REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON THE RESPONSIBLE USE OF ANTIMICROBIALS IN AQUATIC ANIMALS

Paris, 4–6 October 2010

The OIE ad hoc group on the Responsible Use of Antimicrobials in Aquatic Animals (the ad hoc group) met at OIE headquarters in Paris from 4 to 6 October 2010.

The members of the ad hoc group and other participants at the meeting are listed at Appendix I. The adopted agenda is at Appendix II. The following documents were sent to the members of the ad hoc group prior to the meeting:

- draft agenda;
- OIE Member comments on draft Chapter 6.2 Principles for Responsible and Prudent Use of antimicrobial agents in aquatic animals;
- OIE Terrestrial Manual Chapter 1.1.6, Laboratory methodologies for bacterial antimicrobial susceptibility testing;
- antimicrobial resistance: complexities and difficulties of determination – paper by Dr Peter Smith, Department of Microbiology, NUI Galway, Ireland.

Agenda Item 1: Welcome and introduction by Dr Sarah Kahn

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Sarah Kahn, Head of the OIE International Trade Department, welcomed all members and thanked them for their participation. The ad hoc group discussed the draft agenda and made some minor changes.

Dr Vallat joined the ad hoc group in the afternoon of the first day of the meeting. He underlined the importance of the work of this group.

Agenda Item 2: Addressing OIE Members’ comments on the draft chapter ‘Responsible and prudent use of antimicrobials in aquatic animals

The ad hoc group addressed the comments of OIE Members on the draft chapter ‘Responsible and Prudent Use of Antimicrobials in Aquatic Animals’ (see Appendix III).
1. **General Comments**

Some Members asked for a more consistent use of the terms animal, terrestrial animal, *aquatic animal* and the different descriptions of authorities. The *ad hoc* group revised the document and made appropriate changes.

One Member considered that in this chapter in relation to ‘a treatment with an antimicrobial’ the verb ‘prescribe’ is preferable to ‘recommend’. The *ad hoc* group noted that in some jurisdictions some antimicrobial agents for use in aquaculture are available only by prescription of a licensed *veterinarian*, while others are available ‘over the counter’. Therefore the *ad hoc* group decided to use both ‘prescribe’ and ‘recommend’ as appropriate.

2. **Title**

The *ad hoc* group agreed with a Member’s recommendation to change the title of the chapter.

3. **Article 6.2.1**

In Article 6.2.1., a Member proposed to replace ‘registration’ with ‘marketing authorization’. The *ad hoc* group considered that the addition of ‘market authorization’ to the existing text was preferable to replacing the term ‘registration’.

4. **Article 6.2.2**

Some Members commented on Article 6.2.2. and changes were made to improve the wording of this article. One Member proposed to add the words ‘as far as possible’ to objective number 3. The *ad hoc* group concluded that it would not be advisable to add the terms ‘as far as possible’ as this chapter covers objectives of prudent use. In the introductory chapter of this paragraph, it is already reminded that the recommendations are ‘intended to reduce the risk’.

The *ad hoc* group discussed the proposal to separate ‘inter animal transfer’ and ‘animal to human transfer’ in objective number 3 of Article 6.2.2. The transfer of antimicrobial resistant micro-organisms and resistance determinant was recognized as a global issue. Reducing inter animal transmission may also help to reduce animal to human transmission. To split the sentence to address the different pathways of transfer would certainly require adding more bullets. This would be too detailed for general objectives. The group therefore decided to maintain the current sentence.

The *ad hoc* *ad hoc* group agreed with a Member’s comment on objective number 5 and modified the wording accordingly.

A Member proposed to delete objectives number 4 and 6 of Article 6.2.2. Objective number 4 was deleted because objective the objective is already covered by other objectives. Objective number 6 was deleted because the *ad hoc* group agreed that the scope of this objective was broad and already covered by other objectives.

Two Members requested to include anthelmintics, disinfectants and antiseptics in the definition of ‘antimicrobial agent’. However, the members of the *ad hoc* group decided to maintain the current definition to be consistent with the definition in the *Terrestrial Animal Health Code* and other relevant publications.

One Member asked for a definition of ‘aquatic animal health professional’. The *ad hoc* group noted that the term is used in the Aquatic Code and that if a definition is needed, it should be addressed by the Aquatic Animal Health Standards Commission rather than the *ad hoc* group.

5. **Article 6.2.4**

A Member proposed alternate wording for Article 6.2.4. and to add a paragraph to article to highlight the importance of ensuring that the legislation is complied with. The *ad hoc* group agreed with the proposed changes in the wording. However the *ad hoc group* did not include the additional paragraph because it considered that the importance of complying with legislation is already covered in the *Aquatic Animal Health Code*. 
6. Article 6.2.6

A Member considered that the text in Article 6.2.6 places too much responsibility on distributors for the destruction of expired antimicrobials. The *ad hoc* group agreed and changed the wording of the article accordingly.

7. Article 6.2.7

A Member proposed to add an additional paragraph to Article 6.2.7, highlighting the importance of reporting adverse reactions. The *ad hoc* group generally agreed with the comment and slightly amended the wording of the proposed paragraph in accordance with paragraph 4 of Article 6.9.6 of the *Terrestrial Animal Health Code*.

Agenda Item 3: Harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals

The *ad hoc* Group considered the inclusion in the *Aquatic Code* of a new chapter covering the issues addressed in Chapter 6.7 of the *Terrestrial Animal Health Code* ‘Harmonisation of national antimicrobial resistance surveillance and monitoring programmes’. The *ad hoc* group identified major differences between the situation in terrestrial animals and that in aquatic animals. The *ad hoc* group noted that zoonotic bacteria are of major concern with respect to terrestrial animals but that bacteria of this type are of only minor significance with respect to aquatic animals. They also noted the transient nature of the intestinal microflora of aquatic animals and that the term ‘commensal’ is should be regarded differently with respect to aquatic animals. Accordingly, the recommendations in the *Terrestrial Animal Health Code* concerning the examination of commensal bacteria should be modified to address the situation in aquatic animals.

The *ad hoc* group identified 3 areas that could be covered in a chapter in the *Aquatic Code* addressing surveillance and monitoring of antimicrobial resistance:

1. **Aquatic animal safety**

   This concerns the development of resistance pathogens in aquatic animals. There is clear evidence that this can be a major problem. The *ad hoc* group considered that the lack of standardized methods is a major problem in evaluating and making recommendations to address the problem of resistance in these bacteria. The *ad hoc* group did not consider that surveillance and monitoring programmes even if based on correct statistical design would be an efficient way of collecting these data.

2. **Food safety**

   This concerns resistance in human pathogens that are present in aquatic animals and their products. There is little evidence that this is a major problem. With respect to resistance in these human pathogens, standardized methods exist. Appropriate surveillance and monitoring programmes are in the *Terrestrial Animal Health Code* and the recommendations of other agencies responsible for food safety.

3. **Transferable resistant determinants in non-pathogenic bacteria.**

   The extent of risk is uncertain and there are gaps in knowledge of indicators. This issue could be the subject of a formal risk analysis, to be addressed at a future meeting. This risk analysis could suggest suitable monitoring and surveillance protocols.

Aquatic animal safety: There was considerable discussion regarding the main aspects of surveillance and monitoring programmes for aquatic animals. It was agreed that surveillance for resistance in pathogens of aquatic animals should be the first priority and, in the short term, the focus of the new chapter.
Food safety: The importance of surveillance for resistant human pathogens in aquatic animal products was discussed, particularly in light of the relatively small number of human pathogens found in aquatic animal products compared with that found in products of terrestrial species. The ad hoc group believed that the main elements for a programme of surveillance of aquatic animal products would be similar to those described in Chapter 6.7 of the Terrestrial Animal Health Code. The ad hoc group also noted that ‘fish’ appeared to be covered in the text on antimicrobial resistance the Terrestrial Animal Health Code. The ad hoc group considered that a section of the new chapter could address food safety by making reference to the relevant section of the Terrestrial Code, with specific guidance where the situation differs for aquatic animals, such as with respect to commensal organisms. The ad hoc group developed guiding principles for harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals regarding aquatic animal safety as well as to food safety (Appendix IV).

With respect to public health issues beyond food safety, the ad hoc group proposed to develop a section in this chapter to discuss surveillance and monitoring of resistant microorganisms in the environment, i.e. arising from the horizontal transmission of resistance determinants from pathogens of aquatic animals to those of humans.

**Agenda Item 4: Monitoring of the Quantities of Antimicrobials Used in Aquatic Animals**

The ad hoc group was conscious that, for a variety of reasons, many OIE Members would not be in a position to initiate a programme aimed at collecting data on the amounts of antimicrobials being used in aquaculture. The group, however, felt it would be helpful to produce a draft chapter outlining general considerations when designing such programmes. The ad hoc group developed a draft chapter that was based on the current Chapter 6.8 of the Terrestrial Animal Health Code ‘Monitoring of the quantities of antimicrobials used in animal husbandry’ (Appendix V). Noting that an ad hoc Group would be convened to update this chapter of the Terrestrial Code in the next year, the ad hoc Group considered that it might be premature to circulate the draft chapter to OIE Members.

**Agenda item 5: Lack of approved drugs in aquaculture**

The ad hoc group noted with concern that there is a serious shortage of authorized drugs for use in aquaculture. In some major branches of the industry, no authorized antimicrobial agents are available. The ad hoc group urged the OIE to take this into account. This crisis should provide the context for all discussion of antimicrobial agents in aquaculture.

**Agenda item 6: Proposal for new work**

**6.1 Methods of antimicrobial susceptibility testing**

There is a lack, relative to terrestrial animals, of specific methods both for culture and interpretive criteria for susceptibility testing for pathogens in aquatic animals. As a result we are hindered in our ability to address antimicrobial resistance. Three major areas in this work include the development of internationally recognized standards for generating data on antimicrobial susceptibility and the establishment of criteria for interpretation of these data, such as clinical breakpoints and epidemiologic cut-off values.

To address this issue the ad hoc group proposed the development of a discussion paper to describe the current situation and outline possible solutions to the problem. This paper could be delivered at the OIE Global Conference on "Aquatic Animal Health Programmes: their benefits" in Panama on 28-30 June 2011.

In addition, the ad hoc group proposed that OIE establish an ad hoc group on the development of methods for antimicrobial susceptibility testing for aquatic pathogens, and their interpretation. This group should address:

a) guidelines for developing international standards;
b) identification of relevant pathogens;
c) criteria for priority setting for methods development.

OIE ad hoc Group on the Responsible Use of Antimicrobials in Aquatic Animals / October 2010
6.2 Risk assessment for antimicrobial resistance arising from the use of antimicrobials in aquatic animals

This issue was not discussed in detail at the October meeting of the ad hoc group. Members noted that two of its members (Dr Prater and Dr Moulin) were on other working groups (e.g. of the Codex Alimentarius Commission, Task Force on Antimicrobial Resistance) that were addressing this issue. The group, therefore, considered that the most appropriate action, at this time, was to ask these members to produce a discussion document at the earliest appropriate time. This discussion document also could be presented at the OIE Conference on Aquatic Animal Health Programmes in Panama.

6.3. Action item

Teleconference on Friday 19 November 2.00 pm Paris time to discuss feedback from the Aquatic Animals Commission; to review output of the ad hoc group on antimicrobial resistance in terrestrial animals; and to plan future work and a date for the next meeting.
MEETING OF THE OIE AD HOC GROUP ON THE RESPONSIBLE USE OF ANTIMICROBIALS IN AQUATIC ANIMALS

Paris, 4–6 October 2010

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Adopted agenda

1. Agenda Item 1: Welcome and introduction by Dr Sarah Kahn

2. Agenda Item 2: Addressing the members’ comments on the draft chapter ‘Responsible and prudent use of antimicrobials in aquatic animals

3. Agenda Item 3: Harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals

4. Agenda Item 4: Monitoring of the quantities of antimicrobials used in aquatic animals

5. Agenda item 5: Lack of approved drugs in aquaculture

6. Agenda item 6: Proposal for new work.
# List of participants

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Appendix III

CHAPTER 6.2.

PRINCIPLES FOR RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE AQUATIC ANIMALS

Article 6.2.1.

Purpose

These principles provide guidance for the responsible and prudent use of antimicrobial agents in aquatic animals, with the aim of protecting both animal and human health. The Competent Authorities responsible for the marketing authorization, registration and control of all groups involved in the production, distribution and use of veterinary antimicrobials have specific obligations.

Article 6.2.2.

Objectives of prudent use

Prudent use includes a set of practical measures and recommendations intended to reduce the risk associated with the selection and dissemination of antimicrobial resistant micro-organisms and antimicrobial resistance determinants in aquatic animal production to:

1. maintain the efficacy of antimicrobial agents both for veterinary and human medicine and to ensure the rational use of antimicrobials in aquatic animals with the purpose of optimising both their efficacy and safety;
2. comply with the ethical obligation and economic need to keep aquatic animals in good health;
3. prevent or reduce the transfer of both resistant micro-organisms and resistance determinants from aquatic animals to humans and terrestrial animals;
4. maintain the efficacy of antimicrobial agents used in human medicine and prolong the usefulness of the antimicrobials;
5. prevent the contamination of animal derived food with antimicrobial residues that exceed the established maximum residue limit (MRL) occurring in the food;
6. protect consumer health by ensuring the safety of food of aquatic animal origin.

Article 6.2.3.

Definitions

Antimicrobial agent: means a naturally occurring, semi-synthetic or synthetic substance that at in vivo concentrations exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms). Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition.

Article 6.2.4.

Responsibilities of the regulatory authorities

The national Regulatory Authorities, which are responsible for granting marketing authorization for antimicrobials, have a significant role in specifying the terms of the authorization and in providing the appropriate information to the veterinarian or other aquatic animal health professional through product labeling and/or by other means, in support of prudent use of veterinary antimicrobial drugs in aquatic animals.
Appendix III (contd)

It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of veterinary antimicrobial drug applications.

**National governments Competent Authorities** in cooperation with animal and public health professionals should adopt a proactive approach to promote prudent use of antimicrobial agents in aquatic animals as an element of a national strategy for the containment of antimicrobial resistance.

Other elements of the national strategy should include good animal husbandry practices, vaccination policies and development of animal health care at the farm level, and consultation with a veterinarian or other aquatic animal health professional, all of which should contribute to reduction of the prevalence of animal disease requiring antimicrobial treatment.

Regulatory Authorities should expeditiously grant marketing authorizations when criteria of quality, efficacy, and safety are met.

The examination of dossier/Drug marketing authorization applications should include an assessment of the risks to both animals and humans and the environment resulting from the use of antimicrobial agents in aquatic animals. The evaluation should focus on each individual veterinary antimicrobial drug veterinary medicinal product but and take into consideration the class of antimicrobials to which the particular active principle belongs. The safety evaluation should include consideration of the potential impact of the proposed use in aquatic animals on human health, including the human health impact of antimicrobial resistance developing in food-borne micro-organisms found in aquatic animals. An assessment of the impact of the proposed use on the environment should be conducted.

The regulatory authority Competent Authorities should aim to ensure that advertising of antimicrobials complies with national legislation and marketing authorizations granted and discourage direct advertising to aquatic animal producers.

Information collected through pharmacovigilance programmes, including on lack of efficacy, should form part of the Competent Authority's comprehensive strategy to minimize antimicrobial resistance.

Regulatory Competent authorities should disseminate, to veterinarians or other aquatic animal health professionals, information on trends in antimicrobial resistance collected during surveillance programmes and should monitor the performance of susceptibility testing laboratories.

**Competent Authorities** should develop effective procedures for the safe collection and destruction of unused or out-of-date antimicrobials.

**Article 6.2.5.**

**Responsibilities of the veterinary pharmaceutical industry**

The veterinary pharmaceutical industry has responsibilities for providing information requested by the Regulatory Authorities on the quality of antimicrobials. The responsibilities of the veterinary pharmaceutical industry cover pre- and post-marketing phases, manufacturing, sale, importation, labeling and advertising issues.

The veterinary pharmaceutical industry has the responsibility to provide the regulatory Competent Authorities with the information necessary to evaluate the amount of antimicrobial agents marketed. The veterinary pharmaceutical industry should ensure that the advertising of antimicrobials directly to the aquatic animal producer is discouraged.

**Article 6.2.6.**

**Responsibilities of wholesale and retail distributors.**

Distributors should ensure that their activities are in compliance with the national or regional legislation.
Distributors should ensure that information for the appropriate use and disposal of the antimicrobial agent preparation should accompany all distributed products and should also be responsible for maintaining and disposing of the product according to the manufacturer recommendations.

Distributors should have responsibilities in collection and destruction of antimicrobial agents that have passed their expiry date.

Article 6.2.7.

Responsibilities of veterinarians and other aquatic animal health professionals

Responsibilities of veterinarians or other aquatic animal health professionals include identifying, preventing and treating aquatic animal diseases as well as the promotion of sound animal husbandry methods, hygiene procedures, vaccination and other alternative strategies to minimise the need for antimicrobial use in aquatic animals.

Veterinarians or other aquatic animal health professionals should only prescribe or recommend antimicrobial a specific course of antimicrobial treatment for aquatic animals under their care.

The responsibilities of veterinarians or other aquatic animal health professionals are to carry out a proper clinical examination of the aquatic animal(s) and make a diagnosis, based on the clinical examination, the results of laboratory tests and evaluation of environmental factors at the production site (e.g. water quality).

If therapy with an antimicrobial agent is deemed appropriate necessary it should be initiated as soon as possible. The selection of the agent should be based on the knowledge and experience of the veterinarian or other aquatic animal health professional.

As soon as possible, susceptibility testing of the target micro-organism should be used to confirm the choice of treatment. Results of all susceptibility tests should be communicated retained and should be available to the relevant national Competent Authority.

The veterinarian or other aquatic animal health professional should indicate precisely to the aquatic animal producer the treatment regime, including the dose, the treatment intervals, the duration of the treatment, the withdrawal period and the amount of drug to be delivered, depending on the dosage and the number of aquatic animals to be treated.

The veterinarian or other aquatic animal health professional may prescribe or recommend in appropriate circumstances the use of antimicrobial agents extra-/off-label, in conformity with the relevant national legislation and any requirements of importing countries.

Records on the use of antimicrobial agents should be kept in conformity with the national legislation. Veterinarians or aquatic animal health professionals should also periodically review farm records on the use of the antimicrobial agents to ensure compliance with their directions and use these records to evaluate the effectiveness of treatment regimens. Suspected adverse reactions, as well as a lack of effectiveness, should be reported to the Competent Authorities. The associated susceptibility data should accompany the report of lack of effectiveness.

Veterinarians or other aquatic animal health professionals should periodically review farm records on the use of antimicrobial agents to ensure compliance with their directions and use these records to evaluate the efficacy of treatment regimens.
Appendix III (contd)

Article 6.2.8.

Responsibilities of aquatic animal producers

Aquatic animal producers should implement health programmes on their farms in order to promote aquatic animal health and food safety. This can be done through adequate planning of culture strategies to maintain aquatic animal health through biosecurity programmes, vaccination strategies, maintenance of good water quality, etc.

Aquatic animal producers should use antimicrobial agents only on the prescription or recommendation of a veterinarian or other aquatic animal health professional, and follow directions on the dosage, method of application, and withdrawal period.

Aquatic animal producers should ensure that antimicrobial agents are properly stored, handled, and disposed.

Aquatic animal producers should keep adequate records of antimicrobial agents used, bacteriological and susceptibility tests, and to make such records available to the veterinarian or other aquatic animal health professional.

Aquatic animal producers should inform the veterinarian or other aquatic animal health professional of recurrent disease problems and lack of efficacy of antimicrobial treatment regimes.

Article 6.2.9.

Training of antimicrobial users

The training of users of antimicrobials should involve all the relevant organisations, such as Competent regulatory Authorities, pharmaceutical industry, veterinary schools, research institutes, and veterinary professional organisations and other approved users such as aquatic animal owners.

Article 6.2.10.

Research

To address the significant lack of information for numerous species of aquatic animals, relevant Competent Authorities and other stakeholders should encourage public- and industry-funded research.
Appendix IV

CHAPTER 6.X.

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

Article 6.x.1.

Surveillance and monitoring of antimicrobial resistance in target aquatic animal pathogens

1. Source of target aquatic animal pathogens

Bacteria should be obtained from diagnostic laboratories. The strain collections should be comprised in the main of bacteria that have been identified as primary pathogens in epizootics of diseases in populations of aquatic animals. In some cases bacteria belonging to a particular group may be selected for particular study.

2. Laboratories involved in monitoring

Laboratories should be of sufficient size and expertise that are able to fully participate in all necessary intercalibration and validation studies.

3. Methods used to analyse bacterial susceptibility

Participating laboratories should employ standardised, validated international methods for the susceptibility tests.

4. Choice of antimicrobial agents

Drugs. Antimicrobial agents utilized in susceptibility testing should include as a minimum representatives of all major classes to treat the disease in the target species.

5. Reporting of results

All susceptibility data should be reported quantitatively to the relevant national Competent Authority.

Article 6.x.2.

Surveillance and monitoring of antimicrobial resistance in food derived from aquatic animals

1. Surveillance and monitoring programs for products of aquatic animal

For the development of surveillance and monitoring programs for products of aquatic animal origin intended for human consumption the relevant section of the Terrestrial Animal Health Code should be referenced.

2. Potential sources of contamination

Contamination of product with human pathogens from non-aquatic sources should be considered. The source of contamination of aquatic products could come from discharge from human waste, by contamination during processing and agricultural run-off. From a risk analysis perspective it is important to remember that antimicrobial resistance in these human pathogens may be unrelated to antimicrobial agents used in aquaculture.
Appendix IV (contd)

3. **Commensals**

The transient nature of the intestinal micro flora of aquatic animals has a consequence that the term commensal has little application in these animals. Therefore the recommendations in the *Terrestrial Animal Health Code* concerning the examination of commensal bacteria are not considered relevant.

4. **Bacteria suggested for inclusion in a monitoring programme**

   a) *Salmonella* spp;

   b) *Vibrio parahaemolyticus*

   c) *Listeria monocytogenes*;
CHAPTER 6.X.

MONITORING OF THE QUANTITIES OF ANTIMICROBIALS USED IN AQUATIC ANIMALS

Article 6.x.1.

Purpose

The purpose of these recommendations is to describe approaches to the monitoring of quantities of antimicrobials used in aquatic animals.

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 antimicrobial exposure.

The collection of data on antimicrobial use in aquaculture may be constrained in some countries by the lack of available resources, accurately labeled products and poorly understood distribution channels. This chapter may therefore be seen as indicating the direction in which countries should develop with regard to antimicrobial use data.

Article 6.x.2.

Objectives

The information provided in these recommendations is essential for risk analyses and planning, can be helpful in interpreting resistance surveillance data and can assist in the ability to respond to problems of antimicrobial resistance in a precise and targeted way. This information may also assist in evaluating the effectiveness of efforts to ensure prudent use and mitigation strategies and to indicate where alteration of antimicrobial prescribing practices might be appropriate.

The continued collection of this basic information would also help give an indication of trends in the use of animal antimicrobials over time and the role of these trends in the development of antimicrobial resistance in aquatic animal bacteria.

OIE Members may 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 antimicrobials.

Article 6.x.3.

Development and standardisation of monitoring systems

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

1. Sources of antimicrobial data
   a) Basic sources

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

b) Direct sources

Data from animal drug registration, wholesalers, retailers, veterinarians, aquatic animal health professionals, feedstores, feed mills and organised industry associations in these countries might be useful sources. A possible mechanism for the collection of this information is to make the provision of appropriate information by manufacturers to the Competent Authority one of the requirements of antimicrobial registration.

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. In some countries this may be the only practical source of information at the moment.

2. Categories of data

If a Member has the infrastructure for capturing basic animal antimicrobial use data for a specific antimicrobial, 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 active antimicrobial used per antimicrobial class/subclass per year. For active ingredients present in the form of compounds or derivatives, the mass of active entity of the molecule should be recorded. For antibiotics expressed in International Units, the calculation required to convert these units to mass of active entity should be stated.

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 (mediated feed, bath treatment, parenteral delivery) and the method used to calculate the dose (biomass of fish, volume of water treated).

Nomenclature of antimicrobials should comply with international standards where available. Decisions need to be made on what classes of antimicrobials should be considered and what members of various antimicrobial classes should be included in the data collection programme. These decisions should be based on currently known mechanisms of antimicrobial activity and resistance of the particular antimicrobial, pharmacokinetics and its relative potency.

3. Elements for interpretation of antimicrobial usage data

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) lifestage;

c) environmental and culture parameters (seasonality, temperature, salinity, pH);

d) geographical location, specific rearing units.
4. 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 antimicrobial usage or address a specific antimicrobial resistance problem.

When collecting and interpreting antimicrobial usage data it may be important to take into account factors such as temperature, disease conditions, species affected, aquacultural systems (e.g. intensive/extensive), dose rate and duration and length of treatment with antimicrobials.

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