



**MINISTRY OF AGRICULTURE
AND FOOD**

**NATIONAL PLANT PROTECTION
SERVICE**

REPUBLIC OF BULGARIA



**HEALTH AND SAFETY
EXECUTIVE**

**CHEMICALS REGULATION
DIRECTORATE**

UNITED KINGDOM

**SUCCESSFUL IMPLEMENTATION OF TWL PROJECT BG/07/IB/AG/04/UE/TWL
“ADMINISTRATION, COORDINATION AND EVALUATION OF DOSSIERS WITH
REGARD TO AUTHORIZATION OF PLANT PROTECTION PRODUCTS”,
CONTRACT BG2007/303-07-03-0021**

Twinning light project BG/07/IB/AG/04/UE/TWL “ADMINISTRATION, COORDINATION AND EVALUATION OF DOSSIERS WITH REGARD TO AUTHORIZATION OF PLANT PROTECTION PRODUCTS” started on 17 February 2010 by the kick-off meeting of the Project Steering Committee, has been implemented for 5 months of planned activities and was completed on 21 July 2010. The project had agreed budget of EUR 143 822 under the Unallocated envelope of the Transitional Financial Instrument. The selected contractor was the Chemicals Regulation Directorate, UK, direct beneficiary was the NSPP Department “Plant Protection Products”, but participation in the numerous trainings has been taken by a number of experts belonging to other institutions such as bodies of the Ministry of Agriculture and Food, the Ministry of Health and the Ministry of Environment and Waters. The objective of this Twinning Light project was to provide training to the National Service for Plant Protection (NSPP) in order to ensure that the authorisation of Plant Protection Products (PPPs) is effectively performed in accordance with the requirements of the *acquis*. The specific objectives that the project aimed at were the following:

1. A co-ordination system for authorizations to be established with regard to the acceptance, distribution and control of documentation submitted;
2. The NSPP administrative capacity to be strengthened for performance of evaluation of dossiers (including data evaluation and subsequent risk assessment) relating to the authorization of PPPs dossiers - Biological assessment, Phys-chem properties, Environmental fate and behaviour, Ecotoxicology, Toxicology and Residues dossiers and Maximum residues levels;
3. Administrative capacity of PPPs Department within NSPP to be strengthened in order to implement transparent and tracable re-registration procedure of PPPs, meeting the requirements for evaluation laid down in Bulgarian legislation and in line with other EU requirements;
4. NSPP to establish procedures for peer reviews in order to carry out the assessment of the active substances and elaborate a Draft assessment reports for both BG & EU authorizations and conclusions;

To successfully achieve the specific objectives, the project consisted of three separate components:

- **Component A** provided training in the performance of evaluation of dossiers of PPPs (including data evaluation and risk assessment) in 7 scientific areas;
- **Component B** provided training in the area of assisting with the establishment of a co-ordination system for the effective processing of PPPs
- **Component C** provided training in the area of legislation to ensure Bulgarian legislation was in line with the *acquis* and other EU requirements.

Under these three components in 14 major disciplines there were 15 activities implemented, including 1 study visit of Bulgarian experts in the partner's administration.

The Final meeting of the Project Steering committee, held on 21 July 2010 in Sofia reported the successful implementation of all activities planned under the project and the achievement of the related results. We appreciated the flexibility of the approach that the UK Project leader and experts applied to our training needs and assured adaptability and adjusting of the seminars in view to best implement the project. It has been noted at the last meeting that the project has achieved its main objective. The Final Report of the project was signed by both project leaders on 07 September and submitted to the Ministry of Finance (MF) on 13 September. On 12 October we received a notification that the technical part of the report has been approved.

The mandatory results as detailed in the project fiche and achieved were as follows:

1. Established co-ordination system for authorizations with regard to acceptance, distribution and control of documentation submitted;
2. 12 experts trained and able to carry out evaluation of Biological Assessment Dossiers with regard to PPPs authorization;
3. 4 experts trained to be able to carry out evaluation of physical and chemical properties dossiers with regard to PPPs authorization;
4. 8 experts trained to be able to carry out evaluation of pesticide residue and MRLs with regard to PPPs authorization;
5. 4 experts trained in the basic requirements to be met for carrying out evaluation of environmental fate and behaviour dossiers with regard to PPPs authorization;
6. 4 experts trained in the basic requirements to be met for carrying out evaluation of ecotoxicology dossiers with regard to PPPs authorization;
7. 8 experts trained in the basic requirements to be met for carrying out evaluation of toxicological dossiers with regard to PPPs authorization;
8. BG experts able to contribute effectively to EU decisions and discussions. Ability to effectively justify and stand the BG position within EU negotiations.

Scientific experts from NSPP, National Veterinary Service, National Center for Protection of Human Health (NCPHP), and the Ministry of Environment and Waters attended the professional trainings under Component A "Data evaluation and Risk assessment. The total number of participants under Component A has been 36 staff in total, many of them participated in 2 different trainings. Training sessions that

made part of Component B “Coordination system for registration and re-registration of PPPs” covered all the 6-member staff of Department “Plant Protection products” in charge of the co-ordination at NSPP; the Director General of NSPP also took part in some of the sessions. Trainings related to the last Component C “Legislation”, included multilateral participants, some of them belonging to bodies of MAF other than NSPP. Component C activities totaled 26 NSPP participants and 7 participants from other institutions, again many of these 33 experts attended different seminars.

Taking into account the above mentioned number of participants involved and at the same time belonging to different NSPP structures and MAF, MH and MOEW bodies the impact of the project is significant in terms of improved awareness of state experts about new requirements related to policy, assignment of specific tasks, improved coordination and better implementation of the *acquis*; all these result in administrative capacity of all these control bodies being strengthened.

The adoption of the new Regulation 1107/2009 of the European Parliament and the Council regarding placing of plant protection products on the market that replaces Directive 91/414/EEC and entering into force in June 2011 will be one of the challenges which NSPP will face. The trainings delivered in the frames of this project were useful to introduce to Bulgarian experts responsible for administration, coordination and evaluation of dossiers for registration and re-registration the changes which this new legislation will bring. The Regulation which still requires much guidance to be produced and made available to the member states for its enforcement might be interpreted in different ways, so it has been beneficial to know in advance the Chemicals Regulation Directorate approach to different articles and options of the new Regulation and to have a better overview on the timetable related to expected acceleration of evaluation and registration processes and to be better prepared for the forthcoming changes.

The aim of the project was also to provide specific and necessary trainings for the evaluators of active substances and plant protection products from other institutions of the public administration in Bulgaria such as experts from the Ministry of Health and Ministry of Environment and Waters, as well as for the coordinators from NSPP. Both Beneficiary and UK partners are glad to see relations between NSPP experts and other administrations that deal with evaluation and authorization of pesticides strengthened and the coordination between them improved in view to effectively implement the requirements of the EC legislation.

The training delivered under all three Components of this Twinning Light Project has provided the NSPP staff and experts belonging to other bodies of the Ministry of Agriculture and Food (MAF), the Ministry of Health (MH) and the Ministry of Environment and Waters (MOEW) with updated knowledge in the area of Data Evaluation and Risk Assessment in the seven scientific disciplines, assistance with the development of an effective co-ordination department for the processing of PPP applications and assisting NSPP staff in ensuring that the implementation of the legislation complies with the requirements of the *acquis*.