Reporting of sales and use of antimicrobials per animal species by TATFAR members

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1. Introduction

Knowledge about the amounts of antimicrobials used or sold for use in animals can serve a number of purposes [1] including:

- To monitor trends in sales and use and evaluate the effectiveness of control measures being implemented
- As a basis for setting risk management priorities, for example, to better understand in which species/sectors antimicrobials are more commonly being used and why, including antimicrobials considered critically important for human use
- To encourage behaviours that optimize antimicrobial use (AMU) and improve antimicrobial stewardship, which will reduce selection pressure for antimicrobial resistance (AMR)
- To support integrated analysis between antimicrobial sales and/or use with AMR data from bacteria isolated from animals, humans and the environment
- To form the basis of targeted research and development, for example, by helping to identify where there is a need for alternatives to antimicrobials.

The Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) consists of members from Canada, the European Union, Norway, the United Kingdom and the United States. TATFAR members recognize the importance of collecting antimicrobial sales and use data, but there are substantial differences between how and what the countries/regions collect, including:

- Surveillance systems
- Availability of data
- Data collection tools
- Regulatory frameworks
- Metrics/ indicators for reporting data

The aim of this paper is to present the different approaches taken by TATFAR member countries, highlighting some of the key similarities and differences to help stakeholders better interpret the surveillance data presented by the different regions.

2. Definitions

2.1. Antimicrobial Sales, Stratification of Sales, Use and Consumption Data

The definitions of antimicrobial sales and use can be found in Table 1:

Table 1: Differences between antimicrobial sales and antimicrobial use

	Definition	Data Provider (examples)	Data Source (examples)
Antimicrobial Sales*	Amounts of antimicrobials sold, manufactured and/or imported for sale which are indicated/intended for use in animals.	Marketing Authorisation Holders (MAHs)/drug sponsors/pharmaceutical manufacturers, wholesalers, retailers, import license holders	Sales records from data providers to veterinary practices and/or wholesalers

Antimicrobial Use*	Amounts of antimicrobials administered or to be administered, for example prescribed, dispensed, and/or delivered to the farm(er)/veterinarians for a defined animal species and/or animal production sector.	Veterinarians, pharmacies, feed mills, end-users (including farmers and breeders)	Health records, treatment logbooks, delivery notes, invoices from farms, prescriptions, pharmacy records, veterinary practice records

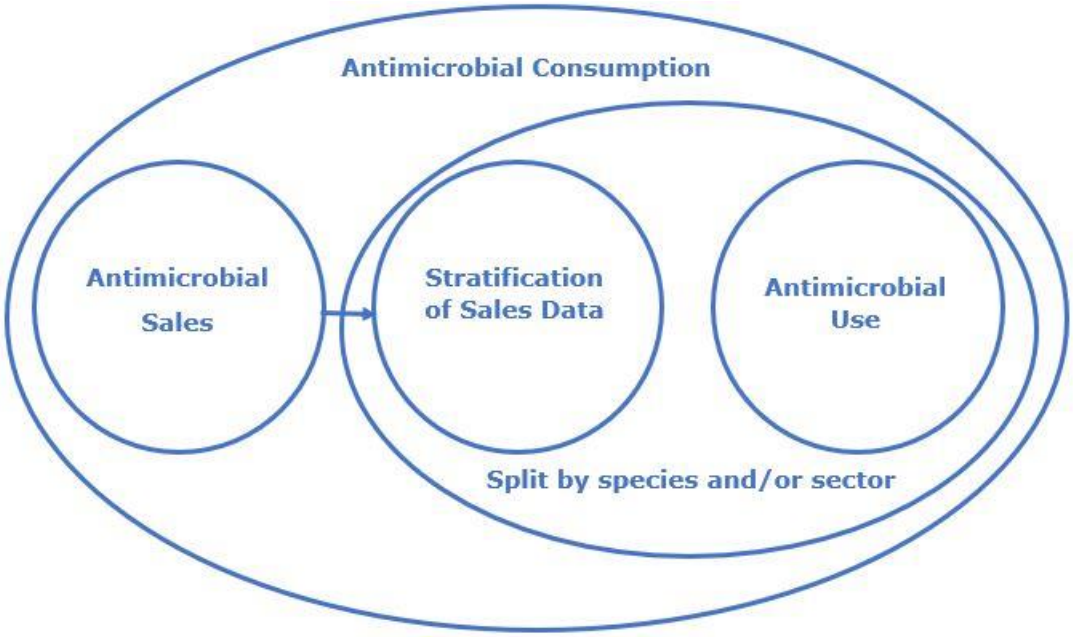
* Adapted from TATFAR member regional definitions [1, 2]

It should be noted that ionophores are not included in the antimicrobial reporting by the European Union, Norway and United Kingdom as they are authorised as feed additives rather than antimicrobial Veterinary Medicinal Products (VMP's).

Stratification of sales data - refers to an estimation of the antimicrobial sales per animal species and/or animal production sector based on an approximate allocation of the proportion of total sales to each of the species and or sectors for which an antimicrobial is used [3], which is commonly estimated and reported by MAHs/drug sponsors.

Antimicrobial consumption - refers to a catch-all term which incorporates data on antimicrobial sales, stratification of sales, and use [1] (see Figure 1).

Figure 1: Diagram showing the interaction between the terms antimicrobial sales, stratification of sales data, antimicrobial use and antimicrobial consumption



The difference between antimicrobial sales and use is that sales occur earlier in the medicine distribution chain, whereas use is closer or equal to the end user. Antimicrobial sales data are often easier and less resource intensive to collect than AMU data. Because most antimicrobial veterinary medicinal products (VMPs) are licensed for multiple species, it is challenging to analyze overall sales by

animal species and/or animal production sector. In addition, purchased antimicrobials might not be used until a later date and there may also be wastage, for example resulting from package sizes that do not meet the dose needed or from products expiring. AMU data are particularly helpful for guiding the development of sector-specific stewardship goals [4]. If use data are collected, it can also allow for benchmarking [5], and can help promote prudent antimicrobial use by fostering a conversation on AMU between veterinarians and farmers, as well as provide a stimulus for improving stewardship. However, whilst acknowledging the importance of farm-level data collection and benchmarking, this document will focus on indicators for high-level monitoring of antimicrobial sales and use.

2.2. Measuring Antibiotic Sales and Use Data

An indicator refers to a metric used to quantify sales or use of antimicrobials during a specified time period. Indicators involve two key elements:

- A **numerator** - this refers to a measure of the amount of antimicrobial sold or used [1] during a specified time period. Examples include weight of antimicrobial active ingredient, number of antimicrobial courses administered or the number of daily doses sold during a calendar year.
    - Weight of antimicrobial active ingredient is commonly reported in milligrams (mg), kilograms (kg), tonnes or pounds (lb).
    - **Defined daily dose** refers to the assumed average maintenance dose per day for an antimicrobial substance or drug used for its main indication [6].
- A **denominator** – this is a measure of the animal population that can potentially be treated (with an antimicrobial) during a specified timeframe [1]. This refers to all animals in a group (e.g., farm, house, flock) that can potentially be treated/exposed to antimicrobials during a specified time period [2].These commonly assess the weight (also known as biomass) of the animal population (e.g., based on slaughter weight, liveweight or weight at time of treatment, in kilograms (kg) or pounds (lb)) and is usually calculated by multiplying the number of animals (e.g., average number of living animals and/or number of slaughtered animals) with an estimated standard weight.

Indicators usually involve a numerator expressed in relation to a denominator representing the population (at risk) over a specified time period[2]. Examples include mg of active ingredient/kg of animal biomass/year, defined daily doses/1000 animals/day, etc.

Examples of specific denominators used to represent animal biomass are:

Population Correction Unit (PCU): The population correction unit (PCU) was established as a denominator for reporting data on the sales of veterinary antibiotics for food-producing animals by the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project [1, 7] and has also been applied in Canada. It is a purely technical unit of measurement, where 1 PCU unit is equivalent to 1 kg of animal biomass. A weight (in kg) representing the 'average weight at the time of treatment' is assigned for each category (species/production type) of animal. This weight is multiplied by the number of heads of animals in the category. The total biomass for all the animal categories gives the PCU for the country (see Table 2). Animals traded for fattening or for slaughter in another Member State are likely to be treated with antimicrobial agents in the country of origin, therefore the final PCU also takes into consideration the biomass of animals traded between countries. It should be noted that for finfish, the total biomass of farmed fish produced (live weight produced) is used rather than taking account of the number of heads.

Target Animal Biomass: This is a denominator developed for the reporting of biomass-adjusted sales data in the US. Animal biomass is defined as the total mass of an animal species, determined by multiplying that species' population by the average weight of that species each year. Food and Drug Administration (FDA) primarily uses U.S. Department of Agriculture (USDA)'s existing databases to estimate annual livestock numbers and average weights for the biomass denominator calculations. The biomass denominator for each species, as it applies to the species-specific estimate of sales for medically important drug classes, is referred to as the target animal biomass (TAB) [8].

2.3. Other Definitions

Active Pharmaceutical Ingredient (API) / Active substance: Any substance used in the fabrication of pharmaceutical drugs/medicines responsible for beneficial health effects produced by use of the product.

Animal Drug Approval: In the US, under Section 512 of the Federal Food, Drug, and Cosmetic Act, an animal drug must be approved by FDA before a drug sponsor can legally market the drug. During the preapproval review process, FDA evaluates information submitted by the sponsor to make sure the drug is safe and effective for its intended use and that the drug is properly manufactured and adequately labelled and packaged. Two additional pathways to the marketplace are available for drugs used in animals depending on certain situations: conditional approval and indexing [9].

Antibiotic: any substance with a direct action on bacteria that is used for treatment or prevention of infections or infectious diseases [1]. In the US, these are referred to as antibacterial or antibiotic drugs [10].

Antimicrobial: any substance with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals and anti-protozoals [11]. In the US the term "antimicrobial" refers broadly to drugs with activity against a variety of microorganisms including bacteria, viruses, fungi, and parasites [10].

Antimicrobial benchmarking: The comparison of a party's AMU with AMU in a pre-defined population of similar parties [2].

Antimicrobial resistance (AMR): Per the Codex Alimentarius definition, it is the ability of a microorganism to multiply or persist in the presence of an increased level of an antimicrobial agent relative to the susceptible counterpart of the same species [12]. An alternative definition (per the FDA) is the ability of bacteria or other microbes to resist the effects of a drug. Antimicrobial resistance, as it relates to bacterial organisms, occurs when bacteria change in some way that reduces or eliminates the effectiveness of drugs, chemicals, or other agents designed to treat bacterial infections [10].

Antimicrobial stewardship: A coherent set of actions that promotes the responsible use of antimicrobials [2]. An alternative definition for antimicrobial stewardship, as defined by the American Veterinary Medical Association (AVMA), refers to the actions veterinarians take individually and as a profession to preserve the effectiveness and availability of antimicrobial drugs through conscientious oversight and responsible medical decision-making, while safeguarding animal, public, and environmental health [13].

ATCvet: This refers to The Anatomical Therapeutic Chemical classification system for veterinary medicinal products developed by WHO, which is a system used in some countries for the classification of substances intended for therapeutic use in veterinary medicine [14].

Drug sponsor: A term used in Canada and USA to denote an applicant, person or entity who files a drug submission [15] or assumes responsibility for the marketing of a new drug, including

responsibility for compliance with applicable provisions of the Federal Food, Drug, and Cosmetic Act and related regulations [16].

Marketing authorisation: A marketing authorisation is granted and allows the placing of a medicine, including veterinary medicinal products, on the market following an evaluation of the product's dossier to determine if its benefits outweigh its risks. This may be known as a product licence, registration or approval. A marketing authorisation can have a different status (e.g., valid, suspended, withdrawn) depending on the medicine life-cycle [12].

Marketing authorisation holder: A term used in Europe that refers to a company, firm or non-profit organisation that holds a medicinal product's dossier [1]. This term is also used in Canada (to be also referred to as sponsor or manufacturer) for the legal entity that holds the notice of compliance, the drug identification number, the medical device licence number, the product licence number or has received approval to initiate clinical trials [17].

Medically important antimicrobial: Antimicrobial substances important for therapeutic use in humans, taking into account the WHO List of Critically Important Antimicrobials for Human Medicine [18], including the classes described in the Annex of the "List of Medically Important Antimicrobials, categorized as Critically Important, Highly Important, and Important", or equivalent criteria established in a national list, where available. It does not include ionophores or other substances determined not to yield a risk of causing foodborne AMR consistent with the Codex Alimentarius Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance [19].

3. Antimicrobial Sales Data Collection and Analysis

3.1. Canada

3.1.1. Antimicrobial Sales Data

From 2006 to 2018, the Canadian Animal Health Institute (CAHI) voluntarily provided data on the quantities of antimicrobials distributed for sale for use in animals to the Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS) of the Public Health Agency of Canada. CAHI coordinated the collection of these data from their members, which represent approximately 90-95% of the animal drug manufacturer industry each year in Canada. To further support antimicrobial resistance surveillance and stewardship, regulatory changes [20] came into force in 2018 requiring manufacturers, importers, and compounders to report annually to Health Canada's Veterinary Drugs Directorate, the sales data for all medically important antimicrobials intended for use in animals [21, 22]. The scope of the sales data includes all medically important antimicrobials on "List A: List of certain antimicrobial active pharmaceutical ingredients" [23], although data providers are encouraged to submit information of those antimicrobials not included in List A such as ionophore antibiotics. The sales data also include information on active pharmaceutical ingredients from importers, compounded products without Drug Identification Numbers (DINs), and List A antimicrobials for use in animals accessed through Health Canada's Emergency Drug Release Program [24].

To implement the regulatory reporting requirements, Health Canada and the Public Health Agency of Canada developed the web-based Veterinary Antimicrobial Sales Reporting (VASR) system [21]. This system collects data on volumes of antimicrobials sold, imported or compounded by animal species and by province/territory. The information requested is for all formulations and/or intended routes of administration. Annual sales of medically important antimicrobials intended for veterinary use of the previous calendar year (January 1 to December 31) must be submitted by manufacturers, importers

and compounders to Health Canada by March 31 of the reporting year. Annual sales report highlights and interactive data are published online [21, 25].

The numerator for national reporting of sales for food-producing animals is mg of antimicrobial active ingredient.

It should be noted that the label claims for use of medically important antimicrobials for growth promotion purposes were removed as of December 1, 2018.

Similar to the approach used in the United States, to protect confidential business information, the VASR data are summarized by antimicrobial class; only antimicrobial classes with three or more data providers are reported. If there are less than three data providers, the antimicrobial quantities are grouped into a "Not Independently Reported" (NIR) category.

3.1.2. Stratification/Estimation of Sales Data by Species

For the sales data, between 2011 and 2018, CAHI members volunteered to provide their distribution data stratified into sales for production animals (including horses) or companion animals. According to CAHI, their members stratified their data based on label claims, and in the situation where multiple species were indicated on the label, the data provider estimated sales for either companion animal or production animals; production animals included livestock and horses.

As of 2018, for VASR, the pharmaceutical manufacturers, importers, and compounders are required to provide estimates of the percentages of packages sold and report sales data stratified by major animal species groups, including: aquaculture, cattle (beef), cattle (dairy), cattle (veal), chickens, cats and dogs, horses, pigs, small ruminants, turkeys, and 'other'. The entry field of 'other' allows data providers to specify additional species captured, if known.

3.1.3. Animal Population Data

The majority of the animal population data comes from Statistics Canada or Agriculture and Agri-Food Canada. Data on animal numbers are also obtained from some national industry associations, such as the Chicken Farmers of Canada, Egg Farmers of Canada, and Canadian Hatching Egg Producers (in situations where there are known gaps in the nationally reported data). The numbers of live horses in 2010 were obtained from Equestrian Canada; no recent data for live horses are available. Fisheries and Oceans Canada provide data on total kilograms slaughtered for marine finfish and shellfish [26, 27]. CAHI provides data on the numbers of cats and dogs.

For sales data, Canada uses three denominators (all representing kg of animals at risk): Population Correction Unit $(PCU)_{EU}$ (using EU standard weights of animals at time of treatment), PCU_{CA} (using Canadian standard weights of animals at time of treatment) and kg $biomass_{SL}$ (using average live weight at time of slaughter).

For the PCU_{EU}, this generally follows the ESVAC's animal categories with a few differences related to data availability and the inclusion of live beef cows [7]. As per ESVAC's approach, for most production animal species, the scope of the data covers both live animals on the farm and slaughtered animals. For animal weights, Canada uses the European average live weights at time of treatment.

For PCU_{CA}, Canada added a few additional poultry populations (egg layers, broiler hatching egg producers and broilers on small lots) and uses Canadian-specific average weights of treatment; these were developed in consultation with industry and/or government stakeholders, or based on surveillance data [28].

For kg biomass$_{SL}$, Canada uses the animal production categories as per the PCU$_{CA}$ and then applies live weights at time of slaughter, which are determined based on carcass weights adjusted for dressing percentages, or as adult weights for animals not raised for slaughter (such as dairy cattle).

Canada calculates a separate PCU$_{CA}$ for production animals and companion animals. The PCU$_{CA}$ for companion animals includes cats and dogs, but excludes birds, pet fish, and exotic animals.

3.1.4. Indicator(s)

In Canada, the indicators for sales data, which are analysed for every calendar year, are currently: milligrams of antimicrobial consumed per population correction unit (mg/PCU$_{EU}$ or mg/PCU$_{CA}$) or mg per kg liveweight at time of slaughter (mg/kg biomass$_{sl}$). Canada also has a mg/PCU$_{CA}$ for cats and dogs. In the future, Canada plans to add dose-based technical units of measurement to report sales data.

3.2. European Union

3.2.1. Antimicrobial Sales Data

The ESVAC project was launched by the European Medicines Agency (EMA) in September 2009, following a request from the European Commission to develop an approach for the harmonised collection and reporting of data on the use of antimicrobial substances in animals from EU and European Economic Area (EEA) Member States.

Through the ESVAC exercise, data are collected every calendar year on the volume of sales of antimicrobial VMPs at package level from the EU Member States, EEA countries, United Kingdom (until 2021) and Switzerland.

The current ESVAC sales and animal population data reporting protocol requires participating countries to report the volume of sales of antimicrobial VMPs for systemic, intestinal, intrauterine and intramammary (dry cow and lactating cow) use, based on the product ATCvet code. All pharmaceutical forms and medicated feed are included except dermatological products and products for sensory organs [7].

The quantity of antibiotic active ingredient in tonnes sold for each VMP presentation is calculated by multiplying the number of packages sold by the strength of the antibiotic active ingredient per package unit, as described in the corresponding product information. Data are collected per VMP presentation and analysed per product form, a term that combines the pharmaceutical form with the route of administration, and for intramammary products, also the therapeutic indication. Since tablets are typically approved only for companion animals, they are excluded from the data sets prior to the normalisation of sales by the denominator.

The numerator is tonnes of each antimicrobial active ingredient.

It should be noted that the use of antimicrobial growth promoters is prohibited in the ESVAC participating countries.

For other projects, e.g., JIACRA, the Agency prepares technical estimates of antimicrobial consumption for pigs and poultry based on the antimicrobial sales data reported to the ESVAC database [29].

In 2023, EMA will publish the last ESVAC report containing 2022 data submitted voluntarily by participating countries. Under Regulation (EU) 2019/6 on VMPs, the collection of data on the volume of

sales of veterinary antimicrobials and on use of antimicrobials in animals, and the reporting of these data to the Agency becomes a mandatory activity of Member States.

3.2.2. Animal Population Data

Animal population data collected include the number of livestock animals (dairy cows, sheep, sows and horses) and slaughtered animals (cattle, pigs, goats, sheep, chickens, rabbits and turkeys), the biomass of farmed fish produced (based on liveweight) and the number of animals moving across EU single market borders by intra-community supplies and acquisitions of animals for fattening or slaughter (cattle, goats, pigs, sheep and poultry).

For each reporting year, animal population data are collected from official European statistics (Eurostat) [30] and national statistics, and for the intra-EU animal trade data are obtained from the Trade control and Expert System (TRACES) [31].

See Section 2.2. for the calculation of the Population Correction Unit (PCU).

As statistics for companion animals (dogs and cats) are not available in all EU/EEA countries, the PCU does not include companion animals.

3.2.3. Indicator(s)

For each calendar year, the main indicator to express consumption of veterinary antibiotics for food-producing animals by the ESVAC project is **mg (active substance)/PCU (kg)**.

When presenting total sales in mg/PCU for all the ESVAC reporting countries, these represent aggregated sales, i.e., total quantity of all antibiotic active substances sold (mg) in all countries divided by the total PCU (kg) of all countries. The sales in mg/PCU are also calculated separately for each participating country and each antimicrobial class.

For companion animals, sales of antibiotic active substances are presented in tonnes.

3.3. Norway

3.3.1. Antimicrobial Sales Data

For sales, the antimicrobial VMPs included in the surveillance system are identical to those for ESVAC [32] and also cover VMPs used on special permit (products approved in another European Economic Area (EEA) country). Sales data has been collected from 1981 for farmed fish and from 1993 for terrestrial animals.

The sources of the sales data for the national report (NORM-VET) [33] are authorised wholesalers and feed mills for which it is mandatory to deliver the data (100% coverage of data sources).

Sales data represent total sales of antimicrobial VMPs and thus the total animal population likely to be treated are covered.

The numerator for overall sales data is kg of antimicrobial active ingredient (for terrestrial food-producing animals, farmed fish and companion animals) and mg of antimicrobial active ingredient for food-producing animals and farmed fish.

3.3.2. Stratification of Sales Data

Approach 1 - to report historical sales data in a harmonised manner, the sales data are split into sales of VMPs authorised for companion animals only while the remaining VMPs are allocated to food-producing animals.

Approach 2 - for reporting according to reduction-targets for terrestrial food-producing animals for the period from 2013 to 2021, use data have been used for further refinement of the sales data (see Appendix 1, NORM-VET [33]) to obtain estimates aggregated for the major terrestrial food-producing animals (cattle, pigs, sheep, goat and poultry).

3.3.3. Animal Population Data

The stratified sales data for the terrestrial food-producing animals (Approach 2) are normalized by the animal population at risk and for farmed fish biomass slaughtered is used as a proxy for the farmed fish at risk. The animal categories included to calculate these denominators are identical to those in ESVAC. Data on the terrestrial food-producing animal population are obtained from Statistics Norway while for farmed fish biomass slaughtered data are obtained from the Norwegian Fish Directorate.

The denominator is the PCU (in kg), which is calculated by applying the same formula as for ESVAC.

3.3.4. Indicator(s)

Approach 1 - historical data, weight-based indicator (kg of active ingredient) for terrestrial food-producing animals, farmed fish and companion animals. Highlighting those antimicrobial classes that the Antimicrobial Advice *Ad Hoc* Expert Group has recommended to restrict due to potential public health concerns [quinolones, 3rd- and 4th-generation cephalosporins and polymyxins (no sales of polymyxins in Norway)] [34].

Approach 2 – estimated sales for cattle, pigs, sheep, goats and poultry and prescribed amounts for farmed fish: kg and mg/PCU, applying the same formula for calculation of the PCU as ESVAC.

3.4. United Kingdom

3.4.1. Antimicrobial Sales Data

Sales of all antibiotics, antiprotozoals (including coccidiostats) and antifungals are provided by marketing authorisation holders, who give information, via a standardised spreadsheet, on the number of packs sold for each pack size. Data are then collected and analysed using a bespoke software system and reported in the UK-VARSS (Veterinary Antimicrobial Resistance and Sales Surveillance) report [35]. Sales data were initially collected on a voluntary basis, starting in 1993, but it became a legal requirement in 2005. The data cover all products used in animals, with the exception of those imported under the Special Import Scheme or extemporaneous products used under the prescribing cascade [36].

The numerator (for antimicrobials) is tonnes of active ingredient (for all species), mg of active ingredient (for food-producing animals by removing tablet sales) and mg of active ingredient for products licensed exclusively for cats and/or dogs.

3.4.2. Stratification of Sales Data

Stratification of sales data is not published by the UK.

3.4.3. Animal Population Data

For food-producing animals, the animal numbers (using the same categories of living and slaughter animals as ESVAC), as shown in Table 2, are collected from national government statistics [37-39] and, for horses, the British Equestrian Trade Association survey [40] (which takes place every five years). Data on dog and cat numbers are obtained from the PDSA Animal Wellbeing (PAW) report [41].

For food-producing animals, the denominator is the PCU (in kg), which is calculated by applying the same formula as ESVAC. For dogs and cats the number of animals is multiplied by average dog and cat weights (provided each year by the Small Animal Veterinary Surveillance Network (SAVSNET) [42], who collect animal weight data from dogs and cats across 300 veterinary practices. In 2022, the average weights were 18.3 kg for dogs and 4.5 kg for cats.

3.4.4. Indicator(s)

Antimicrobial sales data are reported in the national UK-VARSS report [35] on a calendar year basis as:

- Tonnes of antimicrobial active ingredient
- mg/PCU (for food-producing animals) using the ESVAC methodology. To help stakeholders understand this metric better, the UK have also produced a guidance document [43]
- mg/kg (for dogs and cats), using the cat and dog numbers/weights described earlier.

Note that the sales of products licensed for topical use (e.g., sprays/skin creams) or for sensory organs (e.g., eye drops/ear drops) are collected but are not included in the above indicators.

3.5. United States

3.5.1. Antimicrobial Sales Data

Sales data for all antimicrobial drugs that are specifically approved for antibacterial uses or are known to have antibacterial properties are required to be reported, including both medically and non-medically important (i.e., ionophores are included). Antifungals, antivirals, and antiprotozoal drugs that do not have antibacterial properties (e.g., amprolium) are not included.

Historically, drug manufacturers ("sponsors", i.e., holders of approved animal drug applications) have been required to report distribution data to the FDA for all approved animal drug products (21 Code of Federal Regulations 514.80(b)(4)(i)) [44] as part of their annual Drug Experience Report (DER), for all species. They must specify the total number of distributed units of each size, strength, or potency for both domestically distributed and exported animal drug products.

Since 2009, drug manufacturers of approved or conditionally approved animal drug products containing an antimicrobial active ingredient have been required to submit to FDA an annual report on the amount of each such antimicrobial active ingredient in the drug that is sold or distributed in the reporting year for use in food-producing animal species (major and minor) included on approved labels (cattle, swine, chickens, turkeys, fish/shellfish, honeybees, sheep, goats, and game birds). Information must include container size, strength, and dosage form, list of approved target animal species, indications, and production classes specified on the approved label. The number of units sold or distributed in the U.S. and exported must be reported for each month of the reporting year. Data must be submitted by March 31 of each year for the preceding calendar year.

FDA is required to publish a summary report of the preceding year's antimicrobial sales data by December 31 of each year. In accordance with statutory requirements designed to protect confidential business information, annual sales and distribution data are summarized by antimicrobial drug class, and only those antimicrobial drug classes and other categories with three or more distinct sponsors of approved and actively marketed animal drug products are independently reported. Antimicrobial drug classes with fewer than three distinct sponsors are reported collectively as "Not Independently Reported" (NIR).

Antimicrobial sales data are reported by FDA annually as the weight of active ingredient (in kg) sold, for each antimicrobial drug class. For biomass-adjusted antimicrobial sales data, the numerator is the sum of all sales of an antimicrobial drug class, in mg, for a given target animal species in a given year.

3.5.2. Stratification of Sales Data

Since 2016, for purposes of estimating species-specific sales, drug manufacturers are required to report percentage estimates for the 4 major food-producing species (cattle, swine, chickens, and turkeys). All other labelled species are included in an 'other' category. The total of these must account for 100% of the product's sales. Currently, drug manufacturers determine the method through which they will perform the estimations. FDA has not established a uniform methodology that all drug manufacturers must use.

3.5.3. Animal Population Data

Most of the data on agricultural animal population numbers are taken from the U.S. Department of Agriculture National Agricultural Statistics Service (USDA NASS) annual livestock and poultry slaughter summary reports, sector-specific reports (e.g., livestock beef cows and livestock dairy cows, hogs/pigs kept for breeding), and livestock international import/export data using the USDA Foreign Agricultural Service Global Agricultural Trade System (GATS) [45].

Animal categories collected are commercial and farm slaughtered cattle and calves, livestock beef cows, livestock dairy cows, commercial and farm slaughtered hogs and pigs, hogs and pigs kept for breeding (mainly sows), slaughtered chickens (young and mature), and total slaughtered turkeys (see Table 2).

The denominator is based on average weight of slaughter in kg (which changes from year to year, based on information the USDA reports), with some exceptions (e.g., livestock beef and dairy cows; breeding animals). This is called the 'target animal biomass' (TAB) and is calculated on an annual basis for each of the species categories: cattle, swine, chickens and turkeys. Most of the data on animal weights come from the USDA NASS reports. For livestock beef and dairy cows, as well as breeding sows, weights are obtained from literature references or other USDA reports, such as periodic reports for the National Animal Health Monitoring System (NAHMS) and Agricultural Marketing Service (AMS) reports. Animals imported are subtracted from the biomass denominator, and animal exports are added.

3.5.4. Indicator(s)

Antimicrobial sales are reported for independently reportable drug classes as kilograms of API, or estimated annual kilograms for species-specific data [46]. These are then adjusted by an animal biomass denominator and reported as mg/Target Animal Biomass (mg/TAB) at the antimicrobial drug class level, for each of the four major food-producing species. The mg/TAB is calculated as:

mg/TAB = (the sum of all sales of an antimicrobial drug class, in mg, for a given target animal species) divided by (the estimated number of the given target animal species x estimated average weight, in kg, of this species).

If certain animal production category exclusions apply for all products in a given independently reported antimicrobial class, then the animal biomass representing that exclusion would not be included in the denominator. For example, if all products in a given drug class were approved for cattle but specifically not dairy cattle, then the dairy cattle biomass would be excluded for that drug class denominator.

3.6. Summary of animal weight estimates for denominator data applied to antimicrobial sales data in TATFAR countries

Animal biomass (which is used as a denominator for interpreting sales data in all TATFAR participating countries), is usually calculated by multiplying the number of living animals and/or the number of animals slaughtered within a specified timeframe (e.g., calendar year or production cycle) by a standard weight. This standard weight either represents the average weight at time of treatment (as used in the Population Correction Unit methodology applied by EU, Norway, UK and Canada) or the average weight at slaughter/ average living biomass (as applied by US and Canada).

Adjustments are also commonly made based on the number of animals imported from or exported to another country. For example:

- If an animal is imported into a country for fattening or slaughter, then their weight is deducted from the overall animal biomass in the importing country. This is done because they will be included in the slaughter figures for the importing country while some or all of the antibiotic use will have occurred in the country of origin.
- If an animal is exported to another country for fattening or slaughter, then their weight is added to the overall animal biomass of the exporting country. This is done because they will not be included in the slaughter figures while some or all of the antibiotic use will have been in the exporting country.

It should be noted that animal weights and categories can differ when using a denominator for sales rather than use data. This is because:

- National animal population statistics are commonly used to determine the denominator for sales data. However, for antibiotic use data, unless all farms that contribute to national or regional statistics are included, the animal population data used to determine the denominator needs to be collected from each farm that is providing antibiotic use data. For this reason, animal categories that can easily be provided by farms are usually chosen.
- Categories like "number of animals slaughtered" may not be appropriate when collecting data from farms that do not send animals directly to slaughter, such as breeder farms.

Table 2 provides a summary of animal categories and weights used to estimate animal weights in production classes for calculating the denominators applied to sales data (numerators) by TATFAR member countries.

Table 2: Animal production categories and weights used to calculate the denominator in TATFAR Member Countries

Animal categories	Canada [25]			US* [47]	EU/Norway/UK [48]
	PCU_{EU}	PCU_{CA}	$Biomass_{SL}$		
Weights represent	Average weight at time of treatment	Average weight at time of treatment	Average liveweight/ liveweight at time of slaughter	Average liveweight/ liveweight at time of slaughter	Average weight at time of treatment
Cattle					
Slaughtered cows	425 kg	635 kg (dairy) 520 kg (beef)	635 kg	622 kg (commercial and farm slaughtered cattle)	425 kg
Slaughtered heifers	200 kg	200 kg	573 kg	Exclusion category**	200 kg
Steers	425 kg (steers and bulls)	425 kg (steers and bulls)	748 kg (steers and bulls)	Exclusion category	Not applicable
Slaughtered bullocks and bulls	425 kg (steers and bulls)	425 kg (steers and bulls)	748 kg (steers and bulls)	Exclusion category	425 kg
Slaughtered calves and young cattle	140 kg	249 kg	275 kg	108 kg	140 kg
Bovine for slaughter – Import	425 kg	425 kg	748 kg	Combined category of import for feeding and slaughter: 90 kg (cattle imported <90 kg); 199 kg (cattle imported 90 kg to 199 kg); 319 kg (cattle imported 200 kg to 319 kg); 622 kg (cattle imported > 320 kg)	425 kg
Bovine for slaughter - Export	425 kg	425 kg	748 kg	622 kg	425 kg
Fattening bovine - Import	140 kg	289 kg	289 kg	Not applicable	140 kg

Animal categories	Canada [25]			US* [47]	EU/Norway/UK [48]
	PCU_{EU}	PCU_{CA}	$Biomass_{SL}$		
Weights represent	Average weight at time of treatment	Average weight at time of treatment	Average liveweight/ liveweight at time of slaughter	Average liveweight/ liveweight at time of slaughter	Average weight at time of treatment
Fattening bovine - Export	140 kg	296 kg	296 kg	Not applicable	140 kg
Living dairy cows	425 kg	650 kg	650 kg	635 kg	425 kg
Other cows not for slaughter				Not applicable	Not applicable
Living beef cows	425 kg	520 kg	520 kg	528 kg	Not applicable
Pigs					
Slaughtered pigs	65 kg	65 kg	129 kg	131 kg (commercial and farm slaughtered hogs)	65 kg
Pigs for slaughter - Import	65 kg (combined category of import for feeding and slaughter)	65 kg (combined category of import for feeding and slaughter)	129 kg (combined category of import for feeding and slaughter)	Combined category of import for feeding and slaughter: 131 kg (imported pigs for immediate slaughter, ≥ 50 kg); 7 kg (imported pigs <7 kg); 23 kg (imported pigs 7 to< 23 kg); 50 kg (imported pigs 23 to < 50 kg); 131 kg (imported pigs ≥50 kg	65 kg
Fattening pigs - Import					25 kg
Pigs for slaughter - Export	65 kg	65 kg	129 kg	Combined category of export for feeding and slaughter: 131 kg (exported pigs ≥50 kg); 50 kg (exported pigs <50 kg)	65 kg
Fattening pigs - Export	25 kg	3 kg	3 kg		25 kg
Living sows	240 kg	240 kg	240 kg	Not applicable	240 kg

Animal categories	Canada [25]			US* [47]	EU/Norway/UK [48]
	PCU_{EU}	PCU_{CA}	$Biomass_{SL}$		
Weights represent	Average weight at time of treatment	Average weight at time of treatment	Average liveweight/ liveweight at time of slaughter	Average liveweight/ liveweight at time of slaughter	Average weight at time of treatment
Boars				Exclusion category	Not applicable
Hogs and pigs kept for breeding				214 kg (based on culled sow weighted average)	Not applicable
Poultry					
Slaughtered broilers	1 kg	0.84 kg	2.3 kg	2.93 kg (total number slaughtered chickens)	1 kg
Young chickens (included in total slaughter)				2.93 kg	Not applicable
Slaughtered turkeys	6.5 kg	3 kg	8.4 kg	14.6 kg	6.5 kg
Poultry for slaughter - Import	1 kg (<185 g) 1 kg (>185 g)	0.2 kg (<185 g) 2 kg (>185 g)	0.2 kg (<185 g) 2.3 kg (>185 g)	Combined category of import for feeding and slaughter: 0.19 kg (chicken imports < 0.185 kg); 2.93 (chicken imports >0.185 kg)	1 kg
Poultry for slaughter - Export	1 kg	0.2 kg (<185 g) 2 kg (>185 g)	0.2 kg (<185 g) 2.3 kg (>185 g)	Combined category of import for feeding and slaughter: 0.19 kg (chicken imports < 0.185 kg); 2.93 (chicken imports > 0.185 kg)	1 kg
Broiler hatching egg producers		2 kg	2.3 kg	Exclusion category	Not applicable
Broilers – small lots		0.84 kg	2.3 kg	Not applicable	Not applicable
Egg layers		2 kg	2.3 kg	Exclusion category	Not applicable

Animal categories	Canada [25]			US* [47]	EU/Norway/UK [48]
	PCU_{EU}	PCU_{CA}	$Biomass_{SL}$		
Weights represent	Average weight at time of treatment	Average weight at time of treatment	Average liveweight/ liveweight at time of slaughter	Average liveweight/ liveweight at time of slaughter	Average weight at time of treatment
Caprinae					
Slaughtered sheep and goat	20 kg (sheep) 20 kg (goats)	20 kg (sheep) 20 kg (goats)	53 kg (sheep) 32.5 kg (goats)	Not applicable	20 kg
Sheep for slaughter - Import	20 kg (combined category of import for feeding and slaughter)	20 kg (combined category of import for feeding and slaughter)	53 kg (combined category of import for feeding and slaughter)	Not applicable	20 kg
Fattening sheep - Import	20 kg (combined category of import for feeding and slaughter)	20 kg (combined category of import for feeding and slaughter)	53 kg (combined category of import for feeding and slaughter)	Not applicable	20 kg
Sheep for slaughter - Export				Not applicable	20 kg
Fattening sheep - Export	20 kg (combined category of import for feeding and slaughter)	20 kg (combined category of import for feeding and slaughter)	53 kg (combined category of import for feeding and slaughter)	Not applicable	20 kg
Living sheep	75 kg	75 kg	75 kg	Not applicable	75 kg
Goats for slaughter - Import	Not applicable	Not applicable	Not applicable	Not applicable	20 kg
Goats for slaughter - Export	Not applicable	Not applicable	Not applicable	Not applicable	20 kg
Fattening goats - Import	Not applicable	Not applicable	Not applicable	Not applicable	20 kg

Animal categories	Canada [25]			US* [47]	EU/Norway/UK [48]
	PCU_{EU}	PCU_{CA}	$Biomass_{SL}$		
Weights represent	Average weight at time of treatment	Average weight at time of treatment	Average liveweight/ liveweight at time of slaughter	Average liveweight/ liveweight at time of slaughter	Average weight at time of treatment
Fattening goats - Export	Not applicable	Not applicable	Not applicable	Not applicable	20 kg
Equidae					
Living horses	400 kg	500 kg	500 kg	Not applicable	400 kg
Rabbits					
Slaughtered rabbits	1.4 kg	1.4 kg	2.45 kg	Not applicable	1.4 kg
Fish					
Farmed finfish (biomass live weight of farmed fish produced)	Slaughtered fish and shellfish based on liveweight (kg)	Slaughtered fish and shellfish based on liveweight (kg)	Slaughtered fish and shellfish based on liveweight (kg)	Not applicable	Slaughtered fish based on liveweight (kg)
Companion animals					
Cats	Not applicable	4 kg	4 kg	Not applicable	(4.5 kg*** – only for United Kingdom)
Dogs	Not applicable	15 kg [49]	15 kg	Not applicable	(18.3 kg*** – only for United Kingdom)

* FDA re-evaluates animal weights based on USDA updated reports on an annual basis when performing biomass calculations. Included here are animal weight by production category for 2021.

** "Exclusion" categories will not be included in biomass calculations if they are not applicable to the level of detail we can report based on confidential business information.

*** 2021 weights used based on SAVSNET data looking at average (mean) dog and cat weights

4. Antimicrobial Use Data Collection and Analysis

4.1. Canada

4.1.1. Antimicrobial Use Data

The scope of the farm data covers all antimicrobials used on the farms; both medically important antimicrobials and antimicrobials considered not medically important (ionophores and chemical coccidiostats). This use is collected from the major food animal species in Canada, including aquaculture, broiler chickens, grower-finisher pigs, feedlot beef cattle and turkeys, with pilot projects in dairy cattle and layer hens.

CIPARS collects annual farm-level antimicrobial use data using species-specific questionnaires from a network of sentinel veterinarians and their producers, representing approximately 90% of poultry and swine veterinary practices across Canada. CIPARS additionally obtains annual antimicrobial use data covering all aquaculture operations in Canada (based on prescriptions used on aquaculture operations) from Fisheries and Oceans Canada [26, 27].

For the major food animal species (except aquaculture), the numerator used is: weight based (mg of active ingredient stratified by active ingredient, antimicrobial class, route of administration, reason for use, and antimicrobial category of importance to human medicine), dose based (total and class-specific number of Canadian Defined Daily Doses (DDDvetCA) and count based (number of farms reporting use of an antimicrobial). For the aquaculture data, the numerator used is weight-based (kg).

4.1.2. Animal Population Data

For all food-producing species (except aquaculture), the final flock or herd population (# of animals placed in the sample barn during the sampled growing period/production cycle minus half of the recorded mortality) is collected from farm-level information using farm production or food safety records for each species category. For example for pigs, this includes the number of grower-finisher pigs (but does not include the number of sows).

The PCU_{EU} denominator is calculated by multiplying the number of animals with the average weight at treatment, currently using EU standard weights at treatment for slaughtered pigs, chickens and turkeys. As an alternative option for poultry, the PCU_{CA} is calculated using the actual average weight at treatment (averaged from all surveillance years by animal species). For poultry, the kg $biomass_{SL}$ is calculated by using the actual live pre-slaughter weight (highest recorded live weight at the time of farm visit for sample and data collection). For grower-finisher pigs, the kg $biomass_{SL}$ is calculated using the live weight at the time of slaughter. Finally, for the animal-days at risk denominator, the number of animal-days is calculated by multiplying the number of animals by the EU standard weight at treatment and the average length of the sampled growing periods/production cycles. For aquaculture, no animal population data are currently applied.

4.1.3. Indicator(s)

The farm-level data are reported primarily using mg/PCU_{EU}, mg/kg $biomass_{SL}$ and number of defined daily doses in animals using Canadian standards (nDDDvetCA /1,000 animal-days at risk) [50, 51]. The proportion of farms receiving an antimicrobial is also reported and other derivations of these indicators are also used in research (e.g., nDDDvetCA/PCU or nDDDvetCA/kg $biomass_{SL}$).

For aquaculture operations, Canada currently uses a weight-based technical unit of measure (mg or kg) without a denominator.

4.1.4. Sales Data validation

CIPARS compares the sales data to the use data indicators (e.g., mg/PCU) and also compare the kg sales for each species (and relative proportion of antimicrobial classes). However, in some cases, there are important differences in the production types of animals included in each dataset. For example, the VASR swine data cover all stages of pig production, whereas the CIPARS farm swine surveillance includes only the grower-finisher stage.

4.2. European Union

Article 57 of the Regulation (EU) 2019/6 requires Member States to collect data on the volume of sales and on the use of antimicrobial medicinal products used in animals [11] and send collated data to EMA, for the analysis of those data and publication of annual reports. Data on use were not collected at EU-level prior to 2023.

In line with Regulation (EU) 2019/6 and Commission Delegated Regulation (EU) 2021/578, Member States are given a progressive stepwise approach [52] for the collection and reporting of use data so that:

- within two years from 28 January 2022, data shall be collected at least for cattle, pigs, chickens and turkeys - 2023 data to be reported from 2024 onwards;
- within five years from 28 January 2022, data shall be collected for all food-producing animal species - 2026 data to be reported from 2027 onwards;
- within eight years from 28 January 2022, data shall be collected also for other animals which are bred or kept (dogs, cats and fur animals) - 2029 data to be reported from 2030 onwards.

4.3. Norway

4.3.1. Antimicrobial Use Data

Use data are collected covering all VMPs plus all human medicinal products used for food-producing animals, including farmed fish, and horses as well as for companion animals and non-food-producing species such as fur animals. For farmed fish, such data have been collected since 2011 and, for terrestrial animals, since 2012.

The data sources are veterinarians, pharmacies and feed mills for whom it is mandatory to deliver the data for food-producing animals, farmed fish and horses. All representatives for these three data sources are enrolled into the reporting system, i.e., Norwegian Veterinary Prescription Register (NVPR). For companion animals and other non-food-producing animals it is voluntary for the veterinarians to report data to NVPR, while for pharmacies it's mandatory to report such data. Due to the EU-regulation [11] it will be mandatory for Norway to deliver use data per species for food-producing animals, companion animals and fur animals to EMA as well as by animal category for cattle, pigs, chicken and turkey.

The numerator used includes amount of active ingredient (in mg) and, for farmed fish, number of prescriptions per production stage/type.

4.3.2. Animal Population Data

The PCU denominator (in kg) is used to report the data for farmed fish (see antimicrobial sales section).

4.3.3. Indicator(s)

For farmed fish: weight based; # prescriptions per production stages and mg/PCU.

For Atlantic salmon and rainbow trout: # prescriptions for on-growers/number of active locations.

For farmed fish: kg; # prescriptions per production stages/type.

4.3.4. Validation with Sales Data

In Norway, sales data are used to verify the use data, as such data have been collected for a long time and systematic cross-checking of the data across years indicates that all sales of antimicrobial VMPs are collected. Use data are shown to be complete for farmed fish but not for other animal categories. Use data are used for stratification of the sales data (see Appendix 1, NORM-VET [33]) to obtain estimates of use aggregated for the major food-producing animals (cattle, pigs, sheep, goats and poultry).

4.4. United Kingdom

4.4.1. Antimicrobial Use Data

The data collected includes all antimicrobials used, including those that are imported under the Special Import Scheme or extemporaneous products under the prescribing cascade [35]. Unlike sales data, however, antiprotozoals (including coccidiostats) and antifungals are not collected.

Antimicrobial use data are provided by the relevant industry body, and the source of the data varies (as shown in Table 3).

Table 3: United Kingdom Industry Bodies Which Collect Antimicrobial Use Data

Species/sector	Industry body that collects the data	Data source
Pigs	Agriculture and Horticulture Development Board using software called "eMB Pigs" [53]	Medicine volume data uploaded by the farm business every three months, but source can either be farm medicine book use data or what has been dispensed/delivered on to the farm by the veterinarian and/or feed mill.
Meat Poultry (broilers, turkeys and ducks)	British Poultry Council	Medicine volume data provided by the farm business via a spreadsheet every three months. This data may be from farm medicine book use records but more commonly represents what has been dispensed on to the farm by the veterinarian.

Species/sector	Industry body that collects the data	Data source
Laying Hens	British Egg Industry Council	Farm medicine book use records, which includes medicine volume and days treated.
Gamebirds	Game Farmers Association and British Veterinary Poultry Association	Gamebird specific sales/delivery data provided by gamebird veterinarians and feed mills.
Salmon	Scottish Salmon Producers Association	Salmon specific sales/delivery data provided by salmon sector veterinarians.
Trout	British Trout Association	Trout specific sales/delivery data provided by trout sector veterinarians.
Cattle and Sheep	Agriculture and Horticulture Development Board via software called "Medicine Hub" [54]	Medicine volume data uploaded by the farm business annually, but source can either be farm medicine book use data or what has been delivered on to the farm from the veterinarian.

Use data coverage (based on the percentage of animals represented) varies by sector, as shown in Table 4.

Table 4: Industry Coverage for United Kingdom Antimicrobial Use Data

Species/sector	2021 coverage (%)
Pigs	>95%
Meat Poultry (broilers, turkeys and ducks)	90%
Laying Hens	90%
Gamebirds	91%
Salmon	100%
Trout	90%
Cattle and Sheep	No data reported yet

The numerator is volume based in all sectors, i.e., relates to the weight of antimicrobial active ingredient, although the laying hen sector also collects information on the number of bird days treated (i.e., days that birds have received an antimicrobial). This is calculated by adding up the total number of days that birds have received an antimicrobial, e.g., if 500 birds received 4 days of treatment this would be (500 * 4) = 2000 bird days treated.

Providing the data is a requirement under farm assurance schemes (e.g., Red Tractor and Quality Meat Scotland for pigs, the Lion Scheme for laying hens) and by industry bodies (e.g., British Poultry Council).

4.4.2. Animal Population Data

The animal population data are collected from the farms that supply antimicrobial use data, and the same categories and weights are used as for the sales data, with the addition of "ducks slaughtered"

(where each duck is assigned a weight of 1.75 kg). For laying hens, the denominator used is the "number of bird days at risk" which is calculated by adding up the total number of days that birds were on the farm, e.g., if 1000 birds were on the farm for the whole year this would be (1000*365) = 365000 bird days at risk. No denominator data are collected for gamebirds.

4.4.3. Indicator(s)

The following units of measurement are reported in the UK-VARSS report on a calendar year basis:

- Tonnes of active ingredient – all species
- mg/kg – pigs, turkeys, broilers, ducks, salmon and trout
- % bird days ((number of bird days treated/ number of bird days at risk) * 100) – laying hens

4.4.4. Validation with sales data

Antimicrobial sales data are compared with antimicrobial use data to check that they correlate. However, this is not possible for cattle and sheep (where use data are not currently available).

4.5. United States

Currently, there is no nationwide surveillance infrastructure in place within the United States to collect and track antimicrobial use data in food-producing or companion animals. However, U.S. Federal, State, and private partners are exploring methodologies through a variety of activities outlined below.

4.5.1. US Government Activities for Antimicrobial Use Data Collection

The USDA Animal and Plant Health Inspection Service (APHIS) National Animal Health Monitoring System (NAHMS) [47] conducts national-level periodic studies on the health and health management of U.S. domestic livestock and poultry populations; numerous NAHMS studies have also included antimicrobial use data. The most recent reports have been on commercial swine and feedlot cattle operations, with surveys conducted at one point in time in 2017 and again in 2021/2022. However, over the decades NAHMS has collected antimicrobial use data in beef and dairy cattle, small ruminants, swine, poultry, and horses. NAHMS antimicrobial use reports largely focus on general metrics such as the percent of operations that use an antimicrobial for a specific indication, purpose or disease, or the percent of animals that received an antimicrobial, or a specific antimicrobial, for a specific disease while not quantifying the actual amount (mg) used. One exception to this was a study estimating in-feed antimicrobials in swine based on data collected by NAHMS as part of their 2012 national swine study [55]. Additionally, USDA APHIS has recently begun a new collaborative effort, partnering with several animal health and industry organizations, to study antimicrobial use and resistance on commercial swine farms in the Midwestern U.S. as well as a similar project studying antimicrobial use and resistance on broiler operations.

To get a better picture of how antimicrobial drugs are used in livestock production, FDA funded two cooperative agreements to support collection of data on antimicrobial use surveillance methodologies in food-producing animals. One of the food-producing animal projects piloted antimicrobial use data collection methodologies for feedlot and dairy cattle; the other project piloted methodologies for swine, chickens, and turkeys. These groups published an initial series of papers in 2020 describing the first few years of data collection (in one issue of the journal, Zoonoses and Public Health [56]), and the remainder of the projects are anticipated to be completed in 2023 [57].

FDA also funded two ongoing cooperative agreements that are piloting antimicrobial use data collection methodologies for companion animal veterinary practices, with anticipated date of completion in 2025.

FDA Center for Veterinary Medicine (CVM) also asked the Reagan Udall Foundation for the FDA (the Foundation) to seek input from a variety of affected stakeholders about strategies for collecting data about antimicrobial use in food-producing animals. The Foundation is conducting this outreach under a cooperative agreement with FDA CVM. The initial findings of the project were summarized in a report which was presented in a public forum in June 2022 [58]. The possible framework for collecting and analyzing data on antimicrobial use in food-producing animals, was published in August 2023 [59].

In the US, some states conduct AMU data collection activities specific to that state. For the purposes of this paper, only Federal activities are described.

4.5.2. Indicators

The following units of measurement have been reported in above mentioned activities and reports:

- Percent of operations using a specific antimicrobial (USDA NAHMS, multiple studies)
- Percent of animals that received an antimicrobial, or a specific antimicrobial, for a specific indication, disease, or purpose (USDA NAHMS data, multiple studies)
- Estimated use of antimicrobials in U.S. swine operations, by animal age and application, kg (USDA NAHMS)
- Relative use by drug class (percent of total weight); mg active ingredient per kg liveweight marketed (FDA cooperative agreement, swine)
- Treatment Regimens (regimens per cow year; note: a regimen was defined as the administration of an antimicrobial product for therapeutic purposes targeting a single disease event in an individual animal); grams active ingredient per cow year (FDA cooperative agreement, dairy cattle)
- Treatment Regimens (regimens per animal year); mg per kg liveweight sold (FDA cooperative agreement, feedlot cattle)
- Grams of active ingredient per 100,000 birds placed (FDA cooperative agreement, broiler and turkey hatcheries)
- Mg active ingredient per kg liveweight slaughtered (FDA cooperative agreement, broilers and turkeys)

5. Summary tables

Table 4: Summary of antimicrobial sales data collection by TATFAR member countries

TATFAR Member	Antimicrobial Sales Data	Animal Population Data	Indicator(s)
Canada	**Scope:** all medically important antimicrobials (using Canadian listing [18]). Information on non-medically important antimicrobials is voluntarily provided. **Source:** pharmaceutical manufacturers, importers, compounders. **Numerator:** mg active ingredient sold. **Stratification:** provided by pharmaceutical manufacturers, importers, and compounders for aquaculture, cattle (beef), cattle (dairy), cattle (veal), chickens, cats and dogs, horses, pigs, small ruminants, turkeys, and 'other'.	**Scope:** ESVAC categories plus live beef cows, egg layers, broiler hatching egg producers and broilers on small lots, as well as dogs and cats (depending on the indicator). **Source:** national statistics and national industry associations. **Denominator:** kg of animals at risk for food-producing animals: - PCU_{EU} - EU PCU categories and average weights at time of treatment plus living beef cows - PCU_{CA} - additional poultry categories and Canadian average weights at treatment - *kg* $biomass_{sl}$ - same categories as PCU_{CA} but weights based on liveweight at slaughter	**Food-producing animals:** - mg/PCU_{EU} - mg/PCU_{CA} - mg/kg $biomass_{sl}$ **Companion animals:** mg/PCU_{CA}
European Union	**Scope:** (for ESVAC up to 2022) [26] – antimicrobial substances for systemic, intestinal, intrauterine and intramammary use. **Source:** Varies by country but includes sales from MAH and/or wholesalers to wholesalers, pharmacies, veterinarians, feed mills farmers and retailers.	**Scope:** food-producing animals, which includes the number of livestock animals (dairy cows, sheep, sows and horses), slaughtered animals (cattle, pigs, goats, sheep, chickens, rabbits and turkeys) and biomass of farmed fish plus the final biomass takes into account the biomass of the animals moved across borders within the single market for fattening or slaughter. **Source:** official European statistics (Eurostat), national statistics, and certificates data (TRACES).	**All animals:** Tonnes of antimicrobial active substance **Food-producing animals:** mg/PCU

TATFAR Member	Antimicrobial Sales Data	Animal Population Data	Indicator(s)
	Numerator: tonnes of antimicrobial active substance. For food-producing animals, mg of active substance (excluding tablet sales).	**Denominator:** population correction unit (PCU), represents the kg of animal at risk of being treated for food-producing animals. The PCU is calculated by multiplying animals' theoretical weight at the likely time of treatment, corrected by the biomass of animals moved across borders within the single market for FT or SL. For farmed fish, the live-weight slaughtered biomass is used directly.	
Norway	**Scope:** identical to ESVAC and also cover unlicensed VMPs as well as coccidiostats (but these are reported separately). **Source:** wholesalers and feed mills. **Numerator:** - kg of active ingredient - for terrestrial food-producing animals, farmed fish and companion animals. - mg of active ingredient – for food-producing animals (excluding tablets) **Stratification:** Historical sales – split by companion animal and food-producing animals. Targets from 2013 – split by cattle, pigs, sheep goat and poultry.	**Scope:** identical to ESVAC. **Source:** national statistics. **Denominator:** kg of animal at risk for food-producing animals (PCU), which is identical to ESVAC.	**Terrestrial food-producing animals, farmed fish and companion animals:** kg active ingredient **Food-producing animals:** mg/PCU
United Kingdom	**Scope:** all antibiotics, antiprotozoals (including coccidiostats) and antifungals. **Source:** marketing authorisation holders.	**Scope:** for food-producing animals, the same categories of living and slaughter animals are used as ESVAC plus the number of dogs and cats.	**All animal:** tonnes of active ingredient **Food-producing animals:**

TATFAR Member	Antimicrobial Sales Data	Animal Population Data	Indicator(s)
	Numerator: - Tonnes of antimicrobial active ingredient (excluding topical products) - all animals. - mg of antimicrobial active ingredient (excluding topicals) – food-producing animals (by removing tablets) and products licensed exclusively for dogs and/or cats.	**Source:** national statistics as well as the British Equestrian Trade Association (for horse numbers) and the PDSA PAW Report (for dogs and cats). **Denominator:** - kg of animal at risk for food-producing animals (PCU), which is identical to ESVAC. - kg of dog and cat at risk (based on average weights provided by SAVSNET).	mg/PCU **Dogs and cats:** mg/kg
United States	**Scope:** all medically and non-medically important antimicrobials sold/ distributed and exported for food-producing species. **Source:** pharmaceutical manufacturers. **Numerator:** kg and mg of active ingredient. **Stratification of sales:** estimates provided by drug manufacturer for cattle, swine, chicken, turkey and 'other'.	**Scope:** slaughtered cattle and calves, livestock beef cows, livestock dairy cows, slaughtered hogs and pigs, hogs and pigs kept for breeding (mainly sows), slaughtered chickens (young, mature), slaughtered turkeys. **Source:** USDA NASS annual livestock and poultry slaughter summary reports as well as sector specific reports and international trade reports (for imports/exports). **Denominator:** kg of animal at risk for food-producing animals, based on annual average weight at slaughter and livestock animal weights (called 'target animal biomass' (TAB)).	**All food-producing species and separated using stratification for cattle, swine, chicken, turkey and other:** kg of active ingredient **Cattle, swine, chicken and turkey:** mg/TAB – calculated at antimicrobial drug class level

Table 6: Summary of antimicrobial use data collection by TATFAR member countries

TATFAR Member	Antimicrobial Use Data	Animal Population Data	Indicator(s)
Canada	**Scope:** medically and non-medically important antimicrobials (including ionophores and coccidiostats) from the major food animal species, including aquaculture, broiler chickens, grower-finisher pigs, feedlot beef cattle and turkeys, with pilot projects in dairy cattle and layer hens. **Source:** CIPARS using species-specific questionnaires and census prescription data from Fisheries and Oceans Canada. **Numerator:** mg of kg active ingredients (all), number of Canadian Defined Daily Doses for Animals (nDDDvetCA) and number of farms reporting use of an antimicrobial) (terrestrial animals only).	**Scope:** For terrestrial animals, the final flock or herd population (minus half of the recorded mortality) for each of the major food animal species and the number of animals/ days each animal is present on the farm during the reporting period (one production cycle). **Source:** Farm production or food safety records. **Denominator:** Overall weight of animal at risk in kg, based on EU standard weights at treatment ($PCU_{EU,}$ with the exception of weights for beef cattle – Canadian-derived weight), or actual average weights at treatment, and kg $biomass_{SL}$ (using actual pre-slaughter live-weights), number of farms where data are collected and number of 'animal days' (calculated by adding up the number of days each animal was present during the reporting period).	**Broiler chickens, grower-finisher pigs, feedlot beef cattle, turkeys:** - mg/PCU_{EU} (with the exception of weights for beef cattle – Canadian derived) - mg/kg $biomass_{SL}$ - nDDDvetCA /1,000 animal-days at risk **Aquaculture (only a numerator, not an indicator):** mg or kg active ingredient **Sales data validation:** CIPARS compares sales and use data by looking at kg and/or mg/PCU and comparing the top antimicrobial classes
Norway	**Scope:** all veterinary medicinal products (as used for ESVAC sales data) as well as human medicinal products used for food-producing animals, including farmed fish, and horses.	**Scope:** identical to ESVAC. **Source:** national statistics. **Denominator:** kg of animal at risk for aquaculture (PCU).	**Farmed fish:** # prescriptions per production stages and mg/PCU

TATFAR Member	Antimicrobial Use Data	Animal Population Data	Indicator(s)
	Some data also collected from non-food-producing animals. **Source:** all veterinarians (compulsory for food-producing animals and voluntary for non-food-producing animals), pharmacies and feed mills via NVPR. **Numerator:** Amount of active ingredient (in mg) and, for aquaculture, number of prescriptions per production stage.		**Atlantic salmon and rainbow trout:** # prescriptions for on-growers/number of active locations **For farmed fish:** kg; # prescriptions per production stages **Sales data validation:** Sales data are used to verify the use data and use data also used to obtain estimates for stratification of sales (for cattle, pigs, sheep, goats and poultry).
United Kingdom	**Scope:** all antibiotics, currently covering pigs, meat poultry, laying hens, gamebirds, salmon and trout with over 90% coverage for each. There is also a system in development for cattle and sheep. **Source:** supplied on a voluntary basis by industry bodies and source includes veterinary prescription data, feed mill delivery data and farm medicine book data. **Numerator:** weight of antibiotic active ingredient (mg) and, for laying hens, the	**Scope:** the same animal categories that are collected for sales data (with the addition of "ducks slaughtered". For laying hens, the "number of bird days" at risk is also collected (which represents the total number of days that birds were on the farm). **Source:** the data are collected from the farms that are supplying the antimicrobial use data. **Denominator:** for pigs, turkeys, broilers, ducks, salmon and trout, this is based on kg of animals at risk, using the same weights as used for sales data (with the addition of 1.75 kg per duck slaughtered); for laying hens the number of bird days at risk is also collected	**All species:** Tonnes of active ingredient **Pigs, turkeys, broilers, ducks, salmon and trout:** mg/kg **Laying hens:** % bird days ((number of bird days treated/ number of bird days at risk) * 100)

TATFAR Member	Antimicrobial Use Data	Animal Population Data	Indicator(s)
	number of bird days treated (i.e., days that birds have received an antibiotic).	(calculated by adding up the total number of days that birds were on the farm).	
United States	**Scope:** medically and non-medically important antimicrobials; currently collected by various periodic national surveys by production sector, and cooperative agreements for major food-producing species completed in 2023 (cattle, swine, chickens and turkeys). Methods for ongoing nationwide AMU data collection and reporting are being explored. **Source:** supplied on voluntary basis by farms/companies that agree to participate in USDA NAHMS surveys and FDA cooperative agreements. Data may be obtained from USDA NAHMS national survey results, and farm or company records. **Numerator:** varies by type of data collection (e.g., survey vs farm records).	**Scope:** the animal population varies with the type of data collection. Periodic USDA NAHMS surveys focus on specific sectors (e.g., dairy cattle, feedlot cattle, growing and finishing swine, broilers, small ruminants, etc.) and depend on voluntary participation of producers. Researchers which collected data for FDA cooperative agreements recruited voluntary participants from dairy and feedlot cattle sectors, as well as swine and poultry sectors (broilers and turkeys). Methods for nationwide AMU data collection and reporting are being explored. **Source:** the data were collected from farms/companies participating in surveys and cooperative agreement projects. **Denominator:** varies by type of study: for national periodic surveys, may include number of operations, number of animals; for FDA cooperative agreement projects, may include kg liveweight, animal year. Methods for nationwide AMU data collection and reporting are being explored; denominator would be determined based on type of data collected, etc.	Examples of indicators used in existing USDA NAHMS surveys and FDA cooperative agreements include: **Cattle and swine (USDA NAHMS):** - % operations using a specific antimicrobial - % of animals that received a specific antimicrobial for specific disease **(FDA cooperative agreements):** - Relative use by drug class (swine) - mg active ingredient per kg liveweight sold (swine; feedlot cattle) - grams active ingredient per cow year (dairy cattle) - Regimens per animal year (dairy and feedlot cattle)

TATFAR Member	Antimicrobial Use Data	Animal Population Data	Indicator(s)
			Chickens (broilers) and turkeys (FDA cooperative agreements): - grams active ingredient per 100,000 birds placed (broiler and turkey hatcheries) - mg active ingredient per kg liveweight slaughtered (broilers and turkeys) - Methods for nationwide AMU data collection and reporting are being explored; indicators would be determined based on type of data collected, etc.

6. Conclusions

AMR is a global public and animal health concern that is influenced by use of antimicrobial substances in humans and animals. In 2019, AMR caused 1.27 million deaths worldwide and was associated with nearly 5 million deaths [60]. TATFAR was created in 2009 to address the urgent threat of AMR. Technical experts from Canada, the EU, Norway, United Kingdom, and the United States collaborate and share best practices to strengthen domestic and global efforts. One of the key areas of focus for TATFAR, aiming to reduce the threat of AMR, is to encourage appropriate AMU in human and veterinary medicine [61]. As part of that effort, TATFAR members have collaborated through regular exchanges of information on actions and approaches related to monitoring AMU in veterinary medicine.

Systems for collection of data on sales and use of antimicrobials in animals have been developed and continue to evolve. These data can be used to monitor trends in antimicrobial sales and AMU patterns, and when correlated with relevant AMR data, can be helpful in the integrated analyses of AMU and AMR in bacteria isolated from humans, animals, and the environment. A better understanding of AMU patterns is also needed to support ongoing national and regional efforts to encourage the judicious use of antimicrobials in animals and to help ensure the continued availability of safe and effective antimicrobials for animals and humans. In addition, AMU data can help measure the effectiveness of antimicrobial stewardship programs and adherence to country policies and regulations.

This paper summarizes the current approaches taken by TATFAR member regions to collect and report (e.g., metrics and indicators) antimicrobial sales and AMU data. This paper highlights the detailed considerations that have taken place in each country/ region when determining numerators, animal numbers, and weights of animals essential to appropriately report antimicrobial sales or use data. Similarities and differences between countries/regions, including surveillance systems, data availability, providers and sources, as well as approaches to data collection and reporting methodologies, were described. This will help readers to better understand the surveillance data presented by the different countries/regions and provide different options/ideas to any other countries/regions wanting to collect and present antimicrobial sales and use data. While each TATFAR country/ region has their own legal and regulatory framework related to collection, reporting, and use of these data, an overarching commonality is the continued clear commitment to advancing and promoting the prudent and responsible use of antimicrobials in animals.

Annex

Annex 1. Responsible institutions and contacts

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