



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Units of measurement for animals for the collection of data per animal species: Defined Daily Dose (DDDvet) and Defined Course Dose (DCDvet)

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Data collection on consumption of veterinary antimicrobials in Europe – achievements, challenges and way forward

EC workshop with EMA, Brussels, 26 April 2017





# Overview

- DDDvet and DCDvet
- Principles for assignment
- Lists with values



## Defined Daily Dose animal (DDDvet) and Defined Course Dose animal (DCDvet)

Standardised technical units of measurement.

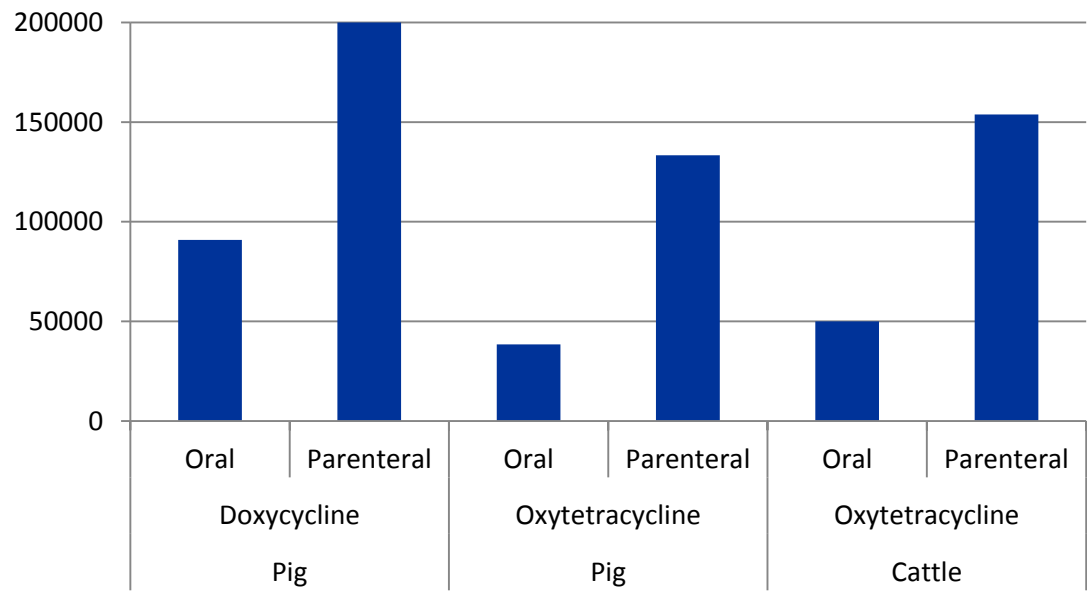
- DDDvet: assumed daily dose per kg body weight.
  - 5 DDDvet used: e.g. *'1 kg animal treated 5 days'* or *'5 kg animal treated 1 day'*.
- DCDvet: assumed course dose per kg body weight.
  - 5 DCDvet used: e.g. *'1 kg animal received 5 treatment courses'* or *'5 kg animal received 1 treatment course'*.

## DDDvet and DCDvet (cont.)

Take into account differences in dosing (daily dose and treatment duration)

→ between species, substances and/or formulations.

Animal weight (kg) that can be treated for 1 day with 1 kg active substance (e.g. doxycycline or oxytetracycline)





## DDDvet and DCDvet (cont.)

- More refined – reflects animal exposure to antimicrobials.
- Not necessarily be assumed to reflect daily doses recommended/prescribed – assigned values nearly always compromise.
- Not applicable for commercial use (e.g. pricing and analyses of drug costs).



# Principles for assigning DDDvet and DCDvet

- Developed in conjunction with ad hoc working group.
- Intended to guide EMA on assignment of DDDvet and DCDvet.
  - To ensure consistency and transparency.
- Considered to represent optimum balance between accuracy and practicability.
- Harmonized to extent possible with human medicine (DDD).
- Adopted after public consultation and published on Agency's website (30 June 2015).



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23 June 2015  
EMA/712015/2014  
Veterinary Medicines Division

Principles on assignment of defined daily dose for animals (DDDvet) and defined course dose for animals (DCDvet)

Draft agreed by European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) drafting group	9 March 2015
Start of public consultation	12 March 2015
End of consultation (deadline for comments)	12 May 2015
Revision agreed by the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) drafting group	8 June 2015

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## Principles for assigning DDDvet and DCDvet (cont.)

- Developed based on data for antimicrobial agents, but in general considered applicable in future for other veterinary therapeutic agents.
  - For some therapeutic agents (e.g. with intermittent schedule) approach would have to be further explored.
- Antimicrobial growth promoters not authorised in EU/EEA countries, therefore principles do not address AGPs.
  - DDDvet/DCDvet should not be used to analyse and report consumption of AGPs.
- Generally based on SPC information provided by 9 MSs (CZ, DE, DK, ES, FI, FR, NL, SE, UK).
  - In cases where SPC info is insufficient, scientific publications/text books will be consulted.



# Lists on the website (April 2016)

[Home](#)>[Veterinary regulatory](#)>[Overview](#)>[Antimicrobial resistance](#)>[European Surveillance of Antimicrobial Consumption](#)>[Units of measurement](#)

## Defined doses for pigs, cattle and broilers

The European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) activity has prioritised establishing 'defined daily dose for animals' (DDDvet) and 'defined course dose for animals' (DCDvet) values for antimicrobials used in **three major food-producing animal species**: pigs, cattle and broilers (poultry).

The values are based on an assumed average daily dose (DDDvet) or treatment course dose (DCDvet) of active substance. They take account of differences in dosing, pharmaceutical form and route of administration used in the different species.

The lists of DDDvet and DCDvet values are available in PDF or Excel format. Please note that the PDF document contains more detail on a number of **exceptions** to the principles for assigning 'DDDvet' and 'DCDvet' values:

- ▶  [Lists of 'DDDvet' and 'DCDvet' values for pigs, cattle and broilers](#)
- ▶  [Lists of 'DDDvet' and 'DCDvet' values for pigs, cattle and broilers](#)

ESVAC relied on detailed dosing data from nine European Union (EU) Member States when assigning the values. To report a missing ingredient or substance, please write to [esvac@ema.europa.eu](mailto:esvac@ema.europa.eu).

The lists are intended for use by EMA to support the ESVAC activity in analysing and reporting antimicrobial consumption using harmonised units, which facilitate comparison of different animal populations. EMA also encourages the use of the standardised units to report consumption data at national level to enable comparison between countries.



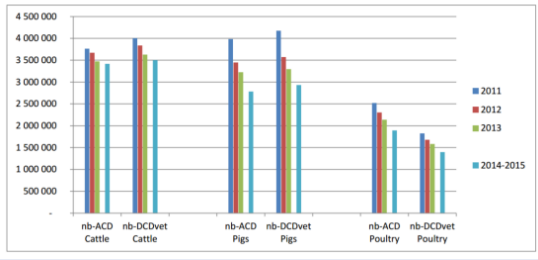
# DDDvet and DCDvet in use



Sales survey of veterinary medicinal products containing antimicrobials in France in 2015



Figure 32: Change in body weight treated since 2011 according to the French and European approaches (tonnes)



平成27年度  
抗菌性物質薬剤耐性評価情報整備事業④  
動物用抗菌剤の使用量調査に関する情報整備

平成28年3月  
東京大学大学院農学生命科学研究科  
杉浦 謙明

A variety of ways of measuring antimicrobial usage exist, the most common being mg of antimicrobials used per kg of livestock (mg/PCU [population corrected unit]), defined daily dose (DDDvet) or defined course dose (DCDvet). The last two methods are effectively an estimation of doses or courses of an antibiotic per animal (European Medicines Agency 2016). All methods have their

**TOOL TO MEASURE ANTIMICROBIAL USE ON FARMS**

**ANTHROPOMETRIC** use in livestock continues to be a prominent type of measurement method and promise to improve monitoring and reduce antimicrobial use. The Commission's response to the CPD report stated that DDDs have continued to reduce antibiotic use in livestock and fish farmed for food, to a multiplex average of 20 mg/kg by 2011 (Department of Health 2010). This will be ongoing progress to measure and reduce antibiotic use at farm and practice level.

A variety of ways of measuring antimicrobial usage exist, the most common being mg of antimicrobials used per kg of livestock (mg/PCU [population corrected unit]), defined daily dose (DDDvet) or defined course dose (DCDvet). The last two methods are effectively an estimation of doses or courses of an antibiotic per animal (European Medicines Agency 2016). All methods have their limitations, for example, mg/PCU may have the potential to misrepresent courses of antibiotics, or courses of antimicrobials simply based on a low mg/kg dose rate. DCDvet and DDDvet are therefore more likely to be accepted as a standardised measure of antibiotic use and reducing how many doses or courses are prescribed per animal. However, DCDvet and DDDvet take into their account the actual amount (mg) of active ingredient.

It is difficult to compare these methods and to conduct cross-country comparisons in different measurement approaches, so we have developed a user-friendly antimicrobial use

**1)** The use of defined antibiotic daily course therapy (DCT) is a value highlighted as a key method to reduce antimicrobial usage in farm fish when antibiotic usage (mg/PCU), the measure in antimicrobial usage in any species including antibiotic, DCDvet by fish would typically reduce antibiotic usage by around only 2 mg/kg (PCU). However, when the same amount is spread using a DCDvet, a reduction in the number of courses of antibiotics used is already large. Because fish value of DCT systems are complex. The method of measuring antimicrobial use and drug use and formulation, and also an option to be the only method of measuring antibiotic use. Therefore, it is vital we use a consistent approach for measuring antimicrobial usage at local and regional level.

**2)** Treatment of clinical mastitis. Reduction in housing new mastitis therapy usage prevents a comparatively small reduction in mg/PCU in reduction from treating every cow with a course of commonly used housing units to avoid would result in a best reduction of around 2 mg/PCU. However, if separate products are widely used in some mastitis systems, a reduction of the average 10 mg/kg (10 mg) of an antimicrobial product would result in a total difference of 20 to 15 mg/PCU. In general, suitable products have a long impact on herd usage when measured in mg/PCU.

**3)** The addition of an antibiotic biofilter. An extremely long mean of DDDvet (mg/PCU) is a measure of antibiotic therapy for a large number of animals and this can result in large numbers of mg/PCU. For example, 15 treatments of an antibiotic biofilter per year would typically represent an amount of around 10 to 20 mg/PCU for a large herd.

**4)** Ventilation in the farm animal industry or greenhouses of antibiotic usage, and pressure on greenhouses to reduce supply as a farm, practice and national level to further reduce antibiotic use. It is likely the major reason for reduction in through disease prevention rather than antimicrobial resistance. A full review of the calculator will be available like to use the antimicrobial use calculator to look at 'what if' scenarios.

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References  
COMMISSION OF EUROPE (2016) Commission response to the review on antimicrobial resistance: monitoring, governance and prevention report. European Commission, Luxembourg, 157 pp.

Department of Health (2010) CPD Report: Commission's response to the CPD report. London: Department of Health, 10/10/10

AM 1610/09/02

表 6-5. ESVAC の経口および注射薬別の DDDvet と DCDvet 算出の基本方針

測定単位	算出方法	経口・単剤	経口・合剤	注射・単剤	注射・合剤
DDDvet	動物種、薬剤、製剤形態ごとに全ての薬の 1 日量平均	1つの薬剤ごとに全ての経口用製剤で同じ DDDvet	経口用単剤と経口用製剤で同じ DDDvet	注射薬と持続型注射薬は同じ DDDvet ブロドラッグは別に設定	単剤、持続型製剤、ブロドラッグに同じ DDDvet
	療日数を乗じたものの全ての値の平均	1つの薬剤ごとに全ての経口用製剤で同じ DDDvet	経口用単剤と経口用製剤で同じ DCDvet	注射薬と持続型注射薬は同じ DCDvet ブロドラッグは別に設定	単剤、持続型製剤、ブロドラッグに同じ DCDvet

注) 単剤 (single) とは一つの有効成分のみを含むものであり、合剤 (combinations) とは 2 つ以上の有効成分を含む製剤です。

(Principles on assignment of defined daily dose for animals (DDOvet) and defined course dose for animals (DCDvet), 2015. ESVAC, p. 7. 2. 9)



## The way forward

- Publication of DDDvet and DCDvet for injectable products containing gamithromycin, tildipirosin and tulathromycin.
  - Methodology for establishing surrogate measure for duration of effect established.
- Discussion with WHO Collaborating Centre for Drug Statistics Methodology on maintenance of lists (pending on above).
- Encourage MSs to use DDDvet/DCDvet to report data on use by species.



## Acknowledgements

The members of the ESVAC ad hoc working group on technical units and the ESVAC DDDvet/DCDvet EAG **Inge van Geijlswijk, Kari Grave, Christina Greko, Erik Jacobsen, Irene Litleskare, Gérard Moulin** and **Cedric Müntener** are thankfully acknowledged for assisting the development of this project as well as providing scientific advice and valuable comments during the development of the principles and the assignment of the DDDvet and DCDvet values.

A special thank you to **Kari Grave** for all her work leading this project and as chair of the ESVAC DDDvet/DCDvet EAG.



# Thank you for your attention

## Further information

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