

ANNEX C1

STANDARD TWINNING PROJECT FICHE

1. Basic Information

1.1 Programme: IPA 2008

1.2 Twinning Number: SR 08 IB AG 01

1.3 Title: **Harmonisation of national legislation with EU legislation for placing on the market and control of Plant Protection Products and implementation of new legal provisions**

1.4 Sector: **Plant Protection Directorate (PPD) of the Ministry of Agriculture, Forestry and Water Management (MAFWM)**

1.5 Beneficiary country: **Republic of Serbia**

2. Objectives

2.1 Overall Objective(s):

To improve the protection of environment, public and plant health through alignment of legislation and administrative structures in the area of Plant Protection Products (PPP's) with the EU acquis.

2.2 Project purpose:

To establish a comprehensive structure for the effective implementation of the control system for PPP's in line with the EU standards.

2.3 Contribution to National Development Plan/Cooperation Agreement/Association Agreement/Action Plan

The priorities outlined in European Partnership with Serbia including Kosovo of 18 February 2008 (Council Decision 2008/213/EC) concern both legislation and its implementation. Updating of the legislation and strengthening of implementation and controls in the areas of food safety, veterinary and phytosanitary issues are identified as a particular short term priority. Medium-term priorities include continuation of strengthening of veterinary, sanitary, phytosanitary and food safety legislation and controls.

Article 97 (Agriculture, and the agro-industrial sector) of the Stability and Association Agreement (SAA) between the EU and Serbia foresees that "Cooperation between the Parties shall be developed in all priority areas related to the Community acquis in the field of agriculture, as well as veterinary and phytosanitary domains. Cooperation shall notably aim at modernising and restructuring the agriculture and agro-industrial sector, in

particular to reach community sanitary requirements, to improve water management and rural development as well as to develop the forestry sector in Serbia and at supporting the gradual approximation of Serbian legislation and practices to the Community rules and standards.’’

3. Description

3.1 Background and justification:

Systematic reform of the PPP’s control systems in Serbia requires significant inputs because of limited existing capacity and because of the fragmented and over-lapping involvement of a large number of institutions which is a legacy of the old system.

To initiate and provide the basis for further adjustment with the legislative framework of the *acquis* a PPP’s Law has been drafted, approved by the Government and forwarded to the Parliament in November 2008, where it awaits adoption. This law clarifies competences between all ministries and authorized institutions which are involved in present control system of PPP’s and states a single national authority responsible for control system of PPP’s (i.e. the Plant Protection Directorate).

The current procedure for granting authorizations of PPP’s in Republic of Serbia is complicated as it requires the involvement of the three ministries, two advisory committees - Committee of poisons and Committee of PPP’s, preparation of two reports (which are not linked to each other) and many Authorised scientific institutes.

The current authorization process of PPP’s in Republic of Serbia is divided into three phases.

Phase 1 – Evaluation of human toxicity, ecotoxicity, environmental fate and behavior

This phase is covered by the Ministry of Environment and Spatial Planning (MESP) according to The Law on the Production and Placing on the Market of Toxic Substances (OJ of FRY, No. 15/1995) and associated sub laws. In conducting this evaluation, the experts from one of nine existing Authorized Scientific institutes generally reviewed dossiers (files) of the applicants.

Applicants are able to choose the institute(s) to whom they will submit their application and there are no specific rules or criteria in order to determine which is the most appropriate institute. Scientific Institutes charge a fee for each application depending on the amount of work required.

The applicant submits the dossier only to the Authorised Scientific Institutes without any consultation with the MESP about completeness of documentation for this evaluation. As a result of the data evaluation, the Authorized Scientific institutes prepares a report (so called Toxicological opinion), which is submitted for discussion in the Toxic Substances Committee.

The Committee gives a recommendation for classification and labelling to the MESP, and on the basis of that, the MESP includes the substance(s) in The List of Toxic Substances. Active substances and plant protection products are classified into one of the following three categories: I (very toxic), II (toxic), III (harmful). These categories are closely linked to the marketing and use of pesticides in the sense that there are certain rules restricting the use of certain categories of pesticides (category I and II) only to professional users. The only document which the MEP possesses in categorising the substance is the Toxicological opinion.

Phase 2 – Establishing of Maximum Residues Level's (MRL's)

During this phase applicants are required to submit residue data in order to set an MRL to the Ministry of Health (MH), according to the Law on the Food Health and Objects of Common Use («OJ of SFRY», No. 53/1991).

In practice, this phase is almost completely skipped because the MH does not have a required expertise. This has been the practice since 1999. The existing MRLs (published in 1992) are not in line with the Serbian Good Agriculture Practice. Subsequent surveillance, monitoring and enforcement is also not carried out.

Because of this lack of expertise in the MH, temporary MRL's are proposed by toxicologists in the Toxicological opinion and the Toxic Substances Committee gives a recommendation for that to the MESP, and the Ministry of Agriculture, Forestry and Water Management (MAFWM) accept those recommended temporary MRL's.

Phase 3 – Evaluation of physical and chemical properties and efficacy

This phase is covered by the MAFWM. The applicant submits a dossier to the Authorised Scientific Institutes and to the MAFWM.

In Serbia there are nine Authorised Scientific Institutes. Five of them perform physical and chemical properties and efficacy tests of PPP's, one of them performs just the physical and chemical properties tests and three of them perform only the efficacy tests. Three of them are accredited by the national accreditation body - ISO 17 025 and one of them has international accreditation (BSI).

In order to confirm the physical and chemical end points that applicants submit, national authorities require the submission of samples of the technical active substance and the PPP's and they conduct a full range of analysis. There is no formal request for what is Good Laboratory Practice (GLP). Before 2005 the applicant submitted a dossier only to the Authorised Scientific Institutes and an application form to the MAFWM. Since 2005, following changes to the rules on pesticide testing methods, applicants must also now submit a dossier to the MAFWM as well.

As with Phase 1, applicants choose the institutes to which they will submit applications and there are no specific rules or criteria on that. Scientific Institutes charge a fee for each application that ranges from €500 - 3,000 depending on the amount of work required (according to Decision of Government FRY, «Official journal FRY», no. 4/2001).

Following the classification as well as preparation and the setting of a temporary MRLs, the respective report is to be produced by the toxicology experts and submitted to the Toxic Substances Committee. The report on efficacy evaluation is to be submitted to the Committee for Pesticides in the MAFWM for an opinion.

Finally, the PPD within the MAFWM issues the certificate of authorization (permission for placing the product on the market) which is valid for 3 years (provisional authorization for new a.s. if only one year efficacy data are available) or for 10 years (full authorization if two years efficacy data are available).

The PPD draft a list of the authorized plant protection products (three times a year) which has been published in the Official Journal and on the official web site of the MAFWM. This list includes information on the PPP's trade name, the holder of authorization, the number of the authorization and the expiration date.

The above system had worked reasonably effectively for a considerable time. However, as described above, the system is currently only partially applied with some parts completely absent.

The main problem in the area of PPP's is the setting of MRL's. The reasons for this are:

- The MRL Committee does not exist
- The setting of MRL's is, in practice, skipped because of ineffective coordination between Ministry of Health (MH), Ministry of Environment and Spatial Planning (MESP) and Ministry of Agriculture, Forestry and Water Management (MAFWM),
- Lack of expertise in relation to assessment of fate and behaviour in the environment, eco-toxicology and residues
- Temporary MRL's have been proposed by toxicologists and adopted unofficially by the Toxic Substances Committee and now by Committee for PPP's in the MAFWM. The MAFWM has formed a new PPP's Committee but this doesn't have legal validity as the legal basis for the new committee has not yet been adopted,
- Existing (1992) MRLs do not accommodate the Good Agriculture Practice or relate to the existing authorizations, surveillance, monitoring and enforcement

In the context of this project and according to recommendations from TAIEX and Food Veterinary Office (FVO) missions to Serbia it is absolutely necessary:

- to designate an authority that will be responsible for the coordination of activities related to the authorization and control of pesticides at national level and also to represent the country abroad;
- to simplify and reorganize the procedure for granting authorizations;

- to provide assistance to Serbian experts through the provision of experience in selected EU Member State (MS) to examine structures and organizations in order to transfer that experience into Serbia;
- to reduce the number of Institutions which are involved in the process to the minimum required for a proper risk assessment avoiding any overlapping of competences;
- to provide assistance in staff training on the evaluation of dossiers;
- to provide training in sampling procedures;
- to provide assistance for the remaining laboratories to be accredited according to ISO 17025.

All implemented projects financed by EU in the previous period (CARDS 2001-2006) dealt with reform, capacity building and equipping the MAFWM but not directly in relation to PPP's.

The responsible state institutions that will be the beneficiary country partners in this twinning project are the PPD within the MAFWM. Other key players involved in the transposition and implementation of EU regulations related to PPP's will include domestic formulators of PPP's, PPP's trading companies, Faculties and scientific institutes and extension services.

Important note: During preparation of the twinning work plan, and later on during implementation of the project, the twinning partners will take due account of the new EU legislation in this field which may be passed from the date of circulation of the twinning fiche.

3.2 Linked activities (*other international and national initiatives*):

Since 2001 up to now the EU and other donors have supported various activities of the MAFWM regarding: the need for an institutional reform; strengthening of the laboratory system, through the supply of equipment and the technical assistance to improve the quality management; supporting the reform and the strengthening on the veterinary, phytosanitary and sanitary inspectorates; the upgrading and the improving of the inspections facilities at external borders; the strengthening of the organisational and managerial capacities (objective setting, budgeting, planning, etc.); the upgrading of the analytical and strategic planning and evaluation capacity; strengthening the protection of plant, animal and public health and strengthening the capacity of the MAFWM in aligning regulations with *Acquis communautaire*.

As mentioned, the previously implemented projects financed by EU within CARDS 2001-2006 annual action programmes dealt with reform, capacity building and equipping the MAFWM but they did not focus directly on alignment of the legislation in relation to the PPP with the *acquis*:

- Upgrading of laboratories (CARDS 2002). Supply of laboratory equipment for national and regional veterinary, phytosanitary and sanitary laboratories.
- Reform of Serbian Veterinary, Phytosanitary and Sanitary Inspectorates (CARDS 2003). This technical project focused on clarifying division of responsibilities between the inspection services involved in control of food chain safety, training of the inspectors and oversight of deliveries of equipment and installation of pre-fabricated buildings for veterinary and phytosanitary inspectors at the selected border posts.
- Supply of Pre-Fabricated Buildings, Containers, Refrigeration and other equipment for veterinary and phytosanitary border inspectors (CARDS 2003).
- Supply of inspection and sampling equipment for the Veterinary and Phytosanitary Inspectorates (CARDS 2005).
- Institutional Capacity Building within the PPD of the MAFWM (CARDS 2005, European Agency for Reconstruction, Contract No. SR2005/IB/AG/02, Twinning partner Ministry of Agriculture and Forestry Policies Republic of Italy, General Directorate for Rural Development) – This Twinning will include the following activities related to PPP's: Development of a strategy in the phytosanitary sector, Administrative capacity building plan, Professional capacity building plan, Strengthen the management of the PPD to oversee the implementation of the development strategy for the phytosanitary sector.
- Institutional Capacity Building of the Food-Chain Laboratories Administration (CARDS 2005, European Agency for Reconstruction, Contract No. SR2005/IB/AG/04, Twinning partner Department for Environment Food and Rural Affairs – Central Science Laboratory) – This Twinning includes the development and implementation of an action plan for the strengthening management of the veterinary, phytosanitary and food-safety laboratory system and strengthen the quality management systems implemented in these laboratories.

The United States Department for Agriculture provides a fund for training of trainers in the field of farmer education for safety and environmentally use of PPP's. Education program, for farmers, started in March 2009, supported by the USAID Agribusiness Project. In those activities 472 farmers are trained and certified. Program will be continued in the autumn 2009 and in the future.

3.3 Results:

1. A clear strategy for the development and implementation of PPP legislation and associated regulations is established

Indicators

- Strategy for adoption and implementation of necessary legislation (including detailed financial requirements) drafted and adopted;
2. Drafting and adoption of legal acts (e.g. laws and by laws) regulating the PPP's area in line with EU *acquis communautaire*

Indicators

- Revision of PPP legislative framework completed
 - Action plan for alignment of PPP's legislation with provision of *Acquis communautaire* prepared and adopted
 - Number of associated laws prepared
 - Number of associated regulations and by-laws prepared
3. Improved capacity of the PPD to carry out its functions in relation to the implementation of PPP legislation and regulations.

Indicators

- Department for evaluations and approvals of PPP's in PPD is established, staffed and operational.
 - Post-registration laboratory established
 - Training need assessment carried out
 - Training programme prepared
 - Training assessment reports
 - Number of staffs trained
4. Improved capacity of the other stakeholders (such are institutes and laboratories) to carry out their functions in relation to the implementation of PPP legislation and regulations.

Indicators

- Transparent procedure for identification of institutes for testing and control defined and adopted
 - Institutes for carrying out testing and control are identified through open competition
 - Standard Operating Manuals for the required analysis defined and adopted
 - Training need assessment carried out
 - Training programme prepared
 - Training assessment reports
 - Number of staff trained
5. All stakeholders, including end-users aware of changes to PPP procedures and their impact

Indicators

- Communication strategy drafted, adopted and implemented
- Number of communication/visibility events organised
- End-users report positively on introduced changes
- Other departments are aware of processes for alignment with *Acquis*

3.4 Activities:

Result 1 - A clear strategy for the development and implementation of PPP legislation and associated regulations is established

Development of clear organisational structure and roles and responsibilities for the various actors involved in PPP system: Systematic reform of the PPP's control systems in Serbia will largely have to be established because of a lack of capacity within the official institutions and because of an inheritance of the old system which is severely fragmented with many authorities and institutes involved and/or having overlapping competences in this area. It is absolutely necessary to reduce the number of Institutions which are involved in the process to the minimum required for a proper risk assessment avoiding any overlapping of competences. The first task under this result should be the development of clear roles and responsibilities for the various actors so that the system functions effectively and without duplication.

To initiate and provide the basis for further adjustment with the legislative framework of the *acquis* a PPP's Law has been drafted, approved by the Government and forwarded to the Parliament in November 2008, where it awaits adoption. This law clarifies competences between all ministries and authorized institutions which are involved in present control system of PPP's and states a single national authority responsible for control system of PPP's (i.e. the Plant Protection Directorate)

Assessment of current systems and revision of existing systems in line with EU requirements: Evaluation and approval of PPP's in PPD are concerned with the administrative and structural side of the Republic of Serbia (RS) system and the scientific and technical aspects of data evaluation by RS specialists. Activities should include the development of EU procedures (assessment of current systems in Republic of Serbia, provision of recommendations for revised systems and procedures, assistance in the drafting and implementation of revised procedures). These procedures and systems specifically relate to:

- **Management of applications** (Assessment of organizational structure and current procedures by PL and STE's in liaison with staff from relevant departments. STEs responsible for training individual Departments within PPD and provide specific assessment and advice on procedures relevant to their specialism during their visit. Project Leader also provide guidance and advice)
- **National authorizations** (authorisation of new active substances and reviews of existing active substances; new authorizations and changes to authorizations for existing active substances; extensions of use/minor use authorizations; mutual recognition, experimental, parallel import and emergency authorizations; re-registration of existing products, authorization of Home Garden products, mixing of other non-pesticidal products used with PPP's)
- **Post-authorisation procedures** (final quarters of Project, advice on monitoring of pesticide residues)

Result 2 - Drafting and adoption of legal acts (e.g. laws and by laws) regulating the PPP's area in line with EU *acquis communautaire*

Harmonization of national legislation with the EU in relation to PPP's needs to be continued through the adoption and implementation of the PPP's Law, and a set of regulations and by-laws dealing with more specific issues of PPP's. To initiate and provide the basis for further alignment with the *acquis* framework legislation the PPP's draft Law has been drafted according to the relevant EU legislation (Council Directive 91/414/EC of 15 July 1991 concerning the placing of plant protection products on the market). This draft Law is approved by the Government and forwarded to the Parliament to the adoption in November 2008. But, it should be beared in mind that the new Regulation which will revise the current Directive 91/414/EEC governing PPP's authorisation is to come into force in the EU. This may imply further modifications to the primary and secondary legislation for PPPs.

Activities which relate to the transposition of the *acquis communautaire* include:

- **Assessment of current legislation on PPP's and all legal documents issued by the regulatory authority for the authorisation of PPP's in the RS**
- **Preparation of the action plan for alignment of PPP's legislation with provision of *Acquis communautaire***
- **Provision of assistance with drafting revised legislation and relevant authorisation documents to ensure harmonisation and compliance with the *acquis***
- **Provision of guidance and training to the RS on consequences of the *acquis* on their legislation (e.g. compliance with new EC decisions on inclusion/non-inclusion of active substances in Annex I prior to entry to the EU)**

Result 3 - Improved capacity of the PPD to carry out its functions in relation to the implementation of PPP legislation and regulations.

Training needs analysis based on results of activity 1.1. and preparation of complementary guidelines and manuals to support implementation of new systems: Activities which contribute to the achievement of this result can include the full range of informal and formal training. Alongside such training, the Twinning Partner should produce complementary guidelines and manuals to support implementation of new systems. If appropriate, there is the possibility to develop training capacity within the PPD particularly in relation to the delivery of training to other stakeholders e.g. in how to carry out an authorisation (see result 3).

Design and delivery of training activities for PPD staff: The activities carried out should follow a comprehensive review of the existing and desired structures within the

PPD and the production of a gap analysis. A training needs analysis should also be completed so that training is based clearly on individual needs.

Specifically, **training activities should increase the capacity of the PPD to carry out and/or monitor the following:**

- **Data evaluation for physical chemical properties and analytical methods** (familiarisation with Annex II and III data requirements and all associated EC and other guidance documents; evaluation of those data and how to carry out any subsequent risk assessment; assessment of case studies; production of a record of the scientific evaluation and final decisions; application of skills to different types of application for authorisation)
- **Data evaluation for environmental fate and behaviour** (familiarisation and training on the three main compartments of the fate and behaviour evaluation)
- **Data evaluation for eco-toxicology** (familiarisation with Annex II and III data requirements and all associated EC and other guidance documents; evaluation of those data and how to carry out the subsequent risk assessment; assessment of case studies; production of a record of the scientific evaluation and final; application of skills to different types of application for authorisation)
- **Data evaluation for mammalian toxicology** (familiarization with Annex II and III data requirements and all associated EC and other guidance documents; evaluation of those data and how to carry out the subsequent risk assessment; assessment of case studies; production of a record of the scientific evaluation and final decisions; application of skills to different types of application for authorization)
- **Data evaluation for operator exposure** (familiarization with Annex II and III data requirements and all associated EC and other guidance documents; evaluation of those data and how to carry out the subsequent risk assessment; assessment of case studies; production of a record of the scientific evaluation and final decisions; application of skills to different types of application for authorization)
- **Data evaluation for residues and consumer risk** (familiarisation with Annex II and III data requirements and all associated EC and other guidance documents; evaluation of those data and how to carry out the subsequent risk assessment; assessment of case studies; production of a record of the scientific evaluation and final decisions; application of skills to different types of application for authorisation)
- **Maximum Residue Levels**
- **Data evaluation for efficacy** herbicides and plant growth regulators, fungicides, insecticides and other zoocides
- **Official Recognition of efficacy testing facilities**

Result 4 - Improved capacity of the other stakeholders (such as institutes and laboratories) to carry out their functions in relation to the implementation of PPP legislation and regulations.

Identify all areas where authorising bodies are required: Activities here will include the development of the authorisation system and procedures and to organise an open competition for institutes and other eligible parties to bid for approval as an officially recognised authorising body.

Evaluation of applications: The competition should be publicised so that all potential agencies are aware of the competition. Support should be provided to applicants in order to complete the application and necessary supporting documents.

Preparation of guidelines and procedures for applying to become an authorising body: The Twinning Partner should develop clear criteria for selection of bodies and should prepare guidelines for the PPD so that they can carry out the evaluation process fairly, consistently and transparently. At the conclusion of this process, all bodies should have been selected and should be provided with further guidance (including required training of their staff) on how to complete their responsibilities. Quality assurance systems should be established to monitor the performance of these bodies, particularly during the early months of their work. Activities might include on-site visits, reviews of reports and also more informal focus groups.

Result 5 - All stakeholders, including end-users, to be aware of changes to PPP procedures and their impact

Development of a clear communication strategy and Production of promotional materials: It is important that all stakeholders are aware of changes in systems, procedures, responsibilities and likely impact of these changes. The work for this result should be based around a clear communication strategy carried out at the start of the project which identifies the individual target groups, the appropriate media to reach these groups, key messages and specific communication actions.

Develop internal communication mechanisms: The communication strategy should include internal as well as external communication. Communication actions within the MAFWM should ensure a smooth information flow between Departments and between staff within PPD.

Project launch and One-to-one meetings with key stakeholders: At the start of the project, there should be a project launch. This event is for all interested parties and the purpose is to provide information on the background, objectives and activities of the project. Before and after this event, one-to-one meetings should be organised with representatives of key stakeholders to ensure they are clear on what is expected from them, and their potential involvement in the project.

Final conference: A final event should be organised to present the results of the project evaluation. This evaluation should be based on quantitative and qualitative information from surveys, focus groups and one-to-one meetings with the full range of stakeholders. Again, the design of this event should be based on an analysis of the key stakeholders and how they can best be informed.

3.5 Means/ Input from the MS Partner Administration:

3.5.1 Profile and tasks of the Project Leader

MS Project Leader:

The Project Leader will manage the project team of selected member state(s) and co-ordinate the implementation of activities. The project leader will establish and maintain links between experts from member state and beneficiary state. He/she will ensure the timely and effective implementation of the project and achievement of results, through proposed activities. He will also be responsible for modifications of Work plan in accordance with identification of needs in the life time of the Project and in this way ensure, that experts input and distribution of their working days will be used in the most efficient and effective way.

The Project Leader will have the following profile:

- University degree;
- senior civil servant ;
- Experiences in management and control and good organizational skills: managing or assisting in management in at least 2 projects.
- Minimum of 7 years of professional experience in the field of plant protection products as public servant or in mandated body in MS is requested (requirements of Council Directives 91/414/EEC and 79/117 and their implementation, administrative procedure within the authorization for plant protection products - from the receipt of application to the preparation of the decision, its management, communication with applicants and the general legal frame, coordinating of the national activities and procedures within the evaluation of the active substance as regard to their inclusion in Annex I of the Directive 91/414/EEC, communication with the European Commission)
- Experiences to work in international and multicultural environment (involvement in at least 2 EU funded projects is required);
- Familiar with the relevant EU regulations;
- Fluency in English.

BC Project Leader:

The BC Project Leader will manage a project team at the Serbian side and will assure that the decision makers at the Ministry level will be informed properly on the implementation of the project. He will ensure close co-operation and overall steering and coordination of the project. He will be also responsible for drafting reports and other documents, related to project management at the Serbian side and will chair Steering Committee meetings (in which the representatives or twinning partners and Contracting

Authority will be represented as a minimum, while representatives of other relevant Ministries and/or stakeholders may be invited as appropriate).

3.5.2 Profile and tasks of the RTA

RTA must have a broad knowledge in the area of plant protection products, which will enable him/her to organize interdisciplinary team for successful implementation of the project. He/she should be an employee of the governmental competent authority (Ministry or Agency) in Member State responsible for plant protection products.

Minimum qualifications required:

- At least five (5) years working in the field of plant protection products in public administration of selected Member state or Mandated body.
- Relevant university degree. MSc or PhD degree in the plant protection area will be considered as an advantage. Experience in implementation of Council Directives 91/414/EEC and 79/117 and administrative procedures for authorization of plant protection products - from the receipt of application to the preparation of the decision, its management, communication with applicants and the general legal frame. Experience in coordinating the national activities and procedures within the evaluation of the active substance associated to their inclusion in Annex I of the Directive 91/414/EEC, and communication with the European Commission.
- Experience in public relations and/or in advertising of plant protection products issues.
- Excellent knowledge of English, since the working language will be English.
- Skills: good communication and coordination skills.

3.5.3 Profile and tasks of the short-term experts

Detailed profiles and tasks of short-term experts will be provided in Twinning Work Plan, indicative requirements are following:

- Short term – plant protection products expert

Minimum qualifications required:

- at least seven (5) years of experience in field of plant protection products in a Member State;
- good working knowledge of English.

University degree in the relevant field:

Detailed profiles and tasks of short-term experts will be provided in Twinning Work Plan, indicative requirements are following:

1. Toxicology and MRL's

- evaluation of the plant protection products within the authorization procedure as regards to: toxicology and establishing of MRL values

- evaluation of the active substances as regard to their inclusion in Annex I of the Directive 91/414/EEC; completion of the EU - Monograph
2. Application technique
- the evaluation of the plant protection product application technique before its placing on the market:
 - the system of control testing of the plant protection product application technique
3. Authorisation
- requirements of Council Directives 91/414/EEC and 79/117 and their implementation
 - administrative procedure within the authorization for plant protection products (from the receipt of application to the preparation of the decision), its management, communication with applicants and the general legal frame
 - coordinating of the national activities and procedures within the evaluation of the active substance as regard to their inclusion in Annex I of the Directive 91/414/EEC, communication with the European Commission
4. Pesticide Chemistry
- evaluation of the plant protection products within the authorization procedure as regards to their: physical and chemical properties, analytical methods, safety and storage, fate and behaviour in the environment
 - evaluation of the active substances as regard to their inclusion in Annex I of the Directive 91/414/EEC; completion of the EU – Monograph
5. Ecological Risks
- evaluation of the plant protection products within the authorization procedure as regards to their risks to: terrestrial vertebrates, water organisms, beneficial arthropods, organisms in soil
 - evaluation of the active substances as regard to their inclusion in Annex I of the Directive 91/414/EEC; completion of the EU – Monograph
6. Biological Efficacy
- evaluation of the biological efficacy of plant protection products within the authorization procedure as regards to: fungicides, insecticides, herbicides and plant growth regulators
 - system of field testing of biological efficacy
 - system of official recognition of testing organisations following the principles of Good Experimental Practice (GEP)
 - minor uses
7. Biological Plant Protection Products
- evaluation of the of biological plant protection products before their placing on the market
 - evaluation of the microorganism as a active substance as regard to their inclusion in Annex I of the Directive 91/414/EEC; completion of the EU - Monograph

4. Institutional Framework

PPD is directly subordinated to the MAFWM and functions as the national single and central authority of the Republic of Serbia in the phytosanitary field for the “plant health (harmful organisms)” and “PPP’s (pesticides)”, according to the Plant Protection law and by-laws and in accordance with Art. 2 (10,11) and 17 of the Council Directive 91/414/EEC. In the PPD doesn’t exist Unit for Application Techniques which must also be involved in the authorisation process of PPP’s. That unit shall be evaluates packaging of the plant protection products and application methods.

The PPD consists of the following departments, sections and units:

- Plant health (department)
- PPP’s and Fertilizers (department)
- Plant variety registration (department)
- Plant variety protection, genetically resources and biological safety (sections)
- Certification of seeds and planting material (sections)
- Legal, Financial and Administrative Unit

Passing of a new Law on Ministries (‘Official Gazette of the Republic of Serbia’, No. 65/08) the Department for the Phytosanitary inspection is separated from the PPD in the General Inspectorate, new distinct competent authority in the MAFWM. This new competent authority is joined inspection services which are, till 5 of July 2008, worked within Directorates or Sectors in the MAFWM, like forestry and game inspection (from the Forestry Directorate), water management inspection (from Water Directorate) and agriculture inspection (from the Sector for inspection supervision, which doesn’t exist anymore).

Other Ministries which are included in PPP’s field are MEP and MH.

The role of MH is in protection of public health and health promotion. The MH is responsible for establishing MRL’s during the authorisation process according to the Law on the Food Health and Objects of Common Use («OJ of SFRY», No. 53/1991) and by-laws. Currently this phase is practically skipped because MH doesn’t have any expertise to do the work.

The role of MEP is evaluation of human toxicity, ecotoxicity, environmental fate and behavior of chemicals including PPP’s during the authorisation process according to the Law on the Production and Placing on the Market of Toxic Substances («Official Journal of FRY», No. 15/1995) and by-laws.

AUTHORITIES	COMPETENCES IN AREA PPP’s
MAFWM	<ul style="list-style-type: none">- registration (authorisathion) PPP’s – authorisation for put on the market PPP’s- permission for import a.s. and PPP’s

	<ul style="list-style-type: none"> - control import consignments of a.s. and PPP's (control documentation and sampling) (annual summary of the controls) - production PPP's (control production lines for PPP's) – certificates - control wholesalers and retailers of PPP's – certificates - control end users of PPP's – doesn't exist (have just started) - authorisation of laboratories for formulation analysis of PPP's and pesticide residue analysis in food of plant origin (simple processed) - organisation systematic controls, which include analysis to assess the degree of contamination of foodstuffs, soil, water and air by pesticides - transposition and implementation of legislation relating to Council Directive 91/414/EEC, 79/117/EEC
MESP	<ul style="list-style-type: none"> - classification and labelling a.s. and PPPs – certificates - permission for transport a.s. and PPPs - control of producers and wholesalers of PPP – certificates - transposition and implementation of legislation relating to Council Directive 1999/45/EC
MH	<ul style="list-style-type: none"> - establishing MRL's – doesn't exist - organisation systematic control degree of contamination of foodstuffs, soil, water and air by contaminants including pesticides - authorisation of laboratories for analysis contamination of foodstuffs, soil, water and air by contaminants including pesticides

According to Art.25 of the Law of Ministries, ministries within framework of their responsibilities are conducting the international cooperation and are to take care of its improvement and secure the harmonization of the regulation with the EU *aquis*.

The implementation of the Project will ensure the full discharge of the responsibilities of the Ministerial institutions with the requirements of the EU and Serbian legislation.

5. Budget

			SOURCES OF FUNDING									
			TOTAL EXP.RE	IPA COMMUNITY CONTRIBUTION		NATIONAL CONTRIBUTION					PRIVATE CONTRIBUTION	
ACTIVITIES	IB (1)	INV (1)	EUR (a)=(b)+(c)+(d)	EUR (b)	%(2)	Total EUR (c)=(x)+(y)+(z)	%(2)	Central EUR (x)	Regional/ Local EUR (y)	IFIs EUR (z)	EUR (d)	%(2)
Activity 1												
contract	X		1,300,000	1,300,000	100							–

1.1												
TOTAL IB			1,300,000	1,300,000	100							
TOTAL INV												
TOTAL PROJECT			1,300,000	1,300,000	100							

6. Implementation Arrangements

6.1 Implementing Agency responsible for tendering, contracting and accounting

Delegation of the European Commission to the Republic of Serbia
Vladimira Popovica 40, GTC Avenue block 19a
11070 New Belgrade
Serbia

Contact person:
Mr. Andrej Papić, Project Manager
Tel.: +381-11-3083200
Fax.: +381-11-3083201
E-mail: andrej.papic@ec.europa.eu

6.2 Main counterpart in the BC

Ministry of Agriculture, Forestry and Water Management
Plant Protection Directorate,
Omladinskih brigada 1, 11070 New Belgrade

RTA Counterpart will be Mrs. Snežana Savčić-Petrić,
Head of the Department for PPP's and Fertilizers,
tel/fax. + 381 (0)11 260 00 81,
E-mail: snezana.savcicpetric@minpolj.gov.rs

BC Project Leader will be: Mr. Jan Boćanski,
Director of the PPD, tel/fax. + 381 (0)11 311 77 29,
E-mail: jan.bocanski@minpolj.gov.rs

6.3 Contracts: One Twinning Contract

7. Implementation Schedule (indicative)

7.1 Launching of the call for proposals (Date)
May 2009

7.2 Start of project activities (Date)
December 2009/January 2010

7.3 Project completion (Date)
July 2012

7.4 Duration of the implementation period (number of months): 30

8. Sustainability

Sustainability is ensured through the adoption of legal framework and establishment of the institutional and organizational mechanisms for the implementation of the reform.

The project helps to create a proper system of risk assessment according to the relevant legislation and organisational structure with EU requirements. Also, project will improve administrative capacity with trained staff in PPD.

The representatives of post registration laboratory will, on the seminars about control of PPP's in the EU, get familiar with the way of its control in the EU and transmit their knowledge to other employees in control organizations.

The project will also assist in definition of follow-up and/or complementary actions to be funded from national budget or by the international donors.

9. Crosscutting issues (*equal opportunity, environment, etc...*)

Cross cutting issues must be taken into account in next phase of project design and later in the project report.

This project has major cross sector impact, including agriculture, environment, health and market. Improved infrastructure in the area of PPP's proved to competitiveness of the agriculture products on domestic and internal market. In this way, by harmonizing standards, trade relations would be easier and lead to a broader impact in improvement and promotion of the Serbian agricultural products (safety for consumers).

The ultimate beneficiaries of the assistance will be:

- primary producers of plant and plant product like end users of PPP's (farmers), which will use only PPP's approved by the competent authority (authorised for the specific purpose with respect to the principles of good agricultural practice) and improve their trade opportunities in food business and
- the general population which will be sure that agricultural products after harvesting do not contain prohibited quantities of residues of PPP's represented through consumer protection organisations.

Equal Opportunity

The Project does not target women specifically, but general improvement in PPP's regulations and standards will be beneficial to all citizens, including women. Equal opportunity principles and practices in ensuring equitable gender participation in the

Project will be guaranteed and information will be provided in the regular reports of the Twinning Partner regarding gender participation rates.

Environment

This project directly relates to the improvement and protection of the environment. It strengthens the capacity of all organisations involved in the implementation of PPP regulations in accordance with EU requirements. Proper risk assessment will be introduced to ensure adherence to EU legislation.

Minority and vulnerable groups

There are no specific actions which are designed for minority and vulnerable groups. However, this project will deal with alignment of PPP's legislation and its outcomes will therefore be beneficial to all citizens.

10. Conditionality and sequencing

Regarding adopted and accepted The National Agricultural Development Strategy (NADS), The Budget, Economy and Fiscal Politic Memorandum and The National Strategy of Serbia for the Accession of Serbia and Montenegro to the European Union (NSA) (see ANNEX IV, Reference to National Development Plan) and in attempting to achieve EU standards in area of PPP's and safety food PPD has been drafted PPP's Law in November 2007.

According to the National Plan for Integration Republic of Serbia in the EU the draft of PPP's law is sent in adoption procedure in fourth quarter 2008 and will be adopted till the end of the 2009.

The draft law of PPP's is harmonized with relevant EU legislation. In that law Serbia is stated one national body responsible for control system of PPP's. All ministries and authorized institutions which are involved in present control system of PPP's and stakeholders are consulted in drafting procedure of the law.

In process of preparation for implementation of this project and new law in area of PPP's the PPD has prepared re-organization of the Department for PPP's and Fertilizers. It means recruitment of additional employees especially in area of toxicology, ecotoxicology, fate and behaviour and maximum residue levels of PPP's and change Rule of organization and systematization working places in the MAFWM which is adopted in September 2008.

ANNEXES TO PROJECT FICHE

ANNEX I

LOGFRAME PLANNING MATRIX FOR		Programme name and number:	
Project Fiche: Harmonization of national legislation with EU legislation for placing on the market and control of Plant Protection Products (PPPs) and implementation of new legal provisions		Contracting period expires:	Disbursement period expires:
		Total Budget: €1.3M	IPA budget: €1.3M
Overall objective	Objectively measurable indicators	Sources of verification	
To improve the protection of environment, public and plant health through alignment of legislation and administrative structures in the area of Plant Protection Products (PPP's) with EU standards	% of harmonization	State/EU report on accession process	
Purpose of the project	Objectively measurable indicators	Sources of verification	Assumptions
To establish a comprehensive structure for the effective implementation of the control system for plant protection products (PPP's) in line with EU standards.	<ul style="list-style-type: none"> Plant Protection Products Law ratified Department for approvals is formed in Plant Protection Directorate – Rules on internal organization of the staff in MAFWM List of official authorising bodies 	<ul style="list-style-type: none"> Official Gazette of the Republic of Serbia Annual Report of the PPD and MAFWM Twinning project reports Tables of Concordance Reports of EC 	<p>Adopting a new Strategy for Agriculture</p> <p>Reform national policy in PPP's area</p>
Results	Objectively measurable indicators	Sources of verification	Assumptions
<p>1. A clear strategy for the development and implementation of PPP legislation and associated regulations is established</p> <p>2. Drafting and adoption of legal acts (e.g. laws and by laws) regulating the PPP's area in line with EU <i>acquis communautaire</i></p>	<ul style="list-style-type: none"> Strategy for adoption and implementation of necessary legislation (including detailed financial requirements) drafted and adopted; Revision of PPP legislative framework completed Action plan for alignment of PPP's 	<ul style="list-style-type: none"> Project progress reports Minutes of Steering Committee Official note on adoption of the strategy Official gazette 	<p>Willingness by the PPD and other Ministries to take forward agreed recommendations emanating from the project (e.g. changes to structure and procedures)</p>

<p>3. Improved capacity of the PPD to carry out its functions in relation to the implementation of PPP legislation and regulations.</p> <p>4. Improved capacity of the other stakeholders (such are institutes and laboratories) to carry out their functions in relation to the implementation of PPP legislation and regulations.</p> <p>5. All stakeholders, including end-users, to be aware of changes to PPP procedures and their impact</p>	<p>legislation with provision of <i>Acquis communautaire</i> prepared and adopted</p> <ul style="list-style-type: none"> ▪ Number of associated laws prepared ▪ Number of associated regulations and by-laws prepared ▪ Department for evaluations and approvals of PPP's in PPD is established ▪ Post-registration laboratory are established ▪ Training need assessment carried out ▪ Training programme prepared ▪ Training assessment reports ▪ Number of staffs are trained ▪ Transparent procedure for identification of institutes for testing and control defined and adopted ▪ Institutes for carrying out testing and control are identified through open competition ▪ Standard Operating Manuals for the required analysis defined and adopted ▪ Training need assessment carried out ▪ Training programme prepared ▪ Training assessment reports ▪ Number of staff trained ▪ Communication strategy drafted, adopted and implemented ▪ Number of communication/visibility events organised ▪ End-users report positively on introduced changes <ul style="list-style-type: none"> ▪ Other departments are aware of processes for alignment with Acquis 	<ul style="list-style-type: none"> • Institute register • 3-month post training questionnaire • On-site visits and monitoring reports • 3-month post training questionnaires • Project progress reports • Reports of the Post-registration laboratory • Final conference report • Media reports 	<p>Staff resources available with professional skills and competences in the PPD</p> <p>No resistance on introduction of control procedures based on risk assessment especially in authorized institutions and other stakeholders</p>
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Activities	Means	Costs	Assumptions
<p>Result 1 - A clear strategy for the development and implementation of PPP legislation and associated regulations is established</p> <p>Development of clear strategy including organisational structure, roles and responsibilities for the various actors involved in PPP system and cost benefit analysis for alignment with the <i>acquis</i>.</p> <p>As per section 9 of the twinning fiche cross cutting issues will be taken into account/ appropriately incorporated in this strategic document.</p> <p>Result 2 - Drafting and adoption of legal acts (e.g. laws and by laws) regulating the PPP's area in line with EU <i>acquis communautaire</i></p> <p>Assessment of current legislation on PPP's and all legal documents issued by the regulatory authority for the authorisation of PPP's in the RS;</p> <p>Preparation of the action plan for alignment of PPP's legislation with provision of <i>Acquis communautaire</i>;</p> <p>Provision of assistance with drafting revised legislation and relevant authorisation documents to ensure harmonisation and compliance with the <i>acquis</i>;</p> <p>Provision of guidance and training to the RS on consequences of the <i>acquis</i> on their legislation (e.g. compliance with new EC decisions on inclusion/non-inclusion of active substances in</p>	1 x Twinning Contract	1,300,000 Euro	<p>Staff are provided with sufficient support and opportunity to use newly acquired skills</p> <p>Eligible institutes are interested in becoming authorised bodies</p>

<p>Annex I prior to entry to the EU).</p> <p>Result 3 - Improved capacity of the PPD to carry out its functions in relation to the implementation of PPP legislation and regulations.</p> <p>Training needs analysis based on results of activity 1.1. and preparation of complementary guidelines and manuals to support implementation of new systems:</p> <p>Design and delivery of training activities for PPD staff. Training activities to increase the capacity of the PPD to carry out and/or monitor the following:</p> <ul style="list-style-type: none"> Data evaluation for physical chemical properties and analytical methods Data evaluation for environmental fate and behaviour Data evaluation for eco-toxicology Data evaluation for mammalian toxicology Data evaluation for operator exposure Data evaluation for residues and consumer risk Maximum Residue Levels Data evaluation for efficacy Official Recognition of efficacy testing facilities 			
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<p>Result 4 - Improved capacity of the other stakeholders (such are institutes and laboratories) to carry out their functions in relation to the implementation of PPP legislation and regulations.</p> <p>Identify all areas where authorising bodies are required</p> <p>Evaluation of applications</p> <p>Preparation of guidelines and procedures for applying to become an authorising body</p> <p>Result 5 - All stakeholders, including end-users, to be aware of changes to PPP procedures and their impact</p> <p>Development of a clear communication strategy and Production of promotional materials</p> <p>Develop internal communication mechanisms</p> <p>Project launch and One-to-one meetings with key stakeholders</p> <p>5.6. Final conference</p>			
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ANNEX II: Amounts (in €) Contracted and disbursed by quarter for the project (IPA contribution only)

Contracted	QR1	QR2	QR3	QR4	QR5	QR6	QR7	QR8	QR ₉	QR10	QR11	QR ₁₂	Total
Contract 1.1				1.3 M									1.3 M
Cumulated				1.3 M									1.3 M
Disbursed													
Contract 1.1				0.3	0.3	0.2	0.2	0.1	0.1	0.05	0.05		1.3 M
Cumulated				0.3	0.3	0.2	0.2	0.1	0.1	0.05	0.05		1.3 M

ANNEX III: Reference to laws and regulations and strategic documents

Reference list of relevant laws and regulations

Currently evaluation of plant protection products and authorization is based on the following acts:

Primary legislation

- 1. The Law on Plant Protection** («Official Journal of FRY», No. 24/98, 26/98),
- 2. The Law on the Production and Placing on the Market of Toxic Substances** («Official Journal of FRY», No. 15/1995)
- 3. The Law on the Food Health and Objects of Common Use** («Official Journal of SFRY», No. 53/1991)

Secondary legislation is based on the Law on Plant Protection:

- Rules on pesticide testing methods («Official Journal of FRY», No. 63/2000, 65/2000, «Official Journal of RS», No. 93/2005)
- Rules on pesticide production line («Official Journal of FRY», No. 68/2001)
- Rules on pesticides trade, import and sampling («Official Journal of FRY», No. 59/2001, «Official Journal of RS», No. 104/2005)
- Rules on pesticide and fertilizer packaging and disposal («Official Journal of FRY», No. 35/1999)
- Rules on offering services in plant protection and control equipments and machines for pesticide application («Official Journal of FRY», No. 42/1999)
- List minor crops for registration pesticides («Official Journal of FRY», No. 24/2003)

Secondary legislation that is based on the Act on the Production and Placing on the Market of Toxic Substances:

- Rules on the Criteria and Methods of Classifications of Toxic substances («Official Journal of FRY», No. 79/1991)
- Ministers decision on the labeling of registered poisons («Official journal FRY», no. 38/1997)
- Ministers decision to legal authorities on the production, placing on the market and control of poisons («Official Journal of FRY», No. 30/1996)

Secondary legislation that is based on the Law on the food health and objects of common use:

- Rules on quantities of pesticides, metals and metalloids and others toxic substances, chemotherapeutics, anabolic and others substances which occurs in food («Official Journal of FRY», No. 5/1992)

EU – legislation

- L230/1 19/08/1991 Council [Directive 91/414/EEC](#) of 15 July 1991 concerning the placing of plant protection products on the market

Amended by:

L221/27	31.08.1993	Commission Directive 93/71/EEC of 27 July 1993
L194/65	29.07.1994	Commission Directive 94/37/EC of 22 July 1994
L227/31	01.09.1994	Council Directive 94/43/EC of 27 July 1994
L354/16	31.12.1994	Commission Directive 94/79/EC of 21 December 1994
L172/6	22.07.1995	Commission Directive 95/35/EC of 14 July 1995
L172/8	22.07.1995	Commission Directive 95/36/EC of 14 July 1995
L65/20	15.03.1996	Commission Directive 96/12/EC of 8 March 1996
L214/18	23.08.1996	Commission Directive 96/46/EC of 16 July 1996
L277/25	30.10.1996	Commission Directive 96/68/EC of 21 October 1996
L265/87	27.09.1997	Council Directive 97/57/EC of 22 September 1997
L353/26	24.12.1997	Commission Directive 97/73/EC of 15 December 1997
L191/50	07.07.1998	Commission Directive 98/47/EC of 25 June 1998
Corrected by L354/66 30/12/1998 and L151/39 18/06/1999		
L21/21	28.01.1999	Commission Directive 1999/1/EC of 21 January 1999
Corrected by L145/40 10/06/1999		
L206/16	05.08.1999	Commission Directive 1999/73/EC of 19 July 1999
L210/13	10.08.1999	Commission Directive 1999/80/EC of 28 July 1999
L57/28	02.03.2000	Commission Directive 2000/10/EC of 1 March 2000
L197/32	03.08.2000	Commission Directive 2000/49/EC of 26 July 2000
L198/39	04.08.2000	Commission Directive 2000/50/EC of 26 July 2000
L276/35	28.10.2000	Commission Directive 2000/66/EC of 23 October 2000
L276/38	28.10.2000	Commission Directive 2000/67/EC of 23 October 2000
L276/41	28.10.2000	Commission Directive 2000/68/EC of 23 October 2000
L309/14	09.12.2000	Commission Directive 2000/80/EC of 4 December 2000
L69/17	10.03.2001	Commission Directive 2001/21/EC of 5 March 2001
L113/5	24.04.2001	Commission Directive 2001/28/EC of 20 April 2001
L164/1	20.06.2001	Commission Directive 2001/36/EC of 16 May 2001
L175/21	28.06.2001	Commission Directive 2001/47/EC of 25 June 2001
L176/61	29.06.2001	Commission Directive 2001/49/EC of 28 June 2001
L276/17	19.10.2001	Commission Directive 2001/87/EC of 12 October 2001
L304/14	21.11.2001	Commission Directive 2001/99/EC of 20 November 2001
L313/37	30.11.2001	Commission Directive 2001/103/EC of 28 November 2001
L55/29	26.02.2002	Commission Directive 2002/18/EC of 22 February 2002
L117/10	04.05.2002	Commission Directive 2002/37/EC of 3 May 2002
L148/19	06.06.2002	Commission Directive 2002/48/EC of 30 May 2002
L189/27	18.07.2002	Commission Directive 2002/64/EC of 15 July 2002
L276/28	12.10.2002	Commission Directive 2002/81/EC of 10 October 2002
L8/7	14.01.2003	Commission Directive 2003/5/EC of 10 January 2003
L81/39	28.03.2003	Commission Directive 2003/23/EC of 25 March 2003
L101/3	23.04.2003	Commission Directive 2003/31/EC of 11 April 2003
L122/1	16.05.2003	Council Regulation (EC) No 806/2003 of 14 April 2003
L124/30	20.05.2003	Commission Directive 2003/39/EC of 15 May 2003
L177/12	16.07.2003	Commission Directive 2003/68/EC of 11 July 2003
Amended by: L125/43 28/04/2004 Commission Directive 2004/65/EC of 26 April 2004		
L184/9	23.07.2003	Commission Directive 2003/70/EC of 17 July 2003
L205/16	14.08.2003	Commission Directive 2003/79/EC of 13 August 2003
Amended by L125/41 28/04/2004 Commission Directive 2004/63/EC of 26 April 2004		
L224/29	06.09.2003	Commission Directive 2003/81/EC of 5 September 2003
L228/11	12.09.2003	Commission Directive 2003/82/EC of 11 September 2003
L247/20	30.09.2003	Commission Directive 2003/84/EC of 25 September 2003
Amended by: L125/42 28/04/2004 Commission Directive 2004/64/EC of 26 April 2004		
L321/32	06.12.2003	Commission Directive 2003/112/EC of 1 December 2003
L325/41	12.12.2003	Commission Directive 2003/119/EC of 5 December 2003

L70/32	09.03.2004	Commission Directive 2004/20/EC of 2 March 2004
L77/50	13.03.2004	Commission Directive 2004/30/EC of 10 March 2004
L120/26	24.04.2004	Commission Directive 2004/58/EC of 23 April 2004
L120/39	24.04.2004	Commission Directive 2004/60/EC of 23 April 2004
L125/38	28.04.2004	Commission Directive 2004/62/EC of 26 April 2004
L127/104	29.04.2004	Commission Directive 2004/71/EC of 28 April 2004
L168/35	01.05.2004	Council Directive 2004/66/EC of 26 April 2004
L309/6	06.10.2004	Commission Directive 2004/99/EC of 1 October 2004
L20/15	22.01.2005	Commission Directive 2005/2/EC of 19 January 2005
L20/19	22.01.2005	Commission Directive 2005/3/EC of 19 January 2005
L70/1	16.03.2005	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005
L90/1	08.04.2005	Council Directive 2005/25/EC of 14 March 2005
L125/5	18.05.2005	Commission Directive 2005/34/EC of 17 May 2005
L241/51	19.09.2005	Commission Directive 2005/53/EC of 16 September 2005
L244/21	20.09.2005	Commission Directive 2005/54/EC of 19 September 2005
L246/14	22.09.2005	Commission Directive 2005/57/EC of 21 September 2005
L246/17	22.09.2005	Commission Directive 2005/58/EC of 21 September 2005
L279/63	22.10.2005	Commission Directive 2005/72/EC of 21 October 2005
L12/17	18.01.2006	Commission Directive 2006/5/EC of 17 January 2006
L12/21	18.01.2006	Commission Directive 2006/6/EC of 17 January 2006
L25/24	28.01.2006	Commission Directive 2006/10/EC of 27 January 2006
L36/37	07.02.2006	Commission Directive 2006/16/EC of 7 February 2006
L44/15	15.02.2006	Commission Directive 2006/19/EC of 14 February 2006
L104/30	13.04.2006	Commission Directive 2006/39/EC of 12 April 2006
L130/27	18.05.2006	Commission Directive 2006/45/EC of 16 May 2006
L187/24	08.07.2006	Commission Directive 2006/41/EC of 7 July 2006
L206/107	27.07.2006	Commission Directive 2006/64/CE of 18 July 2006
L235/17	30.08.2006	Commission Directive 2006/74/EC of 21 August 2006
L248/3	12.09.2006	Commission Directive 2006/75/EC of 11 September 2006
L263/9	23.09.2006	Commission Directive 2006/76/EC of 22 September 2006
L293/3	24.10.2006	Commission Directive 2006/85/EC of 23 October 2006
L349/17	12.12.2006	Commission Directive 2006/131/EC of 11 December 2006
L349/22	12.12.2006	Commission Directive 2006/132/EC of 11 December 2006
		Corrected by Commission Decision 2007/452/EC of 29 June 2007 (L172/83; 30.06.2007)
L349/27	12.12.2006	Commission Directive 2006/133/EC of 11 December 2006
L349/32	12.12.2006	Commission Directive 2006/134/EC of 11 December 2006
L349/37	12.12.2006	Commission Directive 2006/135/EC of 11 December 2006
L349/42	12.12.2006	Commission Directive 2006/136/EC of 11 December 2006
L363/352	20.12.2006	Council Directive 2006/104/EC of 20 November 2006
L35/11	08.02.2007	Commission Directive 2007/5/EC of 7 February 2007
		Corrected by Commission Decision 2008/782/EC of 7 October 2008 (L268/31; 09.10.2008)
L43/13	15.02.2007	Commission Directive 2007/6/EC of 14 February 2007
L97/42	12.04.2007	Commission Directive 2007/21/EC of 10 April 2007
L106/34	24.04.2007	Commission Directive 2007/25/EC of 23 April 2007
L140/44	01.06.2007	Commission Directive 2007/31/EC of 31 May 2007
L202/15	03.08.2007	Commission Directive 2007/50/EC of 2 August 2007
L214/3	17.08.2007	Commission Directive 2007/52/EC of 16 August 2007
L337/100	21.12.2007	Commission Directive 2007/76/EC of 20 December 2007
L87/5	29.03.2008	Commission Directive 2008/40/EC of 28 March 2008
		Corrected by Commission Decision 2008/791/EC of 10 October 2008 (L271/50; 11.10.2008)
L89/12	01.04.2008	Commission Directive 2008/41/EC of 31 March 2008
L94/13	05.04.2008	Commission Directive 2008/44/EC of 4 April 2008
L94/21	05.04.2008	Commission Directive 2008/45/EC of 4 April 2008
L171/9	01.07.2008	Commission Directive 2008/66/EC of 30 June 2008
L172/9	02.07.2008	Commission Directive 2008/69/EC of 1 July 2008
L185/40	12.07.2008	Commission Directive 2008/70/EC of 11 July 2008
L262/31	01.10.2008	Commission Directive 2008/91/EC of 29 September 2008
L316/13	26.11.2008	Commission Directive 2008/107/EC of 25 November 2008
L317/6	27.11.2008	Commission Directive 2008/108/EC of 26 November 2008
L330/6	09.12.2008	Commission Directive 2008/113/EC of 8 December 2008
L337/86	16.12.2008	Commission Directive 2008/116/EC of 15 December 2008
L344/78	20.12.2008	Commission Directive 2008/125/EC of 19 December 2008
L344/89	20.12.2008	Commission Directive 2008/127/EC of 18 December 2008
L48/5	19.02.2009	Commission Directive 2009/11/EC of 18 February 2009
L91/20	03.04.2009	Commission Directive 2009/25/EC of 2 April 2009
L104/23	24.04.2009	Commission Directive 2009/37/EC of 23 April 2009

ANNEX IV: Reference to strategic documents

Reference to EP / SAA

The priorities listed in European Partnership with Serbia including Kosovo of 18 February 2008 (Council Decision 2008/213/EC) concern both legislation and its implementation. Update legislation and strengthen implementation and controls in the areas of food safety and veterinary and phytosanitary issues identified as a particular short term priority. Medium-term priorities include continue strengthening veterinary, sanitary, phytosanitary and food safety legislation and controls.

Under Article 97 (Agriculture, and the agro-industrial sector) of the draft Stability and Association Agreement (SAA) cooperation between EU and Serbia related to the Community *acquis* in the field agriculture as well as veterinary and phytosanitary domains with aim at modernisation and restructuring in particular reach community sanitary requirements and at supporting the gradual approximation of Serbian legislation and practice to the Community rules and standards.

Reference to MIPD

The Multi-annual Indicative Planning Document for the Republic of Serbia 2007-2009 of 26 January 2007 state, in the Main priorities and objectives under sub-component European Standards of Component I, that the main areas of intervention are (among others):

- Supporting the development and implementation of sectors strategies and policies compatible with EC internal market legislation and best practices in areas as veterinary, phytosanitary and sanitary standards, data protection etc. and
- Supporting the development and implementation of strategies and policies in order to establish policies and a regulatory framework compatible with EU standards as follows (among Agriculture and Rural Development): develop capacities to implement EU veterinary, phytosanitary, food safety and quality standards.

The assistance under Component I may be provided in the form of twinning/twinning light support.

Reference to National Development Plan

Integration and EU membership is the ultimate goal The National Strategy of Serbia for the Accession of Serbia and Montenegro to the European Union (NSA). Reinforcing the relevant laws and policies and capacity building the relevant institutions closer to those of the EU in food safety area is presumptive which needs particular attention (interest) and investment.

This project fiche is directed towards meeting these priorities, as well as those set in the National Strategy paper.

One of the main goals of The National Agricultural Development Strategy (NADS), which are stated in The Budget, Economy and Fiscal Politic Memorandum too, is to ensure food which satisfies needs of consumer with regard to quality and safety, and protect the environment from influences of agricultural production (reducing agricultural pollution) through: creating veterinary and phytosanitary services which are corresponding to international standards and legal expectations of Serbian consumers; protecting human health from illnesses transmitted by food and/or animals, adverse effects of pesticides, veterinary drugs and food additives; protecting environment from adverse effects of plant protection products (PPP's), fertilisers and veterinary drugs.

In the Governmental Action Plan for Implementation of Priorities from the European Partnership state that in the sector of Agriculture and Fisheries short-term priorities are to adopt and to implement legislation in phytosanitary area. The PPD of the MAFWM is in charge for those issues. It is necessary to create the Law on PPP's as well as by-laws. In that document are mentioned obstacles for above mentioned activities (lack of staff, need for permanent training).

For initiate and provide the basis for further adjustment with the *acquis* framework legislation PPP's Law has been drafted. According to the National Plan for Integration Republic of Serbia in the EU it is sent in adoption procedure in fourth quarter 2008 and will be adopted till the end of the 2009.

In the Budget, Economy and Fiscal Politic Memorandum for 2008 with projection in 2009 and 2010 stated that the Republic of Serbia, in following medium-term period, will continue agriculture reform on the NADS basis. The main goals agricultural development will be supported through the new laws, new institutions, land reform and privatization in agriculture. Among other, the law about PPPs is going to be adopted according to Directive 91/414/EEC, which guarantee authorisation of active substances and PPPs and control residues of pesticides in plant and plant products.

From March 2005 till the end of 2007 the PPD together with MEP has escorted program for withdrawal authorizations of PPP's containing active substances which are not on the EU market, according to EU decisions concerning the non-inclusion in Annex I to Council Directive 91/414/EEC and withdrawal of authorizations for PPP's containing this active substances (EU decisions till November 2004).

According to this program 27 active substances are considered. For each active substances are determined withdrawal authorization or essential use till defined period (because lack of alternatives or expenditure of stocks) or time limitation of authorizations till 31 of December 2007.

Program has been adjusted in the aim of supersede dam for export agricultural products and reduce of import and purvey of this active substances and PPP's which contains this active substances.