# Calculation of the numerator: kilograms of active ingredients

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Regional ANIMUSE Training for WOAH Focal Points for Veterinary Products 10-12 May 2023, Dubai, United Arab Emirates

## How to start?

Map a distribution system of the veterinary products at national level

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2 If you request that different stakeholders calculate the data, make sure they receive a training and that you can have access to all their calculations





Different considerations for estimating the coverage:

- The number of stakeholders that contributed and their relative contribution to the total
- Animal species covered by the products
- Types of products covered (oral products are usually predominant)

## Understanding WOAH's Antimicrobial Classes

#### Antimicrobial Class Aminoglycosides Amphenicols Arsenicals Cephalosporins (all generations) 1-2 gen. cephalosporins 3-4 gen cephalosporins Fluoroquinolones Glycopeptides Glycophospholipids Lincosamides Macrolides Nitrofurans Orthosomycins Other quinolones Penicillins Pleuromutilins Polypeptides Quinoxalines Streptogramins Sulfonamides (including trimethoprim) Tetracyclines Others Aggregated class data Total ko

### OTHER

All other antibiotics not covered by the antimicrobial classes already listed. This could include novobiocin, fusidic acid, kirromycins, fosfomycin, rifamycins, etc.

### AGGREGATED CLASS DATA

This is for **confidential** data only, <u>not for products having more than one</u> <u>antibiotic</u>. If in your country the data for one antimicrobial class needs to remain confidential, then the data can be reported under this category by selecting this category in ANIMUSE and report the names of the classes to WOAH.

Aggregated Class Data 🗌 😮

#### Aminoglycosides

Veterinary Medical Use<br/>(including prevention of clinical signs)Oral route<br/>(kg)Injection route<br/>(kg)Other routes<br/>(kg)Terrestrial food-producing animals3.6

Which data do you need to have for obtaining kilograms of active ingredients?



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## Analyse the Data at Veterinary Product

Name of the veterinary product

Sometimes the name might indicate the species, active substances or concentrations. If available, use it to cross-check information



Remember, that each calculation must be done by product e.g. tetracycline, neomycin, enrofloxacin, etc.

The strength is expressed:

-in mg or g of the active ingredient per volume or weight or other unit (for example: ml, l, kg, tablet or piece),

-in International Units (IU) per weight, volume or other unit,

-in per cent (%) weight per weight (w/w) or weight per volume (w/v).





Example 1

- **Product Name: Product premix**
- Package size: 500 g
- Sales during a year: 1 500 units
- Molecules and concentrations:
  - Tetracycline 40 mg / 1 g
  - Neomycin 20 mg / 1 g •



Neomycin

 $= \frac{0.02 \, g * 500 \, g}{1 \, g} \ge 1 \, 500$  $= 15\ 000\ g\ /\ 1\ 000$ = 15 kg reported for aminoglycosides class Example 2

- Product Name: Doggy tabs
- Package size: 1 box with 3 blisters (each blister has 10 tabs)
- Imports during a year: 950 boxes
- Molecules and concentrations:
  - Metronidazole 125 mg / 1 tablet •
  - Spiramycin 700 000 IU / 1 tablet •

Active Ingredient 1	Metronidazole
$= \frac{125 mg * 30 piece}{1 piece} \ge 950$ = 3 562 500 mg / 1 000 000 = 3 6 kg reported for the Oth	
- 5. 6 kg reported for the Oth	er class

Active Ingredient 2	Spiramycin
<u> </u>	0
= 19 950 000 000 <b>IU</b> x <b>0.0003</b>	13
= 6 244 350 mg/ 1 000 000	
= 6.2 kg reported for macrolid	es class

**Table 2:** Conversion of International Units (IUs) of certain antimicrobial agents into mg and relevant active entities, based on the ESVAC conversion factors<sup>1</sup>

Antimicrobial agent in the veterinary medicine	Antimicrobial active entity for reporting to WOAH	International Units per mg	Conversion factor t mg for multiplication
Apramycin	Apramycin	552	0.00181
Bacitracin	Bacitracin	74	0.013514
Benzylpenicillin (penicillin G) <sup>2</sup>	Benzylpenicillin	1670	0.0006
Chlortetracycline	Chlortetracycline	1000	0.001
Colistin methane sulfonate sodium (colistimethate sodium INN)	Colistin	12700	0.000079
Colistin sulfate	Colistin	20500	0.000049
Dihydrostreptomycin	Dihydrostreptomy cin	777	0.00129
Erythromycin	Erythromycin	920	0.001087
Gentamicin	Gentamicin	620	0.001613
Kanamycin	Kanamycin	796	0.001256
Neomycin	Neomycin	762	0.00131
Neomycin B (Framycetin)	Neomycin B (Framycetin)	706	0.00142
Oxytetracycline	Oxytetracycline	880	0.00114
Paromomycin	Paromomycin	750	0.00133
Polymyxin B	Polymyxin B	8403	0.000119
Rifamycin	Rifamycin	887	0.001127
Spiramycin	Spiramycin	3200	0.000313
Streptomycin	Streptomycin	760	0.00132
Tetracycline	Tetracycline	982	0.00102
Tobramycin	Tobramycin	875	0.001143
Tylosin	Tylosin	1000	0.001

**Table 3:** Conversion of content stated in mg, g or kg of derivates/compounds of antimicrobial agents in the veterinary product into corresponding mg, g or kg antimicrobial active entity for reporting to WOAH, based on the ESVAC conversion factors<sup>3</sup>



Derivate or compound	Active entity	Conversion factor for multiplication
Benethamine benzylpenicillin <sup>4</sup>	Benzylpenicillin	0.61
Benzathine benzylpenicillin <sup>5</sup>	Benzylpenicillin	0.68
Cefapirin benzathine <sup>6</sup>	Cefapirin	0.78
Cefalexin benzathine <sup>7</sup>	Cefalexin	0.74
Cloxacillin benzathine <sup>8</sup>	Cloxacillin	0.78
Oxacillin benzathine <sup>9</sup>	Oxacillin	0.77
Penethamate hydriodide 10	Benzylpenicillin	0.60
Procaine benzylpenicillin <sup>11</sup>	Benzylpenicillin	0.57

## Context

- Not mandatory.
- Based on the Calculation Tool Excel.
- This Module, as the Calculation Tool, collects data at a veterinary product level to help with the calculation of kilograms of active ingredients.
- Any information provided in the Module **is confidential**, regardless of the confidentiality status of the dossier.



Images from the Calculation Tool - Excel

## ANIMUSE: Calculation Module

## When to use it?

- Any time, 24/7 during.
- For assistance in calculations due to large number of products.
- If there is no national database for collecting data at veterinary product level (use the online entry).
- If there is a national database for collecting data at veterinary product level, but the national system does not perform the calculations (use the injection file).
- When willing to check if the calculations are good.
- When willing to have more data analysis at a molecule or veterinary product level.

CALCULATION MOD	ULE	General
Find a product, active ingredient, ID of the product	2021 2020 <b>2022</b>	
Enter Product Presentation ID	Product name Enter Product Presentation ID Enter Product WOAH It	D Code
Import data	Units and Package Sizes Enter the number of units (by packages) imported or sold in a year or the period of time declared to WOAH	
1 Upload File	Package Sizes	
Add product		
Delete all products	Type of Use ? O Vet. Medical Use	
	Growth Promotion	
	O Vet. Medical Use + Growth Promotion	
	Route of Administration (Optional) Route of Administration	
	Animals Covered by the Product (Optional)	

### () ANIMUSE: How to Use the Calculation Module?



## ANIMUSE: How to Use the Calculation Module?

The Calculation	on Module is accessi	ble <b>24/7</b> .	2021	2020	2022						
It has the <b>same entry fields as the</b>			Product no Product	Product name Product 1				Enter Product Presentation ID A0001			
<b>Calculation Tool</b> (the Excel that some countries have been using).				Units and Package Sizes Enter the number of units (by packages) imported or sold in a year or the period of time declared to WOAH Package Sizes							
			250.0		ml	*	1340		Units		
Bovine     Swine     Sheep       Fish - Salmon or Trout     Fish - Tilapia     Fish	Goats     Poultry     Cervidae     Camelidae     Equ       sh - Catfish     Fish - Marine     Fish - Undefined     (	uines Rabbits/hares Bees - Honey Reptiles Fish Crustaceans Molluscs Amphibians Canines Fe	ir 🖸 Typ	pe of Use	? .	) Vet. Mee	dical Use				
Ornamental Fish					С	) Growth	Prom Se	lect			
Active ingredient hemical compound as declared on the label					С	) Vet. Med	dical ( Or	al			
Active Ingredient Name 💡	Strength of Antimicrobial Agent	Per unit of content					Inj	ection			
Active Ingredient Name Tetracycline	Strength 250 • • Required	1 ml	💉 Ro	ute of Adm	inistratio	<b>n</b> (Option	al) Ot	her			
Result for active ingredient											_
Antimicrobial Class	Calculated amount of antimicrobial agents	Conversion factor	Th	is is a	n exa	mple	on h	ow to	manuall	y enter	
Tetracyclines	83750	kg Not Applicable	pr	oduct nn <i>e</i> cti	data	. The	injec	tion o	f datase	ts and	
	Add an active ingredient				sible	ifun		t mor	e inform	ation or	h
				ls pla	dise c	onta	$a + + h_2$	Δnti	nicrobia	1 Uso Ton	m
				13, pre	use c	oncia			ILLET U U LU	I USE IEU	TIC .

Delete this product

🖬 Save

## ANIMUSE: How to Use the Calculation Module?

	Find a product, active ingredient, ID of the product	2021 2020 <b>2022</b>	
	Enter Product Presentation ID	Product 1 · A0001 · · 250 ml You can also add	Edit product sheet
7	Import data	Image: Control of the same product with same package size	Total units for the year: <b>1,340</b>
	1 Upload File	Number of units (by packages) imported or sold in a year or the period of time declared to WOAH	
/	Add product	Select All	🖀 Delete 🛗 Change year
	Delete all products	1,340 units   Added on 03/05/2023 by Delfy Gochez	<u> </u>
		Items per page: 5 ▼ 1-1 of 1 < >	
-	Product 1   250 ml	Type of Use Vet. Medical Use	
Once t saved, visuali	the product 1s you can ize it in the	Image: Route of Administration       Oral         Image: Animals Covered by the Product       Bovine, Sheep, Goats         Image: Active ingredient       You can informat         Image: Tetracycline       250 mg /1 ml	always <b>edit</b> the product ion or <b>delete</b> it.
search name, i	n (by product molecule or	Antimicrobial Class          Antimicrobial Class       Calculated amount of antimicrobial agents       Conversion factor         Tetracyclines       83.8       kg       Not Applicable	
<u></u> ).		Delete this	s product   Edit product sheet





## ANIMUSE: How to Use the Calculation Module?





## Thank you

and the

For any question, contact us at <u>antimicrobialuse@woah.org</u>