



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Draft EMA guidance for collection of data on antimicrobial use per species from national data collection systems

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

EC workshop with EMA, Brussels, 26 April 2017

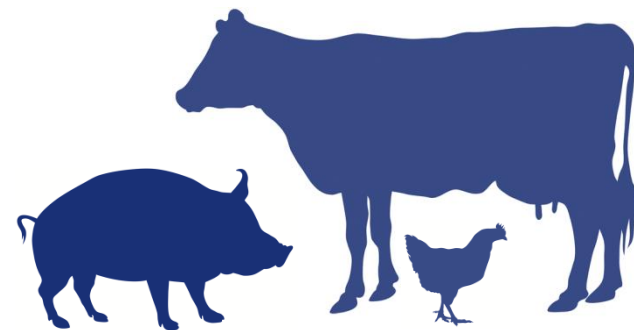
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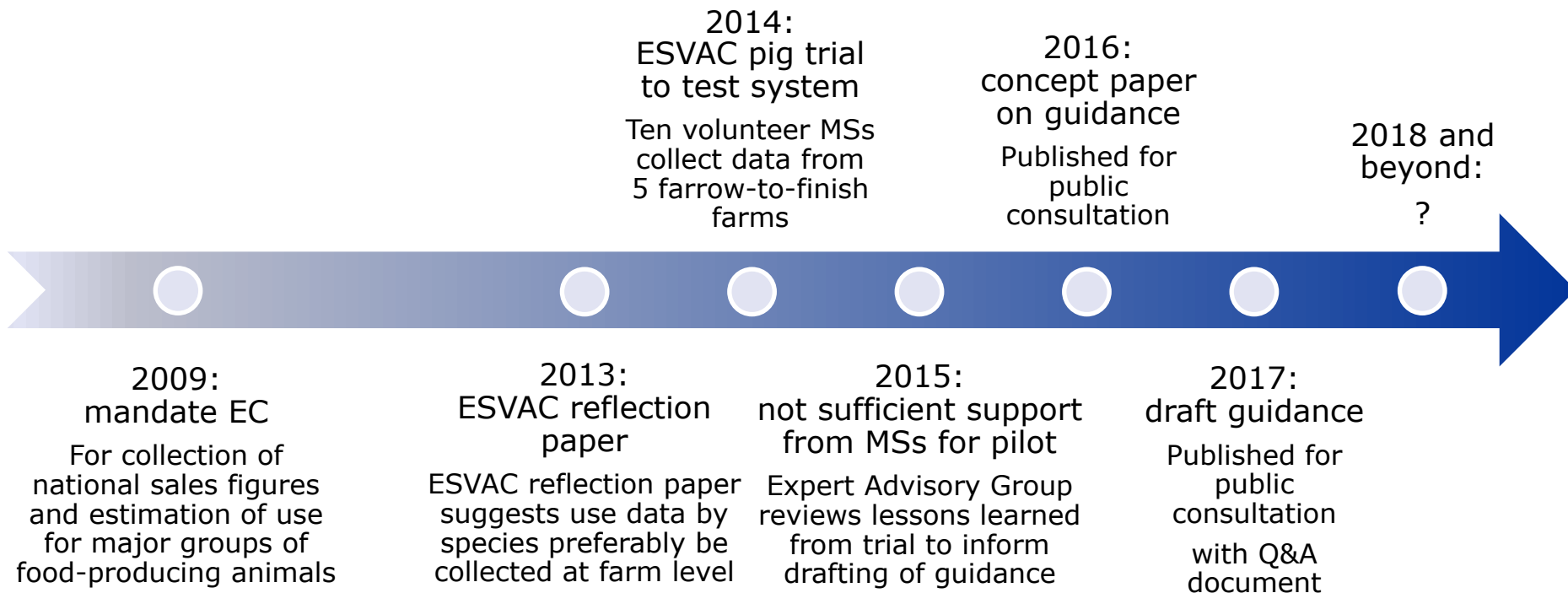
Overview

- Work stream:
 - Background;
 - Objective.
- Guidance:
 - Legal basis;
 - Objectives;
 - Considerations and scope.
- Content guidance:
 - Animal species and categories;
 - Frequency of data provision;
 - Data collection models;
 - Use data;
 - Animal population data.
- Annexes.
- Way forward.





Background work stream data collection by species





Objective of work stream

To foster collection of harmonised and standardised antimicrobial use data by animal species across the EU/EEA countries.

To achieve this EMA/ESVAC will:

- Act as network hub in EU/EEA area bringing together best technical expertise on collection and analysis of use data by species;
- Develop with ESVAC species EAG **guidance for collection of harmonised and standardised data** that allow ESVAC team to collate, analyse and report data at European level on use by species;
- Foster conduct by EU/EEA countries of studies to ensure applicability of guidance throughout EU/EEA area and promote uptake at national level.



Guidance and legislation

- Data collection by species not mandatory at EU/EEA level - this may change after ongoing revision of regulation on VMPs.
- If MS would like to voluntarily provide data to EMA: guidance sets standards for those data.
- Guidance discusses possible data collection models.
- The proposed new regulation on VMPs foresees that EC will outline requirements in delegating/implementing acts.



Objectives of publishing guidance

- Ensure standardisation of key elements of data collection process for those already (or planning to start) collecting data by species and wanting to voluntarily provide those data to EMA in the future.
 - Should increase level of harmonisation of collected data.
- Encourage MSs to initiate collection of use data by species.
- Provide information how to set up data collection system for those who aim to do so.
- Prepare for meeting potential requirements (systems and procedures) for EMA and NCAs in revised regulation.



Rationale and considerations

- Collecting use data by animal species is expensive.
- Some MSs might want to collect more data (on indication, more animal categories, etc.), others not for all animal categories covered in guidance.
- Phased approach suggested for species to be included.
- Pragmatic approach needed.
 - Ensuring required data can be provided by all MSs but sufficient to meet objectives.



Objectives of guidance

- To define type and format of data to be provided to EMA in the future from national data collection systems;
 - For those MSs wishing to provide such data to EMA;
 - For ESVAC team to collate, analyse and report reliable, harmonised data on use by species in EU/EEA across time periods.
- To foster and encourage the collection of harmonised and standardised data by MSs.



Scope of guidance

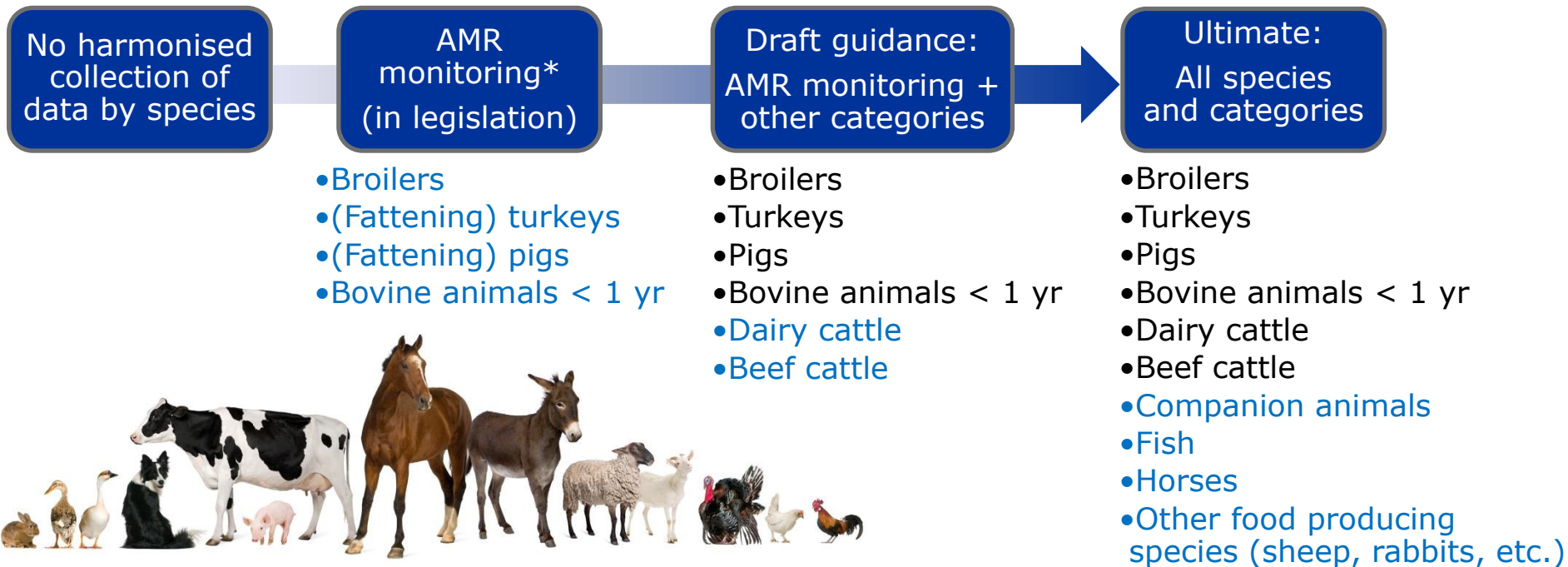
- Not intended to be mandatory, but to detail how ESVAC activity proposes collection of data by species at EU/EEA level.
- To promote collection of data harmonised and standardised across EU/EEA countries and time periods.
- Covers data collection as close as possible to end user but data provided to EMA aggregated at national level.
- Guidance covers priority animal categories in terms of antimicrobial use.
 - Cattle, pigs and poultry (broilers and turkeys).
- To be used by NCAs that collect or want to collect data by species and provide those to EMA in future.



*Commission Implementing Decision (2013/652/EU)

Animal categories

To be determined by MSs and/or EC



No harmonised collection of data by species

AMR monitoring* (in legislation)

Draft guidance: AMR monitoring + other categories

Ultimate: All species and categories

- Broilers
- (Fattening) turkeys
- (Fattening) pigs
- Bovine animals < 1 yr

- Broilers
- Turkeys
- Pigs
- Bovine animals < 1 yr
- Dairy cattle
- Beef cattle

- Broilers
- Turkeys
- Pigs
- Bovine animals < 1 yr
- Dairy cattle
- Beef cattle
- Companion animals
- Fish
- Horses
- Other food producing species (sheep, rabbits, etc.)





Separating beef, veal and dairy?

- Important as distinct sectors.
- Patterns of antimicrobial use are fundamentally different, e.g.:
 - Beef/veal – respiratory disease/diarrhoea especially as calves;
 - Dairy – adult treatments (mastitis/foot disease).





*Commission Implementing Decision (2013/652/EU)

Possible frequency of providing data to EMA

To be determined by MSs and/or EC

E.g. alternating years per species
AMR monitoring*



E.g. annually per species
(phased approach)



For example:

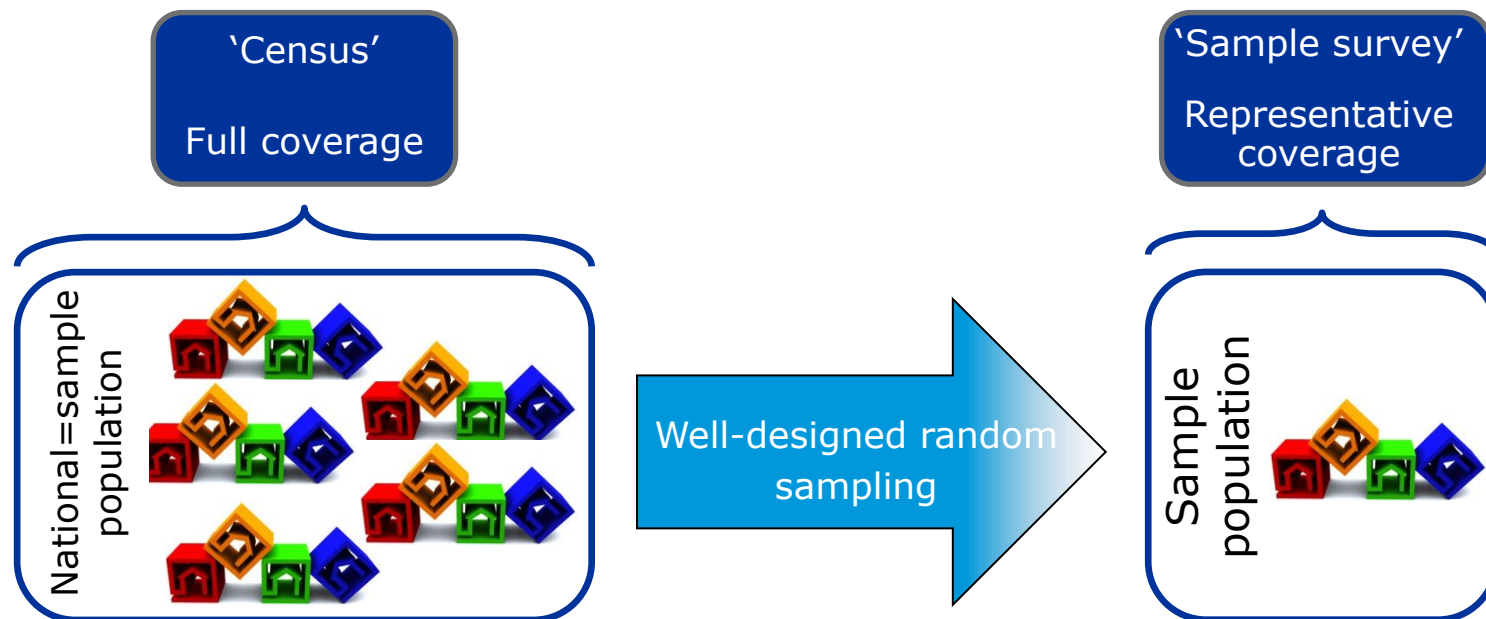
2017	2018	2019	2020
Pigs Bovine < 1 yr	Broilers Turkeys	Pigs Bovine < 1 yr	Broilers Turkeys

2017	2018	2019	2020
Pigs ...	Pigs Broilers ...	Pigs Broilers Bovine < 1 yr ...	Pigs Broilers Bovine < 1 yr Turkeys ...



Coverage of animal production

To be determined by MSs and/or EC





Data collection models

Census - covers use of antimicrobials for (nearly) whole animal production

- + Data collection usually (partly) automated
- + Data on animal population-at-risk collected from Eurostat/TRACES
- + Highest precision national use by species
- + Enables monitoring trends and e.g. effect of intervention measures
- + Data would be available for other national purposes (e.g. benchmarking)
- Very high initial investment (time/finance) and resource demanding

Data collection models (cont.)

Sample survey - *representative sample of farms; well-designed random sampling*

- + Data collection can be partly automated
- + Initially less resource demanding than census
- + Accurate estimate national use by species
- + Data sufficient for monitoring trends and e.g. effect of intervention measures
- Data on animal population-at-risk to be collected from (mixture of) national sources
- Selecting representative sample complex – e.g. define farm type/livestock organisation

Use data that would be provided to EMA*

- Data collection period: one calendar year (regardless of length production cycle).
- Antimicrobial agents:

ATCvet group	ATCvet code
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 ^a	QP51AG

^a Only sulfonamides are to be collected and reported.



Use data that would be provided to EMA (cont.)

Use data can be collected in volume, weight or packages.

- The sources for use data can be:
 - Health records, treatment log books, delivery notes and invoices from the farms;
 - Prescriptions or pharmacy records;
 - Veterinary practice records.

Use data should be aggregated at national/species level before providing to EMA.

- Number of packages used per VMP presentation per species.
- Call for data would come with template including all VMPs marketed in MS.
 - VMPs on special licence or off-label to be included manually.

Variables on use

Variable	Justification
Country	To identify country which collected data
Year	To identify time period (calendar year) for collected data
Species	To identify animal species (or category) for which data are collected
Name of VMP	To identify antimicrobial veterinary medicinal product used
Form	To identify pharmaceutical form (needed for further analysis of data)
Pack size + unit	To enable calculation of amount of active substance in each VMP presentation
Strength AS in VMP	To enable calculation of amount of active substance in each VMP presentation
ATCvet	Only latest version of ATCvet codes should be used
Number of packs	To calculate weight of active substance sold for each VMP presentation



Denominator that would be used by EMA

Denominator: animal biomass at risk of being treated with antimicrobials.

- Utilized to adjust quantity of antimicrobials used across countries/years.
- Calculated by multiplying numbers of animals with standardised average weight at treatment.
- Standardised weights established as for ESVAC sales PCU.
- Mixture of slaughter and/or live animal numbers per sector.



Animal population data that would be provided to EMA

- Data collection period: one calendar year.
- Depending on animal species/category:
 - Number of slaughtered/produced animals in MS/sample;
 - Number of living animals present in MS/sample (e.g. sows and dairy cows);
 - Number of animals traded for fattening or slaughter within EU/EEA.
- If census: data can be collected from Eurostat and TRACES, otherwise from other (national) sources.





Pig denominator

Category	Weights (kg)
Live breeding sows	240kg
Pigs slaughtered	65kg
Pigs imported/exported for slaughter in/from MS (census only)	65kg
Pigs imported/exported for fattening in/from MS (census only)	25kg



Poultry denominators

Sector	Category	Weights (kg)
Broilers	Broilers slaughtered	1kg
	Broilers imported/exported certified for slaughter in/from country (census only)	1kg
Turkeys	Turkeys slaughtered	6.5kg
	Turkeys imported/exported certified for slaughter in/from country (census only)*	6.5kg

* new category, not currently included in sales PCU



Cattle denominators

Sector	Category	Weights (kg)
Dairy	Live dairy cows	425kg
Veal	Calves/young cattle slaughtered	140kg
	Bovine animals imported/exported certified for fattening in/from country (census only)	140kg
Beef	Bulls and bullocks slaughtered	425kg
	Heifers slaughtered	200kg
	Cows slaughtered	425kg
	Bovine animals imported/exported certified for slaughter in/from country (census only)	425kg



Annexes

The guidance document further contains annexes providing additional information:

- Data collection at national level - how to set up a system;
- Use and benefits of antimicrobial use data by species;
- Questionnaire on describing national data collection systems;
- Sample survey - how to define sampling frame, strategy and size;
 - Current established sample size: 169-385.
- Overview of variables in tentative template that would have to be provided to EMA;
- Links to existing reports and guidelines on collection of use data by species.



Next steps guidance

- Guidance published for 6 month public consultation period.
 - Together with Question and Answer document.
 - Comments invited on both documents, especially on proposed models, required data, technical aspects, etc.
 - Deadline for comments: 24 September 2017.
- Revised guidance published Q4 2017/Q1 2018.



The way forward for data collection by species

Call for data would depend on revision of legislation.

- When into force? → time required to set up data collection systems.
 - Depending on available resources at EMA and NCAs: EMA might explore application of guidance with volunteer countries.
 - Many initiatives ongoing in Europe with regard to collecting data by species (also *JPI AMR AACTING project*)
 - Number of countries where such data collection is included in legislation increases.
 - Many animal sectors (industry) are pro-active and have started collecting data.
- How to encourage and stimulate countries to prepare for collection of such data?
- Who to address?



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Thank you for your attention

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