



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Schemes for data collection on antimicrobial use per species from national data collection systems and from the draft EMA guidance – comparison and further considerations of benefits

---

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

EC workshop with EMA, Brussels, 26 April 2017

Marian Bos, Seconded National Expert EMA/ESVAC





# Overview

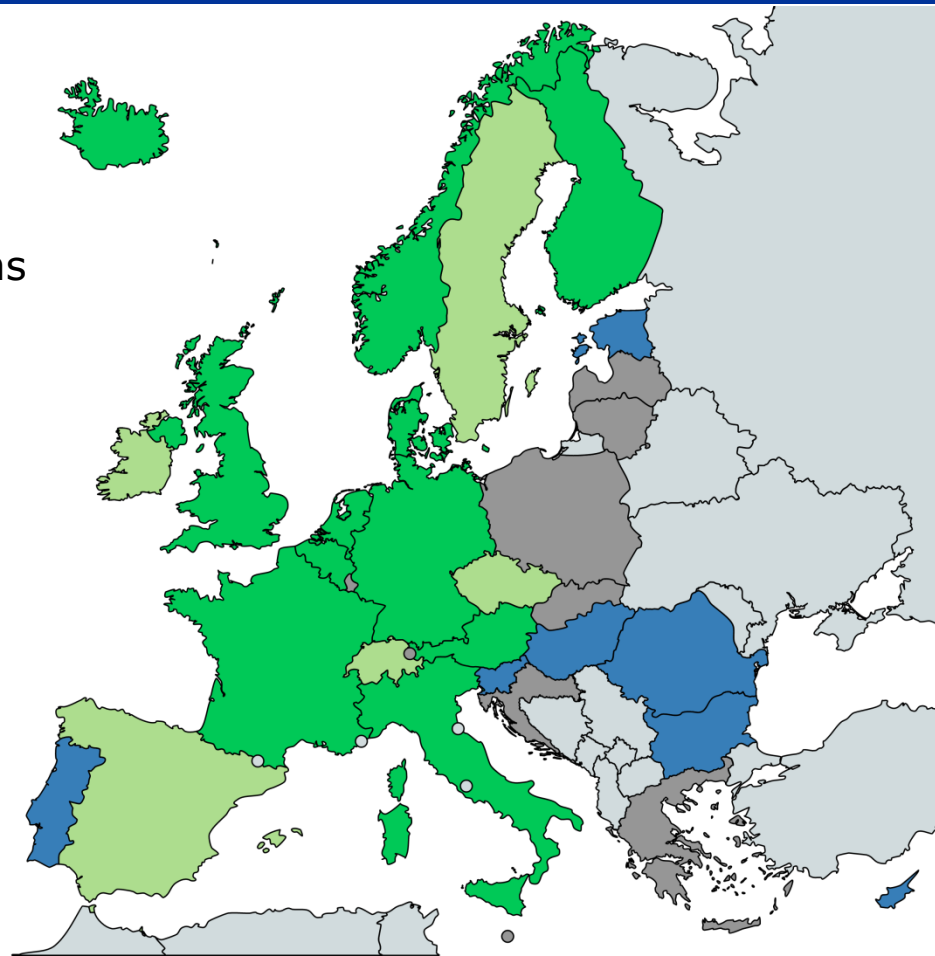
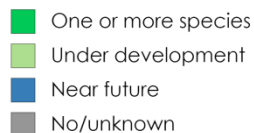
- Current situation in Europe
- Example – existing poultry schemes in Europe
- Benefits collecting use data by species
  - At EU/EEA level
  - At national level
    - Additional variables
- Way forward



## Current situation in Europe

- In eleven countries data collection systems are in place for one or more species.
- In five more countries data collection system is under development.

### Data by species





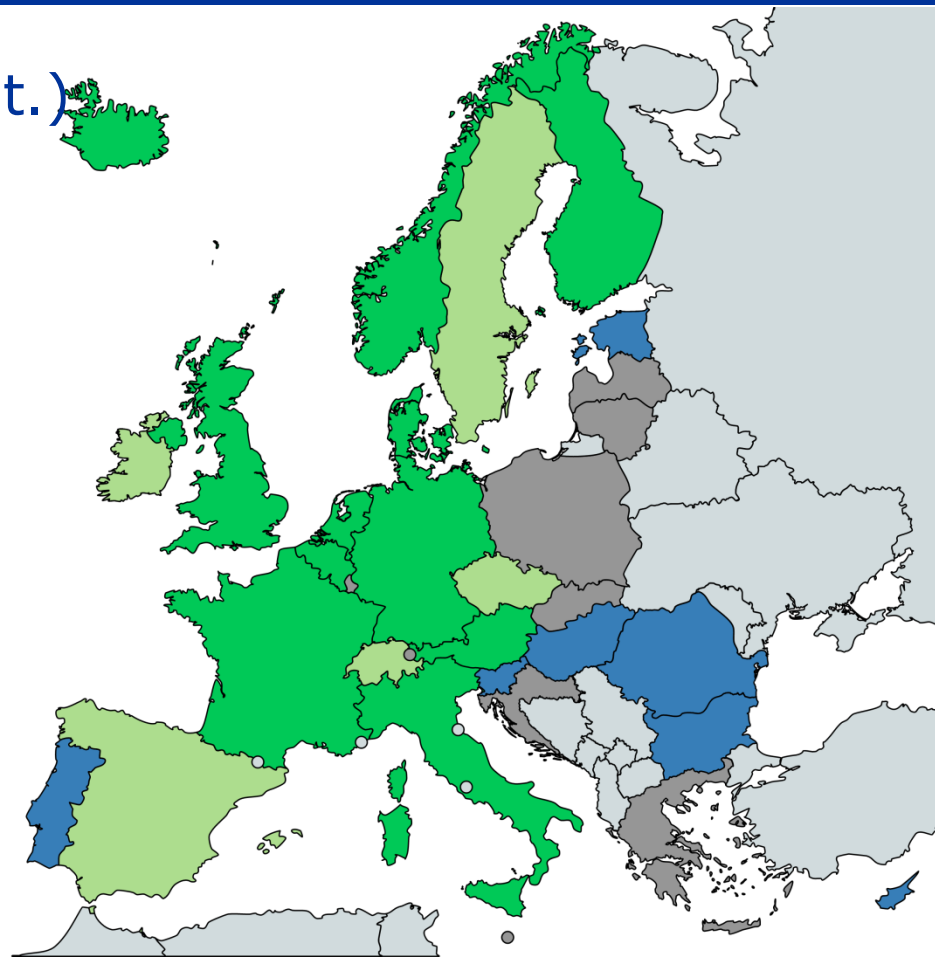
## Current situation in Europe (cont.)

Variation in:

- Objective for data collection, e.g.:
  - Monitoring use in animal sector;
  - Benchmarking individual farms.
- Included species/categories.
- Coverage per species.
- Initiator (e.g. government, industry).
- Data sources.
- Variables.
- Indicators.

### Data by species

- One or more species
- Under development
- Near future
- No/unknown





## Example – existing poultry schemes in Europe

---

Based on publicly available information\*

## Legal basis and initiator

MS	Legal (mandatory) basis	Who	When established
AT	No (members Austrian Quality Poultry Association) Sales/species are mandatory; use voluntary	Government/ industry	2015/2002
BE	Yes	Government	2017
DE	Yes (threshold; turkey fatteners and broilers)	Government	2014
DE2	(Yes: for members of Quality Scheme for food)	Industry	2012
DK	Yes	Government	1995 (2000)
FR	No	Industry	1999 (since 2009 stratified)
NL	Yes	Industry/ Government	2011/2016
NO	Yes	Government	2011 (fish)/2012 (other)
SE*	No (members Swedish Poultry Meat association)	Industry	
UK	No (members British Poultry Council)	Industry	2012



## Included species/categories

MS	Poultry	Broiler	Laying hen	Pullet	Parent flock	Duck	Goose	Game bird	Pigeon	Guinea fowl	Quail	Turkey
AT		✓	✓	✓	✓							✓
BE		✓	✓									
DE		✓										✓
DE2		✓				✓						✓
DK	✓	= ✓	✓		✓	✓	✓	✓	✓			✓
FR	✓	= ✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
NL		✓										✓
NO*	✓	✓	✓									✓
SE**		✓	✓	✓	✓							✓
UK	✓	= ✓				✓						✓
<i>Guidance</i>		✓										✓



## Coverage of animal population

MS	Coverage farms	Coverage production	Comments
AT	~100% (except for laying hens: ~45%)	~100% (except for laying hens: ~80%)	
BE	~ 100%		
DE	National database		Only holdings > 1000 turkeys or >10 000 broilers
DE2			Can also include farms outside Germany
DK	~100%	~100%	
FR	~100%	~100%	
NL	~100%	~100%	Only holdings > 250 birds
NO	~100%	~100%	
SE*		>95%	For broiler and turkey production
UK		~90%	
<i>Guidance</i>		<i>Full or representative</i>	



## Data source and entry

MS	Data source	Who enter the data
AT	Prescriptions/deliveries	Veterinarian
BE	Prescriptions or deliveries	Veterinarian (or contracted third party)
DE	Dispensed prescriptions or health records/treatment log books	Animal keeper, veterinarian or contracted third party
DE2	Veterinary drug records – deliveries or application	Veterinarian (farmer checks data)
DK	Sales	Pharmacy/private company/feed mill/veterinarian
FR	Sales per product presentation	Marketing Authorisation Holder
NL	Delivery notes	Veterinarian
NO	Prescriptions	Veterinarian (and pharmacy)
SE*		Veterinarian
UK	Farm records	Producer
<i>Guidance</i>	<i>All possible</i>	<i>Depending on data source</i>



## Indication and benchmarking of farms

MS	Indication recorded?	Benchmarking of farms?
AT	Yes	No
BE	No (optional)	No?
DE	No	Yes
DE2	Yes (optional)	Yes
DK	Yes (disease category)	No
FR	No	No
NL	No	Yes
NO	No	No
SE*		No
UK	No	No
<i>Guidance</i>	<i>No</i>	<i>No</i>



# Use data and numerator (AM use in indicator)

\* Added after workshop

MS	Use data	Numerator
AT	Dose	Tonnes active substance
BE	Number of packages	
DE	Dosing regimen/total quantity for treatment	Number of treated animals * number of treatment days * number of active substances
DE2	Amount supplied/administered	Treatment units: duration of treatment (incl. days of effect) * number active substances * number treated animals
DK	Number of packages	Kg active substance; DDDA
FR	Number of packages	Weight of active substance (weight of animals that can be treated with amount of antimicrobial sold (based on SPC))
NL	Number of packages	Treatable kg: weight of animals that can be treated with amount of antimicrobial delivered (based on SPC)
NO	Number of packages	Kg active substance; no. DDDvet; no. DCDvet
SE*	Treatment	Number of flocks treated
UK	Quantity active substance	Tonnes of antibiotics used
<i>Guidance</i>	<i>Volume/weight/packages</i>	<i>Weight of active substance</i>



## Population data and denominator (pop. at risk in indicator)

MS	Animal population data	Denominator
AT	No. animals on farm	
BE	No. animals on farm	
DE	No. animals on farm - entered each 6 months	Average no. animals present during 6 months
DE2	No. animals housed in for each flock	Sum of all animals housed in for flocks housed out in specific time period
DK	No. broilers/eggs/turkeys produced No. hens/year (% of cocks)	Live biomass - represents no. standard animals at risk per day in population
FR	Total no. animals	Weight of animals potentially treated with antimicrobials (kg at slaughter or adult)
NL	Average no. animals present in year	Kg-animal-year
NO		
SE*	Number of flocks sampled	
UK		
<i>Guidance</i>	<i>No. birds produced and traded for slaughter</i>	<i>Animal biomass (kg)</i>

\* Added after workshop



# Indicators

\* Added after workshop

MS	Indicator	Interpretation
AT	Tonnes	Quantity consumed in production sector
BE		
DE	Treatment frequency	Number of days animals were treated on average during last 6 months
DE2	Therapy index	Number of treatment units administered on average to each animal
DK	Kg active substance ACDkg	Quantity consumed in production sector - Dose required to treat one kg body weight for entire duration of treatment
FR	ALEA	- ALEA = 1: for a given species, estimated body weight treated is exactly total body weight (product) of animal population
NL	DDDA <sub>NAT</sub> DDDA <sub>F</sub>	- Number of defined daily dose animal for national level consumption - Number of defined daily dose animal for farm level consumption
NO	Kg AS; No. DDDvet; No. DCDvet	Quantity used in sector (in amount of AS, DDDvet and DCDvet)
SE*	% flocks treated	Proportion of flocks treated out of number of flocks sampled
UK	Tonnes	Quantity used in sector
<i>Guidance</i>	<i>Several</i>	<i>Discussed in later presentation</i>



## Benefits for collecting use data by species – at EU/EEA level

- Trends in use across years for defined animal species provided.
- Exposure of animals to antimicrobials - identify where to focus efforts on reducing antimicrobial use, e.g.:
  - Which species/categories consume more than others;
  - In which species more critically important antimicrobials are used.
- In line with ESVAC sales reports:
  - Possibility to better understand and comment on data, based on data sets in species (and targeted measures involved);
  - Certain level of verification of sales data → especially for those countries with complete (or near complete) coverage.



## Benefits for collecting use data by species – at EU/EEA level (cont.)

Possible additional advantages of use of data by species:

- Verification of estimates of use in PSURs.
- Environmental loading – data on use by species could lead to proposing mitigation measures for handling of e.g. manure according to technologies specifically for certain species of animals and certain antimicrobials.
- Identification of areas of concern for antimicrobial use for further research in specific species.



## Benefits for collecting use data by species – at national level

- Policy makers insight into effect of implemented measures (e.g. national responsible use and treatment GLs).
- Risk managers can identify risk factors and tools for risk assessment as well as risk management:
  - At a national/regional level;
  - At animal sector level;
  - At farm level.

(depending on data collection system in each country)





## Benefits for collecting use data by species – at national level (cont.)

Data on AM use in specific age categories of animals (e.g. sows/piglets, weaning pigs, finisher pigs):

- Use per age category:
  - Comparison of variations in use in different animal categories;
  - Broken down by antimicrobial/type of application (oral, other).

Analysis in relation to AMR data of relevance to:

- Animal and public health (surveillance of zoonotic, indicator and/or commensal pathogens) – EU programmes co-financed (EFSA);
- Animal health + effective treatment (surveillance of target veterinary pathogens) (nationally specific programmes, national budgets).



## Additional variables that could be collected for national

Purposes	Example values	Justification
Treatment type	Therapeutic/metaphylactic/ prophylactic Group/individual	Monitoring frequency/cases of such use, prudent use and risk mitigating measures
Treatment indication	Digestive/respiratory/ urinary/reproductive/etc.	To help monitoring frequency of such use, identifying risk mitigation measures
Administration as "off-label use"	Yes/no Cascade use	To help identifying need for products authorised for other target species/ indications/dosing schedule, propose risk mitigation measures
Physiological stage at treatment	Weaner/Sow/etc. One day old broilers	To help identify ategories at risk and risk mitigation measures
Date of event		To identify seasonal influence, or link to disease incidence; this would enable reactive monitoring of use and the impact of planned and unplanned events
Variables on farm identification and farm characteristics	Livestock production system (e.g. calf rearer, farrow-to-finish)	To enable benchmarking and identifying risk mitigation measures



## The way forward

- Publish guidance so (national) data collection schemes would be able to prepare provision of harmonised and standardised data to EMA.  
→ if such requirement included in legislation and after call for data.



# Thank you for your attention

## Further information

---

[esvac@ema.europa.eu](mailto:esvac@ema.europa.eu)

### **European Medicines Agency**

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

**Send a question via our website** [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

Follow us on  **@EMA\_News**



**ROME**

**PEACE  
DEMOCRACY  
SOLIDARITY**

