



European Food Safety Authority

INTERNATIONAL AND INSTITUTIONAL RELATIONS

EFSA AND THE PHARE PROGRAMME

Introduction

Following the request by the Board at its meeting on 24 January 2006 the following note aims at providing up to date information of the implementation of the EFSA Phare programme.

The Phare programme is one of the three pre-accession instruments financed by the European Union to assist applicant countries of Central and Eastern Europe in their preparations for joining the European Union. Through the Phare programme, EFSA is working with the governments of Bulgaria and Romania - acceding countries that are expected to join the EU in 2007 - on food and feed safety issues within EFSA's remit. Within EFSA, the International and Institutional Relations Department is coordinating the implementation of the programme.

National authorities and institutions from Bulgaria and Romania take part in a **Structured Forum for Partnership** that promotes and facilitates:

- Understanding of the mandate and role of EFSA.
 - Exchange of scientific and technical expertise and legal regulatory affairs information.
 - Preparation of the relevant bodies in Romania and Bulgaria, active in the fields related to the work of EFSA.
 - Inclusion of Romania and Bulgaria in crisis co-ordination exercises with EFSA and the development of appropriate crisis information exchange infrastructure.
 - The creation of communication and information exchange systems to support Bulgaria and Romania in their communication activities.
 - Transfer of knowledge on methodologies, in particular on risk assessment and data collection.

An important feature of the Phare programme at EFSA is the exchange of expertise. EFSA invites national experts from Bulgaria and Romania to participate in a variety of activities held throughout Europe where knowledge on food safety and related issues are discussed.

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EFSA Meetings

Officials from Romania and Bulgaria are invited as observers to the regular meetings of EFSA, such as meetings of the Management Board and the Advisory Forum. This invitation covers also the meetings of the Working Groups of the Advisory Forum, specifically the Working Group on Communications and the Working Group on IT, the Task Force on Crisis Communication Requirements and other project groups. Officials from Romania and Bulgaria are also invited to scientific seminars and colloquia, attended by scientific experts from all Member States.

Risk-related events

EFSA organises conferences, seminars and workshops on Risk Analysis, Risk Assessment and Risk Communication in which representatives of Bulgaria and Romania participate.

Up to date, the following events have been organised:

Meeting	Date	Place	Romanian Exp	Bulgarian Exp
2005				
AF communications	14/6/05	Budapest	Mrs Neagu	-
MB + EFSA inauguration	20+21/6/05	Parma	Mr Rusu	-
EPCO – Pesticide assessment meetings	29/6 to 1/7/05	York	Mr Ghinea	
CVO	20/7/05	Parma	Mr Lazar	Mr Likov
EPCO - Pesticide assessment meetings	5 to 21/9/05	York	Mrs Amaritei	Mr Emanuilov
			Ms Cojany	Ms Jivkova
				Ms Mladenova
				Ms Slavova
				Mr Tzentko
MB	13/9/05	Parma	-	Ms Shtereva
EFSA Introductory Conference	15/09/06	Sofia	Mrs Armanu Mr Badicu Mrs Baraitareanu Mrs Belc Mrs Bobe Mr Chelmu Mr Ciocanea Mr Constantinescu Mrs Costache Mrs Costinea Mr Dobrescu	Mrs Koleva Mrs Vasileva Mr Zorov Mr Velkov Mr Chorbadzhiski Mrs Chamova Mrs Popova Mrs Lilova Mrs Mladenova Mrs Stancheva Mrs Rajcheva Mr Stoilov

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			<p>Mrs Ion Mr Ionita Mr Lupescu Mr Monolescu Mr Marin Mr Mencinicopschi Mr Minea Mrs Mira Mrs Mladin Mrs Monea Mrs Nestor Mr Nisipasu Mrs Petriu Mrs Popa Mr Popa Mr Poparlan Mr Radu Mr Rusu Mrs Stanculescu Mr Stefan Mt Taut Mr Voicu</p>	<p>Mr Iotzev Mr Ivanov Mr Marinov Mr Karaivanov Mrs Stojanova Mr Hristov Mr Stanchev Mr Vasilev Mr Tomov Mr Alexandrov Mrs Zagorova Mr Dishkov Mrs Giorgieva Mrs andonova Mrs Kamenska Mr Mutafov Mr Penchev Mr Pavlov Mrs Todorova Mr Ivanov Mr Tenev Mrs Todeva Mrs Mikushinska Mrs Tcherkezova Mrs Petrova Mrs Nicolova Mrs Vrabcheva Mrs Enikova Mrs Gerova Mrs Ivanova Mrs Nikolova Mrs Jordanova Mrs Dimitrova Mrs Jancheva Mr Kralev Mrs Penishlieva Mrs Taseva Mrs Jungareva Mrs Voynova Mrs Mitev Mrs Giorgieva Mrs Stancheva Mrs Kostadinova Mr Goygadzhiev Mr Emanuilov</p>
Task Force on Zoonose Data collection	29+30/9/05	Parma	Mrs Costache	Mr Emanuilov
AF	30/9/05	Cyprus	Mr Rusu Liviu	Ms Kostadinova
AF WG	11 to 13/10/05	Parma	Ms Monea	Ms Voynova

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communications + WS				
IT WG	17+18/10/05	Bratislava	Mr Dutu	-
EFSA Conference on Food and Feed Safety	20+21/10/05	Bucharest	Mr Anca Mr Banu Mrs Belc Mr Bogdan Mr Costantinescu Mrs Costache Mr Costea Mr Dochitoiu Mrs Guran Mr Ilie Mr Ilies Mrs Lipascu Mr Liteanu Mr Lungu Mrs Mamularu Mr Nitu Mrs Pasat Mr Pascu Mr Popa Mrs Savescu Mrs Serbanescu Mrs Stancu Mrs Szenti Mrs Tamas Mr Voicu Mrs Voicu	Mrs Aleksieva Mrs Alexandrova Mrs Babeva Mrs Damyanova Mrs Giorgieva Mr Gospodinov Mr Goygadzhiev Mrs Hristova Mrs Kamenova Mrs Kolarska Mrs Koleva Mr Kopankov Mrs Kosovska Mrs Makeveeva Mrs Marinova Mr Mittev Mr Mutafov Mrs Mutafova Mrs Penushlieva Mr Peshev Mrs Petkova Mrs Popova Mrs Slavyanov Mrs Stancheva Mrs Stavreva Mrs Stoycheva Mrs Taseva Mrs Tchohadjieva Mr Tomov Mr Tuhchiev Mrs Vasileva Mr Velichkov Mr Voynov Mrs Voynova Mrs Vrabcheva Mrs Yancheva Mrs Yungareva Mrs Zagorova
WHO/FAO Meeting	25-27/10/05	Lithuania	Mrs Popa	Mrs Jancheva
EFSA GENTOX Conference	16-18/11/05	Brussels	-	-

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Task Force on Data Collection of Zoonoses Meeting	22-23/11/05	Parma	Mrs Costache	Mrs Taseva
AF Meeting	25/11/05	London	Mr Rusu	
EFSA-Science Colloquium on animal health risk assessment diseases	1-2/12/05	Parma	Mrs Makaveeva	Mr Voicu Mr Taut Mr Tiru
2006				
AF WG Communications	02/02/06	Parma	Mrs Simionescu	
PHARE meeting on Risk Communication	22 February	Parma	Mrs Costinea Mrs Diaconescu Mrs Lipoveanu Mrs Monea Mrs Muresan Mrs Nestor Mr Piscoi Mrs Popa Mrs Popa A.	Mr Alexandrov Mr Goygadzhiev Mrs Paskaleva Mrs Peneva Mrs Penushlieva Mr Petkov Mrs Petrova Mr Todorov Mrs Voynova Mrs Yancheva
PHARE meeting on Zoonoses Training	23 February	Parma	Mrs Andresecu Mr Apostu Mrs Beia Mrs Costache Mrs Dumitrache Mrs Halaciuga Mr Lazar Mrs Mioara Mr Nisipasu Mr Poparlan	Mr Gagnev Mr Goygadzhiev Mrs Halacheva Mrs Ivanova Mr Martinov Mrs Penushlieva Mrs Rubenova Mr Valtchovsky Mrs Voynova Mrs Yancheva
AF Meeting	03 March	Prague	-	-
Task Force on Zoonoses Data Collection meeting	20-21 March	Parma	Mrs Costache	Dr Boykovski

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AF IT WG	20-21 March	Parma	Mr Dutu	Mrs Vladimirova
EFSA Scientific Colloque on Food-based dietary guidelines	21-22 March	Parma	Mrs Murean	Dr Petrova
Training Seminar on I & I issues	27 March	Brussels	Anca Baraitareanu Geta Briciu Constantin Lupescu Felix Nicolecu Ana Maria Popa Mihai Paun Simona Radulescu Liviu Rusu Ionut Sarbu Bogdan Tanasescu Razvan Tiru Dinu Toma	Constantin Aleksipescu Sveja Klau Altankova Liliana Rucanu Simona Radulescu Ana Maria Popa Felix Nicolecu Bogdan Tanasescu Anca Baraitareanu Geta Briciu Mihai Paun Dinu Toma Ionut Sarbu Anton Velichkov Tsvetanka Voynova
MB	29 March	London	Mr Rusu	Ms Kostadinova

Outlook for 2006

For 2006, the focus is on in depth workshops and seminars in the various areas of EFSA's expertise (see below). These seminars and workshops will be organised as a part of the programme, and the exchange of experts from Romania and Bulgaria to EFSA will continue as it does today, with Romanian and Bulgarian experts expected to attend some 40 EFSA expert group meetings during 2006. The topics of the seminars were chosen after the Conference in Bucharest in October 2005, where at the end of the Conference participants filled in questionnaires where they listed their preferred subjects. The following training seminars will be arranged in 2006:

CALENDAR PHARE MEETINGS 2006

February – Risk Communication 22 February 2006
 February – Zoonosis 23 February 2006
 March – International and Institutional Relations 27 March 2006
 May – Legal framework 17 May 2006
 June – Crisis Communication 6 June 2006
 September – GMOs 7 September 2006
 September – Stakeholder Relations 20 September 2006
 September – BSE/TSE 21 September 2006
 October – Data Collection 5 October 2006
 November – PHARE Programme Scientific Conference 7 November 2006

EFSA PHARE website

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Since the start of the project, EFSA decided to dedicate a place on the website where it would be possible to follow the project, in the spirit of openness and transparency:

http://www.efsa.eu.int/about_efsa/enlargement/catindex_en.html

For this purpose, the PHARE project has also been covered in the EFSA Newsletter, which has a readership of some 10 000 readers.

EFSA Staff involvement

The implementation of the EFSA PHARE programme is carried out on the basis of using existing staff resources in EFSA. No funds allocated to EFSA to implement the programme have been used to fund EFSA staff. The implementation of the project is managed by a project co-ordinator assisted by a Steering Committee, and as required throughout the project, by EFSA staff from the scientific, legal, communications and I&I departments. The EFSA International and Institutional Relations Department manages the implementation of the PHARE, and other EU-funded programmes.

Budget Implementation

The EFSA PHARE programme is externally funded by the EU budget earmarked for enlargement and as such EFSA cooperates with DG ENLARGE in the Commission on budget matters. The spending is exactly on track (see annex 1).

Effects of the programme

The stated purpose of the programme (see Programme Description in annex 2) is laid out in the Executive Summary in point 1.3:

a) Aim of the project

The overall objective of the PHARE programme is to prepare Bulgaria and Romania, being the remaining EU candidate countries of the initial ten Candidate Countries of Central and Eastern Europe (CEECs) for participation in all activities of European Food Safety Authority (EFSA) involving Member States.

This project aims therefore:

- To prepare the competent bodies in Romania and Bulgaria, which are active in the fields relating to the work carried out by EFSA, for their future participation in EFSA networks.
- To contribute to the creation of communication and information exchange systems enabling future participation of Bulgaria and Romania in the EFSA networks.
- To transfer knowledge on methodologies used in the fields in the remit of EFSA, in particular on risk assessment and data collection.
- To support Bulgaria and Romania in their communication activities linked to risk assessment.

These aims are addressed in all EFSA's PHARE activities. Bulgarian and Romanian administrators and experts are participating as observers in the expert groups listed in the grid above, as well as to the Advisory Forum and its working groups on Communications and IT. In this way links have been established, communication and information exchange systems have been established, knowledge has been and is being transferred and the participation is widely spread and closely monitored.

ANNEX I

BUDGET SPENDING IN THE PHARE PROGRAMME MEETINGS/ TRAVELS

<u>Name of the meeting</u>	<u>Date</u>	<u>Place</u>	<u>COST</u>
Communications Meeting	14/06/2005	Budapest	265
MB meeting + inauguration0 Parma	20+21/06/05	Parma	1000
EPCO meetings	29/06 to 01/07/05	York	4800
CVO meeting	21/07/2005	Parma	998.61
Mission costs I.Soderlund + C. Majewski	April 2005	Romania	721.5
(april 2005 visiting Romania + Bulgaria)		Bulgaria	
Seminar Sofia	15/09/2005	Sofia	33154.59
MB meeting	13/09/2005	Parma	531.28
EPCO meetings	september 2005	York	8342.28
Zoonose Datacollection	29+30/09/05	Parma	2139.71
AF WG Communication + WS	11 to 13/10/05	Parma	2036.28
AF meeting Cyprus	30/09/2005	Cyprus	1301.79
IT Working Group	17+18/10/05	Bratislava	400 €
Codex meeting	25-27/10/05	Lithuania	3170.9
EFSA WHO conference	16-18/11/05	Brussels	475.36
Conference Bucharest	20+21/10/05	Bucharest	60000
Zoonose Datacollection	22+23/11/05	Parma	677.12
EFSA Colloque	1+2/12/05	Parma	2514.62
AF WG Communication	02/02/2006	Parma	1023.27
Workshop Risk Communication	22/02/2006	Parma	31770
Zoonose training	23/02/2006	Parma	27100
IT Working Group	20+21/03/06	Parma	2500
Zoonose Data Collection	20+21/06/06	Parma	2600
EFSA Colloque	21+22/03/06	Parma	pending
EFSA MB London	29/03/2006	Parma	pending
TOTAL			187522.31

ANNEX II

PHARE PROGRAMME FOR ROMANIA AND BULGARIA

1. Description

1.1 *Title: Progress towards accession: Strengthening the food safety systems in Bulgaria and Romania* Part of the PHARE multi-beneficiary programme on participation of Romania and Bulgaria in Community Agencies in 2004 and 2005.

1.2 *Amount requested from the Commission: €500.000*

1.3 *Executive Summary*

The project is the participation of Romania and Bulgaria in the European Agencies. **“Progress towards accession: Strengthening the food safety systems in Bulgaria and Romania”** is a targeted, pro-active approach to providing pre-accession assistance to participating countries.

b) *Aim of the project*

The overall objective of the PHARE programme is to prepare Bulgaria and Romania, being the remaining EU candidate countries of the initial ten Candidate Countries of Central and Eastern Europe (CEECs) for participation in all activities of European Food Safety Authority (EFSA) involving Member States.

This project aims therefore:

- To prepare the competent bodies in Romania and Bulgaria, which are active in the fields relating to the work carried out by EFSA, for their future participation in EFSA networks.
- To contribute to the creation of communication and information exchange systems enabling future participation of Bulgaria and Romania in the EFSA networks.
- To transfer knowledge on methodologies used in the fields in the remit of EFSA, in particular on risk assessment and data collection.
- To support Bulgaria and Romania in their communication activities linked to risk assessment.

These immediate objectives will be met by the participation of the competent authorities and institutions from Romania and Bulgaria in a Structured Forum for Partnership.

The initial ten Candidate Countries have continued participating increasingly since 1999 in the various Community Agencies. Over the last years €11 million has been awarded to carry out preparatory measures to allow the Central and East European candidate countries to participate in Community Agencies. These projects have been completed, allowing for full membership of the accession countries to these agencies. But concerning Romania and Bulgaria further support is required to allow for full participation upon accession.

EFSA's remit is to provide the necessary scientific advice which underpins the development of food and feed legislation and also covers legislation regarding animal

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health and welfare and GMOs. The building of the confidence of stakeholders and in particular consumers in the safety of the European food supply is a vital component of EFSA's remit. This requires EFSA to be able to work in partnerships with the competent bodies and organisations in each Member State. This new programme will allow the two countries to prepare themselves also for participation in the activities of EFSA and the achievement of the development of the confidence of the existing Member States in the systems in place in the two candidate countries. Importantly this should lead to EFSA, the existing Member States and Romania and Bulgaria being able to work as equal mutually respected partners.

c) *Target groups*

The target groups are the Competent Authorities for food and feed safety in Romania and Bulgaria, in particular those with the same responsibilities as EFSA, their information officers, legal officers, scientists and stakeholder groups.

d) *Main activities and their location*

The activities comprise a series of meetings, visits, seminars, and mini-conferences. All seminars will target Competent Authorities. The mini-conferences proposed will target administrative and scientific audiences with specific activities targeted at audiences with a view to informing the full cross-section of stakeholders in Romania and Bulgaria.

Main activities

The specific topics for seminars and conferences will be based upon the needs present in the beneficiary countries. It is for this purpose that representatives from Bulgaria and Romania will be involved in the programme from the very beginning and as much as possible. To identify the targets, meetings with representatives of EFSA and Bulgarian/Romanian authorities will be arranged to bring the 'contact people' - co-ordinators and experts in the specific fields and areas - together.

Based on the information received conferences and seminars will focus on:

- ❖ The general existing structures to ensure food safety in Europe – separation of risk assessment and risk management. In particular the main roles of EFSA compared to those of the risk managers
- ❖ EFSA's missions, remit and operating principles
- ❖ EFSA's structure and organisation
- ❖ The EFSA Advisory Forum. (The Advisory Forum is the main formal interface between EFSA and the national bodies therefore this programme will give special consideration to the role of Member States in the Advisory Forum)
- ❖ National input into EFSA's scientific and communication work
- ❖ Infrastructure at national level enabling interface with EFSA
- ❖ EFSA's work – how it functions
 - Science
 - How EFSA Panels work, role of working groups, exchange among scientists worldwide
 - Scientific opinions and reports, guidance documents, stakeholder consultations

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- Scientific Colloquia
- Communications
 - Focus on risk communications
 - Contacts to media
 - Publication tools (website, newsletters, brochures and scientific reports)
- Relationship to stakeholders (consumer organisations, NGO's, industry). EFSA operates through strong links with stakeholder groups and these play an important role in building the confidence of stakeholders in the EU food supply

Translation/interpretation into Bulgarian and Romanian respectively will be foreseen for all seminars and conferences as it is likely that many of the participants will not be able to understand or contribute fully if the working language is limited to English. Translations of any accompanying materials will also be ensured.

Locations

The majority of meetings, seminars and conferences will be organised in the two countries ensuring a high degree of participation for the country representatives. However, it is expected that four smaller meetings will be organised in Brussels and Parma. Furthermore, Bulgarian and Romanian participants will also be invited to other meetings which may be held in other parts of Europe as far as the subjects are considered relevant for achieving the project's objectives. Focus in this respect will be given:

- a) to invite representatives from Romania and Bulgaria to the EFSA offices, to build contacts and to develop a close understanding of the work of EFSA
- b) to explain the role of and cooperation between EFSA, member states, the European Commission and DG SANCO
- c) to ensure the highest degree of participation of Bulgarian and Romanian counterparts in other relevant meetings, considering the legal constraints related to their status as observer

Presentations and one round table discussion with representatives of related EU institutions will be organised (potentially including representatives of the European Parliament and Council) in order to explain the work of the EU institutions related to food and feed issues and thus pinpoint the role of EFSA in this process. The intention is to make Bulgaria and Romania familiar with the overall EU process and to facilitate a better understanding of the risk assessment, management and communications activities on food and feed safety at the European level).

As a follow up to this familiarisation exercise and exchange on specific issues, e.g. GMO issues, pesticides, food and feed additives or procedures, networking and media contacts, other areas where information exchange is needed are expected to surface.

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The two countries will also be integrated in the telematics activities of the European Union risk assessment of which EFSA provides a central hub in order to enable full overall integration to be as rapid as possible on accession. This provided that the legal and practical constraints can be overcome during the project's implementation period.

1.4 Objectives

EFSA provides independent scientific advice on all matters linked to food and feed safety - including animal health and welfare and plant protection and GMOs - and provides scientific advice on nutrition in relation to Community legislation.

The Authority communicates to the public in an open and transparent way on all matters within its remit. EFSA's risk assessments provide risk managers (consisting of EU institutions with political accountability, i.e. the European Commission, European Parliament and Council) with a sound scientific basis for defining policy driven legislative or regulatory measures required to ensure a high level of consumer protection with regards to food safety.

The objective of the PHARE programme is to prepare Bulgaria and Romania, being the remaining EU candidate countries of the initial ten Candidate Countries of Central and Eastern Europe (CEECs) for participation in all activities of EFSA involving Member States.

As one of the means to achieve this, the relevant Romanian and Bulgarian authorities and institutions will take part in a Structured Forum for Partnership.

This Structured Forum seeks to encourage and facilitate:

- Early exchange of scientific and technical expertise and legal regulatory affairs information in particular through discussions and short term visits to seek areas for immediate and longer term collaboration as far as possible in the full range of EFSA activities.
- Understanding the mandate and role of EFSA in the independent, transparent scientific evaluation process of risk assessment in food safety (Regulation 178/2002/EC). Information on the Scientific Panels and how they deal with questions received from DG SANCO. The risk analysis carried out by the Working Groups of the panels based on up-to-date scientific information. Participation in the operational work of EFSA in the four components of risk assessment along the food chain: hazard identification, hazard characterization, appraisal of exposures, risk characterisation.
- The informal exchange of information between EFSA, EU member states, Romania and Bulgaria.
- The preparation of the competent bodies in Romania and Bulgaria, which are active in the fields relating to the work carried out by EFSA, for their future participation in EFSA networks.

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- Development of crisis co-ordination contact points, inclusion of Romania and Bulgaria in crisis exercises with EFSA and the development of appropriate crisis information exchange infrastructure.
- The creation of communication and information exchange systems enabling future participation of Bulgaria and Romania in the EFSA networks. Mainly Extranet information exchanges and the participation in the Advisory Forum Communications and IT Working Groups and other working groups as appropriate (meetings, email exchange, information exchange, pre-notifications of EFSA activities and vice versa).
- Support to Bulgaria and Romania in their communication activities linked to risk assessment.
- The transfer of knowledge on methodologies used in the fields in the remit of EFSA, in particular on risk assessment and data collection:
 - (i) The new Directive on the monitoring of Zoonoses and zoonotic agents (2003/99/EC) gives EFSA the task to examine the data collected from Member States and publish a summary report. The data collected will include zoonoses and zoonotic agents in foodstuffs, feed and animals, foodborne outbreaks and antimicrobial resistance. This forum could serve as a dialogue on the specific needs for a data collection; the data collection process (improvement and development), validation of data, reliable and quantitative methods for data analysis (sampling schemes); monitoring processes and coordinated programmes on antibiotic resistance. The latter is particularly important in Salmonella and Campylobacter foodborne outbreaks.
 - (ii) Participation in training sessions of both these countries in processes parallel to the peer review process of the active substances which are intended to be inscribed to Annex 1 of Directive 91/414 on the Plant Protection Products.
- Discussions outside regular meetings with the respective Scientific Panels on the preparation of harmonised scientific guidance documents eg those recently accomplished by EFSA for GMO's.

The Structured Forum shall be a platform for exchanging views on and promoting the implementation of:

- The establishment of dialogue with interested parties.
 - (i) Interested parties: authorities, national scientific bodies and organisations and other groups dealing with food and feed (safety) issues, e.g. authorities with similar tasks and missions to EFSA, consumer organisations, manufacturers, suppliers, trade, NGO's, journalists, politicians, lawyers, scientists.
 - (ii) Topics depending on involved parties

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- The elaboration of guidelines to ensure transparency and appropriate public access to scientific advice linked to regulatory decisions.
- Capacity building. Food authorities and through these food officials and food establishments in both these countries benefit from the PHARE and SAPARD pre-adhesion financing. However, training in risk assessment across the food chain would help complement these two instruments in capacity building.
- The setting up of IT links between EU member states, accession countries and EFSA. See attachment for the authorities of the 25 EU Member States.

The Forum shall also serve to inform and advise about specific aspects of the Community *Acquis* relating to EFSA.

1.5 *Justification*

a) *Perceived needs and constraints in the target countries*

Food safety is one of the most important issues in Europe relative to consumer protection but also for a free movement of foods/feed and trade within the Community. A food crisis does not stop at a country border. That is why these key subjects play an important role in the accession negotiations. It is essential that the candidate countries are informed at an early stage in order to learn more about the fundamental ideas and principles in the Community to start with implementing legislation and regulations procedures accordingly as soon as possible.

As EFSA plays a key role in food safety, the candidate countries should be informed about and involved in the operations of the EFSA, making it possible to take part in its operations on equal footing upon accession. An early introduction into how the European Food Safety Authority operates, including exchange of information concerning emerging issues, scientific expertise and findings will serve to help Romania and Bulgaria prepare themselves for membership. Being part of information networks will also benefit these countries as they will be able to focus on issues which are new to all Member States and enable them to warn Member States of problems detected at an early stage which may in its turn prevent food scares.

The Romanians and Bulgarians have food and feed safety infrastructures in place but there is a need to build both capacity and contacts/links with these from EFSA and vice versa.

b) *List of target groups with an estimate of the anticipated number of direct and indirect beneficiaries;*

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The target groups are in the main the Competent Authorities in Romania and Bulgaria, together with other institutions involved in risk assessment and food and feed safety. The lead agencies are set out below, in bold type.

Bulgaria	<ul style="list-style-type: none">· National Veterinary Service, National Grain Service, Plant variety testing and plant protection; Ministry of Agriculture· The Ministry of Health
Romania	<ul style="list-style-type: none">· The National Sanitary Veterinary and Food Safety Authority (NSVFSA)

The direct beneficiaries are the institutions listed above in bold and their employees. Indirect beneficiaries may be defined at different levels with the next level down including scientific academic and civil society organisations and ultimately could be defined as widely as to include the entire population of each of the countries involved.

Stakeholders other than regulators are targeted by the mini-conferences as follows:

One mini-conference will target 'producers' i.e. industry as well as small and medium sized manufacturers and farmers (representation by associations should be possible as well); another 'users' i.e. consumer organisations and a third mini-conference will separately cover issues related to feedingstuffs. All seminars will target regulators/Competent Authorities.

c) *Reasons for the selection of the target groups and activities*

The target groups comprise the institutions in Romania and Bulgaria in charge of risk assessment of food and feed in those countries.

The activities concentrate on the areas in which the Competent Authorities in the countries concerned have determined that the most benefit can be obtained from a collaborative approach to harmonisation with the EU.

d) *Relevance of the project to the target groups*

In the context of joining the EU, Romania and Bulgaria need to be in a position on accession of being able to assume the responsibilities and discharge the obligations of a Member State. The project is designed to provide the target groups with a detailed working knowledge of the legal remit of the European Food Safety Authority, its work and the network between EFSA and the Member States. The project also seeks to advise Romania and Bulgaria on the work necessary to prepare themselves in participating fully in the work of EFSA. Much of EFSA's work with the Member States depends on good working relations, information exchanges, liaison and collaboration. In this way, the project aims to assist the target groups to be prepared in a practical way to assume the duties and responsibilities of a Competent Authority of a Member State.

1.6 Detailed description of activities.

In line with the methodology set out in section 1.7 below, the nature of the activities described is dependent upon the timing of implementation of the project. The activities described are planned on the basis that the project will run from June 2005 to December 2006. Details of the final programme may differ, especially with regard to those activities linked to pre-defined European meetings, should the timing of the project differ.

In particular the following assumptions underlie the proposal:

(a) Presentation/training part

International and Institutional Affairs

The International and Institutional Affairs Department will provide key Romanian and Bulgarian officials with presentations on and training in its areas of expertise. This includes holding seminars in the structure of the EU institutions, the process of decision making and the role of EFSA in this process.

In addition information concerning the work of the Advisory Forum and in particular its working groups (see Communications below) will be described and materials provided. Crisis co-ordination exercises will be open to Romania and Bulgaria. The necessary infrastructure will be established in order for both Bulgaria and Romania to participate on accession in the work of the Advisory Forum and in case of European food or feed crisis.

Furthermore the links of EFSA to Member States will be elaborated on, both with a view from the founding Regulation and as an introduction to the more elaborate description of the Article 36 networks which will fall under the presentations organised under the heading of Scientific Activities.

Legal Affairs

The EFSA Legal Department will organise training in the horizontal and vertical legal aspects of how EFSA works, specifically targeted at Romanian and Bulgarian legal officers with a view to transferring knowledge and preparing them for the legal framework they will need to help build up in their respective home countries to facilitate the introduction of the EFSA framework and their active participation in EFSA, in Romania and Bulgaria respectively. The training will cover legal aspects linked to EFSA as an independent legal entity and those linked to his mission and tasks.

Communication

Inform the sector and the public in general about food safety and EFSA. Give any support possible to enable the contact persons at the Bulgarian and Romanian authorities to inform the consumers, media, public in general in their own countries about food safety issues themselves. However, it should be within EFSA's remit to keep 'the rest of the world' informed about EFSA's activities in that respect and also on the progress made. An effective coordination and ballot between EFSA and Bulgarian/Romanian

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communications people should be aimed for. Ensure that relevant information material on EFSA (and important press releases on relevant food issues as well) or material linked to risk assessment activities is being translated into Romanian and Bulgarian. Involve Romania and Bulgaria in EFSA information networks such as the Communications and IT Working Groups, the EFSA Extranet and help install videoconferencing facilities.

Training seminars in risk communication could be provided with a view to involve Romanian and Bulgarian communications officials at an early stage.

Scientific Activities

Provide adequate information and detailed explanations of how the European Food Safety Authority addresses scientific questions and issues. Provide training on EFSA structure of Panels, Working Groups and Scientific Committee. Arrange for seminars on risk assessment approaches for food and feed and other methodologies relevant for the development of scientific opinions on emerging food and feed issues.

Provide training to relevant National Authorities on data collection, in particular on consumption patterns and exposure and on zoonotic diseases, and on other essential aspects of the assessment of risks and benefits of food and feed.

Assist in the setting up of Article 36 networks.

(b) Participation in EFSA meetings

Specific meetings

Science colloquia and other scientific/technical meetings of the sort

EFSA Events

Advisory Forum Working Groups (Communications and IT)

Management Board (as observers in the audience)

Observership to experts meetings with MS representation (eg PRAPeR experts groups meetings)

Involvement in EFSA's crisis exercises with Member States

(c) Meetings to be organised by EFSA in Romania and Bulgaria in co-operation with them

Workshops

Information happenings

Mini-conferences

Seminars

Small and specific training events engineered to transfer knowledge on methodologies used in science (see also section on Presentation/Training above) eg on data collection and risk assessment.

Invitations to similar meetings in the EU to be ensured by EFSA.

The purpose of the conferences is

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- To familiarise the candidate countries with the EU approach to risk assessment and risk communications
- To assist Romania and Bulgaria in installing their own systems for fulfilling EU regulations and in particular the supporting principles in the area of risk assessment
- To contribute to informing Romanian and Bulgarian Competent Authorities of their obligations pre- and post- accession
- To obtain feedback regarding the extent to which Romanian and Bulgarian Competent Authorities are capable of meeting their post-accession obligations
- To involve the stakeholders in the food chain: primary producers, food business operators, consumer groups etc
- To publicise the work of the EFSA programme **Progress towards accession: Strengthening the food safety systems in Bulgaria and Romania**

1.7 Methodology

- a) Methods of implementation;
- Direction in accordance with the wishes of a Steering Committee
 - Meetings and workshops led by moderators from EFSA and Member State Competent Authorities
 - Attendance by Romanian and Bulgarian experts as observers at EFSA meetings as far as allowed by current legislation and the EFSA Programme **Progress towards accession: Strengthening the food safety systems in Bulgaria and Romania** budget
 - Investment in information technology
 - Seminars and mini-conferences
 - Priorities will be further defined and chosen following consultation with national authorities
- b) Reasons for the proposed methodology

The proposed methodology is founded on the exchange of EFSA having sought the advice on the practical experience between practising regulators in the EU and those in Romania and Bulgaria. More particularly:

The Steering Committee uses the experience of the Heads of Competent Authorities in both the participating CEECs and Heads of Units in EFSA to provide direction to the project thus ensuring an appropriate focus.

Meetings and workshops provide a forum for discussion of methods to address EFSA and Member States working methods and practices in EFSA. Participation as observers at selected meetings not only enables the observers to be informed of the most recent issues to be addressed within EFSA, but also to become familiar with the risk assessment process. Furthermore, the opportunity provided to extend the network of people with experience in the same field is very valuable.

Exchanges and direct contacts: due to the nature of the work, EFSA plays a major role in building food safety networks as its bedrock. Therefore the

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integration and the collaboration in EFSA's work of the Member States and accession countries on a wide range of scientific data exchanges and bilateral collaboration has to build up in science, institutional activities, the Advisory Forum activities, crisis planning and communication so that on accession the network is able to function. In order to facilitate all these activities it is important that there is a common understanding of the legal framework, constraints and context that EFSA operates in.

The information technology investment is designed to facilitate electronic communication between Romania and Bulgaria on the one hand and EFSA and Member States on the other, thereby facilitating the secure transmission of data.

The purpose of the seminars and mini-conferences is to enable interested parties (stakeholders to be defined by the respective National Food Safety Authorities) to be informed of the benefits and challenges surrounding accession, as well as the progress of the Programme as it is running. At the same time, the conferences will permit participants from EFSA, Romanian, Bulgarian and EU Member States' Competent Authorities to exchange views across disciplinary boundaries.

- c) How the project intends to build on a previous project or previous activities;

There is no previous project

- d) Procedures for internal evaluation

- Progress is monitored by the Steering Committee
- Quarterly progress reports (with a section on each Priority Action Area) are published on the EFSA website
- Reports of each meeting
- Regular 'health check' of the project to ensure that goals are being met and activities are still within the remit and timeframe of the project
- Feedback questionnaires from the workshops: relevance, information, and follow up nationally

- e) Level of involvement and activity of other organisations in the project

Within the Commission - DG SANCO, DG RESEARCH, DG ENLARGE,
Member States - in particular new Member States which may wish to share their experience with the candidates. An advisor from an 'old Member State' with experience in working with EFSA will also be involved (Ireland).

- f) Reasons for the role of each partner

New Member States involvement: The general understanding and problems are (more or less) similar in all new EU member states. As a matter of fact advice is better accepted by advisers being in a similar position and situation than supervisors. By giving practical support instead

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of theoretical information they can add to the implementation and learning process.

Ireland is an 'old' Member States with a recent history of re-organising its food administration and in particularly its interface with the EU- EFSA at national level will also support the project through active involvement in a limited number of key meetings on an ad hoc basis.

g) Team proposed for implementation of the project

Steering Committee PHARE Project:

Antoine Cuvillier
Christine Majewski
Juliane Kleiner
Carola Sondermann
Francois Monnart,
and Ingela Söderlund coordinator

It is also recommended that a fixed contact point in Romania and Bulgaria be defined.

1.8 Duration and indicative time schedule of actions

Meeting frequency, EFSA Programme "Progress towards accession: Strengthening the food safety systems in Bulgaria and Romania, 1 October 2005 – 31 December 2006

Activity:

1. Meetings (41)

Participation in EFSA meetings (estimate of amount of meetings in brackets):

Specific meetings including presentations and one round table discussion with representatives of related EU institutions will be organised (potentially including representatives of the European Parliament and Council) (4)

Science colloquia and other scientific/technical meetings of the sort (5)

EFSA Events (2)

Advisory Forum Working Groups (Communications and IT) (10)

Management Board meetings (as observers in the audience) (8)

Advisory Forum meetings (on the invitation of the Executive Director) (6)

Observership to experts meetings with MS representation (eg PRAPeR experts groups meetings) (4)

Involvement in EFSA's crisis exercises with Member States (2)

2. Visits (5)

Early exchange of scientific and technical expertise and legal regulatory affairs information in particular through discussions and short term visits to seek areas for immediate and longer term collaboration as far as possible in the full range of EFSA activities (3 meetings in 2005 and 2 meetings in 2006 = 5)

3. Seminars (14 in total)

All seminars will target Competent Authorities. They will be organized by the following EFSA departments:

International and Institutional Affairs (4)

The International and Institutional Affairs Department will provide key Romanian and Bulgarian officials with presentations on and training in its areas of expertise. This includes holding seminars in the structure of the EU institutions, the process of decision making and the role of EFSA in this process.

Legal Affairs (4)

The EFSA Legal Department will organise training in the horizontal and vertical legal aspects of how EFSA works, specifically targeted at Romanian and Bulgarian legal officers with a view to transferring knowledge and preparing them for the legal framework they will need to help build up in their respective home countries. The training will cover legal aspects linked to EFSA as an independent legal entity and those linked to his mission and tasks.

Communication including risk communication (4)

Inform the sector and the public in general about food safety and EFSA. Give any support possible to enable the contact persons at the Bulgarian and Romanian authorities to inform the consumers, media, public in general in their own countries about food safety issues themselves.

Training seminars in risk communication could be provided with a view to involve Romanian and Bulgarian communications officials at an early stage.

Scientific Activities (2 – as many others meetings related to scientific activities are scheduled)

Provide adequate information and detailed explanations of how the European Food Safety Authority addresses scientific questions and issues. Provide training on EFSA structure of Panels, Working Groups and Scientific Committee. Arrange for seminars on risk assessment approaches for food and feed and other methodologies relevant for the development of scientific opinions on emerging food and feed issues.

4. Conferences (4 in total)

- Big public conference (1 with some 50 people invited)

In order to take stock of the progress of Romania and Bulgaria and publicise their and EFSA's achievements in implementing the programme by the end of 2006, it is proposed to organize a large public event in 2006.

- Mini-conferences (3 with some 20 invitees each)

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The mini-conferences proposed will target administrative and scientific audiences with a view to informing the full cross-section of stakeholders in Romania and Bulgaria.

Length of the activity:

Meetings and visits normally last 1 day

EFSA Events and Advisory Forums may last 2 days

Seminars normally last 2 days

Conferences normally last 2 days

Date of the activity:

The activities described are planned on the basis that the project will run from June 2005 to December 2006.

2. Expected results

2.1 Publications and other outputs

The EFSA Programme is expected:

- To assist the Romanian and Bulgarian Competent Authorities in reaching a position to be able to participate in the work of EFSA,
- To build greater mutual confidence in order to encourage the future acceptance of research and development data and measures between these authorities,
- To encourage greater understanding between Romanian, Bulgarian AND Member States' Competent Authorities, leading to future co-operation and harmonisation of technical procedures within Europe 27.

The output of results of the EFSA Programme takes mainly the form of published records on the EFSA website. These results will be reported as follows:

- A meeting report for each meeting, seminar, mini-conference or workshop, which will be published on the EFSA web-site (www.efsa.eu.int)
- A press release for each mini-conference, which will be sent to interested parties and published on the EFSA website, as well as the slides from presentations at the conference
- Contractual reports (available in-house)

2.2 Multiplier effects

The programme is targeted at the Competent Authorities in Romania and Bulgaria. Multiplier effects are unlikely.

2.3 Sustainability

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- a) Institutional sustainability
- b) At the end of the project our objective is to have both the accession states further integrated into the EFSA food safety networks, to have a working understanding of the work of the EU in food safety and be able to participate in a concrete manner in collaborative activities. Knowledge build up and collaboration are keystones of EFSA's activities and its relations with the Member States and as such this project will be important in bringing this relationship about. In addition the project will also put in place the necessary access links to the information exchange systems including access to IT systems which facilitate the exchange of food safety information between EFSA and Member States.
- c) Local ownership will be high as the contacts so far with the Authorities indicate that they are very keen to be linked in this manner to EFSA and to be able to build contacts and collaboration activities.
- d) Overall this project will lead to the improved exchanges and sharing of information across Europe on food safety matters. EFSA prepares scientific opinions on food safety matters on a pan-European basis and therefore the scientific basis for the food law making the *Acquis* in this area. To make the *Acquis* relevant to Bulgaria and Romania and early exchange of data and scientific information will be important. The ability to tap into the scientific activities across Europe will also be important for Bulgaria and Romania.
- e) EFSA worked in close collaboration with the previous 10 acceding countries from its earliest operational days and this has ensured a smooth transition for these countries in participating in EFSA's activities on a formal basis and we would look to have this as a main goal for this project.

3. Budget for the project

See budget as Annex to the contract

Annex III

Information relating to Bulgaria and Romania

Bulgaria:

Ministry of Agriculture of the Republic of Bulgaria

Sofia, bul. Hristo Botev 55

Bulgaria

tel. ++359(2)98511255; fax: ++359(2)9806256

e-mail: press@mzgar.government.bg

Central laboratory for veterinary control and ecology (CLVCE).

Address: Str. "Iskarsko Shosse" 5

1528 Sofia

Tel.: 793-023, 978-16-22

Fax: 793-128

Romania:

Ministry of Agriculture, Forests and Rural Development

Web site: www.mapam.ro (only in Romanian)

Ministry address:

24 Carol I Blvd., sector 3, codul postal 020921, oficiul postal 37

Bucharest , Romania

E-mail: comunicare@maa.ro

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Phone unit:

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0040 21 307.85.00

Public Relations Office:

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0040 21 307.85.52

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Ministry of Health

Web site: www.ms.ro (only in Romanian)

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