

CHAPTER 6.3.

MONITORING OF THE QUANTITIES AND USAGE PATTERNS OF ANTIMICROBIAL AGENTS USED IN AQUATIC ANIMALS

Article 6.3.1.

Purpose

The purpose of these recommendations is to describe approaches to the monitoring of quantities of *antimicrobial agents* used in *aquatic animals*, including species reared for food and ornamental purposes.

These recommendations are intended for use in the collection of objective and quantitative information to evaluate usage patterns by antimicrobial class, route of administration and *aquatic animal* species in order to evaluate exposure of microorganisms to *antimicrobial agents*.

The collection of data on the use of *antimicrobial agents* in *aquaculture* may be constrained in some countries by the lack of available resources, lack of accurately labelled products, poorly documented distribution channels and lack of professional consultation or supervision. This chapter may therefore be seen as indicating the direction in which countries should develop with regard to collecting data and information on the use of *antimicrobial agents* in *aquatic animals*.

Article 6.3.2.

Objectives

The information provided in these recommendations is essential for conducting *risk analyses* and for planning purposes. This information can be helpful in interpreting antimicrobial resistance surveillance data and can assist in the ability to respond to problems of antimicrobial resistance in a precise and targeted way. The continued collection of this basic information would help identify trends in the use of *antimicrobial agents* in *aquatic animals* and the potential association with antimicrobial resistance in *aquatic animal* bacteria, including potentially zoonotic bacteria. This information may also assist in *risk management* when evaluating the effectiveness of efforts to ensure responsible and prudent use and mitigation strategies and indicate where alteration of prescribing practices for *antimicrobial agents* in *aquatic animals* might be appropriate. 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 6.3.3.

Development and standardisation of monitoring systems for antimicrobial agents

Competent Authorities may, for reasons of cost and administrative efficiency, collect medical, agricultural, aquacultural and other *antimicrobial agents* use data in a single programme. Where livestock and *aquatic animal* industries are under multiple authorities in a single country, collaboration between the authorities to develop a coordinated monitoring system is necessary to facilitate the collection of data. Additionally, a consolidated programme would facilitate the comparison of *aquatic animal* use data with human use data necessary for a comprehensive *risk analysis*.

Systems to monitor usage of *antimicrobial agents* may consist of the following elements:

1. Sources of data on antimicrobial agents

a) Basic sources

Data from basic sources may include general information without specific attribution (such as, weight, quantity and class of *antimicrobial agents*).

Sources of data will vary from country to country. Such sources may include customs, import, export, manufacturing and sales data.

b) Direct sources

Data from direct sources may include more specific information (such as target *aquatic animal* species, route of administration and active ingredient).

Data from veterinary medicinal product registration authorities, manufacturers, wholesalers, retailers, feed stores and feed mills might be useful sources. A possible mechanism for the collection of this information is to make the provision of appropriate information by veterinary antimicrobial manufacturers to the registration authority one of the requirements of marketing authorisation (registration of the *antimicrobial agent*).

c) End-use sources

Data from end-use sources has the advantage of providing more detailed information on the type and purpose of use and can be complimentary to the other sources.

End-use sources of data may include *veterinarians*, *aquatic animal health professionals* and *aquatic animal* producers. End-use sources may be useful when more accurate and locally specific information is needed (such as extra-/off-label use).

Collection of this type of information can be resource intensive; therefore, periodic collection of this type of information may be sufficient. Data collection should be targeted to the most relevant period of use.

In some countries end-use sources may be the only practical source of information.

d) Other sources

Pharmaceutical industry associations and *aquatic animal* producer associations, veterinary and allied health professional associations, and other stakeholders with indirect knowledge of the quantities of *antimicrobial agents* used may be another source of this information.

Non-conventional sources including Internet sales data related to *antimicrobial agents* may be collected where available. Internet sales data may be particularly useful with respect to ornamental species.

2. Elements for data collection and reporting

a) Basic data to be collected should include:

i) the absolute amount in kilograms of the active ingredient of the *antimicrobial agent(s)* used per year, divided into antimicrobial class/subclass;

for active ingredients present in the form of compounds or derivatives, the mass of active entity of the molecule should be recorded; for *antimicrobial agents* expressed in International Units, the calculation required to convert these units to mass of active entity should be stated; it may be possible to estimate total usage by collecting sales data, prescribing data, manufacturing data, export/import data or any combination of these;

ii) the total number of *aquatic animals* treated and their weight in kilograms.

b) Additional data may be collected to further categorise the exposure of microorganisms to *antimicrobial agents* and may include:

i) species of fish, crustaceans, molluscs or amphibians treated;

ii) purpose e.g. *aquatic animals* for human consumption, use as ornamental species and baitfish;

iii) route of administration (medicated feed, bath treatment, parenteral delivery) and the method used to calculate the dose (biomass of *aquatic animals*, volume of water treated);

iv) indication for use.

The *antimicrobial agents/classes/sub-classes* to be included in data reporting should be based on current known mechanisms of antimicrobial activity / antimicrobial resistance mechanism.

Nomenclature of *antimicrobial agents* should comply with international standards where available.

When making information publically available, the *Competent Authority* should ensure confidentiality and anonymity of individual enterprises.

3. Considerations for data collection

Antimicrobial usage data may be collected on a routine basis and / or at a specific point in time depending on availability of resources and / or the need to monitor usage of *antimicrobial agents* or address a specific antimicrobial resistance problem.

Registration of products with labelling that accurately reflects the intended use of the *antimicrobial agent* will facilitate collection of information on the quantities and usage patterns.

Collection, storage and processing of data from end-use sources requires careful design but should have the advantage of producing accurate and targeted information.

Article 6.3.4.

Elements for interpretation of data on the use of antimicrobial agents

When available, the following information may support the interpretation of antimicrobial usage data and further characterisation of exposure pathways:

- 1) type of aquaculture system (extensive or intensive, ponds or tanks, flow-through or recirculating, hatchery or grow-out, integrated system);
- 2) animal movements (transfer between facilities or from wild to the facility, grading);
- 3) species, life stage, and/or stage of the production cycle;
- 4) environmental and culture parameters (seasonality, temperature, salinity, pH);
- 5) geographical location, specific rearing units;
- 6) weight/biomass, dosage regimes and duration of treatment with *antimicrobial agents*;
- 7) basis for treatment (historical, empirical, clinical, clinical with laboratory confirmation and sensitivity testing).

Factors such as the number/percentage of animals / culture units treated, treatment regimens, type of use and route of administration are key elements to consider for *risk assessment*.

When comparing use of *antimicrobial agents* over time, changes in size and composition of animal populations should also be taken into account.

Regarding data coming from end-user sources, analysis of the use of *antimicrobial agents* may be possible at the regional, local, farm, and the level of the individual *veterinarian* or other *aquatic animal health professional*.
