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

alims
Agencija za lekove i medicinska sredstva Srbije
Medicines and Medical Devices Agency of Serbia

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

REZIDUE CONTROL IN SERBIA & MRLs

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Legislation In-Force

- Law on Veterinary Matters

(OG RS, No. 91/2005 + amend. OG RS, No. 30/2010)

- Food Safety Law (OG RS, No. 41/2009)

- Law on Medicinal Products and Medical Devices

(OG RS, No. 30/2010)

Legislation In-Force

*(In compliance with Directive **96/23/EC** & Commission Decision **97/747/EC**)*

Regulation

on the Programme of Systematic Monitoring of Residues
of Pharmacologically Active Substances, Hormones
and Other Harmful Matters
in Live Animals, Products of Animal Origin and Animal Feedingstuffs
(**OG RS, No. 91/2009**, 6.11.2009.)

*(In compliance with Commission Decision **98/179/EC**)*

Instruction

laying down rules on official sampling for
the monitoring of certain substances and residues thereof
in live animals and products of animal origin
(**No. 323-07-01577/2010-05**, 6.04.2010.)

Legislation In-Force

(In line *with Council Directive 96/22/EC*)

DECISION

on ban on use of certain substances of

veterinary medicinal products

for treatment of food producing animals

(OG RS, No 96/2009)

Bans on the use of hormones and beta-agonists for growth promotion

Related regulations

Maximum levels for pesticides in foodstuffs of animal origin

(*In line with Regulation (EC) No 396/2005*)
Regulation on maximum residue levels of pesticides
in or on food and feed of plant and animal origin
(OG RS, No. 25/2010)

Maximum levels for Contaminants

(*Partly in line with Regulation (EC) No 1881/2006*)
Regulation on the quantities of pesticide, metals, metalloids and other toxic substances, drugs, anabolic and other substances that could be found in foods
(OG SFRY No. 5/92, amend. 11/92 and 32/02).

MRL for veterinary medicines in foodstuffs of animal origin

(*Not in line with Regulation (EC) 37/2010*)
Regulation on the quantities of pesticide, metals, metalloids and other toxic substances, drugs, anabolic and other substances that could be found in foods
(OG SFRY No. 5/92, amend. 11/92 and 32/02).

Related regulations

Medicated feedingstuffs and additives
(*Not in line with Council Directive 90/167/EEC*)
➢ Regulation on quality and other requirements for animal feed **(OG SRY No. 20/2000, amend. OG SRY No. 38/2001)**
➢ Regulation on the maximum levels of harmful substances and compounds in animal feedingstuffs **(OG SFRY No. 2/90)**

Responsibility

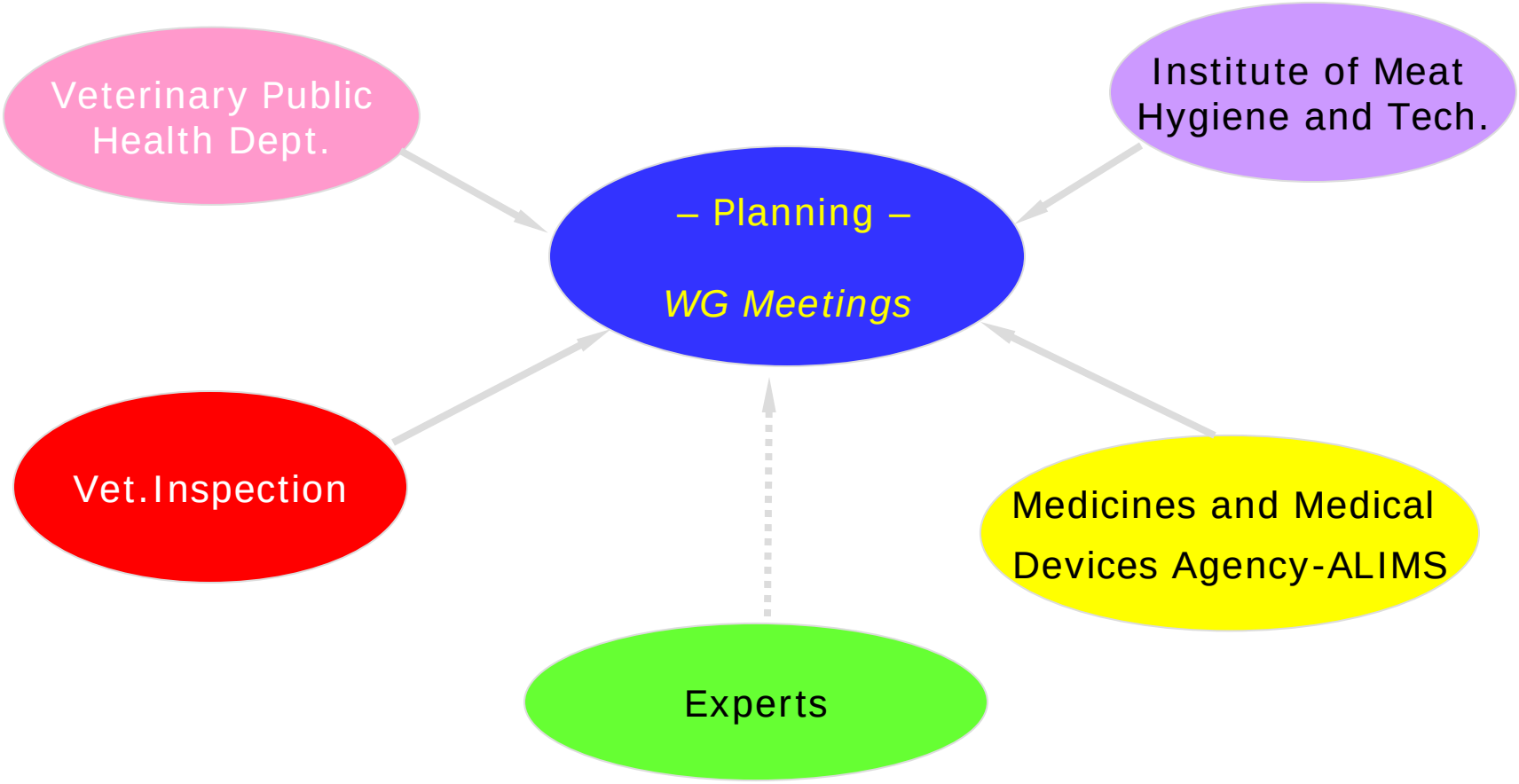
Chief Veterinary Officer/Veterinary Directorate

(**Department of Veterinary Public Health**)
within the Ministry of Agriculture, Forestry and Water Management
is the **CCA for the National Residue Control Plan in Serbia**

Medicines and Medical Devices Agency (ALIMS)
is the Competent Authority for Veterinary Medicines Controls

Institute of Meat Hygiene and Technology (IMHT)
is the only one laboratory currently being employed
by Veterinary Directorate for laboratory analysis of samples
within the National Residues Monitoring Plan (NRMP)

Who is involved in planning?



Statutory Surveillance for Veterinary Residues

Regulation OG RS, No. 91/2009
(Dir. 96/23/EC)
set out the groups of veterinary residues
that Member States/Third Countries are obliged to look for:

Group A:

- stilbenes
- thyrostats
- steroids
- zeranol
- beta agonists
- prohibited substances

Group B:

- antimicrobials
- coccidiostats
- anthelmintic agents
- carbamates and pyrethroids
- NSAIDs
- organochlorines and PCBs
- organophosphates
- heavy metals
- mycotoxins
- dyes (including malachite green)

SERBIA - REZIDUE MONITORING PROGRAMME 2006/2010

Decision 2004/432/EC
on the approval of
residue monitoring plans
submitted by third countries
in accordance with
Council Directive 96/23/EC

LAST AMENDED

Commission Decision
327/2010/EC

EU APPROVED
✓ Bovine
✓ Ovine/Caprine
✓ Swine
✓ Equine (Live)
✓ Poultry
✓ Aquaculture
✓ Milk
✓ Eggs
Rabbit
✓ Wild game
Farmed game
✓ Honey

Implementation

❖ In general, the NRMP is broken down on the basis of number of establishments and their production data. (No. of slaughtered animals; Production quantity)

❖ Based on the approved NRMP, **DVPH** issues weekly orders for sampling to the Regional Veterinary Inspectors (**RVIs**), who then forward orders to local inspection level – Local Veterinary Inspectors (**LVIs**)

❖ Establishments who have had non-compliant results under official residue testing program in current year are included in NRMP for the next year!

Procedure followed in Serbia for identifying risks:

On the basis of the monitoring results, the main risks are defined as:

- ✓ Illegal use of chloramphenicol,
- ✓ Cross-contamination of feed for laying-hens with coccidiostats,
- ✓ Disrespect withdrawal period during treatment of broilers with coccidiostats,
- ✓ Antibiotics in muscle tissue - quinolones,
- ✓ Suspicion if animals are treated against certain diseases, e.g. salmonellosis
- ✓ Chemical elements/heavy metals (mainly cadmium) in offals of wild game and horses for slaughter.

Implementation

The following criteria have been used for selection of substances to be tested:

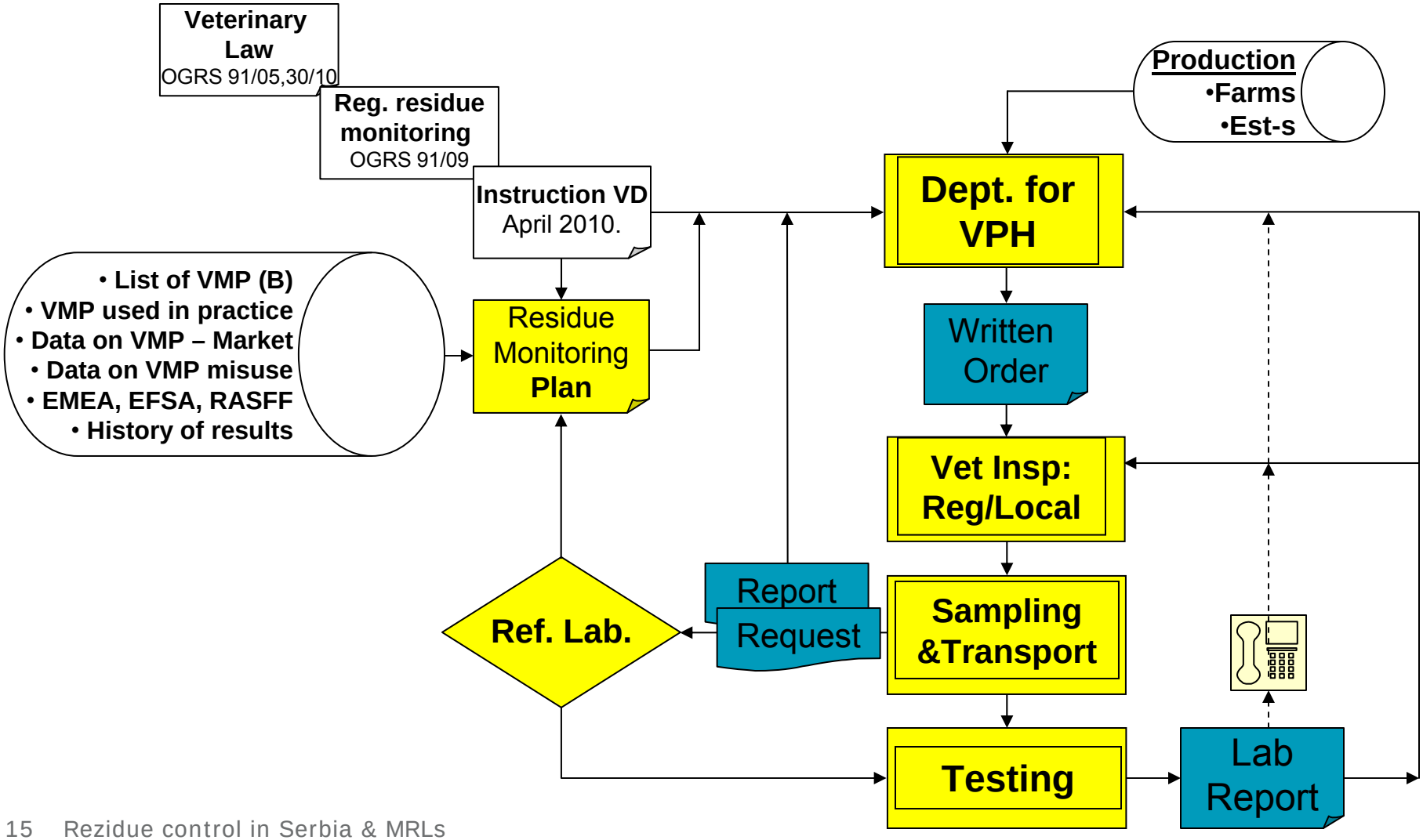
- ✓ Authorized veterinary medicines in Serbia (Group B),
- ✓ Available information on certain veterinary medicines used in practice,
- ✓ Available relevant data on veterinary medicines from the market,
- ✓ Available information on potential misuse of veterinary medicines,
- ✓ Available information from EMEA, EFSA and RASFF sites.

Implementation

Trainings:

Regular trainings and educational seminars are organized for official veterinarians (veterinary inspectors) by the Veterinary Directorate and through different internationally funded Projects/Programmes.

NATIONAL REZIDUE MONITORING PROGRAMME



FVO OVERALL CONCLUSION (Nov 2009)

"The system of residues controls in Serbia offers guarantees with an effect equivalent to those provided for by Community rules.

This is supported by the high rate of compliant results in the national residue control plan"!

CHALLENGES!

- Further transposition of EU legislation,
- Upgrading of planning process,
- Upgrading of procedure followed for identifying (main) risks,
- Implementation of principle – FBOs self-monitoring of residues,
- Upgrading of communication/exchange data between different CA,
- Continuous Training programs for vet inspectors,
- Outsourcing of residue testing to foreign laboratories,
- Monitoring of feedingstuffs,
- Establishing of all relevant MRLs!