Evaluation of existing active substances and registration and surveillance of biocidal products

1. Basic Information
1.1 CRIS Number: 2005/017-488.03.01
Twinning No.: PL2005/IB/EN/01

1.2 Title: Evaluation of existing active substances and registration and surveillance of biocidal products

1.3 Sector: Free movement of goods
1.4 Location: Poland

2. Objectives
2.1 Overall objective(s)
The main objective of the project is preparation for proper realisation of the 10 – year review programme concerning the evaluation of existing active substances and biocidal products containing those substances as well as strengthening the mechanisms of monitoring biocidal products that have been placed on the market.

2.2 Project purpose
Realisation of number of complex training programmes in the field of EU requirements concerning the evaluation of existing active substances and authorization/registration of biocidal products containing those substances, as well as creation of a database of biocidal products and establishment of the surveillance and information system for biocidal products.

2.3 Justification
According to Chapter 22 “Environment”, of “The comprehensive monitoring report on Poland’s preparations for membership”, Polish legislation concerning chemicals and genetically modified organisms (GMOs) is in place and is in line with the acquis. However, in this comprehensive report, weakness of biocidal products legislation was highlighted. A recommendation was also made, to establish authorization procedures for biocides by accession.

Although EU regulations concerning biocidal products are in the middle of being implemented, there is still a strong need for effective approximation and implementation of European legislation concerning biocidal products registration and assessment of dossiers for active substances for use in biocidal products.

Poland participates in the 10 – year review programme concerning the evaluation of existing active substances and registration of biocidal products containing those substances. From 2007, Poland as the Rapporteur Member State will evaluate complete dossiers for existing active substances, within the specified product type.

This project is supposed to implement procedures which Polish competent authorities will have to carry out during the review programme of existing active substances and during the evaluation of dossiers submitted for authorization of products containing active substance(s) listed in Annex I, IA or IB of Directive 98/8/EC.

The project shall provide personnel training, proper know-how management and information exchange to ensure correct realization of obligations laid on Poland as Rapporteur Member State. Referring to the above elaboration and implementation of a biocidal products database is supposed to be very challenging. Polish authorities up to now were not in the possession of suitable decision-support instruments, therefore
well constructed biocidal products database has fundamental meaning. Efficient communication with dictionaries and scientific databases such as IUCLID, EUSES and QSAR would be a perfect tool to deliver and exchange information, especially in the field of risk assessment and gathering of information related to poisoning arising from biocidal products. Proposed training, administrative capacity building and technical assistance are considerably important and seem to be influential for Biocidal Products Department management.

3. Description
3.1 Background and justification:

In the Biocidal Products Department of the Office for Registration, there is a need for the elaboration of procedures, concerning evaluation of documentation and registration process in order to fulfil the relevant requirements of:


Those requirements are given below:

- Evaluation of complete documentation for active substances for use in biocidal products, which shall be included in Annex I or Annex IA to Directive 98/8/EC, shall be done at Community level in cooperation with all Member States; particularly safety assessment and active substance efficacy;

- Evaluation of biocidal products in accordance with provisions laid down in Annex VI to Directive 98/8/EC;

- Execution of an authorisation procedure concerning placing of biocidal products on the market and authorisation in accordance with the general rules of mutual recognition for biocidal product that already have authorisation for placing on the market in another Member State;

- Elaboration and implementation of a biocidal products database, which shall enable cooperation with such scientific databases as IUCLID (International Uniform Chemical Information Data), EUSES (European Union System for
In European Union Member States, from 14th of May 2000, a 10 – year review programme is being realised for the systematic examination of active substances for use in biocidal products. The 10 – year review programme is supposed to create a “positive list of active substances”, permissible for use in biocidal products. Time limits are set in this programme for assessment of active substances used in particular product types (biocidal products are classified in 23 product types, according to their destination).

From 2007, Poland as a Member State would be responsible for the complex evaluation of the dossiers. Poland would be responsible for the verification of existing active substances, which will be incorporated within Member States on the basis of expected 3rd Review Commission Regulation.

The Office for Registration was a beneficiary of twinning project PL/IB/2002/OT/04, “Strengthening the administrative capacity for risk assessment and chemicals control”. The twinning project between Poland and Austria was carried out in the field of activities described below:

a) the implementation of Directive 98/8/EC;

b) institutional and administrative capacity in Biocidal Products Department of the Office for Registration.

The Austrian Environment Protection Agency Report pointed out the necessity to strengthen the institutional and administrative capacity of the Office for Registration. It will be done with the purpose of effective approximation and implementation of European legislation concerning biocidal products registration and assessment of dossiers for active substances for use in biocidal products. Dossier assessment shall also be carried out for final products. The position of the Office for Registration needs to be established, i.e. through improving personnel qualifications in the field of European issues directly or indirectly connected to biocidal products and management capacity.

This project is supposed to ensure the wider know-how exchange, to simplify personnel training and to enable purchasing of additional equipment, necessary to realise tasks following from obligation laid on Poland, preparation and implementation of a database for Biocidal Products Department in the Office for Registration. The project also provides sub-projects realisation and workshops in the frame of biocidal products.

Facing the fact that the list of active substances for use in biocidal products is being prepared at Community level and the placing of biocidal products on the market goes on in particular Member States; from a commercial point of view very important is also the possibility of mutual recognition of authorisation within the Community. It might therefore be desirable to establish a mutual exchange information system between Member States and the Commission, particularly in case of unexpected risk to people, animals or environment.
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Very important is also the fact that Directive obligates Member States to settle suitable means of control and supervision. It should guarantee that during placing on the market, regulations concerning the placing of biocidal products on the market would be observed.

3.2. Linked activities

- **PHARE 2001 – PL 01.02.03 “Market surveillance medicines and medical devices”** - the main goal of the project was implementation of the surveillance system on medical devices authorized for marketing through: surveillance over the placing on the market and using of the medical devices, registration of medicinal devices and manufacturers, registration of the incidents related to medical devices use.

- **PHARE 2002 – 2002/000-196.02.01 “Strengthening medicinal products surveillance and registration system”** - the main goal of this project was assessment and verification of the responsibilities and organizational structure of the Office for Registration, in the light of compliance with EU standards; evaluation and participation in the necessary additional training programmes in the field of new regulations concerning medicinal products. The projects listed above, realised by Medicinal Products and Medical Devices departments, supported formulation of internal procedures and organisational base for the Office for Registration.

- **PHARE 2002 - PL/IB/2002/OT/04 "Strengthening the administrative capacity for risk assessment and chemicals control".**

The main goal of the project is to improve protection of humans and the environment from adverse effects of chemicals through obtaining information on new chemical substances present in the Polish market, risk assessment of new substances and further improvement of surveillance of placing on the market and the use of chemicals.

3.3. Results

3.3.1 Guidelines and procedures concerning evaluation of dossier of active substances in a 10 – year review programme and dossier of biocidal products elaborated.

3.3.2 50 persons of personnel from the Biocidal Products Department of the Office for Registration and experts from Polish scientific and research institutes, academics from universities and faculties of agriculture, biology, chemistry, representatives of ecological and plant protection Ministries departments, experts in ecology, nutrition, occupational medicine and representatives of relevant associations, which are dealing with evaluation of dossier of active substances and biocidal products trained in the frame of risk assessment, which cover:

- risk to human and animal health,
- risk to environment,
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- means necessary for human, animals and environment protection, both during product application according to its destination and in the worst case of application, which might be predicted in reasonable way.

3.3.3 10 persons of personnel from the Biocidal Products Department of the Office for Registration trained in the field of registration, authorisation and mutual recognition procedures of biocidal products.

3.3.4 6 persons of personnel from the Biocidal Products Department of the Office for Registration trained in the field of amended EU legislation, concerning biocidal products and dangerous substances and preparations, new European Chemical Policy - REACH system (Registration, Evaluation and Authorisation of Chemicals) and borderline cases.

3.3.5 60 persons of State Sanitary Inspection and 10 Trade Inspection inspectors trained in the field of classification, packaging, labelling of biocidal products and materials of safety data sheets according to Directive 1999/45/EC and advertising of biocidal products with the provisions of Directive 98/8/EC

3.3.6 20 persons of personnel from the Biocidal Products Department of the Office for Registration and experts from Polish Toxicological Centres trained in the field of classification and labelling of biocidal products and materials of safety data sheets.

3.3.7 Procedures concerning collecting the information related to poisoning arising from biocidal products elaborated and surveillance system for biocidal products established.

3.3.8 Database of biocidal products listed in Biocidal Products Register managed by President of the Office and database of active substances for use in the biocidal products developed and implemented.

3.4. Activities

Contract 1- twinning

Within the twinning contract the following activities are planned:

3.4.1 Elaboration of the guidelines and procedures concerning evaluation of dossier of active substances in a 10 – year review programme and dossier of biocidal products according to the provisions of:

- Commission Regulation No 1687/2002 of 25 September 2002 on an additional period for notification of certain active substances already on the market for biocidal use as established in Article 4(1) of Regulation (EC) No 1896/2000,
- Commission Regulation No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive
3.4.2 Training for the personnel from the Biocidal Products Department of the Office for Registration dealing with the evaluation of the dossier of active substances and biocidal products in the frame of risk assessment, risk management and risk communication.

3.4.3 Training for the personnel from the Biocidal Products Department of the Office for Registration in the field of registration, authorisation and mutual recognition procedures of biocidal products.

3.4.4 Training for the personnel from the Biocidal Products Department of the Office for Registration in the field of amended EU legislation, concerning biocidal products and dangerous substances and preparations, their classification and labelling, new European Chemical Policy - REACH system (Registration, Evaluation and Authorisation of Chemicals) and borderline cases.

3.4.5 Preparation of procedures enclosing guidelines to ensure that biocidal products are classified, packaged and labelled according to Directive 1999/45/EC, where appropriate, they are accompanied by safety data sheets and their advertising is done in conformity with the provisions of Directive 98/8/EC, to strengthen the system of supervision under biocidal products which have been placed on the market.

3.4.6 Training for personnel of the Biocidal Products Department of the Office for Registration and experts from Polish Toxicological Centres in the field of classification and labelling of biocidal products and materials of safety data sheets and training for personnel of State Sanitary Inspection and Trade Inspection inspectors in the field of classification, packaging, labelling of biocidal products and materials of safety data sheets according to Directive 1999/45/EC and advertising of biocidal products with the provisions of Directive 98/8/EC;

3.4.7 Establishing a system concerning information available in cases where suspected poisoning arises from biocidal products;

3.4.8 Developing and implementation of a database of biocidal products listed in Biocidal Products Register managed by President of the Office and database of active substances enable:
- to communicate with dictionaries and scientific databases (IUCLID - International Uniform Chemical Information Data, EUSES - European Union System for the Evaluation of Substances, QSAR - Quantitative Structure Activity Relationship) to deliver information;
- to assess risk to human health;
- to gather information concerning classification and labelling of active substances and biocidal products;
- to collect safety data sheets;
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- to gather information for purposes of research and technological development;
- to collect information related to poisoning arisen from biocidal products;
- to generate reports for European Commission, being a statutory obligation for President of the Office.

One long-term expert – 15 months permanent stay in Poland

- Responsible for:
  - assistance in preparation for the 10-years review programme concerning evaluation of existing active substances through transmitting of know-how,
  - an implementation of authorisation, registration and mutual recognition procedures concerning biocidal products,
  - organisation of steering committees,
  - preparation of training courses and other activities, including course-papers or presentations,
  - preparation of guidance concerning evaluation of dossier of active substances and dossier of biocidal products for Biocidal Products Department of the Office for Registration and a guidance for surveillance system.

- Requirements: good knowledge and experience in the field of acquis communautaire, EU standards and procedures applied in the EU countries with reference to biocidal products; good knowledge and experience in the field of GLP principles would be highly appreciated.

Short-term experts

Responsible for:
- development of contracts component,
- active support during implementation of suggested issue,
- in particular training of State Sanitary Inspection and Trade Inspection inspectors.

Experts should be the specialists in following areas significant for human and animal health:

1. acute and chronic toxicity;
2. irritation;
3. corrosiveness;
4. sensitization;
5. sub acute toxicity;
6. mutagenicity;
7. carcinogenicity;
8. toxicity for reproduction;
9. neurotoxicity;
10. other specific active substance or substance of concern properties;
11. other results follow the physical and chemical properties;
They also should have knowledge of environmental risk assessment with a special concern of biocidal product properties such as:

1. bioaccumulation;
2. environmental persistence;
3. curve shape of toxicity versus ecotoxicological test time;
4. other harmful effects on the basis of toxicological studies;
5. structural analogue substances data;
6. endocrinal effect.

Study stages
In order to prepare personnel of the Biocidal Products Department for evaluation of active substances risk assessment according to the 10-year review programme, it shall consist in a series of trainings in the EU Member State, having experience in evaluation of active substances listed in Part A and Part B to Commission Regulation No 2032/2003. Such character of trainings is necessary regarding the fact that complete active substance dossier (treated in this case as training materials) is located in the Member State responsible for particular active substance evaluation. The other reason for training in Rapporteur Member State is also the confidential character of some documents and test results, included in dossier.

Study stages are supposed to analyse exemplary documentation step by step and under supervision of experts in charge of particular fields of knowledge necessary for evaluation.

Contract 2- technical assistance

Elaboration of a database of biocidal products listed in Biocidal Products Register managed by President of the Office and also of active substances for use in these biocidal products. The database should also include additional information concerning products, active substances and substances of concern, according to requirements of the poison control centre. The database should enable communication with dictionaries and scientific databases to deliver information. Working on the database shall be carried out by taking into account experiences of Member States which posses these kinds of solutions in registration procedures. Development of the database shall help in informing about potential risk produced by biocidal products. It might help in the functioning of the toxicological centre. The database shall also generate reports concerning each potential harmful effect of biocidal product for people, animals and environment; changes of biocidal product constitution, its active substances, impurities, auxiliary substances or residues. Reports would be prepared for EU Competent Authorities and for European Commission according to statutory obligation of President of the Office. Additionally the database would be helpful in the mutual recognition procedure and registry between Member States of European Union.

The database will be set up by a software Contractor, chosen during a bidding procedure. The selected Contractor would be asked to document experience in realization of similar projects, indicate groups of specialists able to perform established tasks, and present the manner in which they plan to elaborate the database. Technical assistance would be divided into following main phases:

- Inception phase which will assure proper organization and preparation of the technical assistance;
• Analysis phase during which the Contractor will analyse all system requirements and prepare a specification that will constitute the basics for carrying out design and executive works during consecutive phases of the project;

• System design and development phase during which the detailed prerequisites will be determined and system functionality coded;

• Implementation phase during which the contractor will prepare the system for operation and its delivery;

• Stabilisation phase will carry out system tests, solve the remaining problems and correct errors. During this phase training documentation will be prepared as well;

• Completion of technical assistance and acceptance of database elaborated

Service agreement would be a part of contract between Contractor and the Office for Registration. Modification and correction possibilities in constructed database would be provided because of changes and amendments in biocidal products legislation. Therefore service agreement shall include relevant part concerning further development of database.

3.5 Lessons learned

According to conclusions and recommendations of “Comprehensive monitoring report on Poland’s preparations for membership” Polish legislation concerning biocidal products was not completely in line with *acquis communautaire*. Comprehensive monitoring report highlighted strong need for establishment of authorisation procedures for biocides. Therefore special group of experts, responsible for amendment of the Act on Biocidal Products was established. This activity was started in order to adjust Polish legal system concerning biocidal products to Directive 98/8/EC.

However, implementation of the Act on Biocidal Products did not solve all problems in the field of biocidal products. Another difficult issue is lack of professional trainings for personnel of Biocidal Products Department and experts from Polish scientific and research institutes, academics from universities, representatives of Ministries departments and representatives of relevant associations, which are dealing with evaluation of dossier of active substances and biocidal products.

Among others, such conclusions appeared after project “Market surveillance medicines and medical devices” realized within PHARE 2001 – PL 01.02.03 for the benefit of Medicinal Products and Medical Devices departments of the Office for Registration. The goal of the project was participation of personnel from Medicinal Products and Medical Devices in the necessary additional training programmes in the field of new regulations concerning medicinal products. Biocidal Products Department became aware that similar trainings would be significant also for experts from biocidal products field.

Another example might be the project “Strengthening medicinal products surveillance and registration system” realised within PHARE 2002 – 2002/000-196.02.01
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programme for the benefit of Medicinal Products Department of the Office for Registration and interactive database which was created in frame of this programme. Biocidal Products Department did not participate in above project, although personnel are aware how valuable an interactive database might be. Therefore, Biocidal Products Department decided to follow Medicinal Products Department’s example and create similar database for biocidal products.

Personnel from Biocidal Products Department has also an opportunity to attend, in some common seminars and workshops organized in Bureau for Chemical Substances and Preparations, in frame of the project PHARE 2002 - PL/IB/2002/OT/04 "Strengthening the administrative capacity for risk assessment and chemicals control". Issues related to risk assessment and risk management are very important for Biocidal Products Department taking into considerations principles for the evaluation of dossiers for biocidal products.

During seminars organized in Bureau for Chemical Substances and Preparations procedures concerning risk management were briefly explained, including short review of Austrian and Dutch regulations/ institutions. After attendance in those workshops the needs of training, precisely in the field of biocidal products, were underlined in the Office for Registration. The Office for Registration has also an opportunity to participate in small component of above mentioned twinning project PL/IB/2002/OT/04. The purpose of this activity was strengthening the administrative capacity for risk assessment and chemicals control in the field of Directive 98/8/EC implementation and institutional and administrative capacity building in Biocidal Products Department. Co-operation with Austrian Environment Protection Agency and conclusions contained in expert reports pointed out that position of the Office for Registration needs to be established, i.e. through improving personnel qualifications in the field of European issues. Those lessons were really mobilizing and encourage Biocidal Products Department to apply for similar support.

4. Institutional framework

According to the Act of 27 July 2001, on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Dz. U. No 126, item 1379 with amendments), the Office is the state budgetary unit dependant on Ministry of Health. The Biocidal Products Department of the Office for Registration is appropriate for issues regarding quality assessment, efficacy and safety of usage, essential for Ministry of Health in making decision concerning biocidal products in accordance with provisions laid down in the Act of 13 September 2002 (Dz. U. No 175, item 1433 with amendments).

Detailed scope of activity of the Office for Registration and its organisational structure are defined in the Statute of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Official Journal of the Minister of Health of 4 November 2002, No 10, item 58 with amendments). The scope of activity of Biocidal Products Department of the Office for Registration shall include in particular:
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a) preparation of documents being a basis for decision making by the Minister of Health on granting authorisations or registrations for low-risk biocidal products;
b) providing information of required documents and activities for authorisation of biocidal products;
c) keeping the register and registration files for low-risk biocidal products;
d) collecting the information and immediate notifying other Member State and the Commission of any such received information concerning potentially harmful effects of authorised biocidal products for humans, animals or the environment, new composition of a biocidal product, its active substances, impurities or residues;
e) preparation of documents being a basis for a decision by the Minister of Health in cases of unforeseen hazard of target organisms for temporary authorisation for placing on the market of biocidal product containing an active substance which is not included in annexes referred to Art. 6 (3) p. 1 and 2 of Biocidal Products Act, not complying the provisions laid down Art. 4 (2) and Art. 9 (2-6), concerning authorisation the placing of biocidal products on the market and registration of low-risk biocidal products;
f) preparatory actions for decisions of the President of the Office to give a decision concerning the permission for research and development involving the placing on the market of an unauthorised biocidal product or active substance intended exclusively for use in biocidal product.

5. Detailed Budget

<table>
<thead>
<tr>
<th>£M</th>
<th>Transition Facility support</th>
<th>Co-financing</th>
<th>Total cost (TF plus co-financing)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Investment Support</td>
<td>Institution Building</td>
<td>Total Transition Facility (=I+IB)</td>
</tr>
<tr>
<td>contract 1 - Twinning</td>
<td>1 500 000</td>
<td></td>
<td>130 000</td>
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<tr>
<td>contract 2 - TA</td>
<td>750 000</td>
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<tr>
<td>Total</td>
<td>2 250 000</td>
<td></td>
<td>130 000</td>
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</table>

(*) contributions form National, Regional, Local, Municipal authorities, FIs loans to public entities, funds from public enterprises
(/**) private funds, FIs loans to private entities

The amount for co-financing for Contract 1 is entirely parallel co-financing. All costs for study visits outside Poland as part of the Twinning will be borne by the beneficiary country.
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In the case of Joint Co-financing, where the final overall cost is lower than foreseen in the project fiche, the National Public and Transition Facility Co-financing are reduced proportionally so as to maintain the agreed rate of co-financing. In the case of Parallel Co-financing, where the final cost is lower than foreseen in the project fiche, it must be shown that the overall objectives of the project have been fully achieved.

6. Implementation Arrangements

6.1 Implementing Agency

PAO:
Mr Tadeusz Kozek, Under-Secretary of State at the Office of the Committee for European Integration;
Aleje Ujazdowskie 9, 00-918 Warsaw
Phone +48 22 455 52 41   Fax +48 22 455-52-43

CFCU:
Foundation Co-operation Fund, CFCU Director,
ul. Górnośląska 4a, 00-444 Warsaw
Phone +48 22 450-98-90   Fax +48 22 450-99-05

CFCU is responsible for handling tendering, contracting and payments of contracts on behalf of the Minister of Health, who is responsible for preparing and implementation of the project.

6.2 Twinning
Long-term expert and short-term experts will assist in project implementation:
- Long-term expert- 15 months
- Short-term experts- consultations in particular issues defined by beneficent
Beneficent- The Office for Registration of Medicinal Products Medical Devices and Biocidal Products

Contact person:
Anna Strzelczyk - The Office for Registration of Medicinal Products Medical Devices and Biocidal Products;
ul. Żąbkowska 41, 03-736 Warsaw
Phone +48 22 492-12-20   Fax +48 22 492-11-99

Supervision:
Barbara Jaworska-Łuczak - The Office for Registration of Medicinal Products Medical Devices and Biocidal Products

6.3 Non standard aspects
N/A

6.4 Contracts
Contract 1- 1 500 000 Euro + Polish parallel co-financing 130 000 Euro
7. **Implementation Schedule**
Start of tendering/call for proposals
IV quarter 2005
Start of project activity
I quarter 2006
Project Completion
IV quarter 2007

8. **Sustainability**
Sustainability will be in the form of properly developed guidelines and procedures concerning evaluation of dossier of active substances in 10 – year review programme and dossier of biocidal products according to relevant *acquis communautaire*. Surveillance system for biocidal products established according to EU standards.

9. **Conditionality and sequencing**

**Conditionality**
The following conditions are considered essential for the success of this project:
- presence of twinning partner from EU Member State;
- financial support

**Sequencing**
- activity of one long-term expert
- activities of short-term experts
- study stages
- technical assistance [contract 2]

**Main stages**
- knowledge of the staff from Biocidal Products Department of the Office for Registration would be increased in the field of EU requirements concerning the evaluation of existing active substances and registration of biocidal products containing those substances.
- information system regarding poisonings involving biocidal products would be established
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**ANNEX 1 TO PROJECT FISCHE**

<table>
<thead>
<tr>
<th>LOGFRAME PLANNING MATRIX FOR</th>
<th>Programme name and number</th>
</tr>
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<tbody>
<tr>
<td>Evaluation of existing active substances and registration and surveillance of biocidal products</td>
<td></td>
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<tr>
<td><strong>Overall objective</strong></td>
<td><strong>Objectively Verifiable Indicators</strong></td>
</tr>
</tbody>
</table>
| The main objective of the project is preparation for proper realisation of the 10 – year review programme concerning the evaluation of existing active substances and biocidal products containing those substances as well as strengthening the mechanisms of monitoring biocidal products that have been placed on the market. | - existing active substances evaluated by Poland as RMS (1st part since the beginning of 2007 till the end of 2008; 2nd part since the middle of 2008 till 2010);  
- well improved system of monitoring under biocidal products by the end of 2008; | -acceptance of reports prepared for EC- on this basis EC will decide on inclusion of active substance to positive list of active substances;  
-summary report concerning realisation of the project; |
## Project purpose (Immediate Objectives)

Realisation of number of complex trainings programmes in the field of EU requirements concerning the evaluation of existing active substances and authorization/registration of biocidal products containing those substances, as well as creation of a database of biocidal products and establishment of the surveillance and information system for biocidal products.

## Objectively Verifiable Indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Sources of Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>16 dossiers of existing active substances being properly evaluated by Poland as RMS during the 10-year review programme by the end of 2008;</td>
<td>- acceptance of reports prepared for EC on this basis EC will decide on inclusion of active substances to positive list of active substances;</td>
</tr>
<tr>
<td>16 dossiers of existing active substances being properly evaluated by Poland as RMS during the 10-year review programme by the end of 2010;</td>
<td>- positive feedback from applicants and other Member States</td>
</tr>
<tr>
<td>Dossiers of biocidal products being properly evaluated in frame of authorisation procedures - one year from submission of complete dossier;</td>
<td>- experts reports after twinning activities;</td>
</tr>
<tr>
<td>Dossiers of biocidal products being properly evaluated in frame of registration procedures - 60 days from submission of complete dossier;</td>
<td>- database of biocidal products listed in Biocidal Products Register and of active substances for use in these biocidal products</td>
</tr>
<tr>
<td>Proper functioning of mutual recognition of authorisations - 120 days from submission of complete dossier;</td>
<td>- acceptance of reports prepared for EC concerning registration of biocidal products;</td>
</tr>
<tr>
<td>Proper functioning of mutual recognition of registrations - 60 days from submission of complete dossier;</td>
<td>- positive feedback from consumers</td>
</tr>
<tr>
<td>Increased and certified knowledge and competency of the BPD staff by the end of 2008;</td>
<td>- acceptance of reports prepared for EC concerning surveillance of biocidal products placed on Polish market</td>
</tr>
<tr>
<td>Surveillance of biocidal products placed on Polish market fully compliant with EU requirements by the end of 2008;</td>
<td></td>
</tr>
<tr>
<td>Existence of the well managed control system of poisonings induced by biocidal products on Polish market by the end of 2007</td>
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</tbody>
</table>

## Sources of Verification

- acceptance of reports prepared for EC concerning authorisation/registration of biocidal products;
- positive feedback from applicants and other Member States;
- experts reports after twinning activities;
- database of biocidal products listed in Biocidal Products Register and of active substances for use in these biocidal products;
- acceptance of reports prepared for EC concerning surveillance of biocidal products placed on Polish market;
- positive feedback from consumers;
- acceptance of reports prepared for EC concerning control system of poisonings induced by biocidal products;

## Assumptions

- willingness of staff at the Office for Registration and a twinning partner (EU Member State) to work in collaboration and coordination with each other;
- suitable tools to achieve objectives, i.e. proper financial and human management.
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<table>
<thead>
<tr>
<th>Results</th>
<th>Objectively Verifiable Indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Guidelines and procedures concerning evaluation of dossier of active substances in a 10 - year review programme and dossier of biocidal products elaborated.</td>
<td>- guidelines enabling proper evaluation of active substances in 10- year review programme in use by BPD of the Office for Registration by the beginning of 2007;</td>
<td>- acceptance of reports prepared for EC- on this basis EC will decide on inclusion of active substance to positive list of active substances</td>
<td>-effective cooperation between authorities and institutions involved in the project implementation</td>
</tr>
<tr>
<td>2) 50 persons of personnel from the BPD of the Office for Registration and experts from Polish scientific and research institutes trained in the frame of risk assessment,</td>
<td>- guidelines enabling proper evaluation of dossiers of biocidal products in frame of authorisation/ registration procedures</td>
<td>- acceptance of reports prepared for EC concerning authorisation/ registration of biocidal products</td>
<td>-proper management of know-how</td>
</tr>
<tr>
<td>3) 10 persons of personnel from the BPD of the Office for Registration trained in the field of registration, authorisation and mutual recognition procedures of biocidal products.</td>
<td>- certificates to participants issued after training for the BPD of the Office for Registration and experts from Polish scientific and research institutes;</td>
<td>-positive feedback from trainings participants-experts reports after twinning activities;</td>
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<tr>
<td>4) 6 persons of personnel from the BPD of the Office for Registration trained in the field of amended EU legislation, concerning biocidal products and dangerous substances and preparations, new European Chemical Policy - REACH system and borderline cases.</td>
<td>- number of BPD staff and number of experts from Polish scientific and research institutes trained by the middle of 2007;</td>
<td>-protocols of executed training;</td>
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<tr>
<td>5) 60 persons of State Sanitary Inspection and 10 Trade Inspection inspectors trained in the field of classification, packaging, labelling of biocidal products and materials of safety data sheets according to Directive 1999/45/EC and advertising of biocidal products with the provisions of Directive 98/8/EC</td>
<td>- 20 persons of personnel from the BPD of the Office for Registration and experts from polish Toxicological Centres trained in 2007;</td>
<td>-information from training participants;</td>
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<tr>
<td>6) 20 persons of personnel from the BPD of the Office for Registration and experts from Polish Toxicological Centres trained in the field of classification and labelling of biocidal products and materials of safety data sheets.</td>
<td>- 60 representatives of State Sanitary Inspection and 10 inspectors from Trade Inspection better skilled in the filed of classification, packaging, labelling of biocidal products and materials of safety data sheets according to Directive 1999/45/EC and advertising of biocidal products with the provisions of Directive 98/8/EC;</td>
<td>- database of biocidal products listed in Biocidal Products Register and of active substances for use in these biocidal products</td>
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<tr>
<td>7) Procedures concerning collecting the information related to poisoning arising from biocidal products elaborated and surveillance system for biocidal products established.</td>
<td>- rapid situation assessment conducted and report from control systems of poisonings induced by biocidal products available;</td>
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<tr>
<td>8) Database of biocidal products listed in Biocidal Products Register managed by President of the Office and database of active substances for use in the biocidal products developed and implemented.</td>
<td>-database of biocidal products listed in Biocidal Products Register and database of active substances completely developed till the end of the project</td>
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### Evaluation of existing active substances and registration and surveillance of biocidal products

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<tr>
<td>2)</td>
<td>Training for the personnel from the BPD of the Office for Registration dealing with the evaluation of the dossier of active substances and biocidal products in the frame of risk assessment, risk management and risk communication.</td>
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<td>3)</td>
<td>Training for the personnel from the BPD of the Office for Registration in the field of registration, authorisation and mutual recognition procedures of biocidal products.</td>
</tr>
<tr>
<td>4)</td>
<td>Training for the personnel from the BPD of the Office for Registration in the field of amended EU legislation, concerning biocidal products and dangerous substances and preparations, their classification and labelling, new European Chemical Policy - REACH system and borderline cases.</td>
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<td>5)</td>
<td>Preparation of procedures enclosing guidelines to ensure that biocidal products are classified, packaged and labelled according to Directive 1999/45/EC, where appropriate, they are accompanied by safety data sheets and their advertising is done in conformity with the provisions of Directive 98/8/EC, to strengthen the system of supervision under biocidal products which have been placed on the market.</td>
</tr>
<tr>
<td>6)</td>
<td>Training for personnel of the BPD of the Office for Registration and experts from Polish Toxicological Centres in the field of classification and labelling of biocidal products and materials of safety data sheets and training for personnel of State Sanitary Inspection and Trade Inspection inspectors in the field of classification, packaging, labelling of biocidal products and materials of safety data sheets according to Directive 1999/45/EC and advertising of biocidal products with the provisions of Directive 98/8/EC;</td>
</tr>
<tr>
<td>7)</td>
<td>Establishing a system concerning information available in cases where suspected poisoning arises from biocidal products;</td>
</tr>
<tr>
<td>8)</td>
<td>Developing and implementation of a database of biocidal products listed in Biocidal Products Register managed by President of the Office and database of active substances enable:</td>
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</table>

| Contract 1 - twinning | - one long- term expert |
| Contract 2 - technical assistance | - several short term experts |

**Preconditions**
- presence of twinning partner from EU Member State;
- financial support.
## Evaluation of existing active substances and registration and surveillance of biocidal products

### ANNEX 2-3: IMPLEMENTATION, CONTRACTING AND DISBURSEMENT SCHEDULE

**“Evaluation of existing active substances and registration of biocidal products containing those substances”**

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#### Implementation schedule

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#### Contracting schedule

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#### Disbursement schedule

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**Key:**
- D = design of sub-project
- C = tendering and contracting
- I = contract implementation and payment
- * show amounts in Meuro increasingly
ANNEX 4: NEEDS ASSESSMENT

Technical Assistance component included in the project fiche is fully addressed for elaboration of a database of biocidal products listed in Biocidal Products Register managed by President of the Office and also of active substances for use in these biocidal products. Current Biocidal Products Register enables only filling in the data received from applicants. Querying and browsing activities are impossible using current Biocidal Products Register. Importing or exporting data to or from present Register does not function at all. Referring to above working on current Biocidal Products Register is very difficult. Additionally, personnel of Biocidal Products Department finds it hard to use and needs better tool, especially because of future evaluation of dossiers for active substances, especially in the field of potential risk produced by biocidal products. Among others, new database shall enable communication with dictionaries and scientific databases such as IUCLID, EUSES and QSAR, in order to deliver information. The database shall also generate reports concerning each potential harmful effect of biocidal product for people, animals and environment; changes of biocidal product constitution, its active substances, impurities, auxiliary substances or residues.

Within technical assistance none hardware investments are planned. However, Biocidal Products Department has strong need for support in elaboration of proper database. Working on the database shall be based on experiences of other Member States, i.e. twinning partners, which posses these kinds of solutions in registration procedures. There is a need to choose professional and reliable software Contractor, responsible for database elaboration. During inception phase, personnel from Biocidal Products Department in co-operation with IT Unit of the Office for Registration shall discuss and prepare proper organization of technical assistance. During second phase the Contractor shall analyze all system requirements and prepare a specification which will constitute the basics for carrying out design and executive works during consecutive phases of the project. In third phase, called design and development of database, detailed prerequisites shall be determined and system functionality coded. During fourth, implementation phase, the Contractor shall prepare the system for operation and its delivery. Fifth phase shall include system tests and errors corrections. Training documentation will be prepared at the end of technical assistance.