importance);  
      
      v) existence of validated susceptibility testing methodologies for the bacterial pathogen;  
      
      vi) existence of quality assurance programmes or other pathogen reduction options that are non-antimicrobial, such as vaccines and Good Agricultural Practices.  

The table below, derived using the above criteria, lists suggested animal bacterial pathogens for inclusion in a surveillance or monitoring programme of food-producing animals. This list is not exhaustive and should be adapted according to the situation in the country.
Annex 12 (contd)

**Table 3. Examples of target animal species and animal bacterial pathogens that may be included in resistance surveillance and monitoring programmes**

<table>
<thead>
<tr>
<th>Target animals</th>
<th>Respiratory pathogens</th>
<th>Enteric pathogens</th>
<th>Udder pathogens</th>
<th>Other pathogens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle</td>
<td><em>Pasteurella multocida</em></td>
<td><em>Escherichia coli</em></td>
<td><em>Staphylococcus aureus</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Mannheimia haemolytica</em></td>
<td><em>Salmonella spp.</em></td>
<td><em>Streptococcus spp.</em></td>
<td></td>
</tr>
<tr>
<td>Pigs</td>
<td><em>Actinobacillus pleuropneumoniae</em></td>
<td><em>Escherichia coli</em></td>
<td></td>
<td><em>Streptococcus suis</em></td>
</tr>
<tr>
<td>Poultry</td>
<td></td>
<td><em>Salmonella spp.</em></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2b) Zoonotic bacteria

a) *Salmonella*

*Salmonella* should be sampled from *animal feed*, food-producing animals, and animal-derived food products and, if relevant, *animal feed*. For the purposes of consistency and harmonisation, animal samples should be preferably be taken from healthy animals at the slaughterhouse/abattoir from healthy animals and feed samples should preferably be taken at the feed mill.

Surveillance and monitoring programmes may also include sampling of the environment at places where animals are kept or handled or bacterial isolates originating from other sources 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 in surveillance and monitoring programmes. The inclusion of other relevant serovars will depend on the epidemiological situation in each country.

All *Salmonella* isolates should be characterised by 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 fingerprinting methods.

bii) *Campylobacter*

*Campylobacter jejuni* and *C. coli* should be isolated from food-producing animals and or 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.

ciii) Other bacteria that are pathogenic for humans, emerging bacterial pathogens

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

*E. coli* and *enterococci* (*Enterococcus faecium* and *E. faecalis*) may be sampled from animal feed, food-producing animals, their environment, and 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, for the purposes of consistency and harmonisation, these bacteria should preferably be isolated from healthy animals, preferably at the slaughterhouse/abattoir, for the purpose of consistency and harmonisation and be monitored for antimicrobial resistance.*

**Article 6.7.6.**

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.

**Article 6.7.7.**

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 surveillance and monitoring purposes. However, recognising that 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 Chapter 3.1. of the *Terrestrial Manual*, concerning laboratory methodologies for bacterial antimicrobial susceptibility testing. Antimicrobial susceptibility data should be reported not only qualitatively (susceptible or resistant), but also quantitatively (minimum inhibitory concentrations [MICs] or inhibition zone diameters), rather than qualitatively.

**Article 6.7.8.**

9. Recording, storage and interpretation of data

1a) 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.

2b) 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.

3e) Consideration should be given to the technical requirements of computer systems when an exchange of data between different systems (compatibility or comparability of automatic recording of laboratory data and transfer of these data between and within resistance surveillance and monitoring programmes) is envisaged. Results should be collected in a suitable national database. They should be and recorded quantitatively:

1i) as distributions of MICs in micrograms per millilitre;

1ii) or inhibition zone diameters in millimetres.
Annex 12 (contd)

4d) The information to be recorded should include, where possible, the following aspects:

   a) sampling programme;
   b) sampling date;
   c) animal species and production type;
   d) type of sample;
   e) purpose of sampling;
   f) type of antimicrobial susceptibility testing method used;
   g) geographical origin (geographical information system data where available) of herd, flock or animal;
   h) animal factors (e.g., such as age, condition, health status, identification, sex);
      i) exposure of animals to antimicrobial agents;
   j) bacterial isolation rate.

5e) The reporting of laboratory data should include the following information:

   a) identity of laboratory,
   b) isolation date,
   c) reporting date,
   d) bacterial species,
   e) serotype or serovar,
   f) phage type,
   g) antimicrobial susceptibility result or resistance phenotype,
   h) genotype.

6f) The proportion of isolates regarded as resistant should be reported. The number of isolates regarded as resistant should be reported as a proportion of the number of isolates tested, including the defined interpretive criteria used.

7g) 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.

8h) The bacterial isolation methods, antimicrobial susceptibility testing methods, standards and guidelines used should be recorded.

9i) For surveillance and monitoring 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. Clinical breakpoints, when available, should also be reported.
10. Ideally, data should be collected at the individual isolate level. This will allow antimicrobial resistance patterns to be recorded over time along with, when available, relevant data on usage of antimicrobial agents and management practices.

Article 6.7.9.

10. Reference laboratory and annual reports

1a) Member Countries should designate a national reference centre that assumes the responsibility to:

   a) coordinate the activities related to the antimicrobial resistance surveillance and monitoring programmes;

   bii) coordinate and collect information from participating surveillance laboratories within the country;

   ciii) produce an annual report on the antimicrobial resistance situation in the country.

2b) The national reference centre should have access to the:

   a) raw data;

   bii) complete results of quality assurance and inter-laboratory calibration activities;

   ciii) inter-laboratory proficiency testing results;

   d)iv) information on the structure of the surveillance or monitoring system;

   ev) information on the chosen laboratory methods.