THE ROLE OF THE DENOMINATOR IN ANTIMICROBIAL SALES AND USE DATA COLLECTION

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Aim of the presentation

Inform on current discussions at the EMA level on the denominator

Highlight on possible additional requirements for Member States for animal data population

Give some background for the presidency questionnaire.

1. Background

$$\frac{\text{Quantity sold in tonnes} \times 10^9}{\text{PCU in kg}}$$

Why a denominator is needed?

- To relate sales to the animal population (mg/PCU)
- To take into account change in the animal population from one year to another

Denominator used currently in ESVAC Reports

Units: **P**opulation **C**orrection **U**nit (PCU) is used as the term for the estimated weight;
1 PCU = 1 kg of different categories of livestock and slaughtered animals.

Principles:
- Use of **EUROSTAT** data for animal species for which data are available for all EU countries
- Additional data from Member States for Rabbits, Horses (Not present in EUROSTAT)
- Dogs and Cats not taken into account in the denominator as data not available in all MSs
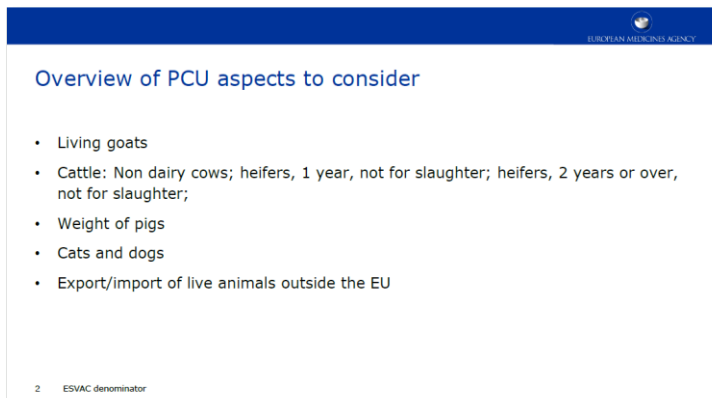- Use **TRACES** data for import and export

Calculation:
multiplying numbers of livestock animals and slaughtered animals by their theoretical
weight at the likely time of treatment.

$$\text{PCU} = \text{total PCU}_{\text{Domestic}} + \text{total PCU}_{\text{Export}} - \text{total PCU}_{\text{Import}}$$

TRAde **C**ontrol and **E**xpert **S**ystem (**TRACES**)

Requests from MSs to change the ESVAC Denominator

- ESVAC denominator review exercise - April 2018
- **Reasons (e.g.):**

  - Some animal categories were not included in the EUROSTAT data when ESVAC started

  - Other categories might be under represented

Overview of PCU aspects to consider

- Living goats
- Cattle: Non dairy cows; heifers, 1 year, not for slaughter; heifers, 2 years or over, not for slaughter;
- Weight of pigs
- Cats and dogs
- Export/import of live animals outside the EU

2   ESVAC denominator

Work suspended in 2019 due to the new EU legislation that foresees official EMA guidelines

Other denominators - WOAH

- WOAH animal biomass

Units: KG Biomass.

Principles:
Use of **WAHIS and FAOstat** data for animal species

Calculation:
Animals lifespan > 1 year: Census Data multiplied by live weight
Animals lifespan < 1 year: Production data (number and weight of animals slaughtered annually)

Weight retained: **Weight at a slaugther**
No correction of import and export (EUROSTAT indigenous data)
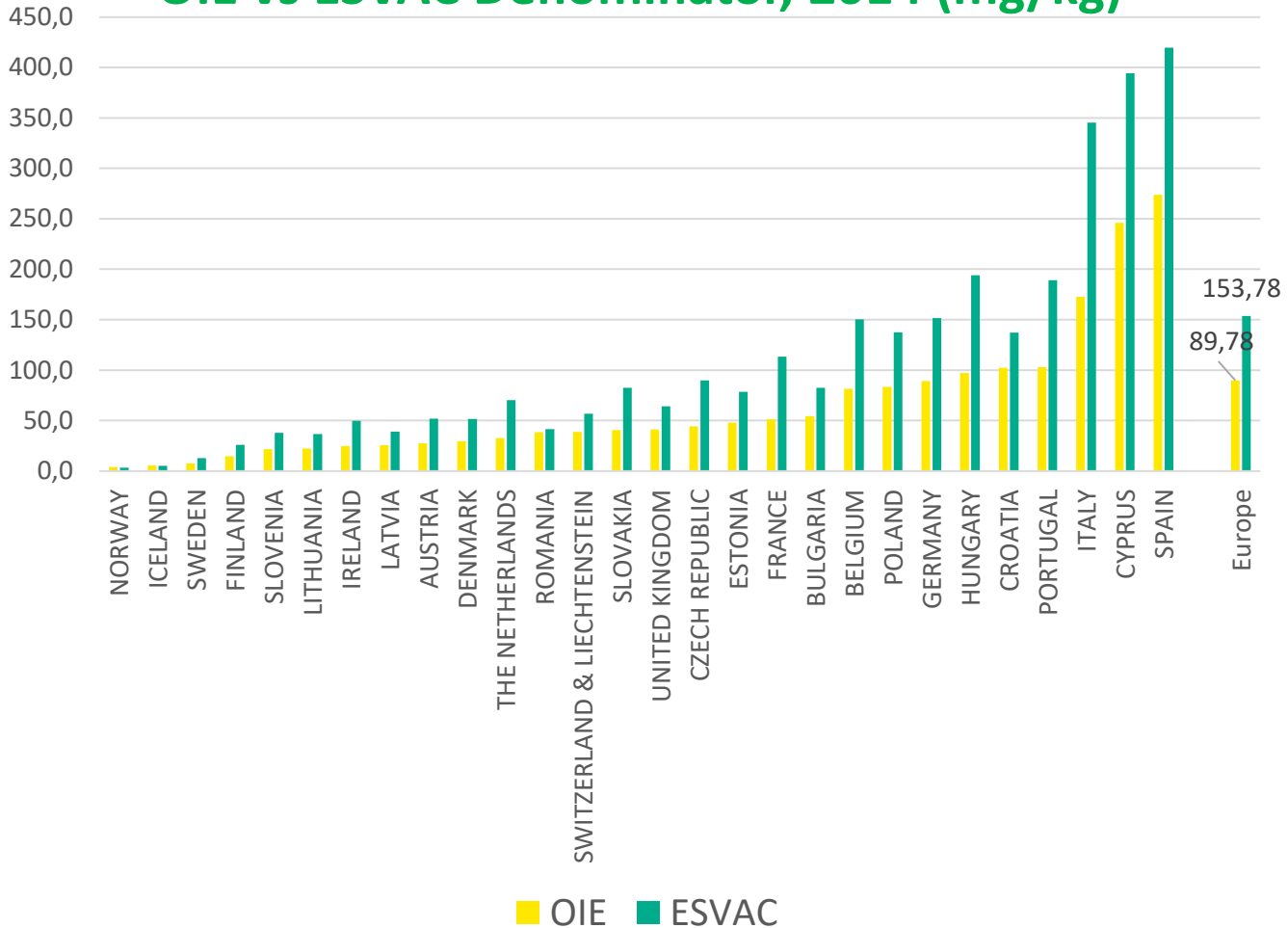
Comparison between ESVAC and WOAH Denominators

ESVAC PCU and OIE animal biomass

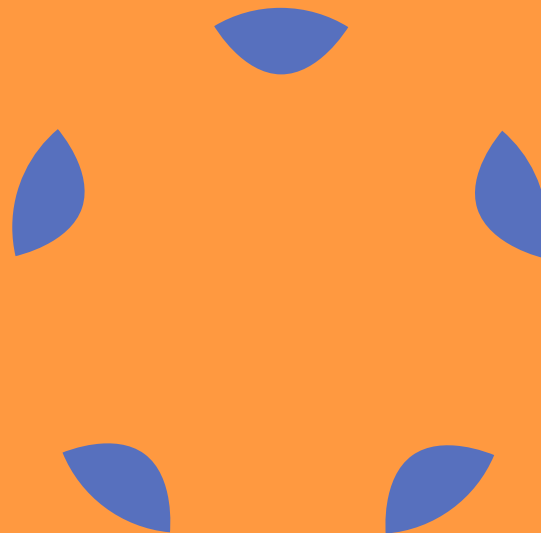| ESVAC PCU	OIE animal biomass
Weight at treatment	(Live) Weight at slaughter
Import and export	Indigenous
Mg/PCU **141** (30 European countries)	Mg/kg **90** (31 Europe)

9   ESVAC denominator

WOAH Denominator 56% higher than ESVAC Denominator

OIE vs ESVAC Denominator, 2014 (mg/kg)

2. Where are we?

EMA - ESVAC Denominators and Indicators *Ad Hoc* Group

Established in 2021

Membership: EMA, EFSA, and EUROSTAT + experts from MSs (mostly ESVAC EAG)

First work performed on the numerator:
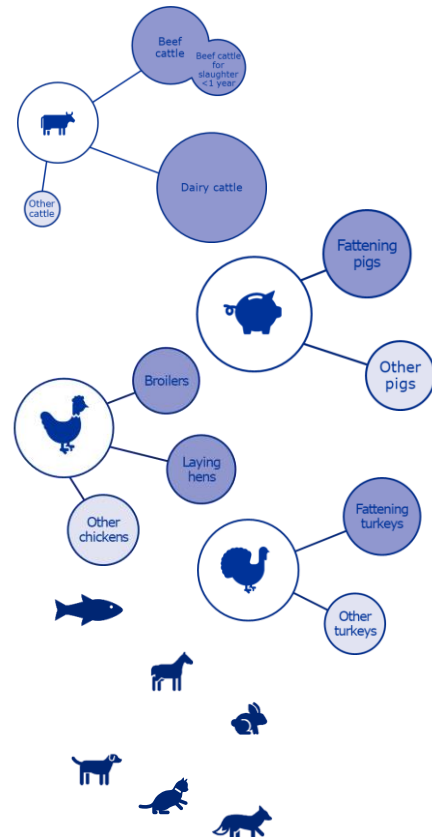
Manual published in June 2022

Antimicrobial use data reporting per animal categories (numerator) - Manual for reporting the data to the Agency

https://www.ema.europa.eu/en/documents/other/antimicrobial-use-data-reporting-animal-categories-numerator-manual-reporting-data-ema_en.pdf

Species and categories of species for which AM use data should be provided

	Regulation 2019/6	Regulation 2021/578 (delegated act)	EMA Manual
28 January 2024	Species including in decision	Cattle	Cattle
		Beef cattle	Beef cattle
		Dairy cattle	Dairy cattle
		bovines <1 year if production > 10 000 tonnes/ year	bovines >1 year if production > 10 000 tonnes/ year
			Other cattle
		Pigs	Pigs
		Fattening pigs	Fattening pigs
			Other pigs
		Chickens	Chickens
		Broiler	Broiler
		laying hens	laying hens (Consumption)
			Other chickens
		Turkeys	Turkeys
		Fattening turkeys	Fattening turkeys
			Other Turkeys
28 January 2027	All food producing species	other poultry (ducks, geese)	Ducks
			Geese
		sheep	sheep
		goats	goats
		finfish (Atlantic salmon, Rainbow trout, Gilthead seabream, European seabass, Common carp)	Atlantic salmon
			Rainbow trout
			Gilthead seabream
			European seabass
			Common carp
		horses	horses
		rabbits (food-producing)	rabbits (food-producing)
		Other species relevant for MS	Other species relevant for MS
28 January 2030	Other animals kept and Bred	dogs	dogs
		cats	cats
		fur animals (minks and foxes)	Minks
			Foxes

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Ongoing work on the denominator:

Defining data sources and calculations for the denominator

- Feedback from the Commission and information on the future Regulation on Statistics input and Output (SAIO)

EUROPEAN MEDICINES AGENCY

Animal biomass methodology & data availability

- **Feedback from EC:** objective is to fulfil the requirements laid down in the EU regulations, including animal species and categories. Any alignment with WOAH standards and methodologies would be desirable, but without deviating from the EU legal obligations.

- **Update from Eurostat:**
  - The basic act on the Statistics on Agricultural Input and Output (SAIO) has not yet been published, compromise was agreed. The first reference year covered by the SAIO would be 2025.
  - The major change regarding the concerned statistics would be about sheep and goat populations which no MS would be fully exempted to provide, but they would deliver these statistics at least three times per decade.
  - In the IAs, we foresee covering, additional to the current statistics, one chicken population and the laying hen (producing eggs for consumption) population, here also, at least three times per decade.
  - The slaughter statistics would cover horse and rabbit meat where significant (no EU coverage).

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Main points already acted:

- Need to define **animal categories´ denominator**

(Sum of all denominator categories will define the **new sales denominator**)

- Use EUROSTAT data and TRACES data when possible

- Ask Member States for Data not reported in EUROSTAT

- Move from **Weight at treatment** to **live Weight at slaughter**

Issues identified

Green Deal Target => Farm to Fork strategy (F2F) target:

The Objective reduce overall EU sales of antimicrobials for farmed animals and in aquaculture by 50% by 2030 (in reference to year 2018):

> *"The Commission clarifies that the sales denominator should remain the same until 2030 to enable F2F target monitorization.*
>
> *It was then indicated that this does not imply that the sales denominator cannot be adjusted for other analyses in parallel."*

Availability of Data on Animal population:

Work already done on detailed analysis of animal population shows that: **Additional data would be needed to ensure an adequate denominator for the species categories.**

Ongoing work

Data that may be requested to be provided by Member States

Not finalised yet!

EMA Manual	Data not available in Eurostat that may be requested from MS
Cattle	Heifer 1–2 years dairy farm / Heifer 1–2 years Beef Farm Heifer, 2 years old or over dairy farm /Heifer, 2 years old or over beef farm
Beef cattle	
Dairy cattle	
bovines <1 year if production > 10 000 tonnes/ year	
Other cattle	
Pigs	Breeding sows on multiplication farms or selection centers
Fattening pigs	
Other pigs	
Chickens	Laying hens producing eggs for consumption Laying hens producing eggs for reproduction Chickens for breeding (parents, grandparents, great grandparents) Pullets
Broiler	
laying hens (Consumption)	
Other chickens	
Turkeys	breeding turkeys (parents, grandparents, great grandparents) and turkeys kept for egg hatching
Fattening turkeys	
Other Turkeys	
Ducks	
Geese	Goose
sheep	On going discussions data not available in all countries
goats	On going discussions data not available in all countries
Atlantic salmon	Atlantic salmon?
Rainbow trout	Rainbow trout ?
Gilthead seabream	Gilthead seabream ?
European seabass	European seabass ?
Common carp	Common carp?
horses	Horses
rabbits (food-producing)	Rabbits
Other species relevant for MS	
dogs	Dogs
cats	Cats
Minks	Minks
Foxes	Foxes

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anses

Will those data be available in Member States ?

EMA will send a questionnaire to MS in order to ask precise questions on the availability of animal population data at the national level.

The new Statistics on Agricultural Input and Output (SAIO) regulation may help, but it will certainly not be sufficient (and will start in 2025)

Response from MSs are needed before evaluate what is feasible.

3. Some reflections
on the aims of the ASU data collection

Aims of the data collection at the EU level: What is in the regulation?

Regulation: 2019/6 recital 50

There is still a lack of sufficiently detailed and comparable data at Union level to determine the trends and identify possible risk factors that could lead to the development of measures to limit the risk from antimicrobial resistance and to monitor the effect of measures already introduced. It is therefore important to continue the collection of such data and further develop it in line with a stepwise approach. That data, when available, should be analysed with data on the use of antimicrobials in humans and data on antimicrobial resistant organisms found in animals, humans and food.

Extract from Manual for reporting the data to the Agency

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.

Member States adjusting or setting up systems for data collection should be aware that such **a review of animal categories 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**.

For example, only **cats** and **dogs** and **fur animals** are included in non-food producing animals. As the collection of data is intended to be exhaustive, **some animal species are lacking**: for example new companion animals, zoo animals (where off label use may be frequent) …

Aims of the data collection at the National level (1)

Objectives at the national level may be similar than those expressed at the EU level. However the « large » animal categories defined at the EU level may not be sufficient to address fully the objectives mentioned.

Some examples:

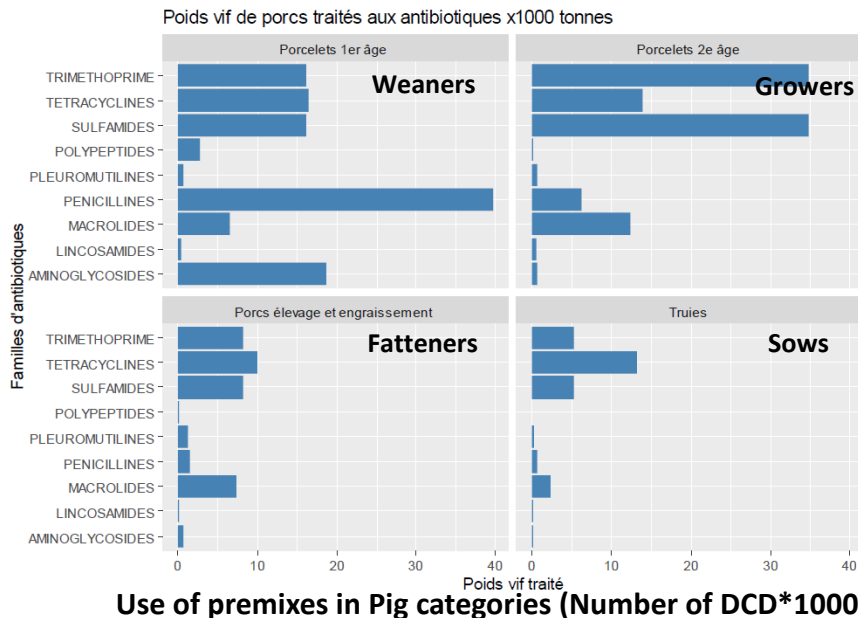**Cattle:** **EU categories**: Beef Cattle, Dairy Cattle, Other cattle, Bovine <1 Year
At national level, it may be advantageous to further increase the granularity of the collected data on the antimicrobial use in cattle, e.g., **dairy cows**, specialised beef cattle production (**veal calves**).

For example, it is well known that young animals are more treated than older animals. Therefore, monitoring of these animal categories is essential to target measures to be taken and to monitor the effect of these measures.

Aims of the data collection at the National level (2)

Pigs: EU categories: Fattening pigs – other pigs

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).**

Poids vif de porcs traités aux antibiotiques x1000 tonnes

Use of premixes in Pig categories (Number of DCD*1000)

Conclusion

The ASU Denominator is still under development.

National data may be required for the denominator to ensure a good match to the numerator.

Further analysis of what is feasible need to be done.

Animal categories subjects to the use data collection are defined in the regulation and may not enable to completely fulfill the EU objectives.

As indicated in recital 50 of the regulation 2019/6,

"It should be possible to make further adjustments to the obligations on data collection when the procedures in the Member States for the collection of data on sales and use of antimicrobials are sufficiently reliable."

Member states should know that adjustments can be made and this need to be taken into account when setting-up national systems.

According to national needs, an increased granularity may be needed to implement targeted actions at national level.

Thank you for your attention!