Bilateral Screening

Prohibition of Substances and Control of Residues

Ministry of Agriculture and Environmental Protection
Veterinary Directorate

Brussels
20 – 24 October 2014
CONTENT

1. Legal framework
2. EU aquis vs. Serbian legislation
3. National reference laboratory
4. National residue monitoring programme
5. Organization and responsibilities
6. Procedures and sampling
7. Official control
8. Measures in case of incompliant result
9. Challenges
LEGAL FRAMEWORK

- Law on Veterinary Matters (OG RS No 91/05, 30/10, 93/12) - art 83.
- Law on Food Safety (OG RS No 41/09)
- Law on Medicines and Medical Devices (OG RS No 30/10, 107/12)
- Law on Plant Protection Products (OG RS No 41/09)
## LEGAL FRAMEWORK

<table>
<thead>
<tr>
<th>EU Aquis</th>
<th>Partially in line with EU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directive 96/23/EC</td>
<td>Rulebook on establishing systematic monitoring of residues of pharmacological, hormonal and other harmful substances in animals, animal products and animal feed (OG RS No 91/09) (OG RS No 91/09)</td>
</tr>
<tr>
<td>Decision 97/747/EC</td>
<td></td>
</tr>
<tr>
<td>Decision 1998/179/EC</td>
<td></td>
</tr>
<tr>
<td>Regulation 37/10/EU</td>
<td></td>
</tr>
<tr>
<td>Directive 96/22/EC</td>
<td>Instruction on rules for official sampling within the monitoring of certain specific substances and residues in live animals and products of animal origin (CVO Decision, No. 323-07-01577/2010-05, April 6th, 2010)</td>
</tr>
<tr>
<td>Regulation 854/04/EC</td>
<td></td>
</tr>
<tr>
<td>Regulation 882/04/EC</td>
<td></td>
</tr>
<tr>
<td>Decision 999/879/EC &quot;BST ban&quot;</td>
<td>Decision on ban on use of certain substances of veterinary medicinal products in veterinary medicine for treatment of food producing animals (OG RS No 96/09)</td>
</tr>
<tr>
<td>Directive 96/22/EC</td>
<td></td>
</tr>
</tbody>
</table>
## LEGAL FRAMEWORK

<table>
<thead>
<tr>
<th>EU Aquis</th>
<th>Partially in line with EU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation EC No 396/2005 Regulation EC No 1881/2006</td>
<td>Rulebook on the maximum residue levels of pesticides in food and feed and on food and feed for which the residue levels of pesticides is established (OG RS 25/10, amm. 28/11, 20/13, 28/11, 29/14, 72/14)</td>
</tr>
<tr>
<td>Directive 90/167/EEC</td>
<td>Rulebook on the quantities of pesticide, metals, metalloids, and other toxic substances, drugs, anabolic and other substances that could be found in foodstuffs MRL of VMP (OG SFRY No 5/92, 11/92 and 32/02)</td>
</tr>
<tr>
<td>Directive 32/2002/EC</td>
<td>Rulebook on quality of feed (OG RS No 4/10, 113/12, 27/14)</td>
</tr>
</tbody>
</table>
Law on Medicines and Medical Devices
(OG RS No 30/10, 107/12)
Directive 2001/82/EC

- Authorisation, production, distribution, dozage and use of veterinary medical products (VMP)
- Definition of premixes
- Prescription for VMP
- Withdrawal period:
  - “cascade” use
  - equinae – List of substances with withdrawal period longer than 6 months
NATIONAL RESIDUE MONITORING PROGRAMME
Art. 11 and 12 - Directive 96/23

Purpose

Effective monitoring and detecting the presence of unauthorized substances and the residue level of veterinary drugs and contaminants in live animals, their excrement and body fluids and in tissue, primary products of animal origin, animal Feed and drinking water

Official checks focused on:

• illegal treatment
• contamination
• undertaking preventive measures for protection of public health
HISTORY

VETERINARY SERVICE
&
INSTITUTE OF MEAT HYGIENE AND TECHNOLOGY

1972
USDA
FSIS

1996
JUS
ISO
96/23
9001
EC

2001
IEC
17025
2002

2003
NRMP
STATE
BUDGET
COMMISSION DECISION
From 1st AUGUST 2013
(2013/422/EU)

amending Decision
2011/163/EU

on the approval of plans
submitted by third countries
in accordance with Article 29

APPROVED
2006 - 2013

- Bovine
- Ovine / Caprine
- Swine
- Equine (live – for slaughter)
- Poultry
- Fish
- Milk
- Eggs

Rabbits

- Wild game
- Farmed game
- Honey
NATIONAL RESIDUE MONITORING PROGRAMME (NRMP)
Annex I – Directive 96/23

Group A

• Substances with anabolic effect and prohibited substances
• Stilbenes, stilbene derivatives, their salts and esters
• Antithyroid agents
• Steroids
• Resorcylic acid lactones
• Beta-agonists
• Substances listed in Annex IV of Regulation, No. 37/10/EC
Group B

1. Antibacterial substances, including sulphonamides,

2. Other veterinary medicinal products
   a. Anthelmintics
   b. Anticoccidials, including nitroimidazoles
   c. Carbamates and pyrethroids

3. Other substances and environmental pollutants
   a. Organochlorine compounds, including PcBs
   b. Organophosphorus compounds
   c. Chemical elements
   d. Mycotoxins
   e. Dyes
**National reference laboratory for residue testing**

**Art. 14 and 15 - Directive 96/23**

Institute of Meat Hygiene and Technology, Belgrade

- Accreditation Certificate, for SRPS/ISO/IEC 17025:2006
- Internal document on implementation of Decision EC 657/02 – analytical methods & results’ interpretation:
  - MRL – maximum residue limit (Regulation 37/2010/EC)
  - MRPL – minimum required performance limit
Institute of Meat Hygiene and Technology
Proficiency Test

✓ **Thiouracil** in bovine urine, EURL for residues of veterinary drugs, Wageningen, Holland. The applied method: LC-MS/MS.
✓ Confirmation of **carbadox** metabolites in pig meat, EURL for residues of veterinary drugs, Fougeres, France. The applied method: LC-MS/MS.
✓ **Heavy metals** in soya flour, FAPAS. The applied method: ICP MS
✓ **Antibiotics and anthelmintics** in compound feed at carry-over level, EURL for residues of veterinary drugs, Wageningen, Holland. The applied method: LC-MS/MS
✓ **Parasiticides and antibiotics** in salmon muscle, EURL for residue of veterinary drugs Wageningen, Holland. The applied method LC-MS/MS.
✓ **Antibiotics and coccidiostats** in bovine muscle, EURL for residue of veterinary drugs, Wageningen, Holland. The applied method LC-MS/MS.
✓ **Anticoccidials** in liver, muscle (turkey) and egg (hen), EURL for residues of veterinary drugs, Berlin, Germany. The applied method: LC-MS/MS
✓ **Tranquilizers** in porcine kidney, EURL for residue veterinary drugs, Wageningen, Holland. The applied method: LC-MS/MS
✓ Confirmation of dye residues in shrimp, study code 13GP/2014, EURL for residue drugs, Fougeres, France. The applied method LC-MS/MS.
✓ **Beta-agonists** in urine, Progetto Trieste, Italy. The applied method EIA.
✓ **Aflatoxin M1** in milk, study code WAC4TD, organized by Progetto Trieste, Italy. The applied method EIA.
NRMP PREPARATION - DATA NEEDED
Art. 4 - 7 - Directive 96/23

- Number of slaughtered animals
- Quantity of products
- List of approved Veterinary Medicine products (ALIMS)
- Incompliant results from previous year:
  - illegal use of chloramphenicol,
  - Micotoxins in feed, raw milk and target tissues
  - Cross-contamination of feed for laying hens with coccidiostatics
  - Disrespect for the withdrawal period during treatment of broilers with coccidiostatics
  - Chemical elements (mainly cadmium) in offals of wild game and horses for slaughter

**information:**
- EFSA, EMEA, RASFF
- Data on VMP – Market/Misuse
- National/International scientific data
NRMP – Organization and responsibilities

REPUBLIC OF SERBIA
MINISTRY OF AGRICULTURE AND ENVIRONMENTAL PROTECTION

VETERINARY DIRECTORATE
Director – Chief Veterinary Officer - CVO

DEPARTMENT FOR INTERNATIONAL TRADE AND CERTIFICATION
HEAD OF DEPT.

DEPARTMENT FOR BORDER VETERINARY INSPECTION
HEAD OF DEPT.

DEPARTMENT FOR VETERINARY INSPECTION
HEAD OF DEPT.

GROUP FOR LEGAL AND GENERAL AFFAIRS
CHIEF OF THE GROUP

UNIT FOR VETERINARY SERVICES
CHIEF OF THE UNIT

DEPARTMENT FOR VETERINARY PUBLIC HEALTH
HEAD OF DEPT.

GROUP FOR FINANCE & ADMINISTRATIVE AFFAIRS
CHIEF OF THE GROUP

DEPARTMENT FOR ANIMAL HEALTH & WELFARE
HEAD OF DEPT.

DISTRICT VETERINARY INSPECTION OFFICES
25 - HEADS OF THE UNITS

EXPORT ESTs
LOCAL VET. INSPECTORS

FOOD SAFETY & QUALITY & ABPs
LOCAL VET. INSPECTORS

ANIMAL HEALTH & WELFARE & VETERINARY DRUGS & FEED
LOCAL VET. INSPECTORS

ADVISOR
NRMP – Organization and responsibilities: Art. 4 - 7 - Directive 96/23

Within the VD, Department of Veterinary Public Health (DVPH) is responsible for:

- Reviewing production data for the previous year
- Drawing up the NRMP
- Preparation and delivering the Sampling Orders
- Coordination and monitoring of the implementation activities of the NRMP
- Sending NRMP for the current year and Results for the previous year to the Commission
NRMP – Organization and responsibilities
Instruction on rules for official sampling within the monitoring

Within Veterinary Inspection Department – Head of Department is responsible for:

• Organization of data collection on number of slaughtered animals and production of primary products of animal origin

• Organization of data collection on official control of production of veterinary medical products

• Taking measures in case of incompliances regarding the work of the inspection
NRMP – Organization and responsibilities

The **Head** of Veterinary Inspection on **District level**:

- Organization of data collection on number of slaughtered animals and production of primary products of animal origin on District level
- Submitting **Sampling** order to local inspector and supervising its implementation
- Keeping and taking care of sampling equipment and documents necessary for official sampling
NRMP – Organization and responsibilities

Local (in charge) veterinary inspector is responsible for:

• Selection of animals / products

• Sampling or supervising the sampling of animals / products

• Packaging, labelling, storage and insurance of integrity of samples

• Organization of transport to laboratory

• Keeping records, results and other relevant documents

• Investigation and taking measures on farms or establishments
Rulebook on establishing of systematic monitoring....
(OG RS No 91/09)
_in line with Directive EC 96/23_

The Rulebook defines:

- The program and plan for implementation of NPMR
- The list of substances (Group A and B)
- The target places, animals, products for sampling
- The obligation and responsibilities of producers
- The obligation and responsibilities within official control
- The measures in case of incompliant results
Rulebook on establishing of systematic monitoring….
(OG RS No 91/09)
Annex III - Directive EC 96/23

Samples within NRMP are taken:

a. On holdings/farms and fisheries from live animals

b. In slaughterhouses or collection centres/coldstores for wild game

c. In establishments for collection and packaging of primary products of animal origin – eggs, milk, honey
Rulebook on establishing of systematic monitoring....
(OG RS No 91/09)
Annex III - Directive EC 96/23

Scope of sampling:

- excrete and body fluid of live animals – bovine, porcine, ovine, caprine, equinae

- excrete and body fluid of slaughtered animals – bovine, porcine, ovine, caprine, equinae, poultry, wild game, fish

- primary products of animal origin (eggs, milk, honey)

- animal feed and water
Producers and food and feed business operators are obliged to:

- Breed and distribute animals and products that do not contain:
  - Prohibited substances
  - Unauthorised substances
  - Substances above maximum residue limits

- Use VMP under supervision of veterinarian, in compliance with prescription and respect of withdrawal period
NRMP – official control:
Art 14, 15 - Directive EC 96/23

Official control is performed with the aim to:

- detect the presence of illegal treatment, use of prohibited or unauthorized substances

- detect the presence of residue of VMP, contaminants which maximum residue levels exceed the level prescribed by legislation or international standards

Official sample:

- Taken without announcement
- Targeted, suspicious, random
- Related to scope and frequency with the aim to detect residues
- Tested in authorized laboratory
INVESTIGATION:
Instruction on rules for official sampling
Directive EC 96/22

All positive findings:

1. Testing with Screening method

2. Testing with Confirmatory method

In the case of positive findings, laboratory immediately informs the person in charge of NRMP /VPH
INVESTIGATION:
Instruction on rules for official sampling
Official measures - Directive EC 96/23

VPH without delay:

- Issuing the Sampling order for enforcement of sampling and guidelines for investigation process;
- Deliver to Head of District Local Veterinary Inspector
- They immediately take all necessary measures:
  - investigate farm of origin
  - discover (possible) path of residue presence
  - take the representative number of samples
  - send information which could be important for further investigation process
INVESTIGATION:
Taken measures
Chapter V- Directive EC 96/23

1. In case of finding unauthorized or illegal treatment of animals
2. Confirmed case of unauthorized or illegal treatment of animals
   (Repetition of positive results)
3. In case when residues exceed the maximum limits
4. In case of finding keeping, production or use of products
5. In case of suspicion of misuse in slaughterhouses
6. In case of suspicion of use of prohibited substances
INVESTIGATION:
Taken measures
Chapter V- Directive EC 96/23

- In case of positive sample, the holding is under special supervision
- Forbid distribution of animals or products
- Frequent sampling on the farm (fees) (6 – 12 months)
- Every carcass with residues of VMP above the MRL has to be disposed

- Other measures undertaken in accordance with points 6.10. of the Instruction and in accordance with articles 107, 143 and 144, 146, 147 – 3), 149, 150, 151 - 2) and 3) and 156 -14), chapter XVI Official Control of the Law on Veterinary Matters (OG RS No 91/05, 30/10, 93/12)
CHALLENGES

• Adoption and implementation of Decision EC No. 657/02 concerning the performance of analytical methods and the interpretation of results

• Regulation No 37/10/EU on pharmacologically active substances and their classification regarding MRL in foodstuffs of animal origin
  – Establishment of MRL for VMP and other substances

• Development of new methods for testing

• Building specialized teams for investigation (including officials from animal health, VMP, feed, expertise from different field of science)

• Improvement of manner of packaging, labeling and traceability of samples = bar codes, exchange of information completely electronically
THANK YOU FOR YOUR ATTENTION