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Report on ESVAC trial for collecting data on consumption of antimicrobial agents in pigs

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Summary

The European Commission has requested the European Medicines Agency (EMA) to develop an approach for collection and reporting of data on national sales of antimicrobial agents, as well as to provide an approach to estimate consumption in at least pigs, cattle and poultry. This is implemented by the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) activity. For the estimation of consumption by species it was decided to start by collecting data on antimicrobial consumption in pigs and therefore the required variables needed to be identified and a protocol and templates needed to be developed. These were subsequently tested during a trial carried out in 2014 on a limited number of farrow-to-finish farms from ten volunteer Member States (MSs). This report describes the trial and its results. Experience from this trial will be used to prepare final guidance which will be published for public consultation at a later date.

The main objectives of the trial were to identify:

1. the extent to which the variables required to analyse and report harmonised and standardised data on consumption of antimicrobials (including those given in medicated feed) and the population of pigs on the farm were available;
2. if all required information on treatments with medicated feed could be captured with the proposed variables or if additional variables were required;
3. the applicability of the templates;
4. the feasibility of the proposed system;
5. the structure of the pig industry in the various participating MSs – i.e. numbers and types of farms, such as farrow-to-finish or finisher farms.

The ten volunteer MSs aimed to collect data on all antimicrobial veterinary medicinal products (VMP) administered to pigs in 2013 on a small convenience sample of five farrow-to-finish farms, for the duration of one calendar year, including antimicrobial agents administered in the form of medicated feed. The data were collected from health records/treatment log books, delivery notes, invoices and prescriptions/veterinary practice records. Furthermore, data on the population of pigs on the farm were collected, as well as data to identify the national pig farming structure. The data collection protocol that was tested can be found in Annex 1.

The collected data were entered in two templates provided by ESVAC: the "ESVAC On Farm" template, containing the basic variables to identify the VMPs and quantities used, as well as the treated pig category and the population of pigs on the farm, and the "ESVAC Pig" template which was country-specific and contained in addition to the basic variables also the variables needed to calculate the quantity of active substance consumed. The variables included in the tested templates can be found in Annexes 2 and 3.

Furthermore, the participants were sent a short feasibility survey to identify the (human) resources used to collect and provide the data. The survey can be found in Annex 4.

Data were collected from 46 farms from 10 countries, comprising 5,491 observations equalling 6,749 records. One country could only collect data for the duration of six months. All potential data sources were used by the participating countries to collect data on consumption of antimicrobial VMPs; for 21 farms this was health records/log books, for 9 farms prescriptions/practice records, for 5 farms delivery notes and for 1 farm invoices. For the other 9 farms a combination of sources was used. Data on treatments with medicated feed were mainly collected from prescriptions/practice records. For

99.7% of the records the quantity of active substance consumed could be calculated, and for 78% of the records the pig category treated was clearly identified. However, when stratified per data source, the pig category treated was indicated in 88% of records from health records/log books, 85% from prescriptions/practice records, 2% from delivery notes and 0% from invoices. The preferred data source based on the outcomes of the trial, when needing to record the treated pig category, would therefore be the prescriptions/practice records and treatment records/log books; delivery notes and invoices also contain sufficient information to quantify consumption.

The data on the population of pigs on the farm were not available or only in part for 12 farms, but for 26 farms both the average numbers of pigs present per age category per year and the numbers of pigs produced on the farm were available. For the other 8 farms either the number of pigs produced or the number of pigs present was available. The number of pigs produced could not be provided for some of the farms due to confidentiality reasons or ownership of the data. The numbers of pigs present were not always known for all categories and had to be estimated. Data on the population of pigs on the farm are essential to standardise consumption using an agreed denominator.

Recommendations were made by participants for further refinement of the guidance (including protocol and template), e.g. to address inclusion of extra variables when collecting data for national purposes and to define more precisely the pig age/weight categories used in the ESVAC framework and the calculation of the data on the population of pigs on the farm and the denominator. Recommendations for the template included amongst others to maintain the worksheet on medicated feed, to provide only the "ESVAC Pig" template (to reduce the resources needed to collect and provide the data) and to clarify certain headings.

The feasibility survey showed that the time needed to fill in the templates varied widely; the median for filling in the "ESVAC On Farm" template was 4 hours and for the "ESVAC Pig" template 12 hours. The average time needed to complete 10 observations in the "ESVAC On Farm" template varied between 18 and 371 minutes, with a median of 43 minutes. The average time needed to complete 10 observations in the "ESVAC Pig" template varied between 6 and 277 minutes, with a median of 26 minutes. It appeared from the trial that slightly more time was needed to fill in the "ESVAC On Farm" template when health records/log books were used as data source than prescriptions/practice records, which might be because the former often needed to be copied by hand. There was no apparent difference between collecting data in the form of number of packages sold or in the form of treatment schedules, in terms of time needed. The least resources were needed for data that could be extracted in an automated manner from a continuous data collection system. Participants indicated that with experience the time needed to collect the data decreased and it was further recommended enabling provision of aggregated data which further reduces time needed to fill in the template.

The majority of pig farms in the participating countries were of the farrow-to-finish, farrow-to-wean and wean-to-finish types. In order to collect sufficient data to represent the pig farms within a country it was recommended by participants to include farrow-to-finish farms as well as farrow-to-wean and wean-to-finish farms in the data collection. Lastly it was recommended, when collecting data from a sample of farms, to stratify the farms in a country based on size (and if necessary on farm type) and to select farms distributed in a representative manner over the small, medium and large size groups.

In conclusion, the trial has shown that it is possible for ESVAC to define those parameters that need to be measured per farm for antimicrobial consumption to be measured in standardised units, by means of either on-farm data collection or use of data on veterinary prescriptions. For ESVAC purposes, collecting harmonised data by species (at farm level) is initially sufficient to analyse trends of antimicrobial consumption in pigs at an EU level. Collecting data by production stage increases considerably the complexity of data collection systems, making it potentially not feasible for many

MSs, but it also provides for a more detailed understanding of antimicrobial use in the pig sector, could have considerable benefit at national level and might be collected by ESVAC at a later stage.

Collecting data on the population of pigs on the farm proved to be challenging and highlighted the need for further discussion in order to agree on a harmonised denominator. The two options for establishing a denominator as provided by the tested protocol both have advantages and draw backs. More experience and in depth reflection is required before ESVAC can be in a position to propose a definitive, harmonised denominator for use at EU level.

The next step for ESVAC in collaboration with the ESVAC species expert advisory group[1] will be to review and decide how best to apply the lessons learnt from this trial. A revised guidance including a protocol and template will be published and discussions initiated within Member States and with the European Commission as to how this guidance could form the basis for collection of harmonised and standardised data throughout the EU.

[1] http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2016/04/WC500204522.pdf

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Terms and abbreviations

- ATCvet: Anatomical Therapeutic Chemical classification system for veterinary medicinal products
- Consumption: purchased, delivered, prescribed or administered amounts of antimicrobials
- DCDvet: defined course dose for animals
- DDDvet: defined daily dose for animals
- EMA: European Medicines Agency
- EU/EEA: European Union/European Economic Area
- ESVAC: European Surveillance of Veterinary Antimicrobial Consumption
- MS: Member State
- Observation (obs): line in a data set containing information as collected on a farm or from a veterinarian corresponding to one treatment or a group of treatments of one or more pigs with an antimicrobial VMP or medicated feed
- Record: contains information on consumption on one farm of one active substance in a VMP or medicated feed; since this term is used per substance in a VMP an observation of a treatment with a combination VMP results in multiple records, i.e. one for each active substance in the VMP
- SPC: Summary of Product Characteristics of a VMP
- VMP: Veterinary Medicinal Product

1. Introduction

1.1. Background

The European Commission has requested the European Medicines Agency (EMA) to develop an approach for the collection and reporting of harmonised and standardised data on the use of antimicrobial agents based on national sales figures, as well as estimates of consumption in at least the major groups of animal species (i.e. pigs, cattle and poultry). This is implemented by the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) activity. The ESVAC activity collects data on sales of antimicrobial agents from the European Union/European Economic Area (EU/EEA) countries and these data are published in annual ESVAC reports, at national and EU level[2]. However, detailed data on the use of antimicrobial agents per animal species are needed to provide further insight.

Information on use provided at farm level leads to a better understanding of the exposure of animals to antimicrobial agents. Collecting data from the end user will give results closest to actual consumption per species and it will enable reporting of consumption by weight group or production stage, as recommended by the 'Revised ESVAC reflection paper on collecting data on consumption of antimicrobial agents per animal species, on technical units of measurement and indicators for reporting consumption of antimicrobial agents in animals'[3] (hereafter referred to as the Reflection paper). Such data can subsequently be analysed and reported by use of defined daily doses for animals (DDDvet) and defined course doses for animals (DCDvet)[4], as established by EMA, and the appropriate denominator.

To collect harmonised and standardised data per species, the required variables needed to be identified and a system had to be developed. Therefore, a draft protocol and templates were developed following the recommendations in the Reflection paper (see Annexes 1-3) and subsequently tested by running a trial on a limited number of farms, collecting data from the farms or the prescribing veterinarian. Ten Member States (MSs) from among the ESVAC network volunteered to take part in the trial in 2014. These MSs were Belgium, Czech Republic, Finland, France, Germany, Italy, Netherlands, Slovakia, Spain and United Kingdom. The aim was to collect 2013 data from five farrow-to-finish farms per country, which was regarded as sufficient for the purposes of the trial.

1.2. Objectives

The trial was performed to test the proposed system (i.e. protocol and templates) for collecting data on antimicrobial consumption in pigs. The trial and its results are described in this report. Experience from this trial will be used to prepare guidance, including protocol and templates, which will be published for public consultation on the Agency's website at a later date. The final guidance will be published on the Agency's website to clarify which minimum required variables need to be collected in the case of a future data collection in the framework of the ESVAC activity and to provide guidance to countries wishing to set up a national data collection system.

[2] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp&mid=WC0b01ac0580153a00
[3] http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/12/WC500136456.pdf
[4] http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/06/WC500188890.pdf

The main objectives of the trial were to identify:

1. the extent to which the variables required to analyse and report harmonised and standardised data on consumption of antimicrobials (including those given in medicated feed) and population of pigs on the farm were available;
2. if all required information on treatments with medicated feed could be captured with the proposed variables or if additional variables were required;
3. the applicability of the templates;
4. the feasibility of the proposed system;
5. the structure of the pig industry in the various participating MSs – i.e. numbers and types of farms, such as farrow-to-finish or finisher farms.

2. Technical notes

2.1. Data collection protocol

The protocol followed during the trial can be found in Annex 1. The ten volunteer MSs aimed to collect data on all antimicrobials (see Annex 1, Table 1) administered to pigs on a small convenience sample of five farrow-to-finish farms, for the duration of one calendar year. This also included antimicrobial agents administered in the form of medicated feed. Data on treatments with zinc oxide were also collected, where possible, in the same manner as those on antimicrobial veterinary medicinal products (VMPs) or medicated feed. Furthermore, data on the population of pigs on the farm were collected, as well as data to identify the national pig farming structure.

The data were collected from health records/treatment log books, delivery notes, invoices and prescriptions/veterinary practice records, based on what was the appropriate (combination of) data source(s) for each farm and country. Countries with an automated continuous data collection system in place were asked to extract the data from their system and provide it to ESVAC in the data collection template. The other countries followed a cross-sectional retrospective data collection approach.

2.2. Data collection templates

The volunteer countries were provided with two templates:

1. the "ESVAC On Farm" template, which was a template that could be printed and used for collecting data when visiting the farms. The template contained the minimum variables needed to identify the VMPs, including medicated feed, the quantities of the VMP used, the treated pig categories and the population of pigs on the farm (see Annex 2);
2. the "ESVAC Pig" template, which was a country-specific template based on the ESVAC sales register and used to provide the complete and final trial data to ESVAC. This template contained the same variables as the "ESVAC On Farm" template, as well as the additional variables (content of active substance per package, conversion factors, etc.) needed to calculate the amount of active substance consumed per observation (see Annex 3).

The "ESVAC On Farm" and "ESVAC Pig" templates offered two ways in which consumption data could be reported: either as the number of packages of the VMP sold/prescribed for the observation or as the treatment schedule applied for the observation. The minimum required variables on consumption of VMPs, to be collected from the farm to calculate consumption of active substance at a later stage, for the two consumption data types are listed in Table 1.

Since it was unclear before the trial if all required information on treatments with medicated feed could be captured with similar variables as those used for treatments with antimicrobial VMPs (see Table 1), a separate worksheet was added to the templates to identify which variables on consumption of medicated feed needed to be collected in order to calculate consumption of active substance at a later stage. The tentative variables tested during the trial are listed in Table 2.

Table 1. Minimum required variables as tested during the trial for establishing consumption of antimicrobial VMPs

Situation	Required variables for recording consumption of VMP
Common data for all observations	• Category of pig treated (e.g. sucking piglets, finishers) • Name of VMP • Package size (e.g. 100 ml, 1 kg) • Name(s) of active substance(s) • Strength of active substance(s) (e.g. 500 mg/g, 100 g/l)
Additional data when consumption data is given as treatment schedule applied	• Number of animals treated • Dose of VMP per administration (e.g. 5 mg/kg body weight[a], 20 ml/animal) • Number of administrations of VMP per day • Number of days the VMP is administered
Additional data when consumption data is given as number of packages prescribed/delivered	• Number of packages

[a] In this case the standardised weight at treatment was used as established in the Reflection paper.

Table 2. Tentative variables as tested during the trial for establishing consumption of antimicrobials administered in the form of medicated feed

Situation	Required variables for recording consumption of medicated feed
Common data for all observations	• Category of pig treated (e.g. sucking piglets, finishers) • Name of VMP • Name(s) of active substance(s) • Strength of active substance(s) (e.g. 500 mg/g, 100 g/kg) • Indicator for determining if quantities given are for premix or medicated feed • Concentration (e.g. 300 ppm, 5 kg/1000 kg) • Quantity of total product (e.g. 30 kg, 3000 kg)
Optional	• Free text field (to be used if consumption of medicated feed cannot be captured with variables listed above)

2.3. Feasibility survey

A short feasibility survey was provided to the representatives of the volunteer countries, which aimed to collect data on resources used for the data collection:

- the number and job title of investigators involved in collecting data on the farms or from veterinarians;
- the amount of time per farm included in the trial spent by investigators collecting data on the farms or from veterinarians;
- the number and job title of data managers involved for collating the data and providing the data to ESVAC;
- the amount of time spent by data managers to collate data and provide data to ESVAC.

The full questionnaire can be found in Annex 4.

3. Trial results

3.1. Availability of required variables

3.1.1. Sources and required variables for data on consumption (numerator)

The protocol and templates provided two options for collecting antimicrobial consumption data, namely the applied treatment schedule or the number of packages sold/prescribed, see Chapter 2.2. During the trial a third option of consumption data was identified: the total amount of a VMP used in the observation (e.g. 12 ml, 100 g).

Table 3 shows an overview of the data types and data sources for the consumption data and the availability of data on the population of pigs on the farm, as used and collected by the volunteering MSs during the trial. On 36 (of 46) farms only one data source was used to collect all VMP consumption data; for 21 farms this data source was health records/treatment log books, for 9 farms the prescriptions/veterinary practice records, for 5 farms the delivery notes and for 1 farm the invoices. For the other 9 farms data from prescriptions/practice records were supplemented with data from either the health records/log books or delivery notes. For 1 farm the data source was unknown as there was no antimicrobial consumption reported on this farm.

For six countries the representatives collected data on medicated feed in a separate 'medicated feed' worksheet. For one of these countries, observations with premixes were also included in the consumption worksheet, but there was no overlap between observations in the medicated feed worksheet and observations in the VMP consumption worksheet. Data on medicated feed were collected from prescriptions/practice records for 7 farms, and from delivery notes (2 farms), health records/log books (2 farms) or a combination of these sources (5 farms). For the other four countries premixes were either recorded solely as VMPs or no medicated feed was used.

All required variables could be collected from all sources to calculate the quantity of active substance used, but the treated pig category was not available from invoices and rarely available from delivery notes.

Participants specifically indicated that treatment log books as data source (filled in by the veterinarian) was resource consuming as the data needed to be manually copied and typed into the template. Advantages mentioned of this data source included that the data contained information on the farm, as well as indications for treatment, the dose applied and the category of pigs treated.

For medicated feed, it was indicated by one participant that delivery notes were more accurate than prescriptions in terms of quantity used (prescriptions overestimated consumption), but they were not always available and did not always contain the required data on the treated pigs. This participant also indicated that prescriptions for medicated feed not always contained information on the unit of the quantity of product prescribed.

Table 3. Type of study, data sources and type of consumption data and data on the population of pigs on the farm (number of farms in brackets denotes the number of farms the information applies to)

MS	Type of study	Total number of farms included	Data source consumption VMPs	Data type consumption VMPs	Data source medicated feed	Available pig farm population data
Belgium (BE)	Cross-sectional	2 farms	• Prescriptions/ practice records (1 farm) • No consumption recorded (1 farm[a])	• Number of packages (1 farm) • No consumption recorded (1 farm)	• Prescriptions/ practice records (1 farm) • No consumption recorded (1 farm)	• Average number of pigs present and number of slaughter pigs produced (1 farm) • Data partly available on average number of pigs present (1 farm)
Czech Republic (CZ)	Cross-sectional	4 farms	• Health records/log book (4 farms)	• Treatment schedule (4 farms)	• Prescriptions for medicated feed (3 farms) • No medicated feed recorded (1 farm)	• Data partly available on average number of pigs present (4 farms)
Finland[b] (FI)	Automated	5 farms	• Health records/log book (5 farms)	• Treatment schedule (5 farms)	• Not applicable[c]	• Average number of pigs present and number of slaughter pigs produced (4 farms) • Average number of pigs present (1 farm)

MS	Type of study	Total number of farms included	Data source consumption VMPs	Data type consumption VMPs	Data source medicated feed	Available pig farm population data
France (FR)	Cross-sectional	5 farms	• Prescriptions/ practice records (2 farms) • Prescriptions/ practice records and delivery notes (3 farms)	• Number of packages (5 farms)	• Delivery notes (2 farms) • No medicated feed recorded (3 farms)	• Average number of pigs present and number of slaughter pigs produced (1 farm) • Number of slaughter pigs produced (4 farms)
Germany[d] (DE)	Cross-sectional	5 farms	• Prescriptions/ practice records (5 farms)	• Number of packages (5 farms)	• Not applicable[c]	• Average number of pigs present (3 farms) • Data partly available on average number of pigs present (2 farms)
Italy (IT)	Cross-sectional	5 farms	• Prescriptions/ practice records and delivery notes (5 farms)	• Number of packages (5 farms)	• Prescriptions/ practice records and delivery notes (5 farms)	• Average number of pigs present and number of slaughter pigs produced (5 farms[e])
Netherlands (NL)	Automated	5 farms	• Delivery notes (5 farms)	• Number of packages (5 farms)	• Not applicable[c]	• Average number of pigs present partly available (5 farms)
Slovakia (SK)	Cross-sectional	5 farms	• Health records/log books (5 farms)	• Treatment schedule (5 farms)	• Not applicable[c]	• Average number of pigs present and number of slaughter pigs produced (5 farms)

MS	Type of study	Total number of farms included	Data source consumption VMPs	Data type consumption VMPs	Data source medicated feed	Available pig farm population data
Spain (ES)	Cross-sectional	5 farms	• Prescriptions/ practice records (1 farm) • Health records/log books (2 farms) • Invoices (1 farm) • Prescriptions/ practice records and health records/log book (1 farm)	• Number of packages (5 farms)	• Prescriptions/ practice records (1 farm) • Health records/log books (2 farms) • No medicated feed recorded (2 farms)	• Average number of pigs present and number of slaughter pigs produced (5 farms)
United Kingdom (UK)	Cross-sectional	5 farms	• Health records/log books (5 farms)	• Treatment schedule (2 farms) • Treatment schedule and total amount of VMP (1 farm) • Number of packages and treatment schedule (2 farms)	• Prescriptions/ practice records (2 farms) • No medicated feed recorded (3 farms)	• Average number of pigs present and number of slaughter pigs produced (5 farms[f])

[a] One farm did not have antimicrobial consumption during the data collection period; [b] Data collection period: 6 months; [c] No medicated feed used/premixes are recorded as VMP; [d] Data were collected from 2014; [e] One farm farrow-to-finish type, other 4 farms specialised types of which 2 farms did not produce slaughter pigs; [f] One farm did not produce slaughter pigs during the data collection period.

3.1.2. Descriptive characteristics of collected data and data quality control

The statistical program R[5] was used to manage and analyse the data. In total, data were collected on 46 farms from 10 countries and comprised 5,131 observations on one or more treatments with antimicrobial VMPs and 360 observations on treatments with medicated feed. One country could only collect data for the duration of six months. The number of observations per farm varied greatly between farms and between countries (Table 4) which reflects the variation in the way data are recorded and collected and the variation in amount of data collected per country. For example, when collecting number of packages sold, two observations may have been entered for a single treatment if a 2 litre presentation and a 1 litre presentation of the VMP had to be sold to obtain the desired amount for the total treatment (3 litre of the VMP). On the other hand, when delivery notes or invoices were used, several treatments could be combined into one observation reporting the total number of packages sold in a certain period. Therefore, the number of observations does not reflect the consumption on a farm.

Table 4. Average and range of number of observations per farm per country (note that this does not reflect number of treatments nor consumption per farm per country)

MS	Average number observations per farm (range) on VMPs	Average number observations per farm (range) on medicated feed	Average total number observations per farm (range)
BE	13 (0 – 25)	11 (0 – 21)	23 (0 – 46)
CZ	530 (408 – 725)	34 (0 – 104)	563 (410 – 753)
FI	139 (31 – 350)[b]	Not applicable[a]	139 (31 – 350)[b]
FR	11 (8 – 16)	1 (0 – 2)	12 (8 – 16)
DE	34 (7 – 76)	Not applicable[a]	34 (7 – 76)
IT	6 (2 – 12)	4 (1 – 9)	10 (5 – 13)
NL	126 (94 – 165)	Not applicable[a]	126 (94 – 165)
SK	80 (11 – 253)	Not applicable[a]	80 (11 – 253)
ES	21 (1 – 48)	25 (0 – 107)	47 (11 – 155)
UK	180 (18 – 417)	11 (0 – 45)	191 (18 – 417)
Sample population	*112 (0 – 725)*	*14 (0 – 107)*	*119 (0 – 753)*

[a] No medicated feed used/premixes were recorded as VMP; [b] Data collected for period of 6 months.

All observations were quality controlled by ESVAC for missing values for therapeutical form (none missing), package size (13 observations), active substance (13 observations), strength of active substance (18 observations) and content of active substance per package (27 observations). Where available from the Summary of Product Characteristics or ESVAC sales register, the missing values were filled in by ESVAC but package size was only filled in when the particular VMP was only available in one size.

All data sources generally provided the data required to calculate the quantity of active substance used in the observation for treatments with antimicrobial VMPs or medicated feed. After completing missing values where possible, no quantity could be calculated for 19 observations from 6 farms from 3 countries because for example the number of treated animals or packages delivered was missing or the content of active substance per package was unknown; see Table 5 for a breakdown of the reasons why consumption could not be calculated. For a further 1,080 observations from 15 farms from

[5] R Core Team (2013). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. ISBN 3-900051-07-0, URL http://www.R-project.org/

7 countries the pig category treated was unknown or not according to the categories defined in the protocol.

Because the data were collected primarily to test the data collection system (protocol and templates), no further quality control (e.g. identification of extreme/unreasonable values for number of packages, dosing or treatment days) of the data was performed.

The 5,491 observations collected from the ten countries included observations on combination products (i.e. products containing more than one active substance) and therefore equalled 6,749 records on consumption of one active substance on a farm. Overall, for 6,730 (99.7%) records the quantity consumed could be calculated. For 5,245 (78%) records the pig category treated was indicated as either sows/boars, sucking piglets, weaners, finishers or gilts. Indication of the pig category treated as defined in the protocol was given for 85% of records based on prescriptions/practice records, 88% of records based on health records/treatment log books, 2% of records based on delivery notes and none of the records based on invoices.

In total, for 26 farms from 7 countries all observations were completely filled in terms of variables on consumption (including pig category treated) as requested during the trial; for two countries this comprised all farms.

Table 5. Number, reason and data source of observations (obs) per farm for which consumption could not be calculated

MS	Number of observations per farm (total for farm)	Reason	Data source
CZ	1 (410)	• Number of treated animals missing (1 obs)	• Health records/log book
DE	1 (76)	• Number of packages prescribed/delivered unknown (1 obs)	• Prescriptions/practice records
ES	1 (19)	• Therapeutical form spray/pig category, strength and content of active substance missing (1 obs)	• Prescriptions/practice records
ES	9 (35)	• Active substance unknown (2 obs) • Package size and content of active substance missing (4 obs) • Therapeutical form spray/strength and content active substance missing (2 obs) • Number of packages prescribed/delivered unknown (1 obs)	• Health records/log book • Prescriptions/practice records
ES	5 (155)	• Package size/content of active substance missing (5 obs)	• Health records/log book

MS	Number of observations per farm (total for farm)	Reason	Data source
ES	2 (11)	• Therapeutical form spray/package size, strength and content of active substance missing (2 obs)	• Health records/log book

3.1.3. Farm population data (denominator)

Neither of the options for the farm population data (number of slaughter pigs produced or average number of pigs present per year per pig category) was available for all farms included in the trial. In Table 3 an overview is given of the availability of each option of the farm population data in the trial. For 4 countries all population data requested was available for all farms (20 farms in total). For a further 3 countries all requested data was available for part of the farms (6 farms). For 4 farms from 1 country only the number of slaughter pigs produced was available and for 4 farms from 2 countries only complete data on the average number of pigs present per day was available. For 12 farms (from 4 countries) data on the population of pigs on the farm was partly available for the variables requested in the trial.

One farm included in the trial did not produce slaughter pigs during the data collection period, and two other farms produced piglets that were sold to other farms for fattening. For some farms the data on the number of slaughter pigs produced were not available due to confidentiality reasons or because the data needed to come from a different source and were not available for the trial specifically. For one country the requested data were not included as such in the automated continuous data collection system at the time of the trial. Those data could therefore only in part be extracted from their existing database.

It was indicated by some participants that the average numbers of pigs present per category were not recorded as such by the farmers or other sources and had to be calculated, resulting in estimated numbers. Also, for one country pig farm population data were given as a range.

3.2. Applicability of templates

Both the "ESVAC On Farm" and the "ESVAC Pig" templates were generally found applicable when the participating country applied a cross-sectional data collection. For one country that extracted data from their automated continuous data collection system, multiplication of data occurred when populating the "ESVAC Pig" template, especially in the case of combination VMPs. However, it was indicated that filling in both the "ESVAC On Farm" template and the "ESVAC Pig" template was very time consuming and updates to the templates have been suggested, see Chapter 4.

Hard copy versions of the "ESVAC On Farm" template were only used at least two countries; in four countries laptops were brought to the farms. Other options applied for collecting the data were using the inventories of the prescribers/sellers and to make photocopies and photos of the log books on the farm. It is unknown whether the data collected in these ways were directly entered into the "ESVAC Pig" template or first entered into the "ESVAC On Farm" template and subsequently transferred to the other template.

3.3. Feasibility of the data collection system

One representative indicated that it was difficult to convince farmers to participate.

Analysis of the results from the feasibility survey showed that the time needed to fill in the "ESVAC On Farm" template varied widely, ranging overall from 0.5 to 80 hours per farm with a median of 4 hours (see Table 6). The average time needed to complete ten observations in this template varied between countries from 18 to 371 minutes, with a median of 43 minutes. Per country, between 1 and 5 investigators collected data per farm; including veterinarians, epidemiologists, technicians/zootechnicians/managers, veterinary inspectors, data managers, administrative officers/assistants and scientific officers.

Table 6. Resources needed for filling in the "ESVAC On Farm" and "ESVAC Pig" templates in the participating countries

MS	"ESVAC On Farm" template			"ESVAC Pig" template		
	Number of investigators per farm collecting data on farms	**Avg. time (hour) spent filling template (range)**	**Avg. time (min.) spent per 10 observations**	**Number of data managers**	**Time (hour) spent filling template**	**Avg. time (min.) spent per 10 observations**
BE	1	2.8 (0.5 – 5)	72	1	12	157
CZ	3	20 (unknown)[a]	21	2	40	11
FI	NA	NA	NA	3	20	17
FR	2	0.9 (0.8 – 1.1)	43	1	4.5	44
DE	1	1 (1 – 1)	18	1	5	18
IT	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
NL	NA	NA	NA	1	6	6
SK	3 – 5	49 (10 – 80)	371	1	184	277
ES	4	2 (1.2 – 4.1)	26	1	10	26
UK	2 – 4	13.6 (4 – 19)	43	5	75	47

Avg.: average; min: minute; NA: not applicable; [a] potential overestimation as data other than required for trial were collected simultaneously.

The data managers spent between 4.5 and 184 hours filling in the "ESVAC Pig" template, with a median of 12 hours (see Table 6). The average time needed to complete ten observations varied from 6 to 277 minutes, with a median of 26 minutes. Per country 1 to 5 data managers completed the template. The data managers included veterinarians, data advisors, (veterinary) epidemiologists, pharmacists, veterinary inspectors, data managers, project managers and scientific officers. It was not clear from the survey whether the data managers were also the investigators collecting the data on the farms or from the veterinarians.

For one of the countries with an automated continuous data collection system in place it was possible to extract most of the required data from their database; this country spent the least resources on filling in the "ESVAC Pig" template: 6 minutes per ten observations. The representative for the other country with an automated continuous data collection system in place could not extract the required data in an automated manner and therefore needed to manually copy the data from the national database into the template, which lead to similar resources needed as the countries following a cross-sectional approach (17 minutes per ten observations).

The three countries that mainly used health records/log books as a data source in a cross-sectional approach appeared to need slightly more time on average to fill in ten observations in the "ESVAC On Farm" template (21, 43 and 371 minutes) than the three countries that mainly used prescriptions/practice records as a data source in a cross-sectional approach (18, 43 and 72 minutes). There did not appear to be a difference when consumption was recorded as number of packages or as treatment schedule.

3.4. Structure of pig industry

Information on the number and type of farms in their country was provided by representatives for nine countries. For the majority of these countries, the highest proportion of farms was accounted for by wean-to-finish farms, followed by farrow-to-finish farms and farrow-to-wean farms. Other types mentioned were weaner farms, finisher farms, farrowing farms, breeding farms and family owned farms. The exact number of farms per type per country depends on the exclusion criteria applied and the source of the data; furthermore it was mentioned that not all farms could be typed in all countries.

4. Outcomes and recommendations following the trial

This report describes the trial of the system developed to collect data on antimicrobial consumption on pig farms. The collected consumption data were analysed to fulfil the objectives of the trial but the results are not presented in this report as this was not one of the objectives and the data were not representative because of the limited number of farms.

4.1. Availability of required variables

The trial showed that the four data sources as proposed by ESVAC (prescriptions/veterinary practice records, deliveries, invoices and health records/treatment log books) have all been used by the volunteer countries, although invoices were rarely used or available as data source. Prescriptions/practice records and health records/log books were preferred over invoices or delivery notes, but the latter two sources were sufficient to give information on the total amount of antimicrobials consumed. For nearly all observations in the data (>99%), the amount of active substance consumed could be calculated or estimated (if based on treatment schedule). However, the pig category treated as requested in the trial was not available in 98% of records from delivery notes and in none of the records from invoices, which reflects that delivery notes or invoices did not usually allow for exact identification of the categories as requested for the trial at the time of the trial. These figures were 15% and 12% for records from prescriptions/practice records and health records/log books, respectively. These outcomes of the trial confirm that the preferred data source when needing to record the treated pig category would be the prescriptions/practice records and health records/treatment log books.

In contrast, collecting data on the population of pigs on the farm (number of slaughter pigs produced and average number of pigs present during the calendar year) proved to be problematic. This is important as the pig farm population data are essential to standardise consumption using an agreed denominator. The trial results (Table 3) showed that for the majority of the participating countries, in general the number of pigs produced on the farm was available. Reasons why the number of slaughter pigs produced could not be provided for some of the farms included confidentiality and ownership of the data. Furthermore, based on the observation that some of the numbers appeared to have been rounded, it appeared that in more cases the numbers provided were estimations, which was confirmed by some participants.

It was recommended by participants that for national purposes countries could collect additional data, e.g. indication for treatment, or simultaneously collect samples for antimicrobial resistance testing. Moreover, ESVAC uses standardised weight at treatment and standardised feed and water intake per pig category, as established by ESVAC, to estimate the consumption based on treatment schedule. It was suggested to add to the guidance that countries may consider adapting these weights or intakes to better reflect the national situation when collecting and reporting data for national purposes.

Other recommendations from participants for further refinement of the guidance were:

- Define more precisely the pig age/weight categories used in the ESVAC framework;
- Consider excluding farms from the data collection if the required data on pig farm population cannot be collected, as in that case a denominator could not be established for these farms;
- Define precisely how to calculate the data on the population of pigs on the farm (e.g. number of pigs produced or average number of pigs present) and the denominator.

4.2. Applicability of templates

During the trial, both the electronic and printed version of the "ESVAC On Farm" template were used, as not in all cases the data collectors had the possibility to bring the laptop into the farm. However, it was recommended after the trial to either find a way in which data entered in the "ESVAC On Farm" template directly transfers to the "ESVAC Pig" template, to avoid having to enter the data twice, or to discard the "ESVAC On Farm" template in favour of only providing the "ESVAC Pig" template. The latter option would also ensure clarity on the variables that would need to be collected in the framework of the ESVAC activity.

It appears from the trial that the worksheet on medicated feed should be maintained in the template since some of the required variables for collecting data on treatments with medicated feed are substantially different from the variables required to collect data on treatments with antimicrobials administered using other pharmaceutical forms, including premixes.

The following specific recommendations were made by participants for revision of the templates:

- Add a variable for the number of weaner pigs produced on the farm during the calendar year;
- Add a variable for the total amount of VMP consumed during the observation/treatment (e.g. 250 ml, 10 g), as an additional form of consumption data (besides the treatment schedule and number of packages);
- Add variables for medicated feed that included more than one active substance (e.g. name and strength of second substance);
- Add variables enabling a distinction between the strength of the active substance(s) in the premix or medicated feed and the concentration of the premix in the feed;
- Provide additional units in the drop-down lists, such as ppm and % (in addition to mg/kg, IU/kg, etc.);
- Clarify headings in the template;
- Group variables on the VMPs together to make filling in the template easier.

4.3. Feasibility of the data collection system

Collecting data on antimicrobial consumption at farm level is highly (human) resource demanding, which was also shown by the feasibility survey conducted during the trial. The MS spending the most resources collected all data manually. The amount of time spent collecting data may also depend on the size of the farm (more pigs may lead to more treatments) and thus also on the structure of the pig industry in the country. Other factors influencing the resources needed are related to the data collected, such as the route of administration most frequently used on the farm (depending on the type of data treatments with injectable products could be recorded as multiple observations each on one animal, whereas an orally administered group treatment could be recorded as one observation) or how data are recorded (e.g. each treatment as one record of the treatment schedule, or the number of packages delivered covering multiple treatments in one record).

It was, however, also indicated that with experience the time needed to collect the data decreased, and allowing for provision of aggregated data will also help reducing the time needed to fill in the template from which the consumption can be calculated. Aggregation of data reported in the framework of the ESVAC activity, i.e. all treatments with one product within a farm can be summarized and reported in one observation, substantially reduced the average number of observations per farm

from 112 (ranging from 0 – 725) to 9 (0 – 25) for the observations on VMPs and from 14 (0 – 107) to 2 (0 – 8) for observations on medicated feed. At national level it may, however, be preferable to collect the raw data, as this allows for data validation and quality check (accuracy and completeness of data), as well as ensuring a harmonised approach on the analysis and reporting of the data.

The feasibility survey also showed that it is much less resource demanding to collect these data in those MSs that have automated data collection systems; completing the "ESVAC Pig" template took on average 13 hours for countries with an automated system, and 47 hours for countries where data collection on farms or from veterinarians was necessary. Decreasing the level of manual data entry will also decrease the risk of errors. Substantial resources will have to be invested during the creation of an automated continuous data collection system, but in the longer term many benefits can be obtained from such automated systems.

In general it was suggested to simplify the collection of data as much as possible, also in order to reduce resources needed to collect the data as much as possible. Other recommendations from the participants were:

- Contact the farmer or veterinarian of the selected farms beforehand and ask them to prepare the data collection by having the requested information available;
- Ask permission for a printed or electronic copy of all entries of the electronic version of the treatment log book, if present, or ask permission to scan or take photos of the documents.

4.4. Structure of pig industry

For the trial it was decided to collect data from farrow-to-finish farms. Yet, the pig industry has become more specialized, leading to fewer farrow-to-finish farms and these might not be considered representative for pig farms in general in some of the countries. It can, however, be concluded from data provided on the national pig structure by the countries volunteering in the trial that farrow-to-finish farms still form a very large group of the pig farms in a country, together with farrow-to-wean and wean-to-finish farms.

The following recommendations were made by participants regarding the farms to be included in the data collection, in cases where MSs collect data from a (representative) sample of farms:

- In order to collect sufficient data to represent the pig farms within a country, include farrow-to-finish farms as well as other farm types such as farrow-to-wean and wean-to-finish;
- Provide guidance on establishing the representative sample of farms per country (and if necessary per farm type in a country) when data cannot be collected from all farms;
- Select farms, where possible, distributed in a representative manner over the small, medium and large size groups, based on a stratification of the farm size in the country.

5. Concluding remarks

The main conclusions as drawn by ESVAC experts on the trial of the system for collection of data from pig farms or veterinarians in terms of the future collection and use of consumption data for pigs by ESVAC are as follows:

- The trial has shown that it is possible for ESVAC to define those parameters that need to be measured per farm for antimicrobial consumption to be measured in standardised units per pig category per unit of production (either number of pigs on the farm or number of pigs produced) by means of either on-farm data collection or use of data on veterinary prescriptions;
- Collecting data on the population of pigs per farm proved to be challenging and highlighted the need for further discussion in order to agree on a harmonised denominator. The protocol provided two options for establishing a denominator, either based on the number of pigs produced or on the number of pigs present on the farm. Both denominators have advantages and draw backs. More experience and in depth reflection was required before ESVAC could be in a position to propose a definitive, harmonised denominator for use at EU level.

Other conclusions are:

- Data can be collected by species and by farm type. Collection of consumption data per production stage (i.e. pig category) provides additional data but increases considerably the complexity of the data collection system, making it potentially not feasible for many MSs.
- For ESVAC purposes, collecting harmonised data by species (at farm level) is initially sufficient to analyse trends of antimicrobial consumption in pigs at an EU level. Collecting data by production stage provides for a more detailed understanding of antimicrobial use in the pig sector, would have considerable benefit at national level and might be collected by ESVAC at a later stage.
- For countries where an automated continuous data collection system is not (yet) implemented, and where therefore collection of data from all farms may not be a short term option, a suitable sampling design to select the sample of farms from which to collect data was identified as a critical need, including the establishment of a representative sample size.
- Due to the high volume and the heterogeneity of the raw data at farm level, there would be a need for MSs to aggregate the data provided to ESVAC. To ensure the quality and completeness of the aggregated data provided, ESVAC will further analyse the level at which aggregation should take place.
- It is not possible to suggest to all MSs to use one particular data source (e.g. prescriptions or treatment log books) or even one form of consumption data (e.g. number of packages or treatment schedule). However, despite the heterogeneity in consumption data, for analysing and reporting harmonised data at EU level that is comparable between MSs, the MSs should ensure that the actual amount of active substance consumed by production stage or farm and the denominator are calculated according to standardised ESVAC methodology.

The main conclusions as drawn by ESVAC for the purposes of those compiling the data at MS level are as follows:

- In some countries, the collection of antimicrobial consumption data cannot be based exclusively on farrow-to-finish farms. Due to differences in the pig farming structure between countries, limiting data collection to this type of farm would not be representative of the pig farming industry in some countries.

- Collecting antimicrobial consumption data at farm level is complicated and highly resource demanding, but collecting aggregated data per farm should reduce the resources needed. Furthermore, providing data to ESVAC which is derived from (aggregated) farm-level data and then aggregated further at MS level should reduce the resources needed by the MS to provide the data to ESVAC and by ESVAC to collate, analyse and report those data.
- Due to the complexity of the data collected, quality control of the data collected at both farm and national level should be established.
- From the current activities by Member States on collecting antimicrobial use data, it seems that the collection of continuous data from e.g. (electronic) veterinary or farm records is preferred over cross-sectional studies from farms. The development of a system to collect these records requires a substantial investment in the first instance and it takes time until such systems function fully effectively, but once established there are many benefits attached to it.

The further process (next steps):

- The trial is only the first step in developing standardised and harmonised measurement of consumption per species at European level. Having established how to measure consumption per farm, the next step would be either to replicate this for all pig farms throughout a Member State or to stratify the pig population by farm type (and potentially farm size), measure consumption in a statistically representative sample per stratum and then extrapolate to the entire population.
- This is a very large scale undertaking that would require detailed analysis per Member State to devise and carry out the necessary programme of data collection, analysis, validation and reporting.
- The next step for the ESVAC expert advisory group will be to review and decide how best to apply the lessons learnt from this trial. A revised guidance including a protocol and template will be published and discussions initiated within Member States and with the European Commission as to how this guidance could form the basis for collection of harmonised and standardised data throughout the EU. The ultimate objective is that the data will be collated by ESVAC for subsequent analyses and reporting of trends in use of antimicrobials per species over time, with the aim that the data eventually allow for an integrated analysis with data on use of antimicrobials in humans, and on resistance in animals, humans and food.

Annex 1 – Protocol as tested in trial "ESVAC test of system for collecting data on consumption of antimicrobial agents in pigs"

Note: this annex contains the protocol which was tested in the trial. This protocol will be revised where needed and should not be interpreted as the guidance provided by the Agency. The final guidance will be published on the Agency's website at a later date.

Table of contents

1. Background

The European Commission has requested the European Medicines Agency to develop a harmonised approach for the collection and reporting of data on use of antimicrobial agents based on national sales figures, as well as estimates on consumption in at least the major groups of animal species.

Currently, ESVAC collects data on sales of antimicrobial agents from the EU/EEA countries and these data are reported through annual ESVAC reports.[6] To fully explain differences in sales data between the European member states (MSs) more detailed data are needed, such as data by species. As a first step the Agency will collect data on antimicrobial consumption in pigs. As part of the preparation of the system for collecting harmonised and standardised data in pigs, the ESVAC Pig Data Collection Protocol (ESVAC Pig Protocol), the ESVAC Pig Data Collection Form (ESVAC Pig Template[7]) and the ESVAC Template Collecting Data On Farms (Farm Template Pigs[8]) for providing data to ESVAC will be subjected to testing on 5 farrow-to-finish farms in 10 volunteer MSs.

The ESVAC Pig Protocol and ESVAC Pig Template have been developed in collaboration with an ad hoc working group (WG), and reflect the recommendations given in the 'Revised ESVAC reflection paper on collecting data on consumption of antimicrobial agents per animal species, on technical units of measurement and indicators for reporting consumption of antimicrobial agents in animals'.[9] Furthermore, the ESVAC Pig Protocol and ESVAC Pig Template are based on information obtained from questionnaires sent to MSs who volunteered to test the protocol and form, and finally on the information obtained through the workshop/training held on 20 May 2014.

In the draft protocol presented during the workshop it is suggested to collect data from 20 farrow-to finish farms. It was indicated by participants that finding 20 farrow-to-finish farms may prove to be difficult in some countries. Farms become more specialized, leading to fewer farrow-to-finish farms and these might not be representative for pig farms in general in some of the member states. Identification of the structure (categorization) of the pig industry is therefore regarded as important for the further development of the protocol for the pilot.

Directive 2001/82/EC as amended, articles 11, 69 and 70 and Directive 96/23 as amended, article 10, requires veterinarians and animal owners to keep detailed records of veterinary medicinal products use. The legislation indicates:

"In particular, Member States may require the maintenance of a record giving at least the following information:
(a) Date;
(b) Name of the veterinary medicinal product;
(c) Quantity;
(d) Name and address of the supplier of the medicinal product;
(e) Identification of the animals treated."

With regard to the data needed for ESVAC in order to assess the amounts used, the Directive 2001/82/EC is insufficient in terms of standardisation on how the quantities should be given in the

[6] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp&mid=WC0b01ac0580153a00
[7] In the report referred to as "ESVAC Pig" template
[8] In the report referred to as "ESVAC On Farm" template
[9] http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/12/WC500136456.pdf

health records, as it reads ‘quantity’ only. Furthermore, there is no requirement in terms of numbers or age category of the animals to be treated.

Therefore, the main aims of the test of the protocol and templates are to identify:

1. The structure of the pig industry – i.e. numbers and types of farms, like farrow-to-finish or finisher farms (information requested in country worksheet ESVAC Pig Template),
2. The extent to which the variables required by ESVAC are available in the health records, from prescriptions, etc.,
3. The applicability of the Farm Template Pigs and the ESVAC Pig Template, including the worksheet on medicated feed,
4. The feasibility of the system (separate Feasibility survey to be filled in).

After the test phase, the test protocol and templates will be adapted where necessary and a pilot phase will follow during which data are collected on pig farms.

2. Collection of data on antimicrobial consumption in pigs

2.1. General considerations

For the test phase, data on consumption are to be collected for defined pig categories (see Table 2). Thereafter, the amounts consumed are to be calculated by the ESVAC team using standardised weights for these categories for the purpose of harmonisation of the reporting of data across the EU (see Table 3).

In the current chapter the data that need to be collected and provided to ESVAC are described and explained; in the next chapter examples are given on how amounts consumed per event will be calculated by the ESVAC team (see chapter 3).

2.2. Data format

Data should be provided to ESVAC according to the ESVAC Pig Data Collection Form (ESVAC Pig Template). This data collection form is country specific and based on the ESVAC 2012 register on sales data of veterinary medical products. The country specific form is attached to the call for test data.

2.3 Which veterinary antimicrobial agents to be collected

The classification system agreed to be used in the ESVAC project is the Anatomical Therapeutic Chemical (ATC) classification system for veterinary medicinal products: ATCvet (See Special Topics/Antimicrobial Resistance on the Agency’s web pages and http://www.whocc.no/atcvet/atcvet_index).

The antimicrobial groups that will be analysed and reported for pigs by ESVAC are shown in Table 1 (these include antimicrobial agents administered as medicated feed).

Table 1. Groups of veterinary antimicrobial agents to be included in the collection of consumption data in pigs (ATCvet = Anatomical Therapeutic Chemical veterinary classification)

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 used as antiparasitic agents	QP51AG

In order to avoid inclusion bias during the data collection all antimicrobial agents used/prescribed should be collected and provided to ESVAC, including dermatological preparations and preparations for the sensory organs (eye and ear preparations; ATCvet codes QS, QD06A). This will also include off-label use such as intramammaries used for wound treatment (QJ51). The same is also applicable for the countries that have continuous data collection systems in place.

2.4. Sample selection and size

A total of five farrow-to-finish farms should be included for the test phase and these should be identified from the national farm identification database and preferably randomly selected. The sampling should take into account the following exclusion criteria:

- Farrow-to-finish farms with less than ten sows,
- Farms with major trading/export of pigs for fattening to other farms or MSs.

2.5. Study type

2.5.1. Automated continuous data collection

If a MS continuously collects data on consumption in an automated manner from veterinarians' and/or farmers' records, the MS should provide the data for the 5 pig farms (selected according to chapter 2.4 and Table 1) to ESVAC using the ESVAC Pig Data Collection Form (ESVAC Pig Template).

2.5.2. Cross-sectional retrospective data collection

For MSs which do not have an automated continuous data collection system in place, the collection of data from the 5 farms should follow a cross-sectional retrospective study design.

2.6. Data to be collected

2.6.1. General information

The test data should be collected for a calendar year (2013) in order to obtain a sufficient amount of data. This duration also excludes seasonal or production round influence on the antimicrobial consumption data.

2.6.2. Data sources

Data on consumption of antimicrobial agents can be collected from the following data sources:

- Health-records or treatment log books,
- Delivery notes,
- Invoices,
- Veterinary prescriptions or veterinary practice records.

Each country should determine what the appropriate data source(s) is, i.e. which data source or combination of sources provides the necessary exhaustive data on antimicrobial consumption for pigs.

2.6.3. Data collection procedure

When data are to be obtained from records kept on the farms, each farm should be visited by a person trained to collect the data. The questionnaire on the requested farm characteristics should be filled in by the investigator together with the farmer during the farm visit.

If data are collected or provided by the veterinarians serving the selected farms, the data should be filled in by the investigator or veterinarian using the Farm Template Pigs. Furthermore, data on farm characteristics need to be collected as well; in some instances it may be necessary to visit the farms as well, to collect these data.

In order to obtain the data required to be filled into the ESVAC Pig Template, the data collection at the farms should preferably be performed by use of the Farm Template Pigs; this template can be printed and filled in during the farm visit. The other option is to enter the required data directly into the excel file (electronic version) of the Farm Template Pigs (if the data collectors bring laptops). Following the data collection on the farm, the information collected has to be transferred to the ESVAC Pig Template after the farm visit.

2.6.4. Data to be provided to ESVAC

The following information should be given in the various worksheets of the ESVAC Pig Template as described below. Variables that follow from the country specific register are already in the ESVAC Pig Template (see chapter 2.6.5.).

2.6.4.1. General information ('Country' worksheet)

- Country: country collecting the data
- Year: data collection year
- Study type: continuous or cross-sectional
- No. farrow-to-finish farms: number of farrow-to-finish farms present in national farm identifier database
- No. farrow-to-wean farms: number of farrow-to-wean farms present in national farm identifier database
- No. wean-to-finish farms: number of wean-to-finish farms present in national farm identifier database

- No. other farms: number of other categories of farms present in national farm identifier database; please state the categories of pigs present in this type of farm

2.6.4.2. Information for each farm ('Farm' worksheet)

- Farm ID: Unique national farm identifier (will not be published)
- Empty period (days): If applicable, observed empty period during data collection year (in days)
- No. slaughter pigs produced: number of slaughter pigs produced for the calendar year of data collection
- No. gilts/sows/boars/sucking piglets/weaners/finishers: average number of pigs present on any day during the data collection year on the farm for the specified categories (see table 2 and 3)
  - The average number should be calculated taking the possible empty period into account
  - All available data on numbers of pigs (per category) should be provided to ESVAC

Table 2. Categories of pigs for which data should be collected

Pig category	Age period
Gilts	Young sows before first farrowing, intended to be breeders
Sows/boars	Any pig meant for production of piglets
Sucking piglets	Birth to start of weaning
Weaners	Weaning period
Finishers	End of weaning period to slaughter

2.6.4.3. Information on consumption ('Consumption (CS or Automatic)' worksheet)

The following information should be collected for each event (record/prescription/delivery/etc.) and farm:

- Country
- Year: data collection year
- Farm ID: Unique national farm identifier (will not be published)
- Date: date of the event (in format dd/mm/yy)
- Data source: source of the event data (i.e. health-records or treatment log books, delivery notes, invoices, prescriptions/practice records)
- No. animals treated: number of animals treated or prescribed
- Pig category treated/prescribed: pig category treated or for which the VMP is prescribed (i.e. gilts, sows/boars, sucking piglets, weaners, finishers; see table 2/3)
- Name of VMP: name of veterinary medicinal product
- Pack size: content of pack
- Pack size unit: unit in which the pack size is given (e.g. ml, g)

- Amount used/prescribed

    a) No. packages: number of packages bought or prescribed for pigs (pack size and pack size unit should be filled in), **or**

    b) Dose per kg animal or per animal

        a. Amount: number of ml or gram per dose

        b. Unit: unit in which the dose is given (e.g. ml/kg body weight, mg/animal, g/animal)

        c. No. doses per day: the number of doses (as given in a. and b.) that is prescribed per day

        d. No. days administered: the number of days the VMP is administered

The above information (for each event), if available, is to be recorded in the ESVAC Pig Template.

2.6.4.4. Information on medicated feed ('Medicated feed' worksheet)

Information on prescribed/delivered medicated feed should be given as detailed as possible, at least per event/entry in the records from which the data are collected. Preferably, concentration of the medicated feed and the dosing should be given. Both the Farm Template Pigs and the ESVAC Pig Template also provide free text fields to fill in the details on the consumption of medicated feed on the farms.

In case oral powder has been prescribed/administered as medicated feed prepared by feed mills (off-label use) this should be recorded in the 'Medicated feed' worksheet.

- Country
- Year: data collection year
- Farm ID: Unique national farm identifier (will not be published)
- Date: date of the event (in format dd/mm/yy)
- Data source: source of the event data (i.e. health-records or treatment log books, delivery notes, invoices, prescriptions)
- No. animals treated: number of animals treated or prescribed
- Pig category treated/prescribed: pig category treated or for which the VMP is prescribed (i.e. gilts, sows/boars, sucking piglets, weaners, finishers; see table 2/3)
- Name of VMP: name of veterinary medicinal product or premix (if unknown: enter 'name unknown')
- Active substance(s): active substances of the VMP or premix
- Premix or feed: indicate whether the concentration given in the next columns is indicated for the premix or the feed (end product)
- Concentration:
    - Amount
    - Unit: unit in which the concentration is given

- Total product:
  - Amount
  - Unit: unit in which the amount of the total product is given
- Free text: to be filled in when the amount of medicated feed cannot be indicated in the variables given above

2.6.5. Country specific ESVAC Pig Template

The following information is already included in the country specific ESVAC Pig Template (taken from the ESVAC sales register):

- ID: national identifier for VMP (if available; else it's created by a macro)
- Name of VMP: name of veterinary medicinal product
- Form: pharmaceutical form (e.g. oral powder, injection)
- Pack size and pack size unit
- ATCvet code: anatomical therapeutic chemical code for veterinary medicinal products

For each active substance of the VMP:

- Ingr: name of substance (ATCvet name)
- Salt: name of salt if applicable (only for colistin when strength given as IU)
- Prodrug: name of prodrug if applicable
- Strength and strength unit
- Conv fact IU: conversion factor international units
- Conv fact prodr: conversion factor prodrug
- Ingr content: content of active substance in package
- Content unit: unit for content of active substance in package (g)
- (Kg used: the amount of active substance used in this event; to be calculated by ESVAC, at least for the test data)

For VMPs used or prescribed that are not included in the country specific ESVAC Pig Template the above information also needs to be filled in.

2.6.6. Additional instructions for filling in the ESVAC Pig Template

- When one VMP is prescribed or used for treatment in multiple events, copy-paste the VMP line to include extra lines with that VMP where/when necessary. This ensures the data on the VMP is entered correctly
- If a specific VMP is not included in the template, this has to be entered into a new line. Note that the same variables as for the products in the register have to be entered
- All events need to be entered into the ESVAC Pig Template, even when not all required data are available

- Include only the information that is available; the ESVAC team will perform the calculations where necessary- e.g. amounts used
- *If you have information on the use of Zinc Oxide, please include this in the template in the same manner as the VMPs are entered*

3. Calculations of amounts consumed

In order to report the consumption data in a harmonised manner, test data provided will be calculated by ESVAC in terms of amounts of active substance used/prescribed (kg) for each event by use of the standardised weights and standardised feed/water intake shown in Tables 3 and 4.

Table 3. ESVAC standardised average weight at treatment for pig categories[10]

Pig categories	Standardised average weight at treatment
Gilts	To be decided
Sows/boars	220 kg
Sucking piglets	4 kg
Weaners	12 kg
Finishers	50 kg

Below, an example is given of how the standardised weight will be applied in order to calculate the amount:

Example: 100 finishers administered with a premix containing oxytetracycline with a daily dose of 100 mg premix/kg animal for 3 days (pack size: 1000 g; strength of active substance: 750 mg/g).

- Total amount per treatment with product Y: 100 * 50 kg * 100 mg premix/kg/day * 3 days = 1,500,000 mg = 1,500 g

From this the number of packages used for this event will be calculated as follows:

- Number of packages: 1,500 g/1000 g = 1.5

Finally, the amount of oxytetracycline used (in kg) will be calculated (in ESVAC Pig Template):

- Kg oxytetracycline: 1.5 packs * 750 mg (substance)/g * 1000 g/pack = 1.125 kg

In case of a VMP with multiple active substances, amounts used (in kg) will be calculated for each substance (by use of the country specific ESVAC Pig Template).

Table 4. Draft* standardised average weight at treatment, feed and water intake per pig category

Pig category	Standardised average water intake	Standardised average feed intake
Gilts	To be decided	To be decided
Sows/boars	22 l	9.7 kg
Sucking piglets	0.4 l	0.2 kg
Weaners	1.2 l	0.5 kg
Finishers	5 l	2.2 kg

* To be further explored

[10] http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/12/WC500136456.pdf

Below, an example is given how the amount of oral powder for solution prescribed in an event is calculated:

Example: 100 finishers administered with product Y containing oxytetracycline with a daily dose of 5 kg oral powder for solution/1000 l water for 3 days (pack size: 5 kg; strength of active substance: 100 g/kg). Assumed water intake for finishers: 5 l water per day.

- Total amount per treatment with product Y: 100 * 5 l/day * 5 kg oral powder for solution/1000 l/day * 3 days = 7.5 kg

From this the number of packages used for this event will be calculated as follows:

- Number of packages: 7.5 kg/5 kg = 1.5.

Finally, the amount of oxytetracycline used (in kg) will be calculated (in ESVAC Pig Template):

- Kg oxytetracycline: 1.5 packs * 100 g (substance)/kg * 5 kg/pack = 0.75 kg

In case of a VMP with multiple active substances, amounts used (in kg) will be calculated for each substance (by use of the country specific ESVAC Pig Template).

Annex 2 – "ESVAC On Farm" template as tested in the trial

Note: this annex describes the variables/headings that were given in the various worksheets of the original "ESVAC On Farm" template as tested in the trial. The template presented here will be revised where needed and should not be interpreted as the guidance provided by the Agency. The final guidance will be published on the Agency's website at a later date.

Tentative variables tested for consumption data ('Consumption' worksheet)

	Column	Variable	Description of variable	Justification if applicable
GENERAL DATA		Farm ID	Unique national farm identifier, needs to be identical to the Farm ID used in the 'Farm' worksheet	To identify population and for linking data from various worksheets
	A	Date	Date of the observation	
	B	Data source	Source of the observation (e.g. health-records or treatment log books, prescriptions, invoices)	To enable tracing of data for validation purposes
PRODUCT INFORMATION	C	Name VMP	Name of the VMP	For validation purposes
	D	Form	Pharmaceutical form (e.g. oral powder, injection)	To allow for reporting of consumption by administration route/form
	E	Pack size	Content of package, including unit (e.g. 50 ml, 500 g)	To allow for calculation of consumption
	F	Strength	Strength of the active substance(s) in the VMP, including unit (e.g. 100 mg/g, 500 g/l)	To allow for calculation of consumption
CONSUMPTION DATA	G	# Packs	Number of packages bought or prescribed for pigs for the observation/treatment	To allow for calculation of consumption
	H	Dose	Amount of VMP given per administration, including unit (e.g. 20 mg/kg b.w., 5 ml/animal)	To allow for calculation of consumption
	I	# Doses/day	Number of doses administered per day	To allow for calculation of consumption
	J	# Days administered	The number of days the VMP is administered	To allow for calculation of consumption
	K	# Animals treated	Number of animals treated or for which the antimicrobial is prescribed	To allow for calculation of consumption
	L	Pig category	Category of the pigs treated or for which the VMP is prescribed (i.e. sows/boars, sucking piglets, weaners, finishers)	To allow for calculation of consumption per pig category

Tentative variables tested for medicated feed ('Medicated feed' worksheet)

	Column	Variable	Description of variable	Justification if applicable
GENERAL DATA		Farm ID	Unique national farm identifier, needs to be identical to the Farm ID used in the 'Farm' worksheet	For linking data from various worksheets
	A	Date	Date of the observation	Reference for determining duplication of data
	B	Data source	Source of the observation (e.g. health-records, delivery notes, invoices)	To enable tracing of data for validation purposes
TREATED ANIMALS	C	No. animals treated	Number of animals treated or for which the antimicrobial is prescribed	To allow for calculation of consumption
	D	Pig category treated	Category of the pigs treated or for which the VMP is prescribed (i.e. sows/boars, sucking piglets, weaners, finishers)	To allow for calculation of consumption per pig category
PRODUCT INFORMATION	E	Name of VMP	Name of antimicrobial veterinary medicinal product or premix	For validation purposes
	F	Name premix/active substance	Name of the premix or active substance in the premix	Important to avoid misinterpretation of substance name if given in other language than English
	G	Premix or feed	Indicate whether the amount given in the next column (I) is indicated for the premix or the feed (end product)	To determine which variables are needed for calculation of consumption
CONSUMPTION DATA	H	Concentration (amount/unit)	Concentration of the premix per unit of feed, including unit (e.g. 2%, 100 ppm)	To allow for calculation of consumption
	I	Total (amount/unit)	Amount prescribed or delivered of premix or feed, including unit (e.g. 6 kg)	To allow for calculation of consumption
		Freetext	Enter any information on consumption that does not fit into the variable described above	

Tentative variables tested for denominator (population data) ('Farm' worksheet)

Column	Variable	Description of variable	Justification if applicable
A	Farm ID	Unique national farm identifier; needs to be identical to the Farm ID used in the 'Consumption' and 'Medicated feed' worksheets	To identify population and for linking data from various worksheets; ESVAC does not need the official national farm identifier but a reference that confirms that there is no data duplication
B	Empty period (days)	Period during which no animals are present (given in days)	To establish denominator for reporting antimicrobial consumption
C	No. slaughter pigs produced	Number of slaughter pigs produced for the calendar year of data collection	To establish denominator for reporting antimicrobial consumption
D	No. gilts	Average number of gilts present per day during the year	To establish denominator for reporting antimicrobial consumption
E	No. Sows/boars	Average number of sows and boars present per day during the year	To establish denominator for reporting antimicrobial consumption
F	No. Sucking pigs	Average number of sucking piglets present per day during the year	To establish denominator for reporting antimicrobial consumption
G	No. Weaners	Average number of weaners present per day during the year	To establish denominator for reporting antimicrobial consumption
H	No. Finishers	Average number of finishers present per day during the year	To establish denominator for reporting antimicrobial consumption

Annex 3 – "ESVAC Pig" template as tested in the trial

Note: this annex describes the variables/headings that were given in the various worksheets of the original "ESVAC Pig" template as tested in the trial. The template presented here will be revised where needed and should not be interpreted as the guidance provided by the Agency. The final guidance will be published on the Agency's website at a later date.

Variables that came from the country specific ESVAC sales register were already completed in the "ESVAC Pig" template, if provided by ESVAC to the countries also participating in the ESVAC sales data collection. All observations for all farms could be filled into one worksheet and per observation one row.

Tentative variables tested for consumption data ('Consumption' worksheet)

	Column	Variable	Description of variable	Justification if applicable
GENERAL DATA	A	Country	Country which collects the data	To identify source of collected data
	B	Year	Data collection year	To identify time period for collected data
	C	Farm ID	Unique national farm identifier, needs to be identical to the Farm ID used in the 'Farm' worksheet	To identify population and for linking data from various worksheets
	D	Date	Date of the observation	
	E	Data source	Source of the observation (e.g. health-records or treatment log books, prescriptions, invoices)	To enable tracing of data for validation purposes
TREATED ANIMALS	F	No. animals treated	Number of pigs treated or for which the antimicrobial is prescribed	To allow for calculation of consumption
	G	Pig category treated/prescribed	Category of the pigs treated or for which the VMP is prescribed (i.e. sows/boars, sucking piglets, weaners, finishers)	To allow for calculation of consumption per pig category
PRODUCT INFORMATION	H	ID	National identifier for VMP	To allow for analysis of historical data and to identify duplicates
	I	Name of VMP	Name of antimicrobial veterinary medicinal product	For validation purposes
	J	Form	Pharmaceutical form (e.g. oral powder, injection)	To allow for reporting of consumption by administration route/form
	K	Pack size	Content of package (e.g. 500 for 500 g, 50 for 50 ml)	To allow for calculation of consumption

	Column	Variable	Description of variable	Justification if applicable
	L	Pack size unit	Unit in which the pack size is given (e.g. ml, g)	To allow for calculation of consumption
	M	ATCvet	ATCvet code for the VMP	To allow for reporting consumption by ATCvet code
CONSUMPTION DATA	N	No. packages	Number of packages bought or prescribed for pigs for the observation	To allow for calculation of consumption
	O	Amount	Amount of VMP given per administration (e.g. 20 for 20 mg/kg, 5 for 5 ml/animal)	To allow for calculation of consumption
	P	Unit	Unit of the amount of VMP given per administration (e.g. mg/kg animal, ml/animal, piece/animal)	To allow for calculation of consumption
	L	No. doses per day	Number of doses administered per day	To allow for calculation of consumption
	M	No. days administered	The number of days the VMP is administered	To allow for calculation of consumption
	S	Total amount per treatment	Total amount of VMP used for the observation	To be calculated by ESVAC
SUBSTANCE INFORMATION	T/AD/AN	Ingr	Name of substance (ATCvet name)	Important to avoid misinterpretation of substance name if given in other language than English; use of ATCvet names facilitates the identification of active substances as well as standardised reporting
	U/AE/AO	Salt	Name of salt if applicable (only for colistin when strength given as international units (IU))	To allow for conversion to weight of active substance
	V/AF/AP	Prodrug	Name of prodrug if applicable (when a product contains a prodrug; e.g. procaine penicillin is a prodrug for benzylpenicilin)	To allow for reporting of consumption of the various prodrugs
	W/AG/AQ	Strength	Strength of the active substance in the VMP (e.g. 500 for 500 mg/g, 100 for 100 g/l)	To allow for calculation of consumption
	X/AH/AR	Strength unit	Unit in which the strength is expressed (e.g. mg/g, g/l, mg/piece)	To allow for calculation of consumption

	Column	Variable	Description of variable	Justification if applicable
	Y/AI/AS	Conv fact IU	Conversion factor international units (IU); when strength is given as IU	To allow for conversion of active substance into mg and for calculation of consumption
	Z/AJ/AT	Conv fact prodr	Conversion factor prodrug	To allow for calculation of consumption
	AA/AK/AU	Ingr content	Content of active substance in package (e.g. 50 for 50 g)	To allow for calculation of consumption
	AB/AL/AV	Content unit	Content of active substance in package (e.g. g)	To allow for calculation of consumption
	AC/AM/AW	Kg used	Kg active substance used in this observation	To be calculated by ESVAC

Tentative variables tested for medicated feed ('Medicated feed' worksheet)

	Column	Variable	Description of variable	Justification if applicable
GENERAL DATA	A	Country	Country which collects the data	To identify source of collected data
	B	Year	Data collection year	To identify time period for collected data
	C	Farm ID	Unique national farm identifier, needs to be identical to the Farm ID used in the 'Farm' worksheet	To identify population and for linking data from various worksheets
	D	Date	Date of the observation	
	E	Data source	Source of the observation (e.g. health-records, delivery notes, invoices)	To enable tracing of data for validation purposes
TREATED ANIMALS	F	No. animals treated	Number of animals treated during this observation	To allow for calculation of consumption
	G	Pig category treated/prescribed	Category of the pigs treated or for which the VMP is prescribed (i.e. sows/boars, sucking piglets, weaners, finishers)	To allow for calculation of consumption per pig category
E IN FO	H	Name of VMP	Name of antimicrobial veterinary medicinal product or premix	For validation purposes

	Column	Variable	Description of variable	Justification if applicable
	I	Active substance(s)	Name of active substance of the VMP or premix (ATCvet name)	Important to avoid misinterpretation of substance name if given in other language than English; use of ATCvet names facilitates the identification of active substances as well as standardised reporting
	J	Premix or feed	Indicate whether the amount given in the next column is indicated for the amount of premix or the amount of feed (end product)	To determine which variables are necessary for calculation of consumption
CONSUMPTION DATA	K	Amount (concentration)	Concentration of the premix per unit of feed (e.g. 2 for 2%, 100 for 100 ppm)	To allow for calculation of consumption
	L	Unit (concentration)	Unit in which the concentration is expressed (e.g. %, ppm, g/kg)	To allow for calculation of consumption
	M	Amount (total product)	Amount prescribed or delivered of premix or feed (e.g. 6 for 6 kg, 10 for 10 kg)	To allow for calculation of consumption
	N	Unit (total product)	Unit for the amount (e.g. kg)	To allow for calculation of consumption
	O	Free text	Enter any information on consumption that does not fit into the variable described above	

Tentative variables tested for denominator (population data) ('Farm' worksheet)

Column	Variable	Description of variable	Justification if applicable
A	Farm ID	Unique national farm identifier; needs to be identical to the Farm ID used in the 'Consumption' and 'Medicated feed' worksheets	To identify population and for linking data from various worksheets
B	Empty period (days)	Period during which no animals are present (given in days)	To establish denominator for reporting antimicrobial consumption
C	No. slaughter pigs produced	Number of slaughter pigs produced for the calendar year of data collection	To establish denominator for reporting antimicrobial consumption
D	No. gilts	Average number of gilts present per day during the year	To establish denominator for reporting antimicrobial consumption
E	No. Sows/boars	Average number of sows and boars	To establish denominator for

Column	Variable	Description of variable	Justification if applicable
		present per day during the year	reporting antimicrobial consumption
F	No. Sucking pigs	Average number of sucking piglets present per day during the year	To establish denominator for reporting antimicrobial consumption
G	No. Weaners	Average number of weaners present per day during the year	To establish denominator for reporting antimicrobial consumption
H	No. Finishers	Average number of finishers present per day during the year	To establish denominator for reporting antimicrobial consumption

Tentative variables tested for pig farming structure ('Country' worksheet)

Variable	Description of variable	Justification if applicable
Country	Country collecting the data	To identify source of collected data
Year	Data collection year	To identify time period for collected data
Study type	Continuous or cross-sectional	
No. Farrow-to-finish farms	Number of farrow-to-finish farms present in national farm identifier database	To establish which farm types and how many are available in the country
No. Farrow-to-wean farms	Number of farrow-to-wean farms present in national farm identifier database	To establish which farm types and how many are available in the country
No. Wean-to-finish farms	Number of wean-to-finish farms present in national farm identifier database	To establish which farm types and how many are available in the country
No. other farms	Number of other categories of farms present in national farm identifier database; please state the categories of pigs present in this type of farm	To establish which farm types and how many are available in the country

Annex 4 – Feasibility survey – trial data collection in pigs

QUESTIONNAIRE FARM 1 - 5

Item	Answer
1) How many hours did it take to collect the data and fill in the ESVAC Template Collecting Data On Farms?	
2) How many investigators were involved?	
3) What type of investigators was involved (e.g. veterinarian, pharmacist, epidemiologist, student)?	
4) Which was used to fill in the ESVAC Template Collecting Data On Farms: paper form or direct entry into the laptop/Excel file?	

GENERAL QUESTIONNAIRE

Item	Answer
1) How many hours did it take to complete the 'ESVAC Pig Data Collection for Pigs' for the 5 sampled farms?	
2) How many data managers were involved?	
3) What type of data managers were involved (e.g. veterinarian, pharmacist, epidemiologist)?	
4) Any comment you would like to add?	

Annex 5 – Country and affiliation of the ESVAC by species contact points providing data

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Annex 6 – ESVAC species Expert Advisory Group

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