CHAPTER 6.8.

MONITORING OF THE QUANTITIES AND USAGE PATTERNS OF ANTIMICROBIALS AGENTS USED IN FOOD PRODUCING ANIMALS ANIMAL HUSBANDRY

EU comments

The EU welcomes the update of this important chapter, the clarity of which has been improved.

However, this chapter would gain in utility if it contained more precise guidance as in chapter 6.7., i.e. with more specifications and protocols. The EU wishes to inform the OIE that detailed guidance is being developed in the EU.

Moreover, it would be valuable if OIE could follow up with practical training courses for countries planning to start monitoring.

Comments are inserted in the text below to be taken into consideration by the TAHSC in its next meeting.

Article 6.8.1.

Purpose

The purpose of these recommendations is to describe an approach to the monitoring of the quantities of antimicrobials agents used in food producing animals animal husbandry.

These recommendations are intended for use by OIE Members to collect objective and quantitative information to evaluate usage patterns by animal species, antimicrobial class, potency and type of use

In order to evaluate antimicrobial exposure in food producing animals, quantitative information should be collected to monitor usage patterns by animal species, antimicrobial agents/class, type of use and route of administration.

Article 6.8.2.

Objectives

The information provided in these recommendations is essential for antimicrobial resistance *risk analyses* and planning purposes and should be read in conjunction with *Terrestrial Code* Chapters 6.7. and 6.10.. This information, is necessary can be helpful in for interpreting antimicrobial resistance surveillance data and can assist in the ability to responding to problems of antimicrobial resistance in a precise and targeted way. The continued collection of this basic information will also help to give an indication of trends in the use of antimicrobial agents in animals over time and potential associations with antimicrobial resistance in animals. This information may also assist in risk management to in evaluateing the effectiveness of efforts to ensure prudent use and mitigation strategies (for example, by identifying changes in veterinary prescribing practices for *veterinarians*) and to indicate where change alteration of antimicrobial usage prescribing practices might be appropriate. The publication of some or all of these data may be helpful for risk communication purposes. , or if changes in prescription practice have altered the pattern of antimicrobial use.

EU comment

> **In the fourth sentence of the paragraph above, the words "<u>responsible and</u>" should be added between the words "to ensure" and "prudent use".**
>
> **In the aquatic animal health code, both responsible and prudent uses are used. The same should go throughout this chapter.**
>
> **Furthermore, the EU is of the opinion that it is important to publish the data, while maintaining the necessary respect for confidentiality. Among motives for publishing data is not only risk communication, it is also e.g. transparency and to allow for risk assessments by all stakeholders. Therefore, the EU suggests the following wording for the last sentence:**
>
> **"The publication of ~~some or all of~~ these data ~~may be helpful~~ <u>is important to ensure transparency and to allow all interested parties to assess trends, to perform risk assessments and</u> for risk communication purposes."**

~~The continued collection of this basic information will 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 *animals*.~~

~~For all OIE Members, the minimum basic information collected should be the annual weight in kilograms of the active ingredient of the antimicrobial(s) used in food animal production. In addition, the type of use (therapeutic or growth promotion) and route of administration (parenteral or oral administration) should be recorded.~~

~~Members may wish to consider, for reasons of cost and administrative efficiency, collecting medical, food *animal*, agricultural 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 6.8.3.

Development and standardisation of <u>antimicrobial</u> monitoring systems

Systems to monitor antimicrobial usage 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.

    b) Direct sources

        Data from ~~animal~~ <u>veterinary medicinal product</u> ~~drug~~ registration <u>authorities</u>, wholesalers, retailers, pharmacists, veterinarians, feed stores, feed mills and ~~organised~~ <u>pharmaceutical</u> industry associations ~~in these countries~~ <u>can</u> ~~might~~ be efficient and practical sources. A possible mechanism for the collection of this information is to make the provision of appropriate information by <u>pharmaceutical</u> manufacturers to the regulatory authority one of the requirements of antimicrobial registration.

    c) End-use sources (veterinarians and food animal producers)

        This may be appropriate when basic or direct sources cannot be used for the routine collection of ~~this~~ <u>the</u> information ~~and~~ <u>or</u> when more accurate and locally specific information is required <u>(such as off label use)</u>.

        Periodic collection of this type of information may be sufficient.

It may be important when developing writing recommendations on antimicrobial resistance usage to take into account factors such as seasonality and disease conditions, species and age affected, agricultural systems and animal movements (e.g. extensive range conditions and feedlots), dose rate, duration and length of treatment with antimicrobials.

Collection, storage and processing of data from end-use sources should be carefully designed, well managed and are likely to be inefficient and expensive processes unless carefully designed and well managed, but should have the capability to produce advantage of producing accurate and targeted information.

d)   Other sources

Non-conventional sources including internet sales data related to antimicrobial agents could be collected where available.

Members may wish to consider, for reasons of cost and administrative efficiency, collecting medical, food producing animal, agricultural and other antimicrobial use data in a single programme. A consolidated programme would also facilitate comparisons of animal use with human use data for *risk analysis* purposes and help to promote optimal usage of antimicrobials.

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

a)   Type of Requirements for antimicrobial use data on antimicrobial use

The minimal data collected at minimum should be the annual weight in kilograms of the active ingredient of the antimicrobial(s) used in food animal production per year. This should be related to the scale of production (see point 3 below). It is 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 food producing animals by species, type of production and their weight in kilograms for food production per year (as relevant to the country of production) is essential basic information.

Information on dose regimes and duration of administration are elements to include when estimating antimicrobial usage in food producing animals.

b)   Reporting formats of antimicrobial use data

EU comment

The report should include a clear description of the method of collection, inclusion criteria and an assessment of the completeness of data.

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

Nomenclature of antimicrobials should comply with international standards where available.

For active ingredients present in the form of compounds or derivatives, the mass of active entity of the molecule should be recorded. For antibiotics antimicrobial agents expressed in International Units, the calculation required to convert these units to mass of active entity should be stated.

EU comment

The EU suggests the following modification of the last sentence of the paragraph above, for consistency with the current terminology:

> **For ~~antibiotics~~ antimicrobial agents expressed in International Units, the ~~calculation required~~ factor used to convert these units to mass of active entity should be stated.**

The reporting of antimicrobial use data may be further organised by species, by route of administration (specifically in-feed, in-water, injectable, oral, intramammary, intra-uterine and topical) and by type of use (therapeutic/non-therapeutic).

Regarding data coming from end-use sources, further breakdown of data for analysis of antimicrobial use at the regional, local, *herd* and individual veterinarian/veterinary practice levels may be possible.

~~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:~~

~~i)~~ ~~The absolute amount in kilograms of active antimicrobial used per antimicrobial family per year, or for a specific antimicrobial chemical entity when this information is required.~~

~~ii)~~ ~~Therapeutic and growth promotion use in kilograms of the specific active antimicrobial.~~

~~iii)~~ ~~Subdivision of antimicrobial use into therapeutic and growth promotion use by animal species.~~

~~iv)~~ ~~Subdivision of the data into the route of administration, specifically in-feed, in-water, injectable, oral, intramammary, intra-uterine and topical.~~

~~v)~~ ~~Further subdivision of these figures by season and region by a Member may be useful. (Note: This may be especially management conditions, or where animals are moved from one locality to another during production.)~~

~~vi)~~ ~~Further breakdown of data for analysis of antimicrobial use at the regional, local, *herd* and individual veterinarian levels may be possible. using veterinary practice computer management software as part of specific targeted surveys or audits. Analysis of this information with the local or regional context could be useful for individual practitioners and practices where specific antimicrobial resistance has been identified and feedback is required.~~

~~b)~~ ~~Classes of antimicrobials~~

~~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 and its relative potency.~~

~~c)~~ ~~Species and production systems~~

~~Countries should keep a register of all animal use of antimicrobials for individual food animal species (cattle, sheep, goats, pigs, poultry, horses and fish) and for specific diseases. This will help to identify possible nonauthorised usage.~~

~~3.~~ ~~Other important information~~

~~Breakdown of farm livestock into species and production categories, including total live weights, would be most useful in any *risk analysis* or for comparison of animal antimicrobial use with human medical use within and between countries. For example, the total number of food *animals* by category~~

~~and their weight in kilograms for food production per year (meat, dairy and draught cattle, and meat, fibre, poultry and dairy sheep) in the country would be essential basic information.~~

<u>Article 6.8.4.</u>

<u>Interpretation</u>

<u>According to the OIE risk assessment guideline (refer to Chapter 6.10.), factors such as the number/percentage of animals treated, treatment regimes, type of use and route of administration are key elements to consider.</u>

<u>When comparing antimicrobial use data over time, changes in the size and composition of animal populations should also be taken into account.</u>

<u>The interpretation and communication of results should take into account factors such as seasonality and disease conditions, animal species and age affected, agricultural systems (e.g. extensive range conditions and feedlots), animal movements, dose regimes and duration of treatment with antimicrobial agents.</u>

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—   text deleted

C H A P T E R   6 . 7 .

HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES

EU comments

The EU welcomes the update of this important chapter, which would need a renumbering with more articles, for better understanding and reference.

Furthermore, there is not enough emphasis on animal pathogens in some of the sections. The guidance seems to be focussed entirely on monitoring of potential food borne resistance. No guidance with relevance for animal pathogens is given on sample sources, and in particular not for type of samples. It is important that the animal health aspect (and thus animal pathogens, including not enteric ones) is also included in this OIE guidance.

The comments inserted in the text below should be taken into consideration by the TAHSC in its next meeting.

Article 6.7.1.

Objective

This chapter provides criteria for the:

1. development of national antimicrobial resistance surveillance and monitoring programmes,

2. harmonisation of existing national antimicrobial resistance surveillance and monitoring programmes,

in food producing animals (e.g. avian, bovine, caprine, equine, ovine, porcine) 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 as core parts of national antimicrobial resistance surveillance programmes. Passive surveillance and monitoring may offer additional information (refer to Chapter 1.4.). Regional cooperation between Members conducting antimicrobial resistance surveillance should be encouraged.

1. Surveillance and monitoring of antimicrobial resistance is necessary to:

1.a) follow ~~trends in~~ antimicrobial resistance trends in bacteria;

2.b) detect the emergence of new antimicrobial resistance mechanisms;

3.c) provide the data necessary for conducting risk analyses ~~with~~ as relevan~~ce~~ to ~~for~~ animal ~~human~~ and human ~~animal~~ health;

4.d) provide a basis for policy recommendations for animal and human public health;

5.e) provide information on for antimicrobial prescribing practices and useful for development of prudent use recommendations.

EU comment

Monitoring of resistance cannot provide information on prescribing practices – that is the topic of monitoring of usage; it can provide information useful for the practices.

Thus, the sentence (5) above should read: "provide information useful for development of antimicrobial prescribing practices and of prudent use recommendation.

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2. National antimicrobial resistance monitoring and surveillance programmes may include the following components:

   a) scientifically-based surveys (including statistically-based programmes);

   b) routine sampling and testing of animals on the farm, at market or at slaughter;

   c) an organised sentinel programme, sampling animals, herds, flocks, and vectors;

   d) analysis of veterinary practice and diagnostic laboratory records.

3. Countries should conduct active surveillance and monitoring. Passive surveillance and monitoring may offer additional information.

4. Targeted surveillance is conducted through an active sampling scheme designed to meet programme objectives. Passive surveillance is conducted when samples are submitted to a laboratory for testing from sources outside the programme.

Article 6.7.3.

The development of antimicrobial resistance surveillance and monitoring programmes

1. General aspects

   Surveillance of antimicrobial resistance at regular ortargeted intervals or ongoing monitoring of the prevalence of resistance in prevalence changes of resistant bacteria from of animals, food, environmental and humans origin, constitutes a critical part of a animal health and food safety strategyies aimed at limiting the spread of antimicrobial resistance and optimising the choice of antimicrobials used in therapy.

   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.

   National antimicrobial resistance monitoring and surveillance programmes may include the following components:

   a) scientifically-based surveys (including statistically-based programmes);

EU comment

All surveys should be scientifically based. Thus, the paragraph above should read:

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

a)   statistically-based surveys;

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b)   routine sampling and testing of food producing animals on the farm, at live animal market or at slaughter;

c)   an organised sentinel programme, for example targeted sampling of food producing animals, herds, flocks, and vectors (e.g. birds, rodents);

d)   analysis of veterinary practice and diagnostic laboratory records.

2.   Sampling strategies

a)   ~~General~~

~~i~~a)   Sampling should be conducted on a statistical basis. The sampling strategy should ensure ~~assure~~:

−   the sample is representative~~ness~~ of the population of interest;

−   the robustness of the sampling method.

~~ii~~b)   The following criteria are to be considered:

−   sample size;

−   sample source (e.g. food producing animal, food, animal feed);

−   animal species;

−   category of *animal* within species (e.g. age group, production type);

−   ~~stratification within category;~~

−   health status of the *animals* (e.g. healthy, diseased);

−   random sample (e.g. targeted, systematic);

−   type of sample ~~specimens~~ (e.g. faecal, carcass, ~~processed~~ food product).

~~b)~~3)   Sample size

The sample size should be: ~~i)~~ large enough to allow detection of existing and emerging antimicrobial resistan~~ce~~t~~e~~ phenotypes~~.~~;

> **EU comment**
>
> **The word "resistant phenotypes" should not be added and the former word "resistance" should be kept.**
>
> **The phenotype is too restrictive at this place, while in any case in point 10.e) there is a reference to genotypes, which definitely should be included.**

~~ii)   not excessively large to avoid waste of resources.~~

Samples size estimates for prevalence of antimicrobial resistance in a large population is provided ~~Details are provided~~ in Table 1 below. ~~Sampling fall follow standard operating procedures.~~

Table 1. Sample size estimates for prevalence of antimicrobial resistance in a large population

	90% Level of confidence	**95% Level of confidence**
Expected prevalence	~~90%~~ Desired precision	~~95%~~ Desired precision

	10%	5%	1%	10%	5%	1%
10%	24	97	2,429	35	138	3,445
20%	43	173	4,310	61	246	6,109
30%	57	227	5,650	81	323	8,003
40%	65	260	6,451	92	369	9,135
50%	68	270	6,718	96	384	9,512
60%	65	260	6,451	92	369	9,135
70%	57	227	5,650	81	323	8,003
80%	43	173	4,310	61	246	6,109
90%	24	97	2,429	35	138	3,445

Calculations based on v6.04b to c Upgrade, October 1997, Centers for Disease Control (public domain software available at hpp://www.cdc.gov/epo/epi/epiinfo.htm)Epi Info version 3.5.1., November 2010, Centers for Disease Control and Prevention (public domain software available at http://www.cdc.gov/). Further information on sample size calculation can be found in Annex 1 of the EFSA Journal (2007), 96, 1-46, "Report including a proposal for a harmonized monitoring scheme of antimicrobial resistance in *Salmonella* in fowl (*Gallus gallus*), turkeys, and pigs and *Campylobacter jejuni* and *C. coli* in broilers.

3̶4. Sample sources

Members should examine their livestock production systems and decide, after *risk analysis*, the relative importance of antimicrobial resistance and its impact on animal and human health.

EU comments

The intention of the above sentence is difficult to understand. Should a total risk analysis on impact regarding animal and public health be performed in order to decide on sample sources? On basis of what information should such an analysis be made, if there is yet no monitoring and thus no data? Is the intention to say: "Members should examine their livestock production systems on basis of available information and assess what sources are likely to contribute most to a potential risk (i.e. a risk based approach)"?

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a) Animal feed

Members should consider including animal feeds in surveillance and monitoring programmes as they may become contaminated with antimicrobial resistant bacteria, e.g. *Salmonella.*

b̶a) Food producing animals

Each OIE Member should examine its livestock production systems and decide, after *risk analysis*, the relative importance of antimicrobial resistance and its impact on animal and human health.

Categories of food producing animals livestock that should be considered for sampling include cattle and calves, slaughter pigs, broiler chickens, layer hens and/or other poultry and farmed fish considered for sampling should be relevant to the country's production systemlivestock and include.

b̶c) Food and animal feed

Members should consider including relevant food products originating from food producing animals in surveillance and monitoring programmes as foodborne transmission Contaminated food is commonly considered to be an important the principal route for the transfer of

antimicrobial resistance. ~~from animals to humans. Plants and vegetables of different types may be exposed to manure or sewage from livestock and may thereby become contaminated with resistant bacteria of animal origin. Animal feed, including imported feed, may also be considered in surveillance and monitoring programmes.~~

~~Table 1. Sample size estimates for prevalence of antimicrobial resistance in a large population~~

~~Expected prevalence~~	~~Level of confidence~~					
	~~90% Desired precision~~			~~95% Desired precision~~		
	~~10%~~	~~5%~~	~~1%~~	~~10%~~	~~5%~~	~~1%~~
~~10%~~	~~24~~	~~97~~	~~2.429~~	~~35~~	~~138~~	~~3.445~~
~~20%~~	~~43~~	~~173~~	~~4.310~~	~~61~~	~~246~~	~~6.109~~
~~30%~~	~~57~~	~~227~~	~~5.650~~	~~81~~	~~323~~	~~8.003~~
~~40%~~	~~65~~	~~260~~	~~6.451~~	~~92~~	~~369~~	~~9.135~~
~~50%~~	~~68~~	~~270~~	~~6.718~~	~~96~~	~~384~~	~~9.512~~
~~60%~~	~~65~~	~~260~~	~~6.451~~	~~92~~	~~369~~	~~9.135~~
~~70%~~	~~57~~	~~227~~	~~5.650~~	~~81~~	~~323~~	~~8.003~~
~~80%~~	~~43~~	~~173~~	~~4.310~~	~~61~~	~~246~~	~~6.109~~
~~90%~~	~~24~~	~~97~~	~~2.429~~	~~35~~	~~138~~	~~3.445~~

~~Calculations based on Epi Info v6.04b to c Upgrade, October 1997, Centers for Disease Control (public domain software available at hpp://www.cdc.gov/epo/epi/epiinfo.htm)~~

4<u>5</u>. Type of <u>S</u>sample ~~specimens~~ to be collected

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EU comment

The word "sample" should be plural, "sample<u>s</u>".

<u>Feed samples should be collected in amounts sufficient for isolation of resistant bacteria of concern (at least 25 g) and should be linked to pathogen surveillance programmes.</u>

Faecal samples should be collected <u>in amounts sufficient for isolation of the resistant bacteria of concern (at least 5 g from bovine and porcine and whole caeca from poultry)</u> ~~all s~~from livestock, ~~and whole caeca should be collected from poultry. In cattle and pigs, a faecal sample size at least of 5 g provides a sufficient sample for isolation of the bacteria of concern.~~

Sampling of ~~the~~ carcasses at the *abattoir* provides information on *slaughter* practices, *slaughter* hygiene and the level of <u>microbiological</u> ~~faecal~~ contamination <u>and cross-contamination</u> of *meat*<u>.</u> ~~during the *slaughter* process.~~ Further sampling <u>of the product at retail sales level</u> ~~from the retail chain~~ <u>may</u> provides <u>additional</u> information <u>on microbiological contamination.</u> ~~prevalence changes before the food reaches the consumer~~.

EU comment

The EU proposes to modify the last part of the sentence above as follows: "… may provide additional information on <u>the overall</u> microbiological contamination <u>from the slaughter to the consumer</u>."

Indeed, sampling at retail level would represent the sum of all contamination, it should be clear here that it's not additional information about initial contamination.

Existing food processing microbiological monitoring and 'hazard analysis and critical control points' (HACCP) programmes may provide useful samples for surveillance and monitoring of resistance in the food chain after *slaughter*.

EU comment

The EU proposes not only to include food processing microbiological monitoring and HACCP programmes in the sampling plans but also any kind of samples used for other food safety purposes.

Table 2 provides examples of sampling sources, sample types and monitoring outcomes.

Table 2. **Examples of sampling sources, sample types and monitoring outcomes ~~of monitoring~~**

Source	Sample type	Outcome	Additional information required/additional stratification
Herd/Flock of origin	Faecal	Prevalence of resistan~~ce in~~ce bacteria originating from animal populations (of different production types) Relationship resistance – antimicrobial~~biotic~~ use	~~Per a~~Age categories, production types, etc. Antimicrobial~~biotic~~ use over time
Abattoir	Faecal	Prevalence of resistan~~ce in~~ce ~~bacterial populations~~ originating from animals at slaughter ~~age~~	
	Caeca/Intestine	As above	
	Carcass	Hygiene, contamination during slaughter	
Processing, packing	~~Meat~~ Food products	Hygiene, contamination during processing and handling	
Point of sales (Retail)	~~Meat~~ Food products	Prevalence of resistan~~ce in~~ce bacteria originating from food, exposure data for consumers	
	Vegetables	~~Prevalence of resistance in bacteria originating from vegetables, exposure data for consumers~~	
Various origins	Animal feed	Prevalence of resistan~~ce in~~ce bacteria originating from animal feed, exposure data for animals	

~~5~~6. Bacterial isolates

The following categories of bacteria could be monitored:

a) Animal bacterial pathogens

Monitoring of antimicrobial resistance in animal pathogens is important, both to:

i) detect emerging resistance that may pose a concern for animal ~~human~~ and human ~~animal~~ health;

ii) guide *veterinarians* in their prescribing decisions.

Information on the occurrence of antimicrobial resistance in animal pathogens is in general derived from routine clinical material sent to veterinary diagnostic *laboratories*. These samples, often derived from severe or recurrent clinical cases including therapy failure, may provide biased information.

EU comment

The information in the paragraph above is relevant to the type of sample and not so much to the type of bacteria. The EU suggests to move and rephrase it.

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b) Zoonotic bacteria

i) *Salmonella*

Salmonella should be sampled from animal feed, food producing animals, cattle, pigs, broilers and other poultry, and animal derived food products. For the purpose of consistency and harmonisation, samples should be preferably taken at the *abattoir*. facilitating sampling and reducing the concurrent costs, samples should preferably be taken at the *abattoir*.

EU comment

The EU proposes a wording for the point on salmonella similar to the one under "Commensal bacteria", and to replace the words "samples should be preferably taken at the *abattoir*" by "bacteria from animals should be isolated from healthy animals preferably at the *abattoir*".

Surveillance and monitoring programmes may also use include bacterial isolates obtained from designated national *laboratories* originating from other sources.

Isolation and identification of bacteria and bacterial strains should follow nationally or internationally standardised accepted procedures.

Serovars of public health epidemiological importance such as *S.* Typhimurium and *S.* Enteritidis should be included. The inclusion selection of other relevant serovars will depend on the epidemiological situation in each country.

All *Salmonella* isolates should be 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 finger-printing methods.

Validated antimicrobial susceptibility testing methods should be used.

EU comment

The sentence above is important but not a component of the present heading. The EU suggests to insert it later on a heading on methods for susceptibility testing, merged with what is currently point 8 (antimicrobials to be used…).

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ii) *Campylobacter*

Campylobacter jejuni and *C. coli* should be isolated from food producing animals and associated food products (primarily from poultry). can be isolated from the same samples as commensal bacteria. Isolation and identification of these bacteria should follow nationally or internationally standardised accepted procedures. *Campylobacter* isolates should be identified to the species level.

Validated antimicrobial susceptibility testing methods should be used.

Agar or broth micro-dilution methods are recommended for *Campylobacter* susceptibility testing. Internal and external quality control programmes should be strictly adhered to.

~~Validated methods with appropriate reference strains are expected to become available in the near future.~~

<table>
<tr><td>

EU comment

The text as regards campylobacter above should be more descriptive and in line with the one on salmonella.

</td></tr>
</table>

    iii)   Enterohaemorrhagic *Escherichia coli*

Enterohaemorrhagic *Escherichia coli* (EHEC), such as the serotype O157, which is pathogenic to humans but not to *animals*, may be included in resistance surveillance and monitoring programmes.

<u>Validated antimicrobial susceptibility testing methods should be used.</u>

<table>
<tr><td>

EU comment

The problem with EHEC is not resistance since antimicrobials is not an important part of the therapy to treat EHEC infections. To get an overall picture on resistance among E. coli in animals, it is better to look at the whole E. coli population.

Furthermore, there should be a paragraph iv) on MRSA, which is very important for AMR issues.

</td></tr>
</table>

    c)   Commensal bacteria

E.~~scherichia~~ coli and *enterococci* (*Enterococcus faecium* and *E. faecalis*) <u>may be sampled from animal feed, food producing animals and animal-derived food products.</u> ~~are common commensal bacteria.~~

These bacteria are <u>commonly used in surveillance and monitoring programmes as indicators, providing information on the potential reservoir</u> ~~considered to constitute a reservoir~~ of antimicrobial resistance genes, which may be transferred to pathogenic bacteria. ~~causing *disease* in *animals* or humans.~~ It is considered that these bacteria should be isolated from healthy *animals*, preferably at the *abattoir*, and be monitored for antimicrobial resistance.

Validated <u>antimicrobial susceptibility testing</u> methods should be used.

~~Table 2.~~ ***Examples of sampling sources, sample types and outcome of monitoring***

~~Source~~	~~Sample type~~	~~Outcome~~	~~Additional information required/additional stratification~~
~~Herd of origin~~		~~Prevalence of resistance in bacteria originating from animal populations (of different production types) Relationship resistance - antibiotic use~~	~~Per age categories, production types, etc. Antibiotic use over time~~
~~Abattoir~~	~~Faecal~~	~~Prevalence of resistance in bacterial populations originating from animals at slaughter age~~	
	~~Intestine~~	~~As above~~	
	~~Carcass~~	~~Hygiene, contamination during slaughter~~	
~~Processing, packing~~	~~Meat products~~	~~Hygiene, contamination during processing and handling~~	

Retail	~~Meat products~~	~~Prevalence of resistance in bacteria originating from food, exposure data for consumers~~	
~~Various origin~~	~~Vegetables~~	~~Prevalence of resistance in bacteria originating from vegetables, exposure data for consumers~~	
~~Various origin~~	~~Animal feed~~	~~Prevalence of resistance in bacteria originating from animal feed, exposure data for animals~~	

6<u>7</u>. Storage of bacterial strains

If possible, isolates should be preserved at least until reporting is completed. Preferably, 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.

7<u>8</u>. Antimicrobials to be used in susceptibility testing

Clinically important antimicrobial <u>agents/</u>classes used in human and veterinary medicine should be <u>included in antimicrobial resistance surveillance programmes</u> ~~monitored~~. <u>Members should refer to Chapter 1.1.6. of the *Terrestrial Manual* and the OIE list of antimicrobials of veterinary importance for monitoring purposes.</u> However, the number of tested antimicrobials may have to be limited according to financial resources.

EU comment

The word "<u>as well as WHO list of human critically important antimicrobials</u>" should be added at the end of the second sentence of the paragraph above.

The first sentence makes reference to antimicrobial used in human and veterinary medicine, thus Members should also refer to the list of critically important antimicrobial for human, established by the WHO.

Furthermore, this section should be expanded to include a comment on the methodology to be used, and in particular on the need for stringent quality control. It would be valuable if this section explains and acknowledges the use of class representatives in antimicrobial susceptibility testing. The reader may get the impression that all substances on the list need to be tested. There are agreed class representatives for most classes, and that considerably narrows down the number of substances that need to be tested.

8<u>9</u>. Type of data to be recorded and stored

~~Data on A~~<u>a</u>ntimicrobial susceptibility <u>data</u> should be reported quantitatively <u>(minimum inhibitory concentrations [MICs] or inhibition zone diameters), rather than qualitatively</u>.

Appropriate<u>ly</u> validated <u>antimicrobial susceptibility testing</u> methods should be used in accordance with Chapter 1.1.6. of the *Terrestrial Manual*<u>,</u> concerning laboratory methodologies for bacterial antimicrobial susceptibility testing.

EU comment

The last paragraph above should be moved to the suggested section on methodology and antimicrobials to be used in testing.

9<u>10</u>. Recording, storage and interpretation of results

a) 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.

b) The storage of raw (primary, non-interpreted) data is essential to allow the evaluation ~~of the data~~ in response to various kinds of questions, including those arising in the future.

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

   i)   as distributions of ~~minimum inhibitory concentrations (MICs)~~ in milligrams per litre;

   ii) or inhibition zone diameters in millimetres.

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

   i)   sampling programme;

   ii)   sampling date;

   iii) animal species/~~livestock~~ category;

   iv)   type of sample;

   v)   purpose of sampling;

   vi)   type of antimicrobial susceptibility testing method used;

   vii) geographical origin (geographical information system data where available) of *herd*, *flock* or *animal*;

   viii) ~~age of A~~*animal* factors (e.g. age, condition, health status, identification, sex).

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

   i)   identity of *laboratory*,

   ii)   isolation date,

   iii) reporting date,

   iv)   bacterial species,

and, where relevant, other typing characteristics, such as:

   v)   sero~~var~~type/serovar,

   vi)   phage-~~ ~~type,

   vii) antimicrobial susceptibility result/resistance phenotype,

   viii) molecular genotype.

f) The proportion of isolates regarded as resistant should be reported, including the defined interpretive criteria ~~breakpoints~~ used.

g) In the clinical setting, breakpoints are used to categorise bacterial strains as susceptible, intermediate ~~susceptible~~ or resistant. These clinical breakpoints~~, often referred to as clinical or~~

pharmacological breakpoints, ~~are~~ may be elaborated on a national basis and may vary between Members.

h) ~~The system of reference used should be recorded.~~ The antimicrobial susceptibility testing standards and guidelines used should be recorded.

i) For surveillance 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.

EU comment

For better clarity, the paragraph on clinical breakpoints, currently g), and epidemiological cut-offs, currently i), should come one after the other. Thus the current paragraph h) should be moved up before g).

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j) Ideally ~~If available~~, data should be collected at the individual isolate level, allowing antimicrobial resistance patterns to be recorded ~~the phenotype of the isolates (resistance pattern) should be recorded~~.

1**1**~~0~~. Reference laboratory and annual reports

a) Members should designate a national reference centre that assumes the responsibility to:

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

ii) coordinate and collect information from participating surveillance laboratories ~~at a central location~~ within the country;

iii) produce an annual report on the antimicrobial resistance situation ~~of~~ in the country.

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

i) raw data;

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

iii) inter-laboratory proficiency testing results;

iv) information on the structure of the monitoring system;

v) information on the chosen laboratory methods.

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

~~Target animals~~	~~Respiratory pathogens~~	~~Enteric pathogens~~	~~Udder pathogens~~	~~Other pathogens~~
~~Cattle~~	*~~Pasteurella~~* ~~spp.~~	*~~Escherichia coli~~*	*~~Staphylococcus aureus~~*	
	~~Haemophilus somnus~~	*~~Salmonella~~* ~~spp.~~	*~~Streptococcus~~* ~~spp.~~	
~~Pigs~~	*~~Actinobacillus pleuropneumoniae~~*	*~~Escherichia coli~~*		*~~Streptococcus suis~~*
		~~Brachyspira~~ ~~spp.~~		
		~~Salmonella~~ ~~spp.~~		

Poultry				*Escherichia coli*

Fish				*Vibrio* spp.

				Aeromonas spp.

EU comment
This table 3 above presents very relevant examples and should not be deleted. It should be moved to point 6, however without reference to fish pathogens that should be covered in the Aquatic Code.

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