FIRST REGULAR NATIONAL REPORT ON THE IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY

Origin of report

Party:	BULGARIA
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Submission	
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Time period covered by this report:	September 11 th , 2003 – September 3 rd , 2007

Please provide summary information on the process by which this report has been prepared, including information on the types of stakeholders who have been actively involved in its preparation and on material which was used as a basis for the report:

The report was prepared by the Bulgarian Ministry of Environment and Water (MoEW) as a competent national authority under the Cartagena Protocol.

During the preparation of the report MoEW consulted the Ministry of Agriculture and Food Supply (CA for Handling, transport, packaging and identification, LMOs for use as feed or for processing) and the Ministry of Health (CA for Handling, transport, packaging and identification, LMOs for use as food or for processing) as well as non-governmental organisations (AgroBioinstitute, Sofia).

In the process of elaboration of the present report, the interim national report sent by Bulgaria according to the decision BS-I/9 has been used as a basis. Therefore, the updated information, contained in the present report covers the period between date of entry of the Protocol and the reporting date.

Obligations for provision of information to the Biosafety Clearing-House

1. Several articles of the Protocol require that info (see the list below). For your Government, if there been provided to the Biosafety Clearing-House (BO encountered regarding provision of that information BCH to determine the current status of your countrequired information below. If you do not have account summary):	are cases where release. The cases where release. The case is any obtain (note: To answer the case) are cases. The case is a case of the c	vant information ex stacles or impediments and question, please missions relative to	ists but has not ents check the the list of
Bulgaria has provided the BCH with all the require	ed information.		
2. Please provide an overview of information that House:	t is required to be pro	ovided to the Biosaf	Cety Clearing-
Type of information	Information exists and is being provided to the Biosafety Clearing-House	Information exists but is not yet provided to the Biosafety Clearing-House	Information does not exist /not applicable
a) Existing national legislation, regulations and guidelines for implementing the Protocol, as well as information required by Parties for the advance informed agreement procedure (Article 20.3(a))	X		
b) National laws, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing (Article 11.5);	X		
c) Bilateral, multilateral and regional agreements and arrangements (Articles 14.2, 20.3(b), and 24.1);	X- Those, provided by the European Commission are valid for Bulgaria as of January, 1st 2007 (date of full membership in the EU)		
d) Contact details for competent national authorities (Articles 19.2 and 19.3), national focal points (Articles 19.1 and 19.3), and emergency contacts (Article 17.2 and 17.3(e));	X		
e) In cases of multiple competent national authorities, responsibilities for each (Articles 19.2 and 19.3):	X		

f) Reports submitted by the Parties on the operation of the Protocol (Article 20.3(e));	X		
g) Occurrence of unintentional transboundary movements that are likely to have significant adverse effects on biological diversity (Article 17.1);			X
Type of information	Information exists and is being provided to the Biosafety Clearing-House	Information exists but is not yet provided to the Biosafety Clearing-House	Information does not exist /not applicable
h) Illegal transboundary movements of LMOs (Article 25.3);			X
i) Final decisions regarding the importation or release of LMOs (i.e. approval or prohibition, any conditions, requests for further information, extensions granted, reasons for decision) (Articles 10.3 and 20.3(d));			X
j) Information on the application of domestic regulations to specific imports of LMOs (Article 14.4);	X		
k) Final decisions regarding the domestic use of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing (Article 11.1);			X
1) Final decisions regarding the import of LMOs intended for direct use as food or feed, or for processing that are taken under domestic regulatory frameworks (Article 11.4) or in accordance with annex III (Article 11.6) (requirement of Article 20.3(d))			X
m) Declarations regarding the framework to be used for LMOs intended for direct use as food or feed, or for processing (Article 11.6)			X
n) Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12.1);			X
o) LMOs granted exemption status by each Party (Article 13.1)			X
p) Cases where intentional transboundary movement may take place at the same time as the movement is notified to the Party of import (Article 13.1);			X

q) Summaries of risk assessments or environmental reviews of LMOs generated by		X	
regulatory processes and relevant information regarding products thereof (Article 20.3(c)).			

Article 2 – General provisions

3. Has your country introduced the necessary legal, administrative and other measures for implementation of the Protocol? (Article 2.1)		
a) full domestic regulatory framework in place (please give details below)	X	
b) some measures introduced (please give details below)		
c) no measures yet taken		

4. Please provide further details about your response to the above question, as well as description of your country's experiences and progress in implementing Article 2, including any obstacles or impediments encountered:

The development, handling, transport, transfer and release of LMOs, except food, food ingredients and pharmaceuticals for human and veterinary use which contain or consist of LMOs or combination of LMOs, are covered by the Bulgarian GMO Act, which entered into effect since 01.06.2005.

This Act has as its objective to protect human health and the environment when carrying out the above mentioned activities in accordance with the precautionary principle, which means priority protection of human health and the environment if any potential harmful effects are likely to be realized, regardless of the existing economic interests or the unavailability of sufficient scientific data.

Complementary, two national regulations are in force since October, 2005:

Regulation on the contained use of GMOs and Regulation on the deliberate release and placing on the market of GMOs.

The development, handling, transport, transfer and release of LMOs, intended for direct use as food or for processing is covered by the Bulgarian Law of Foodstuffs, which enetered into effect since 01.01.2005.

Articles 7 to 10 and 12: The advance informed agreement procedure

See question 1 regarding provision of information to the Biosafety Clearing-House.

5. Were you a Party of import during this reporting period?	
a) yes	
b) no	x
6. Were you a Party of export during this reporting period?	
a) yes	
b) no	x
7. Is there a legal requirement for the accuracy of information provided by exporte jurisdiction of your country? (Article 8.2)	rs <u>1</u> / under the
a) yes	X
b) not yet, but under development	

^{1/} The use of terms in the questions follows the meanings accorded to them under Article 3 of the Protocol.

c) no		
d) not applicable – not a Party of export		
8. If you were a Party of export during this reporting period, did you request any Par review a decision it had made under Article 10 on the grounds specified in Article 12.		
a) yes (please give details below)		
b) not yet, but under development		
c) no		
d) not applicable – not a Party of export	X	
9. Did your country take decisions regarding import under domestic regulatory frame by Article 9.2(c).	eworks as allowed	
a) yes		
b) no		
c) not applicable – no decisions taken during the reporting period	X	
10. If your country has been a Party of export of LMOs intended for release into the ethe reporting period, please describe your experiences and progress in implementing A 12, including any obstacles or impediments encountered:		
Not applicable – not a Party of export		
11. If your country has taken decisions on import of LMOs intended for release into the environment during the reporting period, please describe your experiences and progress in implementing Articles 7 to 10 and 12, including any obstacles or impediments encountered:		
Not applicable – not a Party of import		

Article 11 – Procedure for living modified organisms intended for direct use as food or feed, or for processing

See question 1 regarding provision of information to the Biosafety Clearing-House.

12. Is there a legal requirement for the accuracy of information provided by the applicant with respect to the domestic use of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing? (Article 11.2)		
a) yes	X	
b) not yet, but under development		
c) no		
d) not applicable (please give details below)		
13. Has your country indicated its needs for financial and technical assistance and ca respect of living modified organisms intended for direct use as food or feed, or for pr 11.9)		
a) yes (please give details below)	X	
b) no		
c) not relevant		

14. Did your country take decisions regarding import under domestic regulatory frame by Article 11.4?	eworks as allowed
a) yes	
b) no	
c) not applicable – no decisions taken during the reporting period	X
15. If your country has been a Party of export of LMOs intended for direct use for footprocessing, during the reporting period, please describe your experiences and progress Article 11, including any obstacles or impediments encountered:	The state of the s
Not applicable – not a Party of export	
16. If your country has been a Party of import of LMOs intended for direct use for for processing, during the reporting period, please describe your experiences and progress Article 11, including any obstacles or impediments encountered:	
Not applicable – not a Party of export	
Article 13 – Simplified procedure	
See question 1 regarding provision of information to the Biosafety Clearing-H	Iouse.
17. Have you applied the simplified procedure during the reporting period?	
a) yes	
b) no	X
-, -	71
18. If your country has used the simplified procedure during the reporting period, or i unable to do so for some reason, please describe your experiences in implementing Ar any obstacles or impediments encountered:	f you have been
18. If your country has used the simplified procedure during the reporting period, or is unable to do so for some reason, please describe your experiences in implementing Ar	f you have been
18. If your country has used the simplified procedure during the reporting period, or i unable to do so for some reason, please describe your experiences in implementing Ar any obstacles or impediments encountered:	f you have been rticle 13, including
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18. If your country has used the simplified procedure during the reporting period, or i unable to do so for some reason, please describe your experiences in implementing Ar any obstacles or impediments encountered: Not applicable Article 14 – Bilateral, regional and multilateral agreements and arrange. See question 1 regarding provision of information to the Biosafety Clearing-H	f you have been rticle 13, including ements House.
18. If your country has used the simplified procedure during the reporting period, or i unable to do so for some reason, please describe your experiences in implementing Ar any obstacles or impediments encountered: Not applicable Article 14 – Bilateral, regional and multilateral agreements and arrange See question 1 regarding provision of information to the Biosafety Clearing-H. 19. Has your country entered into any bilateral, regional or multilateral agreements or	f you have been rticle 13, including ements House.
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18. If your country has used the simplified procedure during the reporting period, or is unable to do so for some reason, please describe your experiences in implementing Arrange any obstacles or impediments encountered: Not applicable Article 14 – Bilateral, regional and multilateral agreements and arrange See question 1 regarding provision of information to the Biosafety Clearing-Has your country entered into any bilateral, regional or multilateral agreements or a) yes b) no 20. If your country has entered into bilateral, regional or multilateral agreements or aryou have been unable to do so for some reason, describe your experiences in implements.	f you have been rticle 13, including ements House. Tarrangements? X Trangements, or if
18. If your country has used the simplified procedure during the reporting period, or is unable to do so for some reason, please describe your experiences in implementing Arrany obstacles or impediments encountered: Not applicable Article 14 – Bilateral, regional and multilateral agreements and arrange. See question 1 regarding provision of information to the Biosafety Clearing-H. 19. Has your country entered into any bilateral, regional or multilateral agreements or a) yes b) no 20. If your country has entered into bilateral, regional or multilateral agreements or ar you have been unable to do so for some reason, describe your experiences in impleme during the reporting period, including any obstacles or impediments encountered:	f you have been rticle 13, including ements House. Tarrangements? X Trangements, or if
18. If your country has used the simplified procedure during the reporting period, or it unable to do so for some reason, please describe your experiences in implementing Arany obstacles or impediments encountered: Not applicable Article 14 – Bilateral, regional and multilateral agreements and arrange. See question 1 regarding provision of information to the Biosafety Clearing-Figure 19. Has your country entered into any bilateral, regional or multilateral agreements or a) yes b) no 20. If your country has entered into bilateral, regional or multilateral agreements or ar you have been unable to do so for some reason, describe your experiences in implement during the reporting period, including any obstacles or impediments encountered: Not applicable	f you have been rticle 13, including ements House. X Trangements, or if enting Article 14
18. If your country has used the simplified procedure during the reporting period, or i unable to do so for some reason, please describe your experiences in implementing Ar any obstacles or impediments encountered: Not applicable Article 14 – Bilateral, regional and multilateral agreements and arrange See question 1 regarding provision of information to the Biosafety Clearing-F. 19. Has your country entered into any bilateral, regional or multilateral agreements or a) yes b) no 20. If your country has entered into bilateral, regional or multilateral agreements or aryou have been unable to do so for some reason, describe your experiences in impleme during the reporting period, including any obstacles or impediments encountered: Not applicable Articles 15 and 16 – Risk assessment and risk management 21. If you were a Party of import during this reporting period, were risk assessments of	f you have been rticle 13, including ements House. X Trangements, or if enting Article 14
18. If your country has used the simplified procedure during the reporting period, or i unable to do so for some reason, please describe your experiences in implementing Ar any obstacles or impediments encountered: Not applicable Article 14 – Bilateral, regional and multilateral agreements and arrange. See question 1 regarding provision of information to the Biosafety Clearing-Fe 19. Has your country entered into any bilateral, regional or multilateral agreements or a) yes b) no 20. If your country has entered into bilateral, regional or multilateral agreements or ar you have been unable to do so for some reason, describe your experiences in impleme during the reporting period, including any obstacles or impediments encountered: Not applicable Articles 15 and 16 – Risk assessment and risk management 21. If you were a Party of import during this reporting period, were risk assessments of decisions taken under Article 10? (Article 15.2)	f you have been rticle 13, including ements House. X Trangements, or if enting Article 14

22. If yes to question 21, did you require the exporter to carry out the risk assessment?		
a) yes – in all cases		
b) yes – in some cases (please specify the number and give further details below)		
c) no		
d) not a Party of import / no decisions taken under Article 10	X	
23. If you took a decision under Article 10 during the reporting period, did you requir bear the cost of the risk assessment? (Article 15.3)	e the notifier to	
a) yes – in all cases		
b) yes – in some cases (please specify the number and give further details below)		
c) no		
d) not a Party of import / no decisions taken under Article 10	X	
24. Has your country established and maintained appropriate mechanisms, measures a regulate, manage and control risks identified in the risk assessment provisions of the P 16.1)		
a) yes – fully established	X	
b) not yet, but under development or partially established (please give further details below)		
c) no		
25. Has your country adopted appropriate measures to prevent unintentional transbour of living modified organisms? (Article 16.3)	ndary movements	
a) yes – fully adopted	X	
b) not yet, but under development or partially adopted (please give further details below)		
c) no		
26. Does your country endeavour to ensure that any living modified organism, whether locally developed, undergoes an appropriate period of observation commensurate with generation time before it is put to its intended use? (Article 16.4)	*	
a) yes – in all cases	X	
b) yes – in some cases (please give further details below)		
c) no (please give further details below)		
d) not applicable (please give further details below)		
27. Has your country cooperated with others for the purposes specified in Article 16.5	5?	
a) yes (please give further details below)		
b) no (please give further details below)	X	

- 28. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Articles 15 and 16, including any obstacles or impediments encountered:
- Q 21-23: Bulgaria has not been a Party of import during the reported period. However, as a Member State (MS) of the EU, Bulgaria is a part of the common Community market, decisions for placing GMOs on which are taken on the EU level. In that relation Bulgaria participated, since January 1st, 2007 (the date of full membership in the EU), in the EU authorisation procedure. According to the said procedure (Directive 2001/18/EC, Regulation 1829/2003/EC) each decision taken requires full evaluation of the risk for the human health and the environment. This risk assessment is prepared by the notifier and reviewed by all the MS. In case of notification submitted to Bulgarian competent authorities from the notifier, the latter should pay the costs for the evaluation. In case of notification submitted to another MS no payment is due to Bulgaria for reviewing the risk assessment.
- Q 24: According to the EU legislation, which Bulgaria complies with, a monitoring plan is required (Council Decision 2002/811/EC)
- Q 25: The measures are adopted on the EU level (Regulation 1946/2003/EC) and at national level a contact point for receiving information for such movements is determined and made available to the BCH.
- <u>Q 26:</u> According to Bulgarian GMO Act the risk assessment should be carried out in a scientifically sound and transparent manner, based on available scientific and technical data and the required information may vary depending on the type of the GMOs concerned, the intended use thereof and the potential receiving environment, taking into account, *inter alia*, GMOs already released into the environment;

Article 17 – Unintentional transboundary movements and emergency measures See question 1 regarding provision of information to the Biosafety Clearing-House.

29. During the reporting period, if there were any occurrences under your jurisdiction that led, or could have led, to an unintentional transboundary movement of a living modified organism that had, or could have had, significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States, did you immediately consult the affected or potentially affected States for the purposes specified in Article 17.4?

a) yes – all relevant States immediately	
b) yes – partially consulted, or consultations were delayed (please clarify below)	
c) no – did not consult immediately (please clarify below)	
d) not applicable (no such occurrences)	X

30. Please provide further details about your response to the above question, as well as description of your country's experiences in implementing Article 17, including any obstacles or impediments encountered:

31. Has your country taken measures to require that living modified organisms that are subject to transboundary movement within the scope of the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards? (Article 18.1)		
a) yes (please give details below)	X	
b) not yet, but under development		
c) no		
d) not applicable (please clarify below)		
32. Has your country taken measures to require that documentation accompanying living modified organisms for direct use as food or feed, or for processing, clearly identifies that they 'may contain' living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for information? (Article 18.2(a))		
a) yes	X	
b) not yet, but under development		
c) no		
33. Has your country taken measures to require that documentation accompanying living modified organisms that are destined for contained use clearly identifies them as living modified organisms and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned? (Article 18.2(b))		
a) yes	X	
b) not yet, but under development		
c) no		
34. Has your country adopted measures to require that documentation accompanying living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter? (Article 18.2(c))		
a) yes	X	
b) not yet, but under development		
c) no		
35. Please provide further details about your responses to the above questions, as well as a description of your country's experiences and progress in implementing Article 18, including any obstacles or impediments encountered:		

Article 19 - Competent national authorities and national focal points

See question 1 regarding provision of information to the Biosafety Clearing-House.

The measures are adopted on the EU level (Regulation 1946/2003/EC)

Article 20 – Information-sharing and the Biosafety Clearing-House

See question 1 regarding provision of information to the Biosafety Clearing-House.

36. In addition to the response to question 1, please describe any further details regarding your country's experiences and progress in implementing Article 20, including any obstacles or impediments encountered:

Article 21 – Confidential information	
37. Does your country have procedures to protect confidential information received under the Protocol and that protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms? (Article 21.3)	
a) yes	X
b) not yet, but under development	
c) no	
38. If you were a Party of import during this reporting period, did you permit any notifier to identify information submitted under the procedures of the Protocol or required by the Party of import as part of the advance informed agreement procedure that was to be treated as confidential? (Article 21.1)	
a) yes	
If yes, please give number of cases	
b) no	X
c) not applicable – not a Party of import / no such requests received	
39. If you answered yes to the previous question, please provide information on your eincluding description of any impediments or difficulties encountered:	experience
N.a.	
40. If you were a Party of export during this reporting period, please describe any imp difficulties encountered by you, or by exporters under your jurisdiction if information implementation of the requirements of Article 21:	
N.a.	

Article 22 – Capacity-building

41. If a developed country Party, during this reporting period has your country cooper development and/or strengthening of human resources and institutional capacities in burposes of the effective implementation of the Protocol in developing country Parties least developed and small island developing States among them, and in Parties with extransition?	oiosafety for the s, in particular the
a) yes (please give details below)	
b) no	
c) not applicable – not a developed country Party	X

42. If yes to question 41, how has such cooperation taken place:	
43. If a developing country Party, or Party with an economy in transition, during this your country contributed to the development and/or strengthening of human resources capacities in biosafety for the purposes of the effective implementation of the Protoco developing country Party or Party with an economy in transition?	and institutional
a) yes (please give details below)	X
b) no	
c) not applicable – not a developing country Party	
44. If yes to question 43, how has such cooperation taken place:	
With the expertise accumulated in course of the UNEP/GEF projects on developing of NBFs, The German- Austrian PHARE project and the PSO project (Netherlands-I due to the leading role Bulgaria has always played in biotechnology and biosafety in is now on a position to play more active role in the field of capacity-building in biotand Black Sea region. Such capacity-building needs were already informally expositionals by representatives of the respective countries in the regions.	Bulgaria), as well as the region, Bulgaria safety in the Balkan
45. If a developing country Party or a Party with an economy in transition, have you be cooperation for technical and scientific training in the proper and safe management of the extent that it is required for biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	X
c) no – capacity-building needs remain unmet (please give details below)	
d) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	
46. If a developing country Party or a Party with an economy in transition, have you be cooperation for technical and scientific training in the use of risk assessment and risk biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	X
c) no – capacity-building needs remain unmet (please give details below)	
d) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	
47. If a developing country Party or a Party with an economy in transition, have you be cooperation for technical and scientific training for enhancement of technological and capacities in biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) ves – capacity-building needs partially met (please give details below)	X

c) no – capacity-building needs remain unmet (please give details below)	
d) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	

48. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 22, including any obstacles or impediments encountered:

During the reported period Bulgaria was running the GEF-UNEP Implementation of National Biosafety Frameworks Project (02.2002-02.2005, prolonged till 02.2006).

The main goal of the project is to support the establishment of the regulatory and administrative biosafety management system in order to enable an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology, with a specific focus on transboundary movements in Bulgaria i.e.:

- to establish procedures for risk assessment and monitoring in order to ensure the safe use of modern biotechnology

taking into account national, sub-regional and regional needs.

- to strengthen capacity through training of trainers on the following subjects: a) LMOs risk assessment and risk

management; b) LMOs testing and monitoring; c) legal issues; d) institutional sets up and e) Intellectual Property

Rights/commercial issues.

- to promote and strengthen information sharing and dissemination amo ng the relevant stakeholders, and enhance public awareness. The main capacity-building areas of the project are:
- Ø Human-resources development and training
- Ø Information exchange & data management (including the Biosafety Clearing-House)
- Ø Institutional capacity building (including national regulatory frameworks)
- Ø Public awareness, education and participation
- Ø Risk assessment and other scientific and technical expertise
- Ø Scientific, technical and institutional collaboration

The quarterly operational and financial reports of the project are available at http://www.unep.ch/biosafety/partcountries/ImpBulgaria.htm

The following targets are reached within the project period:

A. Biosafety policy

B. Regulation regime for biosafety

Achievements:

- o GMO Act finalized
- o Regulatory norms for the enforcement of the GMO Act elaborated
- C. System for handling requests for permits

Achievements:

- o started development of a guidance for ensuring biosafety of the contained use of LMOs
- o started survey on the existing internal biosafety system around the world o draft checklists for the inspectors developed

D. Monitoring and inspections

Achievements:

o four risk assessment studies concerning the environmental impact of the release of LMOs on ecosystems

started

o finished 2-year study — Bulgarian Botanical Files - the other project, which operates in the frame of UNEP/GEF implementation project in Bulgaria. The aim of this study consists of summarizing of floristic, ecological and biological information into a dispersal codes that will be used in risk assessment studies for estimation the gene flow from cultvars into wild of weedy species.

E. Public information

Achievements:

see question 49.

Needs remain unmet:

Although the Bulgarian GMO Act is in force which is of a great importance as a starting point for further developments, still several modifications have to be done. More technical and scientific training for enhancement of technological and institutional capacities in biosafety still needed.

PHARE project BG04/IB/EN/02 - "Transposition and Implementation of the Environmental Acquis on Genetically Modified Organisms at National Level".

Partners: Bulgaria, Germany, Austria

This Twinning project, which is currently under implementation, addresses the contained use, deliberate release and placing on the market of GMOs.

This includes assistance in the establishment of reproducible administrative regimes for GMO-related decision making and supervision/inspection.

In this connection, suitable tools for administrative staff like, e.g. standard application forms, checklists, guidelines etc. and methods for scientific risk assessment and risk management and also for handling the issues of traceability and labelling alongside the relevant EU legislation are being developed and conveyed to the concerned Bulgarian authorities.

Additionally, the Twinning project is designed to follow two different approaches to the issue of public participation, information and awareness.

The first approach encounters the establishment of the participation of the public as an important factor for the transparency of the administrative procedure during decision making on the basis of the Aarhus Convention and EU Directive 2003/4/EC on public access to environmental information.

The second approach deals, in a general way and beyond the administrative understanding of the issue, with the transfer of knowledge about modern biotechnology and, especially, genetic engineering, from the scientific community to the public.

The project aims at the achievement of the following <u>results</u>:

- a. Administrative structures capable to manage and enforce requirements as outlined in 90/219/EEC as amended by 98/81/EC and 2001/18/EC Directives (Committee on GMOs and administrative unit within the Ministry of Environment and Water and Ministry of Agriculture and Forestry as well as supervisory authorities);
- b. Assessment of existing laboratories and preparation for their accreditation in order to conduct risk assessment and monitoring of GMO that are released or introduced to the market;
- c. A notification system by those proposing the registration of containment facilities and permission for contained use, addressed to the competent authorities;
- d. Up-dated electronic information system and public registers in an electronic format to record licensed premises, consents granted for GMO containment, release and placing on the market, conditions of containment, risk assessment and monitoring results and other pertinent information outlined in the EC Directives;

e. Inform the public on the legislation and the implementation of the regulations included in the two EC Directives.

PPA05/BG/7/1 GMOs: Enforcement of legislation, control measures and distribution of knowledge

Partners: Bulgaria, Netherlands

This project, which is currently under implementation aims at strengthening the capacity of the Ministry of Agriculture and Food Supply (MAFS) and their inspection services in order to implement GMO policy in line with the EU requirements and to monitor GMOs and GM products on the market.

As a result MAFS should:

• be able to handle the requests for market access for GMO's and genetically modified products in line with EU-requirements;

organise an efficient and effective inspection system developed for GMO's in the market.

• be able to increase public awareness regarding GMO's.

As a result of the training handbooks and manuals will be issued.

Article 23 – Public awareness and participation

49. Does your country promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health? (Article 23.1(a))	
a) yes – significant extent	
b) yes – limited extent	X
c) no	
50. If yes, do you cooperate with other States and international bodies?	
a) yes – significant extent	
b) yes – limited extent	X
c) no	
51. Does your country endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with the Protocol that may be imported? (Article 23.1(b))	
a) yes – fully	
b) yes – limited extent	X
c) no	

52. Does your country, in accordance with its respective laws and regulations, consult decision-making process regarding living modified organisms and make the results of available to the public? (Article 23.2)	•
a) yes – fully	X
b) yes – limited extent	
c) no	
53. Has your country informed its public about the means of public access to the Biosa House? (Article 23.3)	ifety Clearing-
a) yes – fully	X
b) yes – limited extent	
c) no	

54. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 23, including any obstacles or impediments encountered:

Bulgaria the staff of GEF-UNEP Implementation of National Biosafety Frameworks Project project kept and developed the dialogue with the media representatives during the ongoing discussions of the project of the Bulgarian GMO Act in the Parliament i.e. interviews for newspapers, TV, radio stations, participation in public debates, discussion clubs and preparation of the regular Biosafety Newsletters, thus building up wide public awareness. Amongst the achievements of the project are:

- o Introductory seminar for parliamentarians;
- o Training course for journalists
- o Science Media Communications workshop

Bulgarian Biotechnology Information Center Biotechnology Information Center was established as a part of the international network of similar centers.

Valuable information on biotechnology and biosafety has been regularly distributed through the website of the Bulgarian Biotechnology Information Center, news mailing list (scientists, journalists, regulators, NGOs).

The stuff also participated in public debates, round table discussions, writing articles for business and agricultural oriented magazines.

- Q 52: Consulting the public in the decision-making process regarding LMOs is foreseen in the Bulgarian GMO Act e.g. public hearings before taking decision for the release into the environment or placing at the market of GMOs. In order to inform the public before the hearings the information about the certain case is accessible via Internet.
- <u>Q 53:</u> The Bulgarian Biodiversity Portal is a part of the global information exchange network established by the Convention on Biodiversity (Clearing House Mechanism CHM). Its purpose is to offer directly or provide links to the information on biodiversity. From this portal is publicly accessible the Biosafety Clearing House.

Article 24 – Non-Parties

See question 1 regarding provision of information to the Biosafety Clearing-House.

55. Have there been any transboundary movements of living modified organisms between your country	
and a non-Party during the reporting period?	
a) yes	

b) no	X
56. If there have been transboundary movements of living modified organisms between your country and a non-Party, please provide information on your experience, including description of any impediments or difficulties encountered:	
Article 25 – Illegal transboundary movements	
See question 1 regarding provision of information to the Biosafety Clearing-H	ouse.
57. Has your country adopted appropriate domestic measures to prevent and penalize, as appropriate, transboundary movements of living modified organisms carried out in contravention of its domestic measures? (Article 25.1)	
a) yes	X
b) no	
58. Have there been any illegal transboundary movements of living modified organisms into your country during the reporting period?	
a) yes	
b) no	X
59. Please provide further details about your response to the above question, as well as description of your country's experiences in implementing Article 25, including any obstacles or impediments encountered:	
Penalty measures in cases of infringement of Regulation 1946/2003/EC are foresed GMO Act.	en in the Bulgarian
Article 26 – Socio-economic considerations	
60. If during this reporting period your country has taken a decision on import, did it take into account socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities? (Article 26.1)	
a) yes – significant extent	
b) yes – limited extent	
c) no	
d) not a Party of import	X
61. Has your country cooperated with other Parties on research and information exchange on any socio- economic impacts of living modified organisms, especially on indigenous and local communities? (Article 26.2)	
a) yes – significant extent	
b) yes – limited extent	
c) no	X

62. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 26, including any obstacles or impediments encountered:

Although Bulgaria has not been a Party of import during the reported period, the provisions of the Bulgarian GMO Act stipulate that socio-economic impact (s) must be taken into account before each placing on the market/import of LMOs.

Article 28 – Financial mechanism and resources

63. Please indicate if, during the reporting period, your Government made financial resources available to
other Parties or received financial resources from other Parties or financial institutions, for the purposes
of implementation of the Protocol.

a) yes – made financial resources available to other Parties	
b) yes – received financial resources from other Parties or financial institutions	X
c) both	
d) neither	

- 64. Please provide further details about your response to the above question, as well as description of your country's experiences, including any obstacles or impediments encountered:
- 1. GEF-UNEP Implementation of National Biosafety Frameworks Project—see the financial reports of the project.
- **2.** PHARE project BG04/IB/EN/02 "Transposition and Implementation of the Environmental Acquis on Genetically Modified Organisms at National Level"

Other information

65. Please use this box to provide any other information related to articles of the Protocol, questions in the reporting format, or other issues related to national implementation of the Protocol:

Comments on reporting format

The wording of these questions is based on the Articles of the Protocol. Please provide information on any difficulties that you have encountered in interpreting the wording of these questions: