



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 June 2016
EMA/210691/2015-Rev.1
Veterinary Medicines Division

European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)

Web Based Sales Data and Animal Population Data Collection Protocol (version 2)

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1. Introduction

1.1. Terms of reference

The European Commission has requested the European Medicines Agency to take the lead in collating data on the use of antimicrobial agents in animals in the European Union and to manage the database. The European Medicines Agency was asked to develop a harmonised approach for the collection and reporting of data based on national sales figures as well as data on usage in at least major groups of animal species and to ensure comparability with the sale/use of antimicrobial agents in human medicine. The intended use of the surveillance data, both at national and community level would be:

- To aid interpretation of patterns and trends regarding antimicrobial resistance (AMR);
- As input to risk profiling and risk assessment regarding AMR;
- For setting risk management priorities;
- For evaluation of the effectiveness of control measures being implemented;
- To identify emerging use of veterinary antimicrobial agents, e.g. of specific classes of antimicrobial agents such as those identified by World Health Organisation (WHO) as critically important for human medicine;
- To aid comparison of usage of veterinary antimicrobial agents between human and veterinary medicine, time periods and countries;
- As a basis for focused and targeted research and development.

This protocol addresses collection of sales data and data on animal population.

The revision of the Web Based Sales Data and Animal Population Data Collection Protocol includes updated value of the conversion factor for benzathine benzylpenicillin and some minor editorial amendments.

1.2. Approach

To enable harmonised reporting of the data as well as comparison with data between time periods within and between different European countries standardisation and harmonisation of the data collected is of vital importance. This applies also for the animal demographic data that is used to normalise the sales data for reporting of the sales. In ESVAC, a population correction unit (PCU) is used as the denominator and this represents purely a technical unit of measurement. The data sources used and the methodology for the calculation of PCU are comprehensively described in Appendix 2 of the Agency's report 'Trends in the sales of veterinary antimicrobial agents in nine European countries: 2005-2009' (EMA/238630/2011)¹.

The data collection package consists of the following items:

- ESVAC sales and animal population data collection protocol (ESVAC Sales Protocol);
- ESVAC Sales Template;
- ESVAC population correction unit template (ESVAC PCU Template).

¹ Available from the Agency's website via: [Home > Regulatory > Veterinary medicines > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption](#).

In order to obtain reliable and harmonised data in the ESVAC database the ESVAC Sales Protocol, the ESVAC Sales Template and the PCU Template have to be adhered to.

1.3. Target groups of the protocol and templates

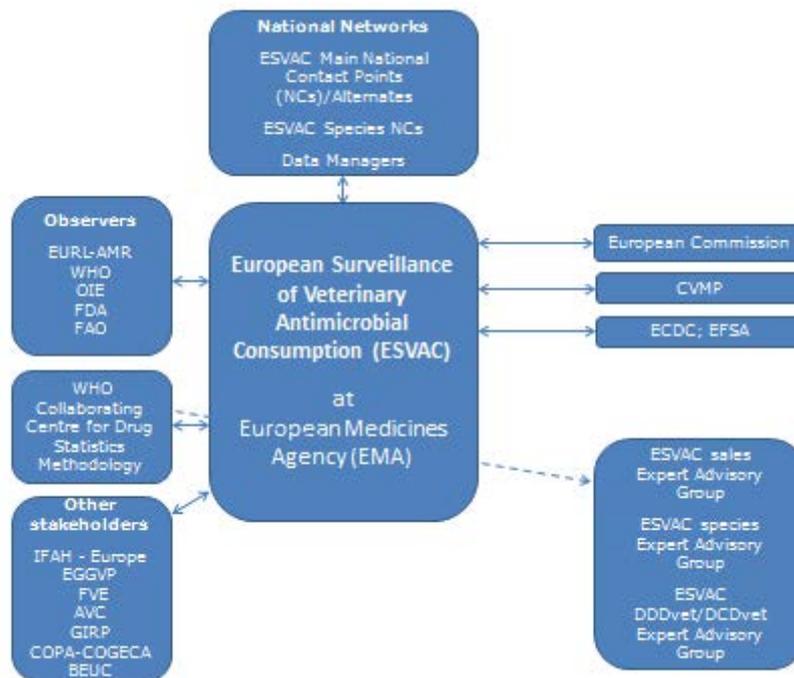
This version of the ESVAC Sales Protocol is primarily developed for web based submission of sales data and animal population data for countries participating in ESVAC but is thought to be applicable also for countries outside the EU/EEA area that want to collect such data.

The web delivery of data allows for the submission of data without using the ESVAC Sales Template; however the requirements of the Data Collection Protocol should be fulfilled. If uploading data directly as comma-separated values (CSV) files without the use of the Excel template as the basis, please disregard the parts of this protocol that are not applicable.

1.4. Organization of the ESVAC project

The ESVAC project is organised into three main work streams: collection of sales data, collection of data on consumption by species and establishing and maintaining lists of defined daily doses animals (DDDvet) and defined course doses animals (DCDvet). Separate expert groups are established for these three work streams. The organisation of the ESVAC project is illustrated in Figure 1. The ESVAC main National Contact Point/Alternates and/or Data Managers are responsible for collecting, validating and submitting sales data and validating the PCU data uploaded by the ESVAC sales team. The ESVAC strategy 2016 – 2020 has been published on the ESVAC web page².

Figure 1. Organisation of the ESVAC project



² Available from the Agency's website via: [Home > Regulatory > Veterinary medicines > Antimicrobial resistance > European Surveillance of Veterinary Antimicrobial Consumption](#)

1.5. Web based delivery of data

The detailed user guide for web based delivery of sales data is described in document ESVAC web data collection – user guide. The user guidance describes the process of uploading the sales data in web, how to correct data sets with errors before submission and finally submission of the sales data in web. No information is provided in this protocol about the questionnaire as the questionnaire varies from year to year. This user guide also includes the collection of data on animal population by the ESVAC sales team and the validation of these data by the participating countries.

2. ESVAC sales data

2.1. Selection of data source

The infrastructure of the distribution of veterinary antimicrobial agents may vary considerably from country to country; such medicinal products are dispensed to the end-users by wholesalers, pharmaceutical industry, pharmacies, veterinarians or a mixture of these. Wholesalers and pharmaceutical industries may also trade between each other and export veterinary antimicrobial agents to other Member States (MS). The first step in setting up surveillance of veterinary antimicrobial agents is therefore to identify and describe of the distribution system for veterinary antimicrobial agents. The data source selected should if possible **provide data on sales to end-users within the country** such as veterinarians, farmers and wholesalers.

2.2. Veterinary antimicrobial agents to be included in ESVAC sales data

To harmonise the veterinary antimicrobial agents to be included in the data sets, the Anatomical Therapeutic Chemical classification system for veterinary medicinal products (ATCvet) is applied (Table 1) (http://www.whooc.no/atcvet/atcvet_index/). This includes all pharmaceutical forms and medicated feed except dermatological preparations (ATCvet group QD) and preparations for sensory organs (ATCvet group QS). The contribution from these groups of antimicrobial agents, in tonnes of active ingredient, to the total amounts is minimal, and therefore the effect of the deviation is negligible.

The veterinary antimicrobial agents (ATCvet groups) to be reported to the ESVAC database are shown in Table 1.

Table 1. Categories of veterinary antimicrobial agents to be included in ESVAC (http://www.whooc.no/atcvet/atcvet_index/)

Groups of antimicrobial agents	ATCvet codes
Antimicrobial agents for intestinal use	QA07AA; QA07AB
Antimicrobial agents for intrauterine use	QG01AA; QG01AE; QG01BA; QG01BE QG51AA; QG51AG
Antimicrobial agents for systemic use	QJ01
Antimicrobial agents for intramammary use	QJ51
Antimicrobial agents used as antiparasitic agents	QP51AG

2.3. Variables to be collected for each veterinary medicinal product (VMP) presentation

Table 2. Variables to be collected for each VMP presentation

Variable	Description of variable	Comments	
COUNTRY	ISO Code http://www.iso.org/iso/country_codes	To identify place of collected sales data	
YEAR		To identify time period for collected sales data	
MA	Marketing Authorisation Number	To enable link with other databases	
PRODUCT INFORMATION	PRESENTATION ID	Medicinal Product Package Code Value Digit code being a unique identifier for each package size, strength and formulation of the VMP presentation. Because it is a key variable in many databases it has to be stable over time i.e. so that VMP presentations no longer available on the market or that are no longer registered still can be identified to allow for analysis of historical data	To allow a unique identification of the Veterinary Medicinal Product (VMP) presentation. To identify and correct duplicates when uploading data in web
	NAME	Medicinal Product Name (in national language) E.g.: Harmony vet 50 mg tablets 2 x 30; Harmony vet long acting 10 mg/ml injection 10 ml	For validation purposes <ul style="list-style-type: none"> • At country level prior to submission in web; • By ESVAC after data submission.
	FORM	Pharmaceutical Form Bolus (BOLUS), Injection (INJ), Intramammary (INTRAMAM), Intramammary dry cow treatment (INTRAMAM-DC), Oral solution and oral powder for water administration (ORAL SOLU), Oral paste (ORAL PASTE), Oral powder (ORAL POWD), Premix (PREMIX), Capsules and Tablets etc. (TABL), Intrauterine preparation (INTRAUT)	
	LONG ACTING	Long-acting injectable preparations It refers to injectable preparations that maintain its antimicrobial activity over a long period of time once injected.	Optional

Variable	Description of variable	Comments
PACKSIZE	Content Quantity in Package: Pack size (numerical only) E.g.: 100 for 100 tablets or 100 intramammaries; 10 for 10 ml injection; Package of 2 kg premix: 2; Box of 10 blisters of 30 tablets: 300; Box of 12 injectors: 12	To allow for calculation of the amount of active ingredient in each VMP presentation <ul style="list-style-type: none"> For validation at country level prior to submission in web; By BI (Business Intelligence) after submission of data.
PACKSIZEU	Content Unit of Measurement E.g.: ML, L, G, KG, PIECE (for e.g. tablets, capsules, bolus and intramammary preparations) To be harmonised with strength unit – e.g. if pack size is 1 KG strength unit should be per KG	To enable calculation of amount active ingredient in each VMP presentation <ul style="list-style-type: none"> For validation at country level prior to submission in web; By BI after submission of data.
ATCVET	ATCvet- 5th level: Anatomic Therapeutic Chemical (Classification) Veterinary	Only last version of ATCvet codes will be accepted by the system. If an ATCvet code has not been assigned for a ingredient the ESVAC sales team has to be contacted.
SPECIES	Animal Species <u>All</u> the animal species for which the VMP is approved. E.g. cattle (CA), poultry (POU)	Optional
NO PACKS	Number of Packages Sold/Year/Country	To calculate weight of active ingredient sold for each VMP presentation <ul style="list-style-type: none"> For validation at country level prior to submission in web; By BI after submission of data; For validation by ESVAC after data submission.
INGR_ID	Ingredient Code Value	Serve as a unique identifier for each ingredient for each product. Needed for data management purposes.

Variable		Description of variable	Comments
INGREDIENT	INGR	Active Ingredient Name (ATCvet name)	<p>Only last version of ATCvet names will be accepted by the system.</p> <p>If an ATCvet name has not been assigned for a ingredient the ESVAC sales team has to be contacted.</p> <p>For combination VMPs the ATCvet name of all the ingredients has to be given but in separate columns.</p>
	SALT	Salt of Active Ingredient	<p>Only in cases when the strength is given in international units (IU), IU/ML or IU/UNIT and when different salts exists.</p> <p>Currently only applicable for colistin sulphate and colistin methane sulphonate.</p> <p>To enable conversion to weight of active ingredient</p> <ul style="list-style-type: none"> • For validation at country level prior to submission in web; • By BI after submission of data.
	PRODRUG	<p>Prodrug name (ATCvet name)</p> <p>E.g.: Procaine penicillin that is the prodrug for benzylpenicillin</p>	<p>Names of prodrugs are listed in Table 3.</p> <p>To allow for calculating the weight of the active ingredient</p> <ul style="list-style-type: none"> • For validation at country level prior to submission in web; • By BI after submission of data.
	STRENGTH	<p>Quantity of the Active Ingredient in Each Unit as declared in name (if not in name as in SPC): Strength (numerical only)</p> <p>E.g. 10 for 10 MG/TABLET, 10 IU/TABLET, 10 MG/ML, 10 IU/ML, 10 MG/PIECE or 10 IU/PIECE</p> <p>In case of a combination VMP strengths has to be given for each ingredient in separate lines</p>	<p>For validation purposes</p> <p>To enable calculation of the amount of active ingredient in each package/product</p> <ul style="list-style-type: none"> • For validation at country level prior to submission in web; • By BI after submission of data.

Variable	Description of variable	Comments
STRENGTHU	<p>Unit of Measurement for Strength E.g.: IU, IU/G, IU/ML, IU/PIECE, G, G/KG, G/L, MG, MG/ML, MG/PIECE</p> <p>In case of a combination VMP unit of measurement strength has to be given for each ingredient in separate lines</p>	<p>To enable calculation of the amount of active ingredient in each package/product</p> <ul style="list-style-type: none"> For validation at country level prior to submission in web; By BI after submission of data.
CONV FACT IU	<p>Conversion Factor IU When strength is given as IU, IU/ML or IU/PIECE</p>	<p>In ESVAC template conversion factor IU will be recorded by use of a macro. Conversion factors are listed in Table 4. To allow for calculation of the weight of the active ingredient in each package by MS for validation of data prior to upload in web.</p> <p>If an ingredient with strength given in IU is not listed, ESVAC sales team should be contacted.</p>
CONV FACT PRODR	<p>Conversion Factor Prodrug Only when strength is given for the prodrug and not for the active ingredient (e.g. procaine penicillin that is a prodrug for benzylpenicillin)</p>	<p>In ESVAC template it will be recorded by use of a macro. Conversion factors listed in Table 3. To enable for the calculation of the weight of the active ingredient in package</p> <ul style="list-style-type: none"> For validation at country level prior to submission in web By BI after submission of data. <p>If a prodrug is not listed ESVAC sales team should be contacted.</p>
CONTENT	<p>Content of Active Ingredient in Package In case of combination VMP the content in the package has to be given separately for each ingredient in separate lines</p>	<p>For validation of data by MS prior to upload in web</p> <ul style="list-style-type: none"> For validation at country level prior to upload and submission in web; By BI after submission of data.

Variable	Description of variable	Comments
CONTENTU	Unit of Active Ingredient in Package To be given in gram (G) for all ingredients In case of combination VMP the content unit has to be given separately for each ingredient in separate lines	For validation at country level prior to upload and submission in web.
TONS SOLD	Tons Sold of Active Ingredient	<ul style="list-style-type: none"> For validation at country level prior to upload and submission in web; For validation by ESVAC after data submission.

2.3.1. Conversion factors of prodrugs

In order to obtain harmonised data, the conversion factors shown in Table 3 are applied to calculate amount of active ingredient sold of a prodrug.

Table 3. Name of prodrugs and prodrug conversion factors

Prodrug	Conversion factor
Benethamine benzylpenicillin	0.65
Benzathine benzylpenicillin ³	0.74
Cefapirin benzathine	0.41
Cefalexin benzathine	0.36
Cloxacillin benzathine	0.43
Oxacillin benzathine	0.69
Penethamate hydriodide	0.63
Procaine penicillin	0.61

2.3.2. Conversion factors when strength is given in IU

When strength is given in international units (e.g. IU/ML) the amount sold has to be calculated to present data in weight of active ingredient. In order to obtain harmonised data, the conversion factors shown in Table 4 will be applied by ESVAC to calculate amount of active ingredient sold. Note that if the strength of an ingredient is reported in IU, the conversion factor from IU to mg as shown in Table 4 is applied to calculate amount of active ingredient sold.

Table 4. Conversion factors for calculation from IU to mg of active ingredient

Ingredient	IU/MG	Conversion factor (MG/IU)
Bacitracin	74	0.01351
Benzylpenicillin ¹	1667	0.00060
Chlortetracycline	900	0.00111
Colistin sulphate	20500	0.00005

¹ Applies to all prodrugs of benzylpenicillin

³ The correction factor was revised at the beginning of 2016

Ingredient	IU/MG	Conversion factor (MG/IU)
Colistin methane sulphonate	12700	0.00008
Dihydrostreptomycin	820	0.00122
Erythromycin	920	0.00109
Gentamicin	620	0.00161
Kanamycin	796	0.00126
Neomycin	755	0.00133
Framycetin	670	0.00149
Oxytetracycline	870	0.00115
Paromomycin	675	0.00148
Polymyxin B	8403	0.00012
Spiramycin	3200	0.00031
Streptomycin	785	0.00127
Tetracycline	982	0.00102
Tobramycin	875	0.00114
Tylosin	1000	0.00100

3. Call for data

Prior to the annual call for data the ESVAC team will update the lists for ATCvet codes and names for each country specific ESVAC sales register (ESVAC Sales Template). A list of new ATCvet codes and names will be provided together with the call.

The ESVAC Data Collection Form contains lists to facilitate that the data are standardised and harmonised prior to the submission.

3.1. Data submission

Data have to be submitted using the ESVAC web application. For countries using the Excel template it is recommended to send the final filled-in Excel template to ESVAC sales team.

4. Filling in the ESVAC Sales Template

4.1. General considerations

The sales data should always be recorded in the country specific ESVAC register (template) provided together with the call for data. For new countries the general ESVAC template should be applied.

In case of combination VMPs, the columns for the INGREDIENT variables have to be filled in for each ingredient in separate columns in the same row.

Enzyme inhibitors such as clavulanic acid are not active ingredients and are not included in the list of ATCvet names of ESVAC and will therefore not be accepted by the ESVAC web system. As it is important to quantify use of e.g. amoxicillin+ clavulanic acid the ATCvet code for the combination with active ingredients should be given (e.g. QJ01CR02 for amoxicillin+ clavulanic acid).

The species column is optional; the purpose is to provide the ESVAC sales team with information for better understanding of the data.

4.2. Comments on the various fields variables

Presentation identifier (ID) (Medicinal Product Package Code Value)

When this information is not available please assign individual value for each package.

The use of a standard and stable Presentation ID, e.g. International Article Number (EAN) (originally European Article Number), might facilitate the traceability of products as well as interaction with other databases (e.g. the EU Veterinary Medicinal Product Database). Furthermore, it enables identification of duplicates.

In case Presentation IDs are not available, these IDs can be derived from other variables. It is recommended to combine the marketing authorisation number (MA), name with the FORM, the PACKSIZE and PACKSIZEU variables. This combination of MA+NAME+FORM+PACKSIZE+PACKSIZEU should be unique per medicinal product package.

Finally in case marketing authorisation numbers are not available, it is recommended to use the line number as Presentation ID. All missing Presentation IDs must be entered without sorting in between to avoid assigning the same ID to two different products.

ATCVET [ATCvet code- 5th LEVEL]

If an ingredient ATCvet code has not been assigned for the VMP/ingredient/combination VMP in question please contact the ESVAC sales team that will ask the WHO Collaborating Centre for Drug Statistics Methodology Norwegian Institute of Public Health (WHO Centre) to provide a code for such products and the data set will be updated by ESVAC sales team when the codes have been assigned.

The ESVAC web system would not allow the upload of a product unless a valid ATCvet code has been assigned (see the user's guide for further information).

INGR _ID [Ingredient Code Value]

If using the macro of the excel template, the INGR_IDs will be assigned automatically by the macro.

If the template is not used or the macro is not used, it is recommended to assign the INGR_ID by concatenating the Presentation ID with the sequence of the ingredient in the medicinal product package separating by a '#', e.g. for a medicinal product package with a presentation ID of "AZE10" containing two ingredients. The first ingredient will be coded "AZE10#1" and the second one "AZE10#2".

INGR [Active Ingredient Name (ATCvet name)]

If an ATCvet name has not been assigned for the VMP please inform the ESVAC project team as soon as possible. When receiving your email the ESVAC project team will ask the WHO Centre to provide the ATCvet name for such ingredients and the ESVAC project team will provide you temporary solution or the correct name when the ATCvet names have been assigned.

CONV FACT IU (Conversion Factor IU) and CONV FACT PRODR (Conversion Factor Prodrug)

These will be recorded automatically by use of a macro designed for the ESVAC Sales Template.

If a Conversion Factor IU or Conversion Factor Prodrug for the ingredient/prodrug in question is not included in the ESVAC Data Collection Form, the ESVAC Sales Team (ESVAC@eu.europa.eu) has to be contacted and will provide the (standardised) value.

5. Validation of the sales data by the national ESVAC NC/data manager prior to submission of data

- Ensure that all data have been submitted by the data providers (wholesaler, pharmacy, industry etc.) by checking if answers have been received from ALL data providers;
- If no sales are reported from any of the data providers or for a VMP presentation ask for a (new) declaration form from the data provider in question in order to avoid errors;
- Check total sales (tonnes) and compare it with previous years;
- Check for likely outliers by identifying extreme values in columns TONS SOLD;
- For outliers compare NO PACKS and TONS SOLD with previous year(s);
- In case of doubt contact the data provider for confirmation;
- If possible check from another source of data.

Once data have been submitted, a report will be provided to you to facilitate such task.

6. ESVAC PCU data

6.1. Animal categories included in PCU

Eurostat, the Statistical Office of the European Union, covers data on numbers and biomass of food-producing animals slaughtered, as well as data on livestock food-producing animals. Therefore, Eurostat is selected as the source⁴ for data on this animal category. In cases where data are not available in Eurostat (e.g. for rabbits), national statistics have to be applied. For horses (food-producing species according to the EU legislation), national statistics provided by the ESVAC national representatives has to be used. As data on dogs and cats are not available in all participating countries, these species were not included in the PCU, in order to have comparable data. Therefore, antimicrobial VMPs approved for use in companion animals only, i.e. tablets, will be excluded from the data sets prior to the normalisation of the sales by the PCU.

Animals exported for fattening or slaughter in another Member State are likely to have been treated with antimicrobial agents in the country of origin, and therefore it is important to correct this for the major species (cattle, pigs, poultry and sheep). However, the Eurostat data on numbers of animals exported or imported for fattening or slaughter are not valid, as these are reported only when above a certain limit, which implies that the Eurostat data represent an underestimate of these for most species and countries. Such data are therefore obtained from TRACES (DG SANCO, European Commission), as these are based on health certificates, which are obligatory for all animals passing any border.

ESVAC sales team will fill in the reference data for the animal categories shown in Table 5 available in Eurostat and TRACES data for the categories available from these data bases. These are the only animal categories that will be accepted by the web system. For categories for which data are not available in Eurostat or TRACES the countries will have to record these values.

⁴ <http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/themes>

EEA countries would have to upload all data as no values are available through Eurostat and TRACES.

Table 5. Animal categories included in the calculation of the population correction unit (PCU) and data types to be reported

Animal category	Numbers/tonnes
Cattle (heads)	
Slaughtered cows	
Slaughtered heifers	
Slaughtered bullocks and bulls	
Slaughtered calves and young cattle	
Import slaughter	
Export slaughter	
Import fatteners	
Export fatteners	
Living dairy cows	
Pigs (heads)	
Slaughtered pigs	
Import slaughter	
Export slaughter	
Import fatteners	
Export fatteners	
Living sows	
Poultry (heads)	
Slaughtered broilers	
Slaughtered turkeys	
Import slaughter	
Export slaughter	
Caprinae (heads)	
Slaughtered sheep and goats	
Import sheep slaughter	
Export sheep slaughter	
Import sheep fatteners	
Export sheep fatteners	
Living sheep	
Import goats slaughter	
Export goats slaughter	
Import goats fatteners	
Export goats fatteners	
Equidae (heads)	
Living horses	
Rabbits (heads)	
Slaughtered rabbits	
Fish (tonnes)	
Biomass live weight	

6.2. Calculation of PCU

Essentially, the PCU for each animal category is calculated by multiplying numbers of livestock animals (dairy cows, sheep, sows and horses) and slaughtered animals (cattle, pigs, lambs, poultry and turkeys) by the theoretical weight at the time most likely for treatment. For animals exported or imported for fattening or slaughter (cattle, pigs and poultry), the PCU is calculated by multiplying the number of animals with a standardised weight (Table 6).

For farmed fish, Eurostat data is given only as live-weight slaughtered, as information on weight at treatment has not been identified; for fish, the PCU is taken as biomass live-weight slaughtered in each country. The PCU of the animals exported for fattening or slaughter in another Member State is added to the PCU of livestock and slaughter animals in the country of origin, because young animals are typically treated more frequently than other age classes; the PCU for animals imported for fattening or slaughter in another Member State was subtracted from the total PCU of livestock and slaughter animals, since it is included in the data on slaughter animals (Eurostat data) and in order to avoid double counting (both in exporting and importing country).

Table 6. Weights used to calculate the population correction unit

Animal category	Weight in kg
Slaughtered or livestock (Eurostat)	
Slaughtered cow	425
Slaughtered heifer	200
Slaughtered bullocks and bulls	425
Slaughtered calves and young cattle	140
Dairy cow	425
Slaughtered pig	65
Living sow	240
Broiler	1
Turkey	6.5
Slaughtered sheep and goats	20
Living sheep	75
Horse	400
Rabbit	1.4
Imported/exported for fattening or slaughter (TRACES data)	
Slaughtered bovine	425
Fattening bovine	140
Slaughtered pig	65
Fattening pig	25
Slaughtered poultry	1
Slaughtered sheep	20
Fattening sheep	20
Slaughtered goat	20
Fattening goat	20

PCU calculation by species, age class and production type

1. Number of animals slaughtered × estimated weight at treatment.
2. Number of livestock × estimated weight at treatment.
3. Number of animals transported (net export) to another country × estimated weight at treatment.

7. Indicator for reporting of the sales data

The main indicator to be applied expressing the sales of veterinary antimicrobials is mg of active ingredient normalised by the population correction unit (mg/PCU):

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

The data will be presented according to the ATCvet hierarchical system, and for combination preparations, each active ingredient will be allocated to the relevant ATCvet code for single substances (e.g. spectinomycin is included in 'Other antibacterials').