

September 17, 2018

Dr. Steven Solomon
Director - Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Place, HFV-1
Rockville, MD 20855

Dear Dr. Solomon,

On behalf of Keep Antibiotics Working (KAW), I write to express our appreciation for the Center for Veterinary Medicine's (CVM) willingness to engage with us in addressing antibiotic resistance and to request that CVM move forward with its proposed method to adjust antimicrobial sales by animal biomass and to apply the method to the 2017 sales data when they are released later this year. KAW also requests that CVM in parallel apply and report sales using the biomass adjustment method developed by the European Medicines Agency to enable comparisons between countries.

KAW asks that you move expeditiously to finalize and start reporting antimicrobial sales data on a biomass-adjusted basis. However, we would strongly urge that such reporting include side-by-side calculations using both an improved version of the FDA proposed method (mg/TAB) (see suggestions below) and a method widely in use in Europe and elsewhere (mg/PCU). The [European method \(mg/PCU\)](#) was developed by the European Medicines Agency (EMA). The EMA method is used to adjust antimicrobial sales in food producing animals from multiple European nations. Addition of the EMA method to CVM's public calculations would lend greater strength and transparency to the reports, since it would facilitate comparison between reports from the FDA with reports from the EMA, Public Health Canada, and the UK, all of which are now including mg/PCU calculations in their reporting. Parallel reporting using both mg/TAB and mg/PCU should begin with adjustments to the 2017 antimicrobial sales data when they are released later this year. We also encourage you to apply the biomass adjustments to data from 2016, the earliest year for which species-specific data are available.

The biomass adjustments for antimicrobial sales data facilitate comparisons across time as animal populations change. These comparisons are essential for measuring the impacts of antimicrobial stewardship efforts and for identifying trends in antimicrobial use. The biomass adjustments are also helpful in understanding how antibiotic

resistance selection pressure varies between food animal sectors and between different countries and regions.

Food Animal Concerns Trust (FACT), a Keep Antibiotics Working member group, has taken the [FDA proposed biomass adjustment method \(mg/TAB\)](#) published by CVM in September 2017 and applied it to the [2016 sales data reported by FDA](#). Based on FACT's efforts to use the proposed methods, we recommend that CVM keep the method simple and rely upon data from the United States Department of Agriculture that are published in the same format each year, allowing year-to-year comparisons. Simplifying the method where possible and using data that are consistently released will improve the transparency of the method and likely increase public acceptance. Given the imprecision of the species breakouts of the antimicrobial sales data, using very precise adjustments involving animal weights and numbers may not add significant value.

To simplify the method and increase its transparency, KAW recommends that the FDA consider removing elements that do not have a substantial impact on the precision of the biomass adjustment. In making this consideration, we encourage the agency to pay particular attention to elements that introduce confusion, create a risk of double counting, or rely on data that is not current or is difficult to access. To inform this effort, FACT has provided the following observations based on its analysis:

- FACT had difficulty finding data for exports and imports of live animals (as opposed to pounds of meat exported). Where such data were available, the impacts on the overall biomass for these were limited.
- It is not clear how much benefit is gained by counting long-lived animals, such as beef breeding and dairy cows, separately from slaughtered animals as proposed on page 7. Most of these animals will eventually be slaughtered and included in the slaughter numbers. Counting them separately creates the risk of double counting, if they are not excluded from the count of long-lived animals during the year in which they are slaughtered. It is unclear how big an impact on final biomass separating these animals out from slaughter will have. Including them only at slaughter, is a more simple approach and consistent with how biomass of more short-lived animals is measured.
- Breaking out poultry in the hatchery as discussed on page 7 has the potential to introduce confusion, since the method normally considers weights at slaughter not at time of treatment. This should be weighed against any advantages of having more finely grained data.
- Data from academic resources or publications, as contemplated on page 7, may be less current and less transparent to the extent that such articles may not be freely available at no cost to the public and are not updated on a regular basis.

KAW asks FDA to move forward quickly with a method that can be used to adjust the data. While we support FDA developing a biomass adjustment method, we urge you to consider whether the observations above might suggest a simpler way forward, without sacrificing meaningful precision.

Finally, KAW recommends that FDA in parallel use the method developed by the EMA (mg/PCU) so that comparisons across regions and between countries can be made. The same animal population data needed for the FDA proposed method can be used for the EMA method so applying the method to U.S. sales data will not require significant additional effort. The World Animal Organization (OIE) has also developed a method for adjusting antimicrobial sales by animal biomass. KAW does not believe the OIE method for biomass adjustment is an appropriate tool for making comparisons because, so far, there is a complete lack of transparency in how this method is applied at the national level making any comparisons using the OIE method impossible.

In conclusion, we ask that the CVM move forward with its proposed biomass adjustment measurement simplifying where appropriate and also applying the EMA method to the U.S. data so that comparisons with other countries can also be made. Since the EMA method is already available, FDA could move forward with applying this method while it continues to develop its own approach.

Sincerely,

A handwritten signature in dark ink, appearing to read "Steven Roach". The signature is fluid and cursive, with the first name "Steven" and last name "Roach" clearly distinguishable.

Steven Roach
Food Safety Program Director
Keep Antibiotics Working member organization Food Animal Concerns Trust