Terms of Reference (ToR) for the project

Part 1

Implementation of the EU System on Chemicals - REACH in Bulgaria

Colophon

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1 Introduction

On behalf of the Netherlands Ministry of Economic Affairs, the Ministry of Foreign Affairs and the Ministry of Housing, Spatial Planning and the Environment, the EVD implements respectively the PSO Pre-accession Programme (PPA), the Matra Pre-accession Projects Programme (MPAP) and the PPA-Environmental Facility (PPA/V).

These Netherlands pre-accession programmes aim to assist the four candidate member states, Bulgaria, Croatia, Romania and Turkey, in meeting the criteria for EU membership through projects dealing with the (consequences of) implementation of European legislation.

The main objective of these programmes is twofold:

- providing assistance to the public sector in the implementation of the *acquis communautaire* or accession related policy;
- establishing lasting relationships between government institutions in The Netherlands and in the recipient countries.

The difference between the three programmes is found in the sectors that are covered: the PPA concentrates on the economic sectors, the MPAP concentrates on the non-economic sectors, and the PPA/V is meant for environmental projects.

The way in which the programmes are arranged in each recipient country is laid down in a policy document, the ‘Memorandum of Understanding’, which forms the legal basis for any activity to be undertaken.

Within the framework of the PPA/V for 2006 the EVD identified the following project in Bulgaria:

<table>
<thead>
<tr>
<th>Title</th>
<th>Implementation of the EU System on Chemicals - REACH in Bulgaria</th>
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<tbody>
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<td>Counterparts</td>
<td>Ministry of Environment and Water</td>
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<td>Beneficiaries</td>
<td>Department on Operative Control and Management of Dangerous</td>
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<td>Substances and the Regional Inspectorates of Environment and</td>
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<td>Water of the Ministry of Environment and Water;</td>
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<td>Economy and Energy</td>
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Duration 24 months

The EVD has formulated the Terms of Reference (ToR) for the project in accordance with the Logical Framework Methodology\(^1\). During the drafting process information and feedback was obtained from the various Bulgarian parties involved and agreement on the content of the ToR was reached with:

- the Department of Operative Control and Management of Dangerous Chemicals of the Ministry of Environment and Water;
- the Division on Protection and Control of Public Health of the Ministry of Health;
- the Department of Free Movement of Goods of the Ministry of Economy and Energy.

These ToR were formulated in full co-operation with the project’s counterpart and beneficiaries and represents all agreements made between the counterpart and beneficiaries and the EVD regarding the framework of the technical assistance foreseen by the project (purpose, results, input of counterpart and beneficiary and required expertise).

The following chapters detail the project design and context, as well as the project organisation, as it was agreed upon with the Bulgarian counterpart and beneficiaries. As such, this document serves as a basis

\(^1\) In annex 1 of the Tender Instructions (part 2) the tenderer may find an information brochure on the Logical Framework Methodology.
for the proposal to be delivered by the tenderer according to the Tender Instructions for the project (part 2).

2 Project context and design

2.1 Overall objective

The project aims to contribute to the accession of Bulgaria to the European Union.

In particular, the project aims to assist Bulgaria with the implementation of the new system on chemicals - the EU Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Accession relevance

The European Commission proposed a new EU regulatory framework for the Registration, Evaluation and Authorisation of Chemicals (REACH) on 29 October 2003 (COM(03) 644). The Council reached a Common Position on 27 June 2006. It is expected that the REACH-regulation will be adopted at the end of 2006.

The aim of REACH is to improve the protection of human health and the environment through the better and earlier identification of the properties of chemical substances. At the same time, innovative capability and competitiveness of the EU chemicals industry should be enhanced. The benefits of the REACH system will come gradually, as more and more substances are phased into REACH.

The REACH system gives greater responsibility to the industry to manage the risks from chemicals and to provide safety information on the substances. Manufacturers and importers will be required to gather information on the properties of their substances, which will help them manage them safely, and to register the information in a central database. An EU Chemicals Agency will act as the central point in the REACH system: it will run the databases necessary to operate the system, co-ordinate the in-depth evaluation of suspicious chemicals and run a public database in which consumers and professionals can find hazard information.

2.2 Problem definition

Institutional setting

The Bulgarian Ministry of Environment and Water (MoEW) is the main competent authority for the implementation of the chemical legislation. In 2003, a new administrative unit on chemicals was established within the MoEW: the Operative Control and Management of Dangerous Substances Department\(^2\). The department consists of 15 experts and is responsible for the notification and the risk assessment of new chemical substances, export/import procedures; bans and restrictions on the marketing and use of certain dangerous chemicals, as well as for the realization of projects and relevant activities in the field of chemicals.

Within the MoEW, the 15 Regional Inspectorates for Environment and Water (RIEWs) are responsible for the enforcement of the chemicals legislation. Approximately 30 experts on chemicals and risk management are appointed for the control of intermediates, banned or severely restricted dangerous chemicals subject to export and import requirements; storage of dangerous chemicals; as well as for the prevention of major accidents involving dangerous substances.

The Ministry of Health (MoH) is responsible for the risk assessment of new substances on human health and the implementation of the legislation in the field of biocides. The administrative unit responsible for

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the implementation of that part of the chemical legislation is the Directorate on Protection and Control of Public Health and consists of 3 experts. The enforcement of the harmonized chemicals legislation is carried out by the regional structures of the Ministry of Health. Over 60 experts in 28 Regional Inspectorates on Control and Protection of Public Health control chemical substances and preparations placed on the market, regarding their classification, packaging and labelling; notified new chemical substances; dangerous chemical substances and preparations, banned or restricted for marketing and use; production of goods, containing banned or restricted dangerous chemicals.

The National Centre for Public Health Protection (NCPHP) is a scientific institute subordinated to the MoH focussing on the following fields: environmental health; occupational health; foods and nutrition; child and schoolchildren's health; communications; behaviour of the health organization; health promotion and disease prevention. The NCPHP assists other governmental bodies, municipal authorities and NGO's in their activities. It also provides consultations to the health administration and the whole health network. NCPHP is involved in international cooperation with EU, WHO, NATO, UNDP, FAO, UNICEF etc.

The Ministry of Economy and Energy (MoEE) is responsible for the negotiations with EU on Chapter 1 “Free movement of goods” including chemicals. The European Integration Directorate co-ordinates the process of transposition of EU rules and elaboration of harmonized Bulgarian chemicals legislation. The experts of the Directorate cooperate with representatives of the chemical industry on a regular basis providing information on EU requirements, new legislation and harmonisation.

The Ministry of Labour and Social Policy (MoLSP) is in charge of the implementation and enforcement of the legislation in the field of health and safety at work. The MoLSP is responsible for the sound risk management of employees at the workplace. It includes both the implementation of Community legislation on occupational health and the national provisions according to the national labour protection legislation. Risk management at the workplace is build upon toxicological information on intrinsic properties of the chemical substances as provided for in the future REACH registration dossier, but specified for the exposure pattern of each workplace scenario. The toxicological evaluation of data on intrinsic properties of a substance and the exposure information relevant for human health consideration is based on the same principles as applied for human health in general and is using the same information on intrinsic properties.

The Bulgarian Chamber of Chemical Industry (BCCI) is a NGO representing the Bulgarian chemical industry. It has been established in 1995, currently has over 60 members and is an associated member of the European Chemical Industry Council, CEFIC. The main objective of the chamber is to assist its members in meeting the requirements of relevant national legislation and to facilitate dialogue between industry and competent authorities. The BCCI participates in discussions on development of the Bulgarian chemical industry, and assists governmental authorities in its work related to the elaboration of environmental legislation and occupational health and safety. The BCCI carries out many activities regarding the implementation of voluntary initiatives of the European Chemical Industries Council “Responsible Care (RC)”, “Industrial Emergency Response System (IERS)”, “Safety and Quality Assessment System (SQAS)” for chemical substances. Through its Responsible Care Committee, the BCCI organizes training, and inspection in companies using this initiative. The BCCI is developing a national scheme called “Transport and Accidents Information Management System” (TAIMS) which aims at providing first level aid during chemical accidents and emergencies.

Current situation

With this harmonisation of EU chemicals law, a completely different scheme for chemicals management was introduced into the Bulgarian legislation. Therefore, a number of projects and activities were undertaken by the Bulgarian authorities in this period in order to support the process of institution building of the Bulgarian administration and to strengthen its readiness to operate in compliance with the EU chemicals legislation.

REACH will change the current system of chemicals management and will bring a new short-term perspective for the Bulgarian administration and the industry to comply with the new legislation while they are lacking practical experience with the implementation of the current system. Bulgaria has not taken part in the REACH preparatory meetings nor the REACH Implementation Projects (RIP.3 en RIP.4) organised by the European Commission. As a consequence, experts at central and regional level have insufficient experience in the practical application of the new harmonized legislation and REACH, enforcement procedures and market surveillance of chemicals. The industry, especially the SME's lack knowledge and awareness of their forthcoming responsibilities under REACH.

Therefore, the Bulgarian authorities would like to learn from the experience gained by the Dutch competent authorities in the implementation of the EU existing substances regulation, particularly the expertise with risk assessment to the human health and the environment of existing chemical substances and the development of corresponding risk reduction measures. The Bulgarian authorities would like to learn from the Dutch experience in the enforcement of the existing chemicals legislation and participation in CLEEN initiatives through exchange of views and experience; possibly elaboration of common enforcement tools; identification of the new needs of competence under REACH and recommendations for reorganisation of the existing enforcement system.

One of the requirements of the REACH Directive is that a national help desk for the industry should be set up. Before this help desk can be established within the MoEW, the scope, the competences and the necessary administrative capacity need to be investigated. This could be done within the underlying project, however, the European Commission Working Group SHERPER is providing assistance to Member States in establishing the national help-desks. Since Bulgaria will be a Member State form January 2007 onwards, in order to prevent any overlap it needs to be investigated during the inception period of the project whether Bulgaria will be included in this training.

The Bulgarian MoEW lacks knowledge and experience in using the REACH-IT system and the IUCLID 5 database for storing substances and REACH data. The database is currently being developed by a OECD Working Group led by the EU. The European Commission will organize a training in the practical application of IUCLID 5 as soon as it is finalized, which is expected to be around June 2007. Therefore, it needs to be investigated during the inception phase whether IUCLID 5 training should be part of the underlying project.

**Project intervention**

The project will provide assistance and strengthen the capacity of the Bulgarian authorities so they are able to revise Bulgarian legislation, to perform their tasks related to REACH and inform the industry about REACH.

First, the REACH provisions need to be explained. Then, the national legislation needs to be assessed and recommendations drafted for necessary changes in the national legislation in order to introduce the REACH provisions. The Bulgarian authorities want the national legislation to lay down the appropriate authority and legal competences of the enforcement bodies under REACH. Moreover, they would like to develop a penalization system applicable to the infringement of those provisions. Secondly, the experts from the relevant ministries need to be trained in dossier evaluation and substances evaluation. Also the guidance documents elaborated under RIP.3 and RIP.4 need to be explained. Furthermore, the experts but also the industry should be trained in the practical application of the REACH-IT system and possibly IUCLID 5, depending on the foreseen training of the European Commission. Finally, the awareness of the industry regarding the REACH Directive and its consequences for the industry needs to raised.
The MoEW feels that the execution of pilot exercises for "pre-registration" and cost analysis for 3 selected chemical enterprises that are subject to REACH provisions could provide the opportunity to test on a limited scale whether the REACH procedures are working well.

Related initiatives (of other donors)

- Phare Twinning project (BG2003/IB-EN/01) “Implementation of the regulations related to the Law on Protection from the Harmful Impact of Chemical Substances and Preparations” executed by the German Ministry for the Environment, Nature Protection and nuclear Safety (BMU). The objective is to assist Bulgaria in aligning the national law, rules and procedures in order to give effect to the EU chemical control legislation, as well as to develop the knowledge concerning the institutional building and the strengthening of the administrative structures, in order to make them capable to implement and enforce the legislation on chemicals.
- Phare Twinning project BG2001/IB-EN/01 “Implementing the Seveso II Directive”- valuable support to industry in its compliance with the Seveso requirements as a result of pilot exercise for development of the documentation necessary for granting permits for 5 selected Seveso pilot enterprises selected on voluntary basis. The overall objective was to support the Republic of Bulgaria in preventing and minimizing the hazards of major industrial accidents through the full harmonization and implementation of the requirements of the Seveso II Directive.
- Phare Twinning project (BG2000/IB-EN/01) “Transposition and basic practical application of the regulations related to the Law on Protection from the Harmful Impact of Chemical Substances and Preparations” (completed) executed by the German BMU. The overall objective was to assist Bulgaria in aligning the national law, rules and procedures in order to give effect to the EU Chemical control legislation, as well as to improve the institutional and administrative framework necessary to implement and enforce the legislation concerning testing and notification of chemical substances and preparations.

2.3 Project purpose

To assist the Bulgarian authorities in the preparation of the new system on chemicals - the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Directive.

2.4 Project results

The following project results are anticipated to be achieved:
1. An advise on necessary chances in national legislation in order to introduce REACH;
2. the Bulgarian authorities are able to perform their tasks in the framework of REACH, including the possible set up of a national REACH help desk;
3. an awareness raising campaign focussed on the industry about the consequences of REACH.

2.5 Types of project activities and methodologies

Considering that most of the project activities are in support of activities to be implemented by the respective beneficiaries, the project's main contribution is to provide them with technical assistance, specifically in terms of project management and technical expertise.

The choice of types of project activities and methodologies is left to the tendering parties. Project results in projects carried out under the framework of the PPA/V are generally achieved by the following type of activities (the list is non-exhaustive):
- analyses, such as SWOT-analysis, GAP-analysis, Force Field analysis, Training Needs Assessment, etc.;
- plans, procedures and strategies, including documents detailing recommendations for the necessary changes;
- documents detailing the implementation of change processes, such as handbooks, manuals, communication plans, management plans, et cetera;
- study visit(s) to relevant institutions in The Netherlands;
• workshops, seminars and conferences;
• training etc.

In order to realise maximum sustainability and impact of the project results, it is advisable to use one or more of the following methodologies: task forces, working groups, counselling, hands on assistance, train-the-trainers and on-the-job training (non-exhaustive list).

2.6 Assumptions and preconditions

It is assumed that during project implementation there is a continued political commitment in both the EU and Bulgaria to European integration. As regards the transposition, implementation and enforcement of relevant *acquis communautaire*, it is assumed that possible changes at political level will not interfere with capacities built and organisational improvements achieved under the project.

It is assumed that all Bulgarian parties involved (ministerial bodies, politicians, NGO's, others) are willing to co-operate in the framework of the project, and will make available (human) resources in order to fully support the project's activities.

It is assumed that the government of Bulgaria will make available sufficient national resources in order to ensure the sustainability of the project’s results.

It is a pre-condition for effective and efficient project implementation that incoming and outgoing missions and other activities are timely planned. This means that both the Dutch and the Bulgarian experts have to take into account the regular tasks of the Bulgarian parties involved and the project activities in which they are engaged. This especially concerns the Operative Control and Management of Dangerous Substances Department of the MoEW and the Directorate on Protection and Control of Public Health of the MoH.

3 Project organisation

3.1 Input provided by the counterpart, beneficiary and contractor

Most activities formulated in these ToR are in support of activities to be implemented by the respective beneficiaries. The institution building nature of this project requires that the counterpart, in co-operation with the respective beneficiaries, assume full responsibility for the implementation of the activities to be supported by the project.

The detailing and/or fine tuning of the input mentioned below by the counterpart and the beneficiary (and if desired other stakeholders) will take place after the start of the project in close consultation between the contractor, the counterpart and the beneficiary. Detailing should be done according to actual circumstances.

Counterpart

The Bulgarian Ministry of Environment and Water will secure the availability of sufficient manpower and expert inputs at counterpart level so as to ensure the successful execution of project implementation activities as well as the project monitoring activities.

Furthermore, the Ministry of Environment and Water will secure a co-ordinator who will be the contact person for the Dutch contractor and the EVD.

The input of the counterparts was agreed upon by means of a Letter of Approval. This letter is attached to these ToR in annex I.
Beneficiaries
The Department of Operative Control and Management of Dangerous Substances and the and the Regional inspection authorities of the MoEW (1), the Division on Protection and Control of Public Health of the MoH (2), the Department of Free Movement of Goods of the MoEE (3) will secure:

- the availability of sufficient manpower and expert inputs at beneficiary level so as to ensure the successful execution of project *implementation activities* as well as the project *monitoring activities*;
- adequate working space for the Netherlands experts carrying out the different activities under the project;
- support to the work of project experts otherwise (such as networking, involving beneficiary organisation, organising arrangements);
- that participants of working visits to The Netherlands have a good written and spoken command of the English language.

The input of the beneficiaries was agreed upon by means of a Letter of Approval. This letter is attached to these ToR in annex II.

Monitoring of the project
A Project Advisory Committee (PAC) will be established to guide and monitor the project.

The PAC should consist of officials who have the responsibility or the mandate to present the views of the Bulgarian counterparts and beneficiaries and who can decide on issues which might influence the project.

Contractor
A (consortium of) Netherlands organisations will be selected through a tendering procedure by the EVD and the responsible Netherlands ministry.

The contractor will be responsible for the implementation of the project. All Dutch institutional, legal and technical experts will in principle be deployed on a short-term basis. The short-term experts should have substantial experience in the relevant subject matter fields.

3.2 Nominated partner
The nominated partners, the Ministry of Housing, Spatial Planning and Environment, Chemicals, Waste and Radiation Protection Directorate (VROM/SAS) and the Expert Centre for Substances of the National Institute for Public Health and the Environment (RIVM/SEC) are the Netherlands public institutions responsible for the implementation of legislation regarding dangerous substances and the introduction of REACH in The Netherlands. The nominated partners should be involved in the specification of the project content and the project planning from the start of the inception phase.

The National Institute for Public Health and the Environment (RIVM) conducts research into public health and environmental issues in the Netherlands. It's Expert Centre for Substances (SEC) is the expert centre of the Netherlands' Administration for problems regarding the hazard and risk assessment and the risk management aspects of chemical substances and genetically modified organisms. These tasks are based on national and international regulations and policies regarding these stressors. SEC also is actively involved in the development of risk assessment methodology. The Chemical Substances Bureau and the Bureau for Genetically Modified Organisms are part of SEC. Pertinent research areas of SEC are human and environmental risk assessment, standard setting, (eco)toxicology, (Q)SARs, and other methods and models for risk assessment.

Participation of the VROM/SAS and RIVM/SEC is necessary from the point of view of realising the project purpose. On the basis of the draft project set up as detailed in chapter 2, it was agreed between the EVD, VROM and RIVM/SEC that participation will take place according to the following mode and intensity:
VROM/SAS will provide expertise for project results 1, 2 and 3. RIVM/SEC will provide expertise for project results 2 and 3. This expertise will cover knowledge and understanding of the current and future chemical legislation as well as strong risk assessment and risk management experiences:

- Thorough understanding and knowledge of the REACH directive and how it has been developed before and during the policy negotiations at the Council and the European Parliament
- Pitfalls and bottlenecks for legal and implementation of the directive
- Thorough understanding and knowledge of the Dutch governmental organization in relation to REACH, including the involvement of the national ministries, institutions and the REACH Helpdesk
- Thorough understanding and knowledge of the REACH Interim Phase, including ongoing and completed work on all the REACH Interim Projects
- Thorough understanding and knowledge of the current chemical legislation related to industrial chemicals, i.e. executing the Dangerous Substance Directive (67/548/EEC), the Existing Substances Regulation (793/93/EC), the Market and Use Directive (76/769/EEC), the Preparations Directive (99/45/EC), the Safety Data Sheets Directive (91/155/EEC), and various related legislation and related guidance documents to these legislations
- Thorough understanding and knowledge of the risk assessment of many types of substances, including industrial chemicals, and including expertise on environmental and human health related toxicological properties, exposure assessment for man (workplace, consumer and man indirect exposed via the environment) and the environment (water, soil, sediment, and air)
- Experienced training in REACH (Estonia, Lithuania) and risk assessment within an international context.

The nominated partners should not be contacted during the tender phase.

### 3.3 Phasing and time schedule

The anticipated duration of the project is 24 months. Provided that the contract for the project will be signed before the end of 2006, the following timeframe will apply:

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</tr>
<tr>
<td>Project inception period</td>
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<tr>
<td>Project implementation period</td>
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<td>Project completion</td>
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