



EXTERNAL RELATIONS

EXECUTIVE SUMMARY

1. The aim of the programme

- 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.

2. Target groups

The target groups were 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.

3. Methodology

- * 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 has been allowed by current legislation and the Programme
- * Investment in information technology
- * Seminars and conferences
- * Priorities were defined and chosen following consultation with national authorities

The methodology was based 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.

4. Achieved results

EFSA asked Romania and Bulgaria to comment on the achieved results (Annex 1). From EFSA's side, the expected results are deemed to have been realised through the many exchanges between competent authorities, experts, administrators, EFSA staff and Member States noted in points 2.1 and 2.2.

FINAL REPORT - EFSA AND THE PHARE PROGRAMME

1. Introduction

This report summarises the results of the completed PHARE programme: “Progress towards accession: Strengthening the food safety systems in Bulgaria and Romania¹. This is the second report to the EFSA Management Board², which has also been kept abreast of developments through the General Update from the Executive Director³.”

1.1 The aim of the 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. The aim of the programme was to achieve, for Bulgaria and Romania:

- 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.

The 29 March 2006 interim report stated the following with regards to how the aim of the project was being met:

“All these aims are in the process of being met. 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.”

At the closing conference in Bucharest 16 November 2006, EFSA took stock of the success of the project, together with Romania and Bulgaria. It was agreed that the aims of the project had been fully met and that in fact both Romania and Bulgaria were already participating fully in the work of EFSA. Membership of the European Union would certainly bring about changes to the positive as Romania and Bulgaria would become full members in EFSA bodies where before they had had observer status (such as the Advisory Forum) or be able to participate fully in for a where non-membership had prevented them from doing so (eg Panel working groups). Please see comments from Bulgaria and Romania on the success of the programme in Annex 1.

¹ Final CD FP 2004 Agencies DEF

² Management Board note – PHARE project 29.3.2006

³ MB 12.9.2006 – 3a

MB 19.12.2006 – 11 Final report on the 2005 – 2006 PHARE project

1.2 Target groups

The target groups were 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. In the case of Bulgaria, the PHARE project brought about the setting up of a coordinating body “*that would coordinate studying of all institutes which are under the different Ministries and services in Bulgaria and would implement functions related to the risk assessment in the field of food protection*”⁴.

1.3 Main activities and their location

The activities included series of meetings, participation by expert in EFSA expert groups, seminars, and conferences. Seminars and conferences targeted Competent Authorities, administrative and scientific audiences, stakeholders and communication experts with the view to informing the full cross-section of stakeholders in Romania and Bulgaria.

1.4 Objective

The objective of the PHARE programme has been to prepare Bulgaria and Romania, for participation in all activities of EFSA involving Member States.

2. Methodology

2.1 Methods of implementation

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 has been 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 conferences
- Priorities were defined and chosen following consultation with national authorities
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2.2 Reasons for the proposed methodology

The methodology was based 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:

⁴ Annex 1

MB 19.12.2006 – 11 Final report on the 2005 – 2006 PHARE project

- The Steering Committee used the experience of the relevant Competent Authorities and Ministries in Bulgaria and Romania and Heads of Units in EFSA to provide direction to the project thus ensuring an appropriate focus. There was continuous follow-up to ensure chosen subjects for seminars and conferences were relevant.
- Seminars provided a forum for discussion of methods to address EFSA and Member States working methods and experiences. Participation as observers at selected meetings not only enabled 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 proved valuable to all parties involved.
- Due to the nature of its work, EFSA plays a major role in building food safety networks as its bedrock. Therefore the integration and the collaboration in EFSA's work of Bulgaria and Romania on a wide range of scientific data exchanges and bilateral collaboration had to build up in science, institutional activities, the Advisory Forum activities, crisis planning and communication so that on accession the networks are able to function. In order to facilitate all these activities it was important that there it a common understanding of the legal framework, constraints and context that EFSA operates in.

3. Results

3.1 Expected results

According to the Description of the Programme⁵ the EFSA PHARE Programme was 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.

3.2 Achieved results

EFSA asked Romania and Bulgaria to comment on the achieved results (Annex 1). From EFSA's side, the expected results are deemed to have been realised through the many exchanges between competent authorities, experts, administrators, EFSA staff and Member States noted in points 2.1 and 2.2.

⁵ European Community Contribution Agreement with an International Organisation, 2005/102-527, Annex 1

4. Recommendations for future projects

Romania and Bulgaria are relatively speaking small countries with a well defined structure for carrying out risk analysis. In the case of Romania there is one National Authority, the NSVFSA (National Sanitary Veterinary and Food Safety Authority). In Bulgaria, the responsibility is split between the Ministry of Agriculture and the Ministry of Health with a coordinating body under the administration of the Ministry of Health (see Annex 1). The approach used for this project may therefore differ from the approach needed in a larger (area, population) country with a more disparate organisation.

It is necessary with an centralised approach in the target countries in order to make sure the funds are used appropriately and systematically. It is therefore recommended that there is one contact point per country, or a small number of administrators which work closely in the same environment. It is recommended that the contact point should work within the national administration to ensure clear lines of communication and also decision making. EFSA enjoyed a very close and fruitful working relationship with the contact points in the Romanian and Bulgarian administrations.

Furthermore it is recommended to closely establish and continuously monitor the needs of the target country. The resources should be used where there is a reasonable possibility to make improvements. It is pointless to start training programmes or run courses in subjects which are not at all established. Officers on both sides need to make a realistic assessment of the needs of the target country, mainly from a scientific point of view, and adapt the programme to assist the target country in the fields within EFSA's remit where there is established scientific activity.

Language barriers are a fact. The scientific community is mostly international and national scientific experts may be able to speak eg English however this should not be taken for granted. Other target groups (stakeholders, administrators) may need interpretation and translation of documents and the need for this should be foreseen.

A long lead time may be needed for planning purposes otherwise EU and local bureaucracy may hinder meeting and travel arrangements. Considerable administrative support is needed on both sides and should not be underestimated. Officers need to get up to speed quickly with how invitations should be formulated, and where they should be sent in order for the target countries to get them through hierarchies efficiently.

5. Budget for the project

The EFSA PHARE programme was externally funded, €500.000, by the EU budget earmarked for enlargement. Please see Annex 2 for a detailed budget breakdown.

6. Openness and transparency

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.

Annex 1

A. Comments from Bulgaria on the completion of the PHARE programme “**Progress towards accession: Strengthening the food safety systems in Bulgaria and Romania**” in December 2006 (Dr Tsvetanka Voynova, Bulgarian contact point for the project)

“Firstly I would like to remark that before this project was realized, a few people from some institutions in Bulgaria knew about EFSA. Currently owing to the succession of workshops organized under this project all the Competent Authorities, all scientists and Stakeholders in Bulgaria know the structure and EFSA’s mission.

On the way to the European integration of Bulgaria many PHARE and Twinning projects have been adopted and carried out by the Bulgarian Competent Authorities and the Stakeholders. The target of any of these projects was not to improve the institutional structure for Risk assessment in Bulgaria. Bulgaria really needed of such kind of projects.

By the help of this project we understood the necessity of the creation of a coordinating body in Bulgaria that would coordinate studying of all institutes which are under the different Ministries and services in Bulgaria and would implement functions related to the risk assessment in the field of food protection. As a result from the beginning of 2006 in Bulgarian Food Law was introduced article 36a, concerning which an expert council will be established at the Ministry of Health. Creation of this expert council is almost finished. Until 1st of January 2007 in Bulgaria we are going to establish not only expert council but also panels just as EFSA’s. Many scientists that will be included in these panels took part, in working groups and conferences organized by EFSA with regard to residues, food additives, animal health and welfare, contaminants in food, nutrition and health claims. Returning into Bulgaria they kept making analyses of the national situation in such area they have participated. Their participation was being supported by this project.

In the framework of this project it was highlighted that scientific knowledge and its applications cannot be treated as though independent from industry and stakeholders. Under this project a workshop for cooperation with the stakeholder was organized. While carrying out the practical exercises on this workshop, with the help of the EFSA’s representatives we determined omissions and problems in that area and we are working by now with a view of improving the cooperation and for better access to the information of the Stakeholders.

Some training courses were conducted concerning risk communication. Participants were learned how to manage in crises situations and how to present any information in a fully understandable way to the public. They were also learnt that they have to work in a narrow cooperation with the other institutions. As a result now the Ministry of Agriculture and Forestry and Ministry of Health work better together in risk communication area.

This project supported some training courses that were carried out concerning zoonoses data collection. Bulgarian participants have gained more experience how they have to search for, collect, analyze and summarize relevant scientific and technical data in the field of zoonoses.

In the end we would like to express our gratitude for the good cooperation and we hope that in the future we could rely on the good common work with EFSA. From our point of view the goals of this project have been reached and Bulgaria is ready for full participation in EFSA’s activities. An evidence for that is as I said before the

MB 19.12.2006 – 11 Final report on the 2005 – 2006 PHARE project

creation of an expert council. The other evidence is the great amount of experts and scientist that took part in the events organized under this project, who were trained and gained more knowledge with the help of the high qualified EFSA's staff.. This project helped very much to Bulgaria in preparing of full integration in the EFSA's structures and it was given an opportunity to be drawn on the experience of Member States and EFSA.

B. Comments from Romania on the completion of the PHARE programme “**Progress towards accession: Strengthening the food safety systems in Bulgaria and Romania**” in December 2006 (Dr Liviu Rusu, Romanian contact point for the project)

“Programme content

All the meetings with EFSA representatives allowed the Romanian participants to understand the informal exchange of information between EFSA and EU member states, the preparation of competent bodies in Romania having responsibilities in areas related to the work carried out by EFSA and their future participation in EFSA network.

The programme contained the relevant training for Romanian experts in order to understand the working procedures of EFSA in both risk assessment and risk communication, the nature of EFSA's work and exchange of information between different stakeholders involved in risk assessment – governmental bodies, industry, consumers, the European Commission, Member States – also participation to EFSA working groups in various fields.

Programme structure

The program was well structured, covering a number of interesting issues for the Romanian participants. The seminars and conferences took into account the general existing structures to ensure food safety in Europe, meaning the separation of risk assessment and risk management, and helped to understand the role of EFSA in the independent, transparent scientific evaluation process of risk assessment as well as EFSA's mission, structure and organisation, EFSA's Advisory Forum activity, the manner of EFSA's work in relation to science, communications and relationships with stakeholders. It was also interesting to find out about the infrastructure at national level interface with EFSA

The structure of seminars and conferences as well as trainings was very successful especially by providing a framework for different stakeholders to meet and become aware of each others opinions and points of view and understand each other.

Relevance of programme to Romania

This Phare programme has assisted Romania in its preparations for joining the European Union. Through this programme, EFSA has been working with the governments of Bulgaria and Romania on food and feed safety issues within EFSA's remit.

The project covered the pre-accession period of Romania to the European Union, when there was a stringent need for the Romanian experts to acquire from the European experience in the food safety field. The opportunity was even bigger for Romanian because the National Sanitary Veterinary and Food Safety Authority was newly established and there was a need of understanding the way European structures function to improve the quality of work that has been done but also to prepare to work within the European structures' network.

MB 19.12.2006 – 11 Final report on the 2005 – 2006 PHARE project

The program was relevant to understand the necessity to identify the targets of the main activities, to develop a crisis contact point, the inclusion of Romania in crisis exercises with EFSA and to develop appropriate information exchange infrastructure. Another important issue was to create a communication and information exchange system, enabling the future participation of Romania in EFSA network. The Romanian part was also interested in the transfer of knowledge on methodology used by EFSA, especially regarding risk assessment and data collection.

The chosen topics for risk assessment: GMO's, BSE/TSE, but also contaminants and pesticide residues allowed the Romanian experts to get inside of such emerging and actuality issues for Romania as well as in Europe.

Risk communication is one of the fields that benefited the most from EFSA's contribution and especially helped us a lot during the avian influenza crisis in Romania.

Quality of planning by EFSA

The planning and the schedule of the program drawn up by EFSA were excellent. Every conference and seminar took place in the convened time-schedule and the order in which they were planned to take place was also very well planned to introduce experts in various activities.

Programme implementation

We consider that the program was very well implemented and the established targets were achieved. Activities were carried out accordingly to the plan and people representing different stakeholders were invited and were glad to participate. The experts invited by EFSA had excellent knowledge in the field and were providing the training that was needed so that the Romanian experts could really understand what risk assessment and communication consist of and how they should proceed.

Theoretical and practical training were both provided and the knowledge gained was applied by the relevant people.

Also, the communication between EFSA and national authorities was explained and understood by Romanian experts.

Feed-back received from our experts?

Our experts appreciated the meetings with EFSA representatives and concluded that the program helped very much to better understand the importance of their mission and responsibilities in their areas of activity, especially in those related to EFSA's tasks and with the view of their future participation to EFSA activities.

Romanian experts showed an increasing interest regarding organising and functioning of European structures related to food safety field.

They also understood that they should increase the quality of the work they do to achieve the higher standards set by EFSA's methodologies for risk assessment.

Excellent feedback came from the Romanian experts. They argued that this programme created the frame for the exchange of information between people that work in different fields, notwithstanding if they are official scientists or carry out research for the industry. Also it helped them a lot to understand the tasks of EFSA and their place as experts in EFSA's activities. It helped them interconnect with colleagues from other countries on personal level and be more informed of issues that are currently emerging.

Also, they had the chance to meet with the stakeholders (consumers, industry) and understand their point of view in various subject, insight that will help them solve problems more easily.

MB 19.12.2006 – 11 Final report on the 2005 – 2006 PHARE project

Furthermore, it has helped them understand what is expected of them in terms of risk assessment and how they can proceed to deliver the best scientific advice to risk managers as well as procedures to assure the relevant data are collected in a form that they are easily to assess.

Overall this project increased the role of risk assessment and risk communication stages in the process of risk analysis and provided a new approach of old issues as well as the identification of new needs – like specific training of experts in the fields related to food safety

Did the programme meet its aim? Is Romania ready for full participation in EFSA activities?

The programme met its aim and the representatives of the Romanian competent authorities are ready for full participation in EFSA activities, as a result of the implementation of this program.

This programme contributed to the strengthening of the Romanian National Sanitary Veterinary and Food Safety Authority in regards of risk assessment and risk communication. Furthermore, it has strengthened the link that governmental bodies have between them and the exchange of information and trust in governmental authorities of other stakeholders in the food safety field, namely industry, consumers and media. The food safety system has benefited a lot and the consumers are more convinced that the authorities and the industry both work together to assure food safety. This programme has also contributed to networking the experts that work both in the governmental bodies but also in the industry and created a frame for genuine communication between people with common interests.

It helped the governmental experts understand that risk communication is of tremendous importance and that risk assessment should be carried out as transparent as possible to gain the trust of all the stakeholders.

Last but not least, the link between the Romanian and Bulgarian scientists was tightened and they will find it a lot easier to work together on issues and problems that concern both parts.

We appreciate that understanding the mandate and role of EFSA supported Romanian experts to achieve the ability to work at the EU standards, contributing in this way to the developing and strengthening of the Romanian food safety system. Moreover, it has improved the NSVFSA recognition as coordinator of the field. Scientific and technical exchange and legal regulatory affairs information supported the Romanian last steps to EU integration and we have now better trained experts and certain parts of food safety system were further developed. The transfer of knowledge on methodologies strongly contributed to developing of important and sensitive domains in Romania such as data collection, risk assessment and risk communication. We appreciate the "experience" of the project added to strong and adequate professional backgrounds made it possible for Romanian experts to understand and improve their work so that they reach the EU standards request for EFSA's activities.”

MB 19.12.2006 – 11 Final report on the 2005 – 2006 PHARE project

7.1 Training seminars and conferences	Per event	10	10500	105000	Per event	8	10000	80000	Per event	2	10000	20000	
7.2 Printing of information material		1	7332	7332		1	8830	8830		6	10000	60000	
Subtotal Other				112332				88830				80000	32332
8. Subtotal direct project costs (1.-7.)				500000				500000				496485	
9. Administrative costs (maximum 7 % of 8., direct eligible project cost)												3515	-3515
10. Total eligible project costs (8.+ 9.)				500000				500000				500000	
11. Contingency reserve* (maximum 5 % of 10., total eligible project costs)													0
12. Total costs(10.+11.)				500000				500000				500000	0

* Contingency reserve can only be used after written approval of the Commission

Per diem rate of 300 euro is the average rate for BG 208 + 212 and RO 354 + 333