



Human and veterinary pharmaceuticals regulation

Towards EU accession: Serbia's regulatory challenges, expectations and opportunities

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Republika Srbija
Ministarstvo zdravlja
Ministarstvo poljoprivrede,
šumarstva i vodoprivrede,
Uprava za veterinu

Republic of Serbia
Ministry of Health
Ministry of Agriculture, Forestry
and Water Management,
Veterinary Directorate



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Antimicrobial resistance in food safety perspective - current situation in Croatia

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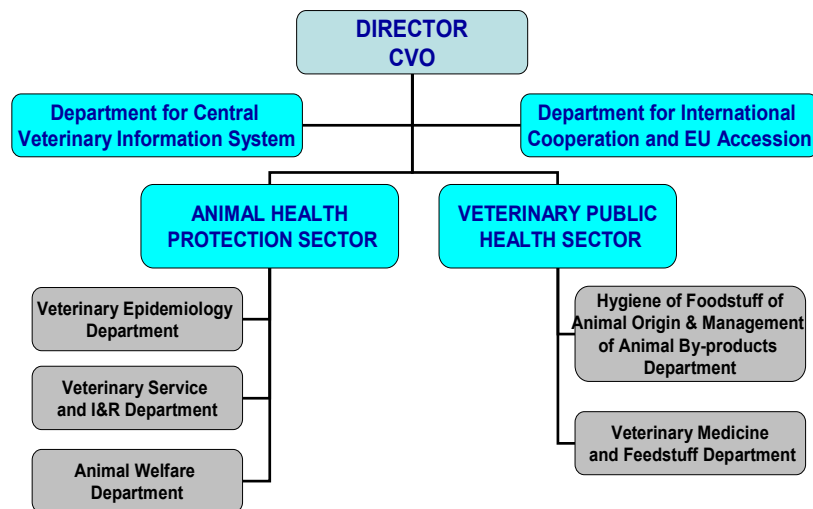
Contents

- Competent authorities;
- Legislation;
- Antimicrobial resistance in primary production;
- National residue monitoring plan;
- Short term plans.

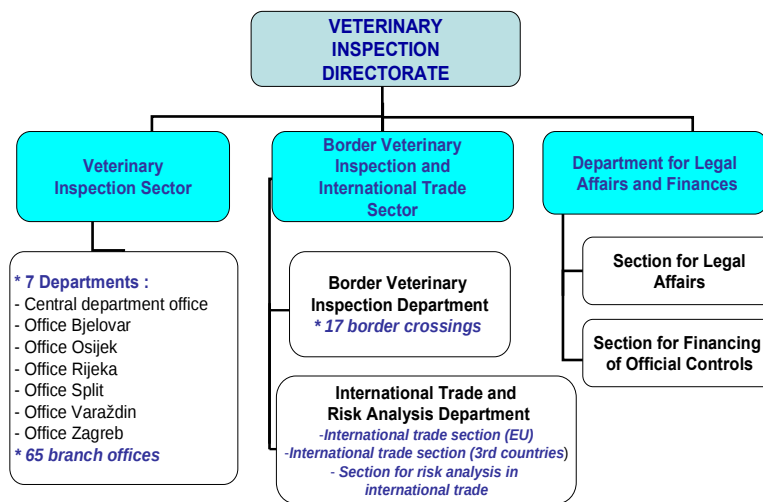


Ministry of Agriculture, Fisheries & Rural Development - *Competent veterinary authorities for AMR*

VETERINARY DIRECTORATE



VETERINARY INSPECTION DIRECTORATE



Competent authorities and organisations included in the Programme implementation Veterinary Directorate

- Legislation,
- Programmes,
- Monitoring & coordination of the implementation,
- Reporting on results



Veterinary Inspection Directorate

- Supervision and control of the Programme implementation,
- Sampling.

Authorized veterinary organizations

- Sampling.

Laboratories

- Croatian Veterinary Institute Zagreb



Legal base-primary legislation

- **Veterinary Act (OG 41/07)**
- **Food Act (46/07)**
- **Act on VMP (84/09)**



Legal base-secondary legislation

- Ordinance on harmonised monitoring of antimicrobial resistance in Salmonella in poultry and pigs (Official Gazette 75/09)- harmonized with the Decision 2007/407
- Ordinance on specific control methods in the framework of the national programmes for the control of salmonella in poultry (Official Gazette 72/08)- harmonized with Regulation 1091/2005
- Salmonella *Gallus gallus* ordinances (Official Gazette 107/07, 44/07, 72/08) – harmonized with Regulations 1168/2006, 1003/2005, 646/2007
- Baseline study in poultry and pig production (Official Gazette 31/10 i 55/10) –harmonized with Decision 2007/516/EC and Decision 2008/55
- Ordinance on official controls performed to ensure the verification of compliance with feed & food law, animal health & animal welfare rules (Official Gazette No 118/04) - harmonized with Regulation 882/2004
- Ordinance on the monitoring of certain substances & residues thereof in live animals & animal products (Official Gazette No 79/08) - harmonized with Directive 96/23
- Order prohibiting the use in stock farming of certain beta-agonists & substances having hormonal or thyrostatic action (Official Gazette No 93/08) - harmonized with Directive 96/22



AMR in primary production- poultry 2009

- Pilot project on poultry- *Salmonella* spp., *E.coli* and *Campylobacter* spp.

- 3 counties with high broiler production
 - 30 *Salmonella* serotypes were tested on AMR
 - 207 *E. coli* serotypes were tested on AMR
 - 10 *Campylobacter* spp. were tested on AMR



AMR PILOT PROJECT 2009-RESULTS

Antimicrobial	No / % resistant <i>Salmonella</i> serotypes	No / % resistant <i>E. coli</i> serotypes	No / % resistant <i>Campylobacter</i> serotypes
Trimetoprim-sulfametoksazol	0	10/4,83%	-
Neomicin	0	16/7,73%	-
Streptomycin	8/26,27%	64/30,92%	-
Amoksicilin+ klavulanska kiselina	0	22/10,63%	-
Ampicilin	0	188/90,82%	10/100%
Gentamicin	0	0	-
Tetraciklin	2/6,67%	91/43,96%	0
Ciprofloksacin	0	49/23,67%	10/100%
Florfenikol	0	1/0,48%	-
Kloramfenikol	0	22/10,63%	-
Ceftiofur	0	5/2,42%	-
Enrofloksacin	0	21/10,14%	9/90%
Cefalotin	0	-	-
Eritrimicin	-	-	0
Ceftriakson	0	-	-
Nalidiksična kiselina	30/100%	-	10/100%



AMR in primary production - pigs 2009

- Pilot project on pigs - *Salmonella* spp. and Methicillin-resistant *Staphylococcus aureus*

- 6 commercial farms with intensive production

- All samples tested on *Salmonella* spp and MRSA
- MRSA isolates were tested for antimicrobial susceptibility
- 3 farms positive on *Salmonella* Typhimurium
- 4 farms with MRSA isolates (mecA gen)





AMR monitoring programmes in primary production 2010

- National monitoring programmes for control of salmonellosis in *Gallus gallus* poultry
 - Laying hens
 - Broilers
- Salmonella isolates are subjected to AMR monitoring
 - One isolate per Salmonella serovar from the same epidemiological unit (flock)/ year is included in the monitoring
- At least 170 Salmonella isolates must be included in AMR monitoring
 - in case of lower number of isolates than the target sample size is available, all isolates must be included in AMR monitoring.



Primary production- *Salmonella* Results

January –June 2010

Antimicrobial	Cut-off value	No / % of resistant serotypes
Cefotaxime	0.5	22/68.7
Nalidixic acid	16	26/81.2
Ciprofloxacin	0.06	26/81.2
Ampicillin	4	27/84.3
Tetracycline	8	32/100
Gentamicin	2	32/100
Chloramphenicol	16	32/100
Streptomycin	32	32/100
Trimethoprim	2	32/100
Sulphonamide	256	22/68.7

Salmonella spp.

- 32 isolates
 - SE — 12
 - SM — 12
 - ST — 2
 - SAg — 1
 - SSef -1
 - SNorw - 1

Baseline studies in poultry primary production 2010 – AMR included

- Broilers hatched in Croatia- baseline study to assess the prevalence of:
 - *Campylobacter* spp. and antimicrobial resistance in broiler flocks,
 - *Campylobacter* spp. and *Salmonella* spp. in broiler carcasses;
- Sampling in 3 major slaughterhouses:
 - 432 slaughter batches to be sampled,
 - delivery of broilers which have been raised in the same flock to a slaughterhouse on one single day.



Baseline studies in pig primary production 2010 – AMR included

- Baseline study in breeding pigs sampled at farm level to assess the prevalence of:

- *Salmonella* spp., and
- Methicilline-resistant *Staphylococcus aureus* (MRSA).



- Preferentially sampling of the holdings with 50 breeding pigs or more
 - representing at least 80 % of the breeding pig population in the country.
- The *Salmonella* and MRSA prevalence are measured separately.

AMR – NATIONAL RESIDUE CONTROL PLAN (NRCP)



- NRCP – belongs to the official controls
 - Group of substances on which samples have to be analyzed
 - Sampling procedure (who is authorized to take samples, how to choose sample, how to take them and what information has to follow a sample)
 - Minimum No. of samples to be taken
 - Laboratory analysis and interpretation of the results
 - Measures in case in a case of non-compliant result

NRCP - GROUPS OF SUBSTANCES THAT ARE ANALYSED

GROUP A — Substances having anabolic effect and unauthorized substances

GROUP B — VMP's & contaminants

(1) Antibacterial substances, including sulphonamides, quinolones

(2) Other veterinary drugs

- Anthelmintics, Anticoccidials, including nitroimidazoles, Carbamates and pyrethroids, Sedatives, Non-steroidal anti-inflammatory drugs (NSAIDs), Other pharmacologically active substances

(3) Other substances and environmental contaminants

- Organochlorine compounds including PCBs, Organophosphorus compounds, Chemical elements, Mycotoxins, Dyes, Others



GROUP B1 — VMP's & contaminants

Antibacterial substances, including sulphonamides, quinolones

- Type of samples:
 - Muscles
 - bovine, caprine, ovine, porcine, equine, rabbits, wild & farmed game, poultry animals and the whole fish
 - Honey, milk and eggs.



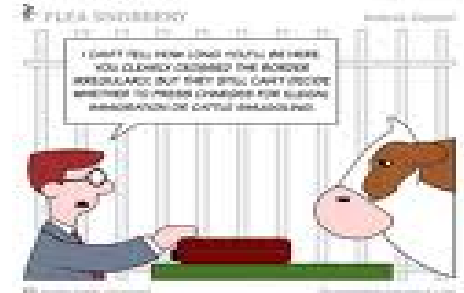
NRCP results in 2009

Type of animals/ animal products	Number of samples	Number of suspect samples on B1 group	Number of positive samples on B1 group
Bovine	719	0	0
ovine & caprine	100	0	0
Porcine	542	4 on B1	0
Equine	69	0	0
Hens	324	0	0
turkeys & guise	274	0	0
rabbit	100	0	0
Wild & farmed game	222	0	0
Aquaculture	148	0	0
Milk - bovine	400	4 on B1	0
ovine & caprine milk	105	0	0
Honey	115	0	0
Eggs	210	0	0
TOTAL	3 328	8 on B1	0



AMR- Border veterinary inspection control of importing consignments

- Annual sampling plan for imported consignments of animal products:
 - Number of samples for all compounds (veterinary drugs, pesticides and unavoidable environmental contaminants)
- Monitoring of imported live animals intended for slaughter:
 - Official controls at slaughterhouses.



Sampling during 2009 at BIP's - Antibiotics and Sulfonamides

Consignment	Number of samples
Meat of domestic pigs	6
Meat of domestic bovine animals	7
Poultry meat	1
Ovine meat	1
Milk	32
Milk based products	6
Honey	6

All samples were tested with negative results.



HR Status in terms of trade with EU

HR Legislation

- Completely harmonized with EU legislation

National monitoring programmes:

- Salmonella in *Gallus gallus* poultry:
 - Breeding flocks and laying hens – EC approved
 - Broilers- currently in the approval procedure
- NRCP - EC approved



PLAN'S 2011.

- **National AMR monitoring programmes**
 - Poultry
 - Salmonella (laying hens, broilers, fattening turkey),
 - Campylobacter in broilers.
 - Pigs
 - Salmonella and MRSA
- **NRCP-continuing**
- **Education**
- **Raising public awareness-animal keepers**
- **Control of VMP trade and distribution**
- **Further cooperation with other Sectors**
 - National (MHSW),
 - International (EC, OIE, EFSA, FAO, WHO).





Thank you very much for your attention !



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