Standard Summary Project Fiche – IPA centralised programmes

Project number 32: 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. Basic information

1.1 CRIS Number: 2008/020-406

1.2 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**

1.3 ELARG statistical code: 03.12

1.4 Location: Republic of Serbia

Implementing arrangements:

1.5 Contracting Authority: EC Delegation to the Republic of Serbia
1.6 Implementing Agency: EC Delegation to the Republic of Serbia

1.7 Beneficiary (including details of project manager):

Plant Protection Directorate of the Ministry of Agriculture, Forestry and Water Management

The Beneficiary institution of the project is the Ministry of Agriculture, Forestry and Water Mangement (MAFWM) – Plant Protection Directorate (PPD), Department for Plant Protection Products and Fertilizers (DPPPF).

Financing:

1.8 Overall cost: **1.300.000 EUR**

1.9 EU contribution: **1.300.000 EUR**

1.10 Final date for contracting: 3 years after the signature of the Financing Agreement

1.11 Final date for execution of contracts: 5 years after the signature of the Financing Agreement

1.12 Final date for disbursements: 6 year after the signature of the Financing Agreement

2. Overall Objective and Project Purpose

2.1 Overall Objective:

To adopt and implement the *acquis communautaire* in the area of plant protection products (PPP's).

2.2 Project purpose:

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

2.3 Link with AP/NPAA/EP/SAA

The European Partnership with Serbia identifies further strengthening of the phytosanitary legislation and controls as one of the priorities for the agriculture sector.

The Stabilisation and Association Agreement (SAA) between EU and Serbia includes a reference to the need for the veterinary and phytosanitary domains to continue their strenghtening.

2.4 Link with MIPD

The Multi-annual Indicative Planning Document (MIPD) for the Republic of Serbia 2007-2009, includes among the main areas of intervention:

- Support to the development and implementation of sectoral strategies and policies compatible with EC internal market legislation and best practices in areas as veterinary, phyto-sanitary and sanitary standards, data protection etc. and

- Support to 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.

This project directly addresses both of these issues by aligning Serbian regulations, procedures and systems with those required in EU member states.

2.5 Link with National Development Plan (where applicable)

N/A

2.6 Link with national/ sectoral investment plans (where applicable)

N/A

3. Description of project

3.1 Background and justification

The current procedure for granting authorizations of PPP's in Republic of Serbia is complicated, requiring the involvement of the three ministries, two advisory committees - Committee of poisons and Committee of PPP's as well as Authorised scientific institutes.

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

Phase 1 – Evaluation of human toxicity, eco-toxicity, environmental impact.

This phase is covered by regulation Ministry of Environmental Protection (MEP) - The Law on the Production and Placing on the Market of Toxic Substances («OJ of FRY», No. 15/1995) and sub laws. In conducting this evaluation the experts in Authorized Scientific institutes generally reviewed dossiers (files) of the applicants (in Serbia exist nine Authorized Scientific Institutes).

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 MEP about completeness of documentation for this evaluation. As a result of the data evaluation, the Authorized Scientific institutes prepares a Toxicological opinion in form of a report, which is then forwarded for discussion to the Toxic Substances Committee.

The Committee gives a recommendation for classification and labelling to the MEP, and on the basis of that, the MEP 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 (MoH), 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 MoH has limited specialist expertise in this area. This has been the practice since 1999. The existing MRLs (from 1992) are not in line with the Serbian Good Agriculture Practise. Subsequent surveillance, monitoring and enforcement is also not carried out.

Because of the limited expertise within the MoH, temporary MRL's are proposed by toxicologists in the Toxicological opinion and the Toxic Substances Committee gives a recommendation for that to the MEP.

Because of this situation the MAFWM has established a new Committee for PPP's which includes a group responsible for MRL setting. That group consist of four members. The PPD is currently in the process of changing the procedures and rules on testing methods of pesticides and documentation for MRL's. As a result of this process it is expected that the rules for definition of the MRLs will largely reflect those in the EU.

Department for pesticides and fertilizers has made a list of existing temporary or permanent MRLs in the Republic of Serbia. This list includes a column for the EU MRL and Codex Alimentarius. It is expected that this list will be completed by mid 2008.

Phase 3 – Evaluation of physical and chemical properties and efficacy

This phase is covered by regulation of the Ministry of Agriculture, Forestry and Water Management (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 limits provided by the applicant, 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 of the rules on pesticide testing methods, applicants must also submit a dossier to the MAFWM.

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 Deciosion of Goverment FRY, «Official journal FRY», no. 4/2001).

Following the classification of the active substance(s) and definition of a temporary MRL, the respective report is submited to the Toxic Substances Committee, and together with the report on efficacy evaluation 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 certain period of time. However, as described above, the system is currently only partially applied with some parts completely absent. The main reasons for this are:

1. Unstable political situation in the last 10-15 years: Serbia has experienced frequent changes in the government structures and some of the responsibilities have been moving between different governmental institutions which, in some cases, resulted in a loss of continuity in strategy and decision making and ineffective co-ordination between the institutions responsible for PPP.

2. The Serbian legal system, which is not currently ready for the changes necessary to align with EU regulations

3. A lack of capacity within the responsible institutions. This relates to the limited number of staff in the existing national bodies, which are responsible for PPP and also to the expertise of those staff.

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 MH, MEP and 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,
- Existing (1992) MRLs do not accommodate the Serbian GAP 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.

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. Harmonization of national legislation with the EU in matters of PPP's needs to be continued through the preparation, 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 adjustment with the legislative framework of the *acquis* a PPP's Law has been drafted.

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 beneficiaries of this project are the PPD within the MAFWM and also the institutes selected under activity 1). 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.

3.2 Assessment of project impact, catalytic effect, sustainability and cross border impact

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

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.

3.3 Results and measurable indicators:

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

Indicators
- Roles and responsibilities of all involved agencies agreed
- Strategy for adoption of necessary legislation in place

2. Increased capacity of the PPD to carry out its functions in relation to the implementation of PPP legislation and regulations.

Indicators
- Staff are utilising new skills to perform PPP-related tasks effectively
- Staff report positively on training received
- Operations manual including standards of performance for all tasks is agreed
- Department for evaluations and approvals of PPP's and post-registration laboratory are established

3. Increased capacity of the other stakeholders to carry out their functions in relation to the implementation of PPP legislation and regulations.

Indicators
- Institutes to carry out testing and control are identified through open competition
- Staff are utilising new skills to perform PPP-related tasks effectively
- Staff report positively on training received
- Operations manual including standards of performance for all tasks is agreed

4. Creating and adopting legal regulation in area of PPP's according to *acquis communautaire*

Indicators
- Revision of PPP legislative framework completed
- Number of associated laws prepared
- Number of associated regulations and by-laws prepared

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

Indicators
- 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

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 the inherited

severely fragmented institutional set up with many authorities and institutes involved and having overlapping competences. 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.

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 .

- National authorization procedures (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 - Increased capacity of the PPD to carry out its functions in relation to the implementation of PPP legislation and regulations.

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).

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 3 - Increased capacity of the other stakeholders to carry out their functions in relation to the implementation of PPP legislation and regulations.

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.

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.

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 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 4 - Creating and adopting legal regulation in area of PPP's according to *acquis communautaire* (Activity 2)

Harmonization of national legislation with the EU in relation to PPP's needs to be continued through the preparation, 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 will

be prepared 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).

Activities which relate to the transposition of the *acquis communitaire* 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
- Provision of assistance with drafting revised legislation and relevant authorisation documents to ensure harmonisation and compliance with the *acquis*
- Provision of guidance 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 5 - All stakeholders, including end-users, to be aware of changes to PPP procedures and their impact

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.

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.

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.

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.

Contracting Arrangement:

This project will be implemented through a Twinning contract.

3.5 Conditionality and sequencing:

There are a number of conditions which need to be met in order for the project to achieve the expected impact. These are:

The Ministries involved in control and management of plant protection products should reach an agreement on division of competencies in this area, which should, ideally, be verified in form of a Government Conclusion, before the project start .

The Ministries concerned explicitly confirm a clear commitment to the achievement of the project results before the project launch.

Staff of the PPD and other departments covered by the project available to participate in the project activities.

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. Therefore, additional employees will need to be recruited especially in area of toxicology, ecotoxicology, fate and behaviour and maximum residue levels of PPP`s.

3.6 Linked activities

Following the Zagreb summit and the endorsement of the Stabilisation and Association Process by EU and Western Balkans Countries, in 2001 the new CARDS programmes funded by EU started.

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 communitaire*.

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 with PPP's legislative, like:

- 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. This Project doesn't implement.
- 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 will include 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 is providing a fund for training of trainers in the field of farmer education for use PPP's. Education program for farmers will start in autumn 2008.

3.7 Lessons learned

This is the first time that a project in the area of PPP's has been implemented in Serbia. The project design takes into account lessons learned in Member States and in particular those

which most recently joined the European Union, especially Czech Republic. Under similar conditions Project in area of plant health and PPP's was implemented during 2002-2004 with Pesticide Safety Directorate (PSD) UK as twinning partner.

Experience from Member States has shown that significant time and effort is required to build the necessary capacity to implement Council Directive 91/414/EEC.

A further project in PPP area which is founded from EU funds, has being implemented in Republic of Croatia. The twinning partner in RC that is Ministry of Agriculture is PSD UK. By implementation of this project in the Republic of Serbia, with the same twinning partner one part of the activities (study tours, seminars) could be performed in Croatia and Serbia at the same time.

Previous experience reveals that the line Ministries had difficulties in agreeing on division of responsibilities in the control of food chain safety, which limited impact of some of the EU funded projects implemented within the framework of the CARDS. Therefore, the firm commitment by the Ministries concerned to reach an agreement on the division of competencies before the project start will be one of the critical factors for the project success.

4. Indicative Budget (amounts in EUR)

				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 1.1	X		1,300,000	1,300,000	*100*							–
TOTAL IB			1,300,000	1,300,000	*100*							
TOTAL INV												
TOTAL PROJECT			**1,300,000**	**1,300,000**	**100**							

NOTE: DO NOT MIX IB AND INV IN THE SAME ACTIVITY ROW. USE SEPARATE ROW

Amounts net of VAT

(1) In the Activity row use "X" to identify whether IB or INV

(2) Expressed in % of the **Total** Expenditure (column (a))

5. Indicative Implementation Schedule (periods broken down per quarter)

Contracts	Start of Tendering	Signature of contract	Project Completion
Contract 1.1	T+1Q	T+4Q	T+11Q

[where T=the date of the signature of the FA and xQ equals the number (x) of quarters (Q) following T].

6. Cross cutting issues (where applicable)

Development Policy Joint Statement by the Council and the European Commission of 10 November 2000 establishes that a number of cross-cutting Issues shall be mainstreamed into EC development co-operation and assistance. Cross-cutting issues will be addressed in the project so as to comply with the best EU standards and practice in that area and in a way which demonstrates how they will be dealt with within the project's framework, its activities and outputs.

Cross-cutting issues will be addressed in a proactive manner, and will present a specific component of projects (at all levels of projects' development, starting from the project identification stage). Synergies between the projects and the objectives of will be identified and developed. Also, the projects' objectives and activities need to be screened in order to ensure they won't impact negatively on gender equality, minorities' inclusion and environment.

Finally, the beneficiary will make sure its objectives, policies and interventions have a positive impact on and are in line with the main principles of gender equality, minorities' inclusion and environment.

6.1 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.**

6.2 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.

6.3 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.

ANNEX 1: LOGFRAME PLANNING MATRIX FOR			
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 3 years after the signature of the Financing Agreement	Disbursement period expires 6 years after the signature of the Financing Agreement
		Total Budget**:** €1.3M	IPA budget: €1.3M
General objective	**Objectively measurable indicators**	**Sources of verification**	
To adopt and implement the *acquis communautaire* in the area of PPP's.	% 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.	• 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	• Official Gazette of the Republic of Serbia • Annual Report of the PPD and MAFWM • Twinning project reports • Tables of Concordance • Reports of EC	Adopting a new Strategy for Agriculture Reform national policy in PPP's area
Results	**Objectively measurable indicators**	**Sources of verification**	**Assumptions**
1. A clear strategy for the development and implementation of PPP legislation and associated regulations is established 2. Increased capacity of the PPD to carry out its functions in relation to the implementation of PPP legislation and regulations.	▪ Roles and responsibilities of all involved agencies agreed ▪ Strategy for adoption of necessary legislation in place ▪ Staff are utilising new skills to perform PPP-related tasks effectively ▪ Staff report positively on training received ▪ Operations manual including standards of performance for all tasks is agreed ▪ Department for evaluations and approvals of PPP's and post-registration laboratory are established	• Project progress reports • Minutes of Steering Committee • 3-month post training questionnaires • Project progress reports • Reports of the Post-registration laboratory	Willingness by the PPD and other Ministries to take forward agreed recommendations emanating from the project (*e.g.* changes to structure and procedures) Staff resources available with professional skills and competences in the PPD

3. Increased capacity of the other stakeholders to carry out their functions in relation to the implementation of PPP legislation and regulations.	▪ Institutes to carry out testing and control are identified through open competition ▪ Staff are utilising new skills to perform PPP-related tasks effectively ▪ Staff report positively on training received ▪ Operations manual including standards of performance for all tasks is agreed	• Institute register • 3-month post training questionnaire • On-site visits and monitoring reports	No resistance on introduction of control procedures based on risk assessment especially in authorized institutions and other stakeholders
4. Creating and adopting legal regulation in area of PPP's according to *acquis communautaire*	▪ Revision of PPP legislative framework completed ▪ Number of associated laws prepared ▪ Number of associated regulations and by-laws prepared	• Official gazette	
5. All stakeholders, including end-users, to be aware of changes to PPP procedures and their impact	▪ End-users report positively on introduced changes ▪ Other departments are aware of processes for alignment with Acquis	• Final conference report • Media reports	
Activities	**Means**	**Costs**	**Assumptions**
1.1. Development of clear organisational structure and roles and responsibilities for the various actors involved in PPP system. 1.2. Assessment of current systems 1.3. Revision of existing systems in line with EU requirements for: ▪ Management of applications ▪ National authorizations ▪ Post-authorisation procedures 2.1. Training needs analysis based on results of activity 1.1. 2.2. Design and delivery of training activities for PPD staff. Should include seminars, workshops, study visits and mentoring. 2.3. Preparation of complementary guidelines and manuals to support implementation of new systems. 2.4. Training activities to increase the capacity of the PPD to carry out and/or monitor the following:	1 x Twinning Contract	1,300,000 Euro	Staff are provided with sufficient support and opportunity to use newly acquired skills Eligible institutes are interested in becoming authorised bodies

▪ 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 herbicides and plant growth regulators, fungicides, insecticides and other zoocides ▪ Official Recognition of efficacy testing facilities 3.1. Identify all areas where authorising bodies are required 3.2. Preparation of guidelines and procedures for applying to become an authorising body 3.3. Evaluation of applications 3.4. Training of appointed authorising bodies 3.5. Monitoring of authorising body performance 4.1. 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 4.2. Provision of assistance with drafting revised legislation and relevant authorisation documents to ensure harmonisation and compliance with the *acquis* 4.3. Provision of guidance to the RS on consequences of the *acquis* on their legislation Development of a clear communication strategy. Project launch One-to-one meetings with key stakeholders Develop internal communication mechanisms Production of promotional materials Final conference			

ANNEX II: Amounts (in €) Contracted and disbursed by quarter for the project (IPA contribution only)

Contracted	QR1	QR2	QR3	QR4	QR5	QR6	QR7	QR8	QR9	QR10	QR11	QR 12	**Total**
Contract 1.1				1.300.000									**1.300.000**
Cumulated				**1.300.000**									**1.300.000**
Disbursed													
Contract 1.1				300.000	300.000	200.000	200.000	100.000	100.000	50.000	50.000		**1.300.000**
Cumulated				**300.000**	**600.000**	**800.000**	**1.000.000**	**1.100.000**	**1.200.000**	**1.250.000**	**50.000**		**1.300.000**

ANNEX III: Institutional Framework – legal responsibilities and statutes

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:

- Plant health
- PPP`s and Fertilizers
- Phytosanitary inspection
- Legal, Financial and Administrative Unit

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 **e**valuation 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	- registration (authorisathion) PPP's – authorisation for put on the market PPP's - permission for import a.s. and PPP's - control import consingments 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 wholesallers and retails of PPP's – certificates - control end users of PPP's – doesn't exist (have just started) - authorisathion of laboratories for formulation analysis of PPP's and pesticide residue analiysis 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 91/4141/EEC, 79/117/EEC
MEP	- 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	- establishing MRL's – doesn't exist - organisation systematic control degree of contamination of foodstuffs, soil, water and air by contaminants including pesticides - authorisathion of laboratories for analiysis 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.

ANNEX IV: Reference to laws, 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

Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market
Council Directive 97/57/EC of 22 September 1997 establishing Annex VI to Directive 91/414 concerning the placing of plant protection products on the market

Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances

Commission Regulation (EC) No 1095/2007 amending Regulation (EC) No 1490/2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and Regulation (EC) No 2229/2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC

Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in and on food and feed of plant and animal origin and amending Council Directive 91/414/EE

Commission Regulation (EC) No 178/2006 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council to establish Annex I listing the food and feed products to which maximum levels for pesticide residues apply

Other Council Directives: 86/362/EEC, 86/363/EEC, 90/642/EEC, 94/73/EC, 78/631/EEC, 81/187/EEC, 81/187/EEC, 91/188/EEC, 92/32/EEC

Commission Directives: 93/71/EEC, 94/37/EC, 94/43/EC, 94/79/EC, 95/35/EC, 95/36/EC, 96/12/EC, 96/46/EC, 96/68/EC, 97/73/EC, 98/47/EC, 1999/1/EC, 1999/73/EC, 1999/80/EC, 2000/10/EC, 2000/49/EC, 2000/50/EC, 2000/66/EC, 2000/67/EC, 2000/68/EC, 2000/80/EC, 2001/21/EC, 2001/28/EC, 2001/36/EC, 2001/47/EC, 2001/49/EC, 2001/87/EC, 2001/99/EC, 2001/103/EC, 2002/18/EC, 2002/37/EC, 2002/48/EC, 2002/64/EC, 2002/81/EC, 2003/5/EC, 2003/23/EC, 2003/31/EC, 2003/39/EC, 2003/68/EC, 2003/70/EC, 2003/79/EC, 2003/81/EC, 2003/82/EC, 2003/84/EC, 2003/112/EC, 2003/119/EC, 2004/20/EC, 2004/30/EC, 2004/58/EC, 2004/60/EC, 2004/62/EC, 2004/71/EC, 2004/99/EC, 2005/2/EC, 2005/3/EC, 2005/34/EC, 2005/53/EC, 2005/54/EC, 2005/57/EC, 2005/58/EC, 2005/72/EC, 2006/10/EC, 2006/16/EC, 2006/19/EC, 2006/45/EC, 2006/5/EC, 2006/6/EC, 2006/39/EC, 2006/41/EC, 2006/75/EC, 2006/76/EC, 2006/131/EC, 2006/132/EC, 2006/133/EC, 2006/134/EC, 2006/135/EC, 2006/136/EC, 2007/6/EC

Commission Guidance Documents: SANCO/10043/2007, SANCO/10328/2004, SANCO 7531, Sanco/1090/2000, Sanco/10472/2003, Sanco/10473/2003, Sanco/221/2000, Sanco/222/2000, Sanco/3989/2001, Sanco/10518/2005, Sanco/10518/2005, Sanco/223/2000, Sanco/3268/2001, Sanco/491/00, SANCO/10329/2002, 9188/VI/97, SANCO/4145/2000, SANCO/3029/99, SANCO/3030/99, Sanco/10597/2003, SANCO/825/00, 7860/VI/97, 7017/VI/95, 7109/VI/94, 1654/VI/94, 7600/VI/95, SANCO/2971/2000, SANCO/10796/2003, SANCO/10393/2004, Sanco/10754/2005, SANCO/10435/2004, SANCO/10696/2004, 7196/VI/99, 1607/VI/97, 7028/VI/95, 7029/VI/95, 7524/VI/95, 7525/VI/95, 7035/VI/95, 7030/VI/95, 7031/VI/95, 7032/VI/95, 7039/VI/95, SANCO/825/00, SANCO/3029/99, SANCO/2007/3131, SANCO/3029/99, SANCO/3346/2001, SANCO/D3/SI2.396179, SANCO/D3/SI2.395857

Reference to EP / SAA

The European Partnership with Serbia and Montenegro including Kosovo as defined by the United Nations Security Council Resolution 1244 of 10 June 1999 and of 30 January 2006 (Council Decision 2006/56/EC) identifies the strengthening of the Serbian administrative capacity to formulate and implement agricultural policies as an on-going priority. The adoption and and implementation phytosanitary framework legislation 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 sectoral 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 standars 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 expected that the draft will be sent in adoption procedure in third quartal 2009 and will be adopted till the end of the first quartal 2010. The National Plan for Integration Republic of Serbia in the EU has been drafted and it is expected that the draft will be adopted by the Government till the end of 2008.

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 adoptted according to Directive 91/414/EEC, which garantee 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 programme 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 programme 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.

Programme 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.

Reference to national / sector investment plans

N/A

ANNEX V: Details per EU funded contract (*) where applicable

For *twinning covenants*: account of tasks expected from the team leader, resident twinning advisor and short term experts

Scope of team leader and resident twinning advisor work:

- requirements of Council Directives 91/414/EEC and 79/117 and their implementation
- administrative procedure within the authorization for plant protection products (from the reciept 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

Scope of work for short term experts:

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