

CHAPTER 6.4.

**DEVELOPMENT AND HARMONISATION  
OF NATIONAL ANTIMICROBIAL RESISTANCE  
SURVEILLANCE AND MONITORING  
PROGRAMMES FOR AQUATIC ANIMALS**

Article 6.4.1.

**Purpose**

This chapter provides criteria relevant to *aquatic animals* and *aquatic animal products* intended for human consumption for:

- 1) the development of national antimicrobial resistance surveillance and monitoring programmes and
- 2) the harmonisation of existing national antimicrobial resistance surveillance and monitoring programmes.

Article 6.4.2.

**Objective of surveillance and monitoring programmes**

*Competent Authorities* should conduct active antimicrobial resistance surveillance and monitoring programmes for *aquatic animals*.

Surveillance and monitoring of antimicrobial resistance is necessary to:

- 1) establish baseline data on the prevalence of antimicrobial resistant microorganisms and determinants;
- 2) collect information on antimicrobial resistance trends in relevant microorganisms;
- 3) explore the potential relationship between antimicrobial resistance in *aquatic animal* microorganisms and the use of *antimicrobial agents*;
- 4) detect the emergence of antimicrobial resistance mechanisms;
- 5) conduct *risk analyses* as relevant to *aquatic animal* and human health;
- 6) provide recommendations on human health and *aquatic animal* health policies and programmes;
- 7) provide information to facilitate prudent use, including guidance for professionals prescribing the use of *antimicrobial agents* in *aquatic animals*.

Cooperation at a regional level between countries conducting antimicrobial resistance surveillance should be encouraged.

The findings of surveillance and monitoring programmes should be shared at the regional and international level to maximise understanding of the global risks to *aquatic animal* health and human health. The publication of these data and their interpretation is important to ensure transparency and to allow all interested parties to assess trends, to perform *risk assessments* and for *risk communication* purposes.

Article 6.4.3.

**General considerations for the design of surveillance and monitoring programmes**

Surveillance of antimicrobial resistance at targeted intervals or ongoing monitoring of the prevalence of resistance in microorganisms from *aquatic animals*, *aquatic animal products* intended for human consumption, and humans constitutes a critical part of *aquatic animal* health and public health strategies aimed at limiting the spread of antimicrobial resistance and optimising the choice of *antimicrobial agents* used in therapy.

For *aquaculture* it is important to conduct surveillance and monitoring of microorganisms that infect *aquatic animals* and microorganisms, including human pathogens, present on food derived from *aquatic animals*.

Article 6.4.4.

**Design of surveillance and monitoring programmes for antimicrobial susceptibility of microorganisms that infect aquatic animals**

An important consideration for the design of surveillance and monitoring programmes for antimicrobial susceptibility of microorganisms that infect *aquatic animals* is the lack of standardised and validated antimicrobial testing methods for a significant number of bacterial species of aquatic importance. When validated methods are available they should be used. Any deviations from standard methodology should always be clearly reported. For tests performed on bacterial species for which standard methods have not been developed full details of the methods used should be provided.

A preliminary requirement for the development of a surveillance and monitoring programme may be the identification and prioritisation of bacteria isolated from *aquatic animals* for methods development.

1. Selection of microorganisms

Information on the occurrence of antimicrobial resistance in microorganisms that infect *aquatic animals* should be derived from regular monitoring of isolates obtained from diagnostic laboratories. These isolates should have been identified as primary causal agents of significant disease epizootics in *aquatic animals*.

It is important that monitoring programmes focus on microorganisms that are associated with the commonly encountered *infections* of the major aquatic species farmed in the region / local growing area.

Selection should be designed to minimise bias resulting from over representation of isolates obtained from severe epizootics or epizootics associated with therapeutic failures.

Microorganisms belonging to a specific species or group may be selected for intensive study in order to provide information on a particular problem.

2. Methods used to analyse microorganism susceptibility to antimicrobial agents

Participating laboratories may perform disc diffusion, minimum inhibitory concentration (MIC) or other susceptibility tests to monitor frequencies of resistance. Protocols that have been standardised internationally and validated for application to the study of microorganisms isolated from *aquatic animals* should always be used.

3. Requirements for laboratories involved in monitoring resistance

Laboratories involved in national or regional monitoring of antimicrobial resistance should be of sufficient capability and have relevant expertise to comply with all the quality control requirements of the standardised test protocols. They should also be capable of participating in all necessary inter-laboratory calibration studies and method standardisation trials.

4. Choice of antimicrobial agents

Representatives of all major classes of *antimicrobial agents* used to treat *disease* in *aquatic animal* species should be included in susceptibility testing.

5. Reporting of results

The results of surveillance and monitoring programmes, including susceptibility data, should be published and made available for use by relevant stakeholders. Both primary quantitative data and the interpretive criteria used should be reported.

6. Surveillance and monitoring for epidemiological purposes

For epidemiological surveillance purposes, use of the epidemiological cut-off value (also referred to as microbiological breakpoint), which is based on the distribution of MICs or inhibition zone diameters of the specific microbial species tested, is preferred.

When reporting interpretations made by application of epidemiological cut-off values, the resultant categories should be referred to as wild type (WT) or non-wild type (NWT). When interpretations are made by the application of breakpoints the resultant categories should be referred to as sensitive, intermediate or resistant.

For microbial species and *antimicrobial agent* combinations, where internationally agreed epidemiological cut-off values have not been set, laboratories may establish their own laboratory-specific values provided the methods they use are clearly reported.

7. Surveillance and monitoring for clinical purposes

The application of clinical breakpoints may be appropriate when the aim of the programme is to provide information to facilitate prudent use, including guidance for professionals in prescribing *antimicrobial agents* in *aquatic animals*.

Selecting *antimicrobial agents* for therapeutic administration on the basis of information gained from the application of validated clinical breakpoints to antimicrobial susceptibility test data for microorganisms isolated from *aquatic animals* is an important element in the prudent use of these agents.

Use of these clinical breakpoints allows microorganisms to be identified as unlikely to respond to the *in vivo* concentrations of *antimicrobial agents* achieved by a given standard therapeutic regime. In order to facilitate the development of these breakpoints, data is required that allows clinical correlation to be completed. For this purpose, where possible, data that relates *in vitro* susceptibility of isolates to the clinical outcome of treatments with specified dose regimes under specific environmental conditions should be collected and reported.

Valuable information with respect to setting clinical breakpoints can be gained from situations where therapeutic failure is reported. The *Competent Authority* should include, in a surveillance and monitoring programme, systems for capturing details of failed treatments and the laboratory susceptibility test of the microorganisms involved.

#### Article 6.4.5.

### **Design of surveillance and monitoring programmes for microorganisms in or on aquatic animal products intended for human consumption**

For details of the sampling protocols and analytical procedures required for surveillance and monitoring programmes for antimicrobial resistance in microorganisms present in *aquatic animal products* intended for human consumption, Chapter 6.8. of the OIE *Terrestrial Animal Health Code* should be consulted.

It is important to note that the word 'commensal' as used in Chapter 6.8. of the OIE *Terrestrial Animal Health Code* has less relevance due to the transient nature of the intestinal microflora of *aquatic animals*. The inclusion of intestinal microflora in surveillance and monitoring programmes should only be considered when there is evidence that these are resident for sufficient time to be a risk factor affected by *antimicrobial agents*.

When designing a sampling programme it is important to consider that contamination of *aquatic animal products* with resistant microorganisms that are capable of infecting humans may arise from sources other than the *aquatic animal*. All sources of contamination should be taken into account, for example entry of raw manure into the aquatic environment. The number of such microorganisms associated with *aquatic animals* is much less than that found in terrestrial animals. However the following species should be included, as a minimum, in a surveillance and monitoring programme:

- 1) *Salmonella* spp.;
- 2) *Vibrio parahaemolyticus*;
- 3) *Listeria monocytogenes*.

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NB: FIRST ADOPTED IN 2012.

