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SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

## Antimicrobial use data reporting per animal categories (numerator)

### Manual for reporting the data to the Agency

As outlined in Article 57 of the Regulation (EU) 2019/6, mandatory reporting of the volume of sales of veterinary antimicrobial products and on the use of antimicrobial medicinal products used in animals is required to enable the direct or indirect evaluation of the use of such products in food-producing animals at farm level.

From 2024, reporting of antimicrobial use in animals should comply with the requirements of the Commission Delegated Regulation (EU) 2021/578. As per its Article 15(1), Member States shall collect data on the use of antimicrobials for cattle, pigs, chickens and turkeys, including all categories and stages, and report these data yearly to the Agency starting from 30 September 2024 (the first year for data collection will be 2023). Additionally, as per Article 15(2), Member States shall collect data on the use of antimicrobials for other food-producing species and report these data yearly to the Agency starting from 30 June 2027 (the first year for data collection will be 2026). Finally, data on the use of antimicrobials for non-food-producing species, namely dogs, cats and fur animals, shall be collected and reported yearly to the Agency starting from 30 June 2030 (first year for data collection will be 2029).

Member States shall ensure that the data covers all uses of the relevant antimicrobial medicinal products during the preceding calendar year within their respective territories, as per Article 13(2) of the Commission Delegated Regulation (EU) 2021/578.

As per Article 7(2), point c), the national contact point and data managers shall consider the relevant guidance documents produced by the Agency, such as manuals or guidelines, to allow for the collection and reporting of standardised and harmonised data to the Agency. A manual on the reporting of antimicrobial use data to the Agency was developed by the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) *ad hoc* expert group on revision of indicators and denominators (ESVAC *ad hoc* group), in collaboration with the ESVAC secretariat and experts from EUROSTAT and European Food Safety Authority (EFSA). Representatives from the European Commission were also invited to the discussions as observers.

When developing the instructions for reporting the antimicrobial use per animal categories according to Regulation (EU) 2021/578, the ESVAC *Ad hoc* expert group considered options with different levels of granularity. The regulation only demands distinguishing the antimicrobial use for few animal species

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into what are hereafter called 'animal categories'. The final choice of instructions for each category sticks closely to the regulation. It was acknowledged that at national level it may be advantageous to increase the granularity of reporting antimicrobial use per animal species with regards to what is to be reported to EMA as per the legislative requirement. Thus, in addition to the established instructions below, further animal categories for reporting antimicrobial use at national level can be considered by each Member State. It should be highlighted that an increase in granularity must be compatible with aggregation and reporting of antimicrobial use data to the Agency, according to the instructions presented below (Tables 1-6).

Regarding the two later stages of reporting (other food-producing animals and non-food-producing animals), the CVMP's 'Advice on implementing measures under Article 57(3) of Regulation (EU) 2019/6 on veterinary medicinal products - Report on specific requirements for the collection of data on antimicrobial medicinal products used in animals' ([EMA/CVMP/131097/2019](https://www.ema.europa.eu/en/press/news/2019/07/19_07_19_cvmp_advice_on_implementing_measures_under_article_573_of_regulation_eu_20196_on_veterinary_medicinal_products_report_on_specific_requirements_for_the_collection_of_data_on_antimicrobial_medicinal_products_used_in_animals)) recommends a review of the list of animal species and categories (i.e., before 2027 and 2030), to allow, where necessary, the inclusion of additional animal species or categories for which antimicrobial data are to be collected. Member States adjusting or setting up systems for data collection should be aware that such a review may lead to additional requirements for reporting. It is therefore recommended that Member States consider collecting data also for other animal species or other relevant categories when establishing their data collection systems.

Should the legislative acts be updated in the future, these instructions would be updated accordingly.

The present Manual was thoroughly discussed with Member States within the ESVAC Change Liaison Network for ASU and was discussed and adopted during the CVMP May 2022 meeting.

## 1. Cattle

As per Article 15(1)(a) of Commission Delegated Regulation (EU) 2021/578, Member States shall collect data on antimicrobial use for **cattle**, while distinguishing **beef cattle** from **dairy cattle** and specifying use in **bovines under one year of age** separately when the production of meat from slaughtered bovines under one year of age exceeds 10,000 tonnes per year. The data shall be reported yearly to the Agency starting from 30 September 2024 (first year of data collection 2023).

Further explanation of the above requirement for reporting antimicrobial use in cattle is detailed in the table below.

*Table 1 - Instructions for reporting data on antimicrobial use for cattle*

Animal species category for which antimicrobial use should be reported	Instructions for reporting the data
<i>Beef cattle</i>	<p>Animals of the species <i>Bos taurus</i> which are raised for <b>meat production</b> and are intended to be slaughtered.</p> <p>Notes:</p> <ul style="list-style-type: none"> <li>- Including antimicrobial use in all other cattle at beef cattle farms, e.g., cows kept for production of calves, calves, heifers and bulls for breeding.</li> <li>- Including antimicrobial use in mixed farms, where the main production is meat production.</li> </ul> <p><i>Beef cattle for slaughter under one year of age</i></p>

Animal species category for which antimicrobial use should be reported	Instructions for reporting the data
	For countries where the meat production of beef cattle intended to be slaughtered under one year of age (male and female calves and young cattle) <b>exceeds 10,000 tonnes per year</b> , the antimicrobial use shall be reported as a separate subset. Other countries can opt to also report these data as a separate subset on a voluntary basis, if available.
<i>Dairy cattle</i>	Animals of the species <i>Bos taurus</i> , which are kept exclusively or principally to <b>produce milk for human consumption</b> including for processing into dairy products.  Notes: - Including antimicrobial use in all other cattle at dairy farms, e.g., calves, heifers, bulls of dairy breed and cull cows. - Including antimicrobial use in mixed farms, where the main production is milk.
Other cattle	All cattle that do not match the description of beef cattle or dairy cattle.  Note: Member States should ensure that the best effort is made to identify and report to EMA the antimicrobial use in cattle in the relevant category. Reporting the use in "other cattle" should be avoided if a more suitable category is available.

It is acknowledged that at national level, it may be advantageous to further increase the granularity of the collected data on the antimicrobial use in cattle, e.g., dairy cows, specialised beef cattle production (veal calves). It should be highlighted that an increase in granularity must be compatible with aggregation and reporting of antimicrobial use data to the Agency, according to the instructions presented above.

## 2. Pigs

As per Article 15(1)(b) of Commission Delegated Regulation (EU) 2021/578, Member States shall collect data on antimicrobial use for **pigs**, while specifying use in **fattening pigs**, and report the data yearly to the Agency starting from 30 September 2024 (first year of data collection 2023).

Further explanation of the above requirement for reporting antimicrobial use in pigs is detailed in the table below.

Table 2 - Instructions for reporting data on antimicrobial use for pigs

Animal species category for which antimicrobial use should be reported	Instructions for reporting the data
<i>Fattening pigs</i>	<p>Animals of the species <i>Sus scrofa domesticus</i> that are bred and raised <b>for meat production</b>.</p> <p>Note: Including antimicrobial use in all animals at farms producing pigs or piglets for meat production, e.g., sows, piglets, weaners, pre-finishers, finishers, gilts and boars.</p>
<i>Other pigs</i>	<p>Non-fattening pigs.</p> <p>Note: Including antimicrobial use in pigs that do not match the description of fattening pigs, e.g., sows that are producing animals for breeding, gilts for breeding and breeding boars in multiplying herds, nucleus and artificial insemination centres.</p>

It is acknowledged that at national level, it may be advantageous to further increase the granularity of the collected data on the antimicrobial use in pigs, e.g., sows, suckling pigs, weaners and fatteners (pre-finishers and finishers). It should be highlighted that an increase in granularity must be compatible with aggregation and reporting of antimicrobial use data to the Agency, according to the instructions presented above.

### 3. Chickens (*Gallus gallus domesticus*)

As per Article 15(1)(c) of Commission Delegated Regulation (EU) 2021/578, Member States shall collect data on antimicrobial use for **chickens**, while specifying use in **broilers** and in **laying hens**, and report the data yearly to the Agency starting from 30 September 2024 (first year of data collection 2023).

Further explanation of the above requirement for reporting antimicrobial use in chickens is detailed in the table below.

Table 3 - Instructions for reporting data on antimicrobial use for chickens

Animal species category for which antimicrobial use should be reported	Instructions for reporting the data
<i>Broilers</i>	<p>All chickens (<i>Gallus gallus domesticus</i>) bred and raised <b>for meat production</b>.</p> <p>Notes:</p> <ul style="list-style-type: none"> <li>- Including antimicrobial use in cockerels and in hatcheries for meat production.</li> <li>- Including antimicrobial use in back-yard chickens for commercial meat production.</li> </ul>

Animal species category for which antimicrobial use should be reported	Instructions for reporting the data
<i>Laying hens</i>	<p>All female chickens (<i>Gallus gallus domesticus</i>) primarily kept <b>for production of eggs for consumption</b>.</p> <p>Notes:</p> <ul style="list-style-type: none"> <li>- Including antimicrobial use in pullets and in hatcheries for egg production.</li> <li>- Including antimicrobial use in back-yard chickens for commercial egg production.</li> </ul>
<i>Other chickens</i>	<p>Any chickens (<i>Gallus gallus domesticus</i>) that do not match the description of broilers or laying hens, e.g., chickens for breeding (parents, grandparents, great grandparents).</p> <p>Note: Reporting the use in “other chickens” should be avoided if a more suitable category is available.</p>

It is acknowledged that at national level, it may be advantageous to further increase the granularity of the collected data on the antimicrobial use in chickens, e.g., parents, grandparents and great grandparents. It should be highlighted that an increase in granularity must be compatible with aggregation and reporting of antimicrobial use data to the Agency, according to the instructions presented above.

## 4. Turkeys

As per Article 15(1)(d) of Commission Delegated Regulation (EU) 2021/578, Member States shall collect data on antimicrobial use for **turkeys**, while specifying use in **fattening turkeys**, and report the data yearly to the Agency starting from 30 September 2024 (first year of data collection 2023).

Further explanation of the above requirement for reporting antimicrobial use in turkeys is detailed in the table below.

Table 4 - Instructions for reporting data on antimicrobial use for turkeys

Animal species category for which antimicrobial use should be reported	Instructions for reporting the data
<i>Fattening turkeys</i>	<p>Turkeys (<i>Meleagris gallopavo domesticus</i>) bred and raised <b>for meat production</b>.</p> <p>Notes:</p> <ul style="list-style-type: none"> <li>- Including antimicrobial use in hatcheries for meat production.</li> <li>- Including antimicrobial use in back-yard turkeys for commercial meat production.</li> </ul>

Animal species category for which antimicrobial use should be reported	Instructions for reporting the data
<i>Other turkeys</i>	Any turkeys ( <i>Meleagris gallopavo domesticus</i> ) that do not match the description of fattening turkeys, e.g., breeding turkeys (parents, grandparents, great grandparents) and turkeys kept for egg hatching.

It is acknowledged that at national level, it may be advantageous to further increase the granularity of the collected data on the antimicrobial use in turkeys, e.g., parents, grandparents and great grandparents. It should be highlighted that an increase in granularity must be compatible with aggregation and reporting of antimicrobial use data to the Agency, according to the instructions presented above.

## 5. Other animal food-producing species:

As per Article 15(2) of Commission Delegated Regulation (EU) 2021/578, Member States shall collect data on antimicrobial use for other food-producing animal species, including all categories and stages, and report the data yearly to the Agency starting from 30 June 2027 (first year of data collection 2026). Food-producing animals are animals bred, raised, kept, slaughtered or harvested for the purposes of producing food, as defined in point (b) of Article 2 of Regulation (EC) No 470/2009.

The antimicrobial use shall be reported when the food production is intended for commercial purposes. Further explanation of the above requirement for reporting antimicrobial use in other animals kept for food production is detailed in the table below.

Table 5 - Instructions for reporting data on antimicrobial use for other food-producing animals

Animal species for which antimicrobial use should be reported	Instructions for reporting the data
<i>Other poultry</i>	<p><u>Ducks</u>: domestic birds of the species <i>Anas</i> spp. and <i>Cairina moschata</i>.</p> <p><u>Geese</u>: domestic birds of the species <i>Anser anser domesticus</i>.</p> <p>Notes:</p> <ul style="list-style-type: none"> <li>- The use of antimicrobials in ducks and geese shall be reported as separate subsets.</li> <li>- The antimicrobial use in other domestic birds (e.g., quails, pheasants, guinea fowls, pigeons, ostriches, etc) shall be reported in 'other food-producing animals', if relevant.</li> </ul>
<i>Sheep</i>	Domestic animals of the species <i>Ovis aries</i> .
<i>Goats</i>	Domestic animals of the subspecies <i>Capra aegagrus hircus</i> .
<i>Finfish</i>	<p><u>Atlantic salmon</u>: farmed finfish of the species <i>Salmo salar</i>.</p> <p><u>Rainbow trout</u>: farmed finfish of the species <i>Oncorhynchus mykiss</i>.</p>

Animal species for which antimicrobial use should be reported	Instructions for reporting the data
	<p><u>Gilthead seabream</u>: farmed finfish of the species <i>Sparus aurata</i>.</p> <p><u>European seabass</u>: farmed finfish of the species <i>Dicentrarchus labrax</i>.</p> <p><u>Common carp</u>: farmed finfish of the species <i>Cyprinus carpio</i>.</p> <p>Notes:</p> <ul style="list-style-type: none"> <li>- The use of antimicrobials in Atlantic salmon, rainbow trout, gilthead seabream, European seabass and common carp shall be reported as separate subsets.</li> <li>- The antimicrobial use in other farmed finfish shall be reported in 'other food-producing animals', if relevant.</li> </ul>
<i>Horses</i>	<p>Domestic animals of the species <i>Equus ferus caballus</i> (including ones declared as not being intended for slaughter for human consumption in the single lifetime identification document referred to in Article 114(1)(c) of Regulation (EU) 2016/429 of the European Parliament and of the Council(7)).</p>
<i>Rabbits</i>	<p>Domestic animals of the species <i>Oryctolagus cuniculus</i> kept for producing food.</p>
<i>Other food-producing animals</i>	<p>Any other domestic animals bred, raised, kept, slaughtered or harvested for producing food, within a specific country.</p> <p>Notes:</p> <ul style="list-style-type: none"> <li>- The use of antimicrobials in other food-producing animals shall only be reported for those production systems that are nationally relevant or where the use is of relevance.</li> <li>- Member States shall use this reporting category in a responsible manner, only reporting meaningful productions and indicating which animal species the productions refer to.</li> </ul>

It is acknowledged that at national level, it may be advantageous to further increase the granularity of the collected data on the antimicrobial use in other food-producing animals, e.g., sheep for milk production, lambs for meat production, goats for milk production or other relevant national production types. It should be highlighted that an increase in granularity must be compatible with aggregation and reporting of antimicrobial use data to the Agency, according to the instructions presented above.

## 6. Non-food-producing animal species

As per Article 15(3) of Commission Delegated Regulation (EU) 2021/578, Member States shall collect data on antimicrobial use for few non-food-producing animal species, namely dogs, cats and fur animals (minks and foxes), and report the data yearly to the Agency starting from 30 June 2030 (first year of data collection 2029).

Further explanation of the above requirement for reporting antimicrobial use in non-food-producing animals is detailed in the table below.

Table 6 - Instructions for reporting data on antimicrobial use for non-food-producing animals

Animal species for which antimicrobial use should be reported	Instructions for reporting
<i>Dogs</i>	Domestic animals of the subspecies <i>Canis lupus familiaris</i> .
<i>Cats</i>	Domestic animals of the species <i>Felis catus</i> .
<i>Fur animals</i>	<p><u>Minks</u>: domestic animals of the species <i>Neovison vison</i>.  <u>Foxes</u>: domestic animals of the species <i>Vulpes vulpes</i> and <i>Vulpes lagopus</i>.</p> <p>Note: The use of antimicrobials in minks and foxes shall be reported as separate subsets.</p>

It is acknowledged that at national level, it may be advantageous to collect further data on the antimicrobial use in other non-food-producing animals, e.g., other pets and zoo animals.