OIE Annual report on antimicrobial agents intended for use in animals

BETTER UNDERSTANDING OF THE GLOBAL SITUATION

WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

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Director General's Foreword

Dr Monique Eloit
OIE Director General

On 21 September 2016, the United Nations General Assembly adopted a political declaration aimed at combating the global threat posed by antimicrobial resistance, confirming the necessity of a 'One Health' approach. The Directors General of the tripartite collaboration – OIE, WHO and FAO – supported this declaration and will in addition to the recommendations of the Interagency Coordination Group on Antimicrobial Resistance, provide a report on the implementation of the political declaration for the UN Secretary General to submit for consideration by Member States at the 74th session of the General Assembly in September 2019.

The need for accurate information on the use of antimicrobial agents in animals is widely recognised. The OIE has taken the lead by creating a global database on the use of antimicrobial agents in animals, in the framework of the Global Action Plan on Antimicrobial Resistance. As a result of the tremendous efforts of its Member Countries, the first and second OIE Annual Report on the Use of Antimicrobial Agents in Animals were published in December 2016 and 2017, respectively.

The very encouraging findings of this third round of data collection were presented at the *Second OIE Global Conference on Antimicrobial Resistance: Putting Standards into Practice,* which was held in Marrakech, Morocco from 29 to 31 October 2018, and the detailed results are provided in this report. This Global Conference brought together government Ministers, OIE Delegates and OIE National Focal Points for Veterinary Products, as well as experts, professionals, policy makers, international organisations and donors, with the aim of increasing understanding of the current global situation on antimicrobial resistance in a One Health approach. The recommendations of the Conference further encourage OIE Member Countries to contribute to the OIE annual collection of data on antimicrobial agents intended for use in animals, and to publish, whenever possible, their own national reports on the sales or use of antimicrobial agents in relation to the animal population of the country

The OIE's partners consider the OIE data collection on the use of antimicrobials in animals and the progress achieved by the 153 OIE Member Countries and two non-OIE Member Countries that participated in the data collection in the third round to be a major milestone in the global effort to contain antimicrobial resistance. The OIE recognises the efforts of the OIE Delegates and the National Focal Points for Veterinary Products in assisting in this extraordinary effort. The OIE also commends the two non-OIE Member Countries that engaged in the data collection in the third round.

Finally, the OIE strongly supports its Member Countries in these efforts through the implementation of its Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials, published in November 2016. The objectives of this Strategy support those established in the Global Action Plan, and reflect the mandate of the OIE through four main objectives: 1) improve awareness and understanding; 2) strengthen knowledge through surveillance and research; 3) support good governance and capacity building; and 4) encourage implementation of international standards.

I hope that this report will further encourage all Member Countries and non-OIE Member Countries to continue to participate in this initiative. Your constant support and involvement will increase the precision and robustness of our understanding of the global use of antimicrobial agents in animals.

Executive Summary

This third *OIE annual report on the use of antimicrobial agents intended for use in animals* gives the global use of antimicrobial agents adjusted for animal biomass for 2015, and presents the overall findings of the third annual data collection on the use of antimicrobial agents in animals, providing a global and regional analysis from 2015 to 2017.

The template used to collect data was designed to allow all countries to participate, regardless of whether a national data collection system currently exists. In 2017, the third round of data collection, completed reports were submitted by 155 Countries: 153 OIE Member Countries (85% of 181 Member Countries) and 2 non-OIE Member Countries. This indicates progress since the first phase of data collection, where 130 Member Countries submitted completed reports.

In the third round of data collection, countries were asked to provide information on the barriers faced in reporting quantitative data on antimicrobial agents intended for use in animals. Thirty-one countries explained their barriers, reporting primarily a lack of regulatory framework, and lack of tools and human resources. Seven Countries (23%) informed that actions will be undertaken in the near future to facilitate their reporting of quantities of antimicrobials to the OIE.

For the responses on the use of antimicrobial agents as growth promoters, a total of 110 responding countries (110 out of 155; 71%) did not use any antimicrobial agents for growth promotion in animals in their countries as of 2017, either with or without legislation or regulations. The 45 remaining countries (29%) reported use of antimicrobials for growth promotion; of these, 18 countries (18 out of 45; 40%) had a regulatory framework that either provided a list of antimicrobials that can be used as growth promoters or provided a list of those that should not be used as growth promoters.

One hundred-eighteen countries (118 out of 155; 76%) reported quantitative data for one or more years between 2015 to 2017, an increase compared to the 89 and 107 countries providing quantitative data in the first and second rounds, respectively. Sources of these data varied among OIE Regions, and were most commonly sales and imports.

The calculations of animal biomass allowed for an analysis of antimicrobial quantities reported adjusted by a denominator. Animal biomass is calculated as the total weight of the live domestic animals in a given population and year, used as a proxy to represent those likely exposed to the quantities of antimicrobial agents reported. Animal biomass was calculated for food-producing species of countries reporting quantitative data for the year 2015, primarily using data from the OIE World Animal Health Information System (WAHIS) and the Food and Agriculture Organization Statistics (FAOSTAT). 2015 was the target year of this third round of data collection, and had the highest number of submissions of quantitative data.

The global estimate of antimicrobial agents used in animals in 2015 adjusted by animal biomass, as represented by the quantitative data reported to the OIE from 91 countries, was 168.75 mg/kg. An approach for an upper level estimate of 172.39 mg/kg was made adjusting by country-level estimates of how much data on antimicrobial agents used in animals they covered in 2015. The 2015 analysis reflects a much stronger global participation in the data collection, with an increase of 31 reporting countries, and an estimated global biomass coverage of 71%, increased from 37% in 2014.

As a result of the many challenges that we now know countries face as they advance towards quantitative data collection on antimicrobial use in animals, the OIE advises caution in interpretation and use of quantitative data presented in this report. The report transparently describes the reasons for uncertainty associated with both the complex and simple estimates presented. Limitations of this analysis include quantitative data source errors, which may lead to overcounting of antimicrobial amounts by some countries new to the process of data collection.

The OIE remains strongly committed to supporting our Members in developing robust measurement and transparent reporting mechanisms for antimicrobial use, but the challenges for many of our Members must not be under-estimated. Concurrent to engagement with countries to improve these data, the methodology for calculating animal biomass will be refined. While data collection systems further develop, this annual report will provide an essential global and regional analysis of antibiotic use in animals, and changes over time.

Acknowledgements

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The OIE would also like to thank all OIE Member Countries as well as non-OIE Member Countries, Delegates, National Focal Points for Veterinary Products and other governmental officials who contributed to the third annual collection on data of antimicrobial agents used in animals, without which such knowledge and insight could never be gained on the global use of antimicrobial agents in animals.

The OIE thanks the members of the OIE Scientific Commission on Animal Diseases who gave their encouragement and support for this initiative since the beginning.

Acronyms and Abbreviations

AMR	Antimicrobial resistance
AMU	Antimicrobial use
CIPARS	Canadian Integrated Program for Antimicrobial Resistance Surveillance
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
FAO	Food and Agriculture Organization of the United Nations
NAP	National Action Plan
OIE	World Organisation for Animal Health
PVS	Performance of Veterinary Services
WAHIS	World Animal Health Information System
WHO	World Health Organization

OIE Glossary[1]

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

Growth promotion, growth promoters (according to the new version of Chapter 6.9 of the *Terrestrial Code*, adopted during the 86th OIE General Session): means the administration of antimicrobial agents to animals only to increase the rate of weight gain or the efficiency of feed utilisation.

Monitoring: means the intermittent performance and analysis of routine measurements and observations, aimed at detecting changes in the environment or health status of a population.

Surveillance: means the systematic ongoing collection, collation, and analysis of information related to animal health and the timely dissemination of information so that action can be taken

Veterinary Authority: means the Governmental Authority of a Member Country, comprising veterinarians, other professionals and paraprofessionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the Terrestrial Code in the whole territory.

Veterinary legislation: means laws, regulations and all associated legal instruments that pertain to the veterinary domain.

Veterinary medicinal product: means any product with approved claims to having a prophylactic, therapeutic or diagnostic effect or to alter physiological functions when administered or applied to an animal.

Veterinary medical use (according to the new version of Chapter 6.9 of the *Terrestrial Code*, adopted during the 86th OIE General Session): Means the administration of an antimicrobial agent to an individual or a group of animals to treat, control or prevent disease:

- to treat means to administer an antimicrobial agent to an individual or a group of animals showing clinical signs of an infectious disease;
- to control means to administer an antimicrobial agent to a group of animals containing sick animals and healthy animals (presumed to be infected), to minimise or resolve clinical signs and to prevent further spread of the disease;
- to prevent means to administer an antimicrobial agent to an individual or a group of animals at risk of acquiring a specific infection or in a specific situation where infectious disease is likely to occur if the drug is not administered.

Veterinary Services: means the governmental and non-governmental organisations that implement animal health and welfare measures and other standards and recommendations in the *Terrestrial Animal Health Code* and the OIE *Aquatic Animal Health Code* in the territory. The Veterinary Services are under the overall control and direction of the Veterinary Authority. Private sector organisations, veterinarians, veterinary paraprofessionals or aquatic animal health professionals are normally accredited or approved by the Veterinary Authority to deliver the delegated functions.

[1] For the purpose of the *OIE Terrestrial Code* [1]

1. Introduction

1.1. Background

For two decades, the World Organisation for Animal Health (OIE) has engaged in combating antimicrobial resistance through a One Health approach. On a global level, the mitigation of antimicrobial resistance is crucial for the protection of human, animal, plant and environmental health.

During the 83rd General Session, the OIE Member Countries officially committed to combat AMR and promote the prudent use of antimicrobials in animals and stated their full support for Global Action Plan on AMR, developed by the World Health Organisation (WHO) in close collaboration with the OIE and Food and Agriculture Organization of the United Nations (FAO). [2] One year later, during the 84th General Session, the World Assembly of Delegates directed OIE to compile and consolidate all the actions to combat AMR, [3] and the resultant OIE Strategy on AMR and the Prudent Use of Antimicrobials was published in November 2016. [4]

The structure of this OIE Strategy supports the objectives established in the Global Action Plan, and reflects the mandate of the OIE as described in its Basic Texts and Strategic Plans, through four main objectives: (1) Improve awareness and understanding; (2) Strengthen knowledge through surveillance and research; (3) Support good governance and capacity building; and (4) Encourage implementation of international standards.

Towards development of these objectives in its Member Countries, the OIE engages with National Focal Points for Veterinary Products in its Member Countries. During the 76th General Session of the World Assembly of Delegates in May 2008, OIE Delegates were asked to nominate National Focal Points for Veterinary Products, who would provide technical assistance in improving and harmonising national policies for control of veterinary products in their countries. The OIE, through its Regions, organises regular seminars for these Focal Points to support good governance and capacity building in its Member Countries, and harmonised implementation of OIE standards for responsible and prudent use of antimicrobials.

In many countries today, antimicrobial agents are widely available with virtually no restriction or control. Of the 135 OIE Member Countries assessed through the OIE Performance of Veterinary Services (PVS) Pathway[2] as of November 2018, many do not yet have complete and relevant legislation and/or accompanying compliance programmes to ensure appropriate conditions for the import, manufacturing, distribution and use of veterinary medicinal products, including antimicrobial agents. As a result, these agents may circulate freely, like ordinary goods, may be falsified or substandard, and/or may be provided unaccompanied by clinical or laboratory diagnosis. This inappropriate quality and/or use of antimicrobial products creates conditions of high risk for the development and spread of resistance. During the new 7th edition of the OIE PVS Tool, a new Critical Competency (CC) was added: *CCII-9 Antimicrobial resistance (AMR) and antimicrobial use (AMU)*. This CC will allow a more specific understanding on AMR and AMU surveillance, One Health governance of AMR, AMR specific drug regulation and the veterinary contribution to National Action Plans on AMR.

[2] The PVS Pathway is a staged process of evaluation, planning and targeted support to national Veterinary Services based on agreed OIE international standards. The methodologies are based on the OIE PVS Tool which has recently been updated and defines 45 critical competencies, each describing 5 levels of advancement. Independent, OIE trained and certified PVS Experts conduct PVS missions and activities in OIE Member Countries on a voluntary basis. See - http://www.oie.int/solidarity/pvs-pathway/

Currently, very little information is available worldwide on resistance patterns in animal pathogens. Surveillance of antimicrobial resistance in animal pathogens is important to assess the level and evolution of antimicrobial resistance in animals.

The OIE international standards published in the *Terrestrial Animal Health Code*, Chapter 6.8. 'Harmonisation of national antimicrobial resistance surveillance and monitoring programmes' includes examples of target animal species and animal bacterial pathogens that may be included in resistance surveillance and monitoring programmes; [5] the *Aquatic Animal Health Code*, Chapter 6.4. 'Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals'; [6] and the *Manual of Diagnostic Test and Vaccines for Terrestrial Animals*, Chapter 2.1.1 'Laboratory methodologies for bacterial antimicrobial susceptibility testing' provide a basis for such surveillance and monitoring [7]. Work is currently being undertaken to refine recommendations for harmonisation of microbial susceptibility testing in veterinary laboratories.

In addition to surveillance of antimicrobial resistance, monitoring of antimicrobial use is critical to understanding possible areas of risk for the development of resistance. In 2012, the OIE developed a questionnaire with the following objectives: (1) to enhance the OIE's engagement in the initiative to prevent antimicrobial resistance; (2) to conduct a survey of the implementation by OIE Member Countries of OIE *Terrestrial Animal Health Code* Chapter 6.9. 'Monitoring of the quantities and usage patterns of antimicrobial agents used in food producing animals'; (3) to improve awareness of antimicrobial use in animals by OIE Member Countries and; (4) to determine what actions are needed and to help the OIE to develop its strategy in this field. A total of 152 out of 178 (85%) OIE Member Countries completed the questionnaire. The answers received showed that, in 2012, 27% of responding Member Countries had an official system in place for collecting quantitative data on antimicrobial agents used in animals.

The results were presented at the first OIE Global Conference on the Responsible and Prudent Use of Antimicrobial Agents for Animals held in March 2013 in Paris, France. The recommendations resulting from the conference to OIE Member Countries included:

- To develop and set up an official harmonised national system for collecting data on the monitoring of antimicrobial resistance in relevant animal pathogens and quantities of antimicrobial agents used in food producing animals at the national level based on the OIE standards.
- To contribute to the OIE initiative to collect data on the antimicrobial agents used in food producing animals (including through medicated feed) with the ultimate aim to create a global database hosted by the OIE.

Following these recommendations, in 2015, the OIE World Assembly unanimously adopted Resolution No. 26 during the 83rd General Session, officially mandating the OIE to gather data on the use of antimicrobial agents in animals worldwide. [2] This global database was created in compliance with Chapters 6.9. of the *Terrestrial Animal Health Code* (Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals) and 6.3. of the *Aquatic Animal Health Code* (Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals) [8, 9].

In the framework of the Global Action Plan on Antimicrobial Resistance, the OIE leads the building and maintenance of the global database on antimicrobial agents intended for use in animals, supported by FAO and WHO within the tripartite collaboration. [10]

The OIE launched its first annual data collection on antimicrobial agents intended for use in animals in OIE Member Countries in the last trimester of 2015. The template and guidance documents were developed by the OIE *ad hoc* Group on Antimicrobial Resistance (AMR), endorsed by the Scientific Commission for Animal Diseases, and tested by Member Countries through regional training seminars for OIE National Focal Points for Veterinary Products.

During this first phase of data collection on antimicrobial agents used in animals, 130 Member Countries (n = 180; 72%) participated. The report resulting from this impressive participation in the first annual data collection, the *OIE annual report on the use of antimicrobial agents in animals: Better understanding of global situation*, was published in December 2016 [11]. This first report provided a global and regional analysis of qualitative data on the current situation of governance of veterinary antimicrobials, and quantitative data on antimicrobial agents intended for use in animals provided from 2010 to 2015 by participating Member Countries.

The second round of data collection took place between October 2016 and May 2017, and was distributed to non-OIE Member Countries in the Americas in addition to the OIE's 180 Member Countries[3]. The second *OIE annual report on antimicrobial agents intended for use in animals: Better understanding of global situation*, was published in December 2017 [12]. The third round took place between October 2017 and May 2018 and was distributed to non-OIE Member Countries in the Americas in addition to the OIE's 181 Member Countries[4].

As part of the third round of the data collection, the OIE requested quantitative data on antimicrobials used in animals for the 2015 calendar year, but also accepted data from the years 2016 and 2017. The wider timespan of quantitative data collected allows for countries in various stages of development of their antimicrobial use monitoring systems to contribute to the OIE data collection. However, this request presents a challenge for data analysis. As the timespan of quantitative data collected from the third round of data collection presented in this report is broad, making comparisons between regions or assessment of trends is difficult. Comparison of quantitative data also require a denominator with which to interpret the antimicrobial quantities reported.

To address these challenges, this report provides an examination of quantitative data in the context of relevant animal populations, and includes an analysis of antimicrobial quantities adjusted for animal biomass on a global and regional level by year. The focus year of this additional analysis is 2015, using quantitative data reported to the OIE by 91 countries during the first three rounds of data collection.

In the fourth round of data collection, currently underway, the OIE has requested quantitative data for 2016, but will also accept data for 2017 and 2018. Accepting some repeated years of quantitative data from previous rounds while continuing engagement with participating countries provides an opportunity for countries to correct and enrich the quality of these data where relevant. Over time, and once the reporting of data has become more routine, the OIE will request data for one specific calendar year. This way, OIE reporting will progress in parallel with the development of data collection systems in its Member Countries, as global monitoring on the use of antimicrobial agents becomes more systematic and reliable.

In this third round of data collection, 153 Member Countries (of 181 Member Countries) and 2 non-OIE Member Countries responded to the OIE questionnaire, with 76% (118 out of 155 countries) providing quantitative data on antimicrobial agents intended for use in animals. Given the impressive participation of OIE Member Countries and their expressed desire to further increase transparency on antimicrobial agents intended for use in animals, it is expected that countries will continue to report quantitative information with each successive data collection and increase the quality of the data.

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[3] During the first and second phases of data collection, the OIE comprised 180 Member Countries. During the 2017 General Assembly, Curaçao officially became an OIE Member Country, bringing the total number to 181.

[4] During the third round of data collection, the OIE comprised 181 Member Countries. During the 2018 General Assembly, Saint Lucia officially became an OIE Member Country, bringing the total number to 182. However, as this addition occurred after the completion of the third round of data collection, mention of the total number of Member Countries throughout this report will refer to 181 countries unless otherwise stated.

Every year, more countries progress the implementation and development of monitoring systems on antimicrobial agents used in animals. This progress was highlighted in Technical Item 1 of the 85th General Session held in May 2017, titled "Global action to alleviate the threat of antimicrobial resistance: progress and opportunities for future activities under the One Health initiative". This Technical Item was undertaken to inform on the current situation of antimicrobial resistance mitigation initiatives in Member Countries, as reported by each country through a questionnaire. Member Country responses showed an increase in adherence to OIE standards since 2015 for surveillance of antimicrobial use (49% since 2015 compared to 37% before) and resistance (34% since 2015 compared to 25% before) in animals. [13]

These results show that Member Countries are not only developing the needed monitoring systems, but are doing so in compliance with international standards. Following the presentation of the results of the Technical Item, the Assembly adopted Resolution N°38, endorsing eleven recommendations for future activities under the 'One Health' initiative. Among these recommendations was one emphasising the significance of continuing the global data collection on the use of antimicrobial agents in animals. [14]

1.2. Scope

This report presents the results of the third round of the annual collection of data on antimicrobial agents intended for use in animals. The data collection highlights the current situation of governance of veterinary antimicrobials in responding OIE Member Countries and participating non-OIE Member Countries, and includes submissions of quantitative data where countries are able to provide them to the global database on the use of antimicrobial agents in animals. Where countries are not able to contribute quantitative data, the report also highlights the barriers they described that impede them in data collection, analysis and/or reporting.

In addition to the descriptive analysis of the third round of data collection, the report includes a global and regional analysis of quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass. The focus year of this quantitative analysis is 2015.

Currently, countries report data mainly from sales or imports of antimicrobial agents from the OIE List of Antimicrobial Agents of Veterinary Importance, which prioritises antimicrobials crucial to maintaining the health and welfare of animals worldwide. The data collection template and resulting report were prepared taking into account the differences between OIE Member Countries in their governance and surveillance of veterinary antimicrobials.

For countries reporting quantitative data, the amounts of antimicrobial agents intended for use in animals that were sold, purchased or imported were provided to the OIE in kilograms (kg) of antimicrobial agent (chemical compound as declared on the product label). These reported figures were calculated according to the guidance provided in Annex 8.

The information provided to the OIE by each country was done in confidence, and for the purpose of better understanding the global and regional situation of the use of antimicrobial agents in animals. This report therefore does not present any data on an individual country level. Nevertheless, Member Countries are encouraged by the OIE to publish national reports on the use of antimicrobial agents in animals whenever possible, and are requested to indicate if such data are available online in the OIE template. The list of countries with national reports on veterinary antimicrobial usage available can be found in Section 9 of the report, along with the relevant links.

2. Materials and Methods

2.1. Antimicrobial Quantities Reported

Resolution No. 26 of the 83rd General Session in 2015, 'Combating Antimicrobial Resistance and Promoting the Prudent Use of Antimicrobial Agents in Animals', included recommendations that:

3. The OIE develop a procedure and standards for data quality for collecting data annually from OIE Member Countries on the use of antimicrobial agents in food-producing animals with the aim of creating an OIE global database to be managed in parallel with the World Animal Health Information System (WAHIS).

4. OIE Member Countries set up an official harmonised national system, based on OIE standards, for the surveillance of antimicrobial resistance and the collection of data on the use of antimicrobial agents in food-producing animals, and actively participate in the development of the OIE global database.

In response to these recommendations, the OIE *ad hoc* Group on Antimicrobial Resistance developed a template for harmonised data collection, as well as guidance for its completion. This template was translated in the three official OIE languages (i.e. English, French and Spanish). Following experience from the first and second round of data collection, the following changes related to antimicrobial growth promoters were made to the OIE template:

1. Countries were asked if antimicrobial agents were used as growth promoters in their countries, irrespective of whether legislation or regulation existed (Baseline Information, Question 11)
2. Countries were asked if legislation or regulation existed for the use of antimicrobial agents as growth promoters (Baseline Information, Question 12)
3. Countries that reported having legislation or regulation for antimicrobial agents as growth promoters were also asked on the type of legislation (Baseline Information; Question 13)

An Annex to the guidance was also provided giving more detailed instructions on mathematical calculations to obtain quantities of active ingredients from veterinary medicinal products containing antimicrobial agents sold. All antimicrobial agents destined for use in animals and contained in the *OIE List of Antimicrobial Agents of Veterinary Importance* [15], in addition to certain antimicrobial agents used only for growth promotion, were reportable.

The updated template (Annex 6) and accompanying guidance documents (Annexes 7 and 8) were sent to all 181 OIE Member Countries and 11 non-OIE Member Countries by email in October 2017. The deadline for submission was the 1 December 2017, but responses were accepted on a conditional basis until mid-May 2018.

As with the first and second rounds of data collection, countries responded to the questionnaire through an Excel document using predefined conditional formulas and analysis tools. This document, referred to as the 'OIE template' contains four worksheets labelled 'Baseline Information', 'Reporting Option 1', 'Reporting Option 2', and 'Reporting Option 3'.

Part A (Contact Person for Antimicrobial Agents Use Data Collection) and Part B (General Information) of the 'Baseline Information' sheet can be answered by any country, and collect information on the current situation of governance of veterinary antimicrobials, such as the competent authority for regulation of antimicrobial use in animals, use of growth promoters and barriers to reporting quantitative data on antimicrobial agents used in animals, if any. For countries able to provide quantitative data on antimicrobial agents intended for use in animals, the Baseline Information sheet

also contains questions relevant to data collection in Part C (Data Collection of Antimicrobial Agents Intended for Use in Animals), such as year covered, data sources and food-producing species included. Countries providing multiple years of quantitative data are asked to provide a single template for every year of data, with Part C modified if necessary to reflect the reported quantitative data.

Following completion of the Baseline Information, the template either directs countries to submit the questionnaire if no quantitative data were available, or complete one of the three 'Reporting Options' if quantitative data were available. The three reporting options represent increasing levels of detail of quantitative data on antimicrobial classes used in animals, with the possibility of separating amounts reported by type of use (Veterinary medical use, which includes use to treat, control or prevent disease; and Non-veterinary medical use, which includes use for growth promotion[5]), animal groups (Terrestrial, Aquatic or Companion) and routes of administration.

All responses submitted by the contact person within a Member Country were validated by the country's Delegate. Responses were compiled and analysed at OIE Headquarters.

Whenever necessary, staff of OIE Headquarters engaged with respondents for clarification and validation of responses. These questions were addressed to the contact person listed, most often OIE National Focal Points for Veterinary Products.

2.2. Animal Biomass Estimation Methodology

Background

To compare quantitative data reported on antimicrobial agents intended for use in animals between regions and over time, a rate is necessary to evaluate these data in the context of associated animal populations, which vary in size and composition. Towards this goal, and in conjunction with the development of the antimicrobial use database, the OIE *ad hoc* Group on Antimicrobial Resistance agreed to analyse the antimicrobial quantities reported using animal biomass as a denominator.

Animal biomass is calculated as the total weight of the live domestic animals in a given population and year, used as a proxy to represent those likely exposed to the quantities of antimicrobial agents reported. As data on antimicrobial agents are reported by country, animal biomass for the purpose of this report is the total weight of that country's production animals. At this time, due to insufficient data, it was not possible to incorporate companion animals in total biomass.

Animal biomass is currently employed as a denominator in analysis of quantitative antimicrobial use data by other national and regional antimicrobial use surveillance groups, such as the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC), the U.S. Food and Drug Administration (FDA), the Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS), and the Japanese Veterinary Antimicrobial Resistance Monitoring System (JVARM).

[5] The OIE template for the third round of data collection used the terms "therapeutic use" and "growth promotion". The former term has been updated in this report in accordance with the decision of the OIE World Assembly in May 2018 to adopt the standardised definitions which now appear in the OIE *Terrestrial Animal Health Code* Chapter 6.9 Article 6.9.2. [8] (http://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/current/chapitre_antibio_monitoring.pdf)

Data Sources and Methodology Development

While several methodologies have been developed for the calculation of animal biomass by other surveillance groups, none could be directly used for the OIE global database. Particularly, these methodologies utilise available data on animal populations detailed by production class, estimates of live animal weights, import/export data, and total annual populations of production groups living less than one year (i.e., poultry, veal calves, fattening pigs, lambs and kids). On a global level, such detailed data are not yet available for many countries.

Data collected by global animal surveillance databases (WAHIS[6], FAOSTAT[7]) are point-in-time species-level census data[8] with little-to-no detail relating to production class. Such data are difficult to interpret given that production classes within a species can have very different average weights, such as beef cattle and veal calves. Additionally, given that census data are collected at a specific time of the year, the total annual population is not known for production groups which are slaughtered and repopulated a certain number of times within one year (this multiplication factor is hereafter referred to as 'cycle factor').

Development of the methodology for calculation of an annual animal biomass utilised globally available census data from the OIE WAHIS interface. WAHIS data are reported by National Veterinary Services through the OIE Delegate, with the active support of OIE Focal Points for Animal Disease Notification, and the figures are subsequently validated by OIE staff. When an animal population figure is not reported to WAHIS, the data point is left blank.

FAOSTAT animal population data were used as a complementary dataset. FAOSTAT data are similarly primarily obtained from national governments, but sources expand beyond National Veterinary Services to National Statistics Offices and other relevant agencies. When a national government does not report a figure to FAOSTAT, FAO uses local expert resources to estimate a figure, or their statistical team to imputate[9] a data point. The two datasets are therefore similar but can display significant variation.

Where census data were used, the WAHIS and FAOSTAT figures were first cross-referenced with each other, and then with national reports or literature when necessary. FAOSTAT data were utilised when a WAHIS data point was not available or was outside of expected variation without explanation.

In addition to census data, FAOSTAT also reports numbers and tonnes of production animal species slaughtered by country each year, similarly undifferentiated by production class. As WAHIS does not collect this information, FAOSTAT slaughter data was used exclusively when these data were needed. For species living less than one year, it was necessary to use data on number of animals slaughtered to represent an annual population, as this information cannot be extrapolated from point-in-time census data without a cycle factor.

The formulas for calculating biomass by species were developed with these considerations in mind using the two globally available datasets, WAHIS and FAOSTAT, and the results compared to references from countries where more detailed animal population data by production class were available. These references include animal biomass figures either directly supplied from Member Countries, or calculated from animal population data in Eurostat, the statistical office of the European Union.

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6 OIE World Animal Health Information System

7 United Nations Food and Agriculture Organization Statistics

8 Point in time census data represents the number of living animals in a country at the time of survey

9 Imputation is the process used to determine and assign replacement values for missing, invalid or inconsistent data that have failed edits (OECD).

The formulas chosen for calculation of the OIE denominator reflect the best fit estimations using the more general global animal population data (WAHIS, FAOSTAT) when compared to these available reference figures. The derived formulas were then applied to all countries providing quantitative data for the target year.

The methodology for calculation of animal biomass was developed with the support and validation of the OIE *ad hoc* Group on Antimicrobial Resistance, and shared with Member Countries in the report of the OIE Scientific Commission for Animal Diseases meeting of September 2017. The potential for inaccuracies in the estimation of animal biomass, in particular from extrapolating data available for one region of the world to other regions, is further discussed in section 5.3 of the report.

Year of Analysis

2015, the target year of the third round of data collection, is the focus of the additional analysis of antimicrobial quantities adjusted for the animal biomass denominator. Countries providing quantitative data on antimicrobial agents intended for use in animals in 2015 during the first three rounds of data collection were included in this additional analysis.

Calculations of Live Weights for All Species

Live weights of animals were calculated using FAOSTAT slaughter data, where available, using the following two formulas:

$$carcass\ weight\ (kg) = \frac{weight\ of\ species\ slaughtered\ (kg)}{number\ of\ species\ slaughtered\ (heads)}$$

Carcass weights were converted to live weights from the animal at time of slaughter using conversion coefficients (k) as defined by Eurostat. [16] Conversion coefficients represent the difference between a processed carcass weight and the expected live weight of that animal species before slaughter, expressed as a fraction.

$$live\ weight\ (kg) = \frac{carcass\ weight\ (kg)}{conversion\ coefficient\ (k)}$$

For the purposes of this report, 'live weight' refers to the calculated weight (in kg) of an animal before slaughter, unless otherwise specified.

Methodology for Calculating Species Biomass by Country

As animal population data are collected on a country level, animal biomass was calculated for each of the following species for each country that reported quantitative data to the OIE for 2015.

All weights and biomass figures are measured in kilograms (kg).

Bovine (including cattle and domestic buffalo) biomass was calculated according to the following principles:

1. Countries were grouped by sub-region as defined by livestock unit classifications.[10] A sub-regional mean live weight was then determined by calculating the average live weight of bovines for countries within the sub-regional grouping;

[10] Livestock units, used for aggregating the numbers of different categories of livestock, are usually derived in terms of relative feed requirements. Conversion ratios are generally based on metabolisable energy requirements, with one unit being considered as the needs for maintenance and production of a typical dairy cow and calf. [17]

2. Using the sub-regional mean live weight, a representative weight of the sub-regional bovine population was extrapolated by applying expected population ratios and weights of the bovine production categories (adults, young stock, calves). Population ratios were determined using an anticipated renewal rate of 30%, and average weights were estimated using livestock unit ratios by production class as defined by Eurostat; [18]

   The representative weight determined for each sub-region was then multiplied by the census population of bovines for each country within the sub-region.

Swine biomass was calculated according to the following formula:

$$(live\ weight\ \times\ number\ slaughtered) + (census\ population\ \times\ sow\ weight\ \times\ 0.09)$$

Whereby,

$live\ weight\ \times\ number\ slaughtered$ represents the expected biomass of fattening pigs slaughtered in a country in one year,

And $census\ population\ \times\ sow\ weight\ \times\ 0.09$ represents the expected biomass of pigs retained for breeding purposes, calculated with the following considerations:

- Sow weight: the standard weight of a sow in Europe is 240kg (ESVAC 2017). This weight was adapted by region using livestock unit ratios (Americas = 240kg, Asia, Far East and Oceania = 240 kg, Africa = 192kg);
- 0.09 is the expected percentage of sows in a given swine population, as calculated from Eurostat animal population data.

Poultry biomass was calculated according to the following formula:

$$\begin{aligned}&(live\ weight\ chicken\ \times\ number\ of\ chicken\ slaughtered)\\&+\ (live\ weight\ turkey\ \times\ number\ of\ turkey\ slaughtered)\\&+\ (live\ weight\ ducks\ \times\ number\ of\ ducks\ slaughtered)\\&+\ (live\ weight\ geese\ \times\ number\ of\ geese\ slaughtered)\end{aligned}$$

Equidae biomass was calculated according to the following formula:

$$\begin{aligned}&(live\ weight\ horse\ \times\ horse\ census\ population)\\&+\ (live\ weight\ donkey\ \times\ donkey\ census\ population)\\&+\ (live\ weight\ mules\ \times\ mule\ census\ population)\end{aligned}$$

The live weight of horses, donkeys, and mules was calculated for regions where equine slaughter is common and data were available. For regions where equine slaughter is not practiced and/or where data were unavailable, live weights were adapted using livestock unit ratios.

Sheep and goat biomass were calculated according to the following formula:

$$(live\ weight\ \times\ number\ slaughtered)\ +\left(census\ population - \frac{number\ slaughtered}{1.5}\right)\times\ 75\ kg$$

Whereby,

$(live\ weight\ \times\ number\ slaughtered)$ represents the expected biomass of sheep and goats slaughtered in a country in one year,

And $\left(census\ population - \frac{number\ slaughtered}{1.5}\right) \times 75\ kg$ represents the expected biomass of animals retained for breeding purposes, calculated with the following considerations:

- 1.5 is the average number of breeding cycles per year;
- The standard weight of a breeding small ruminant in Europe is 75kg (ESVAC 2017). This weight was used globally based on livestock unit ratios.

Rabbit biomass was calculated according to the following formula:

$$(live\ weight\ \times\ number\ slaughtered)\ + \left(census\ population - \frac{number\ slaughtered}{5}\right) \times\ 4.5\ kg$$

Whereby,

$(live\ weight\ \times\ number\ slaughtered)$ represents the expected biomass of rabbits slaughtered in a country in one year,

And $\left(census\ population - \frac{number\ slaughtered}{5}\right) \times 4.5\ kg$ represents the expected biomass of animals retained for breeding purposes, calculated with the following considerations:

- 5 is the average number of breeding cycles per year;
- The standard weight of a breeding doe is 4.5 kg. [19]

Camelid and cervid biomass were calculated according to the following formula:

$$standard\ weight\ \times\ census\ population$$

According to the following considerations: [20]

- Standard weight cervid: 80kg
- Standard weight camel: 600kg
- Standard weight, llama/alpaca: 100kg

Farmed fish biomass was included in the total biomass only for countries that included aquaculture in their reported data on antimicrobials intended for use in animals. Aquaculture data are collected in WAHIS and FAOSTAT as tonnes produced annually.

Data on farmed crustaceans, molluscs and amphibians were excluded given the relatively small size of these populations, and inconsistency in their reporting.

Cats and dogs were not included in the calculation of animal biomass at this time due to inconsistency in reporting of their populations, and lack of information on average weights. For the countries where companion animal data was available, their contribution to overall animal biomass was found to be relatively minor (<1%). In the future, an analysis of companion animal data will hopefully become feasible.

Changes to Methodology for Calculation of Animal Biomass

Previously, the methodology included the use of 'indigenous' slaughter data[11] to offset the effect of trade of live animals on the biomass. Due the current unavailability of the 'indigenous' slaughter dataset, slaughter data not adjusted for trade was used for the 2015 analysis. The results of the 2014 analysis as shown in this report have been recalculated using the unadjusted slaughter data to support comparison.

2.3. Antimicrobial Quantities Adjusted for Animal Biomass

Quantitative data reported on antimicrobial agents intended for use in animals was adjusted for animal biomass according to the following calculation:

$$\frac{antimicrobial\ agents\ reported\ (mg)}{animal\ biomass\ (kg)}$$

For a regional and global analysis, country data for both the numerator and denominator, respectively, were summed according to OIE Region before the rate was calculated.

3. Results of the Third Round of Data Collection

3.1. Global Analysis

General Information

The OIE maintains Regional offices throughout the world, including ones in Africa, the Americas, Asia, Far East and Oceania, Europe and the Middle East. The data collection template was sent to all OIE Member Countries from all OIE Regions. In addition, the template was sent to non-OIE Member Countries that, from the second round of data collection, asked to be part of the survey. The list of all OIE Member Countries is provided in Annex 9.

In the first round of data collection, launched in October 2015, 130 OIE Member Countries responded to the questionnaire (n= 180; 72%). In the second round of data collection, launched in October 2016, 146 countries responded: 143 from OIE Member Countries (n = 180; 79%) and 3 non-OIE Member Countries. In the third round, from October 2017 to May 2018, 155 countries submitted completed reports to the OIE Headquarters: 153 from OIE Member Countries (n = 181; 85%) and 2 non-OIE Member Countries demonstrating their increasing commitment to this effort.

Profile of the Contact Person

Each OIE Member Country must designate a Delegate; most commonly the person selected leads the country's official Veterinary Services. In the 76th General Session, held in May 2008, the World Assembly determined that OIE Delegates should also nominate National Focal Points to assist them in their work on specific topics. Of these, the designated National Focal Points for Veterinary Products are responsible for any information relating to veterinary medical products in the country. Since 2008,

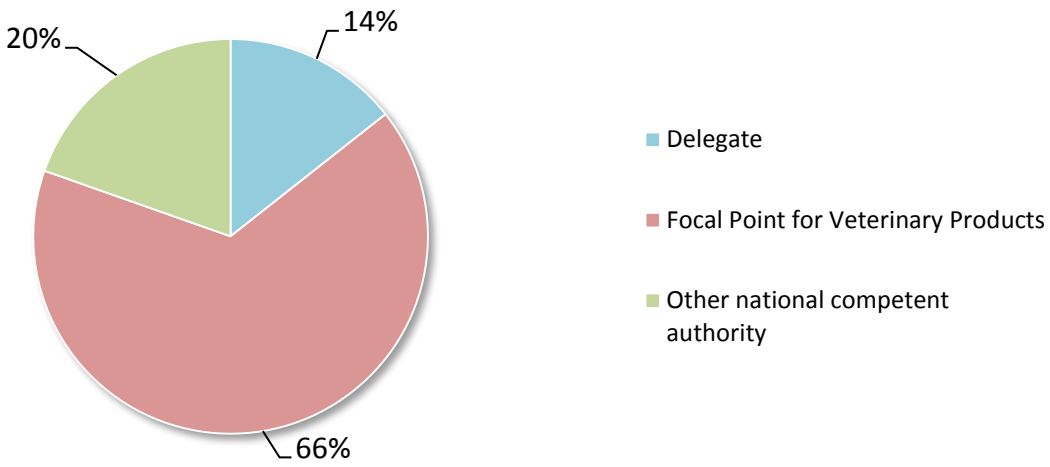
[11] 'Indigenous slaughter' refers to data on slaughter of animals of native origin. Exported animals are added to the reported figures, and slaughtered animals of foreign origin are excluded. (*FAO Statistics, Livestock statistics; Concepts, definitions and classifications, January 2011*).

the OIE has been training and supporting the Focal Points for Veterinary Products through regional or sub-regional seminars.

Given that OIE Delegates and National Focal Points only exist in OIE Member Countries, the following analysis on contact persons excludes non-OIE Member Countries.

For the third round of antimicrobial use data collection, the OIE template was most frequently completed by the Member Country's National Focal Point for Veterinary Products (101 out of 153 Member Countries). This highlights the significant role of OIE Focal Points for Veterinary Products in the success of data collection and supports the OIE's efforts in conducting regular Focal Point trainings towards establishment of a robust regional and global network of national experts in Veterinary Products (Figure 1).

Figure 1. Contact Person Profile of 153 Member Countries that Submitted the OIE Report in 2017



Reporting Options

The data collection template was designed to allow all countries to participate in the annual data collection, even if the quantitative data on antimicrobial agents intended for use in animals were not nationally available. Even if no quantitative data collection system exists in the country, the template section titled "Baseline Information" can be still be completed. This section contains three parts, as described in Table 1.

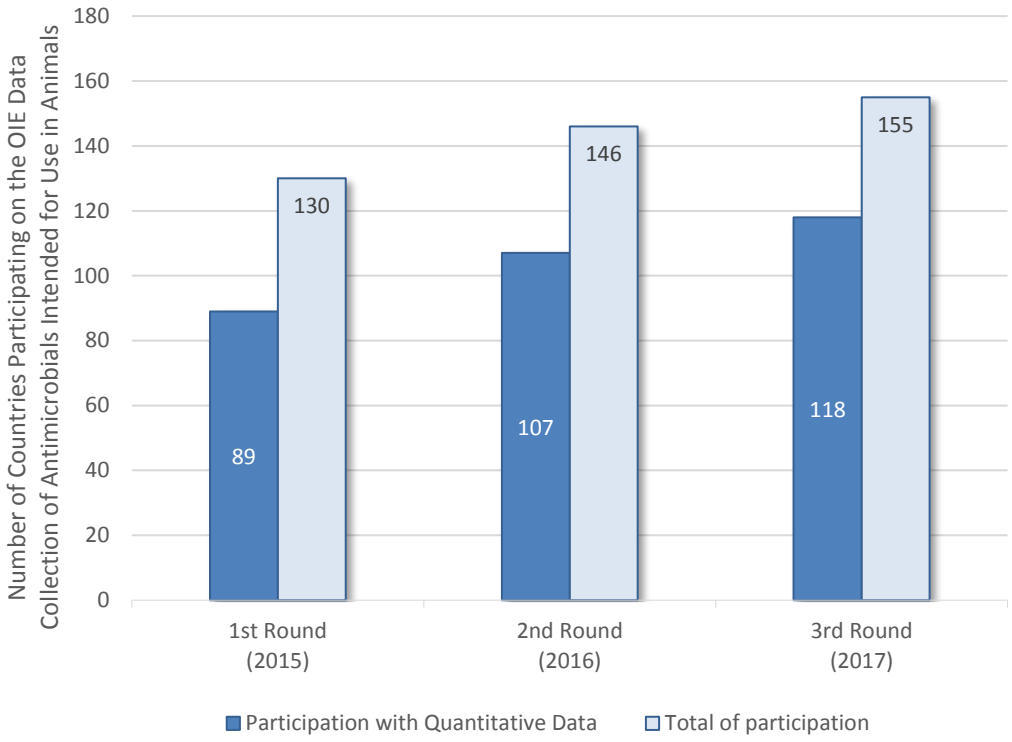
Table 1. Baseline Information Sections and How Countries Respond Based on Available Data

Baseline Information Sections	Countries not able to provide quantitative antimicrobial use data	Countries able to provide quantitative antimicrobial use data
Part A. Contact Person for Antimicrobial Agents Use Data Collection	✓	✓
Part B. General Information	✓	✓
Part C. Data Collection on the Use of Antimicrobial Agents in Animals		✓

In the third round of data collection, Baseline Information parts A and B were completed by 155 countries (153 Member Countries and 2 non-OIE Member Countries). Of these, 9 countries were new in the data collection, and 24 countries, that missed the second round, participated for the second time since their submission in the first round.

The ability of a country to provide quantitative information reflects its capacity to collect detailed data on antimicrobial agents intended for use in animals. For the first round of data collection, 89 OIE Member Countries reported quantities of antimicrobial agents intended for use in animals (n = 130; 68%). In second round of the data collection, 107 countries (n = 146; 73%) reported quantitative data. In the third round, 118 countries (n = 155; 76%) reported quantitative data, demonstrating growing commitment to development of monitoring systems for veterinary antimicrobial agents (Figure 2).

Figure 2. Number of Countries Participating in All Rounds of the Data Collection

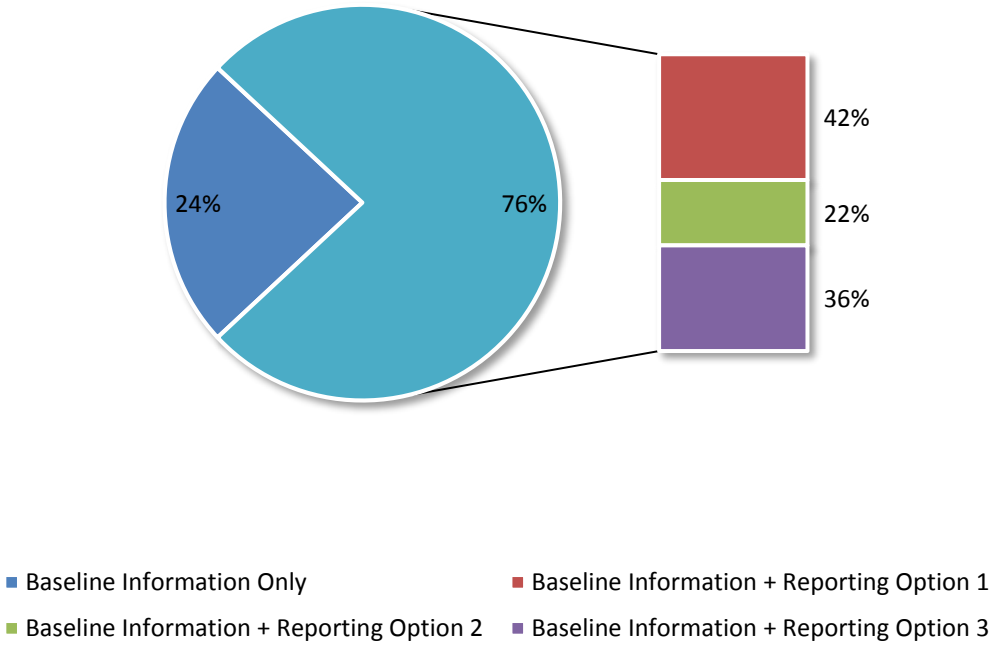


Quantitative data collection (Part C) is further broken down into three sections: 'Reporting Options' 1, 2 and 3, where the actual quantities of antimicrobial agents for use in animals are reported with increasing specificity.

Reporting Option 1 allows countries to distinguish quantities of antimicrobial agents by type of use (veterinary medical use or growth promotion [8]) and this option was chosen most frequently by respondents (50 out of 118 countries). Reporting Option 2 allows countries to distinguish quantities of antimicrobial agents by type of use and animal groups (food-producing terrestrial and aquatic species and companion animals) and was chosen by 26 countries. Finally, Reporting Option 3, which allows countries to distinguish quantities of antimicrobial agents by type of use and routes of administration (distinguishing by group of animals is optional), was chosen by 42 countries (Figure 3).

To see the full OIE template for data collection, see Annex 6.

Figure 3. Reporting Option Used by 155 Countries in the Third Round of Data Collection



Country Barriers to Providing Quantities of Antimicrobial Agents in Animals

Since the second round of data collection, a question was added to the template in order to understand the barriers impeding countries from reporting amounts of antimicrobial agents in animals. This information is useful for guiding discussion on overcoming barriers during training Seminars of Focal Points for Veterinary Products and increasing availability of quantitative data in the future, and reflects challenges in National Action Plan implementation that would also be assessed during the Performance of the Veterinary Services (PVS pathway) evaluation.

In the third round, specific progress was observed from the 38 countries that reported barriers during the second round. Eleven countries passed from reporting only Baseline Information to reporting quantitative data for the first time. Most of these 11 countries had previously reported a lack of cooperation/coordination between national authorities and private sector, and a lack of tools and human resources.

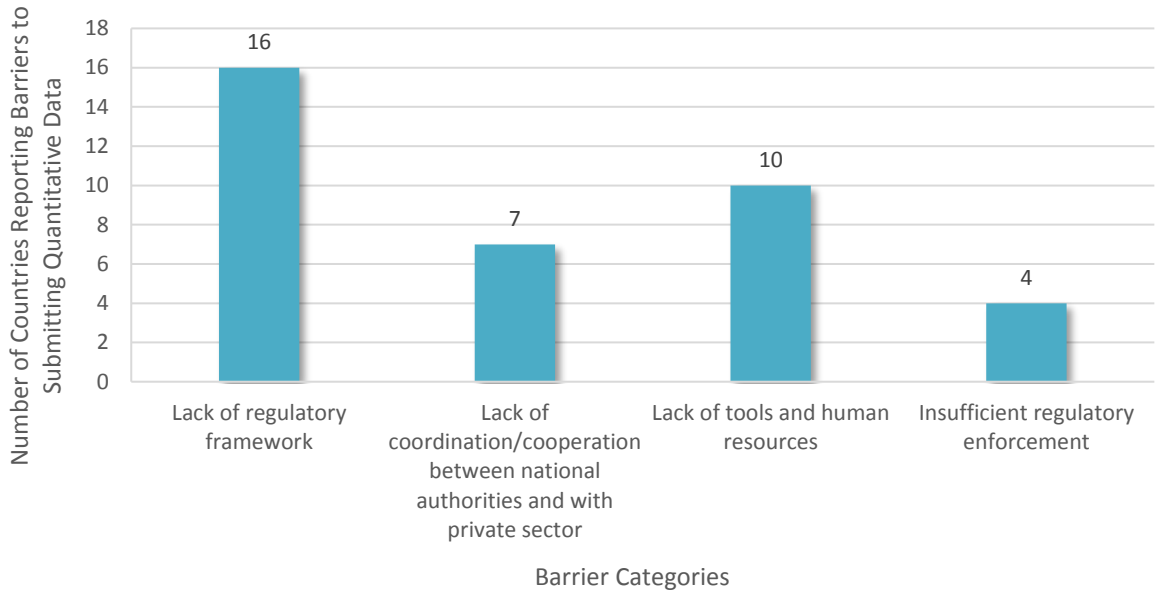
Of the responding countries for the third round, 37 (n = 155; 24%) provided Baseline Information and no quantitative data. Of these, 31 countries (n = 37; 84%) explained their barriers to reporting quantities of antimicrobial agents intended for use in animals to OIE.

The barriers highlighted by responding countries have been grouped into four main categories (Figure 4). Usually, countries reported one barrier. Five countries reported 2 barriers.

Most of the barriers to providing quantitative data on antimicrobial agents intended for use in animals can be grouped into the categories of lack of regulatory framework and lack of tools and human resources. The relative importance of these categories may change when analysing the results on a regional level.

For a description of the barrier grouping categories, see the following explanatory section for each category.

Figure 4. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in 31 Countries in the Third Round of Data Collection



LACK OF REGULATORY FRAMEWORK:
Nine countries indicated that for the years reported, no regulatory framework existed for the manufacture, registration, distribution, commercialisation and pharmacovigilance of veterinary products.

Six countries stated that their legislation did not provide the government with a legal basis for collecting data on antimicrobial agents intended for use in animals. Four countries mentioned that despite relevant legislation, a mechanism for collecting such data did not exist.

Three countries under this category reported that actions to address the lack of legislation on veterinary products and/or the monitoring of antimicrobial agents were planned or already in process:

- One country notified that a lack of a regulatory framework for the manufacture, registration, distribution, commercialisation and pharmacovigilance of veterinary products was already identified and was just recently incorporated into their legislation, this will allow them to report amount of antimicrobials intended for use animals to the OIE, for future rounds.
- One country informed of a plan to work on legislation pertaining to distribution and importation of antimicrobial agents in animals and draft a National Action Plan (NAP) on AMR following a One Health approach. This country also responded to the *Country Progress in the Implementation of the Global Action Plan on Antimicrobial Resistance: WHO, FAO and OIE Global Tripartite Database*[12] (hereafter, *Global Tripartite Database*), stating that the animal health sector (terrestrial and aquatic) are actively involved in developing and implementing the AMR NAP.

[12] http://www.who.int/antimicrobial-resistance/global-action-plan/database/en/

- One country, that during the second round of data collection reported that WHO assisted them to draft a NAP on AMR that included a provision for development of regulations on veterinary drugs, informed that the pertaining legislation is in process of finalisation and enforcement. In addition, it was noted that in the *Global Tripartite Database*, the country reported a level C (National AMR Action Plan developed that addresses human health, animal health and other sectors); while one year earlier, the country reported a level B (National AMR Action Plan under development or plan involves only one sector or Ministry).

LACK OF COORDINATION/COOPERATION BETWEEN NATIONAL AUTHORITIES AND WITH PRIVATE SECTOR:

Within this category, 5 countries reported that the relevant data were held by another national authority, outside of the veterinary or agricultural Competent Authority. For these countries, the OIE requested further information on which agencies were involved on the data collection, 4 countries indicated the quantities of antimicrobial agents intended for use in animals were under the legal authority of the Ministry of Health.

Three countries reported a lack of collaboration and coordination with relevant stakeholders in the country, usually the veterinarians. For these countries, the lack of collaboration with the private sector was reported in addition to a lack of data collection software.

LACK OF TOOLS AND HUMAN RESOURCES:

Eight countries described their main problem in data collection to be that records (mainly imports of veterinary products and the information related to their authorisation) were not yet digitalised. For these countries, the time burden would be too great to calculate kilograms of active ingredients for veterinary products. Four of these countries stated that they were already in the process of developing software or were in an implementation phase, and therefore expected to contribute with quantities of antimicrobials during the fourth round of data collection. Two countries that stated software was the main barrier for reporting the quantities, also mentioned that the Veterinary Services should conduct awareness activities on antimicrobial resistance and prudent use of antimicrobials (mainly for farmers, veterinarians and pharmaceutical industry) in order to allow a good data coverage and data quality.

Two countries were not able to report the antimicrobial quantities, due to lack of dedicated staff within the government for collection and analysis of the data. One of these countries had previously sent antimicrobial quantities, but during the third round of data collection, the Focal Point for Veterinary Products was absent, and the country was only able to send the Baseline Information. Another sent the amounts of antimicrobials in a different template than the one proposed by OIE. This country did not clarify the necessary information to analyse the data (e.g., year, data sources, coverage of data) as the Focal Point for Veterinary Products was absent from the office due to social crisis in the country.

INSUFFICIENT REGULATORY ENFORCEMENT:

Three countries stated that the amount of illegal veterinary products on the market impeded calculation of quantities of antimicrobials agents intended for use in animals. One of these countries explained that the regulatory control and data management of imports of veterinary products is not centralized, and the border points are not well controlled. Two countries mentioned the following barriers to accessing quantitative data: unlicensed manufacturers, unknown wholesalers and retailers and the use of veterinary products by unauthorised persons.

One country explained that the importers do not register and import veterinary products as the market is too small and fall below the minimum quantities for bulk purchases, therefore, human medicines are used for animals. This country also mentioned that veterinarians import small quantities exclusively for use in livestock and poultry, that are difficult to track.

SUMMARY ON BARRIERS:
Most respondents who communicated barriers to the OIE, faced challenges with the structure, harmonisation or enforcement of their regulatory frameworks, especially those pertaining to the manufacture, registration, distribution, commercialisation and use of veterinary products. Development of a robust regulatory framework within these countries should be prioritised to enable monitoring the use of antimicrobial agents in animals. The work of the OIE through the PVS pathway is essential in helping the countries to identify their gaps and to develop stronger legislative and enforcement frameworks.

Another significant barrier was the lack of tools that facilitate the collection and analysis of data, as in some countries the records (mainly imports of veterinary products and the information related to their authorisation) were not yet digitalised. Half of these countries confirmed that they are already in discussion to develop such a tool in order to provide the data in future OIE data collections.

Antimicrobial Agents Used for Growth Promotion

During the 2016 OIE General Session, Member Countries adopted Resolution No36, "Combating Antimicrobial Resistance through a One Health Approach: Actions and OIE Strategy" agreeing to the recommendation that:

> 5. OIE Member Countries fulfil their commitment under the Global Action Plan to implement policies on the use of antimicrobials in terrestrial and aquatic animals, respecting OIE intergovernmental standards and guidelines on the use of critically important antimicrobial agents, and the phasing out of the use of antibiotics for growth promotion in the absence of risk analysis. [3]

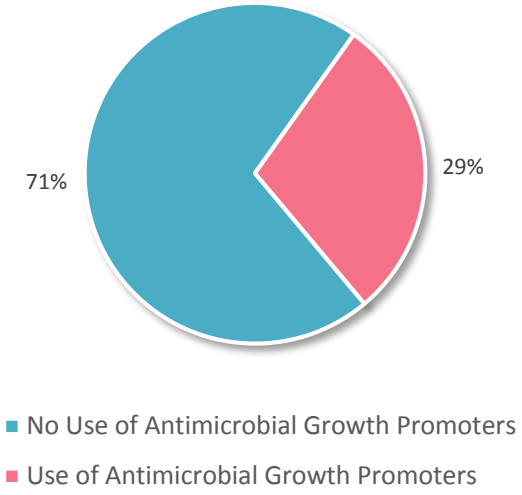
During the second round of data collection, where country responses to the question of the authorisation of antimicrobials as growth promoters had changed from the previous year without explanation, further clarifications were requested. This follow-up indicated that the question as phrased in the OIE questionnaire was being interpreted differently by different responding countries, and from year to year. To improve understanding, for the third round of data collection, this question was reworded to obtain clearer results on both legislation and use of antimicrobial agents as growth promoters.

The Baseline Information section of the OIE template includes a question for countries to report any antimicrobial agent authorised or used in animals as growth promoters. Ionophores were excluded for reporting as they are mostly used for parasite control and have different regulatory classifications in different countries; however, 14 countries report the use of these molecules as growth promoters where monensin and halquinol were mentioned by 8 countries.

In this third round of data collection, a total of 110 (n = 155; 71%) responding countries did not use any antimicrobial agents for growth promotion in animals in their countries, either with or without legislation or regulations. For further explanation on the legislation, please refer to the following explanatory section. The 45 remaining countries (n = 155; 29%) reported use of antimicrobials for growth promotion. (Figure 5a).

The results of the third round compared to previous rounds, show an apparent increase in countries that do not use antimicrobial agents as growth promoters. *However, as in the third round the questions related to growth promoters changed, the results depicted in Figure 5a should be interpreted with caution when comparing with previous rounds.*

Figure 5a. Use of Antimicrobial Growth Promoters in 155 Countries in 2017



REGULATORY FRAMEWORK FOR ANTIMICROBIAL AGENTS USED AS GROWTH PROMOTERS

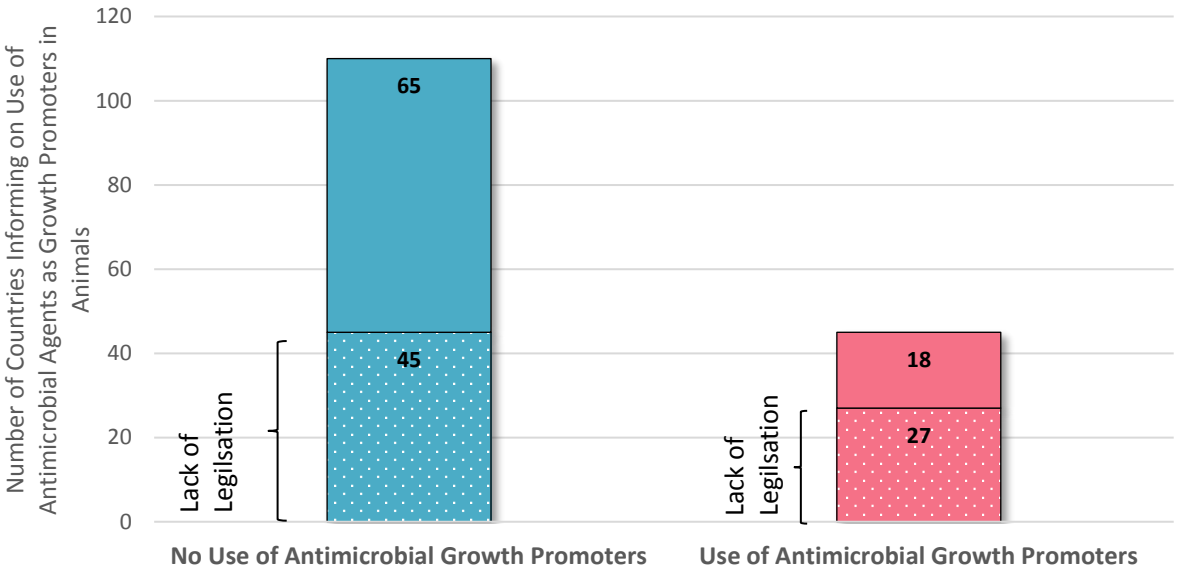
In the template and guidance sent for the third round, all countries, regardless of their response to the question relating to use or not of antimicrobial growth promoters, were asked to respond to the following question: *Does your country have legislation/regulations on the use of antimicrobial growth promoters in animals?*

All 45 countries that answered 'Yes' to this question were then asked to indicate which type of legislation/regulations exists in the country. In most of the cases, when legislation/regulations exist in a country, the regulatory framework bans the use of antimicrobials as growth promoters (Figure 5b).

As presented in Figure 5a, 45 countries stated no use of antimicrobials as growth promoters even though no regulatory framework exists. In some cases (n = 6), the countries stated that these molecules are banned without a regulatory framework; therefore, the OIE asked these countries to provide further information on how antimicrobial growth promoters are banned in the absence of legislation or regulations. The following situations were mentioned:

- The country's legislation is being amended to ban growth promoters. Meanwhile, the following approaches are being taken to guarantee that these products are not available in the market: to not allow their import; to monitor the manufacture companies to only produce antibiotics for veterinary medical use; and to not allow their registration. The latter approach was recommended in one country by its Ministry of Health and in another by its Registration Committee.
- The country's legislation has a list of banned drugs that do not explicitly cover growth promoters. However, the Director General of the Veterinary Services has taken the decision to not allow these types of products. The decision has made it compulsory to comply by all stakeholders.

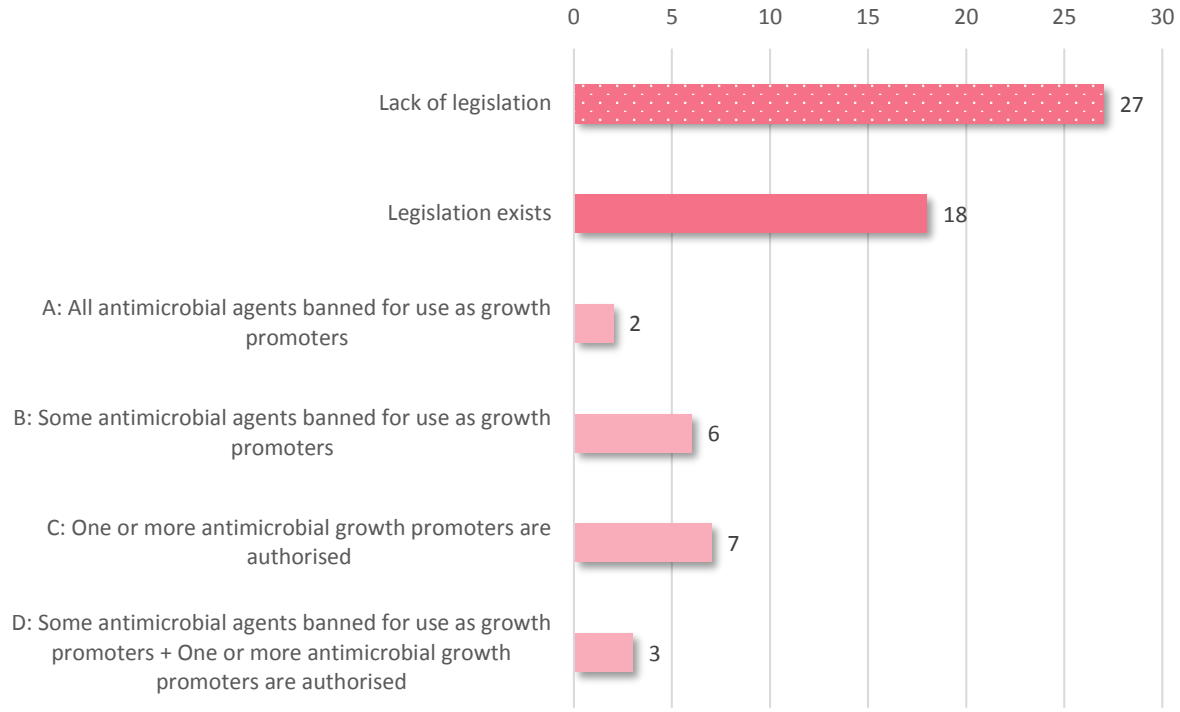
Figure 5b. Use of Antimicrobial Growth Promoters by Legislation, in 155 Countries in 2017



Most (27) of the countries reporting the use of antimicrobials as growth promoters do not have a regulatory framework (n = 45; 60%). Among this group, two countries mentioned that they are working with pharmaceutical companies to voluntarily remove growth promotion claims from the labels of all products that are considered to be Medically Important Antimicrobials in human medicine. One of these countries mentioned that this requirement comes into force in December 2018. Both countries mentioned their success in this collaborative approach with the private sector.

For those countries (18) using antimicrobials as growth promoters with a regulatory framework (n = 45; 40%), the legislation is either providing a list of antimicrobials that can be used as growth promoters (n = 7) or providing a list of molecules that should not be used as growth promoters (n = 6), while in some cases both type of lists are being established (n = 3). It was found that two countries with legislations that ban growth promoters reported the use of these molecules in the field (Figure 6), indicating that implementation of the legislation in these two countries is needed. One of these countries informed the OIE that the following molecules, labelled for veterinary medical purposes, are being used as growth promoters by poultry farmers: oxytetracycline, colistin and erythromycin.

Figure 6. Type of Legislation for Growth Promotion in 45 Countries that Reported the Use of Growth Promoters in 2017



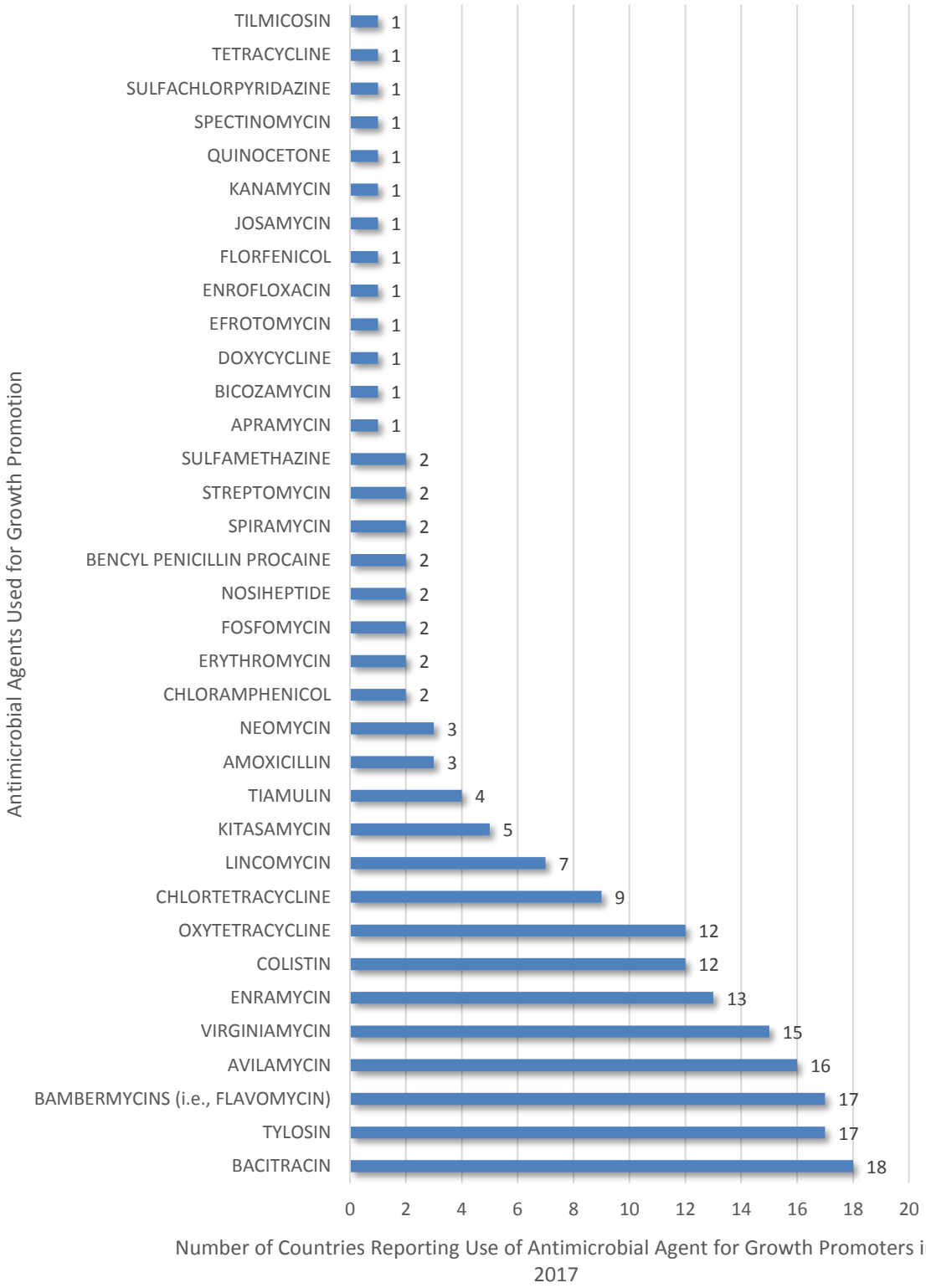
LIST OF ANTIMICROBIAL AGENTS USED FOR GROWTH PROMOTION

The 45 countries reporting use of antimicrobial agents for growth promotion were further asked for a list of antimicrobial agents (by active ingredient) either authorised as growth promoters, or known to be used in cases where legislation on this issue did not exist.

Thirty countries (n = 45; 67%) responded with a list of antimicrobial agents used for growth promotion. The most frequently listed antimicrobial agents for this purpose were bacitracin and tylosin, classified as Veterinary Highly Important Antimicrobial Agent and Veterinary Critically Important Antimicrobial Agent respectively, according to the *OIE List of Antimicrobial Agents of Veterinary Importance.* Colistin was mentioned by 12 countries (Figure 7). Eight of these countries informed that their legislation concerning growth promoters will change within the next months or year; by the time this report was published, 3 countries will have already banned colistin for growth promotion and 2 countries will have banned all growth promoters.

Three countries provided antimicrobial classes rather than active ingredients used for growth promotion, and so were not included in the analysis for Figure 7. Analysis at a regional level by antimicrobial class is presented in the annexes by OIE Region (Annexes 1 – 5). One country that provided a list of molecules authorised as growth promoters had also provided a list of antimicrobial classes that are used in the field without authorisation.

Figure 7. Antimicrobial Agents Used for Growth Promotion in Animals in 30 Countries in 2017



Thirty countries using antimicrobial agents as growth promoters (n = 45; 67%) also provided quantitative data on antimicrobial agents intended for use in animals. Fourteen of these countries (n = 30; 47%) could distinguish these quantities by use for growth promotion and veterinary medical purposes.

3.2. Antimicrobial Quantities

Using one of the three 'Reporting Option' sections of the data collection template, countries can report national quantities of antimicrobial agents intended for use in animals. In a 2012 OIE questionnaire on Member Country engagement in the issue of AMR[13], 23 Member Countries provided quantitative data to the OIE. For the first round of data collection, from October 2015 to May 2016, 89 Member Countries provided quantitative data.

In this third round of data collection, the number of countries reporting quantitative data increased to 118, covering any calendar year between 2015 and 2017.

Years of Quantitative Data Reported

Table 2. Breakdown of Country Response Types in Third Round of Data Collection

Number of countries that responded to the OIE questionnaire	155
Number of countries that provided quantities of antimicrobial agents	118
Number of countries that provided quantitative data for only one year between 2015 and 2017	112
Number of countries that provided quantitative data for more than one year between 2015 and 2017	6

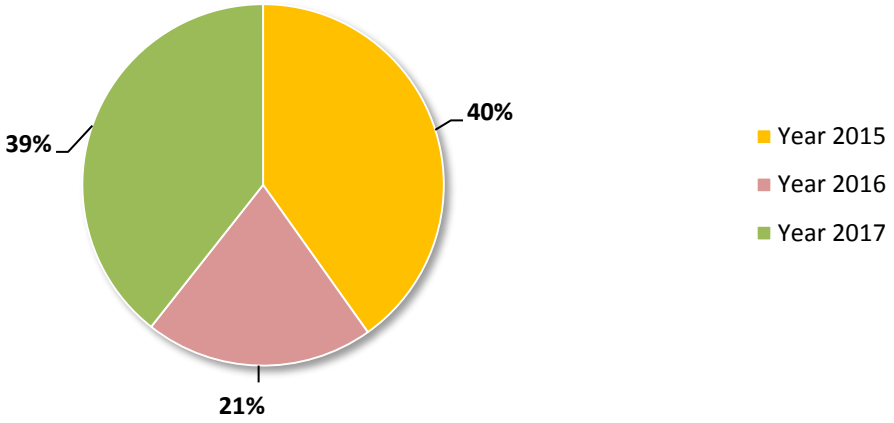
For this third round of data collection, countries were requested to provide quantitative data for 2015, but data were accepted for 2016 and 2017. The OIE also accepted multiple submissions from any country who wished to provide data for more than one year.

Most countries providing quantitative data (112 out of 118; 95%) submitted data for only one year between 2015 and 2017. Six countries submitted quantitative data for more than one year within this timeframe. Given these multiple submissions, 127 responses were provided by 118 countries (Table 2) in the third round of data collection.

Fifty-one responses, mainly from Europe, (n = 127; 40%) provided data for 2015 during the third round of data collection (Figure 8). Analysis at a regional level by years is presented in annexes by OIE Region (Annexes 1 – 5).

[13] See introduction for background on the 2012 Questionnaire

Figure 8. Years of Quantitative Data Reported in Third Round of Data Collection, from 127 Responses Provided by 118 Countries



The following analysis describes the results from the 118 countries that provided quantitative data during the third round of data collection, covering any year between 2015 and 2017.

Period of Time Covered

In the third round of data collection, countries were asked to specify the length of the calendar year covered by their data (e.g., 1 January to 31 December). This question was added in the second round as some countries informed during the first round that their quantitative data only covered a certain number of days.

A response to the question on time period was provided by 114 countries (n = 118; 97%) reporting quantities of antimicrobials intended for use in animals. Globally, the average time period covered was 350 days; this information shows that most countries are providing quantitative data for most of a calendar year.

Quantitative Data Sources Captured

The OIE data collection template includes an exhaustive list of possible quantitative data sources, in accordance with Chapter 6.9 of the *Terrestrial Animal Health Code* (Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals) and with Chapter 6.3 of the *Aquatic Animal Health Code* (Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals). Multiple choices were possible in responding to this question, including the option 'other'.

All countries' data sources were analysed, and all countries where the data duplication was considered to be a risk were then asked for clarification of their answers and/or data collection systems. After the clarifications, 94 countries (n = 118; 80%) changed their answers or proved there was no duplication or overlapping data sources. The remaining countries (24 out of 118; 20%) that did not provide clarification to the OIE were excluded from Figure 9.

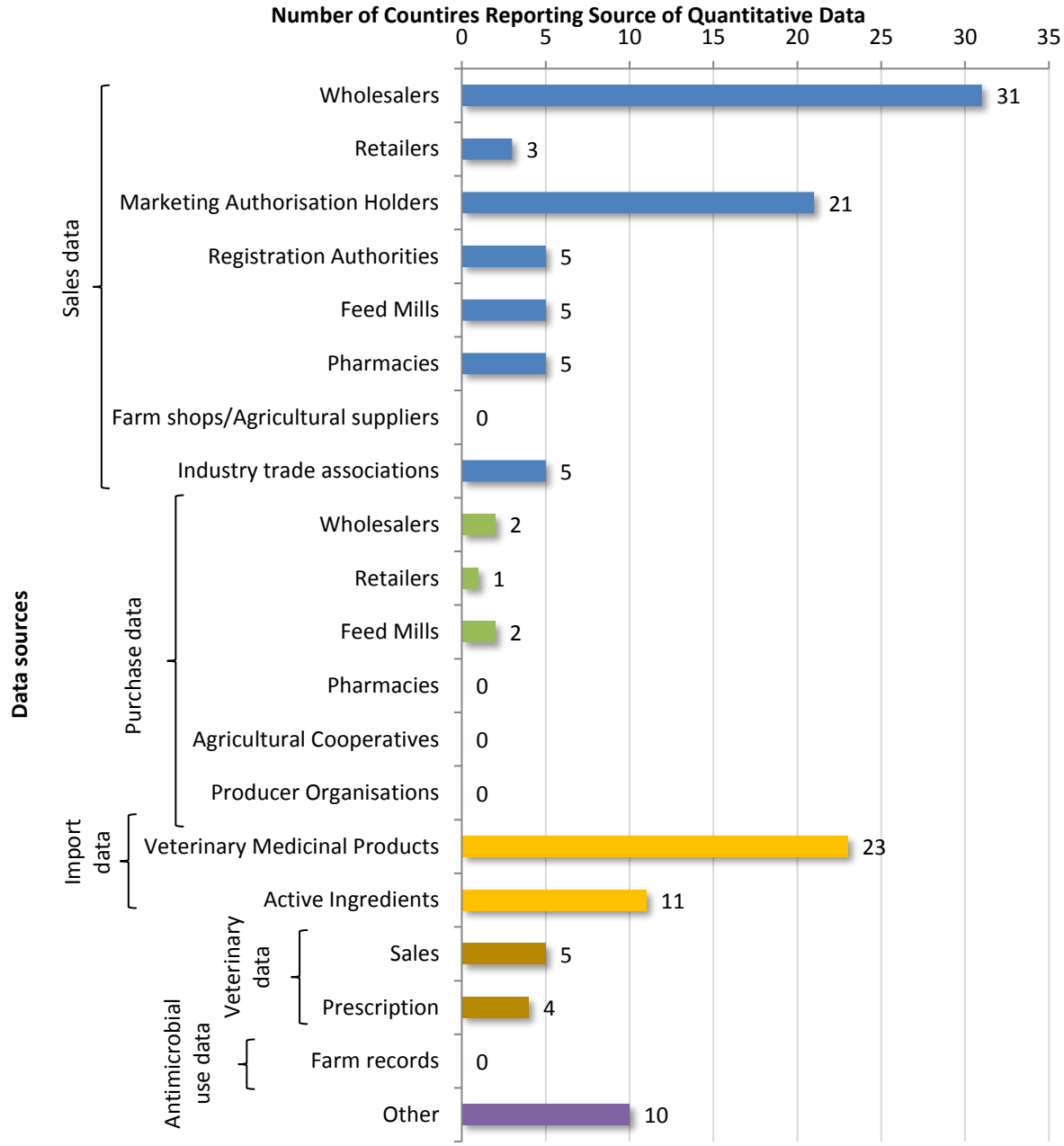
In the Guidance for Completing the OIE template for the Collection of Data, countries were asked to provide data from as close to the point of use (i.e., administration) as possible. However, among the 94 countries that reported quantitative data with no risk of doubling on the data sources, 'Antimicrobial use data – Farm records' – the category representing on-farm administration of

antibiotics – was not selected as a data source (Figure 9). All other data sources represent use through what was sold, imported or manufactured for intended administration to animals.

Sources of quantitative data were most commonly sales data, particularly of wholesalers and Marketing Authorisation Holders, which were selected by 31 and 21 countries respectively. Following sales data, import data as declared by custom authorities was the next most common source of reported quantities of antimicrobial agents intended for use in animals.

For a full explanation of quantitative data sources, see the Guidance for Completing the OIE template for the Collection of Data (Annex 7).

Figure 9. Validated Data Sources Selected by 94 Countries Reporting Quantitative Data from 2015 to 2017

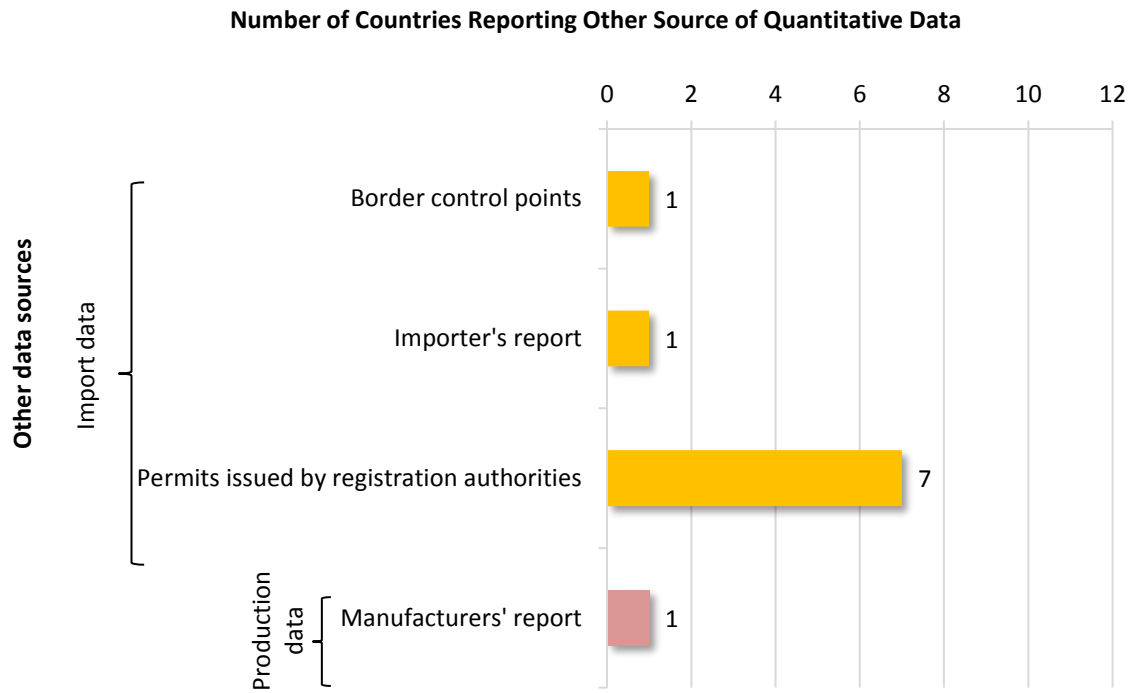


OTHER DATA SOURCES REPORTED

Ten countries (n = 94; 11%) reported 'other' sources of quantitative data from the provided options. When this response was selected, countries were asked to describe these other data sources. The responses were grouped by category.

Other sources of quantitative data most commonly reported were from other levels of import control outside of customs declarations, particularly from permits authorising importation of antimicrobials as issued by registration authorities (Figure 10). In some countries where the importation of a product is not confirmed after issue of a permit, these quantities may not represent antimicrobial agents actually entering the country and used in the animal population.

Figure 10. 'Other' Source of Data Described by 10 Countries Reporting Quantitative Data from 2015 to 2017



Quantitative Data Sources Not Captured

Countries were asked to estimate the extent to which their data represented overall sales of antimicrobial agents intended for use in animals, as a percentage of the total sales in their country. This question was responded by 117 countries (n = 118; 99%) that provided quantitative data.

As a global average, quantitative data coverage achieved was 85%. This average quantitative data coverage shows that in a number of countries, surveillance systems do not capture the totality of antimicrobial agents intended for use in animals. *However, this figure should be interpreted with caution, as data coverage estimations are made subjectively by each country.* By definition, this question aims to identify quantitative data that is inaccessible, and therefore the responses can vary in accuracy.

SOURCES NOT CAPTURED BY THE DATA

The 69 countries that did not cover 100% of available quantitative data (n = 117; 59%) were asked to provide further information on uncaptured data sources.

Sixty-four countries (n = 69, 94%) responded with an explanation on uncaptured data sources. Responses were grouped by category. All countries' uncaptured data sources were analysed and, if needed, further asked on their data collection systems. After the analysis, the uncaptured data sources were validated for 40 countries (n = 64; 62%). The remaining countries (24 out of 64, 38%) were excluded from this analysis. Countries could have reported more than one uncaptured data sources.

Most of the uncaptured data sources derive from sales data not provided, particularly those of industry stakeholders that did not respond to government requests for information. Lack of import data was also a significant contributor, reported by 15 countries.

Table 3 describes the quantitative data coverage lost due to lack of access to data sources, as estimated by 40 countries. This question allows countries to self-report which type of data they were unable to access, and what percentage of total possible available data was estimated to be lost due to this inaccessibility. For countries naming an uncaptured data source, the mean, minimum and maximum reported estimates of related coverage lost are shown. The information in Table 3 highlights which data sources countries consider necessary in order to provide complete coverage. However, these categories may not be relevant in all countries.

Table 3. Estimation of Quantitative Data Not Captured Based on Lack of Access to Sources, as Reported by 40 Countries in the Third Round of Data Collection

Sources Estimated Not Captured in Quantitative Data	Number of Countries Naming Uncaptured Data Source	Estimated Data Coverage Lost		
		Mean	Minimum	Maximum
Sales Data				
Partial response from relevant stakeholders	7	50%	20%	95%
Illegal or unofficial veterinary products	6	26%	10%	40%
Antibiotics authorised for humans that are used in companion animals	4	4%	1%	10%
Veterinary products with special license*	2	3%	1%	5%
Medicated feed	2	1%	1%	1%
From veterinarians	1	15%	15%	15%
Not all antimicrobial classes were included	1	40%	40%	40%
Companion animals	1	15%	15%	15%
Import Data				
Illegal or unofficial veterinary products	10	27%	5%	70%
From Ministry of Health or human pharmacies	4	33%	5%	70%
Veterinary Products with special license*	3	14%	10%	18%
Partial data, not from a whole calendar year	2	19%	8%	30%
Companion and zoo animals	1	2%	2%	2%
Production Data				
Manufacturer's report	1	15%	15%	15%

* For the purpose of this report, 'Veterinary products with special license' means: veterinary products for self-supply, donation or with special permission from the government

Quantitative Data Differentiation by Animal Groups

For the purposes of the OIE survey, animal groups are separated into: 'Terrestrial food-producing animals', 'Aquatic food-producing animals' and 'Companion animals'. Multiple choices were possible in responding to this question.

During the second round of data collection, 43% of countries could differentiate the amount of antimicrobial between the animal groups. An increase is noted in the third round, where 55 countries (n = 118; 47%) provided data differentiated between group of animals (Figure 11), this corresponds with the increase of countries reporting their antimicrobial quantities through Reporting Option 2 and 3.

Figure 12 shows that more countries were able to report data for food-producing animals than for companion animals. Usually, countries used more than one animal group to report their antimicrobial quantities.

Most of the data come from sales and imports, and the attribution of antimicrobial quantities by animal group is based on species types represented on product labels, where this is available and specified. For countries where product labels cover a wide variety of species, it would be more difficult to report quantitative data differentiated by animal group.

Figure 11. Differentiation by Animal Groups Among 118 Countries Reporting Quantitative Data from 2015 to 2017

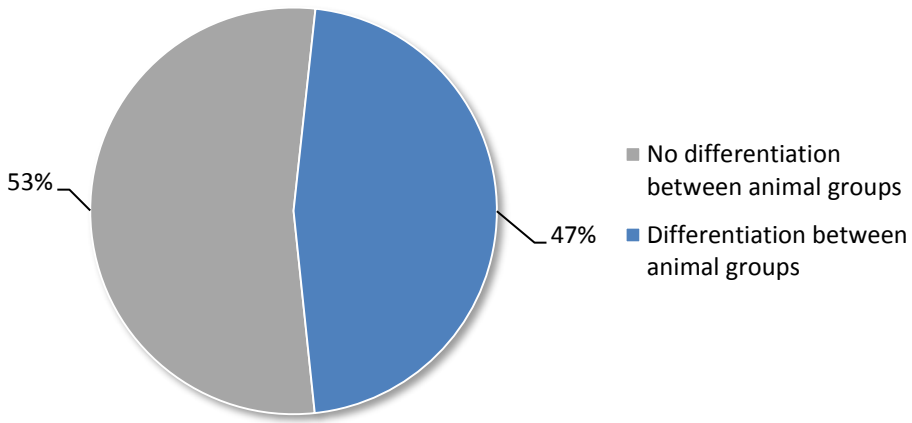
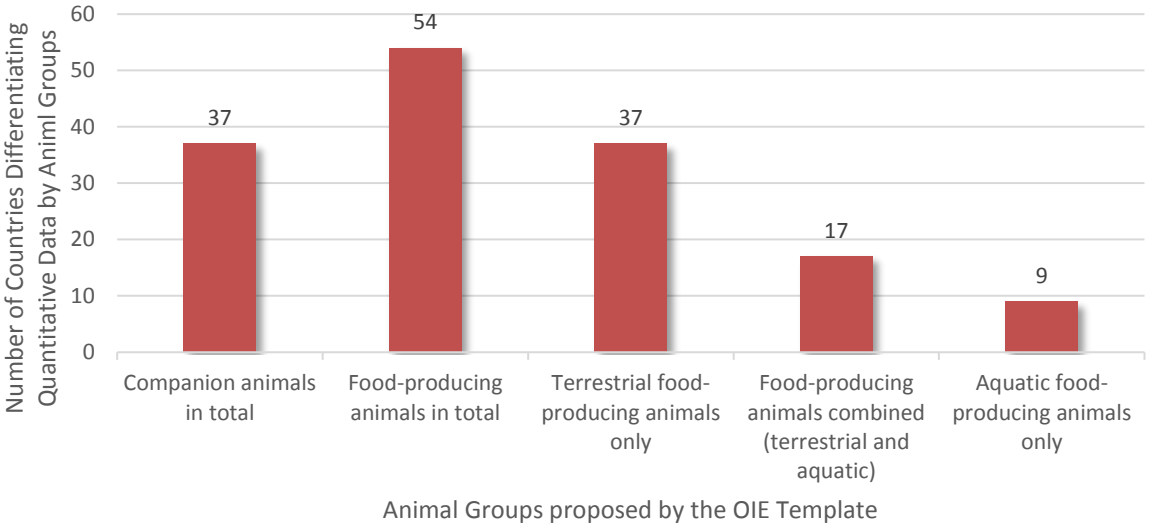


Figure 12. Representation of Quantitative Data from 55 Countries Able to Distinguish by Animal Group from 2015 to 2017



Sixty-three countries of those reporting quantitative data (n = 118; 53%) were not able to distinguish amounts of antimicrobial agents by groups of animals. Of these, most (50 out of 63; 79%) reported antimicrobial quantities through Reporting Option 1, which allows reporting for all animal species, and distinguishes quantities only by purpose of use (veterinary medical use or growth promotion [8]). Thirteen of these countries (n = 63; 21%) used Reporting Option 3, which allows for distinction by type of use, animal groups and route of administration, but provided data only separated by type of use and/or route of administration. This suggests that the labelling of veterinary products in these countries clearly separates out the routes of administration, but may cover a wide variety of species.

Nine countries (of 62 countries reporting that aquatic animals were covered by the data 15%) were able to report quantitative data for 'Aquatic food-producing animals' separately from other animal groups using mainly Reporting Option 3 (7 out of 9; 78%).

Food-Producing Animal Species Covered by Quantitative Data

Animal species produced for food varies between countries. Understanding these differences between countries is necessary for planning analysis of reported antimicrobial quantities adjusted for animal biomass (see section 4).

The 118 countries that provided quantitative data were asked to pick the food producing animal species covered by their data from a supplied list in the OIE template. The breakdown of food producing species included in the reporting countries datasets is shown in Figure 13.

For descriptive purposes, species from the list of options provided in the OIE template were grouped according to the following categories:

A. POULTRY
- *a.* Layers – commercial production for eggs
- *b.* Broilers – commercial productions for meat
- *c.* Other commercial poultry
- *d.* Poultry – backyard

B. BOVINES
- *a.* Cattle
- *b.* Buffaloes (not *Syncerus caffer*)

C. SHEEP AND GOATS

a. Sheep
b. Goats
c. Sheep and goats (mixed flocks)

D. PIGS

a. Pigs – commercial
b. Pigs – backyard

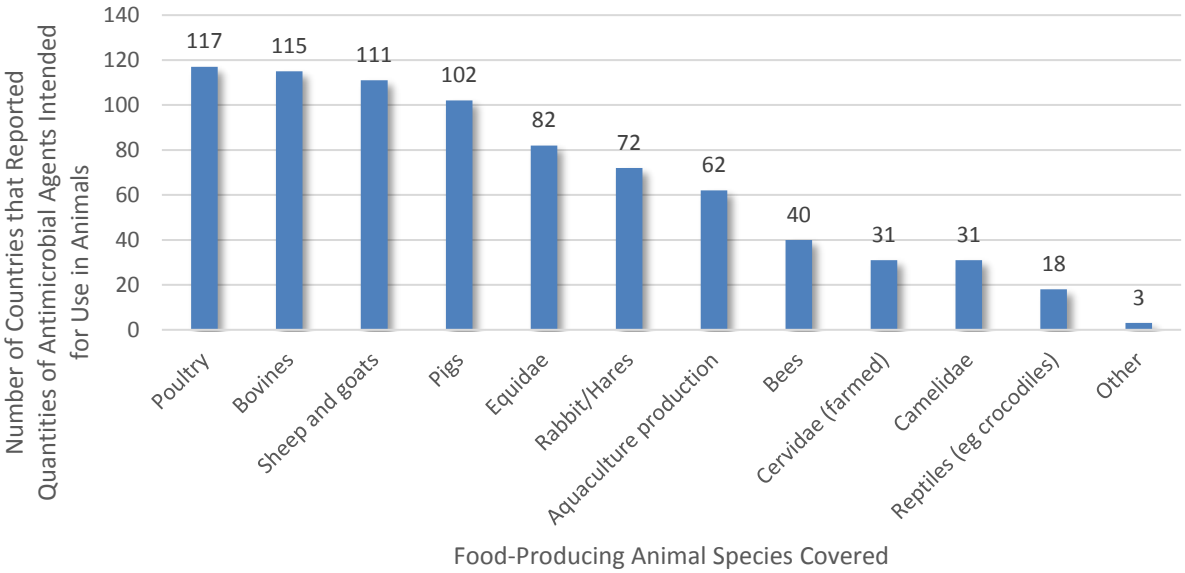
E. AQUACULTURE PRODUCTION

a. Fish – aquaculture production
b. Crustaceans – aquaculture production
c. Mollusc – aquaculture production
d. Amphibians

One country that provided data for companion animals only was excluded from Figure 13.

In the third round of data collection, poultry was mentioned by all 117 countries reporting quantitative data for food-producing species. Bovines, sheep and goats, and pigs were also included by most countries (Figure 13).

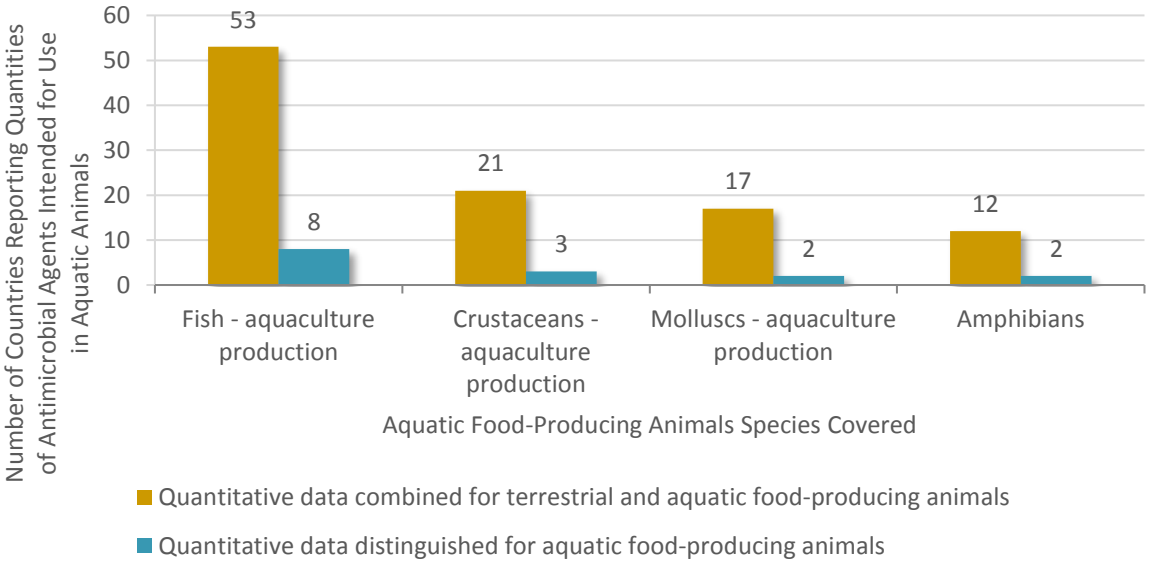
Figure 13. Food-Producing Animal Species Included in Quantitative Data Reported by 117 Countries from 2015 to 2017



In most cases, quantitative data for aquaculture represents farmed fish. For the 62 countries that provided amounts of antimicrobial agents for 'Aquatic food-producing animals', quantities for 'Crustaceans – aquaculture production', 'Molluscs – aquaculture production' and 'Amphibians' are reported mainly when data for 'Fish – aquaculture production' were also available. Figure 14 highlights the aquatic food-producing species covered by countries reporting quantitative data, separated by capacity to distinguish data for terrestrial and aquatic food-producing animals.

Globally, 9 countries were able to distinguish quantitative data specifically for 'Aquatic food-producing animals', and 4 of these 9 countries were from Europe.

Figure 14. Aquatic Food-Producing Animal Species Included in Quantitative Data Reported by 62 Countries from 2015 to 2017

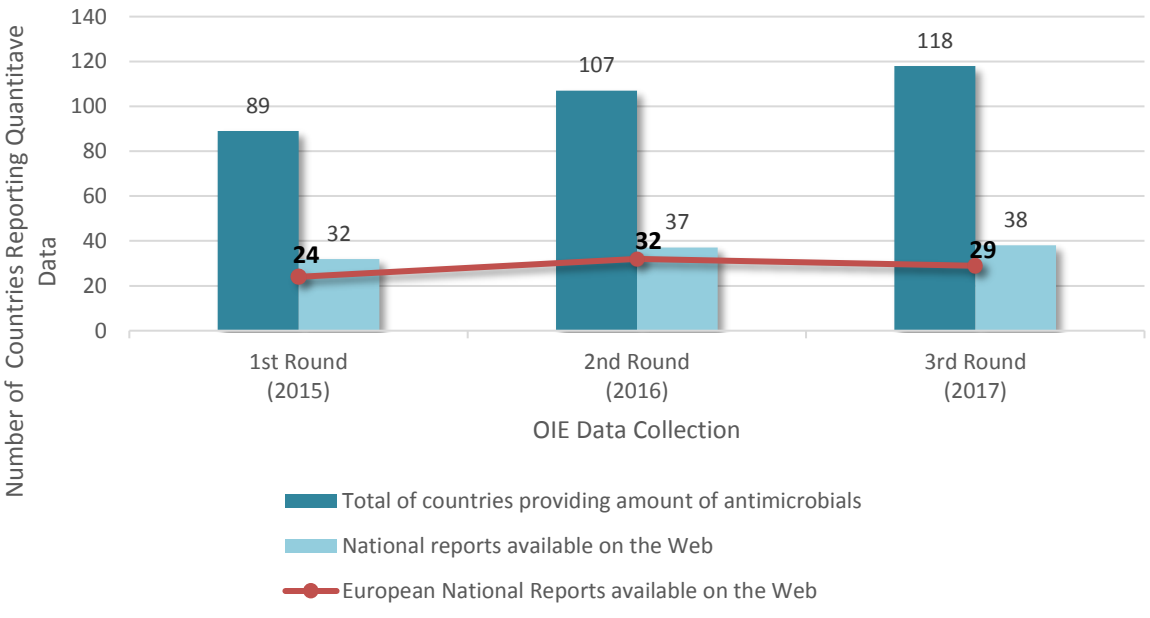


National Reports Available Online

In the OIE template, countries were asked if a national report for the antimicrobial agents used in animals was available on the Web. In the third round of data collection, 83 countries (n = 118; 70%) did not publish national reports on quantities of antimicrobial agents used in animals online, Europe is the only region where more than 50% of countries' national reports are available on the Web (Figure 15).

The OIE encourages all Member Countries to publish their own national reports on the sales or use of antimicrobial agents in animals, to ensure transparency and to assess trends.

Figure 15. Number of Countries Participating in All Rounds of the OIE Data Collection with National Reports Available on the Web



Routes of Administration

During the third round of data collection, 42 countries chose to report their quantitative data through Reporting Option 3, the only option which allows for distinction of the data by route of administration. Among these 42 countries, a majority reported higher amounts of antimicrobial agents used via oral route.

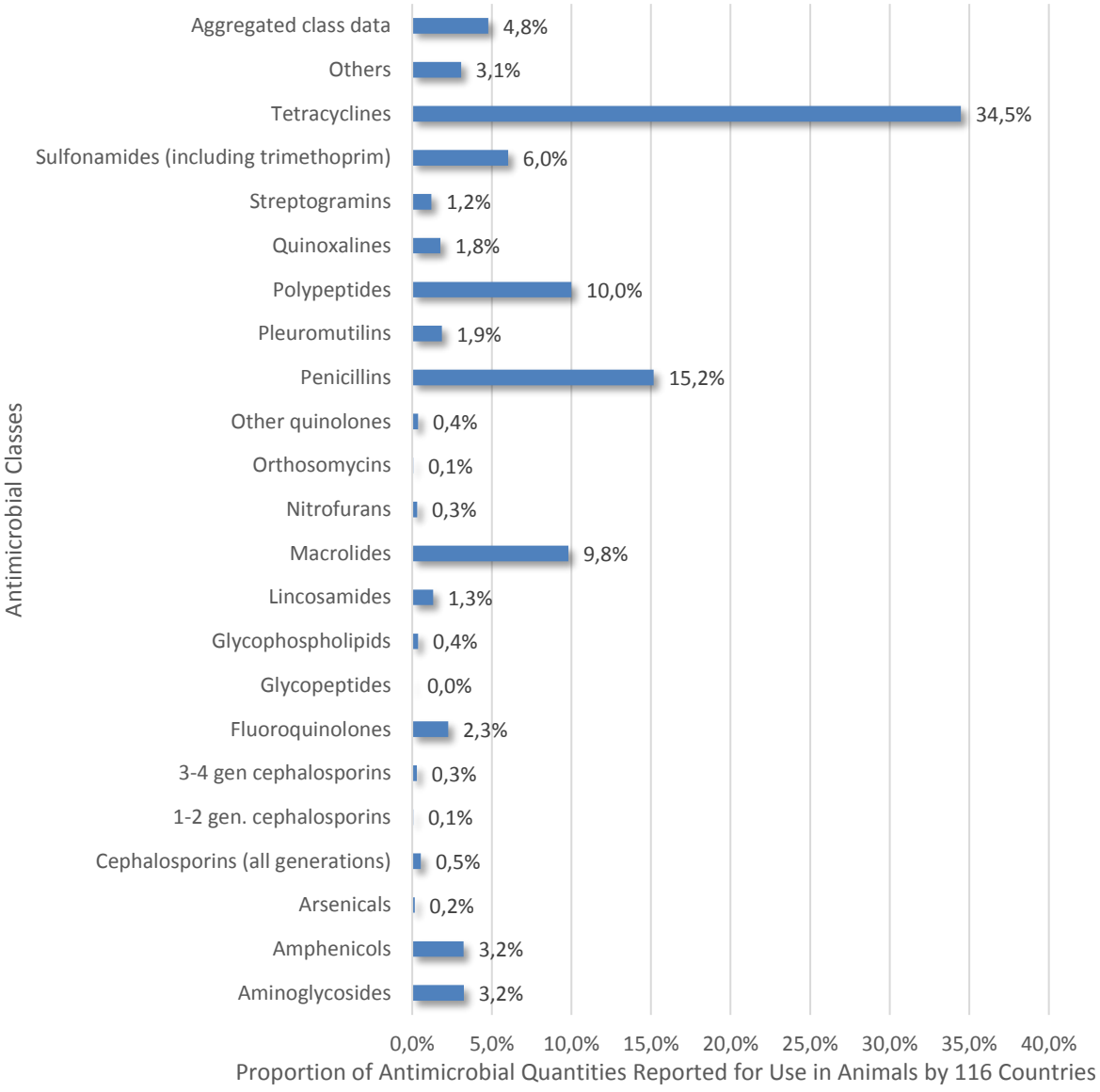
Reporting Option 3 allows for distinction of the data by type of use (veterinary medical use vs growth promotion [8]) and animal groups in addition to route of administration. However, 13 countries (n = 42; 31%) using this option distinguished data only by type of use and route of administration, indicating that they were not able to identify which animal groups the agents were being used in. Of the 29 countries (n = 42; 69%) able to distinguish quantitative data by animal groups using Reporting Option 3, injection administration was most commonly reported for use in terrestrial food-producing animals. In aquatic food-producing animals and companion animals, oral administration was reported more commonly.

Antimicrobial Classes Reported

During the third round, 118 countries provided quantitative data on antimicrobial agents intended for use in animals. However, two countries were excluded from Figure 16 as their data were excessively large and could not be explained.

Among the 116 countries providing quantitative data, tetracyclines were the most commonly reported antimicrobial class (Figure 16).

Figure 16. Proportion of Antimicrobial Quantities (by Antimicrobial Class) Reported for Use in Animals During the Third Round by 116[14] Countries from 2015 to 2017



Some countries reported quantities of antimicrobial agents differentiated by group of animals using Reporting Options 2 or 3. Among these countries, tetracyclines were the most commonly reported antimicrobial class used in terrestrial food-producing animals (Figure 17a). Penicillins were more commonly reported for companion animals, and amphenicols for aquatic food-producing animals (Figure 17b and 17c).

[14] Two Countries that reported extremely high figures were excluded from this analysis

Figure 17a. Proportion of Antimicrobial Classes by Terrestrial Food-producing Animals as Reported by 33 Countries during the Third Round from 2015 to 2017

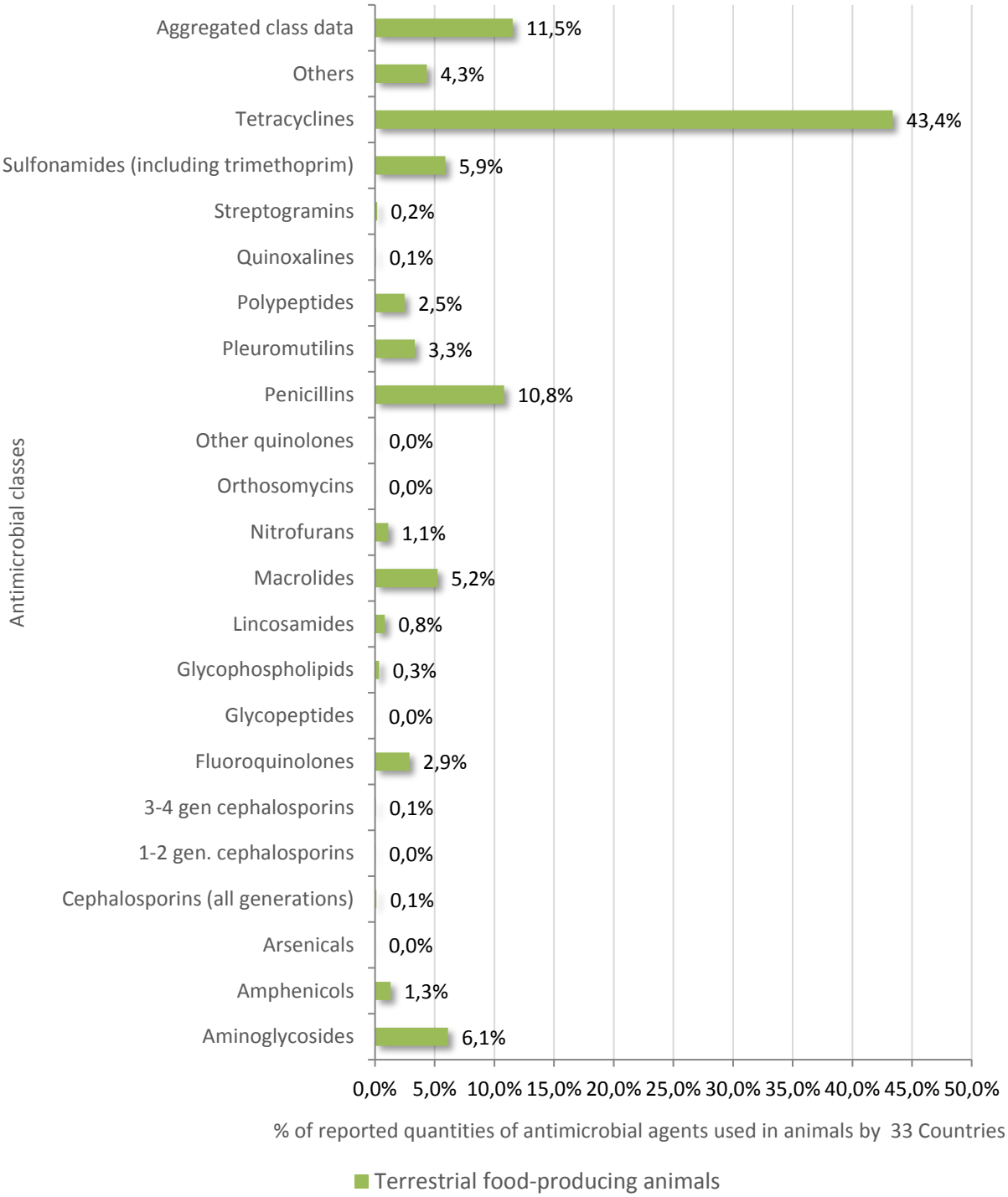


Figure 17b. Proportion of Antimicrobial Classes by Aquatic Food-producing Animals as Reported by 9 Countries during the Third Round from 2015 to 2017

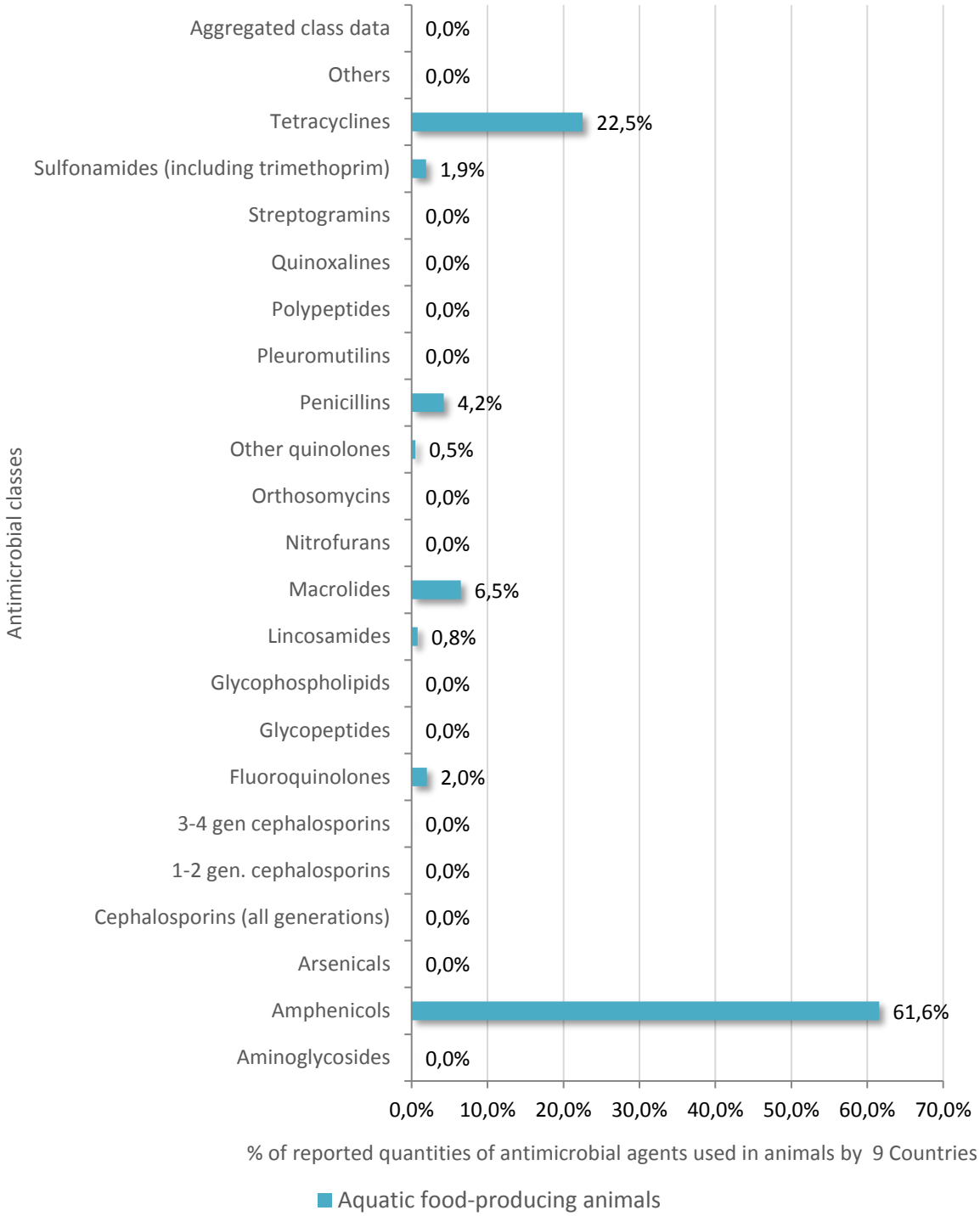
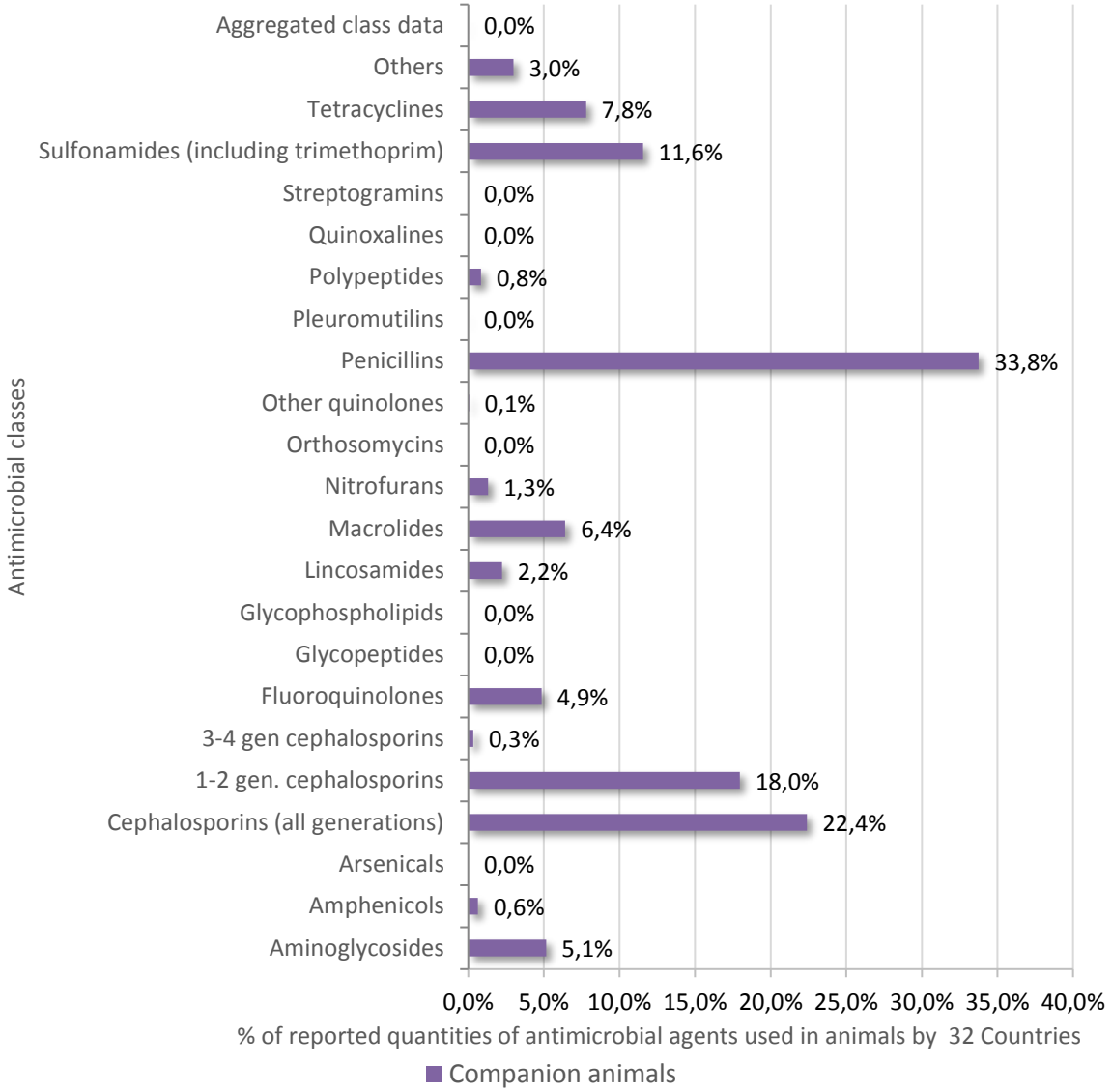


Figure 17c. Proportion of Antimicrobial Classes by Companion Animals as Reported by 32 Countries during the Third Round from 2015 to 2017



HIGH USE OF ANTIMICROBIAL CLASSES

During the third round of Data Collection, it was noticed that 15 countries (n = 118; 14%) allocated more than 70% of their total amount of antimicrobials intended for use in animals in one antimicrobial class (Table 4). Eleven of these countries (n = 15; 69%) were from Africa.

The 15 countries reporting more than 70% of their amounts for one antimicrobial class were further asked to explain any known reason for the high levels of use for a single antimicrobial class. Four countries (n = 15; 27%) responded. Two countries reporting high levels of use for tetracyclines explained that traditionally this class has been the most available and accessible on the market (several brands and formulations), in addition to its low cost; one of these countries mentioned that among the tetracyclines' class, oxytetracycline is the most used. A third country also reporting high use for tetracyclines, mentioned that this class is available over-the-counter, the main reason for the high sales on this class. One country explained that the high levels of use for the 'Other quinolones' class could be attributed to the use of these products in poultry production.

Table 4. Antimicrobial Classes with More than 70% of the Total Amount of Antimicrobials Intended for Use in Animals, by 15 Countries During the Third Round of Data Collection

Antimicrobial Class	Number of Countries with High Levels of Use in a Specific Antimicrobial Class	Antimicrobial Quantities Allocated in the Antimicrobial Class (Tonnes)	Use of the antimicrobial class compared to the total amount reported (%)		
			Mean	Minimum	Maximum
Aminoglycosides	1	15	82.42%	82.42%	82.42%
Other quinolones	1	344	85.34%	85.34%	85.34%
Penicillins	3	35	81.98%	70.81%	95.49%
Tetracyclines	10	15 181	83.74%	71.22%	99.88%

3.3. Analysis by OIE Region

The OIE considers its country membership within five regions: Africa; the Americas; Asia, Far East and Oceania; Europe; and the Middle East. The data collection template was sent to all OIE Member Countries in all OIE Regions. In addition, the template was sent to selected non-OIE Member Countries that, since the second round of data collection, asked to be part of the survey. The list of all OIE Member Countries is provided in Annex 9.

In the third round of data collection, from October 2017 to May 2018, 155 countries submitted completed reports to the OIE Headquarters: 153 from OIE Member Countries (n = 181; 85%) and 2 non-OIE Member Countries (Table 5). The proportion of responses received from the different OIE Regions varies from 58% to 94% (Figure 18). Responses from non-OIE Member Countries were included in the analysis of the Americas for geographical reasons.

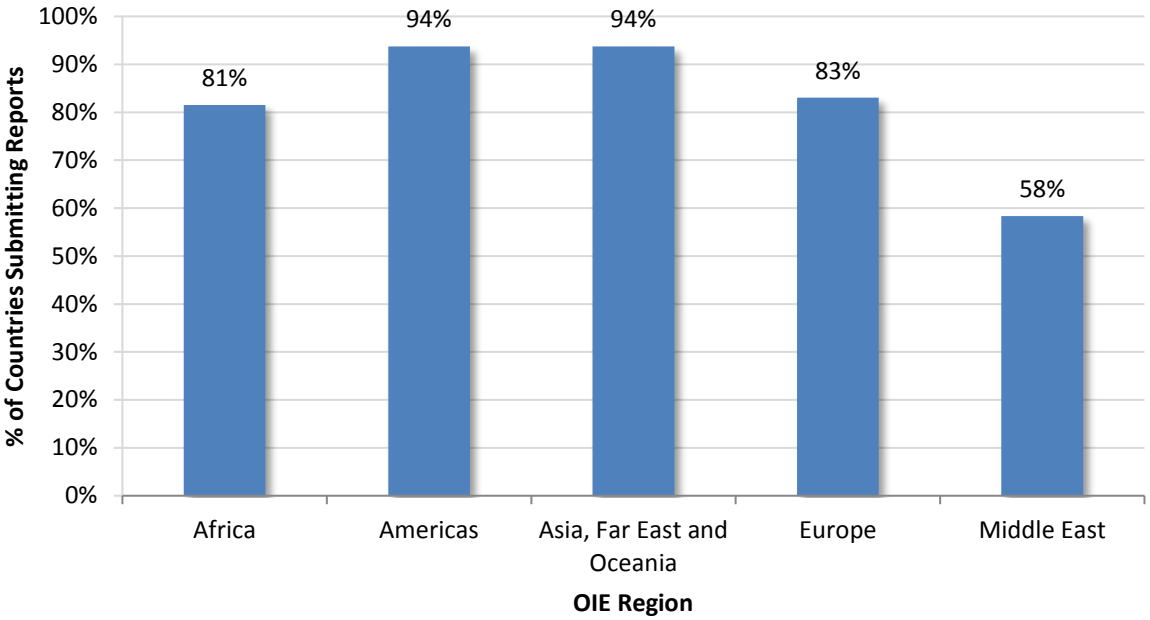
For specific information for the OIE Region, refer to the Annex for each region (Annexes 1-5).

Table 5. Number of Countries that Responded to the OIE Survey in the Third Round of Data Collection, by OIE Region

OIE Region	Number of Countries that Submitted Reports by OIE Region	Number of OIE Member Countries*
Africa	44	54
Americas**		
Member Countries	28	30
Non-OIE Member Countries	2	n/a
Asia, Far East and Oceania	30	32
Europe	44	53
Middle East	7	12

* *Distribution of countries by OIE Region is done according to the OIE Note de Service 2010/22 – Annex 9*
** *Due to geographic distribution, non-OIE Member Countries were included in the Americas*

Figure 18. Percentage of Countries that Responded to the OIE Survey in the Third Round of Data Collection, by OIE Region



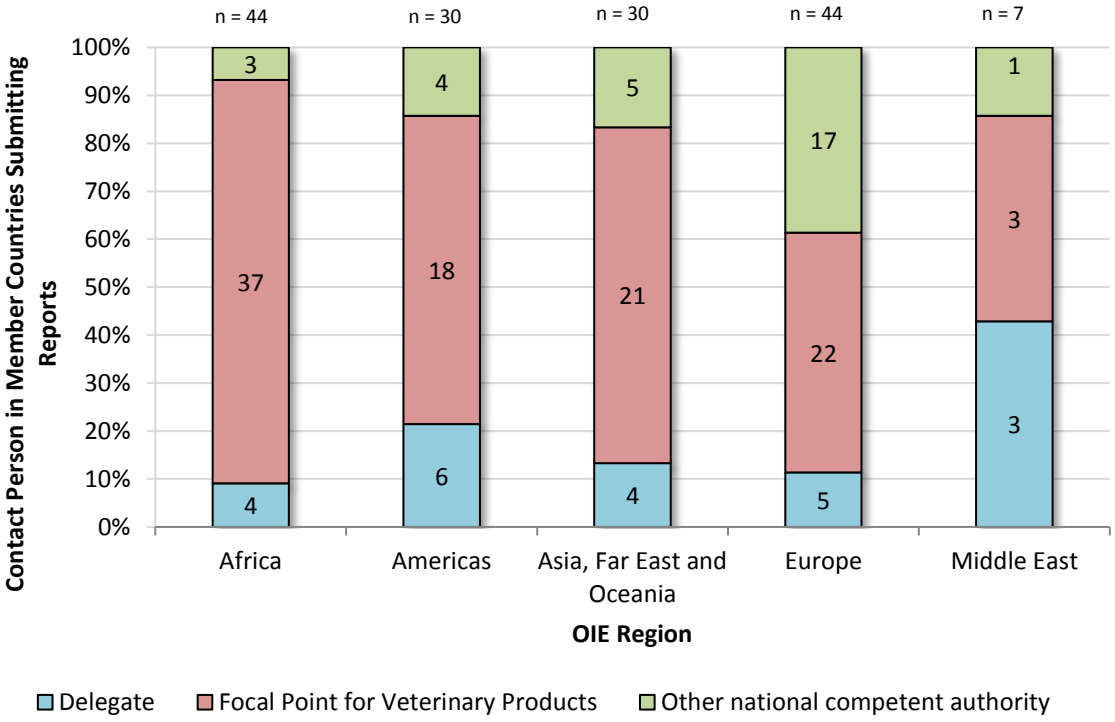
Profile of the Contact Person

Each OIE Member Country must designate a Delegate; most commonly the person selected leads the country's official Veterinary Services. In the 76th General Session, held in May 2008, the World Assembly determined that OIE Delegates should also nominate National Focal Points to assist them in their work on specific topics. Of these, the designated National Focal Points for Veterinary Products are responsible for any information relating to veterinary medical products in the country. Since 2008, the OIE has been training and supporting the Focal Points for Veterinary Products through regional or sub-regional seminars.

Given that OIE Delegates and National Focal Points only exist in OIE Member Countries, the following analysis on contact persons does not include non-OIE Member Countries.

The OIE recognises the efforts of National Focal Points for Veterinary Products, as in most Member Countries, the National Focal Point for Veterinary Products was responsible for completion of the template. However, in Europe the Focal Points were less often responsible for responding to the survey, with another national competent authority supplying the data. This result may be linked to differing levels of progress in development of data collection systems, where a specific person may already be dedicated to this topic (Figure 19).

Figure 19. Regional Proportion of Contact Person of 153 Member Countries that Submitted the Response to the OIE Survey in the Third Round of Data Collection



Reporting Options

When differentiated by OIE Region, more Member Countries from Europe provided quantitative data than other OIE Regions and systematically chose a more advanced Reporting Option to do so (Figures 20 and 21). Most countries in the European Union already have a detailed system in place for data collection on antimicrobial agents intended for use in animals. These data are reported to the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project that was launched by the European Medicines Agency in September 2009.

When compared with the second round of data collection, it was noted that the number of Member Countries providing quantitative data from Africa and Asia, Far East and Oceania increased 15% and 32%, respectively.

Of the European Member Countries reporting quantitative data, 25 countries did so through Reporting Option 3 (n = 38; 66%), which allows distinction by routes of administration in addition to animal groups and type of use. However, 8 countries (n = 25; 32%) did not distinguish quantitative data by animal group and instead reported under ‘All animal species’.

Figure 20. Data Type Provided by 155 Countries Responding to the OIE survey in the Third Round of Data Collection, by OIE Region

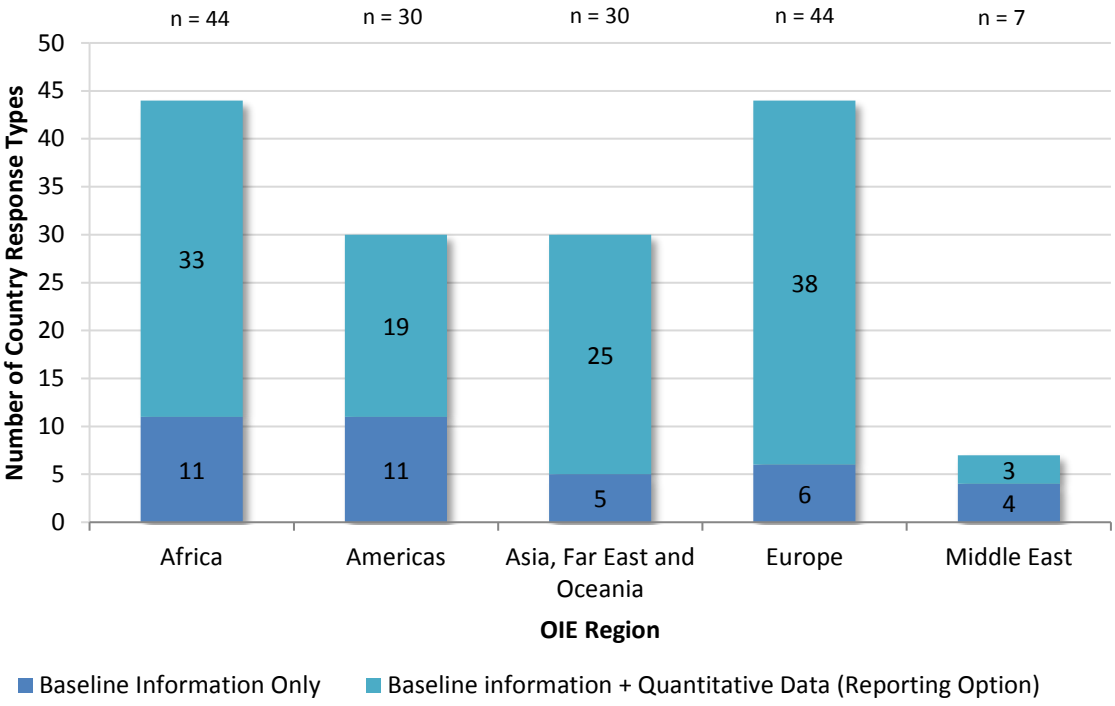
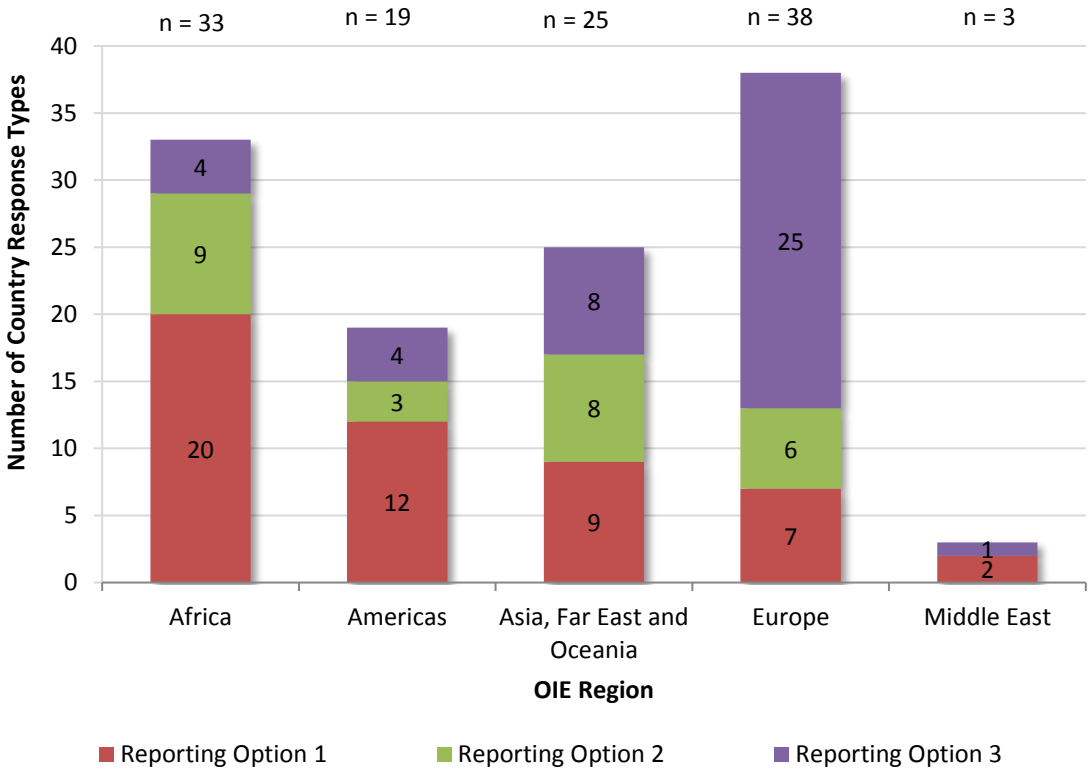


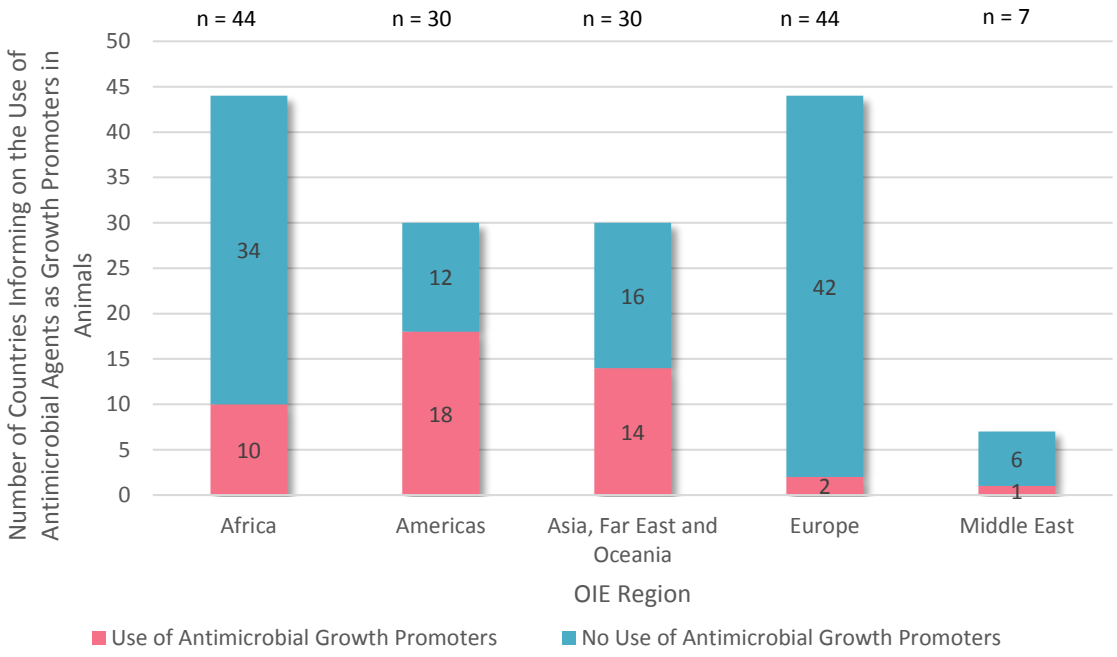
Figure 21. Reporting Option Used to Provide Quantitative Data by 118 Countries in the Third Round of Data Collection, by OIE Region



Antimicrobial Agents Used for Growth Promotion

When differentiated by OIE Region, the Americas and Asia, Far East and Oceania have the highest proportions of countries using antimicrobial growth promoters (Figure 22). Europe has been working on this issue for many years and this is reflected in the responses provided, where Europe is one of the regions with the lowest percentage of the use and authorisation of antimicrobial growth promoters.

Figure 22. Number of Countries Using Antimicrobial Agents for Growth Promotion in Animals in 2017, of 155 Responding Countries, by OIE Region



LACK OF REGULATORY FRAMEWORK FOR ANTIMICROBIALS USED AS GROWTH PROMOTERS

Forty-five countries reported the use of antimicrobial agents for growth promotion. Of these, 27 countries (n = 45; 60%) did not have a regulatory framework.

Among these 27 countries, a regulatory framework for use of antimicrobial agents as growth promoters was found to be lacking in the following numbers of countries reporting use of antimicrobials for growth promotion in the OIE Regions: 7 in Africa (n = 10; 70%), 13 in the Americas (n= 18; 72%) and 7 in Asia, Far East and Oceania (n = 14; 50%). In the Americas, 2 countries without a regulatory framework mentioned their cooperative work with the pharmaceutical companies for voluntary removal of growth promotion claims from the labels of all products that are considered to be Medically Important Antimicrobials in human medicine. Both countries mentioned their success in this collaborative approach with the private sector. All countries in Europe and the Middle East (n= 2 and n = 1, respectively) using antimicrobial agents as growth promoters have a regulatory framework for the use of these molecules. Based on these results, countries in the Americas frequently reported that a regulatory framework on antimicrobial growth promoters was lacking.

For more information on this question, refer to the sub-section relevant to growth promoters in Section 3.1, Global Analysis.

4. Focus on 2015: Additional Analysis of Antimicrobial Quantities

This section provides an additional analysis of globally reported quantitative data on antimicrobial agents intended for use in animals adjusted by animal biomass, focusing on 2015.

This analysis has been done with the understanding that many countries contributing to the OIE database are in the first stages of development of their national monitoring systems on antimicrobial use in animals. Even for those countries able to provide quantitative information, some data resources may be currently inaccessible, and calculation errors, where present, are still being resolved. Simultaneously, data collection on animal populations is also progressing on a global level. *It is expected that these first estimates will be refined over time, and therefore, should be interpreted with caution.*

4.1. Antimicrobial Quantities

Corrections Made to 2014 Data

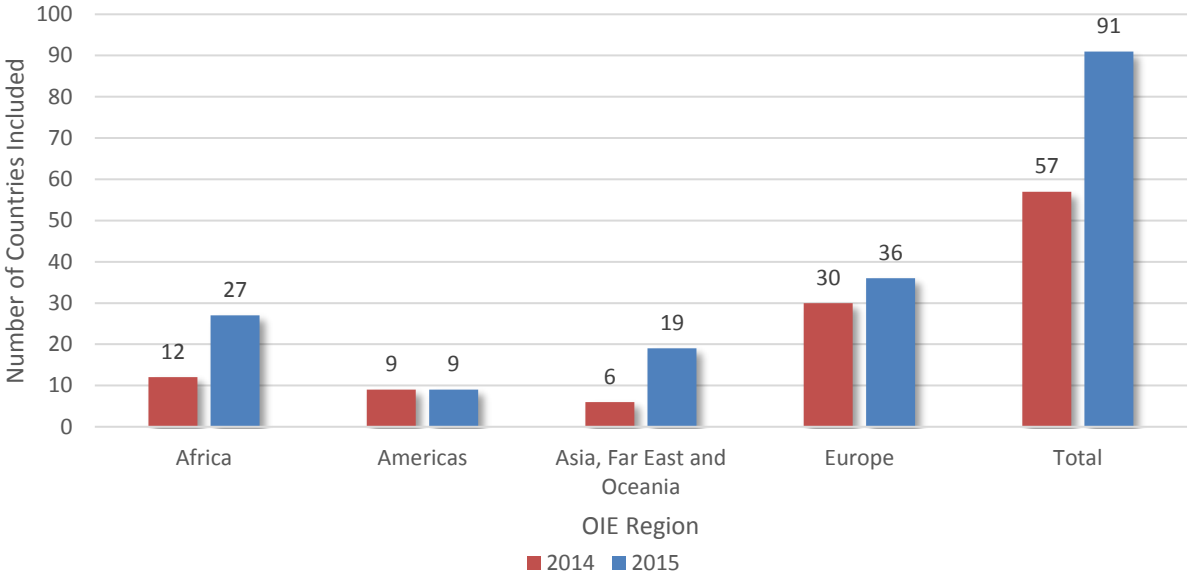
Throughout this section, 2015 results are compared to the results of the 2014 analysis. The 2014 data were updated based on new information and corrections reported by Member Countries in the third round, and therefore may differ from the results of the previous report.

Corrections to previous antimicrobial quantitative data included recalculations due to discovered errors, additions of previously inaccessible data, and corrections of the calendar year covered by the data. Some countries where errors in 2014 calculations were discovered were retroactively removed from the 2014 analysis pending validation. Additionally, as explained in the methodology section, all 2014 animal biomass figures were recalculated given currently available slaughter data. All analysis for 2014 included in this report reflects the most current information.

Regional Representation of Countries Included in 2015 Analysis

For all 3 rounds compiled, 91 countries provided validated quantitative data on antimicrobial agents intended for use in animals for 2015. The regional distribution of countries included in the 2015 analysis is shown in Figure 23. Due to geographic considerations, one non-OIE Member Country providing quantitative data for 2015 was included in the Americas for the 2015 analysis.

Figure 23. Number of Countries Included in 2015 Analysis by OIE Region



A lack of validated data from the Middle East did not allow for the inclusion of this OIE Region in the 2015 analysis. Future data submissions from this OIE Region may permit a 2015 analysis of antimicrobial quantities adjusted by animal biomass in following reports.

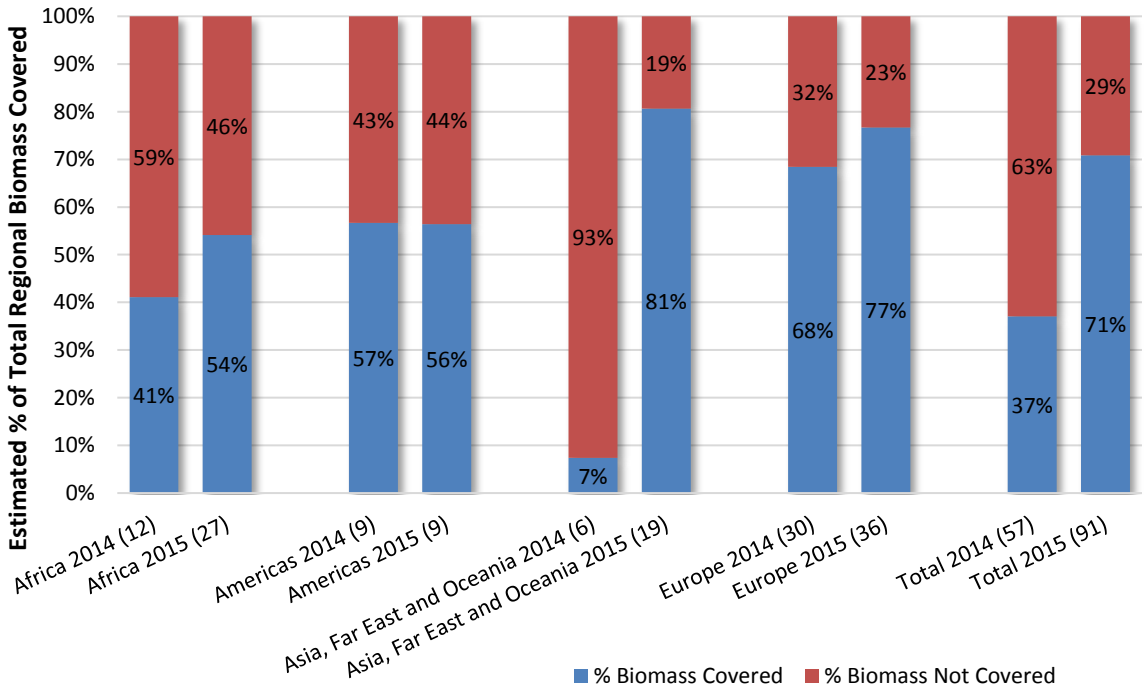
Animal Population Covered by 2015 Data

Figure 24 shows the estimated percentage of the total regional animal biomass covered by the 91 countries included in the analysis of antimicrobial quantities for 2015, compared to the coverage achieved in the 2014 analysis. These estimates were made by calculating the ratio of FAOSTAT meat production figures for the reporting countries relative to the regional total. The number of countries in each OIE Region contributing to this coverage is also included.

Asia, Far East and Oceania and Europe had particularly high animal population coverage for 2015, with responding countries representing approximately 81% and 77% of the regions' total animal biomass respectively. These figures show a significantly increased contribution relative to 2014, particularly for Asia, Far East and Oceania. Africa's coverage also increased to 54%. Coverage in the Americas was stable at 56%.

From the 91 countries included in the 2015 analysis, the estimated coverage of total animal biomass from the four OIE Regions is 71%, almost doubling the 2014 coverage (37%).

Figure 24. Estimated Percentage of Total Regional Biomass Covered by Countries Reporting Quantitative Data for 2014 and 2015

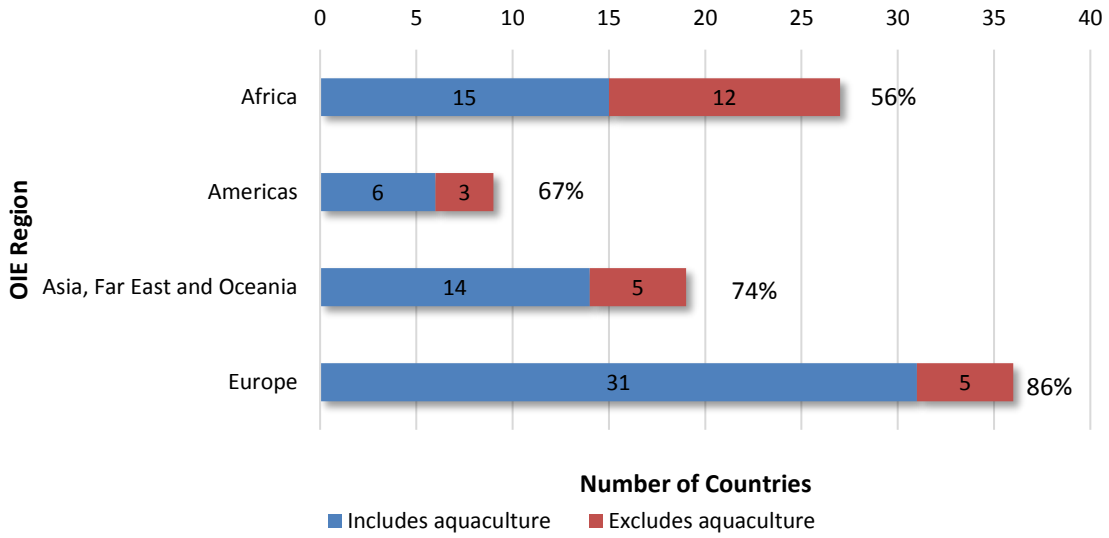


Animal Groups Covered by Data in 2015

Of the countries providing quantitative data for 2015, 66 countries (n = 91; 73%) reported that in addition to terrestrial animals, their data covered aquatic food-producing animal species or could not be distinguished by animal group.

As shown in Figure 25, the highest proportion of countries including aquatic food-producing animals in the reported quantitative data on antimicrobial agents was in Europe (86%; 31 of 36 countries). Seventy-four percent of countries in Asia, Far East and Oceania (14/19), 67% of countries in the Americas (6/9), and 56% of countries in Africa (15/27) reported quantitative data that included aquatic food-producing animal species.

Figure 25. Countries Including Aquatic Food-Producing Animal Species in Quantitative Data for 2015



Tonnage of Antimicrobial Quantities Reported In 2015

Table 6 shows the total tonnage of antimicrobial agents intended for use in animals for 2015, as reported to the OIE during the first three rounds of data collection.

In the OIE template for quantitative data collection, countries are also asked to estimate the extent to which their data represented overall sales of antimicrobial agents intended for use in animals, as a percentage of the total estimated sales in their country. For example, a hypothetical country may report that the quantitative data reported covers only 80% of all estimated national sales of antimicrobial agents used in animals based on known sources of lacking data.

When the antimicrobial quantities reported were adjusted for these coverage estimates, the quantities as shown in Table 6 were obtained. *These coverage-adjusted figures should be interpreted with caution, as data coverage estimations are made subjectively by each country.* By definition, this question aims to identify quantitative data that is inaccessible, and therefore the responses can vary in accuracy. However, these coverage-adjusted quantities can be considered an upper level estimate of antimicrobial use in animals.

In order to properly interpret tonnage of antimicrobials reported, the size and composition of each country's animal populations must be considered. For this reason, we refer the reader to Section 4.3, Antimicrobial Quantities Adjusted for Animal Biomass, to interpret differences in regional quantities of antimicrobial agents intended for use in animals.

These regional totals are only representative of the quantities of antimicrobial agents intended for use in the animals for the animal biomass covered in each OIE Region (shown below in %). *They should not be considered representative of the total amounts of antimicrobials consumed in any OIE Region, or in any particular country.*

Table 6. Reported Quantity of Antimicrobial Agents Intended for Use in Animals by OIE Region, 2015

OIE Region	Number of Countries Included in Analysis of 2015 Quantitative Data	% of Total Estimated Biomass Covered	Quantities Reported (in tonnes)	Quantities Reported Adjusted by Estimated Coverage* (in tonnes)
Africa	27	54%	3,067	3,674
Americas	9	56%	14,600	15,108
Asia, Far East and Oceania	19	81%	75,820	76,530
Europe	36	77%	9,013	9,467
Total	91	71%	102,500	104,779

* *Estimated coverage: this refers to the subjective estimates countries made with respect to the extent to which their data represented overall sales of antimicrobial agents intended for use in animals. In this column the figure was adjusted to represent 100% of the total estimated amount (as further explained in Section 3.2).*

4.2. Animal Biomass

As described in the methodology, animal biomass was calculated for 91 countries providing quantitative data for 2015 during the first three rounds of data collection. Farmed fish were included in the biomass for countries reporting that their data covered aquaculture, or could not be distinguished by animal group (n = 66; 65%)

The following figures represent only those countries participating in reporting of quantitative data on antimicrobial agents intended for use in animals, and should not be considered representative of global animal populations or biomass, or for any particular OIE Region.

Animal Biomass Covered by the 2015 Additional Analysis: Global View

Table 7 shows the animal biomass (in 1,000 tonnes) of farmed animals covered by 2015 quantitative data, as reported to the OIE during the cumulating information obtained in all 3 rounds of the data collection.

The figures reported in this table reflect the number of countries providing quantitative data, the relative size and average weights of their animal populations in 2015.

Table 7. Animal Biomass Covered by Quantitative Data Reported to the OIE for 2015 Obtained by the Accumulation of Information from All 3 Rounds of Data Collection, Results for 91 Countries

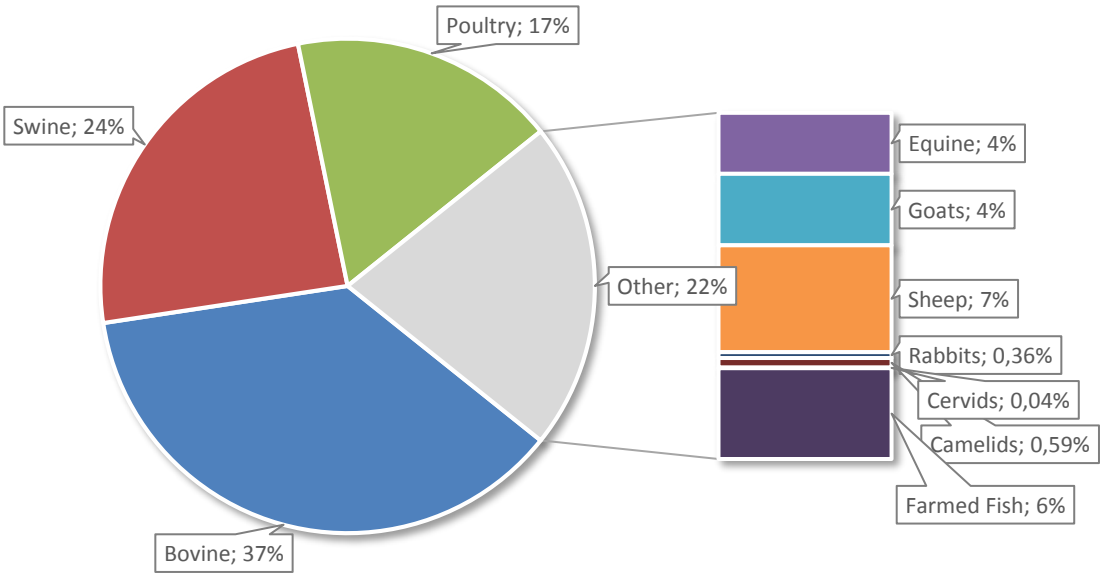
Animal species	Biomass (in 1,000 tonnes)	Percent of Results for 91 Countries
Bovine	224,169	37%
Swine	147,052	24%
Poultry	106,317	17%
Equine	23,020	4%
Goats	26,986	4%
Sheep	40,317	7%
Rabbits	2,218	0.36%
Camelids	3,606	0.59%
Cervids	236	0.04%
Farmed Fish	34,267	6%
All Species	608,188	100%

Figure 26 shows the global species composition of animals at risk for exposure to the antimicrobial quantities reported to the OIE for 2015. These percentages are a function of animal populations in the reporting countries, as well as their average weights.

Across the four OIE Regions covered by the analysis, bovines (37%) make up the largest contribution to animal biomass for the quantitative data reported. Swine (24%) and poultry (17%) also play a significant role, with sheep (7%), farmed fish (6%), equines (4%), and goats (4%) playing relatively minor roles in this analysis. The contributions of rabbits (0.36%), camelids (0.59%), and cervids (0.04%) are negligible for the covered countries.

These percentages may change significantly over time if the numbers or composition of countries in the OIE Regions providing quantitative data changed. This is expected to occur as data reporting capacity of countries increases.

Figure 26. Species Composition of Animal Biomass for 91 Countries Included in 2015 Quantitative Data Analysis



Animal Biomass Covered by the 2015 Additional Analysis: Regional View

Table 8 highlights the regional species composition of biomass by OIE Region, for 91 countries submitting quantitative data for 2015 in the first three years of the data collection.

Table 8. Animal Biomass Covered by Quantitative Data Reported to the OIE for 2015, Regional Results for 91 Countries

	Africa	Americas	Asia, Far East and Oceania	Europe
Number of Countries	27	9	19	36
Bovine Biomass (in 1,000 tonnes)	38,220	80,080	59,894	45,975
Swine Biomass (in 1,000 tonnes)	1,985	20,590	89,985	34,493
Poultry Biomass (in 1,000 tonnes)	4,372	36,812	40,924	24,209
Equine Biomass (in 1,000 tonnes)	5,580	7,813	7,112	2,516
Goat Biomass (in 1,000 tonnes)	14,399	519	10,641	1,427
Sheep Biomass (in 1,000 tonnes)	12,018	2,723	16,913	8,662
Rabbit Biomass (in 1,000 tonnes)	38	10	1,818	353
Camelid Biomass (in 1,000 tonnes)	2,978	358	263	6
Cervid Biomass (in 1,000 tonnes)	19	30	83	105
Terrestrial Animal Biomass (in 1,000 tonnes)	79,609	148,934	227,633	117,746
Farmed Fish Biomass (in 1,000 tonnes)	378	1,305	30,918	1,667
All Species Biomass (in 1,000 tonnes)	79,987	150,239	258,550	119,412

Regional biomass covered by the reported quantitative data (Table 8) is affected by the number and characteristics of countries providing quantitative data in each OIE Region, including the relative size and average weights of their animal populations in 2015. Therefore, the composition of animal biomass is better represented as percentage of total biomass for the Region (Figures 27-30).

Figure 27. Species Composition of Animal Biomass for the 27 Countries in Africa Included in 2015 Quantitative Data Analysis

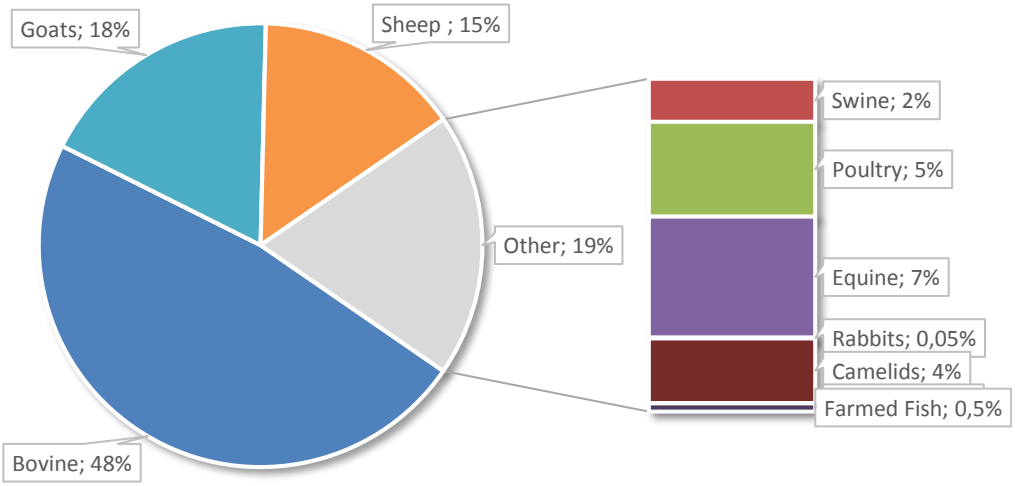


Figure 28. Species Composition of Animal Biomass for the 9 Countries in the Americas Included in 2015 Quantitative Data Analysis

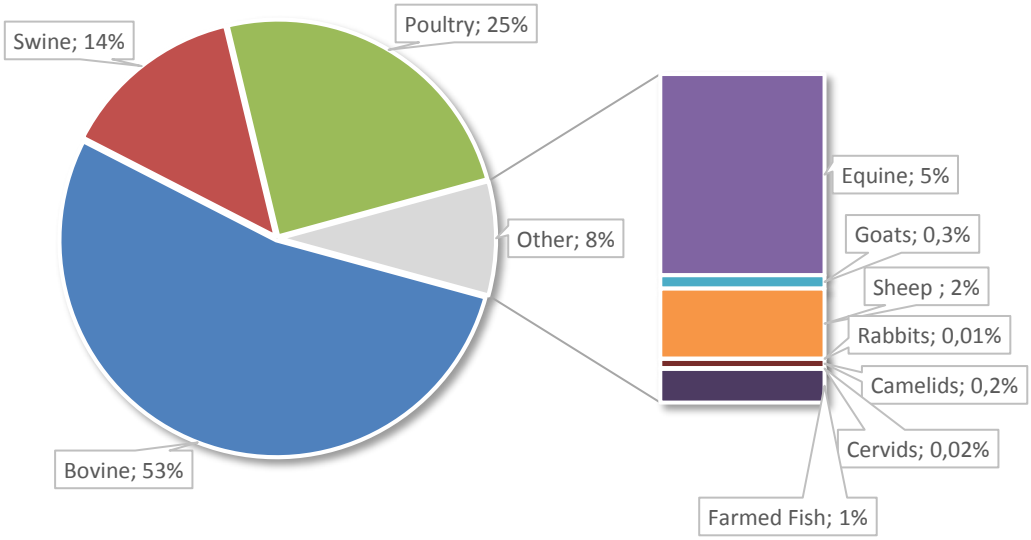


Figure 29. Species Composition of Animal Biomass for the 19 Countries in Asia, Far East and Oceania Included in 2015 Quantitative Data Analysis

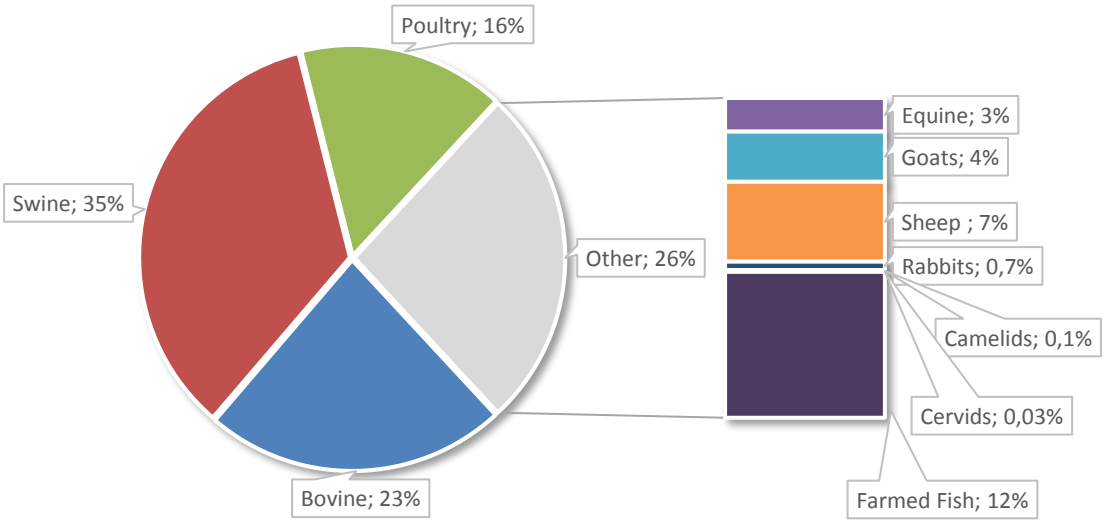
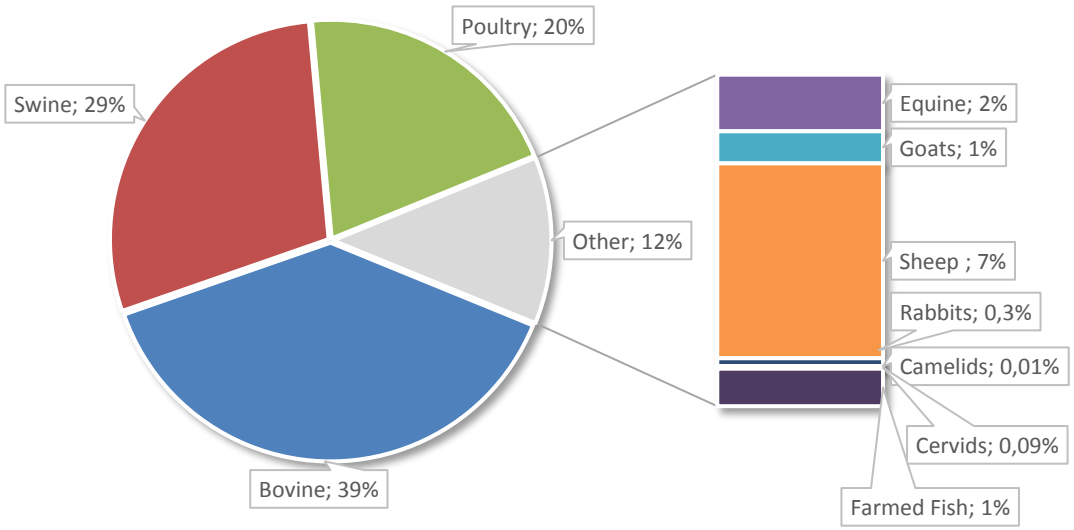


Figure 30. Species Composition of Animal Biomass for the 36 Countries in Europe Included in 2015 Quantitative Data Analysis



TERRESTRIAL ANIMALS

In this analysis, bovines were the most significant[15] contributor to biomass in the Americas (53%), followed by Africa (48%), and Europe (39%). In Asia, Far East and Oceania, swine (35%) surpassed bovines (23%) as the most significant contributor to biomass. Swine were also significant in Europe (29%), and relatively less so in the Americas (14%) and Africa (2%). Poultry were also a major species in the Americas (25%), Europe (20%) and Asia, Far East and Oceania (16%), but were relatively minor in Africa (5%).

[15] The use of the term 'significant' in this section does not denote statistical significance. Statistical analysis could not be undertaken at this stage as only one year of data was adjusted for animal biomass.

In most regions, sheep and goats were a minor contributor to biomass (7% and 4% respectively in Asia, Far East and Oceania, 7% and 1% respectively in Europe, and 2% and 0.3% respectively in the Americas). In Africa, sheep and goats were relatively more significant, contributing 15% and 18% to the total biomass respectively.

Rabbits were most significant in Asia, Far East and Oceania, contributing 0.7% to the total biomass. Camelid species were most significant in Africa, contributing 4% to the region's total biomass. Cervids had a negligible impact on biomass (<0.1%) in all OIE Regions.

These results should be interpreted with caution for all species for which slaughter data predominantly contributed to the calculation of biomass (swine, poultry, sheep and goats and rabbits). These percentages may underestimate the significance of species that are often slaughtered outside of slaughterhouses for personal consumption. The amount of slaughter undertaken outside slaughterhouses and the extent to which this population is captured in slaughter data is expected to vary significantly between countries and regions.

AQUATIC ANIMALS

Percentages of farmed fish should also be interpreted with caution as fish biomass was only included where countries either reported that their data on antimicrobial agents covered aquaculture, or that they could not distinguish between animal groups. Therefore, the effect of farmed fish on biomass is skewed by the number of countries in that OIE Region for which antimicrobials used in aquaculture were included. These percentages should not be considered representative of the regional aquaculture production.

For the purposes of the 2015 analysis of quantitative data, aquaculture was most significant in Asia, Far East and Oceania, where farmed fish made up 12% of the covered animal biomass. In the Americas, Africa and Europe, farmed fish made up 1% or less of the covered animal biomass.

CHANGES IN ANIMAL BIOMASS COMPARED TO 2014 ANALYSIS

Populations represented in the animal biomass analysis reflect the number, size and animal population dynamics of the countries reporting data to the OIE during the given year of analysis. In Africa, the Americas and Europe, the estimated percentage of total regional biomass covered remained relatively stable from 2014 to 2015 (Figure 24), and the species composition of the animal biomass also remained relatively unchanged.

Asia, Far East and Oceania saw the most dramatic increase in estimated percentage of total regional biomass covered, from 7% in the up to date 2014 analysis to 81% in the 2015 analysis. This increased regional coverage resulted in a more significant change in species composition relative to the other regions, notably a relative increase in representation of sheep, goats and farmed fish, and relative decrease in poultry.

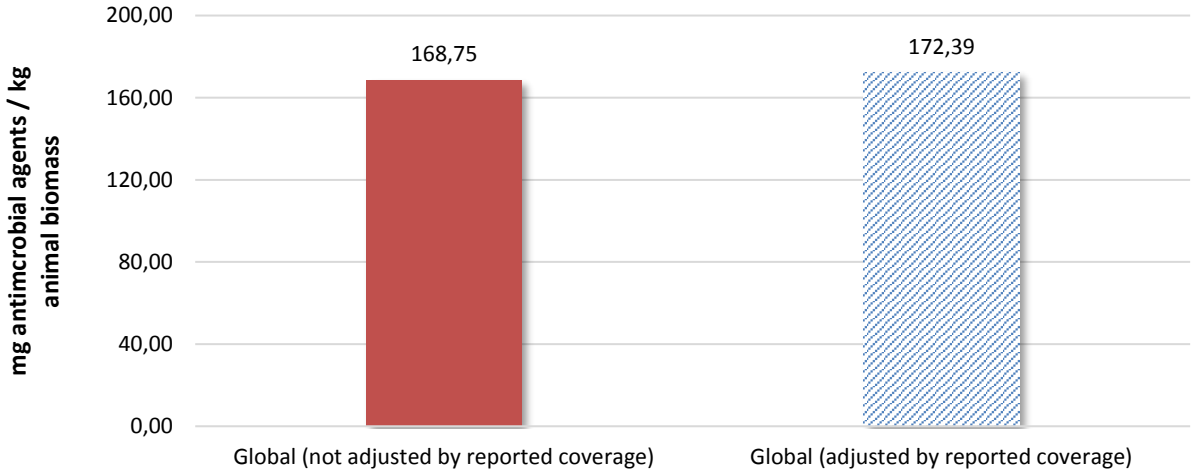
4.3. Antimicrobial Quantities Adjusted by Animal Biomass

2015 Antimicrobial Quantities Adjusted by Animal Biomass, Global View

Figure 31 provides an overview of antimicrobial agents intended for use in animals adjusted by animal biomass. The estimates compile the data of 91 countries providing data in first three rounds of data collection for 2015, from 4 OIE Regions (Africa, Americas, Asia, Far East and Oceania and Europe).

The first estimate of 168.75 mg/kg represents a global estimate of antimicrobial agents used in animals adjusted by animal biomass, as represented by the quantitative data reported to the OIE from 91 countries during the first three rounds of data collection for 2015. The second estimate of 172.39 mg/kg represents the same quantitative data, additionally adjusted by country-level estimates of how much data on antimicrobial agents intended for use in animals they covered in 2015. These coverage estimates are subjective to each reporting country, but can provide an upper level estimate of global antimicrobial use in animals.

Figure 31. Global Quantities of Antimicrobial Agents Intended for Use in Animals Based on Data Reported by 91 Countries for 2015, Adjusted by Animal Biomass(mg/kg)



CHANGES IN MG/KG RESULTS COMPARED TO 2014 ANALYSIS

As described in Section 4.1, the 2014 analysis of antimicrobial quantities adjusted by animal biomass was updated to reflect new information reported by countries in the third round of data collection. Some figures were corrected, one more country was added, and some countries describing previous errors in their calculations were retroactively removed from the analysis. The updated mg/kg global estimate for 2014 is 88 mg/kg, with an upper level estimate of 92.70 mg/kg when adjusted by estimated coverage.

While the 2015 results reflect an apparent increase in antimicrobials used globally, these results cannot be compared to the 2014 analysis and should be interpreted with caution. The 2015 analysis reflects a much stronger global participation in the data collection, with an increase of 31 reporting countries, and an estimated global biomass coverage of 71%, increased from 37% in 2014. As more countries begin the process of establishing data collection and the global biomass coverage increases, the accuracy of reported data will stabilise and trends over time will be more readily discernible.

2015 Antimicrobial Quantities Adjusted by Animal Biomass, Regional View

Figure 32 provides a regional view of antimicrobial agents intended for use in animals adjusted by animal biomass of countries within that region. Both estimates for each OIE Region incorporate the data of 91 countries providing data in the three rounds of data collection for 2015.

The lower estimate for each OIE Region represents the quantitative data reported to the OIE from that region during the first three rounds of data collection for 2015, adjusted by animal biomass. The high estimate for each OIE region represents the same quantitative data, additionally adjusted by country-level estimates of how much data on antimicrobial agents intended for use in animals they covered in 2015. These coverage estimates are subjective to each reporting country, but can provide an upper level approach of global antimicrobial use, including unregulated sources.

Estimates of data coverage were lowest in Africa, leading to the widest variation between antimicrobial quantities reported and those adjusted by country's estimates of data coverage. In Asia, Far East and Oceania, countries were the most confident of their data coverage.

Figure 32. Quantities of Antimicrobial Agents Intended for Use in Animals Adjusted by Animal Biomass, 2015 Regional Comparison (mg/kg)

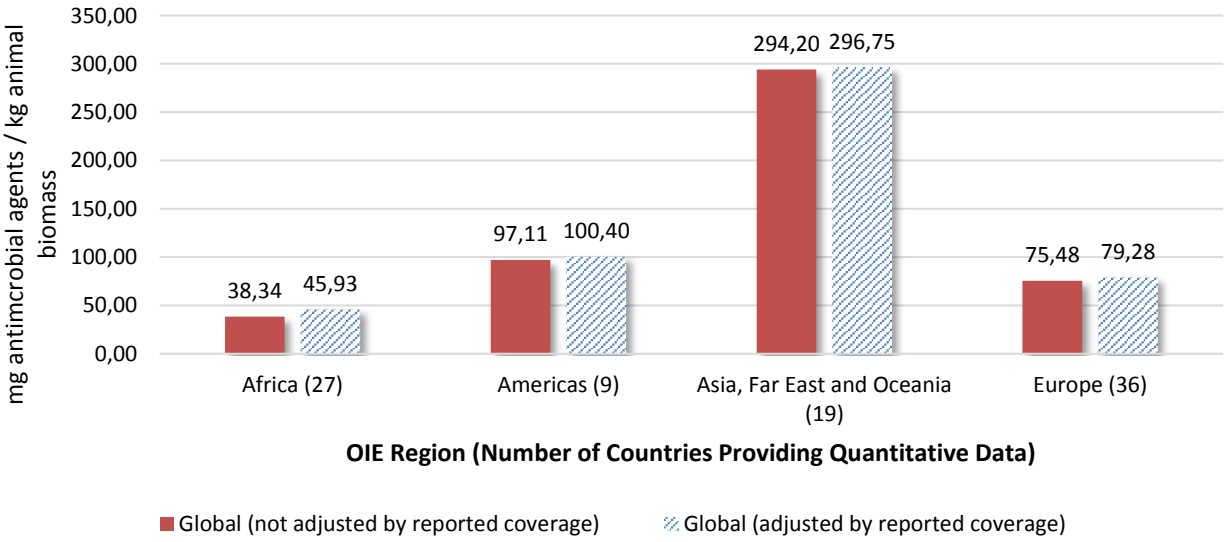


Table 9 displays the same regional figures of antimicrobial quantities adjusted by animal biomass (with the upper level estimates adjusted by country estimates of data coverage in parentheses). Additionally, some characteristics of the data distribution by OIE Region are provided, including the median, standard deviation and range.

These results show that in 2015, Asia, Far East and Oceania reported the most antimicrobial agents intended for use in animals among the four regions. However, this region also displayed the most variation between individual countries.

Table 9. Antimicrobial Quantities Adjusted by Animal Biomass, by OIE Region, 2015

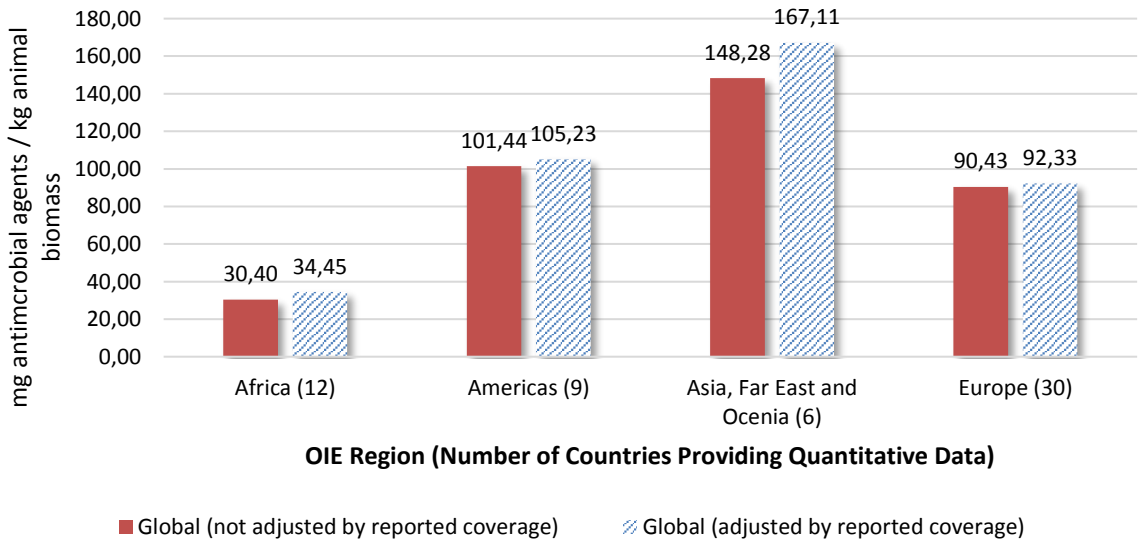
OIE Region	Number of Countries	% Covered of Total Regional Estimated Biomass	Antimicrobial Quantities Adjusted by Animal Biomass (and estimated data coverage) (mg/kg)	Descriptive Statistics		
				Median (mg/kg)	Standard deviation (mg/kg)	Range (mg/kg)
Africa	27	54%	38.34 (45.93)	6.39 (8.95)	52.87 (64.40)	198.04 (232.99)
Americas	9	56%	97.11 (100.40)	47.92 (50.75)	74.72 (78.18)	212.63 (224.12)
Asia, Far East and Oceania	19	81%	294.20 (296.75)	42.00 (52.50)	107.70 (114.23)	375.29 (375.29)
Europe	36	77%	75.48 (79.28)	35.78 (35.97)	80.44 (89.07)	339.62 (364.75)

It is important to interpret the estimates of antimicrobial quantities adjusted by animal biomass (mg/kg) in the context of animal biomass coverage for the region. Estimates for the total estimated regional animal biomass covered by the quantitative data reported for 2015 were calculated and explained in Section 4.1. Changes in reporting countries and in regional animal biomass coverage across years of analysis may significantly change the results. The OIE is working with Member Countries to continue to improve and maintain data coverage in order to allow for an evaluation of trends over time.

Changes in 2014 Antimicrobial Quantities Adjusted by Animal Biomass, Regional View

The 2014 results, updated since the previous report, are shown below for comparison (Figure 33).

Figure 33. Quantities of Antimicrobial Agents Intended for Use in Animals Adjusted by Animal Biomass, Updated 2014 Regional Comparison (mg/kg)



Overall, while noting the need for caution in comparison of 2014 and 2015 results at global and regional level due to the differences in the contributing countries, the trends between regions are retained. In 2015, Europe's reported antimicrobial quantities adjusted by animal biomass reduced from 90 mg/kg to 75 mg/kg. These reductions are in line with the results reported by ESVAC for the same year, for those countries that participate. For the Americas and Africa, the 2015 results are quite similar to those for 2014, despite the new contributions of countries in Africa.

The most notable change compared to the 2014 analysis is for Asia, Far East and Oceania, where mg/kg results nearly doubled. This is unlikely to reflect a dramatically increasing trend in consumption of antimicrobials in this region, but rather is the resulting effect of an increase in the number of countries reporting data. For the 2014 analysis, it was noted that regional animal biomass coverage in Asia, Far East and Oceania was particularly low (7%) and that a future increase of quantitative data reported covering a larger percent of total animal population of the region may substantially impact estimates. In the 2015 analysis, Asia, Far East and Oceania has the largest coverage of its animal populations (81%), and therefore the data reflects a better though still not complete picture.

5. Discussion

5.1. Progress Made by Member Countries

During the third round of data collection, an increased number of Member Countries were engaged in data reporting than in the previous rounds.

Of the 153 Member Countries that submitted reports, 128 had also participated during the second rounds of data collection. Among these 128 Member Countries, the following progress was noted:

- 11 Member Countries (n = 34; 32%) passed from reporting only Baseline Information to reporting quantitative data on antimicrobial agents used in the animals for the first time. Most of these (8 Member Countries) used Reporting Option 1, which allows for distinction of the quantitative data by antimicrobial class and by type of use (veterinary medical use or growth promotion). Two Member Countries used Reporting Option 2, which allows for a distinction by animal group (terrestrial food-producing, aquatic food-producing and companion animals) in addition to type of use. One Member Country reported their quantitative data using Option 3, which allows for distinction of quantitative data by type of use, animal groups and routes of administration.
- 12 Member Countries (n = 56; 23%) who had previously reported quantitative data through Reporting Option 1 or 2 progressed to more detailed reporting in this round. 11 Member Countries moved from reporting quantities through Reporting Option 1 to one of the two higher level options: 9 were found to have switched to Reporting Option 2, and two switched to Reporting Option 3. One Member Country that had previously reported through Option 2 now used Reporting Option 3.

It is important to note that Africa, showed the highest number of countries progressing to more detailed reporting of their quantitative data.

The barriers described by the 31 Member Countries unable to provide quantitative data on antimicrobials used in animals in the third round of data collection have been described in Section 3.1 of this report. Among this group, 7 Member Countries (n = 31; 23%) confirmed that action will be taken in the near future to facilitate their reporting of quantities of antimicrobials to the OIE.

5.2. Limitations in the Analysis of Antimicrobial Quantities

All the countries that reported quantities of antimicrobial agents intended for use in animals did so using the template that OIE created. This document collects essential information to analyse the amounts of antimicrobials (Baseline information, part C, Annex 6). In addition to this document, an annex was provided to perform the calculations to report kilograms per active ingredient (Annex 8).

Data sources:

During the third round of data collection, 54 countries (n = 118; 46%) reported data sources indicating a possibility for over-estimated, duplicated or overlapping data (see examples below).

Data duplication or over-estimation was considered to be a risk when the following situations were reported in a country's data sources:

- Import data of active ingredients or manufacturing data reported without taking into account the potential for re-exports;
- Import data of veterinary products reported by a country also providing data on sales of veterinary products (domestic and imported);
- Import, sales or purchase data of veterinary products reported in addition to usage data at a farm level;
- Data from wholesalers or Marketing Authorisation Holders in addition to data from retailers, prescriptions, pharmacies or farm records.

Countries where these possible situations were identified were present in all the OIE Regions, however, they were most predominant in Africa (n = 18), followed by the Americas (n = 15) and Asia, Far East and Oceania (n = 14).

The OIE engages with countries where these situations are noted to highlight and clarify possible areas of data duplication or over-estimation. As most of these countries are in the first stages of development of their data collection systems, it is expected that it will take time to implement official processes and to provide accurate data. The OIE is working closely with these countries to understand their systems and support them to understand and address limitations in their data.

Calculation of quantitative data:

Wherever possible, the data reported by countries were checked by the OIE against existing reference sources, either using the previous year's reported data or national reports available online. The indicator for this comparison was a calculated 'percentage of change'.

During the third round, this analysis could be conducted for 86 countries where data from previous years were available for comparison. In 43 countries (n= 86; 50%), the data varied more than 25% from one year to another, and in some countries reached ± 100-200% variation; in a particular case a change of almost 1550% was observed. Such a change was considered unlikely to reflect the true situation.

In the countries with high percentages of unexplained change (>25%), the OIE inquired how the calculations to obtain kg of antimicrobial agents were carried out. Through this process, errors in the calculations were discovered where countries did not follow or misinterpreted the procedure in Annex 8. Errors in the calculations were present in all OIE Regions. However, Africa presented the highest number of Member Countries experiencing such challenges (n=18), and this can be attributed to the fact this region also represents the most recent participants in data collection.

The OIE will continue to work on this issue with its Member Countries through its Regional Trainings for National Focal Points for Veterinary Products, where the guidelines are reviewed and Member Countries can ask the OIE questions and share experiences with their peers.

Development of antimicrobial monitoring systems:

During the second round of data collection, 107 Countries reported quantitative data on antimicrobial agents intended for use in animals, and 91 of these also participated during the third round of data collection.

In the third round of data collection, 12 Countries (n = 91; 13%) made amendments to the quantitative data they had reported during the second round. These amendments corresponded to errors noted in the calculations, or availability of new data, including data from additional months in the year, or data from wholesalers or pharmacists newly participating in the data collection.

Taking into account that most of countries worldwide are just beginning to report quantitative data on antimicrobials intended for use in animals and that errors in data sources have already been noted that may result in some instances of data duplication, caution is necessary in the interpretation of the results. As stated in the annual European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report:

> *It is generally agreed that it usually takes at least three to four years to establish a valid baseline for the data on sales of veterinary antimicrobial agents. Consequently, the data from countries that have collected such data for the first or even second time should be interpreted with due caution*.

5.3. Limitations in the Estimation of Animal Biomass

The animal biomass methodology was developed with the goal of best representing animal biomass in all OIE Regions, with different animal populations and data collection systems. The biomass figures obtained from this methodology reflect a margin of error, which will be reduced over time as data collection is further refined (see Section 6, Future Developments).

Calculation methodology of average animal weights:

Different antimicrobial use surveillance programmes have used various methodologies for determination of animal average weights towards calculation of total biomass. In the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC), estimated average weights at time of treatment are used. [21] The Canadian Integrated Surveillance Program for Antimicrobial Resistance (CIPARS) uses the same standard weights at time of treatment, as well as Canadian standard weights. [22] The surveillance programs of Japan [23] and the United States [24] take a different approach, instead using estimates of average animal weights by production category, rather than focusing the estimates on a time at treatment.

For the purposes of this report, it was determined that the latter approach, using estimates of live average weight without focus on time of treatment, would be most appropriate. Antimicrobial compounds used and their labelling, including target species and production class, vary widely on a global scale, with data on these differences unavailable on a global scale. Given these variations, it is not feasible to estimate weights at time of treatment for all countries reporting data to the OIE. Instead, average weights were calculated using globally available slaughter data as reported by FAOSTAT, for all species and regions where these data were available.

The average weights calculated for this report are therefore larger than estimated weights at time of treatment, resulting in a larger denominator and a decreased relative mg/kg estimate of antimicrobial agents used intended for use in animals. Therefore, the results reported in OIE analyses of antimicrobial quantities adjusted by animal biomass are not directly comparable to those of ESVAC or the CIPARS estimates, which are based on treatment weights.

Specificity of data:

As described in the methodology, the globally available data sources on animal population, FAOSTAT and WAHIS, are not reported by production class for the year 2015. However, it is necessary to stratify species population by production class to better assign average weights, for example, to separate veal calves from adult cattle. The methodology for calculation of biomass therefore utilises some necessary standard animal reproduction rates to extract a best estimate of the population breakdown by production class. These rates will vary between species, countries and production systems, and therefore, are not ideally representative of any one country's or region's animal populations.

Animals imported and exported:

Imported and exported animals are commonly subtracted and added, respectively, from animal populations when calculating animal biomass, as done in ESVAC and CIPARS. This is done so that only animals raised in the country, the time during which they would have been treated with antibiotics, are considered. At this time, available data does not support incorporation of import/export data in the calculation of animal biomass on a global level.

In the 2014 analysis, an effort was made to minimise the effect of animals imported/exported by using 'indigenous' slaughter data wherever slaughter data were applied, which considers only domestic animals slaughtered in a country. For the 2015 analysis, this dataset was no longer available. An analysis of variance done on the 'indigenous' and non-'indigenous' slaughter data available from 2010-2013 demonstrated no significant variation in any of the three major animal species considered in the biomass calculation (bovines, swine and poultry). It was therefore decided to proceed with the 2015 analysis using non-'indigenous' slaughter data. The corrected 2014 results as also shown in this report were retroactively recalculated using the same non-'indigenous' data source in order to reduce differences between years of analysis. No slaughter data utilised for calculating animal biomass in this report incorporated trade data, impacting accuracy for countries with a significant live animal export trade relative to national slaughter.

Extrapolations within the methodology:

Carcass conversion factors: The methodology for calculation of average animal weight from slaughter data necessitates a conversion factor from carcass weight to live weight at time of slaughter (Section 2.2). Presently, these conversion factors are only available for Europe. It is not currently known how well European conversion factors apply to other countries that may have different slaughter practices, but it is likely they differ. The significance of this difference and its impact on the accuracy of the biomass calculation for all countries cannot be estimated.

Reproduction rates and weights: Data on reproduction rates were not collected at the time of reporting, nor was slaughter data for cervids, camelids, and equines in some regions. Therefore, this information was taken from literature where necessary, or extrapolated from regions where data was available (such as in the case of live weights of equines). The extent to which these literature and extrapolated weights and reproduction rates represent the true situation in any country is expected to vary.

Animal species not retained in denominator:

In development of the current denominator methodology, it was decided at this time not to include companion animals in the calculation of animal biomass. Data on populations of cats and dogs are available in WAHIS, and not in FAOSTAT, however, many countries do not report these figures, or report them inconsistently. Another consideration is the need to better understand whether reported cat and dog populations represent owned or stray animals, as this would affect the likelihood of their treatment with antimicrobials.

For the countries where cat and dog populations were available, it was seen that their contribution to overall biomass was minor (<1%). However, as some countries do include antimicrobials used in companion animals in their reported quantitative data, there is expected to be a small effect on results by excluding these species. As excluding them decreases this denominator, this effect, if any, would be a minor increase in antimicrobial quantities adjusted for animal biomass.

In the future, a goal would be to provide a separate analysis for antimicrobial agents used in companion animals, as more countries are able to report these population data, and distinguish antimicrobial quantities by animal group.

5.4. Barriers to Collect Antimicrobial Quantities

For the countries unable to report antimicrobial quantities, the main barriers reported were the structure or enforcement of their regulatory framework for veterinary products. It was also noted that there are countries that reported the lack of an electronic tool that is able to collect and analyse data (mainly from imports) that was connected to the information related to the authorisation of veterinary products, in order to perform the calculations of active ingredients (see section 3.1, Country Barriers to Providing Quantities of Antimicrobial Agents in Animals).

Many countries have described processes underway to facilitate future collection and reporting of antimicrobial use data in animals. Similarly, in line with their commitments made to the Global Action Plan, countries are also in the process of developing and implementing National Action Plans to advance regulations on veterinary antimicrobials and facilitate interactions between sectors. Given these developments, it is expected that the reported barriers will be reduced over time, increasing the availability of global antimicrobial use data in animals.

6. Future Developments for the Antimicrobial Use Survey

After the results of third round of the data collection, the OIE made changes to the template for the fourth round regarding the use of antimicrobials in companion animals, noting that there are some countries that consider *Equidae* as companion animals, as food-producing animals or both. There is a need for clarity on how countries categorise *Equidae* for the reporting of quantitative data (i.e., terrestrial food-producing animals or companion animals). To address this situation, the OIE added two questions related to companion animals, this will enable a more nuanced understanding of the situation in a country.

The OIE will continue working closely with Member Countries to support them in calculating kilograms of active ingredients of antimicrobials. An automated system for this calculation will be developed over time to assist Member Countries in this effort. This automated system will particularly help Member Countries with the burden of manually calculating kilograms of active ingredients, and avoid errors with these calculations.

The OIE will also continue to refine its methodology for the calculation of animal biomass, based on globally available data, and communication with its Member Countries through its regional offices.

An important next step in this process will be collaboration with the OIE World Animal Health Information and Analysis Department (WAHIAD). In consultation with the OIE *ad hoc* Group on Antimicrobial Resistance, new species and animal sub-categories have been added to the OIE World Animal Health Information System (WAHIS) data collection guidelines. These new population sub-categories are now being implemented in the WAHIS and will allow to refine the data on animal biomass over time.

OIE-WAHIS, the next generation of the WAHIS data collection interface, is currently in development and will incorporate further updates to the collection of global animal population data. In addition to more sub-categories representing detailed production data where Member Countries are able to supply it, the interface will also include free text boxes allowing for description of the reported data. OIE-WAHIS will also additionally support the reporting of data on average live weights and number of animals slaughtered in Member Countries.

Aside from collection of more detailed global animal population data, more work is needed to validate some of the conversion factors used in the methodology, which were frequently extrapolated from European data. Particularly, better understanding potential regional variation in carcass conversion factors (for estimating live weights) and annual multiplication rates of species living less than one year (i.e., 'cycle factor') are necessary within the current methodology to ensure its applicability on a global scale. The OIE is currently working with its Regional Offices to obtain better estimates on these variables across regions.

7. Conclusions

This report is the result of a significant commitment by OIE Member Countries to the development of data collection systems on antimicrobial agents intended for use in animals. This global initiative, the first of its kind, highlights not only reported quantitative data where countries are currently able to provide it, but also the current situation of governance of veterinary antimicrobials worldwide, and barriers to quantitative data collection. This information is critical to the international effort to promote the responsible and prudent use of antimicrobial agents in animals, and the capacity to measure trends over time.

Contributions to the database have continued to grow, with increasing engagement from countries. The OIE also commends the participating non-OIE Countries for their invaluable efforts, and will continue to support their engagement with the data collection. Results of the third round of data collection have demonstrated a growing capacity worldwide for collection of more quantitative data, while also increasing in quality.

Simultaneously, as more data on animal populations becomes globally available, it is expected that the methodology for calculation of animal biomass will be further refined. With the concurrent development of quantitative data collection and calculation of animal biomass, this annual report will allow for comparison of global and regional trends on antimicrobial agents intended for use in animals over time.

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ANNEXES

Annex 1 Africa, Responses from the Third Round of Data Collection

Annex 2 Americas, Responses from the Third Round of Data Collection

Annex 3 Asia, Far East and Oceania, Responses from the Third Round of Data Collection

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Annex 6 OIE Template

Annex 7 Guidance for Completing the OIE Template for the Collection of Data on Antimicrobial Agents Used in Animals

Annex 8 Annex to the Guidance for Completing the OIE Template for the Collection of Data on Antimicrobial Agents Used in Animals

Annex 9 Distribution of Countries by OIE Region

Annex 1. Africa, Responses from the Third Round of Data Collection

Table A1. General Information for Africa

General Information for Africa	
Number of Member Countries	54
Number of Member Countries responding to the questionnaire	44 (81%)
Number of Member Countries providing only qualitative data	11 (25%)
Number of Member Countries providing quantitative data	33 (75%)

Barriers to Providing Quantities of Antimicrobial Agents in Animals

Eleven Member Countries (n= 44; 25%) responded with Baseline Information (qualitative data) and no quantitative data on antimicrobial agents used in animals (Table A1), and explained the barriers to reporting quantities of antimicrobial agents used in animals to the OIE. Member Countries could report more than one barrier relevant to their situation, and responses were grouped by category (Figure A1). For further information on the category groupings, please refer to the explanatory section in the global analysis for this report.

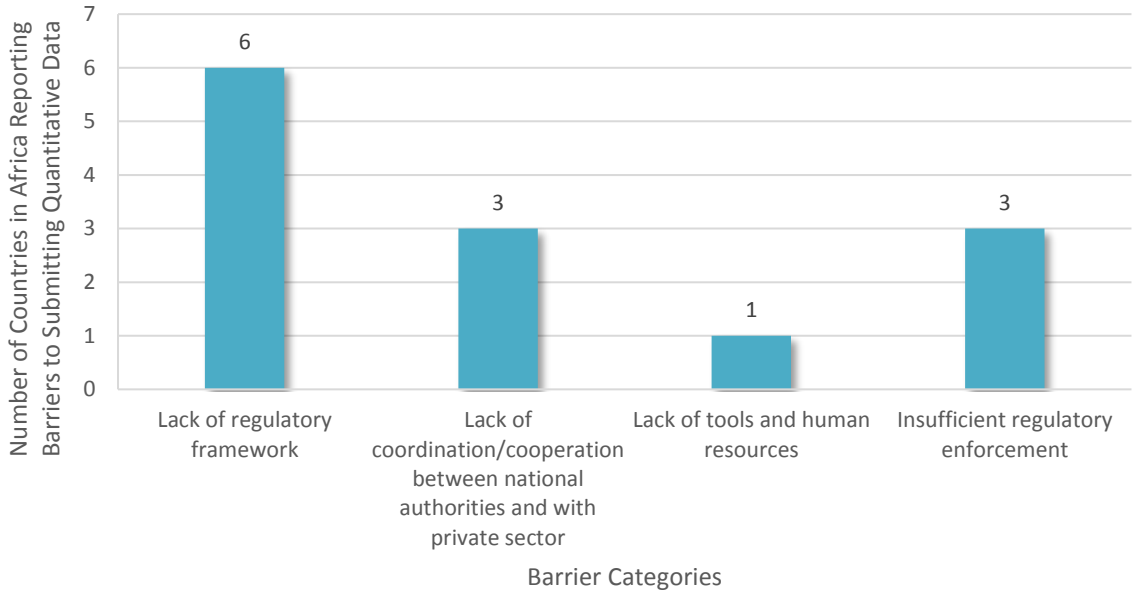
About half of the responses in Africa (6 out of 11; 55%) mentioned that the main impediment to reporting amounts of antimicrobials were the lack of a regulatory framework. Of these, 5 countries (n = 6; 83%) describe the lack of regulatory framework for the manufacture, registration, distribution, commercialization and use of veterinary products.

Two Member Countries described a lack of coordination/cooperation with the Ministry of Health, one of these countries stated that even if cooperation was resolved, no data collection mechanism exists to monitor amounts of imports in the country. Another country described lack of coordination/cooperation with private veterinarians as a key barrier together with insufficient regulatory enforcement.

Three Member Countries reported insufficient regulatory enforcement for collection of data, including black market sales and usage of antimicrobials in the field by unauthorised persons. One of these countries confirmed that the Veterinary Services are not aware of which veterinary pharmacies or veterinarians are selling veterinary products in the country.

One African Member Country explained its main challenge in data collection was that import records were not capturing the necessary information to perform the calculations to obtain kilograms of active ingredients for veterinary products, but confirmed that it is already in discussions to develop such a software.

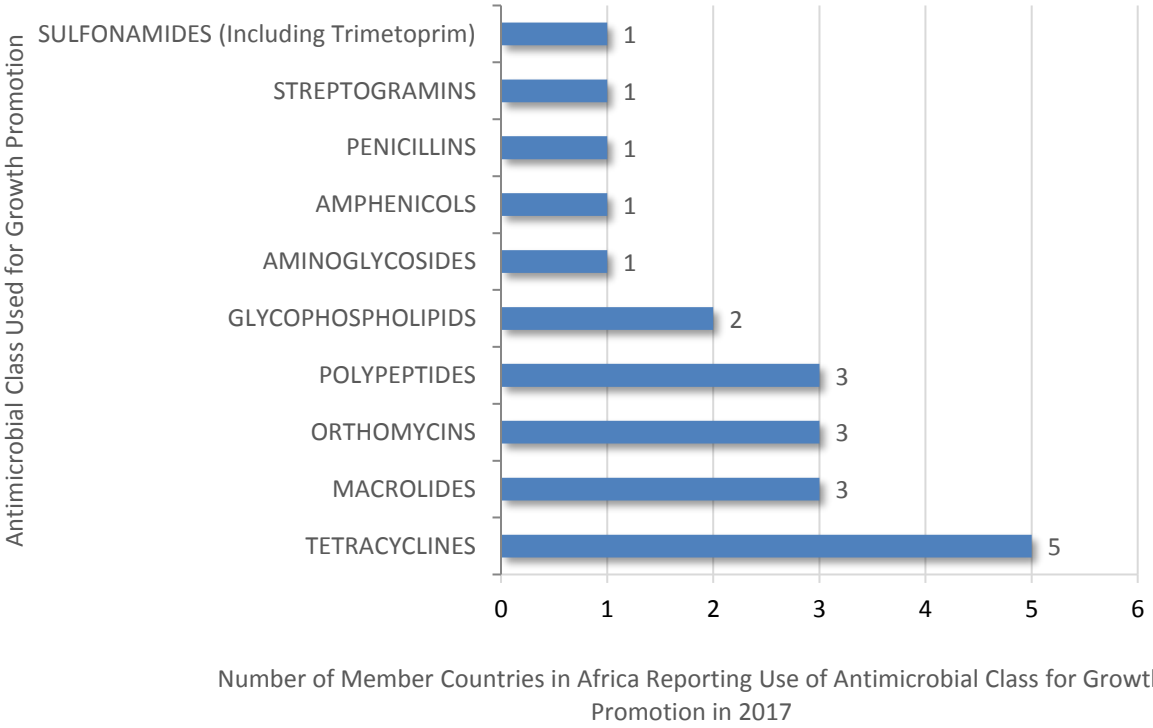
Figure A1. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in 11 Countries in Africa During the Third Round of Data Collection



Antimicrobial Agents Used for Growth Promotion

Ten African countries (n = 44; 23%) use antimicrobial agents as growth promoters. Of these, 7 Member Countries (n = 10; 70%) provided a list of antimicrobials used for growth promotion, with Tetracyclines most commonly named (Figure A2).

Figure A2. Antimicrobial Growth Promoters Used in Animals in 7 Member Countries in Africa in 2017

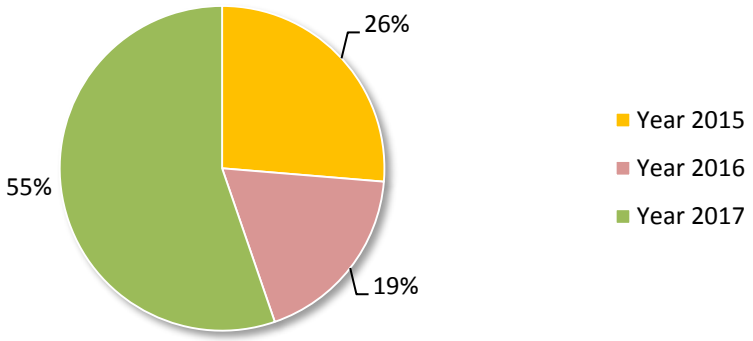


Years of Quantitative Data Reported

Based on 33 responses from African Members, the most commonly reported year for quantitative data on antimicrobial agents intended for use in animals was 2017 (Figure A3). These findings reinforce what was presented in the previous OIE reports that most Member Countries in Africa have only recently begun to collect this information and therefore only have access to current information.

Africa is the region where Member Countries are progressing quickly to provide amount of antimicrobials intended for use in animals. Twenty-One Member Countries progressed from reporting only Baseline Information (qualitative data) in the first round, to reporting quantitative data in the second and/or third round.

Figure A3. Years of Quantitative Data Reported from 33 Member Countries in Africa During the Third Round of Data Collection



Quantitative Data Sources Captured

All African countries' data sources were analysed, and all countries where the data duplication was considered to be a risk were asked for clarification of their answers and/or data collection systems. After the clarifications, 27 countries (n = 33; 82%) changed their answers or proved there was no duplication or overlapping of data sources. The remaining countries (6 out of 33; 18%) that did not provide clarification to the OIE were excluded from Figure A4, reporting quantitative information from 2015 to 2017.

From the list of data source options provided in the OIE template, import data for veterinary products was most commonly chosen, with 8 Member Countries (n = 27; 30%) selecting this option (Figure A4). In addition, 5 Member Countries described other data source not provided in OIE List, relating to Import data as well (Figure A5).

Figure A4. Data Sources Selected by 27 African Member Countries Reporting Quantitative Information from 2015 to 2017

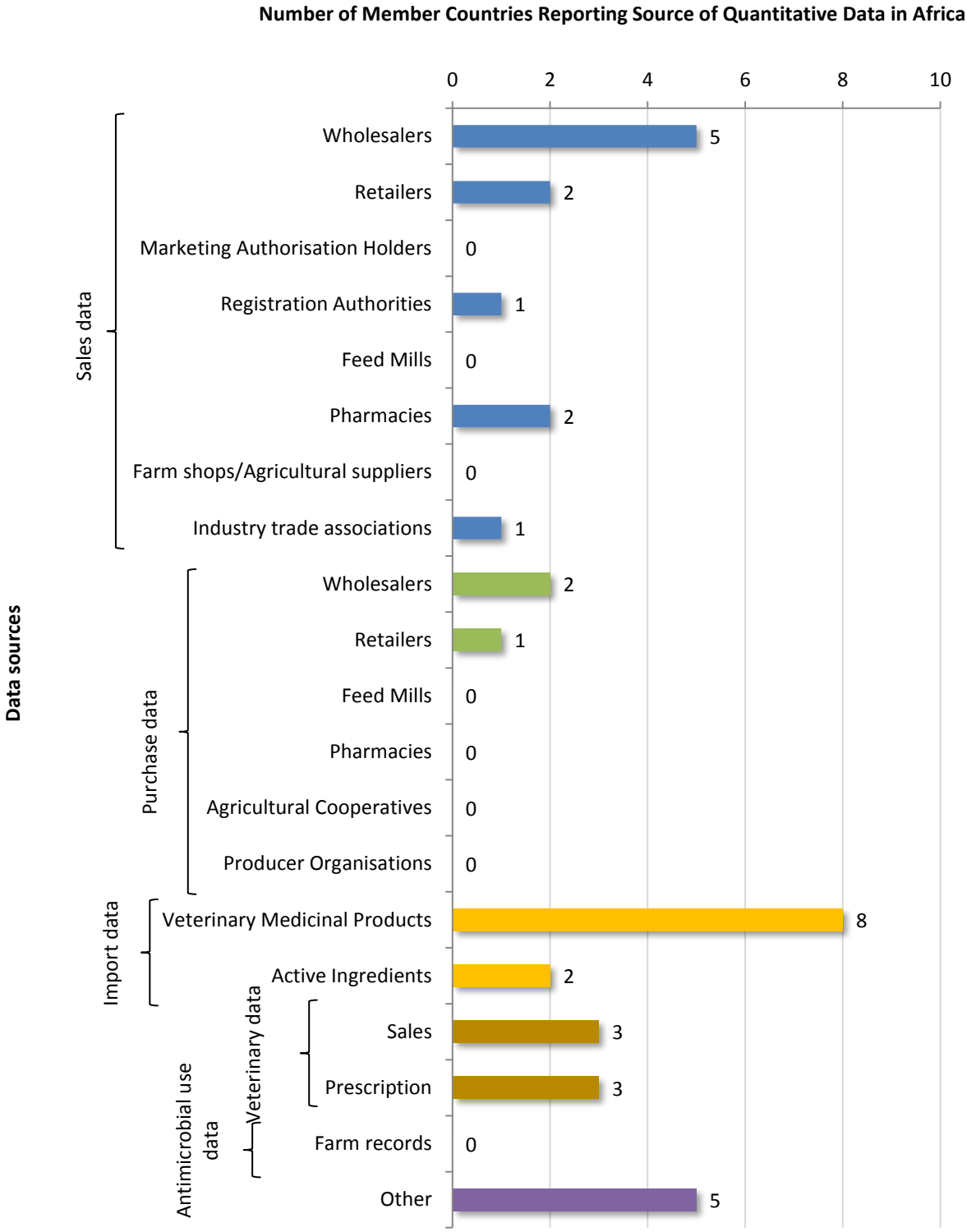
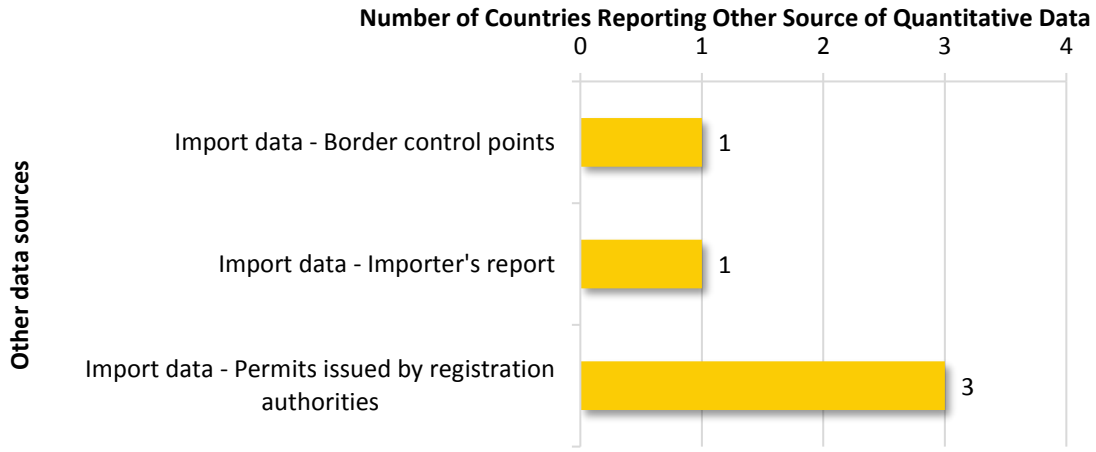


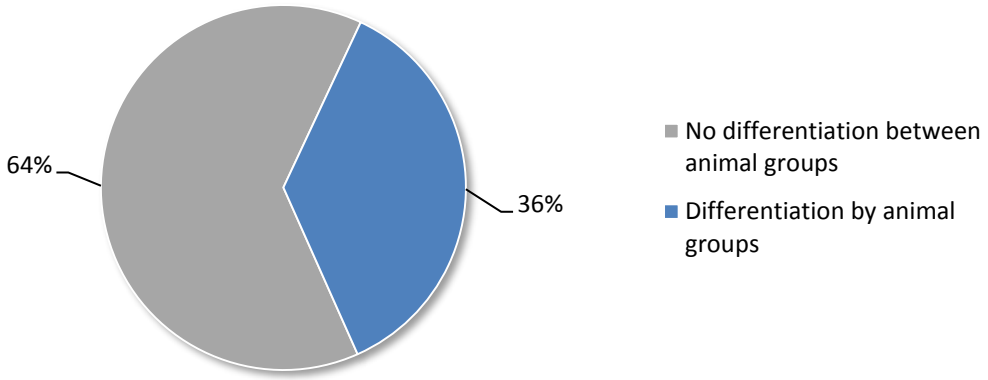
Figure A5. 'Other' Source of Data as Explained by 5 Member Countries in Africa Reporting Quantitative Information from 2015 to 2017



Quantitative Data Differentiation by Animal Groups

Most of the quantitative data from the African Member Countries cannot be differentiated by animal group. This result corresponds with the African Region's predominant use of Reporting Option 1, which does not allow for differentiation by animal group (Figure A6). For the 12 African countries (n = 33; 36%) that were able to distinguish antimicrobial quantities by animal groups, data were provided mainly for terrestrial food-producing animals.

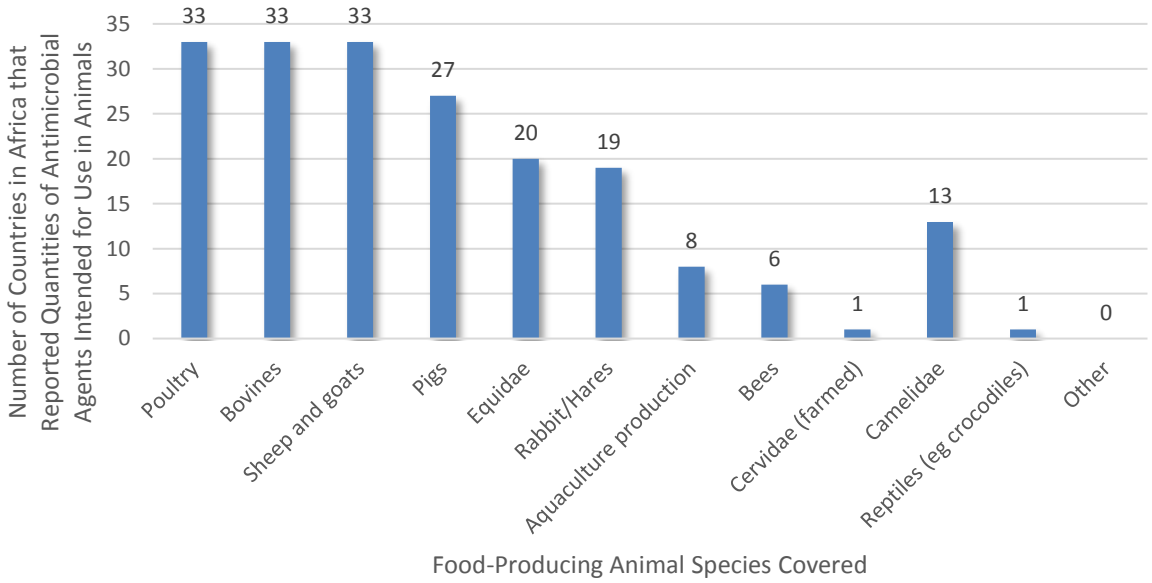
Figure A6. Differentiation by Animal Groups Among 33 Member Countries in Africa Reporting Quantitative Data from 2015 to 2017



Food-Producing Animal Species Covered by Quantitative Data

In the 33 African Member Countries that reported quantitative data on antimicrobial agents intended for use in animals, the food-producing species most frequently covered by the data were poultry, sheep and goats and bovines (Figure A7). Among the poultry production types, 'layers - commercial production for eggs' were named by 32 African countries (n = 33; 97%). For further information on the grouping of species see Section 3.3 of this report. Within the 4 regions analysed, Africa is the region were camelidae were more commonly name by Member Countries.

Figure A7. Food-Producing Animal Species Included in Quantitative Data Reported by 33 African Member Countries from 2015 to 2017

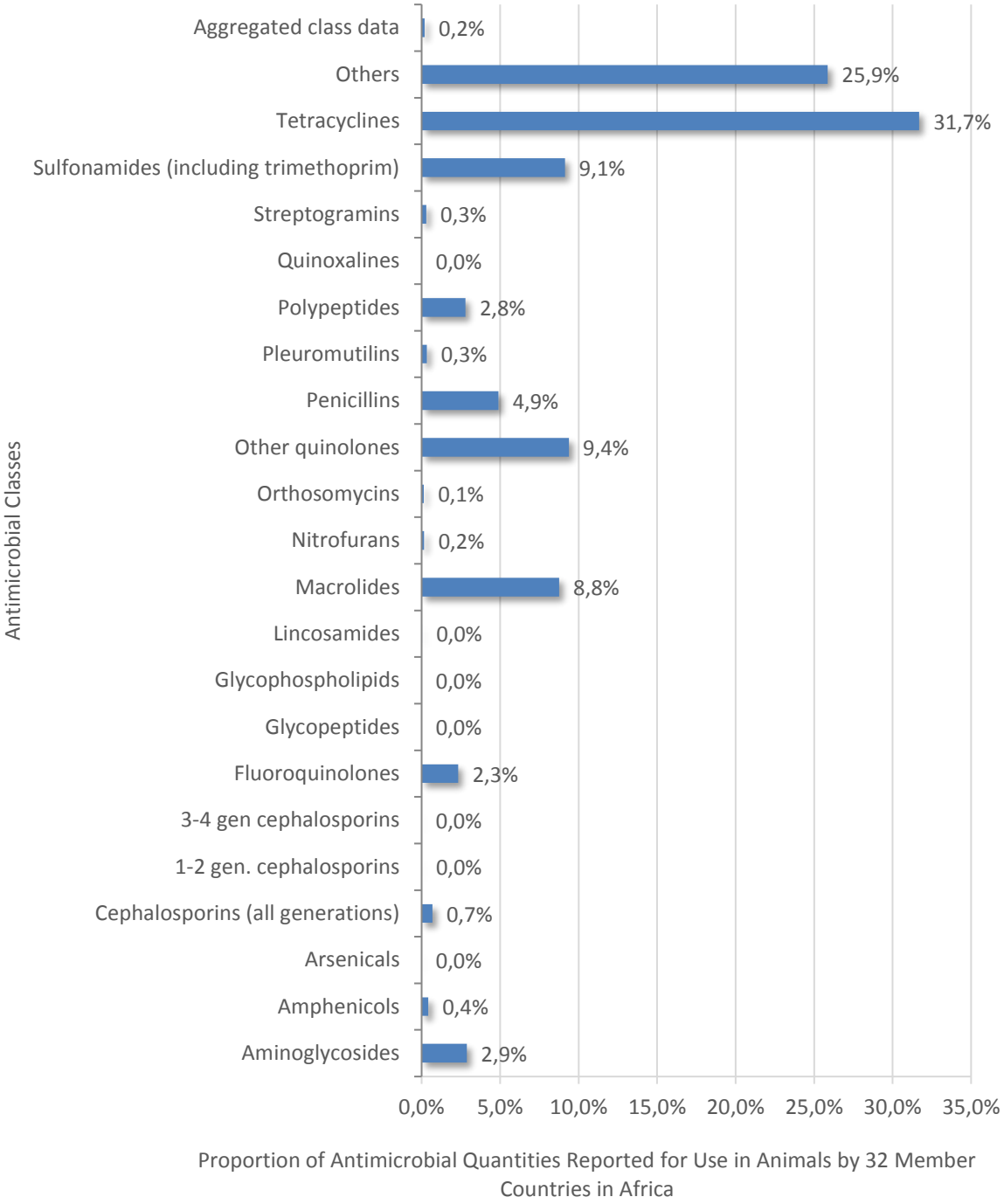


Antimicrobial Classes Reported

During the third round, 33 African countries provided quantitative data on antimicrobial agents intended for use in animals. However, one country was removed from Figure A8 because its data were excessively large and could not be explained.

In Africa, the largest proportion of all reported antimicrobial classes were tetracyclines, followed by 'Other quinolones' (Figure A8). Under the group of others most of the countries (4 out of 6; 67%) reported fosfomycin.

Figure A8. Proportion of Antimicrobial Quantities (by Antimicrobial Class) Reported for Use in Animals by 32[16] African Member Countries from 2015 to 2017



[16] One Member Country that reported extremely high figures was excluded from this analysis

Annex 2. Americas, Responses from the Third Round of Data Collection

Table A2. General Information for the Americas

General Information for the Americas	
Number of countries*	32
Number of countries responding to the questionnaire	30 (94%)
Number of countries providing only qualitative data	11 (37%)
Number of countries providing quantitative data	19 (63%)

*30 Member Countries and 2 non-OIE Member Countries

In the third round of data collection, the data collection template was also sent to non-OIE Member Countries that during the second round asked to be part of the survey.

In the Americas, 30 countries submitted completed reports to OIE Headquarters: 28 from OIE Member Countries (n = 30; 93%%) and 2 non-OIE Member Countries. The responses from non-OIE Member Countries were included in the analysis of the Americas for geographical reasons (Table A2).

Barriers to Providing Quantities of Antimicrobials Agents in Animals

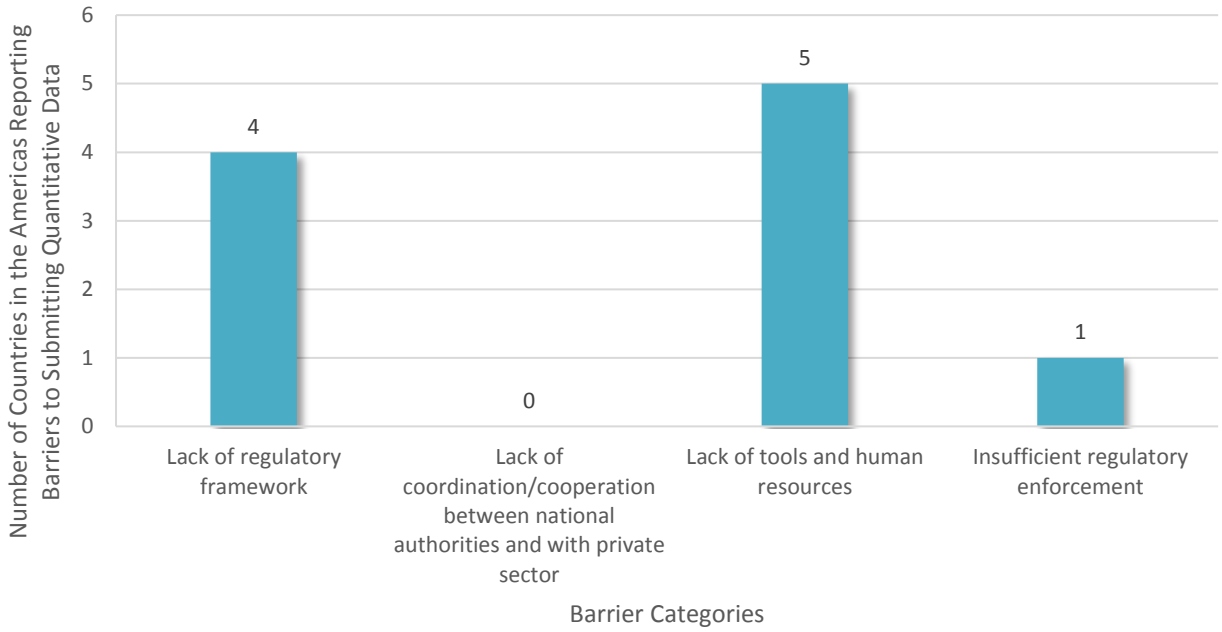
Eleven countries (n = 30; 37%) responded with Baseline Information (qualitative data) and no quantitative data on antimicrobial agents used in animals. Of these, 9 countries (n = 11; 82%) explained the barriers to reporting quantities of antimicrobial agents used in animals to the OIE. Countries could report more than one barrier relevant to their situation, and responses were grouped by category (Figure A9). For further information on the category groupings, please refer to the explanatory section in the global analysis for this report.

Half of the responses in the Americas (5 out of 9 countries; 56%) mentioned that the main impediment to reporting amounts of antimicrobials were a lack of tools and human resources. Two countries explained that the information for registration and tracking of import of veterinary medicinal products was not digitalised or did not captured the necessary information to perform the calculations to obtain kilograms of active ingredients for veterinary products. Both countries confirmed that discussion on the specifications software have already started, and expected to contribute with quantities of antimicrobials during the fourth round of data collection. Three other countries did not provide the amount of antimicrobials due to lack of dedicated staff to collect and analyse the data; one of them also reported the lack of a system to collect the data.

Four countries reporting a lack of regulatory framework explained that the data collection is not currently mandatory in their countries and therefore the data cannot be demanded.

One country explained that the importers do not register and import veterinary products as the market is too small and fall below the minimum quantities for bulk purchase, therefore, human medicines are used for animals. This country also mentioned that veterinarians import small quantities exclusively for use in livestock and poultry that are difficult to track.

Figure A9. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in 9 Countries in the Americas During the Third Round of Data Collection

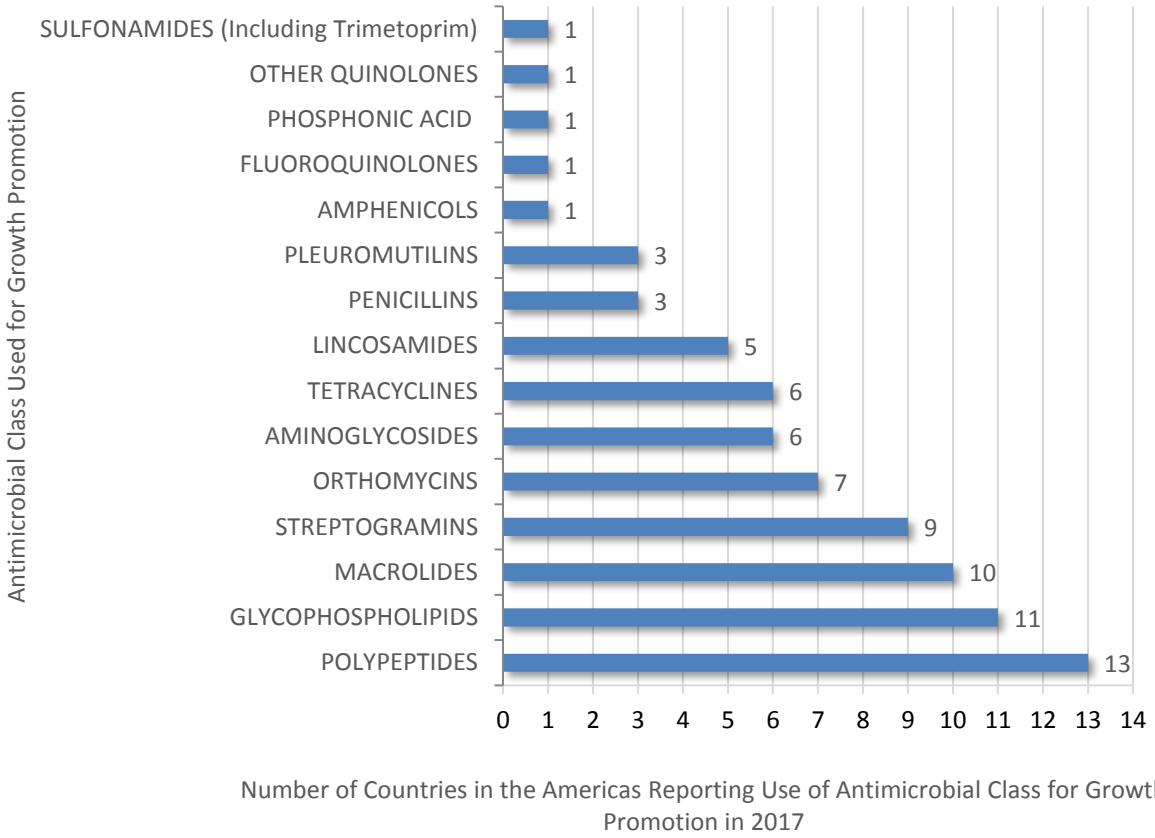


Antimicrobial Agents Used for Growth Promotion

Eighteen countries (n = 30; 60%) in the Americas use antimicrobial agents as growth promoters. Of these, 15 countries (n = 18; 83%) provided a list of antimicrobials used for growth promotion, with polypeptides most commonly named (by 13 countries), followed by glycophospholipids (Figure A10). The Americas is the OIE Region with the most number of Member Countries reporting a lack of legislation or regulation for antimicrobial as growth promoters when using these molecules (13 out of 18 countries, 72%). However, among this groups two countries confirmed that they are working in cooperation with pharmaceutical companies for a voluntary removal of growth promotion claims from the labels of all products that are considered to be Medically Important Antimicrobials in human medicine.

Ionophores were excluded for reporting as they are mostly used for parasite control and have different regulatory classifications in different countries; however, 9 countries in the Americas reported the use of these molecules as growth promoters, where monensin was mentioned by 7 countries and salinomycin and halquinol by 6 countries.

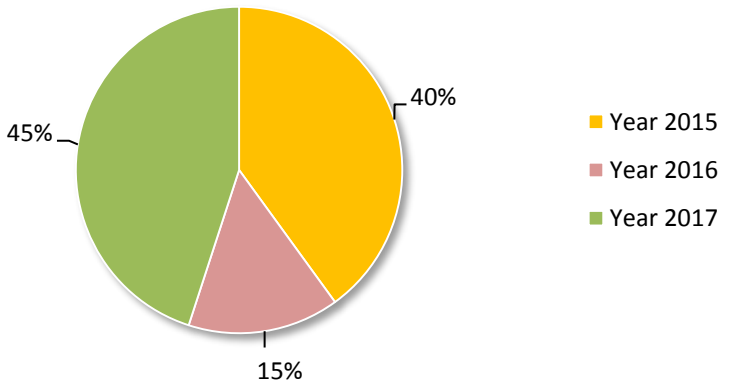
Figure A10. Antimicrobial Growth Promoters Used in 15 Countries in the Americas in 2017



Years of Quantitative Data Reported

Most of the 19 countries reporting quantitative data from the Americas did so for 2017 (45%), followed by 2015 (40%), the latter was the target year for of the third round of data collection (Figure A11). Countries in the Americas have continued to demonstrate commitment during the third round of the annual data collection with 3 countries progressing from reporting only Baseline Information (qualitative data) in the second round, to reporting quantitative data in the third round.

Figure A11. Years of Quantitative Data Reported from 19 Member Countries in the Americas During the Third Round of Data Collection

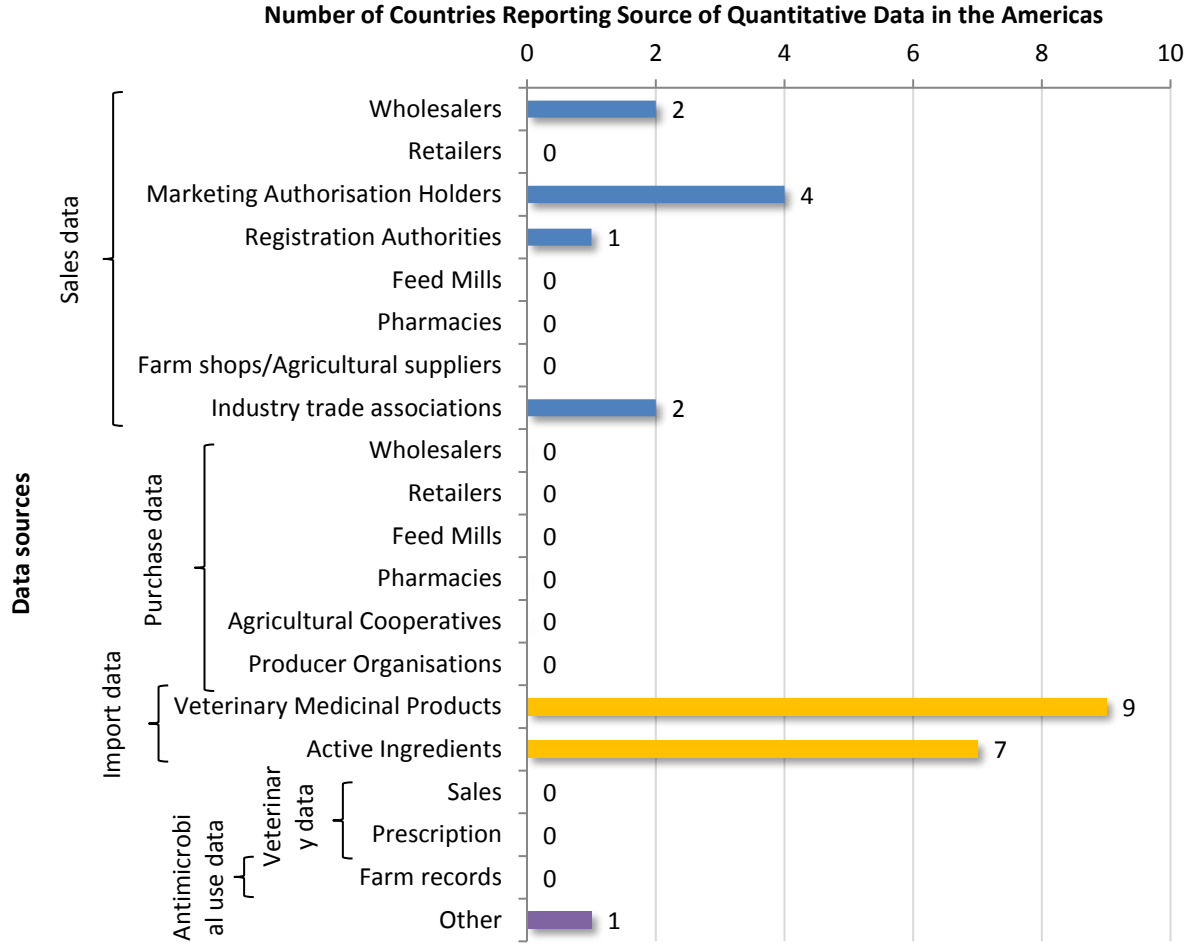


Quantitative Data Sources Captured

All the data sources from the Americas were analysed, and all countries where data duplication was considered to be a risk were asked for clarification of their answers and/or data collection systems. Following the clarifications, 14 countries (n = 19; 74%) changed their answers or proved there was no duplication or overlapping on the data sources. The remaining countries (5 out of 19; 26%) that did not clarify to the OIE were excluded from Figure A12 reporting quantitative information from 2015 to 2017.

From the list of data source options provided in the OIE template, import data were most commonly chosen by the countries in the Americas, particularly import data from veterinary medicinal products (final product), rather than the active ingredients used to elaborate them. One country choosing 'other' data sources, described that the data came from import permits issued by registration authorities. Multiple choices were possible in responding this question, including the option 'other'.

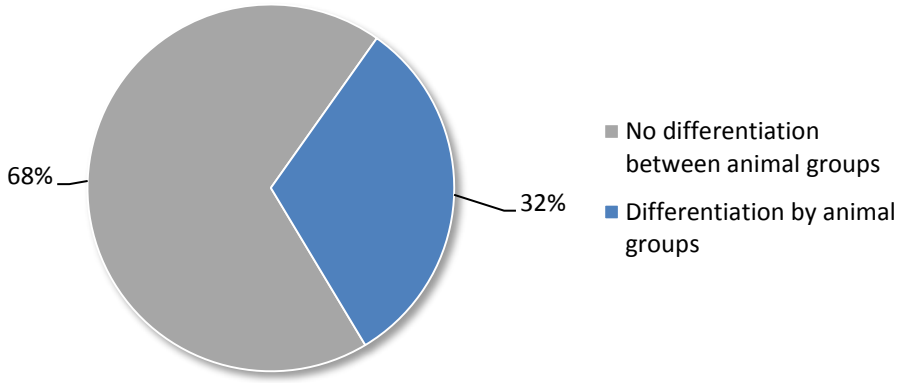
Figure A12. Data Source Selected by 14 Countries in the Americas Reporting Quantitative Information from 2015 to 2017



Quantitative Data Differentiation by Animal Groups

Most of the quantitative data from the Americas cannot be differentiated by animal group. This corresponds with the predominant use of Reporting Option 1 in the Americas, which does not allow for differentiation by animal group (Figure A13). Six countries (n = 19; 32%) were able to distinguish antimicrobial quantities by animal groups, mainly by companion animals; one country provided data only for companion animals.

Figure A13. Differentiation by Animal Groups Among 19 Countries in the Americas Reporting Quantitative Data from 2015 to 2017

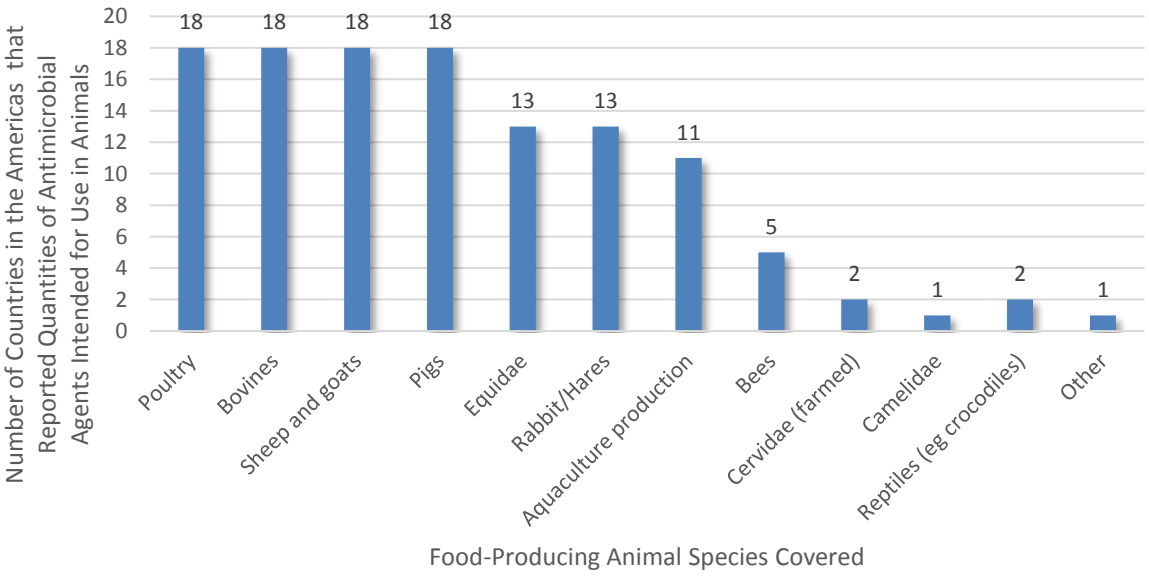


Food-Producing Animal Species Covered by Quantitative Data

Of the 18 countries providing quantitative data for food-producing animals in the Americas, the covered species most frequently reported were poultry, bovines, pigs and sheep and goats. (Figure A14); one country was excluded from this analysis as provided data only for companion animals. Among these groups, 'layers – commercial production for eggs', 'cattle' and "pigs – commercial' were named by all 18 countries. For further information on the grouping of species see Section 3.3 of this report.

One Member Country declared that ostriches are also considered food-producing animals and covered by the data.

Figure A14. Food-Producing Animal Species Included in Quantitative Data Reported by 18 Countries in the Americas from 2015 to 2017

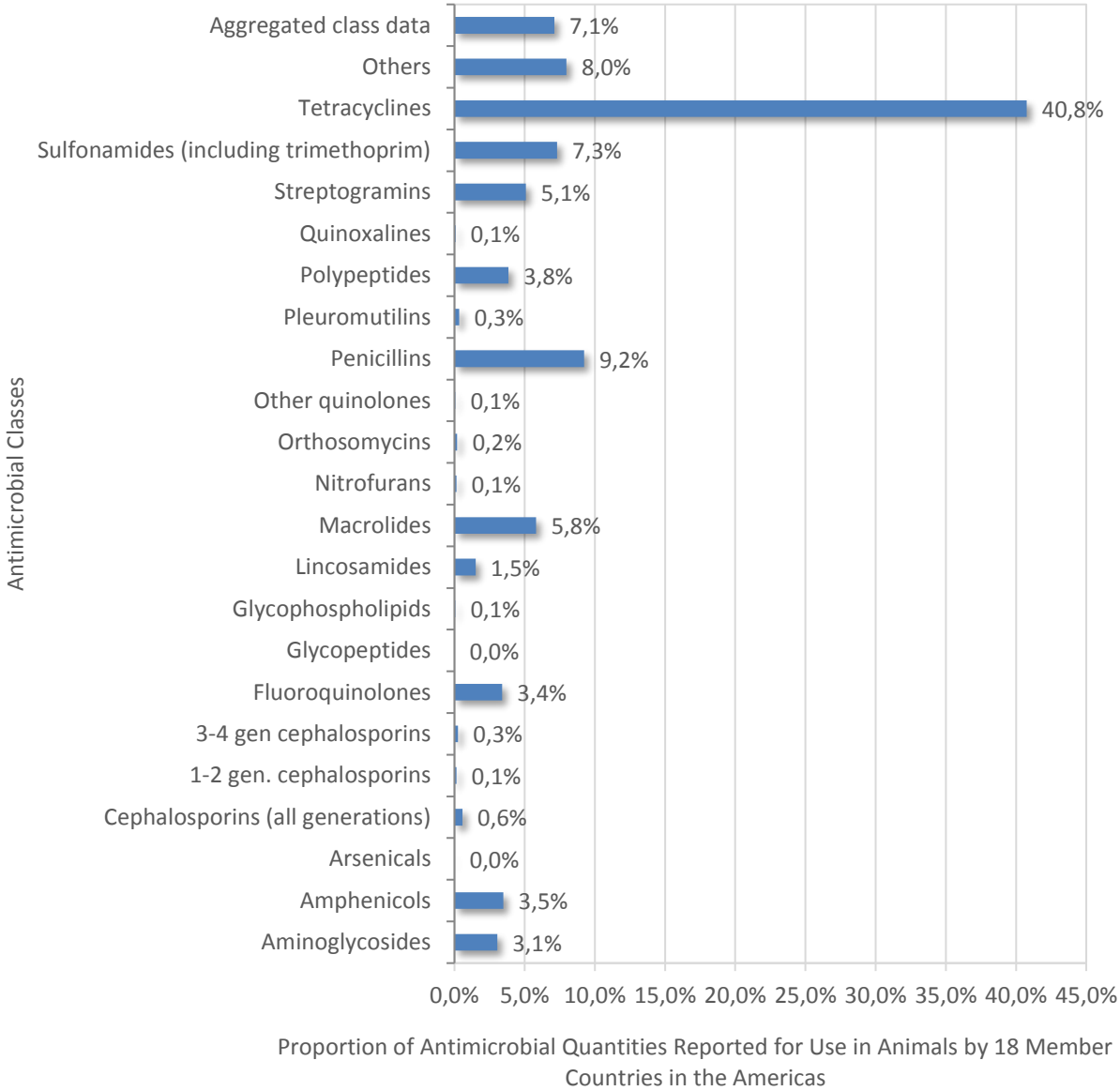


Antimicrobial Classes Reported

During the third round, 19 countries from the Americas provided quantitative data on antimicrobial agents intended for use in animals. However, one country was removed from Figure A15 because its data were excessively large and could not be explained.

In the Americas, the largest proportion of all reported antimicrobial classes were tetracyclines followed by penicillins (Figure A15). Eleven countries provided data under the group of 'others' but only 9 provided the list of antimicrobials included; most of these countries reported use of fosfomycin (5 out of 9; 56%), followed by metronidazole (2 out of 9; 22%).

Figure A15. Proportion of Antimicrobial Quantities (by Antimicrobial Class) Reported for Use in Animals by 18[17] Countries in the Americas from 2015 to 2017



[17] One Member Country that reported extremely high figures was excluded from this analysis

Annex 3. Asia, Far East and Oceania, Responses from the Third Round of Data Collection

Table A3. General Information for Asia, Far East and Oceania

General Information for Asia, Far East and Oceania	
Number of Member Countries	32
Number of Member Countries responding to the questionnaire	30 (94%)
Number of Member Countries providing only qualitative data	5 (17%)
Number of Member Countries providing quantitative data	25 (83%)

Barriers to Providing Quantities of Antimicrobial Agents in Animals

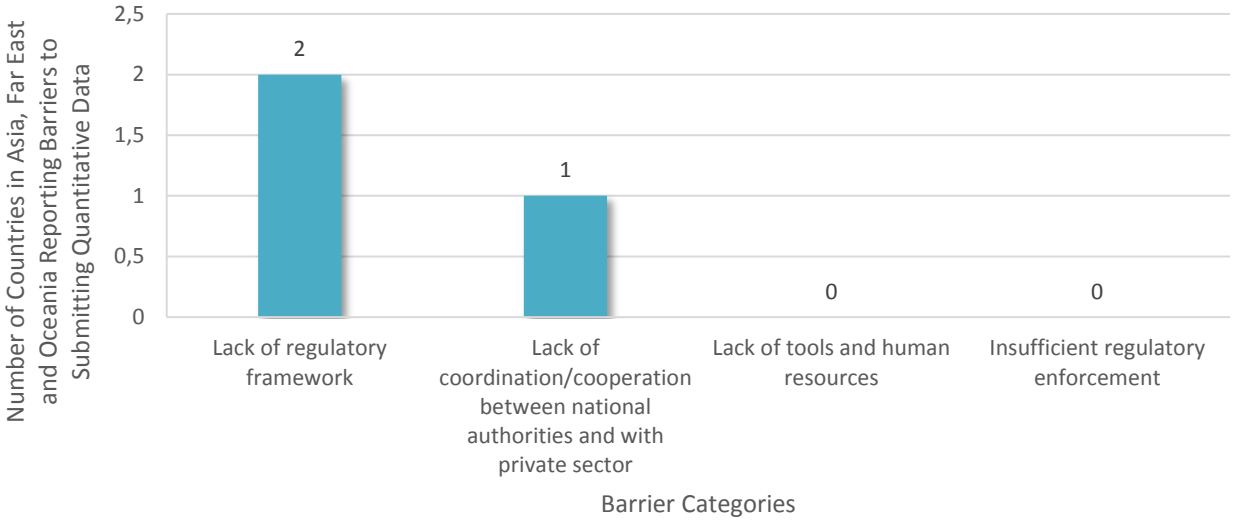
Since the second round of data collection, 3 Member countries graduated from reporting only Baseline Information to reporting quantitative data for the first time. These countries had previously reported a lack of cooperation/coordination between national authorities.

During the third phase, 5 Member Countries (n = 30; 17%) responded with Baseline Information (qualitative data) and no quantitative data on antimicrobials agents used in animals (Table A3). Of these Member Countries, 3 explained the barriers to reporting quantities of antimicrobial agents used in animals. Member Countries could report more than one barrier relevant to their situation and responses were grouped by category (Figure A16). For further information please refer to the explanatory section for each category in the global analysis for this report.

Two Member Countries described the reason why they were unable to report quantitative data was due to a lack of regulatory framework; both of these Member Countries specified that there was no regulatory framework for registration, authorisation, manufacture or importation of veterinary products, and one also described a general lack of regulatory framework for animal health.

The Member Country describing a lack of coordination/cooperation between national authorities and with private sector, indicated that the regulation of veterinary products and its data were held by another agency in the government.

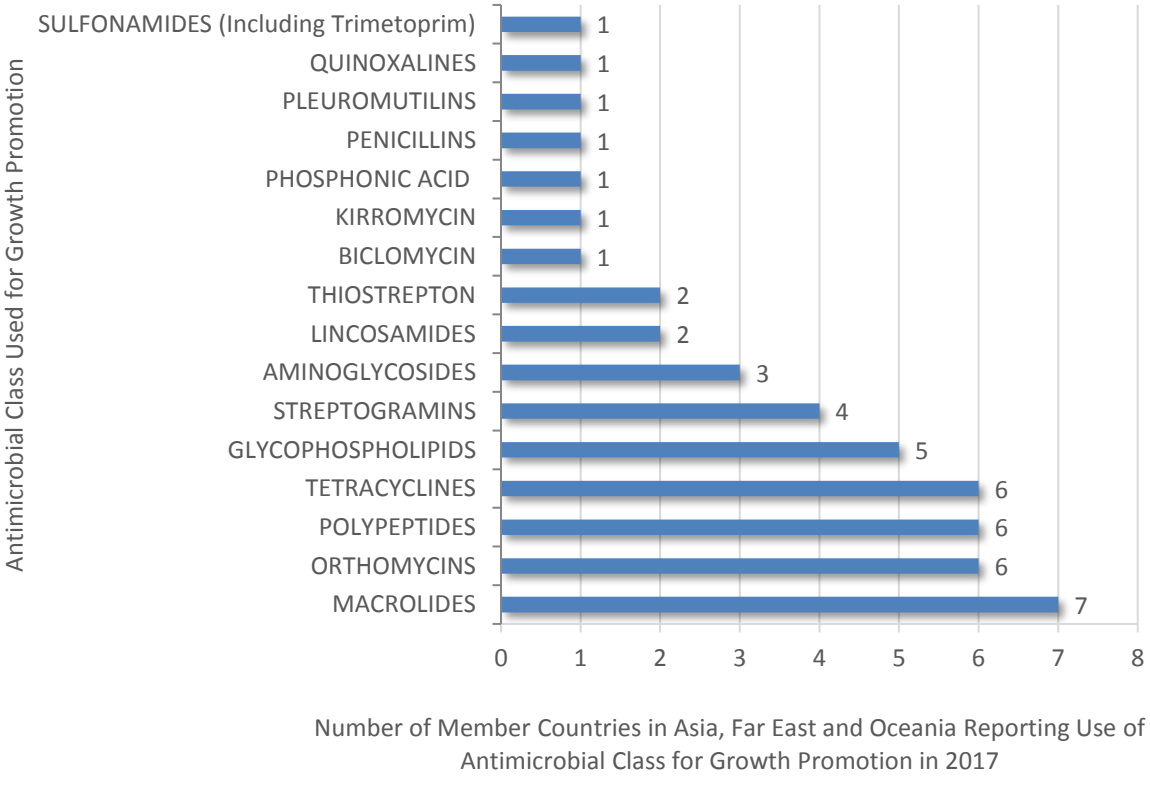
Figure A16. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in 3 Member Countries in Asia, Far East and Oceania During the Third Round of Data Collection



Antimicrobial Agents Used for Growth Promotion

Fourteen Member Countries (n = 30; 46%) reported use of antimicrobials as growth promoters. Of these, 10 Member Countries (n = 14; 71%) provided a list of utilised agents, the most frequently listed antimicrobial agents for this purpose were macrolides, followed by orthomycins, polypeptides and tetracyclines (Figure A17).

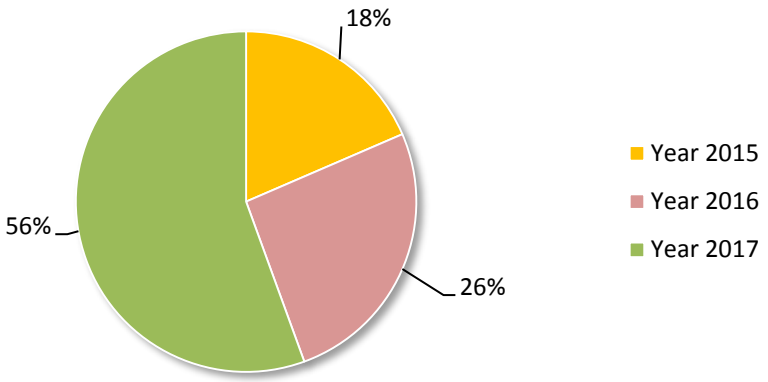
Figure A17. Antimicrobial Growth Promotors Used in Animals in 10 Member Countries in Asia, Far East and Oceania in 2017



Years of Quantitative Data Reported

Based on 25 responses from Member Countries in Asia, Far East and Oceania, the most commonly reported year of quantitative data on antimicrobials agents intended for use animals was 2017 (Figure A18). Some countries were able to provide data for 2015, the target year for the third phase of the data collection. As stated in previous reports, these findings suggest that many Member Countries in Asia, Far East and Oceania have only recently begun collecting this information, and consequently only have access to current information.

Figure A18. Years of Quantitative Data Reported from 25 Member Countries in Asia, Far East and Oceania During the Third Round of Data Collection

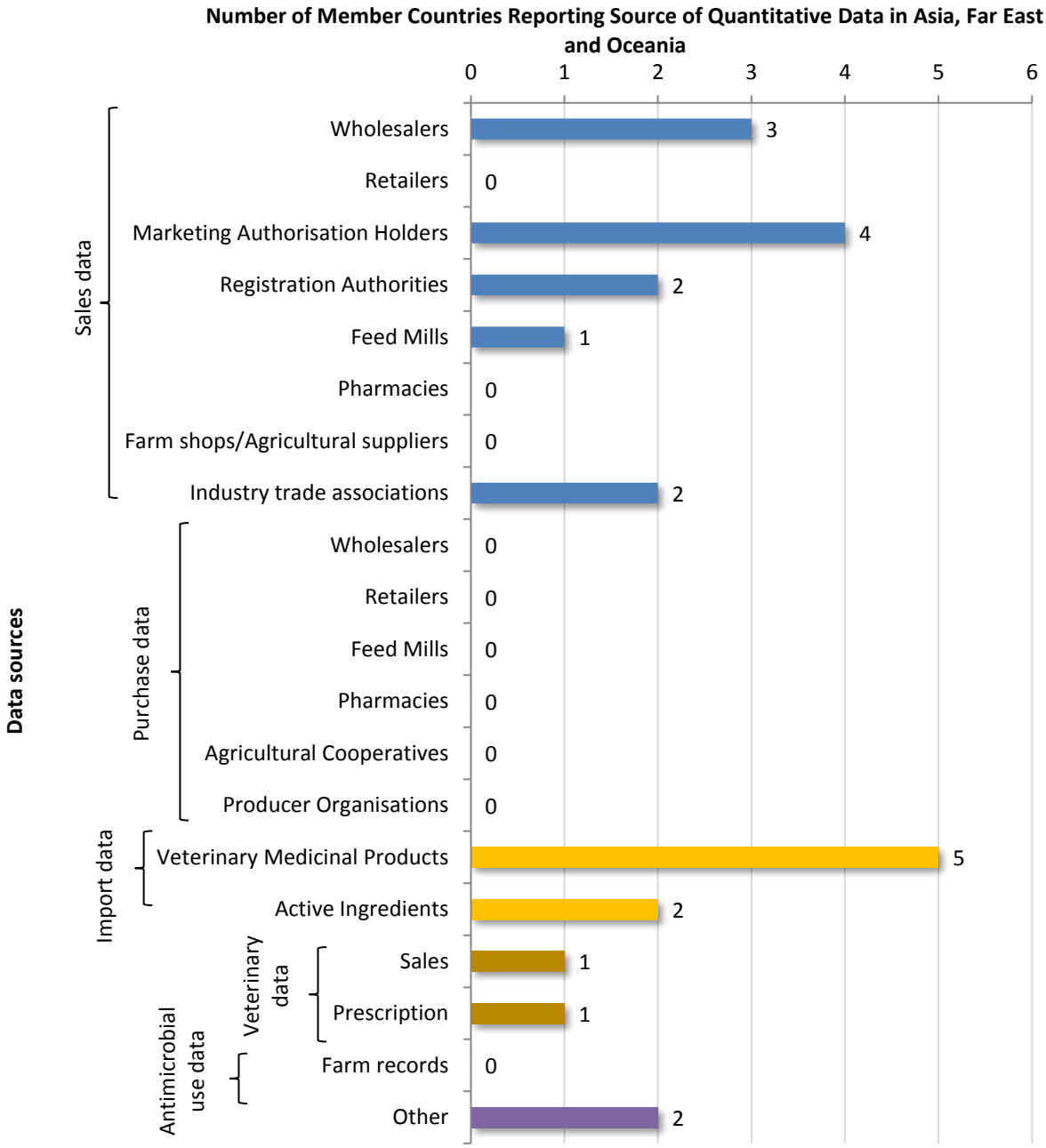


Quantitative Data Sources Captured

All the data sources from Asia, Far East and Oceania were analysed, and all countries where the data duplication was considered to be a risk were asked for clarification of their answers and/or data collection systems. After the clarifications, 16 countries (n = 25; 64%) changed their answers or proved there was no duplication or overlapping on the data sources. The remaining countries (9 out of 25; 36%) that did not clarify to the OIE were excluded from Figure A19 reporting quantitative data from 2015 to 2017.

From the list of data source options provided in the OIE template, sales data for veterinary products was most commonly chosen, with 10 Member Countries (n = 16; 63%) selecting this option (Figure A19). Multiple choices were possible in responding to this question, including the option ‘other’.

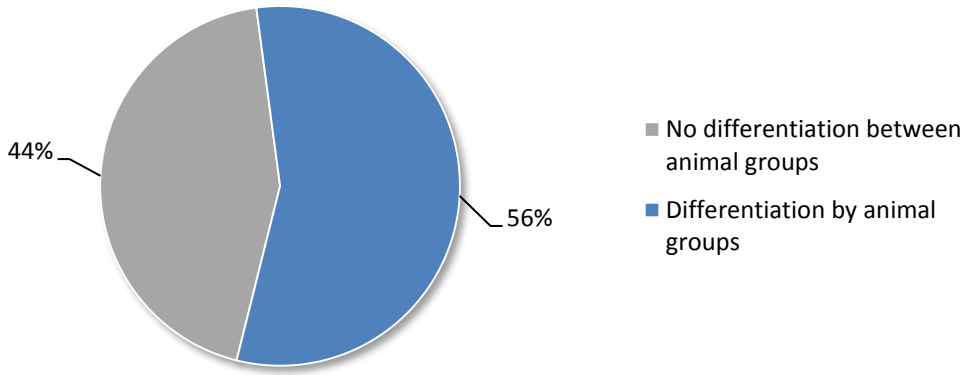
Figure A19. Data Sources Selected by 16 Member Countries in Asia, Far East and Oceania Reporting Quantitative Information from 2015 to2017



Quantitative Data Differentiation by Animal Groups

Most of the data from Member Countries in Asia, Far East and Oceania can be differentiated by animal groups. This result corresponds with the region's predominant use of Reporting Option 2 and 3, which allows for differentiation by animal group (Figure A20). Fourteen countries (n = 25; 56%) were able to distinguish antimicrobial quantities by animal groups, mainly by terrestrial food-producing animals.

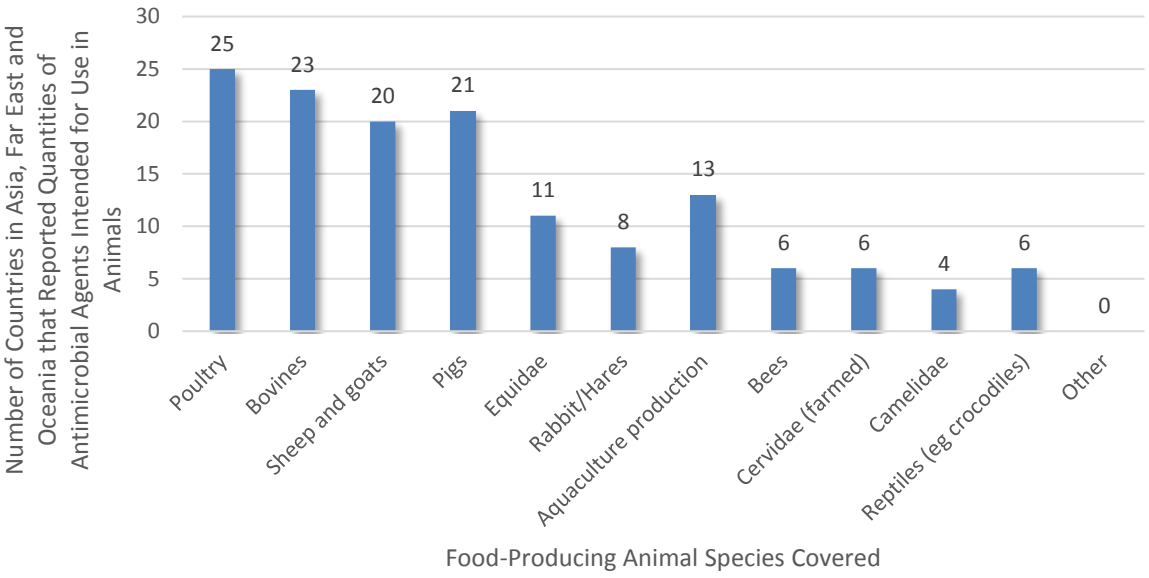
Figure A20. Differentiation by Animal Groups Among 25 Member Countries in Asia, Far East and Oceania Reporting Quantitative Data from 2015 to 2017



Food-Producing Animal Species Covered by Quantitative Data

In the 25 Member Countries in Asia, Far East and Oceania that reported quantitative data on antimicrobial agents intended for use in animals, the food-producing species most frequently covered by these data were poultry, bovines and pigs (Figure A21). Among the different production types, cattle and layers – commercial production for eggs were named by 23 and 22 countries respectively. For further information on the grouping of species see Section 3.3 of this report. Asia, Far East and Oceania is the second region where aquaculture production was more commonly named by Member Countries.

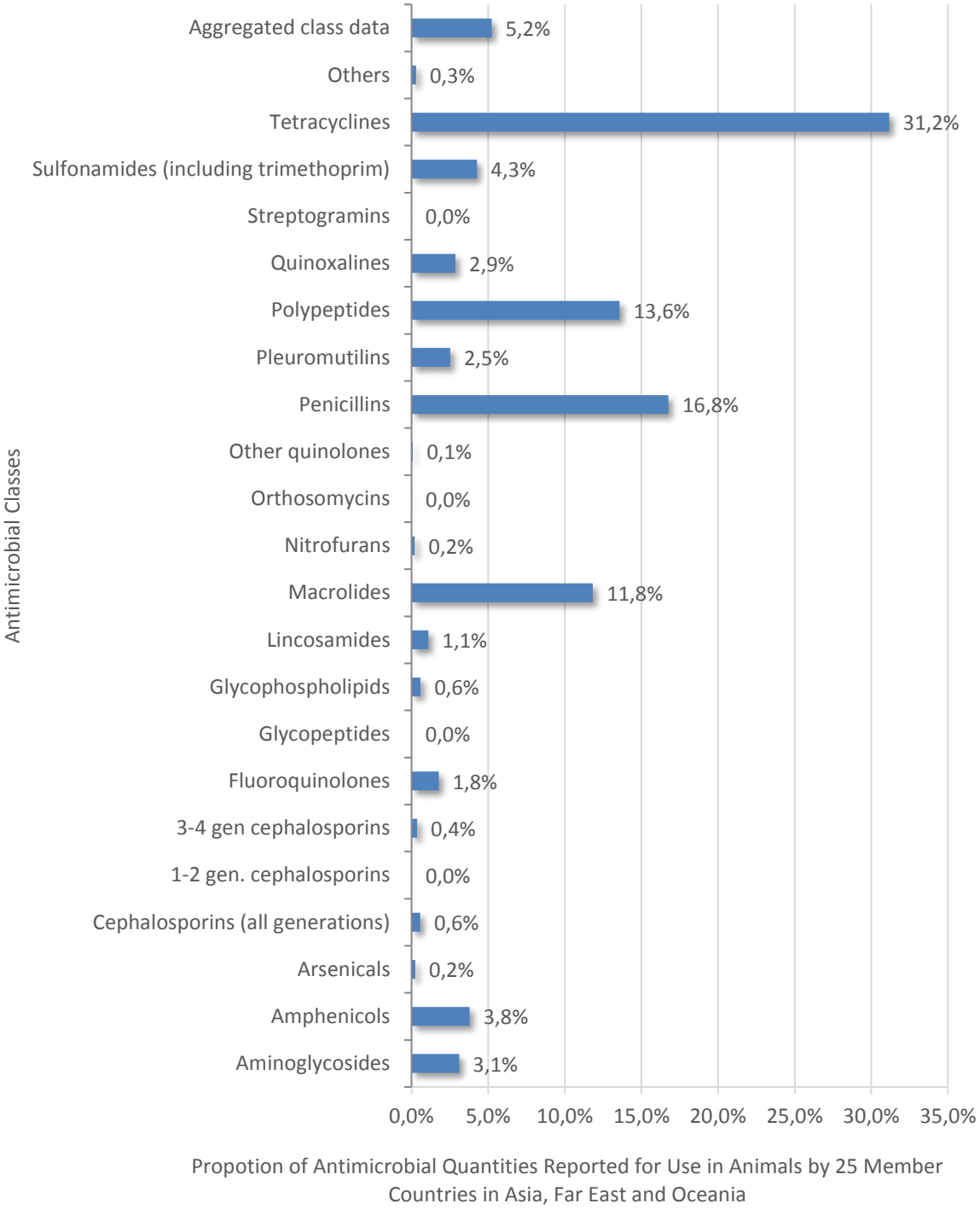
Figure A21. Food-Producing Animal Species Included in Quantitative Data Reported by 25 Member Countries in Asia, Far East and Oceania from 2015 to 2017



Antimicrobial Classes Reported

In Asia, Far East and Oceania, the largest proportion of all antimicrobial classes for which quantities were reported were tetracyclines and penicillins, followed by polypeptides (Figure A22).

Figure A22. Proportion of Antimicrobial Quantities (by Antimicrobial Class) Reported for Use in Animals by 25 Member Countries in Asia, Far East and Oceania from 2015 to 2017



Annex 4. Europe, Responses from the Third Round of Data Collection

Table A4. General Information for Europe

General Information for Europe	
Number of Member Countries	53
Number of Member Countries responding to the questionnaire	44 (83%)
Number of Member Countries providing only qualitative data	6 (14%)
Number of Member Countries providing quantitative data	38 (86%)

Barriers to Providing Quantities of Antimicrobial Agents in Animals

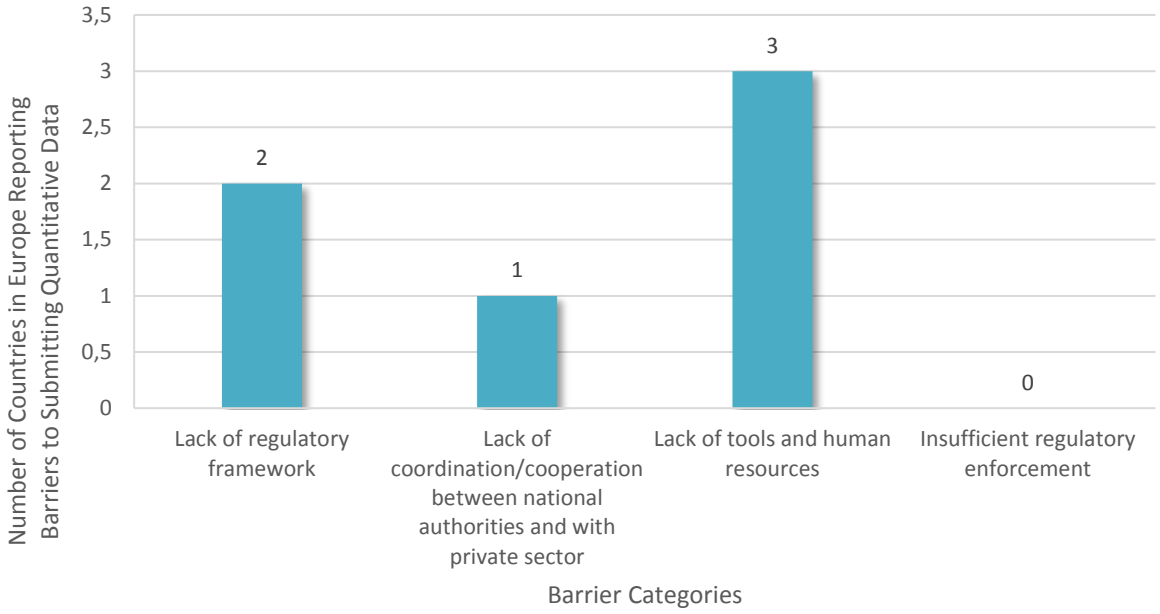
During the third phase, 6 Member Countries (n = 44; 14%) responded with Baseline Information (qualitative data) and no quantitative data on antimicrobials agents used in animals (Table A4). Of these Member Countries, 4 explained the barriers to reporting quantities of antimicrobial agents used in animals. Member Countries could report more than one barrier relevant to their situation and responses were grouped by category (Figure A23). For further information please refer to the explanatory section for each category in the global analysis for this report.

Three Member Countries described the lack of a software to analyse the data as the reason they were unable to report quantitative data; of these, 2 countries explained that were in the process of writing the specifications for the software or at the implementation phase, and expected to contribute quantitative data during the fourth round of data collection. Two of these countries also mentioned other categories including 'lack of regulatory framework' and that 'lack of coordination/cooperation between national authorities and with the private sector'.

Two Member Countries that cited the lack of a regulatory framework explained that their data collection system is at developmental stage.

One Member Country described impediments to reporting amounts of antimicrobials related to a lack of coordination and cooperation with private sector veterinarians.

Figure A23. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in 4 Member Countries in Europe During the Third Round of Data Collection



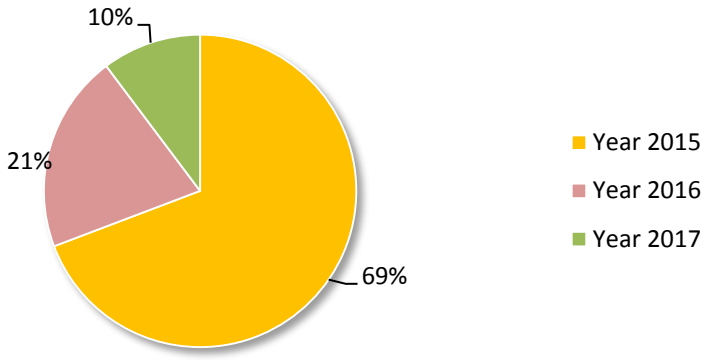
Antimicrobial Agents Used for Growth Promotion

Two Member Countries (n= 44; 5%) reported using antimicrobial growth promoters in animals. Both countries confirmed that they were already working on the legislation in order to ban the use of antimicrobial growth promoters. One country will have already banned growth promoters by the time this report is published. These countries did not provide a list of antimicrobials used as growth promoters.

Years of Quantitative Data Reported

Most of the 38 Member Countries reporting from Europe provided quantitative data on antimicrobial agents intended for use in animals for 2015, the target year of data collection for the OIE (Figure A24). Most of the countries of this OIE Region are accustomed to reporting sales of veterinary antimicrobial agents through the ESVAC protocol, for which the 2015 data had already been collected.

Figure A24. Years of Quantitative Data Reported from 38 Member Countries in Europe During the Third Round of Data Collection



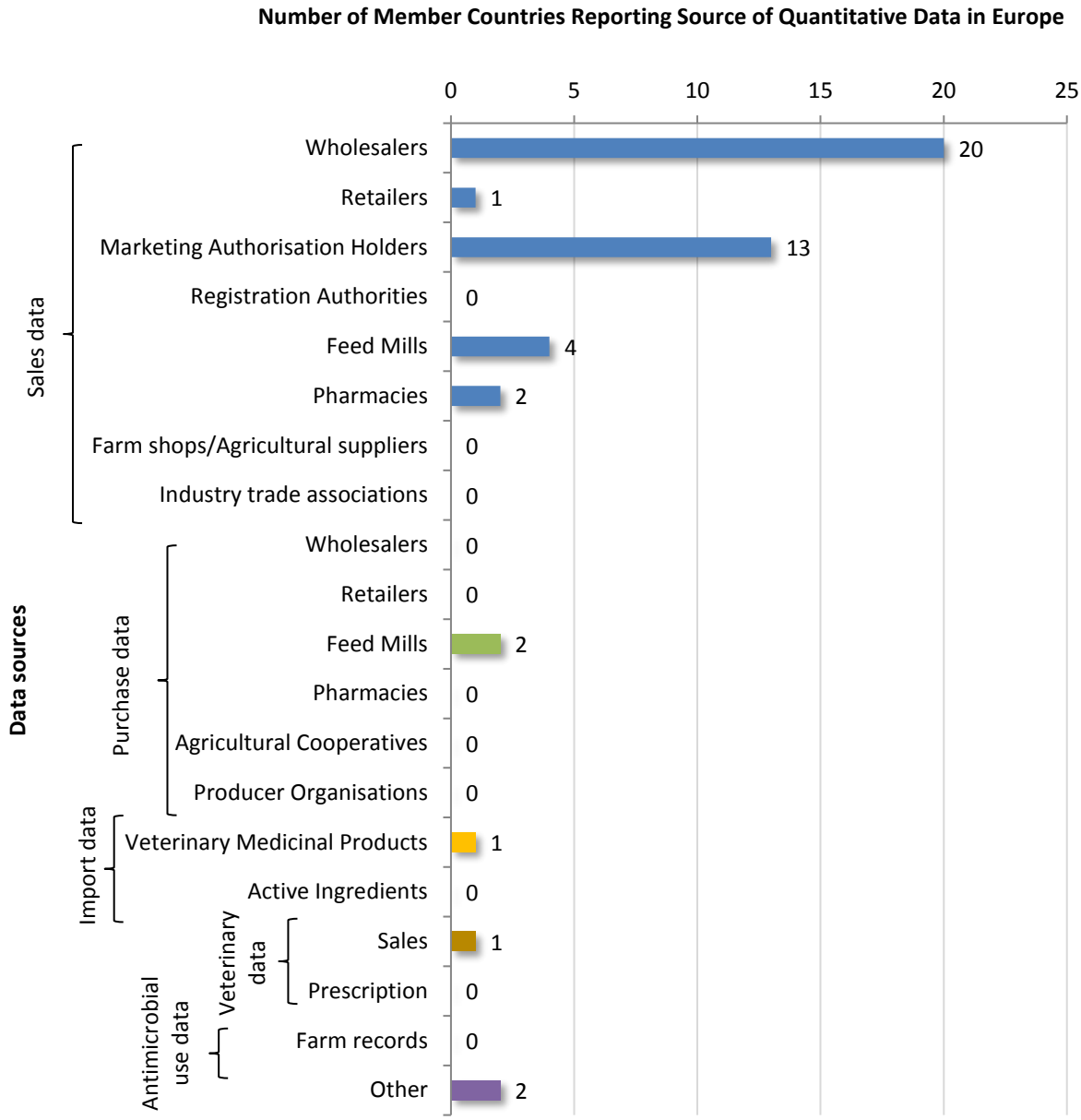
Quantitative Data Sources Captured

All European countries' data sources were analysed, and all countries where the data duplication was considered to be a risk were then asked for clarification of their answers and/or data collection systems. After the clarifications, 34 countries (n = 38; 89%) changed their answers or proved there was no duplication or overlapping on the data sources. The remaining countries (4 out of 38; 11%) that did not clarify to the OIE were excluded from Figure A25reporting quantitative information from 2015 to 2017.

From the list of data source options provided in the OIE template, sales data from wholesalers was selected by 20 Member Countries in Europe, followed by sales from Marketing Authorisation Holders chosen by 13 Member Countries (Figure A25).

The 2 Member Countries reporting 'other' sources identified data from import permits issued by registration authorities, and production data reported directly from manufacturers.

Figure A25. Data Sources Selected by 34 European Member Countries Reporting Quantitative Information from 2015 to 2017

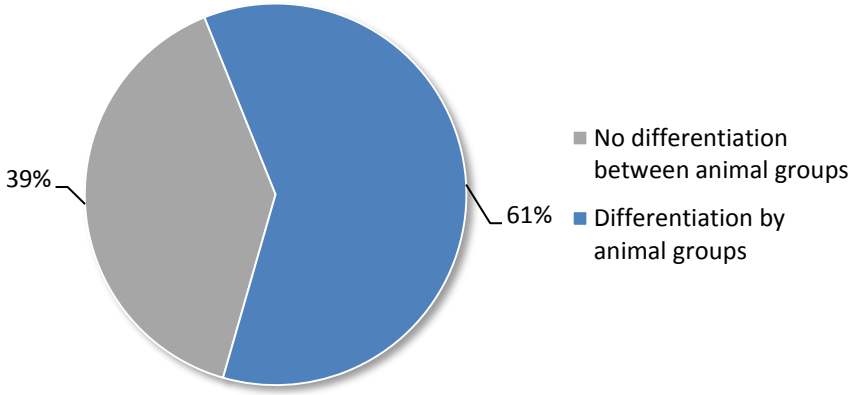


Quantitative Data Differentiation by Animal Groups

More than half of the quantitative data reported to the OIE from European Member Countries were differentiated by animal groups (Figure A26). These results correspond with the European Region's predominant use of Reporting Option 2 and 3. Twenty-three countries (n = 38; 61%) were able to distinguish antimicrobial quantities by animal groups, mainly by food-producing animals (terrestrial and aquatic animals combined).

Globally, 9 Member Countries were able to distinguish quantitative data specifically for 'Aquatic food-producing animals', and 4 of these 9 Member Countries were from Europe.

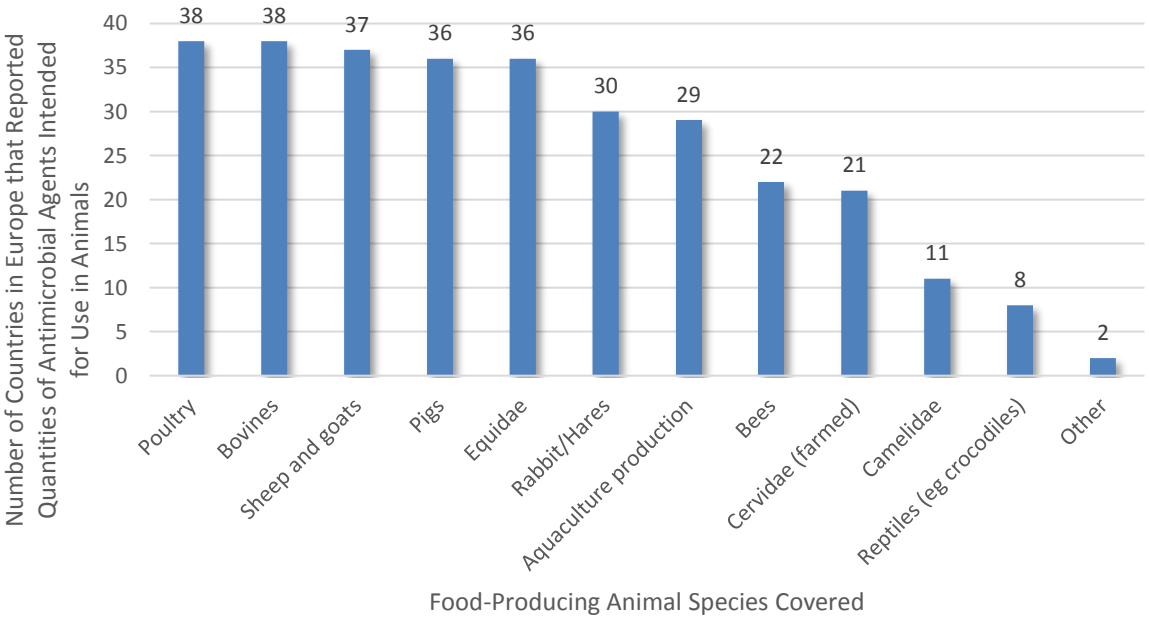
Figure A26. Differentiation by Animal Groups Among 38 Member Countries in Europe Reporting Quantitative Data from 2015 to 2017



Food-Producing Animal Species Covered by Quantitative Data

In the 38 European Member Countries that reported quantitative data on antimicrobial agents intended for use in animals, the food-producing species most frequently covered by the reported data were poultry, bovines, sheep, goats and pigs (Figure A27). Among the different production types, cattle and broiler chickens were named by 38 and 37 countries, respectively. For further information on the grouping of species see Section 3.3 of this report.

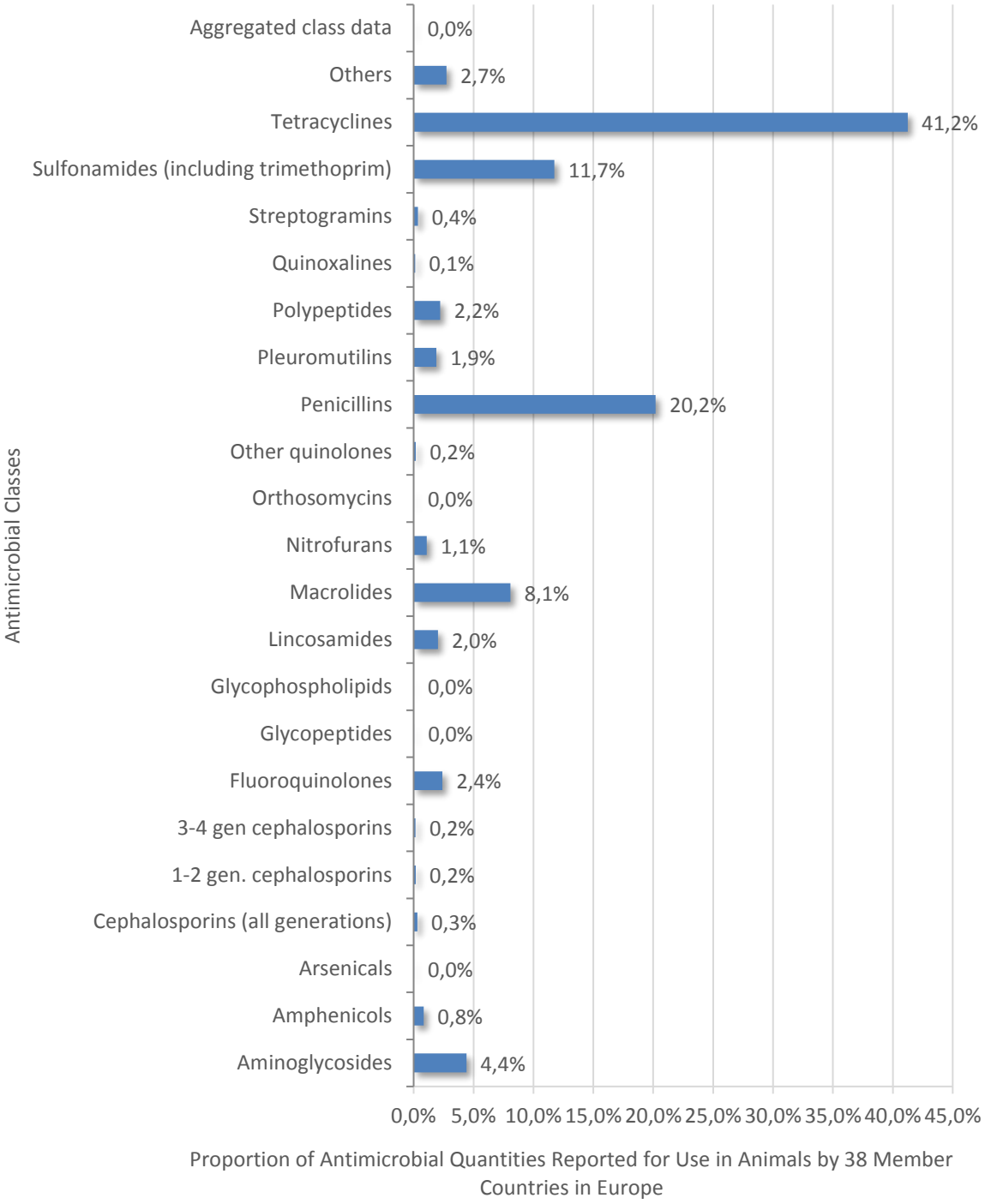
Figure A27. Food-Producing Animal Species Included in Quantitative Data Reported by 38 European Member Countries from 2013 to 2016



Antimicrobial Classes Reported

In Europe, the largest proportion of all antimicrobial classes reported for use in animals were tetracyclines followed by penicillins (Figure A28). Under the category of 'others' 16 countries reported rifaximin (n = 25; 64%), and 13 reported metronidazole (n = 25; 52%).

Figure A28. Proportion of Antimicrobial Quantities (by Antimicrobial Class) Reported for Use in Animals by 38 Member Countries in Europe from 2015 to 2017



Annex 5. Middle East, Responses from the Third Round of Data Collection

Table A5. General Information for the Middle East

General Information for the Middle East	
Number of Member Countries	12
Number of Member Countries responding to the questionnaire	7 (58%)
Number of Member Countries providing only qualitative data	4 (57%)
Number of Member Countries providing quantitative data	3 (43%)

Due to confidentiality concerns, most variables included in the survey cannot be published in this report for the Middle East region as the data represents only a small number of Member Countries (Table A5). Higher participation by Member Countries in the Middle East Region in the future would allow a more in-depth study of the data.

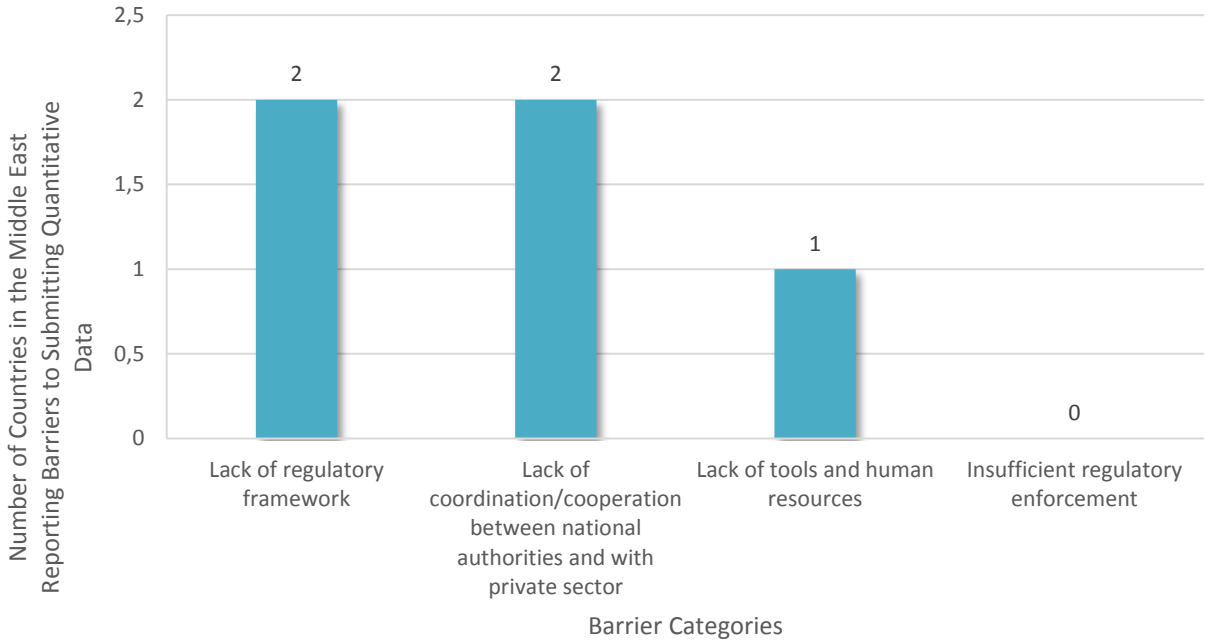
Barriers to Providing Quantities of Antimicrobial Agents in Animals

During the third phase, 4 Member Countries (n = 7; 57%) responded with Baseline Information (qualitative data) and no quantitative data on antimicrobials agents used in animals, and explained the barriers to reporting quantities of antimicrobial agents used in animals (Table A5). Member Countries could report more than one barrier relevant to their situation and responses were grouped by category (Figure A29). For further information please refer to the explanatory section for each category in the global analysis for this report.

Two Member Countries described the lack of regulatory framework as the reason they were unable to report quantitative data; one country explained that the AMR National Action Plan has been developed but not implemented. Its implementation will facilitate data collection on antimicrobials intended for use in animals in the future. One country indicated that there was currently no regulatory framework for the manufacture, registration, distribution, commercialisation and pharmacovigilance veterinary products, but it is in the process of developing necessary legislation.

One Member Country reported that the relevant data were held by another national authority and was in discussion to obtain the data for future OIE reports. One country reported that there was lack of collaboration with private veterinarians and pharmacies; in addition, this country mentioned the lack of a software that could be used to analyse import data.

Figure A29. Country Barriers to Reporting Quantitative Data on Antimicrobial Agents Intended for Use in Animals in 4 Member Countries in the Middle East During the Third Round of Data Collection



Annex 6. OIE Template

Q	*** This sheet of the OIE template should be completed by all OIE Member Countries *** Please refer to the Guidance document for further instructions.	
	A. Contact Person for Antimicrobial Agents Use Data Collection	
1	**Title**	<free text field>
2	**Name (First name, SURNAME)**	<free text field>
3	**Role with respect to the OIE**	☐ OIE Delegate ☐ OIE Focal Point for Veterinary Products ☐ Other
4	**Organisation**	<free text field>
5	**Organisation's Address**	<free text field>
6	**Country**	<free text field>
7	**Phone Number**	<free text field>
8	**Email Address**	<free text field>
	B. General Information	
9	**Are data on the amount of antimicrobial agents intended for use in animals available?**	☐ Amounts available - Yes ☐ Amounts available - No
10	*Please indicate why the data are not available at this time in your country, if the answer to Question 9 is 'No'*	*<free text field>*
11	**Are antimicrobial agents used for growth promotion purposes in animals in your country?**	☐ Yes ☐ No ☐ Unknown
12	**Does your country have legislation/regulations on the use of antimicrobial agents as growth promoters in animals?**	☐ Legislation/regulation exists - Yes ☐ Legislation/regulation does not exist - No
13	**If your country has legislation/regulation on the use of antimicrobial agents as growth promoters in animals, could you please indicate the appropriate case that applies in your country?**	☐ All antimicrobial agents banned for use as growth promoters ☐ Some antimicrobial agents banned for use as growth promoters ☐ One or more antimicrobial growth promoters are authorised for use
14	**Please provide a list of antimicrobial agents authorised as growth promoters, if any**	*<free text field>*
	*If your response to Question 9 is '**No**', please kindly send this template, once validated by the OIE Delegate and with your OIE Delegate in copy, to the OIE Antimicrobial Use Team at:* antimicrobialuse@oie.int *If your response to Question 9 is '**Yes**', please kindly complete Section C "Data Collection".*	
	C. Data collection of Antimicrobial Agents Intended for Use in Animals	
	*** Please provide data for **2015** If you have data for another year, please select the year from the list below ***	
15	**Year for which data apply** (Please select only one year per template)	☐ 2015 (target year) ☐ 2016 ☐ 2017
16	**Time period for which data are provided** (e.g., 1 January to 31 December 2015)	<free text field>
17	**Data source**	**Sales data** ☐ Sales data - Wholesalers ☐ Sales data - Retailers ☐ Sales data - Marketing Authorisation Holders ☐ Sales data - Registration Authorities ☐ Sales data - Feed Mills ☐ Sales data - Pharmacies ☐ Sales data - Farms Shops/Agricultural Suppliers ☐ Sales data - Industry Trade Associations **Purchase data** ☐ Purchase data - Wholesalers ☐ Purchase data - Retailers ☐ Purchase data - Feed Mills ☐ Purchase data - Pharmacies ☐ Purchase data - Agricultural Cooperatives ☐ Purchase data - Producer Organisations **Import data** ☐ Import data - Customs declarations - Veterinary Medicinal Product ☐ Import data - Customs declarations - Active Ingredient **Veterinary data** ☐ Veterinary data - Sales ☐ Veterinary data - Prescriptions **Antimicrobial use data** ☐ Antimicrobial use data - Farm Records **Other data source(s)**

Questions in **bold** are mandatory. Please provide this information as requested. Questions in *grey italics* are optional.

Please provide the contact information of the person completing this template, in case there are queries on the information provided. Please select the appropriate 'Role with respect to the OIE' from the list.

Please provide the telephone number in the format " (country code) phone number ".

Growth Promotion refers to the use of antimicrobial substances to increase the rate of weight gain and/or the efficiency of feed utilisation in animals by other than purely nutritional means. The term does NOT apply to the use of antimicrobial agents for the specific purpose of treating, controlling or preventing infectious diseases, even when an incidental growth response may be obtained.

Please provide data for **2015**. If you have data for another year, please select the year from the list. We will accept data for other years , **but not from before 2015**. If you would like to provide data for additional years, please fill out one template per year of data.

From the list of options, indicate the data sources from which the information on the amount of antimicrobial agents for use in animals was obtained. Multiple selections are possible. **In case you use multiple sources, please be aware of the risk of doubling or overlapping the data.**

18	*Clarification of the data source, if your response to Question 17 is 'Other'*	*<free text field>*	Please provide an estimate of the extent to which the quantitative data you report is representative of the overall antimicrobial sales for use in animals (percentage of the total sales in your country in relation to overall use).
19	**Estimated coverage of accessible data out of total amount (in %)**	**0%**	
20	*Explanation of estimated coverage*	<free text field>	Please explain which data are not captured on the antimicrobial agents used in animals reported by your country.
21	**Is the information extrapolated from representative samples?**	☐ Data extrapolated from representatives samples - Yes ☐ Data extrapolated from representatives samples - No	Please indicate whether the data provided have been extrapolated from representative samples (e.g., at farm or veterinary level).
22	*Explanation of extrapolations carried out, if your response to Question 21 is 'Yes'*	*<free text field>*	
23	**Can data be differentiated by animal group?**	☐ Data differentiated by animal group - Yes ☐ Data differentiated by animal group - No	For the purposes of the database, animal group means: 'Terrestrial food-producing animals', 'Aquatic food-producing animals' or 'Companion animals'. If your data is differentiated by any of these groups, please select 'Yes'.
24	**Animal groups <u>covered by the data</u>**	☐ Data with no differentiation (all animals combined) ☐ Data for terrestrial and aquatic food animals (all food-producing animals combined) ☐ Data for terrestrial food-producing animals ☐ Data for aquatic food-producing animals ☐ Data for companion animals	Please indicate which animal groups are covered by your data. Multiple selections are possible.
25	**Food-producing animal species <u>covered by the data</u>**	☐ Cattle ☐ Pigs - commercial ☐ Pigs - backyard ☐ Sheep ☐ Goats ☐ Sheep and goats (mixed flocks) ☐ Layers - commercial production for eggs ☐ Broilers - commercial production for meat ☐ Other commercial poultry ☐ Poultry - backyard ☐ Buffaloes (excluding Syncerus caffer) ☐ Cervidae (farmed) ☐ Camelidae ☐ Equidae ☐ Rabbits/Hares ☐ Bees - Honey ☐ Fish - aquaculture production ☐ Crustaceans - aquaculture production ☐ Molluscs - aquaculture production ☐ Amphibians ☐ Reptiles (e.g., crocodiles) ☐ Other ☐ All	Please indicate which food-producing animals are covered by the data. Multiple selections are possible. For the purpose of this database, the following terms are defined: **Pigs – commercial:** pigs including piglets, fattening pigs and breeding pigs . **Sheep/goats (mixed flocks):** use this option only if there are mixed flocks and you cannot differentiate between sheep and goats in your country. **Other commercial poultry:** it includes turkey, duck, geese, quail, guinea fowl, pheasant, pigeon, ostrich, etc. in commercial production . **Poultry – backyard:** poultry including chickens and hens in backyard or village flocks . **Equidae:** domestic horses, donkeys and their crosses .
26	*Clarification of other species considered to be food-producing, if your response to Question 25 is 'Other'*	*<free text field>*	When 'Other' is selected in Question 25, please clarify the other animal species that are raised for food production that are covered by the data.
27	**Can data be differentiated by route of administration?**	☐ Data differentiated by route of administration - Yes ☐ Data differentiated by route of administration - No	
28	**National report(s) on sales/use of antimicrobials agents in animals available on the web?**	☐ Report available on the web - Yes ☐ Report available on the web - No	
29	*Please provide the link to the report, if the answer to Question 28 is 'Yes'*	*<free text field>*	

According to your responses to the questions above, you are invited to fill in the following Reporting Option:		
REPORTING OPTION	**Appropiate for your Country**	
Option 1	NO	If you answered 'No' to Question 23, then Reporting Option 1 may be the best adapted Reporting Option for the data you can report.
Option 2	NO	If you answered 'Yes' to Question 23, then Reporting Option 2 may be the best adapted Reporting Option for the data you can report.
Option 3	NO	If you answered 'Yes' to Question 23 and Question 27, then Reporting Option 3 may be the best adapted Reporting Option for the data you can report.

OIE template for the collection of data on antimicrobial agents intended for used in animals
Reporting option 1 - Overall amount sold for/used in animals by antimicrobial class; with the possibility to separate by type of use

Antimicrobial Class	Overall Amount: Growth Promotion + Therapeutic Use All animal species (kg)	Amount: Therapeutic Use (including prevention of clinical signs) All animal species (kg)	Amount: Growth Promotion All animal species (kg)
Aminoglycosides	0		
Amphenicols	0		
Arsenicals	0		
Cephalosporins (all generations)	0	0	0
1-2 gen. cephalosporins	0		
3-4 gen cephalosporins	0		
Fluoroquinolones	0		
Glycopeptides	0		
Glycophospholipids	0		
Lincosamides	0		
Macrolides	0		
Nitrofurans	0		
Orthosomycins	0		
Other quinolones	0		
Penicillins	0		
Pleuromutilins	0		
Polypeptides	0		
Quinoxalines	0		
Streptogramins	0		
Sulfonamides (including trimethoprim)	0		
Tetracyclines	0		
Others	0		
Aggregated class data	0		
Total kg	0	0	0

*If **'Aggregated class data'** are reported , please list the classes combined*	*<free text field>*	List all classes for which the amounts were combined, using whenever possible the 'Antimicrobial class' terms or the terminology of the OIE list of antimicrobial agents of veterinary importance. Substances included in the data aggregation that are not part of the recommended terminology should also be listed. If one class was reported that needs to remain confidential, please enter 'Confidential'.
*If **'Others'** are reported under 'Antimicrobial class', please list the classes reported*	*<free text field>*	Describe the class or classes reported as 'Others', using whenever possible the terminology of the OIE list of antimicrobial agents of veterinary importance.
*Please report any additional **calculations** applied*	*<free text field>*	Please describe the calculations carried out in addition to the ones recommended by the OIE in sections 1 and 2 of the annex to the instructions for the completion of the OIE template.

OIE template for the collection of data on antimicrobial agents used in animals
Reporting option 2 - Overall amount sold for/used in animals by antimicrobial class; with the possibility to separate by type of use and species group

	Overall Amount: Growth Promotion + Therapeutic Use	Amount for: Therapeutic Use (including prevention of clinical signs)					Amount: Growth Promotion
Antimicrobial Class	All animal species (kg)	All animal species (kg)	Companinon animals (kg)	All Food-producing animals (terrestrial & aquatic) (kg)	Terrestrial Food-producing animals (kg)	Aquatic Food-producing animals (kg)	All Food-producing animals (terrestrial & aquatic) (kg)
Aminoglycosides	0	0		0			
Amphenicols	0	0		0			
Arsenicals	0	0		0			
Cephalosporins (all generations)	0	0	0	0	0	0	0
1-2 gen. cephalosporins	0	0		0			
3-4 gen cephalosporins	0	0		0			
Fluoroquinolones	0	0		0			
Glycopeptides	0	0		0			
Glycophospholipids	0	0		0			
Lincosamides	0	0		0			
Macrolides	0	0		0			
Nitrofurans	0	0		0			
Orthosomycins	0	0		0			
Other quinolones	0	0		0			
Penicillins	0	0		0			
Pleuromutilins	0	0		0			
Polypeptides	0	0		0			
Quinoxalines	0	0		0			
Streptogramins	0	0		0			
Sulfonamides (including trimethoprim)	0	0		0			
Tetracyclines	0	0		0			
Others	0	0		0			
Aggregated class data	0	0		0			
Total kg	0	0	0	0	0	0	0

*If **'Aggregated class data'** are reported, please list the classes combined*	*<free text field>*	List all classes for which the amounts were combined, using whenever possible the 'Antimicrobial class' terms or the terminology of the OIE list of antimicrobial agents of veterinary importance. Substances included in the data aggregation that are not part of the recommended terminology should also be listed. If one class was reported that needs to remain confidential, please enter 'Confidential'.
*If **'Others'** are reported under 'Antimicrobial class', please list the classes reported*	*<free text field>*	Describe the class or classes reported as 'Others', using whenever possible the terminology of the OIE list of antimicrobial agents of veterinary importance.
Please report any additional calculations applied	*<free text field>*	Please describe the calculations carried out in addition to the ones recommended by the OIE in sections 1 and 2 of the annex to the instructions for the completion of the OIE template.

OIE template for the collection of data on antimicrobial agents used in animals

Reporting option 3 - Overall amount sold for/used in animals by antimicrobial class; with the possibility to

	Overall Amount: Growth Promotion + Therapeutic Use	Amount: Therapeutic Use (including prevention of clinical signs)															Amount: Growth Promotion
	All Animal Species	All animal species			Companion animals			All food-producing animals (terrestrial and aquatic)			Terrestrial food-producing animals			Aquatic food-producing animals			All food-producing animals (terrestrial and aquatic)
Antimicrobial Class	All routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	All routes (kg)
Aminoglycosides	0	0	0	0				0	0	0							
Amphenicols	0	0	0	0				0	0	0							
Arsenicals	0	0	0	0				0	0	0							
Cephalosporins (all generations)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1-2 gen. cephalosporins	0	0	0	0				0	0	0							
3-4 gen cephalosporins	0	0	0	0				0	0	0							
Fluoroquinolones	0	0	0	0				0	0	0							
Glycopeptides	0	0	0	0				0	0	0							
Glycophospholipids	0	0	0	0				0	0	0							
Lincosamides	0	0	0	0				0	0	0							
Macrolides	0	0	0	0				0	0	0							
Nitrofurans	0	0	0	0				0	0	0							
Orthosomycins	0	0	0	0				0	0	0							
Other quinolones	0	0	0	0				0	0	0							
Penicillins	0	0	0	0				0	0	0							
Pleuromutilins	0	0	0	0				0	0	0							
Polypeptides	0	0	0	0				0	0	0							
Quinoxalines	0	0	0	0				0	0	0							
Streptogramins	0	0	0	0				0	0	0							
Sulfonamides (including trimethoprim)	0	0	0	0				0	0	0							
Tetracyclines	0	0	0	0				0	0	0							
Others	0	0	0	0				0	0	0							
Aggregated class data	0	0	0	0				0	0	0							
Total kg	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

*If **'Aggregated class data'** are reported, please list the classes combined*	*<free text field>*	List all classes for which the amounts were combined, using whenever possible the 'Antimicrobial class' terms or the terminology of the OIE list of antimicrobial agents of veterinary importance. Substances included in the data aggregation that are not part of the recommended terminology should also be listed. If one class was reported that needs to remain confidential, please enter 'Confidential'.
*If **'Others'** are reported under 'Antimicrobial class', please list the classes reported*	*<free text field>*	Describe the class or classes reported as 'Others', using whenever possible the terminology of the OIE list of antimicrobial agents of veterinary importance.
Please report any additional calculations applied	*<free text field>*	Please describe here calculations carried out in addition to the ones recommended by the OIE in sections 1 and 2 of the annex to the instructions for the compilation of the OIE template.

Annex 7. Guidance for Completing the OIE Template for the Collection of Data on Antimicrobial Agents Used in Animals

Introduction

The OIE proposes to collect data on antimicrobial agents intended for use in animals from OIE Member Countries implementing Chapter 6.8, "Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals" of the OIE *Terrestrial Animal Health Code* and Chapter 6.3 "Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals" of the OIE *Aquatic Animal Health Code*, and to contribute to the global effort against antimicrobial resistance.

Member Countries differ in the degree to which they collect, collate and publish data on antimicrobial sales or use in animals and also in the degree to which they can stratify the quantities of antimicrobial agents intended for use in animals or for use in different animal species.

Through this initiative, by means of a specific template (hereafter "OIE template"), the OIE seeks to collect data on antimicrobial agent intended for use in animals from all OIE Member Countries in a harmonised way. Using a phased approach, the OIE will initially focus on **sales**[18] of antimicrobial agents intended for use in animals as an indicator of actual use. All antimicrobial agents intended for use in animals and listed in the OIE List of antimicrobial agents of veterinary importance[19], plus certain antimicrobial agents only used for growth promotion should be reported. The exceptions are ionophores, which are mostly used for parasite control and therefore need not be reported as antimicrobial agents. The OIE places highest priority on food-producing animals; however, data on all animals, *including companion animals*, may be reported. Reporting will occur at antimicrobial class level and, on one occasion, at sub-class level.

For the purpose of reporting data on antimicrobial quantities (amounts sold or imported for use in animals expressed in kilograms (kg) of antimicrobial agent, i.e., chemical compound as declared on the product label, that is to be calculated from the available information as explained in the Annex to this Guidance document), animals are grouped into 'all animal species', 'companion animals', 'all food-producing animals', 'terrestrial food-producing animals', and 'aquatic food-producing animals'.

Further refinement of the OIE collection of data on antimicrobial agent sales or use in animals is anticipated in light of the experience gained with the utilisation of the OIE template and additional changes might be necessary as Member Countries capabilities of reporting stratified data develop.

Please contact antimicrobialuse@oie.int for any question on the OIE template.

Required information and choices for reporting

As noted before, OIE Member Countries differ in the degree to which data on antimicrobial sales for use in animals is accessible and in the degree to which the quantities of antimicrobial agents used in animals can be further differentiated, for example, by species. Therefore, three different Reporting Options are proposed, using different individual sheets of the OIE template: 'Baseline

[18] **'Sales',** in the context of the OIE data collection on antimicrobial agents used in animals, should be interpreted to include data on import of antimicrobial agents for use in animals.

[19] http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Eng_OIE_List_antimicrobials_May2015.pdf

Information', 'Reporting Option 1', 'Reporting Option 2', and 'Reporting Option 3'.

The Baseline Information sheet allows participation of all Member Countries: and should be completed by all. On this sheet, some fields are formatted in *italics and grey;* these fields are optional, but Member Countries are encouraged to provide information to the greatest extent possible. Subsequently, and in accordance with the level of detail of data on antimicrobial agents used in animals available in the reporting country, either the sheet labelled Reporting Option 1, or the sheet labelled Reporting Option 2 or the sheet labelled Reporting Option 3 should be completed – only one of the three Reporting Options should be selected.

Baseline Information

This sheet collects administrative information relevant to the data collected with this template. It should be completed by all OIE Member Countries.

Based on the answers provided by the countries, the table at the bottom of the sheet is provided to help OIE Member Countries to decide which Reporting Option is the most adapted to their data available.

	Field name	Information to be provided
	A. Contact Person for Antimicrobial Agents Use Data Collection (Please provide the contact details of the person entering the information)	
1	**Title**	Salutation (e.g., Dr, Ms, Mr).
2	**Name**	First or given name, SURNAME or FAMILY NAME.
3	**Role with respect to the OIE**	Please choose either 'Delegate', 'National Focal Point for Veterinary Products' or 'Other' to describe your relation to the OIE.
4	**Organisation**	Name of the organisation for which you work, administrative subunit, and position.
5	**Organisation's Address**	Full mailing address of your organisation.
6	**Country**	Country name.
7	**Phone Number**	Please provide the telephone number in the format "(country code) phone number".
8	**Email Address**	Email address where you can best be reached.

	B. General Information	
9	**Are data on the amount of antimicrobial agents intended for use in animals available?**	Please indicate whether quantitative data (i.e., data on the amount) on antimicrobial agents intended for use in animals are available, by choosing 'Yes' or 'No'. If quantitative data is available for part of your country, choose 'Yes'.
10	*Please indicate why the data are not available at this time in your country, if the answer to Question 9 is 'No'*	Please indicate the reason why the data are not available in this moment in your country. If the answer to the previous question is 'No'.
11	**Are antimicrobial agents used for growth promotion purposes in animals in your country?**	Please indicate if antimicrobial agents as growth promoters are being used in your country, by choosing 'Yes', 'No' or 'Unknown'.

12	**Does your country have legislation/regulations on the use of antimicrobial agents as growth promoters in animals?**	Please respond by ticking either 'Legislation/regulation exists - Yes' or 'Legislation/regulation does not exist - No'.
13	**If your country has legislation/regulation on the use of antimicrobial agents as growth promoters in animals, could you please indicate the appropriate case that applies in your country?**	Please respond by ticking either 'All antimicrobial agents banned for use as growth promoters', 'Some antimicrobial agents banned for use as growth promoters' or 'One or more antimicrobial growth promoters are authorised'.
14	*Please provide a list of antimicrobial agents authorised as growth promoters, if any*	If any antimicrobial growth promoters are authorised for use in animals, please list the antimicrobial agents (active ingredient name, not product name) authorised for use as growth promoters in animals.
If data on the amount of antimicrobial agents intended for use in animals are not available in your country, the completion of the OIE template is terminated after completing Question 14 of the Baseline Information sheet.		
C. Data Collection of Antimicrobial Agents Intended for Use in Animals (Reserved to the Countries where data are available)		
15	**Year for which data apply** (Please select only one year per template)	Please provide data for 2015. If you have data for another year, please select the year from the list. We will accept data for other years, but not from before 2015. If you would like to provide data for additional years, please fill out one template per year of data.
16	**Time period for which data are provided** (e.g., 1 January to 31 December 2015)	Please provide further information regarding the reporting year, especially if the data only covers a portion of the calendar year.
17	**Data source**	Please describe the origin of the data on antimicrobial sales for use in animals, the preferred data at this stage. The template provides options for data sources, and you are asked to report all data sources that apply. Chapter 6.8 of the *OIE Terrestrial Code* and Chapter 6.3 of the *OIE Aquatic Code* provide more detail on potential sources of such information. Possible data sources include: • Sales data - complete data on antimicrobials agents sold to / bought from wholesalers. • Purchase data - data based on sampling of a limited number of wholesalers and requiring extrapolation to estimate the full amount of antimicrobials purchased, but should be used with care. • Import data - complete import data from customs. • Veterinary data - complete or representative sample information obtained from veterinarians; if representative sample information is obtained extrapolation to the estimated full use may be possible. • Antimicrobial use data - complete or representative sample information obtained from farm records; if representative sample information is obtained extrapolation to the estimated full use may be possible. • Other data - all other ways of delivering antimicrobial agents to the animals, including distribution through state veterinary services. It is suggested to develop an overview of the drug distribution system in your country. Mapping out the distribution pathways in your country will help you identify the most appropriate source of information on antimicrobial agents for

		use in animals. Great care is necessary to avoid duplicate or multiple reporting of quantities; mapping out the distribution will also help you devise measures aimed at avoiding multiple reporting. Ideally, the source of information should be as close to the point of use as possible. Experience has shown that whenever possible, sales data at the package level should be collected, keeping in mind that the data will be measured in kg of antimicrobial agent (please refer to the annex of this document for details on the necessary conversions). Good communication between all parties involved in the data collection is critical to obtain good data sets.
18	*Clarification of the data source, if your response to Question 17 is 'Other'*	If under Data source the option 'Other' is selected, please explain here which source of information was used.
19	**Estimated coverage of accessible data on total amount (in %)**	Please provide an estimate of the extent to which the quantitative data you report are representative of the overall antimicrobial sales for use in animals (percentage of the total sales in your country in relation to overall use).
20	**Explanation of estimated coverage**	Please explain in this field which data were not captured on the antimicrobial agents used in animals reported for your country in the OIE template. Data coverage may vary by geographical aspects; examples include but are not limited to situations that use may be well known for urban but not rural areas, or that use in certain representative regions is well known but not actually measured throughout the whole country. Incomplete data coverage may include situations where importation is not covered, or partial statistical sampling of relevant establishments (farms, veterinary practices, etc.) is carried out. Another source of incomplete data may lie in market segment coverage, where incomplete data is available from certain market segments (e.g., some production systems are not covered, such as extensive versus intensive farming systems or certain wholesalers who do not report their data).
21	**Is the information extrapolated from representative samples?**	Please indicate whether the data provided in your report have been extrapolated from representative samples.
22	*Explanation of extrapolations carried out, if your response to Question 21 is 'Yes'*	Please explain in this field the nature of any extrapolations that were carried out in order to provide the data recorded in the OIE template.
23	**Can data be differentiated by animal group?**	Please respond by ticking 'Yes' or 'No'. For the purposes of the database, animal group means: 'Terrestrial food-producing animals', 'Aquatic food-producing animals' or 'Companion animals'. If your data is differentiated by any of these groups, please select 'Yes'.
24	**Animal groups covered by the data**	Please indicate here which animal groups are covered by the data provided, by selecting the appropriate category or categories from the list. The choices are: 'Data with no differentiation (all animals combined)', 'Data with no differentiation between terrestrial and aquatic animals excluding companion animals', 'Data for terrestrial food-producing species', 'Aquatic food-producing animals', 'Data for aquatic food-producing animals' and 'Data for companion animals'. Multiple selections are possible.
25	**Food-producing animal species covered by the data**	Animal species considered to be food-producing animals vary between countries. The OIE needs to gain an understanding of how this difference impacts the data reported to the OIE and future reporting of summary data by the OIE. Please indicate which animals are considered to be food-producing animals covered by the data. Multiple selections are possible.
26	*Clarification of other species considered to be food-producing, if your response to Question 25 is 'Other'*	Please provide any explanations you may feel necessary to explain which animal species covered by the data are raised for the purpose of providing food for humans.

27	**Can data be differentiated per route of administration?**	Please respond by ticking either 'Yes' or 'No'.
28	**National report(s) on sales/use of antimicrobial agents in animals available on the web?**	Please respond by ticking either 'Yes' or 'No'.
29	*Please provide the link to the report, if your response to Question 28 is 'Yes'*	If answer is 'Yes' to Question 28, please insert the link to the site where the report is available on the internet.

Classes of antimicrobial agents for reporting

All antimicrobial classes used in animals (for therapeutic use including prevention of clinical signs, as well as growth promotion, whether classified as veterinary medicines or not, *with the exception of ionophores*) should be included in the table by the reporting OIE Member Country.

Antimicrobial class	Guidance
Aminoglycosides	Includes aminocyclitols (e.g., streptomycin, dihydrostreptomycin and spectinomycin) and all other aminoglycosides (e.g., gentamicin, kanamycin, neomycin, apramycin).
Amphenicols	Includes florfenicol and thiamphenicol.
Arsenicals	Includes nitarsone, roxarsone and others.
Cephalosporins	May be reported as **Cephalosporins (all generations)** or in relevant category groupings (**1-2 generation cephalosporins** and **3-4 generation cephalosporins**).
Fluoroquinolones	Includes danofloxacin, difloxacin, enrofloxacin, marbofloxacin and other fluoroquinolones, but not other quinolones (e.g., flumequine, oxolinic acid, nalidixic acid), which are reported separately.
Glycopeptides	Includes avoparcin and others.
Glycophospholipids	Includes bambermycin (i.e., flavomycin).
Lincosamides	Includes lincomycin, pirlimycin and others.
Macrolides	Includes substances with all macrolide structures, such as erythromycin, spiramycin, tylosin, tylvalosin, gamithromycin, tildipirosin, tulathromycin and others.
Nitrofurans	Includes furazolidone, nitrofurantoin, nitrofurazone and others.
Orthosomycins	Includes avilamycin and others.
Other quinolones	Includes flumequine, nalidixic acid, oxolinic acid and others.
Penicillins	Includes all penicillins (e.g., natural penicillins, aminopenicillins and others), but excludes other beta lactam antimicrobials like cephalosporins.
Pleuromutilins	Includes tiamulin, valnemulin and others.
Polypeptides	Includes bacitracin, colistin, polymyxin B and others.
Quinoxalines	Includes carbadox, olaquindox and others.
Streptogramins	Includes virginiamycin, pristinamycin, and others.
Sulfonamides (including trimethoprim)	Includes all sulfonamides, as well as trimethoprim and similar compounds.
Tetracyclines	Includes chlortetracycline, doxycycline, tetracycline, and oxytetracycline.
Others	All others not covered, including coumarin antimicrobials, e.g., novobiocin, fusidic acid, kirromycins, phosphonic acids like fosfomycin, rifamycins, thiostrepton.
Aggregated class data	It may not be possible to individually report sales by class name for one or more antimicrobial classes for animal use (e.g., to protect confidential (proprietary) information or as required by legislation). Such amounts may be reported in this line.

Antimicrobial class	Guidance
	Report here the individual or cumulative amounts of antimicrobial classes used in animals that cannot be reported independently for confidentiality / proprietary reasons. If more than one data aggregation exists in your country, please sum them up for the OIE template. In cases where the amounts sold for more than one class are reported as aggregated data, please enter <AGG> in the table for those substances for which sales quantities have been included in the aggregated amount, and list the names of the classes of antimicrobial agents that cannot be reported individually in the free-text field called ***'If 'Aggregated class data' are reported, please list here the classes combined'*** located underneath the table collecting the antimicrobial quantities.

Explanatory notes on the free-text fields below the tables Reporting Options 1, 2 and 3 are provided.

Field name	Information to be provided
If 'Aggregated class data' are reported, please list the classes combined	If for your country there are ***Aggregated class data***, please list the names of the classes of antimicrobial agents that cannot be reported individually. If sales for only one antimicrobial class that needs to remain confidential are reported as ***Aggregated class data***, please enter the word 'Confidential' in this free-text field. Whenever possible, use the 'Antimicrobial class' terms explained above or the terminology of the *OIE List of antimicrobial agents of veterinary importance*. Aggregated data may include substances that are not mentioned in the definition of 'Antimicrobial classes for use in animals'. In such cases, please specify any additional classes of antimicrobials which are included in the reported amount for ***Aggregated class data*** that are not listed in the table.
If 'Others' are reported under 'Antimicrobial class', list the classes reported	Please describe the class or classes reported as 'Others', using whenever possible the terminology of the *OIE List of antimicrobial agents of veterinary importance*.
Please report any additional calculations applied	Please describe calculations carried out in addition to the ones recommended by the OIE in Sections 1 and 2 of the Annex to the Guidance for completing the OIE template.

The amount of the antimicrobial agents intended for use in animals in kilograms (kg) should be reported. Where data are available in the form of

- number of packages of a given pharmaceutical preparation sold
- international units
- % weight per volume (% w/v)

mathematical conversion will be necessary, which is explained in the Annex to this document. In cases where the amount sold for the listed class is part of a data aggregation reported under 'Aggregated class data', please enter the three letters <AGG> in the table for all classes, for which quantities sold have been summarised.

Ideally, the OIE is interested in the amount of active ingredient (moiety), that is, the substance as listed in the *OIE List of antimicrobial agents of veterinary importance* (e.g., benzylpenicillin), not the total weight of the actual chemical compound (salt, ester or other, for example: sodium or potassium benzylpenicillin) contained in a veterinary medicinal product or traded as bulk material. At this stage of the project, the precision gained by the refined reporting of amounts of active ingredient, achieved by mathematical conversion of amounts of chemical compound as declared on the product label, is not justified. Therefore, the OIE template will accept the amounts of chemical compound as declared on the product label. Data on amounts of active

ingredients will also be accepted, but the **additional calculations carried out should be described in the corresponding free-text field on the Reporting Option 1, 2 or 3 sheets in the OIE template.**

For data sourced from customs, import or other bulk trading, information will likely come as tons of chemical compound. **Please convert into kg** for reporting in the OIE template; the Annex provides conversion factors from different weight units to kg.

For veterinary medicinal products, the content of the antimicrobial agent(s) may be stated in one of several ways, including strength in

- milligram (mg) or gram (g) of the active ingredient per volume or weight or other unit, for example millilitre (ml), or kilogram (kg) or tablet,
- International Units (IU) per weight, volume or other unit, or
- in percentage (%) weight per weight (w/w) or weight per volume (w/v).

The Annex provides details on the necessary conversions.

For veterinary medicinal products containing more than one antimicrobial agent, the amounts of each should be added to the respective class columns.

If there are no quantities to report for a class or route of administration, please enter a zero (0) in the corresponding field of the table.

Please refer to the Annex of this document for detailed examples and the calculations necessary to report kg of antimicrobial agents intended for use in animals. As explained above, in most cases the amount of the chemical compound as declared on the product label can be reported, though OIE Member Countries wishing to provide more refined data on amounts of active ingredients are welcome to do so, on the condition that they describe the calculations used.

Reporting Option 1

Overall amount sold for use / used in animals by antimicrobial class, with the possibility to separate **by type of use**.

The sheet Reporting Option 1 is designed for the reporting of data on amount or type of antimicrobial agents used in all animals. Data may be reported overall for all animal species, but can be separated by antimicrobial class and possibly by type of use (therapeutic use including prevention of clinical signs, or growth promotion; see definitions below).

For this Reporting Option 1, complete the columns “Therapeutic Use” (including prevention of clinical signs) and “Growth Promotion”. The sum of sales for “Therapeutic Use” and “Growth Promotion” should equal the amount entered in the column “Overall Amount (Growth Promotion + Therapeutic Use)” for each class.

Reporting Option 2

Overall amount sold for use / used in animals by antimicrobial class, with the possibility to separate by type of use **and animal groups**.

If the data can be differentiated by use in all food-producing animals, companion animals and / or by use in terrestrial and aquatic food-producing animals, Reporting Option 2 is the appropriate choice. Further differentiation by antimicrobial class, therapeutic use, including prevention of clinical signs, or growth promotion is possible.

If sales of antimicrobial agents for use in animals can be differentiated into sales for therapeutic purposes, for growth promotion and additionally by animal group, please complete under the heading “Therapeutic Use (including prevention of clinical signs)” the columns for “All Animal Species”, “Companion Animals”, “All Food-producing Animals (terrestrial and aquatic)”, “Terrestrial Food-producing Animals”, and “Aquatic Food-producing Animals”. These animal groups include all age groups and life stages of the relevant group. The first column of the table

"Overall Amount (Growth Promotion + Therapeutic Use)" allows reporting of the total amount for all uses and animal categories per antimicrobial class. The last column labelled "Growth Promotion" captures the amounts sold for growth promotion purposes in terrestrial and aquatic food-producing animals.

For Reporting Option 2, "Growth Promotion" can be reported jointly for terrestrial and aquatic food-producing animals.

Reporting Option 3

Overall amount sold for use / used in animals by antimicrobial class, with the possibility to separate by type of use, species group and **route of administration.**

If the data can be differentiated by route of administration, Reporting Option 3 is the appropriate choice. Further differentiation by antimicrobial class, by use in companion animals, food-producing species and, where possible, by use in terrestrial and aquatic food-producing species as well as therapeutic use, including prevention of clinical signs, or growth promotion, is possible.

In the category of "Therapeutic Use (including prevention of clinical signs)", the OIE is interested in differentiating the proportion of sales by route of administration for mass treatment (e.g., via feed) versus those more suited for treatment of individual animals (e.g., injection route, other routes). If sales for therapeutic use can be sub-divided by route of administration, please report the quantities used for each route of administration. If further differentiation by animal group is possible, then it should be reported if the data are available.

For Reporting Option 3, "Growth Promotion" can be reported jointly for terrestrial and aquatic food-producing animals.

Column label	Guidance
Oral route	Includes all orally administered pharmaceutical forms, including "in water" or "in feed" administration, but also oral bolus administration.
Injection route	Includes all forms of parenteral administration that readily lead to elevated blood levels of the active ingredient, such as subcutaneous, intramuscular, intravenous, including intravenous infusion (intravenous drips).
Other routes	Summarises all other routes of administration, including intramammary preparations, and, mostly for aquatic animals, the bath route where an animal or a group of animals immersed in a solution containing the active ingredient.

Glossary of Terms

For the purpose of this database, a number of terms require clarification, in order to ensure a harmonised approach to data collection.

- **Active ingredient**

  Antimicrobial agents are chemical compounds that can come in various forms. In order to render an antimicrobial agent suitable for use in a veterinary medicine, or to achieve desirable pharmacokinetic or organoleptic properties, antimicrobial agents can exist as different salts or esters or other chemical compounds. The **active ingredient** is the part of the chemical compound responsible for the antimicrobial action. The name used to refer to an antimicrobial agent listed on the *OIE List of antimicrobial agents of veterinary importance* is generally identical to the **active ingredient** of that agent.

- **Antimicrobial agent**
  As defined in the glossaries of the *OIE Terrestrial Code* and the *OIE Aquatic Code*, this means a naturally occurring, semi-synthetic or synthetic substance that exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms) at concentrations attainable *in vivo*. Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition. In the context of the OIE template, this term is being used as a general reference to substances with antimicrobial activity.

- **Antimicrobial classes for use in animals**
  Any antimicrobial agent belonging to the antimicrobial classes listed on the *OIE List of antimicrobial agents of veterinary importance* is included. In addition, antimicrobial agents used exclusively for growth promotion are also included. With the exception of ionophores, which are mostly used for parasite control, all uses of these substances should be reported, whether the antimicrobial agents are categorised as veterinary medicines or not.

- **Chemical compound as declared on the product label**
  As explained for active ingredient, an antimicrobial agent may exist in the form of various chemical compounds. For example, benzylpenicillin (the active ingredient) the sodium, potassium, procaine, benzathine or benethamine salts, and the prodrug penethamine hydroiodide are used in veterinary medicine. In consequence they may be traded as bulk products or be included in veterinary medicinal products containing antimicrobial agents (see explanation below). The term **chemical compound as declared on the product label** refers to the substance as it is reported on the label of a veterinary medicinal product or a bulk container or in the information provided to customs. This may be either the active ingredient (e.g. benzylpenicillin) or the complete chemical compound (e.g. sodium benzylpenicillin).

- **Extrapolation**
  An approach by which the total amount of antimicrobial agents used in animals was derived from a limited, but representative dataset. Details on the approach should be provided. Caution should be exercised in situations where the data sources are not representative of the whole. For example, extrapolation from a limited number of wholesalers may not adequately represent the entire antimicrobial sales market.

- **Food-producing species**
  The animal species that are managed by people for the purpose of producing food for humans. The relevant species may differ between countries.

- **Growth promotion, growth promoters**
  In line with the definition developed by *Codex Alimentarius* in *CAC/RCP 61-2005*, Growth Promotion refers to the use of antimicrobial substances to increase the rate of weight gain and/or the efficiency of feed utilization in animals by other than purely nutritional means. The term does NOT apply to the use of antimicrobial agents for the specific purpose of treating, controlling, or preventing infectious diseases, even when an incidental growth response may be obtained. **Growth promoters** in the context of this template are antimicrobial agents used for the purpose of growth promotion.

- **Quantitative data**
  The term 'quantitative' refers to a type of information based in quantities or else quantifiable data (objective properties) — as opposed to 'qualitative' information which deals with apparent qualities (subjective properties). Quantitative data may also refer to mass, time, or productivity. In the context of this template, **quantitative data** means that the amount of antimicrobial agents used in animals can be determined, for example through information on amount of antimicrobials imported, or number of packages of specific antimicrobial products used in animals, and is reportable in the metric 'kg antimicrobial agent'.

- **Sales of antimicrobial agent(s) used in animals** versus **use data**
  For the purpose of data collection through the OIE template, **sales data**, also referred to as 'amount of antimicrobial agent(s) used in animals' relates to the amounts of antimicrobial agents imported and/or sold within a country for use in animals. Sales data are used as an approximation of actual use. **Use data** refers to the amount of antimicrobial agents actually administered to animals. Such data are difficult to collect in most environments, as the data sources would be at the level of individual farmers or veterinarians.

- **Therapeutic use**
  Administration of an antimicrobial agent to animals to prevent, control or treat infection or disease. Acknowledging that the OIE template may be completed without consulting this guidance document, it was agreed that for reasons of clarity the OIE template would use 'Therapeutic use (including prevention of clinical signs)' in the table headings of all Reporting Options.

- **Veterinary medicinal product containing antimicrobial agent(s)**
  As defined in the glossaries of the *OIE Terrestrial Code* and the *OIE Aquatic Code*, the term *veterinary medicinal product* means any product with approved claim(s) to having a prophylactic, therapeutic or diagnostic effect or to alter physiological functions when administered or applied to an animal. A veterinary medicinal product containing antimicrobial agent(s) refers to veterinary medicinal products used for their antimicrobial effect due to one or more antimicrobial agents they contain.

Annex 8. Annex to the guidance for completing the OIE template for the collection of data on antimicrobial agents used in animals

Considerations on converting content of antimicrobial active ingredients in veterinary medicines into kilograms

Calculating the quantities to report in kilogram (kg)

Data on antimicrobial agents intended for use in animals comes in different forms. The OIE template for the collection of data on antimicrobial agents used in animals (OIE template) is designed to collect data on the amounts of chemical compound as declared on the product label. The information may vary, ranging from bulk quantities of antimicrobial agents to numbers of packs of a veterinary medicinal product. The content of antimicrobial agents in such products can be stated in a number of possible ways. It will be necessary, where appropriate, to calculate the required data to populate the OIE template.

Detailed instructions are provided to harmonise some aspects of data reporting:

- Transformation of bulk quantities (section 1);
  use this section if you need to convert quantities of raw material, e.g. from import data into the required format.
- Data on veterinary medicinal products (section 2), including conversion from International Units (IU) to kg (section 2. (ii)
- Recommendations are made in section 3 for further optional conversions, aimed at achieving refined reporting of active entities, the ultimately desired format. If such calculations are made, they should be reported in the OIE template in the free text field provided on the sheets for Reporting Option 1, 2 and 3.

The following abbreviations and symbols will be used:

Symbol/abbreviation	Explanation
Strength	amount of antimicrobial agent per unit of veterinary product
% w/v	per cent weight per volume
mg	milligram
g	gram
kg	kilogram
t	ton (metric)
ml	millilitre
l	litre

1. For data on bulk quantities

Such information is usually sourced from customs, import or other bulk trading. It will likely come as a weight in a number of possible units (e.g. metric tons) of chemical compound and needs to be converted to kg. When conversion into kg is necessary, follow the steps below. If additional conversion factors are needed, please contact the OIE at antimicrobialuse@oie.int.

Step 1: Multiply the amount of antimicrobial agent, i.e. the chemical compound as declared on the product label with the appropriate conversion factor from the table 1 below.

$$Antimicrobial\ agent\ (kg) = \ antimicrobial\ agent\ (unit\ Z)\ x\ conversion\ factor$$

Table 1: Converting weight units into kg

Unit reported (unit Z)	Conversion factor to kg (for multiplication)
Metric ton	1000
Imperial ton (long)	1016
Imperial ton (short)	907.18
Stone (Imperial)	6.35
Imperial Pound	0.4536
Ounce	0.0283

2. For data on veterinary medicinal products

For veterinary medicinal products containing antimicrobial agents, data on quantities sold is likely to be available as numbers of packages of product sold, with each package containing a specified quantity of medicinal product with a specified amount of antimicrobial agent. In such cases, the amount of antimicrobial agent (chemical compound as declared on the product label) per package needs to be calculated first, and subsequently the result needs to be multiplied with the number of packages of the presentation sold to obtain the overall amount of antimicrobial agent, which should be reported in kg.

The most common ways to indicate the content of the antimicrobial agent(s) of a veterinary medicinal product are:

(i) Strength in mg or g of the active ingredient per volume or weight or other unit, (for example: ml, l, kg, tablet),
(ii) Strength in International Units (IU) per weight, volume or other unit,
(iii) Strength in per cent (%) weight per weight (w/w) or weight per volume (w/v).

Each situation requires a different kind of mathematical conversion.

2. (i) – content of antimicrobial active ingredient (antimicrobial agent) stated in milligram per volume or weight or other unit (for example millilitre, litre, kilogram, tablet) of content

Step 1: Calculation of the content of antimicrobial agent per package

Multiply the amount of antimicrobial agent (chemical compound as declared on the product label) per unit of content, that is, the strength of the product, with the total number of units contained in the package

$$Content\ of\ antimicrobial\ agent\ \ per\ package = Strength\ (amount\ antimicrobial\ agent\ per\ unit) x\ number\ of\ units\ per\ package$$

Example A:
Tiamulin 100 g/kg premix for medicated feeding stuff; package sizes: (a) 1 kg, (b) 5 kg and (c) 20 kg

Calculation of content of antimicrobial agent, tiamulin, per package:

(a) $Pack\ content = 100\ g/kg\ x\ \ 1\ kg = \ \ 100\ g$
(b) $Pack\ content = 100\ g/kg\ x\ \ 5\ kg = \ \ 500\ g$
(c) $Pack\ content = 100\ g/kg\ x\ 20\ kg = 2000\ g$

Example B:
Tetracycline intrauterine tablet containing 2000 mg tetracycline hydrochloride per tablet; package sizes: (a) carton with 1 blister of 5 intrauterine tablets, (b) carton with 4 blisters of 5 intrauterine tablets each (20 tablets), (c) carton with 20 blisters of 5 intrauterine tablets each (100 tablets).

Calculation of content of antimicrobial agent, tetracycline, per package:

(a) Pack content = 2000 mg x 5 = 2 g x 5 = 10 g
(b) Pack content = 2000 mg x 20 = 2 g x 20 = 40 g
(c) Pack content = 2000 mg x 100 = 2 g x 100 = 200 g

Example C:
Tilmicosin 300 mg/ml solution for injection for cattle; package sizes: containers of 100 ml and 250 ml; packs of *(a)* 6, *(b)* 10 and *(c)* 12 units of 100 ml and 250 ml.

Calculation of content of antimicrobial agent, tilmicosin, per package:

(a) Container content = 300 mg/ml x 100 ml = 30000 mg = 30 g
Pack content: (a) 6 x 30 g = 180 g,
(b) 10 x 30 g = 300 g
(c) 12 x 30 g = 360 g
(b) Container content = 300 mg/ml x 250 ml = 75000 mg = 75 g
Pack content: (a) 6 x 75 g = 450 g,
(b) 10 x 75 g = 750 g
(c) 12 x 75 g = 900 g

Step 2: Sum up the antimicrobial agent contained in all presentations and packages sold

Convert all contents of antimicrobial agent calculated under step 1 to the same weight unit and add up the total

Step 3: If necessary: convert the total sum of antimicrobial agent contained in all packages of all presentations sold to kg

Multiply the result from step 2 with an appropriate conversion factor to achieve the result in kg

2. (ii) – content of antimicrobial agent (chemical compound as declared on the product label) in International Units (IU) per weight, volume or other unit (for example millilitre, litre, kilogram, tablet) of content

Where the strength of the antimicrobial agent in the veterinary medicinal product is stated International Units (IU) per unit of finished product, an additional conversion step is necessary to obtain results in mg, g, or kg. Table 2 is used to convert content of antimicrobial agents declared in IU on the product label into mg for reporting to the OIE: either divide the total number of IUs of an antimicrobial agent by the value in the column 'International Units (IU) per mg' for this agent in table 2, or, if multiplication is preferred, multiply the total number of IUs with the conversion factor listed for the agent. To convert mg values into kg, please multiply the result of the conversion with 1×10^{-6} equalling 0.000001.

For some antimicrobial agents in veterinary medicinal products, the IU content or strength may be stated in respect to the active entity rather than to the chemical compound actually included; for example: a product may contain penethamate hydroiodide, or procaine benzylpenicillin, but the stated strength in IU refers to benzylpenicillin (product X containing penethamate hydroiodide, equivalent to xx IU benzylpenicillin, or, product Y containing procaine benzylpenicillin, equivalent to yy IU benzylpenicillin). For such cases, use the conversion factor for the relevant active entity listed in table 2 (in the examples used: benzylpenicillin). To convert mg values into kg, please multiply the result of the conversion with 1×10^{-6} equalling 0.000001.

If additional conversion factors are needed or have been used, please contact the OIE at antimicrobialuse@oie.int.

Step 1: Calculating the content of antimicrobial agent per package in IU

Multiply the amount of IU antimicrobial agent per unit of content with the total number of units contained in the package

$$Content\ of\ antimicrobial\ agent\ \ per\ package\ in\ IU = Strength\ (amount\ IU\ antimicrobial\ agent\ per\ unit)\ x\ number\ of\ units\ per\ package$$

Step 2: Converting the content of antimicrobial agent per package in IU into mg

$$\text{Content of antimicrobial agent per package in } mg = Content\ of\ antimicrobial\ agent\ \ in\ IU\ \text{x}\ conversion\ factor$$

Steps 3-4: Follow steps 2-3 described for (i)

Table 2: Conversion of International Units (IUs) of certain antimicrobial agents into mg and relevant active entities, based on the ESVAC conversion factors[20]

Antimicrobial agent in the veterinary medicine	Antimicrobial active entity for reporting to OIE	International Units per mg	Conversion factor to mg for multiplication
Bacitracin	Bacitracin	74	0.013514
Benzylpenicillin (penicillin G)	Benzylpenicillin	1666.67	0.0006
Chlortetracycline	Chlortetracycline	900	0.001111
Colistin methane sulfonate sodium (colistimethate sodium INN)	Colistin	12700	0.000079
Colistin sulfate	Colistin	20500	0.000049
Dihydrostreptomycin	Dihydrostreptomycin	820	0.00122
Erythromycin	Erythromycin	920	0.001087
Gentamicin	Gentamicin	620	0.001613
Kanamycin	Kanamycin	796	0.001256
Neomycin	Neomycin	755	0.001325
Neomycin B (Framycetin)	Neomycin B (Framycetin)	670	0.001492
Oxytetracycline	Oxytetracycline	870	0.001149
Paromomycin	Paromomycin	675	0.001481
Polymyxin B	Polymyxin B	8403	0.000119
Rifamycin	Rifamycin	887	0.001127
Spiramycin	Spiramycin	3200	0.000313
Streptomycin	Streptomycin	785	0.001274
Tobramycin	Tobramycin	875	0.001143
Tylosin	Tylosin	1000	0.001
Tetracycline	Tetracycline	950	0.001

2. (iii) – content of antimicrobial agent (chemical compound as declared on the product label) *in per cent (%) weight per weight (w/w) or weight per volume (w/v) of content*

The amount of antimicrobial agent contained in a veterinary medicine concerned may be stated in per cent weight per weight (% w/w) (example 1: product X contains tylosin 100% w/w or, example 2, product Y contains amoxicillin 22.2 % w/w) or in per cent weight per volume (% w/v) (example: product Z contains procaine benzylpenicillin 30% w/v). Such figures first need to be converted into mg/g, g/g, or mg/ml, followed by the calculations described under (i).

Converting % w/w: Conversion calculations are performed by relating the content of antimicrobial agent to 1 g of the finished product. Divide the percentage value by 100 to obtain the amount of antimicrobial agent in g per g finished product.

$$value\ antimicrobial\ agent\ in\ g\ per\ gram\ finished\ product = \frac{\frac{value\ (\%)}{100}\ x\ g}{1\ g\ (finished\ product)}$$

[20] http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500189269

Example 1: Product X containing 100% w/w tylosin will contain 100/100 x g = 1 g tylosin per g finished product.

Example 2: Product Y containing 22.2% w/w amoxicillin will contain 22.2/100 = 0.222 g amoxicillin per g finished product.

Continue with Steps 1-3 of (i)

Converting % w/v: Conversion is based on the assumption that 1 ml of the products weighs 1000 mg. Multiply the percentage value with 10 to obtain the content in mg/ml.

$$value\ antimicrobial\ agent\ in\ g\ per\ ml\ finished\ product = \frac{value\ (\%) x\ 10\ \ x\ mg}{1\ ml\ (finished\ product)}$$

Example: Product Z containing 30% w/v benzylpenicillin will contain (30 x 10 x mg)/1ml, equal to 300 mg/ml benzylpencicillin.

Continue with Steps 1-3 of (i)

3. Additional recommendations for further conversions of quantities of antimicrobial agents

For pragmatic reasons the OIE accepts the reporting of antimicrobial agents in amounts of chemical compound as declared on the product label of the veterinary medicinal product. However, OIE Member Countries may wish to carry out further calculations to report amounts of active entity. If such further calculations are carried out, please describe them in the OIE template.

(i) Calculating the total amount expressed in weight of chemical compound as declared on the product label of a veterinary medicinal product into antimicrobial active entity (e.g. salt into base)

This step may be carried out once the steps described in section 1 or section 2. (i) have been completed.

As an example, for the antimicrobial agent tiamulin that is often available in the form of tiamulin hydrogen fumarate (the chemical compound as declared on the product label), the conversion formula to tiamulin (the active entity) would be:

Salt (including base): Tiamulin hydrogen fumarate MW 609.8
Base: Tiamulin MW 493.7
Conversion factor = MW base/MW salt (including base) = 0.81

Multiply the final result in kg obtained by following steps 1 to 3 with the appropriate conversion factor

$$Content\ of\ active\ entity\ (kg) = Content\ of\ chemical\ compound\ as\ listed\ on\ the\ label\ (kg)\ x\ \ conversion\ factor$$

(ii) The antimicrobial agent is in the form of a prodrug, expressed in weight

Where the antimicrobial agent contained in the veterinary medicinal product is a long-acting salt (example: benethamine benzylpenicillin) or a pro-drug (example: penethamate hydroiodide) and the content is stated in weight in reference to the actual chemical compound (example: product x contains 500 mg/ml benzylpenicillin benzathine), an additional conversion step as described below is needed to calculate the amount of active entity. When the antimicrobial agent is described in reference to the active entity (example: product y contains cloxacillin

benzathine equivalent to 500 mg cloxacillin activity) the conversion using a prodrug conversion factor described below is not necessary.

Taking the prodrug conversion factors used by the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) program managed by the European Medicines Agency, as a starting point, table 3 lists the suggested conversion factors for relevant long-acting salts and prodrugs. The amount of the actual chemical compound as declared on the product label (example: benzylpenicillin benzathine) needs to be multiplied with the prodrug conversion factor to obtain the corresponding amount of the active entity (example: benzylpenicillin.

If additional conversion factors are needed or have been used, please contact the OIE at antimicrobialuse@oie.int.

Table 3: Conversion of content stated in mg, g or kg of long-acting salts and prodrugs of antimicrobial agents in the veterinary product into corresponding mg, g or kg antimicrobial active entity for reporting to the OIE, based on the ESVAC conversion factors[21]

Antimicrobial agent (prodrug)	Active entity	Prodrug conversion factor for multiplication
Benethamine benzylpenicillin	Benzylpenicillin	0.65
Benzathine benzylpenicillin	Benzylpenicillin	0.74
Cefapirin benzathine	Cefapirin	0.41
Cefalexin benzathine	Cefalexin	0.36
Cloxacillin benzathine	Cloxacillin	0.43
Oxacillin benzathine	Oxacillin	0.69
Penethamate hydroiodide	Benzylpenicillin	0.63
Procaine benzylpenicillin	Benzylpenicillin	0.61

Step 1–3: As described in section 2. (i)

Step 4: Multiply the final result in kg obtained by following steps 1 to 3 with the appropriate conversion factor listed in table 3

$$Antimicrobial\ agent\ (active\ entity)(kg) = antimicrobial\ agent\ (chemical\ compound\ as\ declared\ on\ the\ product\ label)(kg)\ x\ prodrug\ conversion\ factor$$

For bulk quantities of antimicrobial agents in form of prodrugs, the additional step 2 described below should be applied after the calculations described in section 1.

Step 2: If the antimicrobial agent is a long-acting salt or prodrug listed in table 3 above, additionally multiply with the corresponding conversion factor.

$$Antimicrobial\ agent\ (active\ entity)(kg) = Step\ 1\ antimicrobial\ agent\ (chemical\ compound\ as\ declared\ on\ the\ product\ label)\ kg\ x\ prodrug\ conversion\ factor$$

[21] http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500189269

Annex 9. Distribution of Member Countries by OIE Region

AFRICA (54)

1. ALGERIA
2. ANGOLA
3. BENIN
4. BOTSWANA
5. BURKINA FASO
6. BURUNDI
7. CAMEROON
8. CABO VERDE
9. CENTRAL AFRICAN (REP.)
10. CHAD
11. COMOROS
12. CONGO (REP. OF THE)
13. CONGO (DEM. REP. OF THE)
14. CÔTE D'IVOIRE
15. DJIBOUTI
16. EGYPT
17. EQUATORIAL GUINEA
18. ERITREA
19. ESWATINI
20. ETHIOPIA
21. GABON
22. GAMBIA
23. GHANA
24. GUINEA
25. GUINEA-BISSAU
26. KENYA
27. LESOTHO
28. LIBERIA
29. LIBYA
30. MADAGASCAR
31. MALAWI
32. MALI
33. MAURITANIA
34. MAURITIUS
35. MOROCCO
36. MOZAMBIQUE
37. NAMIBIA
38. NIGER
39. NIGERIA
40. RWANDA
41. SAO TOME AND PRINCIPE
42. SENEGAL
43. SEYCHELLES
44. SIERRA LEONE
45. SOMALIA
46. SOUTH AFRICA
47. SOUTH SUDAN (REP. OF)
48. SUDAN
49. TANZANIA
50. TOGO
51. TUNISIA
52. UGANDA
53. ZAMBIA
54. ZIMBABWE

AMERICAS (30)

1. ARGENTINA
2. BAHAMAS
3. BARBADOS
4. BELIZE
5. BOLIVIA
6. BRAZIL
7. CANADA
8. COLOMBIA
9. COSTA RICA
10. CUBA
11. CURACAO
12. CHILE
13. DOMINICAN (REP.)
14. ECUADOR
15. EL SALVADOR
16. GUATEMALA
17. GUYANA
18. HAITI
19. HONDURAS
20. JAMAICA
21. MEXICO
22. NICARAGUA
23. PANAMA
24. PARAGUAY
25. PERU
26. SURINAME
27. TRINIDAD AND TOBAGO
28. UNITED STATES OF AMERICA
29. URUGUAY
30. VENEZUELA

MIDDLE EAST (12)

1. AFGHANISTAN
2. BAHRAIN
3. IRAQ
4. JORDAN
5. KUWAIT
6. LEBANON
7 OMAN
8. QATAR
9. SAUDI ARABIA
10. SYRIA
11. UNITED ARAB EMIRATES
12. YEMEN

ASIA, FAR EAST AND OCEANIA (32)

1. AUSTRALIA
2. BANGLADESH
3. BHUTAN
4. BRUNEI
5. CAMBODIA
6. CHINA (PEOPLE'S REP. OF)
7. FIJI
8. INDIA
9. INDONESIA
10. IRAN
11. JAPAN
12. KOREA (REP. OF)
13. KOREA (DEM. PEOPLE'S REP. OF)
14. LAOS
15. MALAYSIA
16. MALDIVES
17. MICRONEISA (FED. STATES OF)
18. MONGOLIA)
19. MYANMAR
20. NEPAL
21. NEW CALEDONIA
22. NEW ZEALAND
23. PAKISTAN
24. PAPUA NEW GUINEA
25. PHILIPPINES
26. SINGAPORE
27. SRI LANKA
28. TAIPEI (CHINESE)
29. THAILAND
30. TIMOR LESTE
31. VANUATU
32. VIETNAM

EUROPE (53)

1. ALBANIA
2. ANDORA
3. ARMENIAA
4. AUSTRIA
5. AZERBAIJAN
6. BELARUS
7. BELGIUMS
8. BOSNIA AND HERZEGOVINA
9. BULGARIA
10. CROATIA
11. CYPRUS
12. CZECH REP.
13. DENMARK
14. ESTONIA
15. FINLAND
16. FRANCE
17. GEORGIA
18. GERMANY
19. GREECE
20. HUNGARY
21. ICELAND
22. IRELAND
23. ISRAEL
24. ITALY
25. KAZAKHSTAN
26. KYRGYZSTAN
27. LATVIA
28. LIECHTENSTEIN
29. LITHUANIA
30. LUXEMBOUR
31. MALTA
32. MOLDOVA
33. MONTENEGRO
34. NETHERLANDS (THE)
35. NORTH MACEDONIA
36. NORWAY
37. POLAND
38. PORTUGAL
39. ROMANIA
40. RUSSIA
41. SAN MARINO
42. SERBIA
43. SLOVAKIA
44. SLOVENIA
45. SPAIN
46. SWEDEN
47. SWITZERLAND
48. TAJIKISTAN
49. TURKEY
50. TURKMENISTAN
51. UKRAINE
52. UNITED KINGDOM
53. UZBEKISTAN