

# Reflection paper on the use of fluoroquinolones in food producing animals

Considerations from the Spanish National Authority



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12.10.2006

# Actions Taken

- Harmonization of the SPC for enrofloxacin
- Spain had undertaken regular surveillance of fluoroquinolone resistance in campylobacter, Salmonella and Escherichia coli .
- Training for veterinarians, farmers...
- An annual marketed control.

# Harmonisation of SPC

## Regulatory aspects

- **Circular 19/2002** “ Harmonisation of SPC and package leaflet for the veterinarian medicinal products containing enrofloxacin”
- EMEA/CVMP/612/01 Guideline on the SPC for antimicrobial products”

# HARMONIZATION of SPC

## 4.1 Pharmacodynamic Properties

- The antibacterial spectrum relevant for the target species and intended use.
  - └ MIC data

# Harmonization of SPC

## ■ 5.5 Special precautions for use

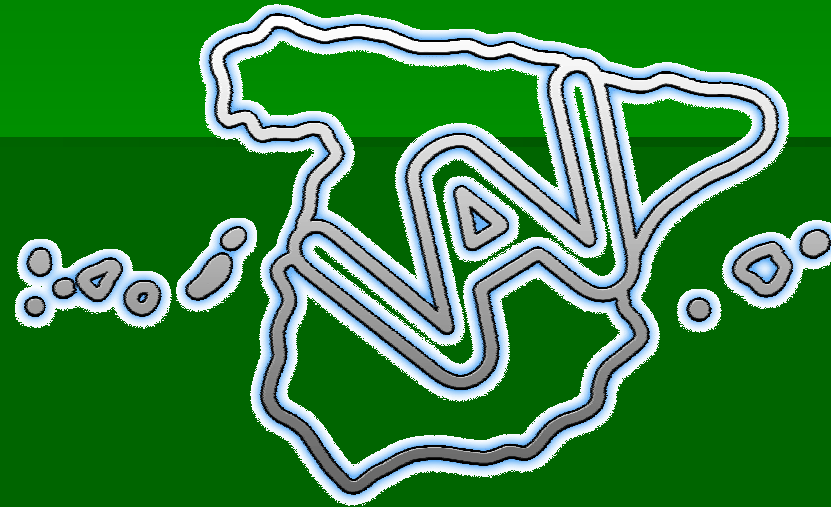
- - Due to a high risk of development of resistance in bacterial species, enrofloxacin should only be used as a treatment of last choice and only when treatment failure and susceptibility testing indicates that the use of other anti-microbials is ineffective."
- - Inappropriate use of fluoroquinolones may increase the prevalence of bacteria resistant to the enrofloxacin present in the product and may decrease the effectiveness of treatment with enrofloxacin and related substances.

# surveillance

Spain has a national resistance monitoring programme

- VAV Network

# VAV NETWORK



**VAV NETWORK: Network of surveillance of antimicrobial resistance in bacteria of veterinary origin.**

**V: Vigilancia** (surveillance)

**A: Antibiorresistencias** (antibio-resistance)

**V: Veterinaria** (veterinary)

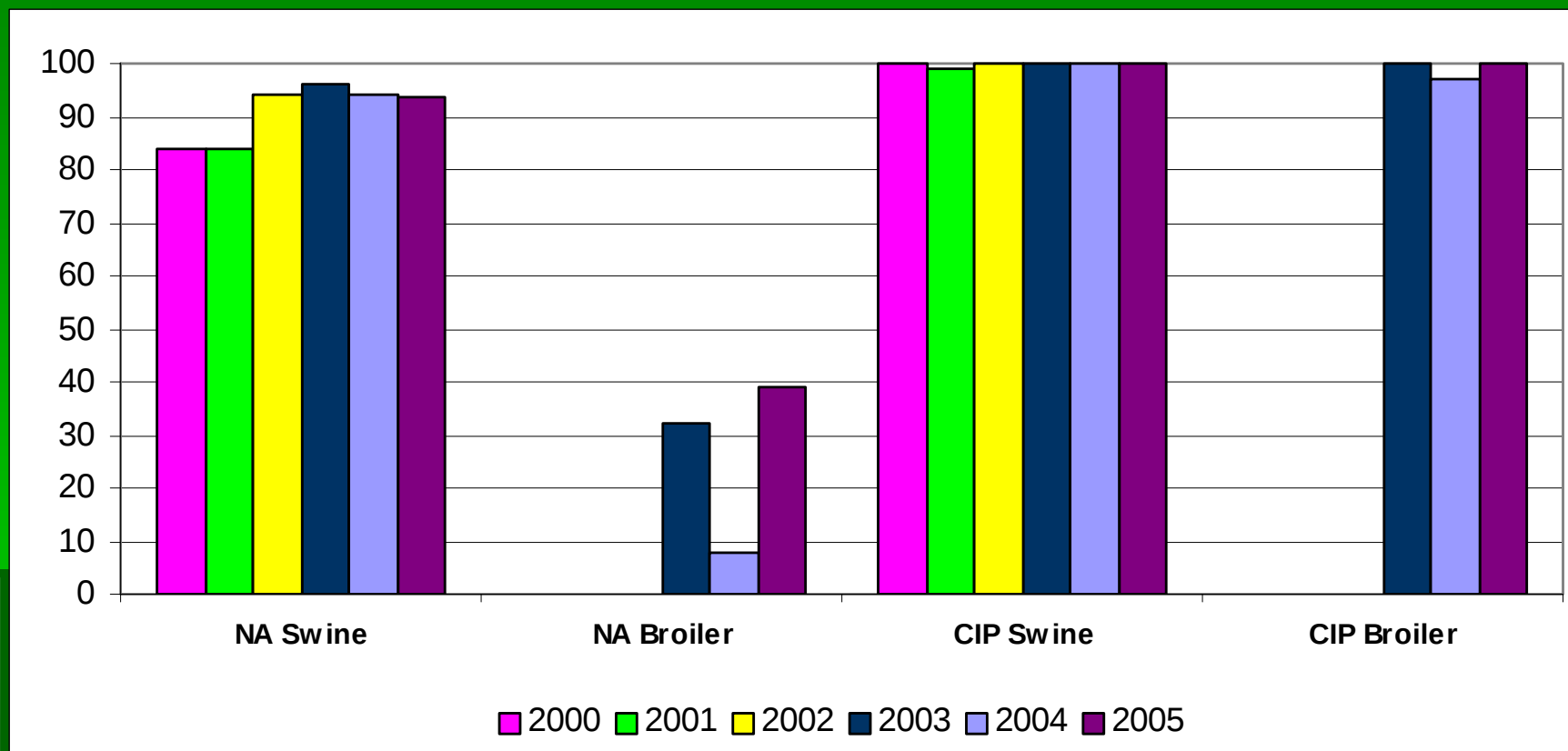
# Structure VAV Network

| HEALTHY ANIMALS                                                                                                                                                      | SICK ANIMALS                                                                                                                                                                 | FOOD FROM ANIMAL ORIGIN                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SWINE AND POULTRY                                                                                                                                                    | POULTRY, SWINE, RUMINANTS, RABBITS, SMALL ANIMALS                                                                                                                            | MEAT, MILK, EGGS                                                                                                                                                         |
| <i>Salmonella enterica</i><br><i>Campylobacter coli</i><br><b>(ZONOSSES)</b><br><i>Escherichia coli</i><br><i>Enterococcus faecium</i><br><b>(FAECAL INDICATORS)</b> | <i>Escherichia coli</i> ,<br><i>Staphylococcus aureus</i><br><i>Salmonella</i> , <i>Pseudomonas</i> ,<br><i>Pasteurella</i> , <i>Streptococcus</i> ,<br><i>Campylobacter</i> | <i>Salmonella enterica</i><br><i>Campylobacter coli</i><br><b>(ZONOSSES)</b><br><br><i>Escherichia coli</i><br><i>Enterococcus faecium</i><br><b>(FAECAL INDICATORS)</b> |

# Results, Healthy Animals: QUINOLONES



*Salmonella* spp.

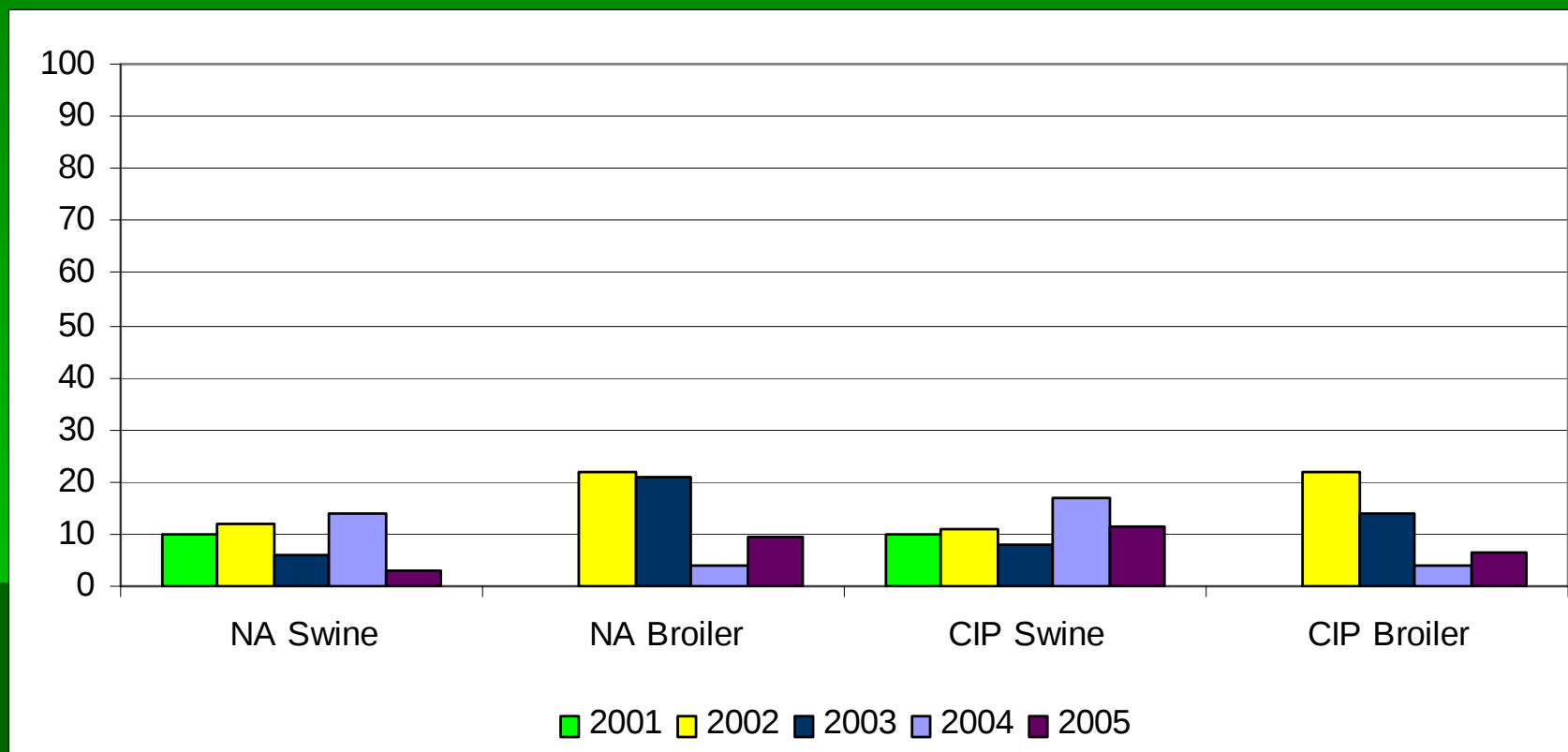


% SUSCEPTIBILITY; NA: nalidixic acid; CIP: ciprofloxacin

# Results, Healthy Animals: QUINOLONES



*Campylobacter* spp.

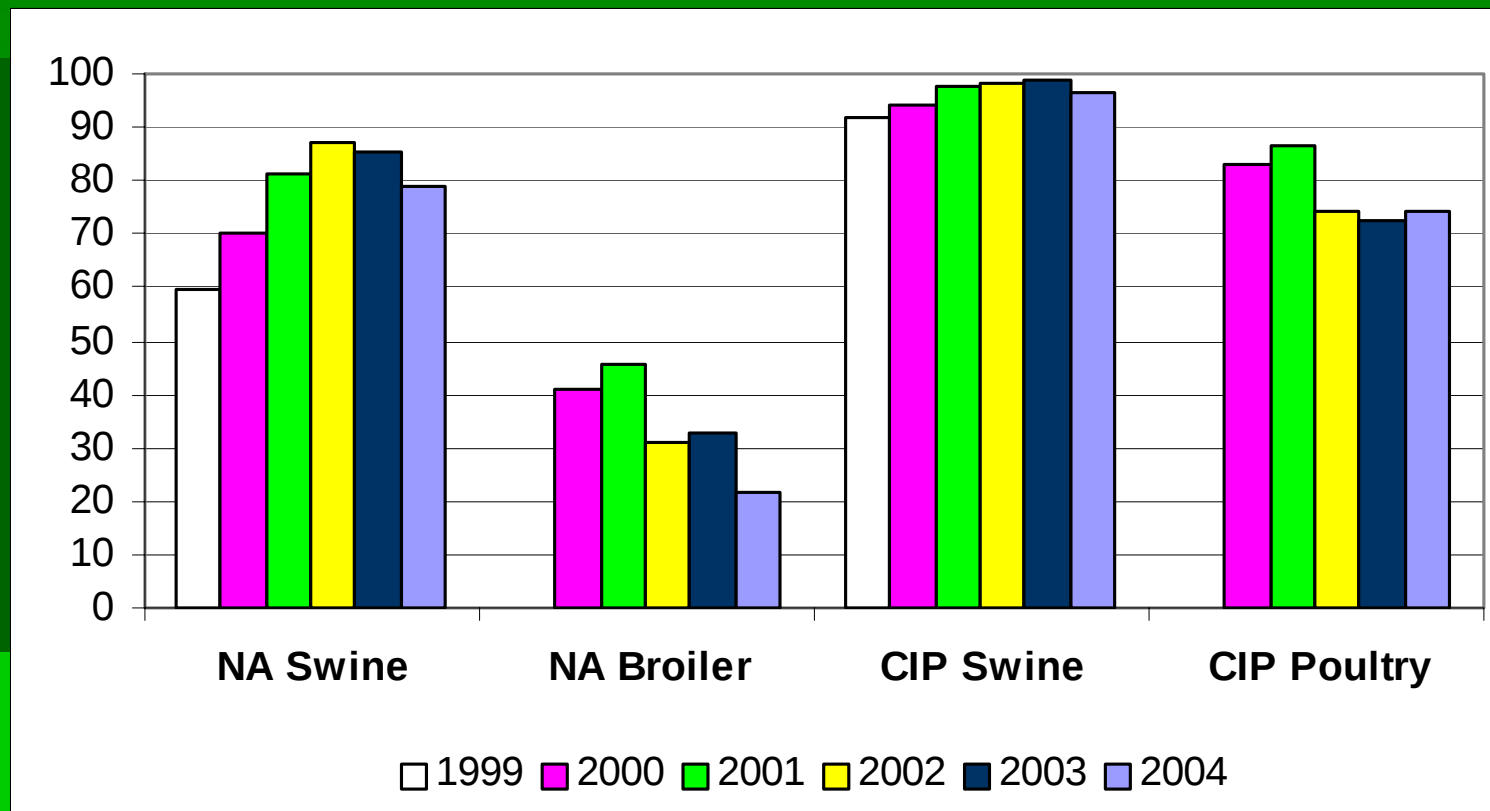


% SUSCEPTIBILITY; NA: nalidixic acid; CIP: ciprofloxacin

# Results, Healthy Animals: QUINOLONES



*Escherichia coli*



% SUSCEPTIBILITY; NA: nalidixic acid; CIP: ciprofloxacin

# Training for veterinarians, farmers...

- The Spanish Agency ( AEMPS) together with veterinary Colleges and Professional Veterinary Bodies is providing training and courses for veterinarian practitioners and farmers.

# Training for veterinarians, farmers...

- Targets points:
  - Strategies for avoids resistances and promote prudent use of fluoroquinolones.
  - Prudent used of fluoroquinolones in animals.

# Training for veterinarians, farmers...

- **prudent use guidelines on the use of antimicrobials for animals.**
- One is to veterinarian practitioners
  - “The veterinarian practitioners and the rational and prudent use of antimicrobials**
- One to farmer
  - “Farmers and the rational and prudent use of antimicrobials**

# Control of the annual amounts marketed .

- Pharmacovigilance
- Veterinary Prescription
- Annual marketing declaration.

# Future actions

- Guidelines on the prudent use of (Fluoro) quinolones for animals
- Review the dosage regimens of all fluoroquinolones.

# Proposal by AEMPS

- In our opinion all MS with a significant number of (fluoro)quinolones should implement similar recommendations/ measures

# Thank you very much for your attention

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