



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# ESVAC 2012

## Results and state of play

---

Kari Grave/Jordi Torren Edo/Arno Muller/David Mackay





# Outline

---

- ESVAC mandate
- Sales of veterinary antimicrobial agents in 9 European countries for 2005-2009
- Collecting standardized overall sales data on antimicrobial VMPs at package level from the MSs
  - approaches
  - hazard points and state of play
- *Ad hoc* working groups on collecting data per animal species and on units of measurement



# Brief summary Commission mandate on the ESVAC project [SANCO/E2/KDS/rz D(2008) 520915]

---

Commission requests the EMA to

- ✓ Develop a harmonised approach for collection and reporting of data on antimicrobial VMPs
  - based on national sales figures
  - combined with estimations of usage in at least major groups of species (poultry, pigs, veal, other ruminants, pets and fish);
- ✓ Collect the data from MSs and manage the data base;
- ✓ Draft an annual report with the data from MSs



# Trends in sales of veterinary antimicrobial agents in 9 European countries: 2005-2009

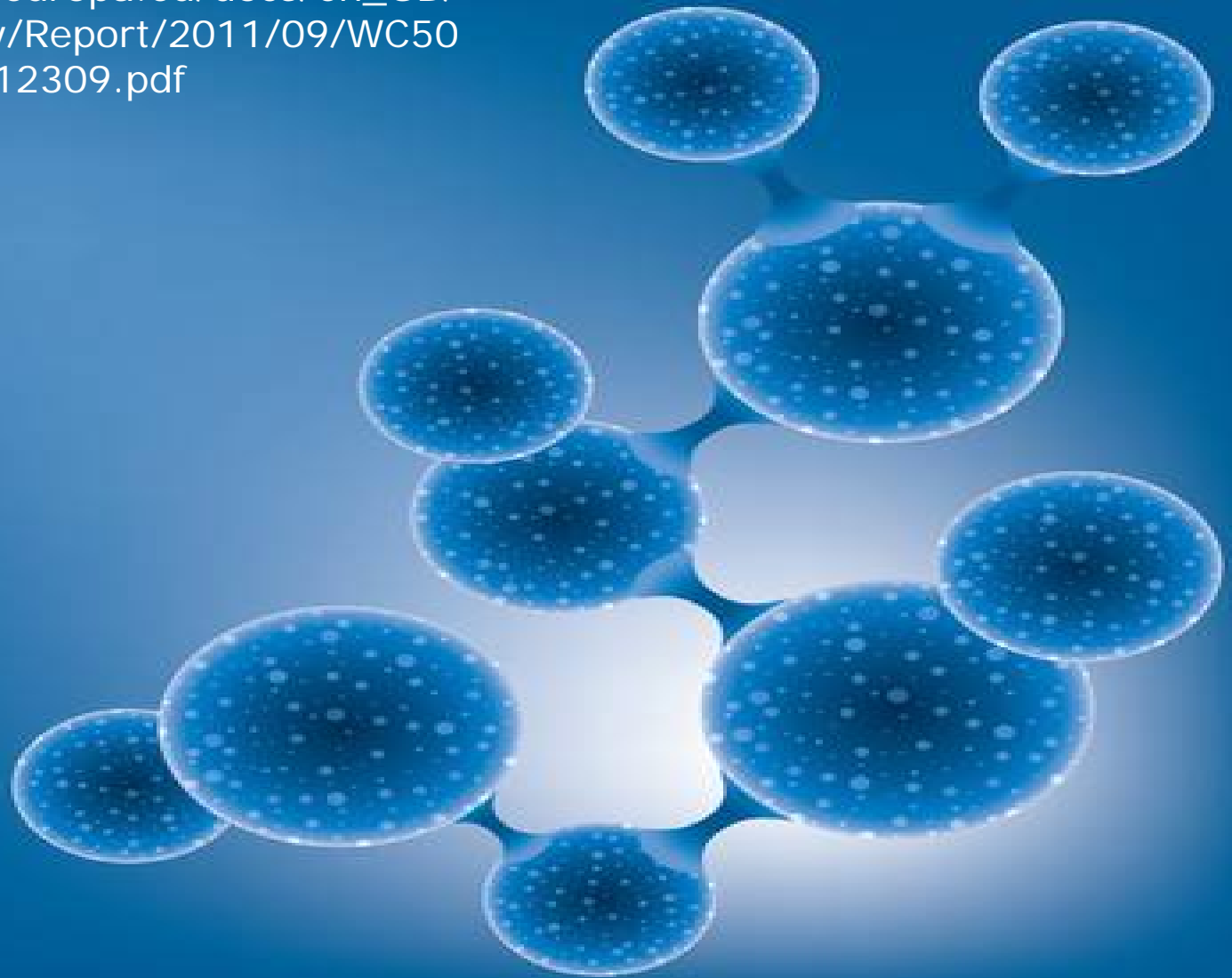
---

- Main aim of study
  - To identify trends and patterns of sales of veterinary antimicrobial agents by use of already existing data in order to document the situation
- Material and methods (protocol)
  - Harmonised aggregated sales data of clearly defined classes of veterinary antimicrobial agents were collected retrospectively for the years 2005-2009. *Note that some countries had to reanalyse the data in order to meet the criteria*
  - Data normalised by taking into account the animal population

# Trends in the sales of veterinary antimicrobial agents in nine European countries

Reporting period: 2005-2009

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Report/2011/09/WC500112309.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/09/WC500112309.pdf)





# Material

---

- Material
  - All countries included AM agents for systemic, intramammary and intrauterine use for terrestrial animals
  - All but two countries included AM agents sold for farmed fish
- Coverage
  - 7 countries reported 100% coverage, 2 countries reported 98% coverage
- Concluded that the data gives a valid picture of sales of the 9 countries



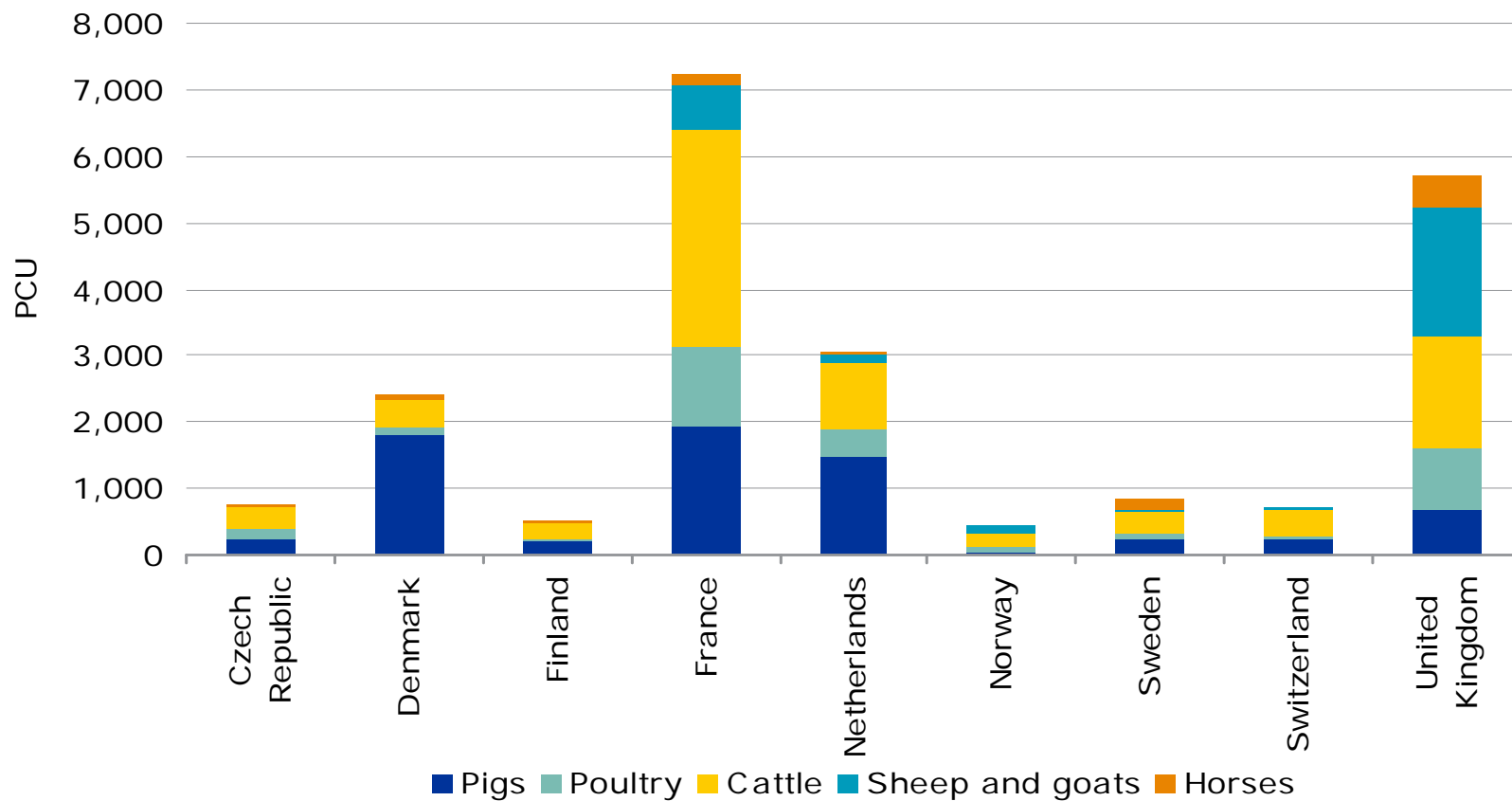
## Normalising sales data by animal population

---

- ✓ Population correction unit (PCU) used as term for the estimated weight of livestock and slaughtered animals
- ✓ PCU introduced as a proxy for the animal biomass at risk of being treated with an antimicrobial VMP
- ✓ Data source for livestock and slaughtered animals: Eurostat as publicly available and based on same methodology for collection of data for all MSs
- ✓ To report the data, the annual sales figure in each country was divided by the estimated PCU in the corresponding year.



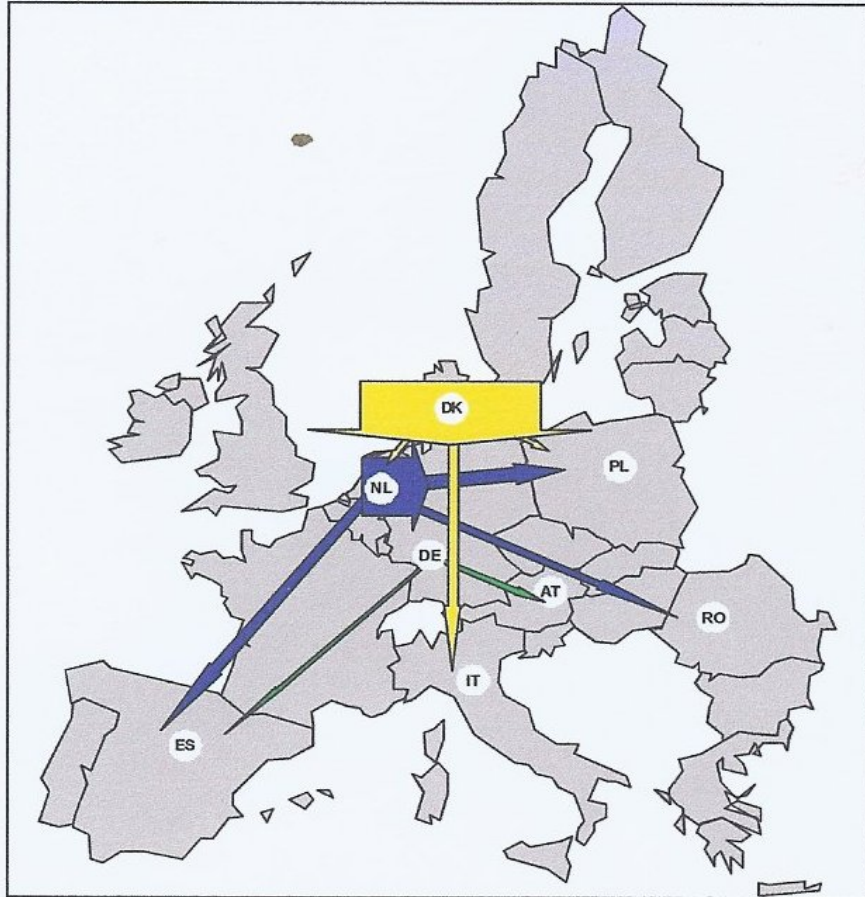
Estimated PCU (1,000 tonnes) in the 9 countries for 2009. A substantial difference is observed between the countries





# Transport of animals taken into account when calculating PCU

**Figure 6: Net exchanges of young pigs**  
Scheme of the intra-EU exchanges (2008)

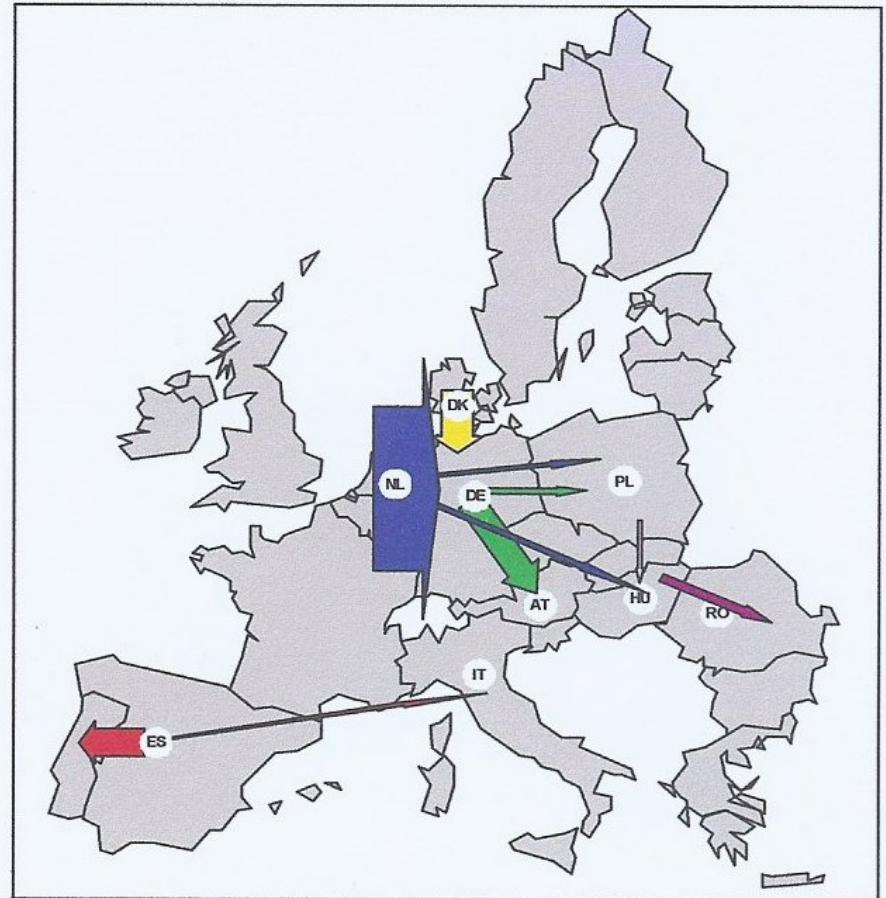


Source: Eurostat ([comext](#))

*Arrow width is proportional to the volume of intra-EU foreign trade surplus (in tons).*

*The 10 main surpluses on pigs weighing less than 50 kg account for 89% of the overall balances*

**Figure 7: Net exchanges of pigs for slaughtering**  
Scheme of the intra-EU exchanges (2008)



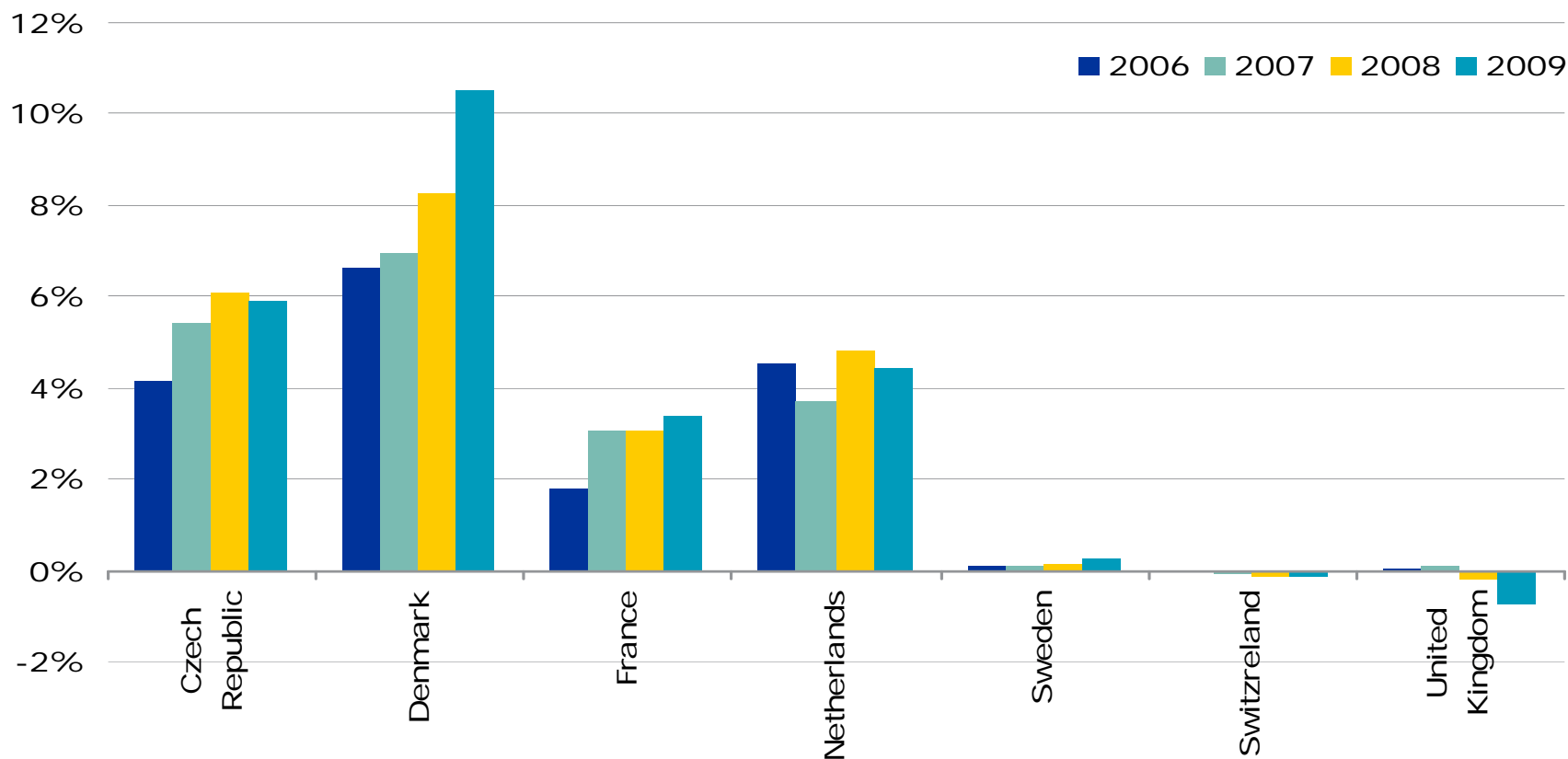
Source: Eurostat ([comext](#))

*Arrow width is proportional to the volume of intra-EU foreign trade surplus (in tons).*

*The 10 main surpluses on pigs with a live weighing at least 50 kg account for 88% of the overall balances*

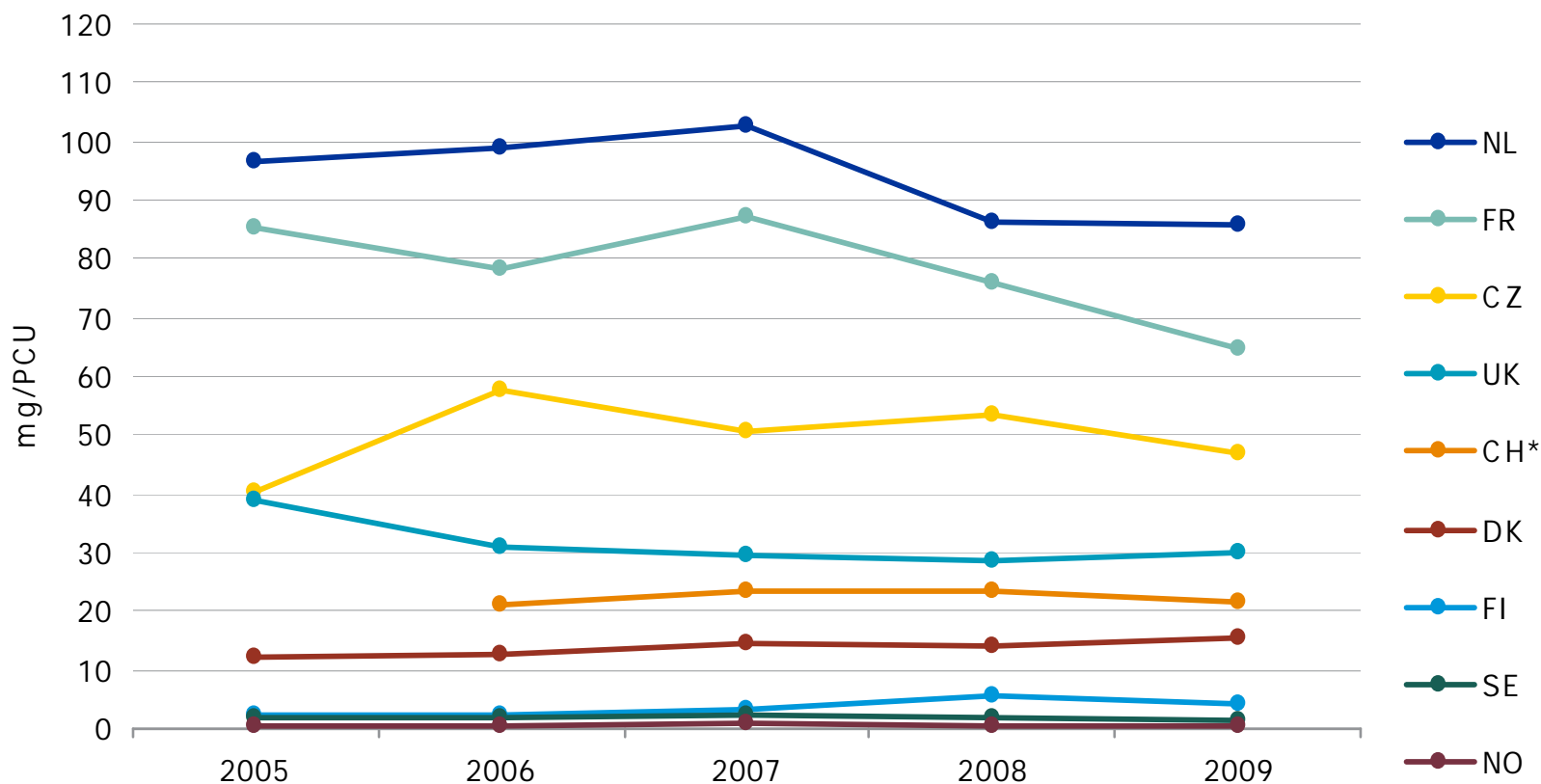


## % PCU of total PCU for animals exported or imported (net balance) for fattening or slaughter in another MS\*



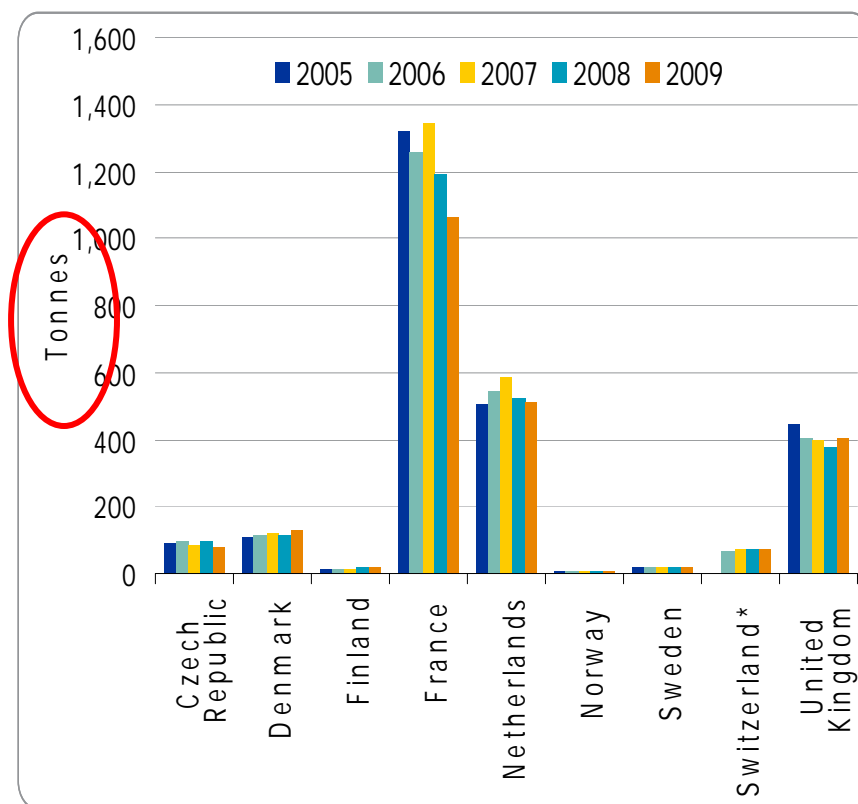
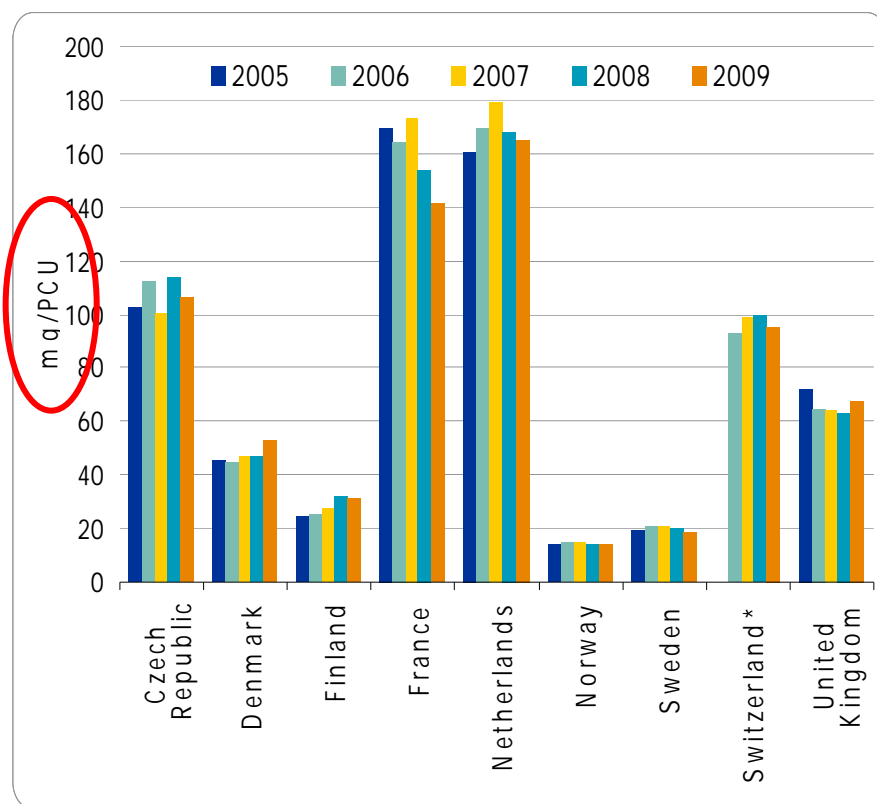


# Trends in the sales, in mg/PCU, of antimicrobial VMPs in 9 European countries



\*No data 2005

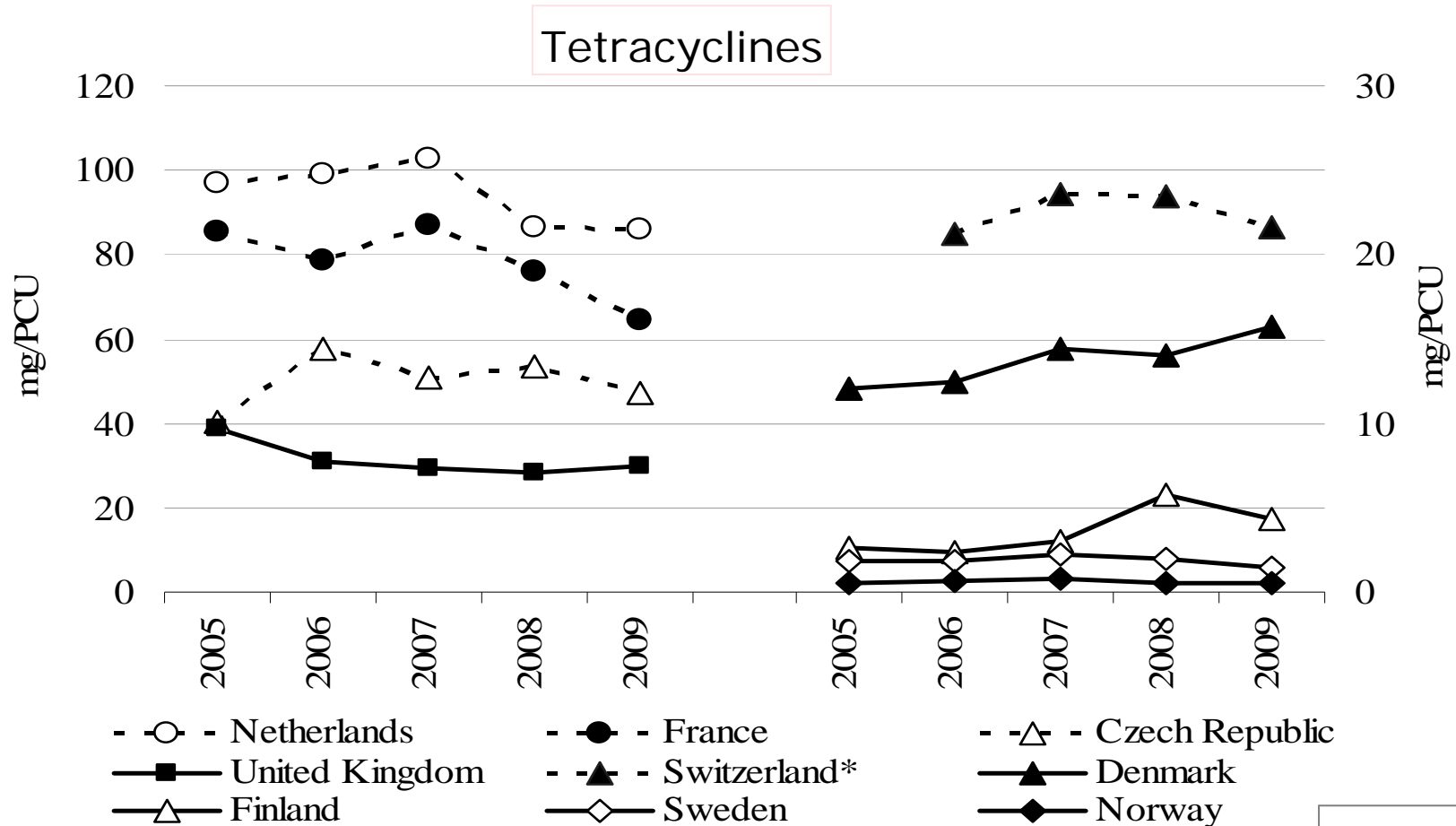
- Sales show only 12 fold difference when given as mg/PCU while when given in tonnes 190-220 fold differences between the least- and most selling countries
- Shows the importance of correcting the sales figures by animal population



\*Switzerland: 2006-2009

-8.3% decline in overall sales of antimicrobial VMPs, in mg/PCU, during 2005-2009 (Switzerland not included)

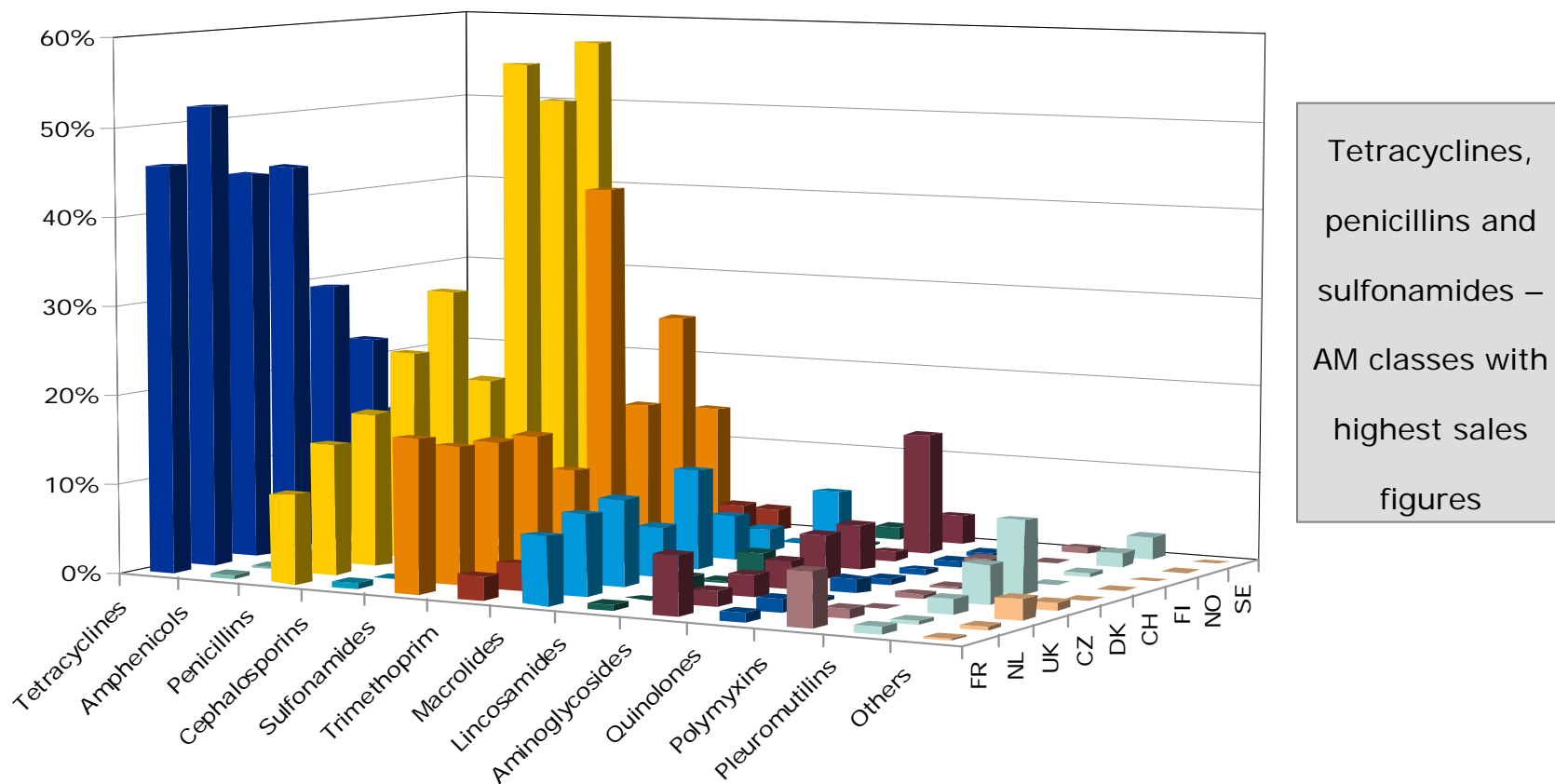
-Mainly accounted for by decline in sales of tetracyclines in France and the Netherlands (Note the differences in the scales)



\*No data 2005



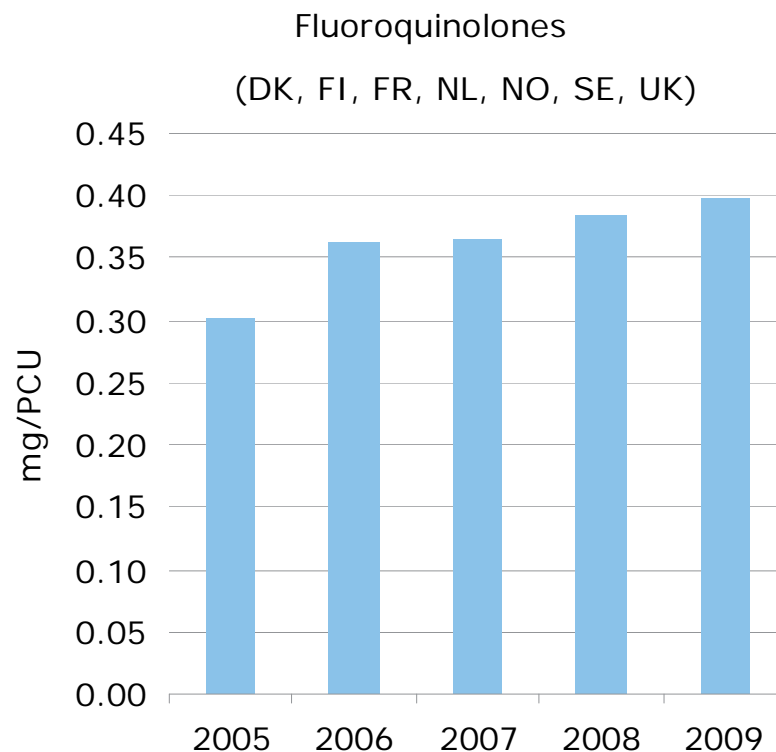
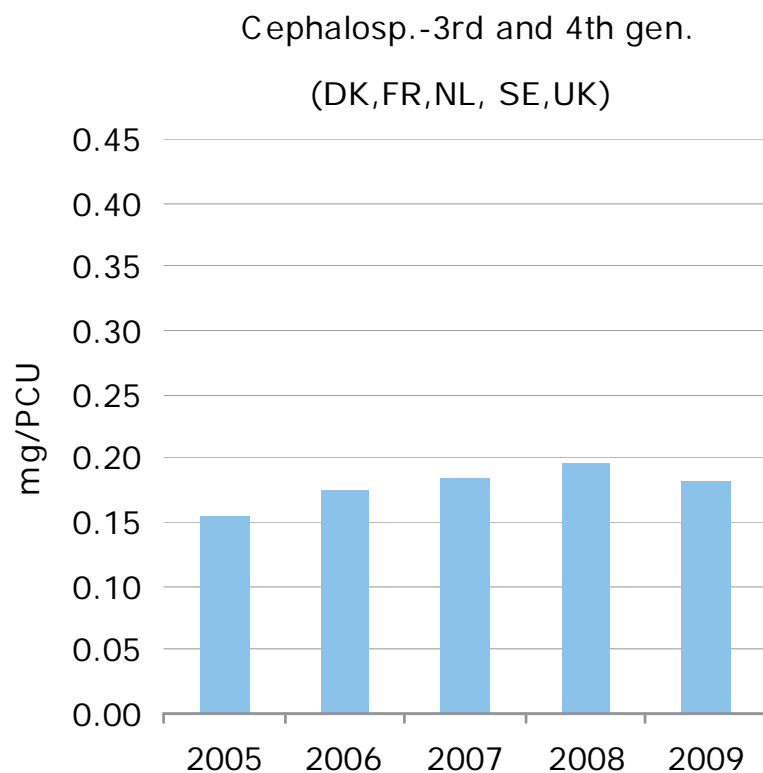
## Substantial differences in prescribing patterns of various AM classes (2009 data) - % of total mg/PCU







## Increase sales of antimicrobial agents characterised by the WHO as critical important in human medicine





## Summary- trends in the sales for 2005-2009

---

- Sales data gives a valid picture of the sales in the 9 countries
- Significant differences in
  - prescribing patterns
  - mg sold of AM agents/PCU between countries observed.
- Differences cannot be described by differences in animal demographics alone
- Increase in use of critical important antimicrobial agents observed
- In 8 countries - aggregated data (Switzerland not included)
  - mg/PCU declined by 8.3%





## State of play Phase II [Pilot phase (2010-2012)]

### Collecting standardised data **at package level**

---

- ESVAC protocol and data collection form (ESVAC template) developed together with experts from MSs
- ESVAC data base and **ESVAC data program developed** (applied for quality check/logical validation of the data)
- 20 countries has informed the Agency that they will provide data according to ESVAC template – 18 have delivered
- Original deadline was 1 September but deadline extended to 15 February
  - Countries already collecting data had all to change how to record the data
  - many of the countries are collecting data for first time

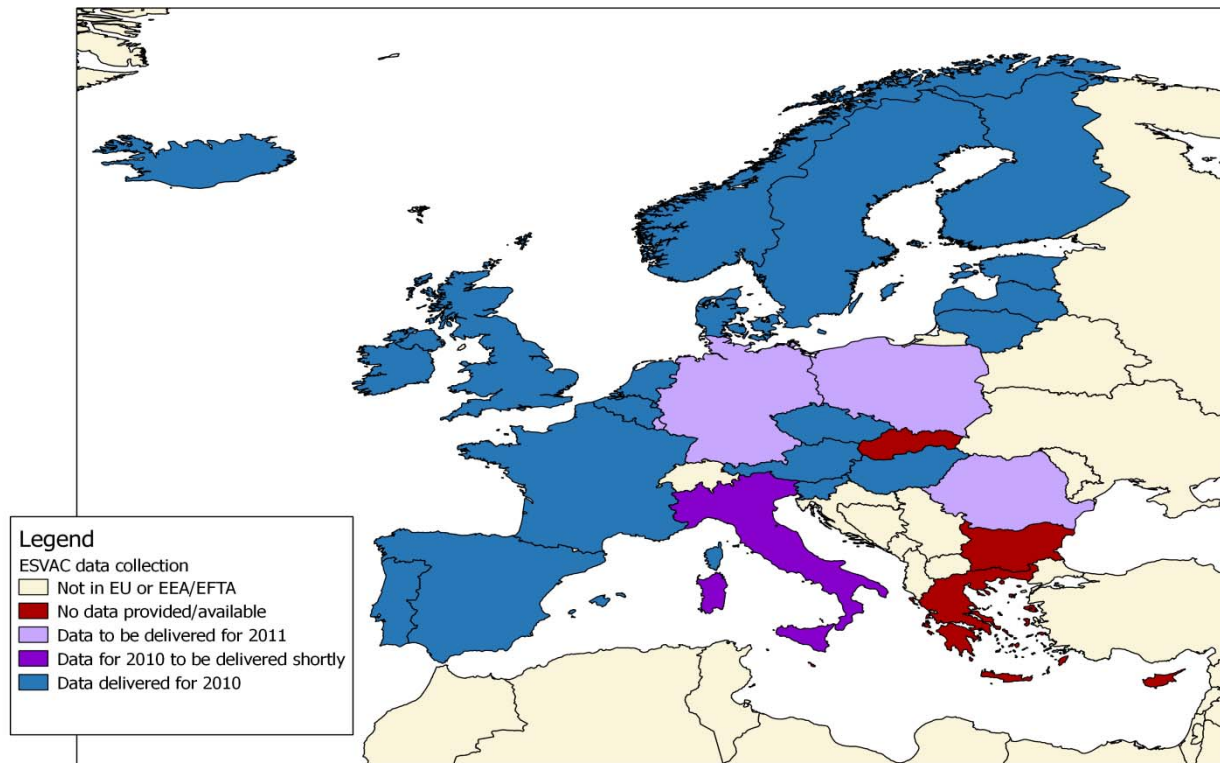


## State of play Phase II [Pilot phase (2010-2012)] Collecting standardised data **at package level** cont

---

- Data from 14 countries now validated and consent to save the data in the ESVAC database given;
  - 2-5 days to validate the data for each country
- Countries that have approved their data to be saved in the ESVAC database within **1 March** will be included in the report
- For ingredients lacking ATCvet code/name - these have been assigned by the WHO Collaborating Centre for Drug Statistics Methodology and the approved ESVAC data will be/have been updated.

## Collecting standardised data – state of play Phase II cont. Countries delivered/to deliver data for 2010 – 18 MSs + Iceland and Norway





## Semi-automatic calculation of PCU

---

- Program to import Eurostat, TRACES, and other species data and to calculation of the PCU from these data developed
  - Validated by use of the PCU calculated manually for 2009
- The data will be used to compute the consumption in mg/PCU
- In the future, to integrate the PCU program into the ESVAC program, one program will then be able to manage consumption and PCU data.



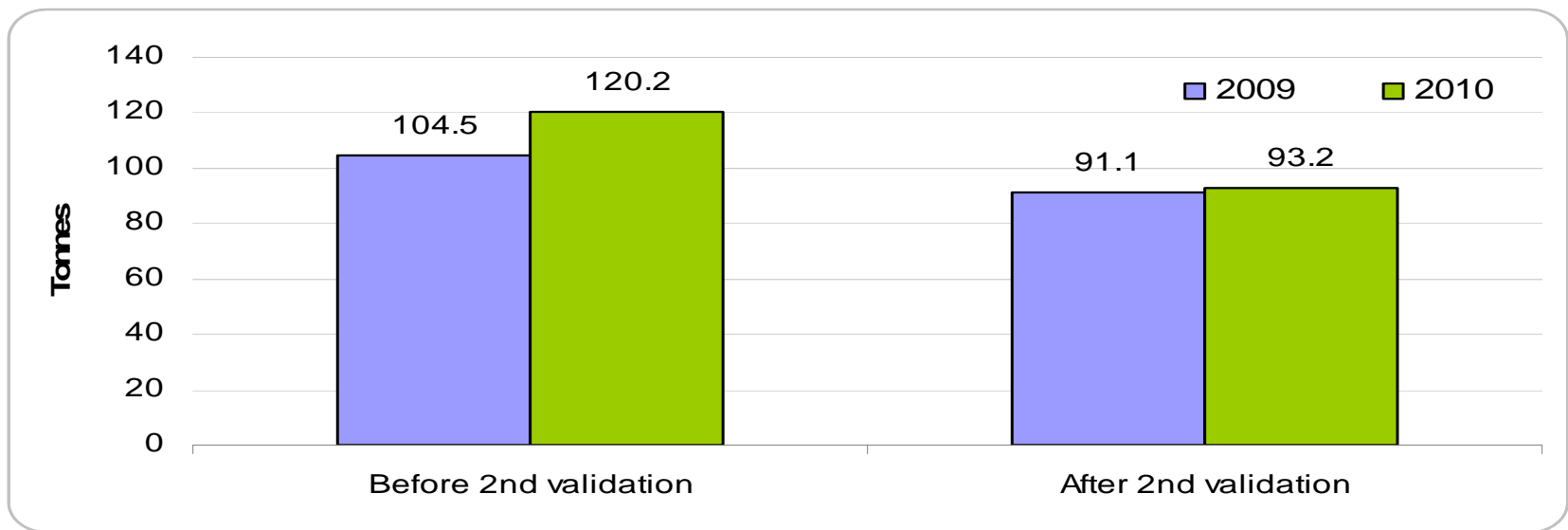
## Obtaining valid data - major hazard points

---

- Under reporting
- Double/triple reporting
- Incorrect pack size and strength given
- Number of packages sold reported by data provider
- Ireland suggest that it takes at least 3 years to establish a valid base line. This is also the experience from human medicine.

[http://www.imb.ie/images/uploaded/documents/Report\\_consumption\\_vet\\_antimicrobials\\_2010\\_Nov\\_2011\\_final\\_clean.pdf](http://www.imb.ie/images/uploaded/documents/Report_consumption_vet_antimicrobials_2010_Nov_2011_final_clean.pdf)

# Errors in the data provided on NO SOLD - example from Ireland



- Before validated a 2<sup>nd</sup> time an increase of 15% from 2009 to 2010 was observed while after correction of the data this figure was 2%
- Errors solely due to wrong sales figures reported by data providers



## Summary – collecting standardized data at package level

---

- It takes at least 3 years to establish a valid base line
- In 2 years, ESVAC has been able to collect detailed sales data on veterinary antimicrobial agents at package level from 19 countries

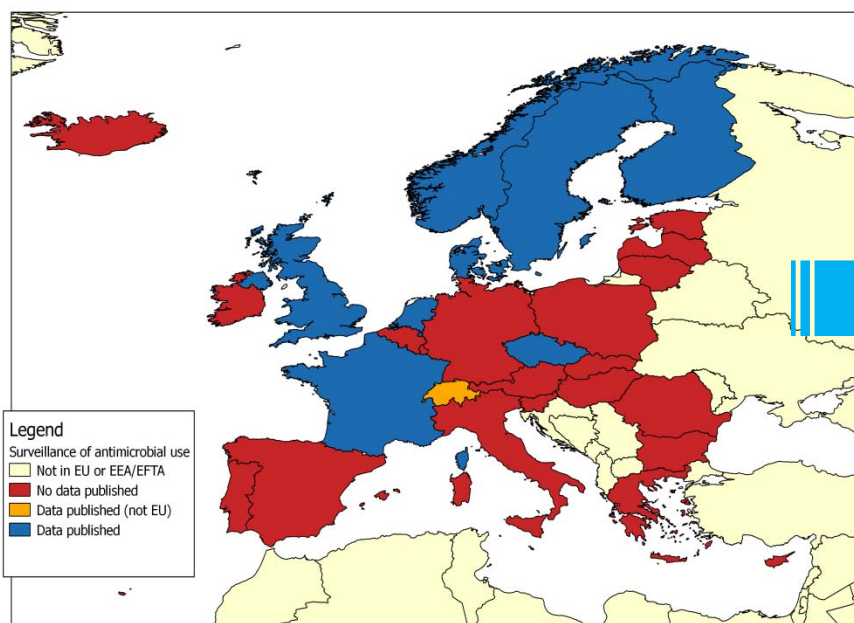




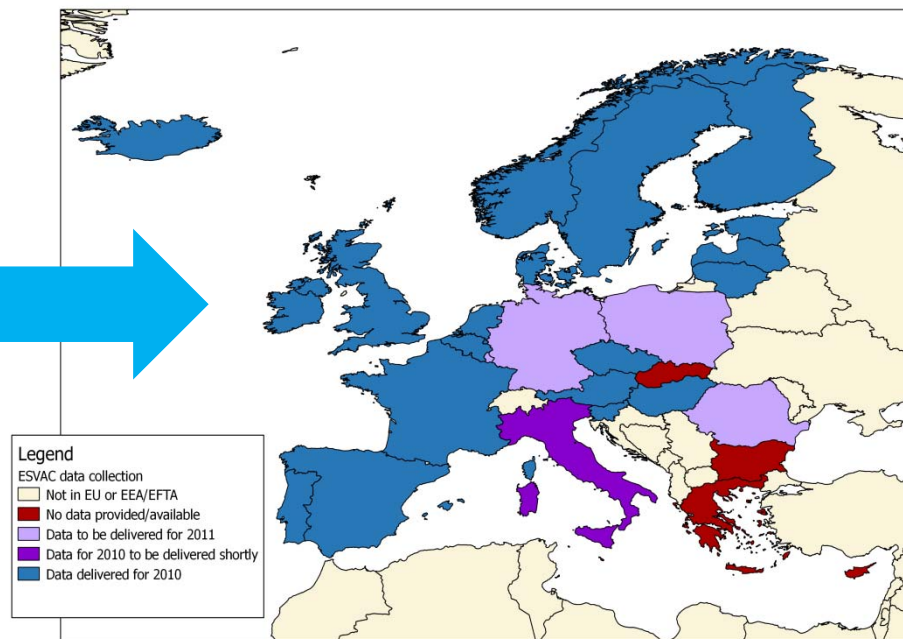
# Summary cont.

8 EU/EEA countries with established surveillance programs in 2009

20 EU/EEA countries delivered/to deliver ESVAC data for 2010



The 7 EU countries accounted for approx. 37% of the slaughtered biomass of cattle, pigs, poultry, sheep and goat in EU



18 EU countries accounts for approx. 80% of the slaughtered biomass of cattle, pigs, poultry, sheep and goat in EU





Next step - Phase II [Pilot phase (2010-2012)]

Collecting standardised data **at package level**

---

- **Call for 2011 data sent out during March**
  - The filled in ESVAC template – i.e. the ESVAC register (2010) for each country - will be updated with ATCvet codes when applicable and sent with the call individually for each country
  - For countries collecting the data for the first time the ESVAC Data Collection Form with updated ATCvet codes will be sent out



# The ESVAC project plan - state of the play

---

A multiphase approach including four partly overlapping phases

- Phase I: Investigation phase (completed)
- Phase II (2010-2012): Pilot project collecting standardized overall sales data from MSs willing to participate (20)
- Phase III (2013 – onwards): Collect and report overall national data from all MS
- **Phase IV (2014 – onwards):** Collect and report data per species



# Collecting data by species and unit of measurement (Phase IV)

---

13-14 October 2011 ESVAC workshop on

- Establishment of technical unit of measurement in order to correct for differences in dosage and
- Collecting data by species

Attended by

- Invited experts, including from WHO CC on Drug Statistics Methodology
- ECDC and EFSA
- Observers from FAO, OIE, and WHO (FDA invited but apology)



# Why did we decide to start with Phase IV already now?

---

Communication from the Commission to the European Parliament and the Council Action plan against the rising threats from Antimicrobial Resistance

- *“Promotion and extension of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) with the collaboration of EMA to obtain harmonised data **on the usage per animal species** and production categories as well as for different indications from all Member States”*



# Why did we decide to start with Phase IV already now cont?

---

## TATFAR Recommendation 3:

### ***Collaborate on collection of data on sales and use of veterinary antimicrobials in food producing animals***

The US and EU should work closely with the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) and OIE to achieve this goal.

The work would also address the development of common units of measurement of antimicrobial drug use that are needed for the further analysis and comparison of the data. Preferably, data collection should allow stratification by product type, to allow efficient prioritisation of control measurements.



## Why did we decide to start with Phase IV already now cont?

---

- ✓ Informed that “new” countries are initiating the collection of data by species and develop national units of measurement. In order to avoid that MSs build up different systems, need starting the harmonisation work now
- ✓ MSs has asked that EMA provide a venue for discussion on these topics
- ✓ We need to already now start the preparation in order to collect harmonised data by species and report these in a standardised manner in the next years



## State of play/next steps –unit of measurement and collecting data by species

---

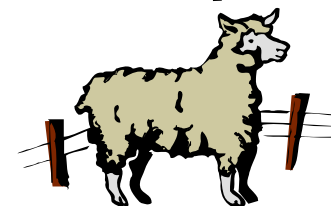
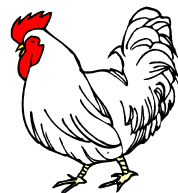
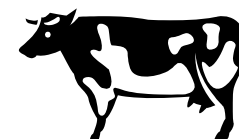
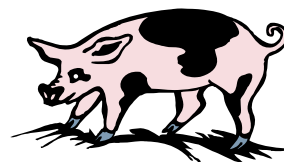
- *Ad hoc* working group on unit of measurement established (5 MS + expert from WHO CC on Drug Statistics Methodology)
  - Terms of reference agreed on
  - First step to develop a reflection paper – to be sent out for consultation
- *Ad hoc* working group on collecting data by species established (5 MS + WHO AGISAR chair of Usage subcommittee)
  - Terms of reference agreed on
  - First step to develop a reflection paper - to be sent out for consultation



# Future

Overall sales data  
(core data) collected  
from all **27 MSs**  
reported as mg/PCU

Collecting data by animal  
species



Introduction of Defined Daily  
Dose, Defined Cure Dose or other  
units of measurement for the  
reporting of the data

