



**Republic of Serbia  
Ministry of Agriculture, Trade,  
Forestry and Water Management**

**PLANT PROTECTION  
DIRECTORATE**

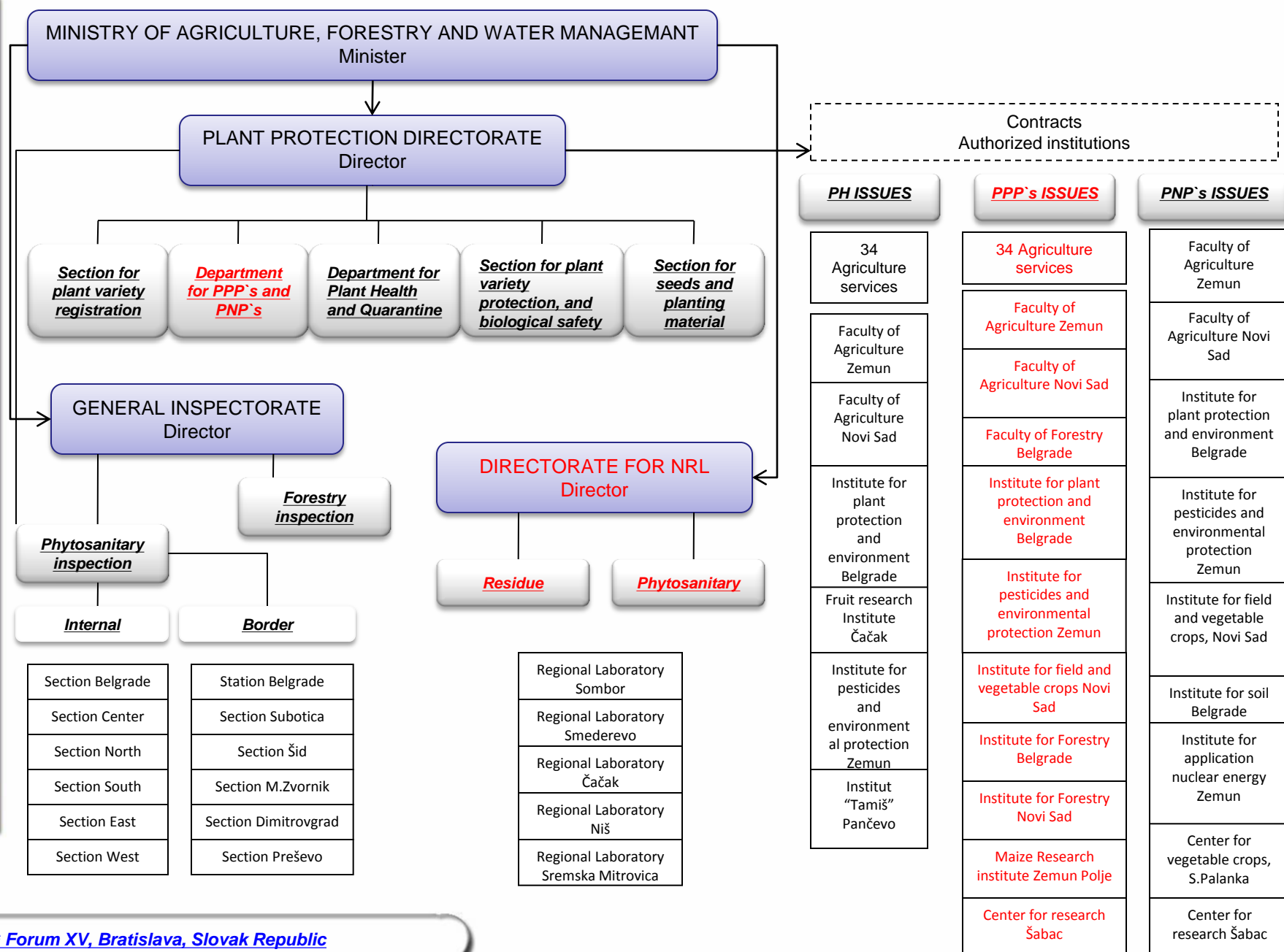
**CEUREG Forum XV**

**6-7 October, Bratislava,  
Slovak Republic**

**Omladinskih brigada 1,  
11 070 Novi Beograd**

***Seminar for Food Safety Policy Making and  
Management, (JFY 2010), J10 – 00727***







**PLANT PROTECTION DIRECTORATE**  
**Director**

*Director's office*

Legal advisor (1 position)  
Finance advisor (1 position)

***Section for  
plant variety  
registration***

Head

Maize and oil  
plant  
(1 position)

Fodder plants and  
small grains  
(1 position)

Vegetable, sugar  
beet, tomato and  
tobacco  
(1 position)

Fruit and grape  
(1 position)

Analyses  
(1 position)

Record keeping  
(1 position)

***Department for  
PPP's and  
PNP's***

Head

Coordination of  
registration  
activities  
  
(2 positions)

Phys/chem. of  
PPP's and PNP's,  
efficacy PPP's and  
nutritive value  
PNP's  
  
(5 positions)

***Section for  
Plant Health  
and Quarantine***

Head

Planning and  
monitoring of  
activities in the  
field of plant  
health  
  
(2 position)

Monitoring of  
regulations,  
recommendations  
and international  
standards in the  
area of plant  
health  
(1 position)

Establishment of  
phytoregister and  
plant passport  
system  
(1 position)

Keeping records in  
the field of plant  
health  
(2 positions)

***Group for plant  
variety protection  
and biological safety***

Head

Cooperation and  
monitoring regulations  
in the field plant  
breeder's rights  
  
(1 position)

Keeping the registers  
and data base for the  
protection of plant  
breeder's rights  
  
(1 position)

GMO  
  
(1 position)

***Group for seeds  
and planting  
material***

Head

Organizing and  
monitoring the  
certification of  
seed and planting  
material  
  
(2 positions)

Monitoring of  
regulations,  
recommendations  
and international  
standards in the  
area of seeds and  
planting material  
  
(1 position)

***Phytosanitary  
inspection***

***Internal  
Head***

55  
inspectors

***Border  
Head***

35  
inspectors

***Phytosanitary  
inspection for  
Food safety  
(in place of  
clearance)***

Head

18 inspectors

***142 employees***





SRB	EU	Plan of adoption
<p>The Law on Plant Protection Products (O.J. RS No 41/09)</p>	<p>Directive 91/414/EEC Regulation (EC) No 1107/2009 – basic substances, adjuvants Directive 2009/128/EC – IPM, training all professional users, distributors and advisors, inspection of equipment in use, specific measures to protect the aquatic environment Directive 2009/127/EC</p> <p><b>REGISTRATION WILL TAKE PLACE IN TWO PHASES:</b></p> <ol style="list-style-type: none"> <li>1. Re-registration of existing PPP`s: Will apply since 31/12/2013 (Article 11 to 25) (<b>capacity building of CA and interested parties</b>)</li> <li>2. Registration of new PPP`s till 31/12/2013 – according to the Law on Plant Protection (criteria relating to necessary documentation is defined)</li> </ol> <p><b><u>Amendments related to: DNRL, recognition of registration, list of approved a.s, organization of inspection of equipment, collection of data, progressive implementation with EU requirements</u></b></p>	<p>Amendments</p> <p>IV quarter of 2011 or I quarter of 2012</p>
<p>The List of approved active substances - (without <i>Confirmatory data</i>) (DRAFTED/Revision)</p>	<p>Council Directive 91/414/EEC; Annex I – Active substances authorized for use in plant protection products <b>Regulation No 540/2011 (including 541/2011, 542/2011, 2011/60/EU, 2011/328/EU, 2011/329/EU ...)</b></p>	<p>IV quarter of 2011 (after of adoption of amendments)</p>
<p>Progressive implementation of measures required to align PPP`s on Serbian market with requirements of the EU</p>	<p>/</p>	<p>IV quarter of 2011 (after of adoption of amendments)</p>

**Elements of new legislation apply.** Articles 11-25 (to be revised) of the Serbian Act (2009) apply. Transposition of EU List and data requirements and Uniform Principles. Data protection put in place.  
List establishes conditions (purity & specified impurities and restrictions and identifies areas for particular attention.  
Confirmatory data not transposed but action considered in Serbia if regulatory outcome results in action within the EU.

**Accession (exact date unknown)**

**Withdrawal** of products containing active substances subject to a 'non-inclusion' decision in the EU. Phase out proposed 6+6+6.

### New products

Apply EU standards – Appropriate Annex II and III data required or letter of access. Technical specification verified as acceptable. Uniform Principle assessment. Data protection applied. Where possible a recognition process is favoured (using UP assessments from EU MSs) .

### Existing product alignment (re-registration)

Based (as far as possible) on a recognition process (using UP assessments from EU MSs) and aligned (as far as possible) with the renewal programme (allowing a period for EU Member States to complete renewal under the Regulation to allow those fully compliant authorisations to be recognised in Serbia. May need to accelerate if accession earlier ?

2011	2012	2013	2014	2015	2016	2017	2018	2019	2020?
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### Preparatory period

- Develop and refine plan for alignment
- Plan transitional period between 'old' and 'new' product procedures (pre- and post- 31 Dec 2013)
- Revise legislation and establish necessary secondary legislation
- List of withdrawn substances – product phase out
- Training to ensure EU alignment programme can be delivered (both technically and administratively)
- Establish communication strategy, in particular, to involve and inform registrants.
- Extension to product expiry dates to allow post 2013 processes to operate efficiently.

### Access to active substance data (Annex II) and verification of acceptable technical specification

Process to check active substance compliance with EU standards in all Serbian PPP. Authorisation holders required to demonstrate access to Annex II data (data or letter of access) and to confirm the technical specification and where necessary equivalence of technical specification to the reference source accepted in the EU risk assessment.

Revoke non-compliant products.

In this process apply specific provisions of approval related to purity/impurities and restrictions.

**Regulation 1107/2009 applies directly at accession.**

### In the period leading up to accession:

- finalise any new necessary legislative provisions (repeal elements of existing national legislation at accession)
- establish/refine procedures to implement fully the EU processes for areas such as zonal authorisation.

**TWINNING PROJECT**  
**SR/08/IB/AG/01**



SRB	EU	Plan of adoption
The Rule on content and manner of treatment and keeping of documentation for assessment of active substances and basic substances (DRAFTED)	Council Directive 91/414/EEC; Annex II – Requirements for the dossier to be submitted for the Inclusion of an active substance in Annex I <b>Commission Regulation No 544/2011 - implementing Regulation No 1107/2009 as regards the data requirements for active substances</b>	IV quarter of 2012
The Rule on content and manner of treatment and keeping of documentation for assessment of plant protection products (DRAFTED/Revision)	Council Directive 91/414/EEC; Annex III – Requirements for the dossier to be submitted for the Authorization of a plant protection product <b>Commission Regulation No 545/2011 - implementing Regulation No 1107/2009 as regards the data requirements for plant protection products</b>	IV quarter of 2012
The Rule on content of label for plant protection products as well as standard phrases for special risks and safety precautions for the protection of humans or the environment and manner of handling with empty packaging of plant protection products (DRAFTED/Revision)	Directive 91/414/EEC; Annex IV – Standard phrases for special risks for humans or the environment; Annex V – Standard phrases for safety precautions for the protection of humans or the environment <b>Commission Regulation No 547/2011 - implementing Regulation No 1107/2009 as regards labelling requirements for plant protection products</b>	II quarter of 2012
The Rule on content of label for plant protection products as well as standard phrases for special risks and safety precautions for the protection of humans or the environment and manner of handling with empty packaging of plant protection products (DRAFTED/Revision)	Directive 91/414/EEC; Annex VI - Part I Uniform principles for evaluation and authorization of chemical plant protection products; Part II - Uniform principles for evaluation and authorization of plant protection products containing microorganisms <b>Commission Regulation No 546/2011 - implementing Regulation No 1107/2009 as regards uniform principles for evaluation and authorisation of plant protection products</b>	IV quarter of 2012

## **Implementation of the official pesticide residues monitoring programme**

<b>SRB</b>	<b>EU</b>	<b>Plan of adoption</b>
Rule on maximum residue levels of plant protection products in or on food and feed of plant and animal origin (O.J. RS No 25/2010)	<b>Regulation (EC) No 396/2005</b> <b>Commission Regulation (EC) No 178/2006 (Annex I)</b> <b>Commission Regulation (EC) No 149/2008 (Annex II, III, IV)</b> <b>Commission Regulation (EC) No 260/2008 (Annex VII)</b>	-
The Rule on monitoring program of PPP`s and residues for 2011 (was DRAFTED)	<b>Commission Regulation (EC) No 1213/2008</b>	No funds needed
Rule on methods of sampling and analyses of residues of PPP`s in food (DRAFTED/Revision)	<b>Commission Directive 2002/63/EC</b> <b>Commission Decision 2002/657/EC</b>	IV quarter of 2011





Article	Related to	Actions
Article 44	<b>IPM: Plant protection products shall be used in accordance with the principles of good agricultural practice and integrated pest management</b>	<ul style="list-style-type: none"> <li>• By-law is drafted (basic principle) (NPI – II Quarter 2012)</li> <li>• <b>TAIEX AGR 34820 18 to 19 January 2010 - Workshop on Integrated pest management</b> (Fitosanitario Regione Emilia-Romagna), Principles and Criteria of Integrated Pest Management</li> <li>• <b>Twinning Project SR2005/IB/AG/02 - 22 - 24 September 2010 - Workshop on Integrated pest management</b>, Decision Support System for Integrated Pest Management, Guidelines</li> <li>• <b>USDA funds</b> (2008, 2011) – Integrated production of potato, vegetables</li> </ul>
Article 46	<b>Trainings of end users of PPPs</b>	<ul style="list-style-type: none"> <li>• Start in 2005 with USDA</li> <li>• 2006: Manual</li> <li>• 2007: Training of trainers (people from regional Agricultural services)</li> <li>• 2009: Pilot project with USAID Agribusiness Project / 500 farmers are educated</li> <li>• 2011: 2000 farmers are educated</li> <li>• 2011: Additional trainings for trainers (in September)</li> <li>• 2012: Rules on program of education (drafted)</li> </ul>
Article 46	<b>Aerial spraing</b>	Shall be allowed only for such plant protection products for which it was assessed in the registration procedure that they may be applied from aircraft and if this method of application is allowed by the decision on registration.
Article 49		Protection of Bees, Aquatic Organisms and other non-target organisms
Article 51	<b>Inspection of Equipment</b>	<ul style="list-style-type: none"> <li>• Start in 2010 with USAID Agribusiness Project</li> <li>• 2010/2011: Training of trainers (eng. agr. mech. from regional Agricultural services and Agricultural schools )</li> <li>• 2012: Rules on inspection of equipment (first draft)</li> </ul>



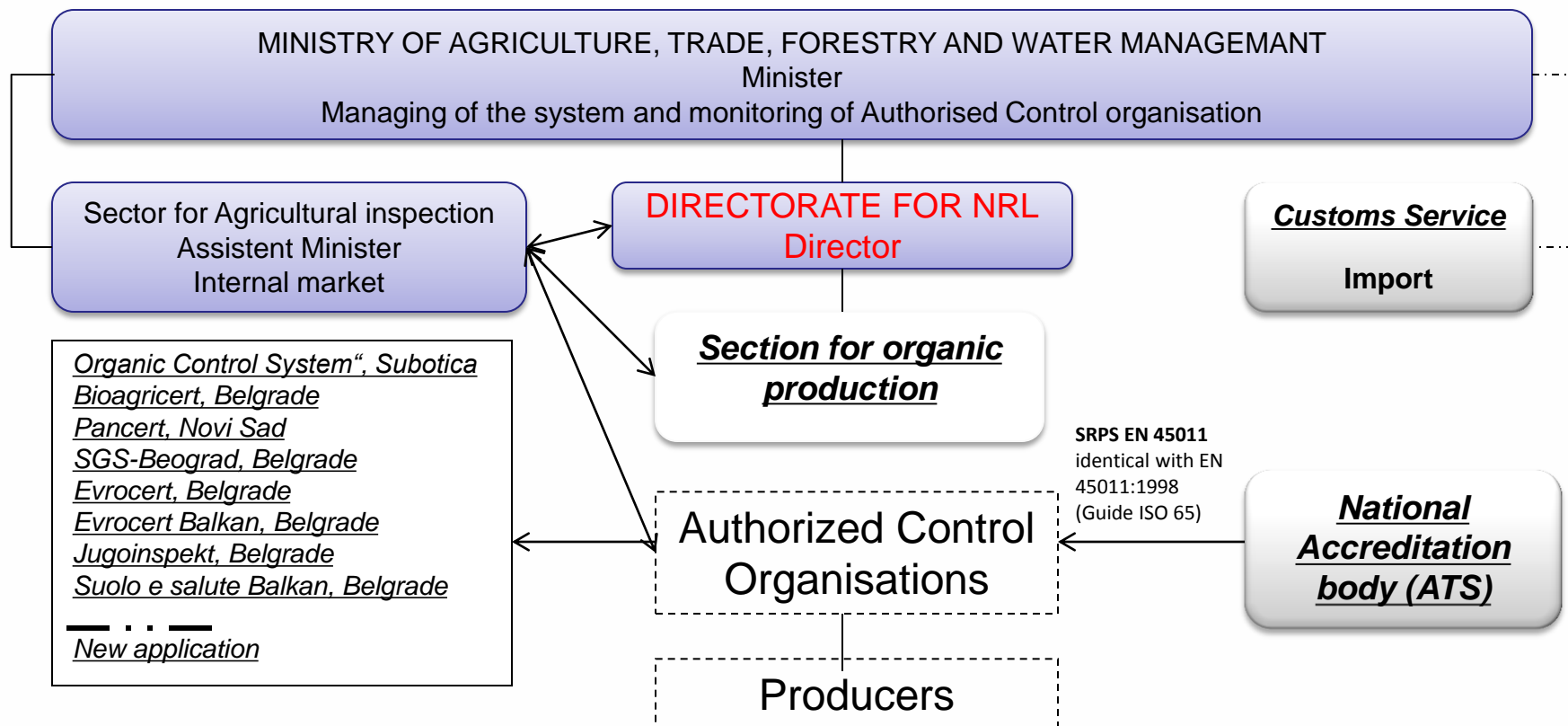


## Legal background

- The Law on organic production (OJ of RS No 30/10) (Council Regulation No 834/2007)
- The rules on control and certification in organic production and on methods of organic production (OJ of RS No 48/11) (Commission Regulation (EC) No 889/2008)
- In process of adoption – The rules on documentation for issuing of certificate, conditions and manner of distribution and import of organic products (Commission Regulation (EC) No 1235/2008)
- 2010: Application to the EU COM for inclusion in the list of third countries

## Statistic data (2010):

134 producers; 2722 ha arable land; 1566 ha pastures; 5006 ha collecting wild plants; 583 bovine; 1033 swine; 369 hives







*Thank you for your  
attention*

