U.S. FOOD & DRUG ADMINISTRATION

Center for Veterinary Medicine

Addendum: Revised Method for Calculating Cattle Biomass Denominator to Adjust Antimicrobial Sales Data for Food-Producing Animals

1. Executive Summary

Beginning in 2025, FDA will implement revised cattle biomass calculations that more comprehensively capture the U.S. cattle population potentially treated with antimicrobials. The modifications address limitations in the original methodology by incorporating previously uncounted cattle subpopulations, including breeding stock, replacement animals, and youngstock maintained longer than one calendar year. These changes, developed in consultation with USDA's National Agricultural Statistics Service (NASS) and Animal and Plant Health Inspection Service (APHIS), result in an average 18.3% increase in calculated cattle biomass compared to the previous methodology.

The revised approach will be applied to antimicrobial sales and distribution data beginning with 2025 reporting (for 2024 sales data) and implemented retrospectively to 2016. Additionally, changes in antimicrobial reporting requirements necessitated development of a new exclusion category for amphenicols, ensuring the biomass denominator accurately reflects only those cattle populations eligible for treatment with this drug class.

2. Background and Rationale

FDA published a concept paper for public comment in 2017 that proposed the use of a biomass denominator to adjust annual antimicrobial sales and distribution data for medically important antimicrobial drugs sold or distributed for use in food-producing animals (cattle, swine, chickens, and turkeys) in the United States. In 2022, FDA published a report and interactive summary to make this information available to the public, and the interactive summary is updated annually following publication of the annual FDA sales and distribution summary report (1, 2).

Unlike the other major food-producing species (swine, chickens, and turkeys) that have relatively short production cycles and are predominantly captured through slaughter data, cattle production involves complex, multi-year lifecycles with distinct subpopulations serving different production purposes. These factors precipitated FDA to revisit the cattle biomass calculations to ensure accurate representation of the total cattle population potentially treated with antimicrobials.

The original methodology calculated target animal biomass (TAB) for cattle primarily using USDA NASS slaughter data, livestock inventory data for adult beef cows, adult lactating dairy cows, and cattle import and export information. This captured most cattle in commercial production but had limitations in accounting for the complete production lifecycle of cattle, particularly those animals maintained longer than one calendar year, such as breeding stock and replacement animals (i.e., heifers, bulls) and youngstock (calves under 500 lbs. not intended for slaughter as veal).

The revised method improves cattle biomass estimates by incorporating the complete production lifecycle of animals maintained longer than one calendar year (breeding animals and youngstock). This comprehensive approach provides a more accurate representation of the cattle population potentially receiving antimicrobial treatments, thereby improving the precision of biomass-adjusted antimicrobial sales data. In addition, when the amphenicol drug class

became independently reportable in 2020, FDA needed to develop a new exclusion category that accounts for amphenicol label restrictions, ensuring the denominator accurately includes only those cattle populations eligible for amphenicol treatment.

3. Methodology Changes

3.1 Overview of Modifications

The modified cattle TAB calculations incorporate several cattle subpopulations that were not previously captured in the existing USDA slaughter count data. Live animal population counts and weights of beef heifers, dairy heifers, other heifers, calves under 500 pounds, and bulls 500 pounds and over were added to the cattle biomass denominator because these subpopulations represent living stock maintained longer than one calendar year for breeding and replacement purposes. Live animal counts for several cattle subpopulations available in USDA reports were excluded from the calculation to avoid double-counting. For example, the 'steers 500 lbs and over' category was not included as this group is already captured in the NASS slaughter data.

Table 1: Modified Cattle Biomass Calculation
The added cattle subpopulations to the modified cattle biomass calculations are shown in bolded font.

Production Class	Population	Reference	Weight	Reference
Cattle - commercial and farm slaughtered	P1	1	W1	1
Calves - commercial and farm slaughtered	P2	1	W2	1
Cattle imported for immediate slaughter	P3	2	W3	1
Cattle Imported < 90 kg	P4	2	W4	2
Cattle Imported 90 kg to 199 kg	P5	2	W5	2
Cattle Imported 200 kg to 319 kg	P6	2	W6	2
Cattle Imported > 320 kg	P7	2	W7	1
Exported cattle for slaughter	P8	2	W8	1
Livestock beef cows (Jan 1 following-year inventory for population)	P9	3	W9	4
Livestock dairy cows (milk cows, Jan 1 following-year inventory for population)	P10	3	W10	5
Livestock beef replacement heifers	**P11**	**3**	**W11**	**6**
Livestock dairy replacement heifers	**P12**	**3**	**W12**	**6**
Other heifers	**P13**	**3**	**W13**	**6**
Calves under 500 lbs.	**P14**	**3**	**W14**	**7, 8**
Bulls 500 lbs. and over	**P15**	**3**	**W15**	**4**

Formula Comparison:

Original Cattle TAB*:* This formula multiplies each population count by its corresponding weight, then adds slaughtered cattle and subtracts exported cattle to avoid double-counting.

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*Formula: Original Cattle TAB = (P1*W1) + (P2*W2) – (P3xW3) – (P4*W4) – (P5*W5) – (P6*W6) – (P7*W7) + (P8*W8) + (P9*W9) + (P10*W10)*

Modified Cattle TAB: This enhanced formula includes the same base calculations as the original method, plus five additional cattle subpopulations (P11 through P15) representing breeding stock and youngstock maintained longer than one year.

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*Formula: Modified Cattle TAB = (P1*W1) + (P2*W2) – (P3*W3) – (P4*W4) – (P5*W5) – (P6*W6) – (P7*W7) + (P8*W8) + (P9*W9) + (P10*W10) + (**P11*W11**) + (**P12*W12**) + (**P13*W13**) + (**P14*W14**) + (**P15*W15**)*

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a. Population and Weight Methodology

FDA utilizes domestic livestock population data from USDA database reports from the NASS and U.S. data from the Global Agricultural Trade System of the Foreign Agricultural Service to estimate annual livestock numbers for the biomass denominator (3, 4, 5). When referencing USDA's published reports, CVM uses the most recent data available in a publication. The modified cattle biomass calculations continue to rely primarily on USDA NASS livestock inventory data (3) and slaughter reports (4) for population and weight estimates, respectively. The newly incorporated cattle subpopulations (beef replacement heifers, dairy replacement heifers, other heifers, calves under 500 pounds, and bulls 500 pounds and over) are captured through NASS January 1st livestock inventory reports, which provide annual snapshots of cattle populations by category.

Reference weights for the newly added cattle subpopulations are based on established industry standards and USDA research on heifers and beef cow-calf management practices. Specifically, weight estimates are derived from the Bovine Alliance on Management and Nutrition 2007 report (6) and the USDA NAHMS Beef 2017 Part I report (7), ensuring consistency with recognized livestock production data.

The modified cattle TAB calculations include the "calves under 500 pounds" population, accounting for calves not slaughtered as veal. The average weight of calves was determined by calculating the midpoint between the average birth weight of beef and dairy calves and 500 pounds. This approach captures the average weight of calves throughout their growth period from birth to the 500-pound threshold, providing a representative weight for biomass calculations.

Table 2: Calf Weight Calculation Methodology

Parameter	Weight (lbs.)	Source/Calculation
Average birth weight – beef calves (Angus and Hereford breeds)	89	Published references (9)
Average birth weight – dairy calves (Jersey and Holstein breeds)	93.5	Published References (8)
Average calf birth weight	**91.3**	**Average of beef and dairy weights**
Upper threshold	500	Category definition
Final average weight for calves under 500 lbs.	296	Midpoint calculation

Consistent with the original methodology, the modified approach maintains adjustments for imported and exported cattle to ensure the biomass denominator reflects only those animals potentially treated with antimicrobials sold in the U.S. domestic market (5).

b. Development of Cattle Amphenicol Exclusion Category

The original FDA biomass technical concept paper specified that if additional levels of detail in species-specific estimated sales of certain drug classes become available in the future, FDA would consider what animal categories are appropriate for each TAB calculation based on the approved indications for antimicrobial products included in the numerator.

Where TAB is used to adjust species-specific estimated antimicrobial sales data, only the animal categories applicable to the approved indications on marketed antimicrobial products are included in the denominator (except for drug classes included within the "NIR" category that cannot be reported independently, so no specific exclusions are made for the denominator for these). The level of detail to which CVM can independently report species-specific estimated sales data create limited instances where TAB includes less than all the animal categories for a species – referred to as a TAB Exclusion Category.

Historically, the Lincosamide drug class in chickens represented the only example in the biomass calculations where an exclusion category applied. This is because Lincosamides for chickens are 1) approved for broilers and replacements, not for use in layers or breeders or 2) approved for "chickens up to 7 days old." Given that biomass of layers and breeders under 7-days old would be minimal, only young chickens are included in Chicken TAB for Lincosamides (i.e., Young Chicken TAB).

In addition to the general biomass improvements described above, changes in antimicrobial reporting requirements necessitated development of a new exclusion category specific to the amphenicol drug class in cattle. CVM identified the need to calculate a new Exclusion Category for "Beef and Nonlactating Dairy Cattle" to use in the cattle TAB calculations specific for amphenicols when this drug class became independently reported beginning in 2020.

Amphenicols are approved for use in beef cattle and non-lactating dairy cattle but are not approved for veal calves or dairy cattle 20 months of age and older. Consequently, the amphenicol TAB exclusion category includes the biomass of only beef cattle, replacement heifers, and calves not intended for veal slaughter. The amphenicol exclusion category denominator is calculated by subtracting the biomass for livestock dairy cows (milk cows) and biomass for calves at slaughter from the modified total cattle biomass. This approach

ensures that only cattle populations eligible for amphenicol treatment are included in the denominator when calculating mg/TAB values for this drug class.

Amphenicol Exclusion Category Formula: This formula calculates biomass for cattle eligible for amphenicol treatment by subtracting the biomass of dairy cows (P10*W10) and the biomass of slaughtered calves (P2*W2) from the total modified cattle biomass, since amphenicols are not approved for lactating dairy cattle or veal calves.

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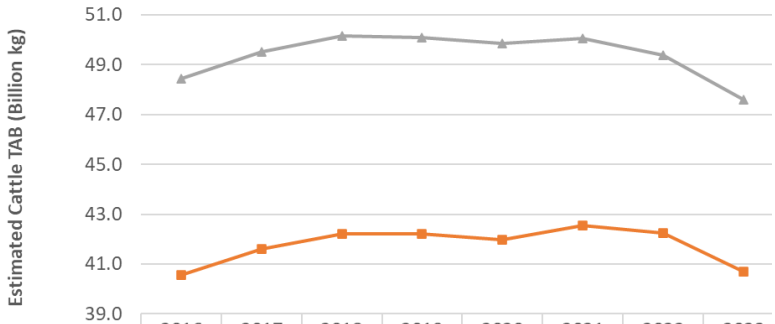
*Formula: Beef and nonlactating dairy TAB = Modified Total Cattle TAB – (P10*W10) – (P2*W2)*

The beef and non-lactating dairy exclusion category is utilized only for the amphenicol drug class beginning in 2020, when antimicrobial drug sales data for amphenicols were first reported independently. This exclusion category operates alongside the general cattle biomass improvements and will be applied retrospectively to 2020 data when the revised methodology is implemented.

4. Impact and Validation of Methodology Changes

A comparison of the previous cattle TAB using the original calculation methodology to the modified method revealed similar trends over time and an average percent increase of 18.3% over years 2016 to 2023 (Figure 1). This increase demonstrates that the original methodology was undercounting the cattle population potentially treated with antimicrobials by not capturing the complete production lifecycle of cattle maintained longer than one calendar year.

***Figure 1** - Comparison of Previous and Modified Cattle TAB Methodology (2016-2023)*



	2016	2017	2018	2019	2020	2021	2022	2023
Estimated Cattle TAB (billion kg) - previous method	40.5	41.6	42.2	42.2	42.0	42.6	42.2	40.7
Estimated Cattle TAB (billion kg) - new method	48.4	49.5	50.1	50.1	49.9	50.1	49.4	47.6
Percent Difference	19.5%	19.1%	18.8%	18.6%	18.8%	17.6%	16.9%	16.9%

The average percent difference between methods across all years was **18.3%** increase in cattle biomass when comparing the new Cattle TAB to the previous cattle TAB methodology.

While the modified methodology results in higher absolute biomass values, the year-to-year trends remain consistent between the original and revised approaches. This validation confirms that the enhanced methodology provides more accurate context for antimicrobial sales data without fundamentally altering the directional patterns observed in historical data. The upward adjustment reflects a more comprehensive capture of the U.S. cattle population, thereby improving the precision of biomass-adjusted antimicrobial sales calculations.

The modified cattle TAB calculations will be implemented beginning in 2025 for reporting year 2024 antimicrobial sales and distribution data, with retrospective application to 2016 data to ensure consistency across the time series.

5. Conclusion

FDA's modification to cattle biomass represents an important update to the biomass denominator methodology. The complexities associated with calculating total biomass of cattle populations in the U.S. and changing marketing status for particular drug classes and their uses over time necessitated a more comprehensive approach to revisit the cattle biomass calculations to ensure accurate representation of the total cattle population potentially treated with antimicrobials. The new methodology will be applied retrospectively to 2016 data to ensure consistency across the time series, with changes reflected in the Interactive Summary online dashboard. The amphenicol exclusion category will be applied retrospectively to 2020 data, when amphenicols first became independently reportable.

Other species TAB (i.e., for turkey, chicken, and swine) were not modified in this method revision due to the lack of needing to account for additional animal subgroups categorized as youngstock and breeding animals. This addendum represents an improvement on the biomass methodology for cattle, with enhanced accuracy achieved through collaboration with USDA experts and incorporation of previously uncounted cattle subpopulations.

Improvements to analysis of antimicrobial sales data using tools such as the biomass denominator are part of FDA's ongoing efforts to support the judicious use of antimicrobials for animals and people, particularly for interpretation of antimicrobial sales and distribution data.

6. References

1. US Food and Drug Administration, Center for Veterinary Medicine. FDA’s Proposed Method for Adjusting Data on Antimicrobials Sold or Distributed for Use in Food-Producing Animals, Using a Biomass Denominator. 2017. Available from: https://www.fda.gov/animal-veterinary/antimicrobial-resistance/biomass-adjusted-antimicrobial-sales-and-distribution-data-food-producing-animals-interactive

2. US Food and Drug Administration, Center for Veterinary Medicine. Antimicrobial Use and Resistance in Animal Agriculture in the United States, 2016-2019. Summary Report. June 2022. Available from: https://www.fda.gov/media/159544/download?attachment

3. U.S. Department of Agriculture, National Agricultural Statistics Service. Cattle Inventory by Class and Calf Crop - United States (data extracted from reports spanning years 2016-2024). Accessible from: https://usda.library.cornell.edu/concern/publications/h702q636h

4. U.S. Department of Agriculture, National Agricultural Statistics Service. Livestock Slaughter Annual Summary - United States (data extracted from reports spanning years 2016-2024). Available from: https://usda.library.cornell.edu/concern/publications/r207tp32d?locale=en

5. USDA Foreign Agricultural Service, Global Agricultural Trade System (GATS). Available from: https://apps.fas.usda.gov/gats/default.aspx

6. Smith, Julie. HEIFER GROWTH AND ECONOMICS: TARGET GROWTH. Bovine Alliance on Management and Nutrition, 2007. Available from: https://www.aphis.usda.gov/animal_health/nahms/dairy/downloads/bamn/BAMN07_HeiferGrowth.pdf

7. USDA APHIS NAHMS Beef 2017: Beef Cow-calf Management Practices in the United States. Accessed from: https://www.aphis.usda.gov/animal_health/nahms/beefcowcalf/downloads/beef2017/beef-2017-part2.pdf

8. Urie NJ, Lombard JE, Shivley CB, Kopral CA, Adams AE, Earleywine TJ, Olson JD, Garry FB. Preweaned heifer management on US dairy operations: Part I. Descriptive characteristics of preweaned heifer raising practices. J Dairy Sci. 2018 Oct;101(10):9168-9184. doi: 10.3168/jds.2017-14010

9. USDA Agricultural Research Service. (2001). Sire breed means for preweaning traits of calves produced in cycle VI of the GPE program (1997 and 1998 calf crops). In Germplasm evaluation program progress report no. 20 (Table 2). Roman L. Hruska U.S. Meat Animal Research Center in cooperation with University of Nebraska, Institute of Agriculture and Natural Resources, Agricultural Research Division. Available from: https://www.ars.usda.gov/sp2userfiles/place/54380000/gpe/gpe20.pdf

10. Food and Drug Administration (FDA). Biomass-Adjusted Antimicrobial Sales and Distribution Data in Food Producing Animals: Interactive Summary. Rockville, MD: U.S. Department of Health and Human Services. Available from: https://www.fda.gov/animal-veterinary/antimicrobial-resistance/biomass-adjusted-antimicrobial-sales-and-distribution-data-food-producing-animals-interactive