

USA COMMENTS

MONITORING OF THE QUANTITIES AND USAGE  
PATTERNS OF ANTIMICROBIALS USED IN  
AQUATIC ANIMALS

Article 6.4.1.

**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 by OIE Members to collect objective and quantitative information to evaluate usage patterns by antimicrobial class, route of administration and animal species in order to evaluate exposure 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 labeled products, ~~and~~ poorly understood distribution channels and without professional consultation or supervision that leads to illegal use. 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.

Rationale: Additional remarks from the Joint FAO/WHO/OIE Expert Consultation on Antimicrobial Use in Aquaculture and Antimicrobial Resistance Seoul, South Korea, June 13-16, 2006

Article 6.4.2.

**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 legal, 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 is important to ensure transparency and to allow all interested parties to assess trends, to perform risk assessments and for risk communication purposes.

Rationale: Additional suggested language regarding zoonotic potentials. The remark regarding the 'legal' use of antimicrobials is from the Joint FAO/WHO/OIE Expert Consultation on Antimicrobial Use in Aquaculture and Antimicrobial Resistance Seoul, South Korea, June 13-16, 2006.

## Development and standardisation of monitoring systems for antimicrobial agents

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

### 1. Sources of data on antimicrobial agents

#### a) Basic sources

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 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 authorization (registration of the antimicrobial agent).

#### c) End-use sources (*veterinarians, aquatic animal* health professionals and producers)

This source has the advantage of providing more detailed information on the type and purpose of use and can be complementary to the other sources. This source may be useful when more accurate and locally specific information is needed (such as extra-/off-label use).

Because collection of this type of information can be resource intensive, 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 at the moment.

#### d) Other sources

Pharmaceutical and 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 could be collected where available.

Registration of products with labeling that accurately reflects the intended use of the antimicrobial agent will facilitate collection of information on the quantities and usage patterns. OIE Members are encouraged to support each other in the development of this infrastructure.

OIE Members may also wish to consider, for reasons of cost and administrative efficiency, collecting medical, agricultural, aquacultural and other antimicrobial use data in a single programme. A consolidated programme would also facilitate comparisons of animal use with human use data for relative *risk analysis* and help to promote optimal usage of antimicrobial agents. Additionally, where livestock and aquatic animal industries are under multiple authorities in a single country, coordination between the authorities is encouraged.

### 2. Types and reporting formats of antimicrobial usage data

If a Member has the infrastructure for capturing basic animal use data for a specific antimicrobial agent, then additional information can be considered to cascade from this in a series of subdivisions or levels of detail. Such a cascade of levels should include the following:

- a) 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.

The total number of *aquatic animals* cultured and their maximum and mean weight in kilograms through the production cycle is important basic information.

- b) Subdivision of antimicrobial use into species of finfish, crustacean, or mollusk treated.
- c) Subdivision by purpose e.g. *aquatic animals* for human consumption, use as ornamental fish and baitfish.
- d) Subdivision of the data into the route of administration (medicated feed, bath treatment, parenteral delivery) and the method used to calculate the dose (biomass of fish, volume of water treated)

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 antimicrobials should comply with international standards where available.

### 3. Considerations for data collection

Antimicrobial usage data could 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.

When collecting and interpreting the data it is important to take into account factors such as temperature, disease conditions (epizootiology), species, ~~and~~ age and weight/biomass affected, aquacultural systems (i.e. intensive / extensive), dosage and duration of treatment with antimicrobial agents.

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

Rationale: Oral and parenteral antimicrobial agent dose (and therefore quantity of active ingredients used) will be calculated on a biomass/weight basis. To be useful in estimating antibiotic use, the maximum and mean biomass of fish through the production cycle should be provided.

#### Article 6.4.4.

### **Elements for interpretation of data on the use of antimicrobial agents**

In order to maximize the value of usage data, it may be beneficial to collect additional information. Such information will, when available, aid in the interpretation of usage data.

These are examples of some factors that can be considered:

- a) type of aquaculture system (extensive or intensive, ponds or tanks, flow-through or recirculating, hatchery or grow-out, integrated system);
- b) animal movements (transfer between facilities or from wild to the facility, grading)
- c) species and life stage;
- d) environmental and culture parameters (seasonality, temperature, salinity, pH);
- e) geographical location, specific rearing units;
- f) dosage regimes and duration of treatment with antimicrobial agents

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.

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