1. Basic Information
1.1 Desiree Number: PL01.05.03  
1.2 Title: Biological safety system  
1.3 Sector: Environment  
1.4 Location: Poland

2. Objectives
2.1. Overall Objectives
The main long-term objective of the project is to establish a national biological safety system and to participate in the global safety system covering the release of genetically modified organisms (GMO) to the environment and their introduction to the market (turnover).

2.2. Immediate objectives
Implementation of this project will support national actions aiming at reaching the following immediate objectives: establishing a competent body which will manage the issues related to GMO; establishing accredited laboratories in selected places in Poland (on the basis of the existing facilities), furnished in appropriate equipment and with specially trained human resources. Those laboratories will carry out various research work, depending on the type of laboratory (modified food, seed-bearing material, micro-organism strain etc.); protection of the Polish borders by creating the check-points on selected border crossings; establishment of the systems of utilizing wastes from GMO, particularly with regard to bodies working on GMO (e.g. research institutes, sewage plants etc.); establishment of an electronic information system for the needs of activities concerning GMO (registration and gathering information about GMO); carrying out trainings for supervisory authorities dealing with GMO and education of the public on issues related to the biological safety as well as publishing and popularization of materials concerning GMO.

2.3. Accession Partnership and NPAA Priority
NPAA Priority 22.7: Creating a supervision system over the use of GMO according to the EU requirements. In the NPAA the following tasks concerning GMO are to be completed: establishing an electronic information system for the needs of activities with respect to GMO (registration and gathering information about GMO); education of the society in issues related to the biological safety, publishing materials concerning GMO; carrying out trainings for employees dealing with GMO.

2.4 Contribution to National Development Plan n.a.

2.5. Cross Border Impact n.a.

3. Description
3.1. Background and justification
The use of GMO is still quite controversial because biotechnology could be harmful to the environment, especially to the human life and the life of flora and fauna. GMO are usually used in closed circuit processes, released to the environment and introduced to turnover as products. With respect to the above, it is well justified to create a biological safety system that among others will result from the Convention on Biological Diversity and the Protocol on Biological Safety signed in Cartageny. The biological safety system is a global issue and its goal is to ensure a safe use of GMO in closed circuits, safe release of GMO into the environment for reasons other than turnover, safe introduction of GMO products, safe export and transit of GMO products. It is indispensable to establish a monitoring and supervision system in case of any activities related to GMO and to create an information system as well as communication with the society regarding biological security. Currently, legal provisions on GMO-related institutional structure and management principles, i.e. supervising authorities, reporting bodies and comprehensive procedures to manage GMO, are being developed in Poland. New bill on GMO adopted by the Council of Ministers on the 5th December 2000 envisages that a national competent authority responsible for all issues concerning GMO will be established with its head reporting directly to the Minister of the Environment (GMO Inspector, supported by his staff). Executive orders to this bill are still under preparation. Also regulations aiming at establishing norms on safe usage of those organisms in which the genetic material has been changed in a different than natural way of reproducing or hybridizing are being prepared. Issues concerning the biological safety are quite new in the domestic regulations, therefore they need further work which can be supported by experts from more experienced EU member states. New Polish laws regarding GMO will be mainly based on the following directives:

3.2. Linked Activities
On the turn of 1998/99 a project called “National Biological Safety Program” was accomplished. It was financed by the UNEP, supervised by the Ministry of Environmental Protection, Natural Resources and Forestry and implemented by the Institute of Plant Breeding and Acclimatization in Radzików near Warsaw. The project included training and aimed at defining the basis of the Biological Safety Program. It resulted in defining the needs of Poland regarding biological safety system and creating draft legal acts in this respect.

In March 2000 the Polish side organized a meeting with the representatives of the Dutch Ministry of Housing, Spatial Planning and Environment on the progress of work on the subject “Implementation of national structures of biological safety in pre-accession countries of Central and Eastern Europe”. During this meeting efforts were made to define the needs of Poland in order to fully develop this system in the future. Co-operation with the Dutch in this regard is foreseen for 3 years.

3.3. Results
1/ establishing a coherent security system to ensure that uncontrolled spreading of GMO in the environment, including the introduction of GMO products to the market,
2/ control over GMO that are already in the turnover as well as over GMO that are being introduced to the market (full control of GMO before introducing them) through system of accredited laboratories,
3/ establishing system of utilizing GMO to prevent the appearance of GMO from uncontrolled sources (e.g. in case of an accident) in the environment,
4/ organizing an electronic information system and supervision over flow of information concerning GMO in Poland,
5/ familiarizing the society with GMO-related issues,
6/ training relevant human resources to ensure efficient and more professional functioning of competent authorities.

3.4 Activities
Twinning: Verification (validation) of existing institutions and bodies dealing with GMO (mainly research institutions, which conduct scientific research on molecular biology and biotechnology); Assessment of technical conditions in the research institutions and other bodies dealing with GMO in order to establish reference (accredited) laboratories, based on existing facilities; According to the currently prepared regulations, these institutions should possess relevant laboratory equipment, qualified staff with appropriate education background and professional training to guarantee proper work of the body. Such accredited bodies should have 5 years experience in conducting this kind of research; Establishing precise principles and procedures of monitoring and control with regard to releasing live GMO to the environment; The risk assessment due to releasing GMO into the environment should be produced by the applicants (producers, merchandisers) who request from the authorities the permission to use GMO. The assessment would be based on research and analysis performed at the cost of an applicant. The report would be verified by the experts – members of the ministerial advisory-consultative body (Commission on GMO); Establishing precise principles and procedures for introducing GMO and GMO-containing products to the market – similar to those which concern releasing GMO to the environment; Verification (validation) of existing systems and facilities and creating new systems for management (utilisation) of GMO wastes; Developing electronic information system enabling fast flow of information concerning GMO; creating data bases on GMO; developing special GMO-web site serviced by the Ministry of the Environment; Implementation of the control system aiming at strengthening the borders; New GMO regulations currently under development provide that the General Custom Office (GCO) should be informed about all decisions concerning introducing GMO to the market, export and transit of GMO-containing products. GCO will send these information to the relevant custom offices in the country. The custom offices will co-operate on GMO with decision making bodies and with the institutions responsible for carrying research on GMO. In case of doubts, samples of materials for analysis should be forwarded to the relevant research institution; Developing the system of information and communication on biological safety with authorities and the public, through training of the personnel
responsible for monitoring and control, general education of the society (media, lectures etc.), issuing printed materials on biological safety system including GMO.

New bill on GMO envisages the participation of public in making decisions concerning GMO and in particular in introducing GMO to the market (sale of GMO-containing products). In order to provide for this, educational activities aimed at increasing general knowledge about GMO would be carried out by researchers working with GMO and the civil servants who are responsible for implementation of biological safety system.

4. Institutional Framework
The Ministry of the Environment will be the supervisor of the project. It is expected that the MoE will co-operate with other central government bodies, especially with: the Ministry of Health, the Ministry of Agriculture and Rural Development and the State Committee for Scientific Research. The essential work of the project will be carried out only by units with appropriate experience and appropriate employees, especially various research institutes already familiar with issues related to GMO, such as: Institute for Plant Breeding and Acclimatization (in Radzików near Warsaw), Institute of Biochemistry and Biophysics of the Polish Academy of Sciences, Institute of Genetics, National Food and Nutrition Institute, National Veterinary Research Institute, Institute of Animal Breeding, Academies of Agriculture, Agricultural Variety Research Center.

5. Detailed budget (MEUR)

<table>
<thead>
<tr>
<th>Component</th>
<th>Phare Support</th>
<th>National Co-financing</th>
<th>IFI</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Investment</td>
<td>Institution Building IB</td>
<td>Total PHARE (=I+IB)</td>
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<tr>
<td>Twinning</td>
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<td>1.76</td>
<td>0.115</td>
<td>1.875</td>
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<tr>
<td>Equipment</td>
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<td>1.00</td>
<td>0.25</td>
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<tr>
<td><strong>TOTAL</strong></td>
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<td><strong>1.76</strong></td>
<td><strong>0.365</strong></td>
<td><strong>3.125</strong></td>
</tr>
</tbody>
</table>

The co-financing funds for the project implementation will be available.

6. Implementation Arrangements

6.1. Implementing Agency
PAO: Mr. Pawel Samecki, Under-Secretary of State at the Committee of European Integration Office, Al.Ujazdowskie 9, 00-918 Warsaw, Poland, Tel.: (+48 22) 455 52 41; fax: (+48 22) 455 52 43
CFCU: Mr Wojciech Paciorkiewicz, Director of CFCU, 6/12 Nowy Swiat St., 00-400 Warsaw, Poland, Tel.: (+48 22) 661 79 27; fax: (+48 22) 661 72 26, E-mail: cfcu@cofund.org.pl

6.2. Twinning
The leading and responsible body for the project is the Ministry of the Environment. Enforcement of this project will require co-operation between: the Ministry of Environment, the Ministry of Health as well as the Ministry of Agriculture and Rural Development and the Committee for Scientific Research (the Ministry of Science).

This project will be enforced by research institutes, research centers and other specialized institutions like: Institute for Plant Breeding and Acclimatization in Radzików, Institute of Biochemistry and Biophysics of the Polish Academy of Science, Institute of Genetics, National Food and Nutrition Institute, National Veterinary Research Institute, Institute of Animal Breeding, Academies of Agriculture, Agricultural Variety Research Center. The following institutions will also co-operate: National Institute of Hygiene, Chief Sanitary Inspectorate.

Contact persons: Mr Zbigniew Krzeminski, Acting Director of the Department of Forestry, Nature Conservation and Landscape, Ministry of the Environment, 52/54 Wawelska St., 00-922 Warsaw, Poland, Tel. (48 22) 5792249, fax (48 22) 5792555, E-mail: zkryzm@mos.gov.pl, cc. Ms Agnieszka Dalbiak (as above; e-mail: adalbiak@mos.gov.pl), Mr Jacek Ochocinski, specialist, Department of Foreign Funds Management, Ministry of the Environment, 52/54 Wawelska St., 00-922 Warsaw, Poland, Tel: (+48 22) 5792590, fax: (+48 22) 5792795, e-mail: jochocin@mos.gov.pl

The EU partner will support national authorities in the preparation of the training curricula, educational materials, conducting training, building information and control system, identification of investment needs and for quality driven effective implementation of the project. The key specific tasks for the EU twin partner will be as follows: identifying and purchase of special laboratory equipment used for analyzing DNA (Accredited laboratories should already have at their disposal appropriate basic laboratory equipment for research on molecular biology, DNA analysis. The additional input would be mainly purchase of the identified lacking equipment and/or indispensable reagents for analyses);
purchasement of special equipment and establishing of the security system in bodies utilizing wastes of GMO; creating databases (purchase suitable equipment - hardware and software, trainings of staff); educating control authorities and the society (organizing seminars, lectures etc., issuing printed materials on biological safety system including GMO). The PAA and MS experts should have experience in all GMO-related issues; preferably they should represent governmental agencies as well as research institutions, accredited laboratories and relevant consulting companies from the EU MS. PAA will be located at the Department of Forestry, Nature Conservation and Landscape, Ministry of the Environment.

6.3 Non-standard aspects
There are not any non-standard procedures foreseen. DIS manual will be followed.

6.4. Contracts
Twinning 1.875 MEUR (Phare Support 1.75 MEUR, National Co-financing 0.115 MEUR)
Equipment 1.25 MEUR (Phare Support 1.0 MEUR, National Co-financing 0.25 MEUR)

7. Implementation Schedule
7.1. Start of tendering/call for proposals – March 2002
7.2. Start of project activity – June 2002
7.3 Project completion – May 2004

8. Equal opportunity
It is envisaged that both men and women will be equally treated in all activities. Qualifications, specialization and previous work achievements will be the only criteria for selecting the executors.

9. Environment
This project is aimed at environmental protection. It establishes a protection system (against uncontrolled spreading GMO in the environment, unintended release GMO to the environment), detailed control and monitoring system which reduces GMO’s impact on the environment.

11. Investment criteria: n.a.

12. Conditionality and sequencing
Adoption of the new Act on GMO. On the basis of this law new institutions responsible for GMO should be created. Milestones:
• establishing a competent body which will manage the issues related to GMO,
• establishing the accredited laboratories in selected places in Poland (on the basis of the existing facilities),
• creating the check-points on selected border crossings,
• establishment of the systems of utilizing wastes from GMO,
• establishment of an electronic information system,
• carrying out trainings for supervisory authorities dealing with GMO and education of the public on issues related to the biological safety.
These actions will be conducted concurrently:
• Assessment and validation of research units and other bodies working with GMO;
• Assessment of technical conditions of different research facilities working with GMO;
• Establishment of thorough principles of monitoring and supervision when releasing GMO into the environment;
• Establishment of principles of a monitoring and supervising system when introducing GMO and their products to the environment;
• Verification of existing and establishing new systems of utilizing GMO wastes;
• Establishing communication system which will enable appropriate flow of information,
• Introducing supervision system which will strengthen the country borders,
• Creating information and communication system with the society regarding biological security.
### Annex 1: LOGFRAME PLANNING MATRIX

#### Programme name and number
**Biological safety system** - End Contracting: 15/12/2003 - End Disbursement: 15/12/2004

<table>
<thead>
<tr>
<th>Overall objective</th>
<th>Objectively Verifiable Indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
</tr>
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<tr>
<td>The main long-term objective of the project is to establish a national biological safety system and to participate in the global safety system covering the release of genetically modified organisms (GMO) to the environment and their introduction to the market (turnover).</td>
<td>Accredited, laboratories exist, functioning systems of utilizing GMO wastes, functioning information system on GMO (e.g. web-site and network)</td>
<td>Reports, certificates of accreditation, Internet web-site</td>
<td>Assumptions</td>
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#### Project purpose

<table>
<thead>
<tr>
<th>Objectively Verifiable Indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
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</thead>
<tbody>
<tr>
<td>Support in establishing a competent authority which will manage the issues related to GMO; support in establishing accredited laboratories in selected places in Poland furnished with appropriate equipment and with specially trained human resources. Protect Polish borders by creating check-points on selected border crossings. Establish systems of utilizing wastes from GMO, particularly with regard to bodies working on GMO (e.g. research institutes, sewage plants). Establish an electronic information system for the needs of activities with respect to GMO. Carry out trainings for supervisory authorities dealing with GMO and educate the public on issues related to the biological safety as well as publish and popularize materials concerning GMO.</td>
<td>Efficient information flow (Internet, web-site, publications, databases), functioning system of accredited laboratories, trained staff of the laboratories, trained staff of the supervisory authorities, national GMO authority exist, check-points on borders.</td>
<td>GMO-related issues as the one of the priorities for the Polish government, proper co-operation of all units working on GMO, access to reliable information, available financial sources.</td>
</tr>
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</table>

#### Results

<table>
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<tr>
<th>Objectively Verifiable Indicators</th>
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<td>establishing a coherent security system to ensure that uncontrolled spreading of GMO in the environment, including the introduction of GMO products to the market, will not be possible, control over GMO that are already in the turnover as well as over GMO that are being introduced to the market (full control of GMO before introducing them) through system of accredited laboratories, establishing system of utilizing GMO to prevent the appearance of GMO from uncontrolled sources in the environment (e.g. in case of an accident), organizing an electronic information system and supervision over flow of information concerning GMO in Poland and abroad, familiarizing the society with GMO-related issues, training relevant human resources to ensure efficient and more professional functioning of competent authorities.</td>
<td>functioning security system, including the accredited laboratories, effective data processing, enforced procedures of GMO analyses, functioning databases in Internet available scientific and popular publications</td>
<td>sources of financing available – adequate provision from the state budget, adequate management and available human resources, support from other relevant institutions.</td>
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#### Activities

<table>
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<th>Means</th>
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<td>Verification (validation) of existing institutions and bodies dealing with GMO; Assessment of technical conditions in the research institutions. Establishing precise principles and procedures of monitoring and control with regard to releasing live GMO to the environment, Identifying and purchasing of special laboratory equipment necessary for analyzing DNA. Verification (validation) of existing systems and facilities and creating new systems for management (utilisation) of GMO wastes. Buying (or upgrading) the special equipment for the security system in bodies utilizing wastes of GMO. Implementation of the control system aiming at strengthening the borders. Establishment of databases (purchasing of suitable equipment – hardware and software, trainings; Educating actions (trainings, lectures, publications etc.) for the control authorities and the society.</td>
<td>Effective co-operation with other institutions, Adequate provision from state budget, adequate human resources available.</td>
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**Total budget**: 3.125 MEURO  
**Phare budget**: 2.76 MEUR  
**Date of drafting**: February 2001
**ANNEX 2-4: Implementation, contracting and disbursement schedules**

**PROJECT TITLE:** Implementation of the biological safety system in Poland

| Date of drafting: | February 2001 |
| Planning period: | June 2002 - May 2004 |
| Budget Allocation Cost Estimate | €2.76 M |

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<td>2.76 MEUR</td>
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Legend: D – design of projects / C – tendering and contracting / I - contract implementation and payment