



**Report from the Norwegian Institute of Gene Ecology (GenØk)
to the Norwegian Ministry of Foreign Affairs**

**The Gateways Institutes Program (GIP), a pilot
project.**

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Foreword

This pilot project report is submitted by the Norwegian Institute of Gene Ecology (GenØk) to The Norwegian Ministry of Foreign Affairs (MFA). The one-year pilot project named "The Gateways Institutes of Gene Ecology" was funded by the Ministry from March 2005. The objectives were to initiate institutional research capacity building in biosafety, collaboration and network building between developing countries, GenØk and future Gateways institutes both in the South and in the North.

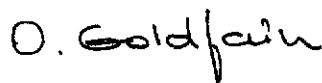
The report may be considered a final report for this year's pilot project, but also a progress report pointing to future needs and collaboration within the initiative.

The project, its outcome and future plans, are highlighted issues that are clearly identified as cooperation needs linked to the action plan for capacity building under the UN Cartagena Protocol on Biosafety. The same needs for research collaboration, technology transfer and network building have also been identified by United Nations Environmental Programme (UNEP) in its Bali Strategic Plan and repeatedly emphasized by many developing countries as an important way forward. This is especially important for the purpose of supporting governments and authorities, in order to enhance capabilities to implement, operate and assess future outstanding issues linked to the Cartagena Protocol at national, regional and global levels. The Action Plan of the Protocol has been revised during the COP/MOP-3 meeting in Brazil in March 2006, where representatives from GenØk also met with a number of the collaborating partners under the Gateways initiative.

With GenØk becoming a "National Competence Centre in Biosafety", as outlined in the Norwegian Government Platform 2005-2009, it will certainly increase its abilities and ambitions to take on board new challenges. This will be done in pace with its institutional expansion, development and increased capability, including further capacity building initiatives, besides the necessary and highly needed biosafety research activities.

As the conclusions and suggestions in this report show, it is extremely important to continue the Gateways initiative.

Tromsø, May 19th 2006.



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General Manager



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Introduction

The idea and initiative of the Gateways Institutes Program has been elaborated in cooperation between GenØk and the New Zealand Institute of Gene Ecology (NZIGE). The draft project document for “The Gateways Institutes Program (GIP)” was written and prepared during the autumn of 2004 in collaboration between GenØk, NZIGE and the United Nations Environment Programme (UNEP). For further reading regarding the Gateways initiative, see the draft GIP document from April 2005 (attached as Annex I).

GenØk has had a Memorandum of Understanding (MoU) with UNEP since February 2004, linked to GenØk’s general capacity building program in biosafety. The MoU was finalised in December 2005. The collaboration with UNEP included the International Holistic Training Courses in Tromsø, the Master education program, the Forecast Service Database and a book/CD-ROM. It also included a Norwegian GenØk representative working at UNEP’s head office in Nairobi for six months, until March 2005. The MoU with UNEP was signed before the plans of the Gateways Institute Program were initiated.

Under the pilot project period from April last year GenØk has been carrying out feasibility studies in Zambia, Ethiopia and China in order to explore the possibilities for cooperation with institutions in the South. The outcome has so far been a signed MoU with “The National Institute for Scientific and Industrial Research (NISIR)” of Zambia (see annex II), and a signed MoU with “The Nanjing Institute of Environmental Sciences (NIES/SEPA)” of China. Meetings with the Ethiopian Environmental Protection Agency (EPA) and the Mekelle University, with the initial aim of building a future regional Gateways institute in Ethiopia, were also undertaken. All the institutions involved have national responsibilities connected to implementation of the Cartagena Protocol on Biosafety, except for the Mekelle University in Ethiopia. There have also been some preliminary discussions with representatives from research institutions in Saudi Arabia and the Solomon Islands with the aim of future research collaboration linked to the Gateways network.

In connection with the meetings in Ethiopia, Zambia and China, information exchange meetings with the Norwegian Embassies in the respective countries were organized, including a meeting with representatives from the Embassy in Bangkok, Thailand.

Based on an initiative from GenØk in collaboration with the “Deutsche Gesellschaft fuer Technische Zusammenarbeit (GTZ)” and the German Federal Ministry for Economic Cooperation and Development (BMZ), a European workshop was organized in Germany. Several donor institutions (including the EU Commission) and research institutions working with biosafety research and capacity building initiatives in developing countries participated. The outcome is the “European Network on Biosafety Research and Capacity Building” that will keep regularly meetings with the aim of cooperation and harmonization of joint efforts. The report and its recommendations (see attachment III) were made available at COP/MOP 3, as document UNEP/CBD/BS/COP-MOP/3/INF/10.

GenØk has recently received a grant from the Norwegian *Fredskorpset* on a 2-year exchange of research personnel between NISIR and GenØk.

Summary

This report summarise the different meetings and achievements that has taken place under the one year pilot project of “The Gateways Institute Program”. The report gives at the same time recommendations for how the initiative could be further developed.

In connection with visits to the countries within the program, it has been arranged information exchange meetings with the Norwegian Embassies. The Gateways initiative has also had close collaboration with representatives from the “Deutsche Gesellschaft fuer Technische Zusammenarbeit (GTZ)”. This German governmental donor institution has offices both in Ethiopia and China, and has at the same time collaboration with the African Union regarding detection laboratories for GMOs. The collaboration between GTZ and GenØk included their participation at the meetings in Zambia and Ethiopia, and an arrangement of a workshop in Germany for European institutions involved in biosafety capacity building.

In chapter 1. Zambia, we describe the meetings and discussions that ended with a signed Memorandum of Understanding (MoU) in August 2005 between GenØk and the National Institute for Scientific and Industrial Research (NISIR) of Zambia. The MoU was clearly supported by the board and the Technical Committee of NISIR. The MoU received also full support at a high level meeting at the Ministry of Science Technology and Vocational Training (MSTVT), which is the Zambian ministry with the main responsibility for NISIR. The objective of the MoU is to promote research co-operation in connection with the following activities:

- a) Take necessary measures towards the establishment of the Gene Ecology Institute of Southern Africa (GEISA) as a member of the Gateways Institute Network,;
- b) Training and education of Zambian scientists at MSc and PhD levels; and
- c) Exchange of scientists between GENØK and NISIR, and the other Gateways institutes within the Network.

Connected to the collaboration between the two institutions it was taken an initiative for an application under the main program of the Norwegian Fredskorpset. A two-year exchange program of scientific staff was granted in March 2006 and the exchange between the institutions will start in June 2006.

In chapter 2. Ethiopia, we describe the outcome of the meetings and plans we have initiated in Ethiopia. The discussions elaborated in cooperation with the Ethiopian Environmental Protection Agency (EPA) who is supporting and willing to join Gateways Institutes network. The Mekelle University has been proposed as a host institution for the Gateways institute. GenØk is awaiting a final draft proposal for the initiative from the university, and will most probably have follow-up meetings with the University and the EPA later this year.

In chapter 3. China, the initiatives and outcome of the meetings between the State Environmental Protection Administration (SEPA), the Nanjing Institute of Environmental Sciences (NIES) and GenØk is reported. The discussions concluded with a broad support for entering into a similar MoU between NIES and GenØk, as the one between NISIR of Zambia and GenØk. NIES and SEPA were invited to Norway. A delegation with four representatives from both institutions arrived in Norway on 7th May 2006 and a MoU was signed between NIES and GenØk 10th of May 2006. It was arranged a meeting in Oslo between the delegation, the Ministry of Environment, the Ministry of Foreign Affairs and GenØk. It was also arranged a meeting with the Biotechnology Advisory Board and a 3 day visit to GenØk and the University of Tromsø.

In chapter 4. “The Gateways Institute Program (GIP)”, the present situation and the future needs for the Gateways initiative are discussed. The pilot project has had high activity, and from GenØks point of view, satisfactory results. The need for biosafety research activities and collaboration between the developed and the developing countries is increasing. In this regard the focus on biosafety capacity building has never been more urgent than at present, both due to lack of necessary biosafety

knowledge and the rapid development and dissemination of gene technologies and GMOs worldwide. Issues covered in the draft Gateways document are therefore explained, with emphasis on e.g. training in biosafety research and detection methodologies, and collaboration regional, south-south and south-north.

The workshop arranged in collaboration with GTZ, that established the “European Network on Biosafety Research and Capacity Building” is also reported. The workshop gave clear recommendations for capacity building linked to research as well as the need for European cooperation regarding future biosafety capacity building activities initiated in Europe.

Initial discussions with institutes from Saudi Arabia and the Solomon Islands regarding future research collaboration and linkages to the Gateways initiative are also described in this chapter.

In chapter 5. Economy and Finances, we explain the need for funding the future planned activities under the Gateways initiative, especially with emphasis on Zambia and China. The pilot project has entirely been dependent on the finances provided by MFA. The pilot project should although also be seen in light of the ongoing capacity building initiatives at GenØk, financed by NORAD, as an initial trigger for the Gateways initiative.

It is expected that establishment of Gateways Institutes in Zambia and China are dependent on economic support for a period of up to 5 years. It is also expected that China will be able to carry more of the initial costs of establishing a biosafety research institute than Zambia, but both countries are clearly in need of economic support in establishing biosafety research activities at their new laboratories.

In chapter 6. Final Conclusions and Recommendations, the plans and recommendations for activities, prioritisation and building the future for the Gateways initiative are described in 9 points. The two major challenges will first be to secure funding for further activities and to secure capacity at GenØk to take on board the challenges. It is therefore recommended that a “secretariat” to be established at GenØk in order to administrate and coordinate the Gateways network.

To build the European network, with collaboration and harmonisation of biosafety capacity building as the main objective, should be further elaborated. In this regard the donor institutions of Europe will be invited in a common effort to initiate biosafety projects in developing countries, in line with the action plan of the Cartagena protocol.

All the activities and initiatives linked to the Gateways program, also the European network initiative, are today completely dependent on GenØk as the steering and driving force. A consequence of this is that the whole Gateways Institutes Program is very vulnerable without a solid basis at, and a comprehensive involvement by, GenØk.

1. Zambia

1.1 Meetings in Zambia and Norway to facilitate collaboration between NISIR and GenØk

During GenØk's mission to Zambia there were carried out meetings and discussions with the National Institute for Scientific and Industrial Research (NISIR), the Ministry of Science Technology and Vocational Training and the Norwegian Embassy in Lusaka. A representative from the German GTZ was invited to attend the meetings. The reason for this is the common interests of GenØk and GTZ to build biosafety capacity in Africa. GTZ has already different ongoing biosafety activities in collaboration with the African Union. Future co-operation between GenØk and GTZ regarding building research institutions and detection laboratories in developing countries is feasible, and therefore seen as a possible and welcoming co-operation.

Meetings at NISIR

At the first meeting at NISIR we were introduced to the major tasks of the institute and updated on the ongoing activities at NISIR funded by NORAD and being partly implemented through the collaboration with the Norwegian Directorate for Nature Management (DN). We were shown the laboratories under renovation, which are located at the shared premises between the Zambian Seed Certification Institute and NISIR. The already ongoing biosafety project at NISIR, founded by NORAD, was seen as a very good basis for developing future research collaboration under the gateways initiative between NISIR and GenØk. The possibility to transform also other laboratories and buildings into appropriate biosafety research facilities was also seen as reasonable, and could clearly be linked to a future Gateways institute at NISIR.

During the meeting it was stated that the importance of the laboratory had been stressed repeatedly by the Zambian private sector, namely the exporters who want to guarantee GMO-free commodities. Zambia has a close co-operation with Namibia, which also insists on GMO-free maize imports, where import mainly takes place from South Africa.

At a later meeting in December 2005 the laboratory was inspected once more, revealing that the almost finalised facility was ready to receive the necessary instruments and equipment needed for future detection and research activities.

The second meeting at NISIR was conducted in present of the Technical Committee of NISIR. The outcome of the meeting was that the Technical Committee of NISIR advised the Board of Directors of NISIR to enter into co-operation with GenØk on the Gateways Institute Initiative. Due to the highly common opinion and interests regarding the need for biosafety research activities between NISIR and GenØk, it was decided to start the drafting of a MoU as prompt as possible.

Meeting at Ministry of Science Technology and Vocational Training (MSTVT)

Collaboration between GenØk and NISIR on the Gateways found support during the high-level meeting at the MSTVT in April 2005. The meeting was attended by the acting Permanent Secretary and the Directors of Development & Planning, Human Resources & Administration and Vocational Training & Enterprises.

1.2 Meetings with the Norwegian Embassy in Lusaka

The meeting with the Norwegian Embassy in Lusaka was kept mainly in order to exchange information regarding the collaboration between NISIR and GenØk. It was also a purpose of the meeting to receive information regarding the Norwegian biosafety project in Zambia and to discuss possible future support from the Embassy for the Gateways initiative. It was expected that Zambia through MSTVT and NISIR would apply for further support from the Norwegian Government through

the Embassy in Lusaka, both for a continuation and expansion of the ongoing biosafety project. If the NISIR/GenØk gateways collaboration was linked to a future *Zambian project application*, the representative from the Embassy expected that a possible implementation of the project would be administrated by the Norwegian Embassy, as is the case with the ongoing project.

1.3 Meeting at the Directorate for Nature Management regarding a new application for biosafety support from NISIR and MSTVT

The issue of a new application from Zambia for support from Norway, including the laboratory at NISIR and the collaboration under the gateways initiative, was also raised in a meeting at The Directorate for Nature Management (DN) in October 2005. On the basis of a draft application document made by MSTVT and NISIR, the future *Zambian request for Norwegian support and collaboration in biosafety management, GMO-detection and needed research* was discussed. At the meeting it was stated by the representatives from NISIR and MSTVT that an integration of a future Gateways Research Institute linked to the new laboratory of NISIR, was one of several *Zambian intentions within the future project application and collaboration with Norway*.

1.4 The memorandum of understanding (MoU) between NISIR and GenØk (annex II)

As a follow up on the meetings in Zambia, the discussions and drafting of the MoU took place through e-mail and during the meetings of the parties (MOP 2) to the Cartagena protocol that took place in May 2005. The MoU between GenØk and NISIR was signed during the International Biosafety Course in Tromsø in August 2005. The principal objective of the MoU is to promote co-operation between the Parties in the following activities:

- a) Take necessary measures towards the establishment of the Gene Ecology Institute of Southern Africa (GEISA) as a member of the Gateways Institute Network.;
- b) Training and education of *Zambian scientists at M.Sc and PhD levels; and*
- c) Exchange of scientists between GENØK and NISIR, and the other Gateways institutes within the Network.

1.5 Future research collaboration between NISIR and GenØk linked to the main program of Fredskorpset

In December 2005 representatives from GenØk undertook a feasibility study at NISIR in order to determine the basis for an exchange project and to contribute to the creation of a sound partnership agreement. The Norwegian *Fredskorpset* has granted an application for an exchange program, where two researches from NISIR and one from GenØk will be spending 2 and 1 year in the respective institutions, starting in June 2006. The aim and objectives of the project under Fredskorpset has been separated into the three following main areas:

- a) To scientifically collaborate in a comprehensive research project with the aim of increasing important knowledge and data regarding possible health and environmental effects from genetically modified organisms (GMOs).
- b) To enhance the capability and potential of both research institutions with regard to a long-term collaboration under the Gateways Institutes Program (GIP).
- c) To increase the potential of NISIR, and hence *Zambian authorities, to handle biosafety issues linked to the implementation of the National biosafety regulations, management procedures and needed biosafety research activities in support of the UN Cartagena Protocol on biosafety.*

The collaboration between NISIR and GenØk regarding point b) above should also be seen in light of the future establishment of a “Gene Ecology Institute of Southern Africa (GEISA)” at NISIR, intended to become a member of the Gateways Institutes Program.

At the present NISIR has only one qualified scientist working in their laboratory. The laboratory, therefore, requires qualified and experienced *Zambian scientists and technical staff in the future*. The practical training of research staff in appropriate instrument use and calibration, research and detection methodologies, combined with increased theoretical knowledge regarding gene technologies and

possible effects from GMOs on environment and health, will be an expected outcome of this exchange program. The training and achieved knowledge will benefit both NISIR as a research institution and as an institution implementing the Cartagena Protocol at the National level, including an increased fundament for providing appropriate recommendations to authorities and the Zambian Government.

This type of training, in order to build research and laboratory capacity, is from GenØks perspective essential for the future collaboration between NISIR and GenØk. This will build a fundament for a possible long-term research co-operation under the planned network of the Gateways Institutes Program.

1.6. Conclusions and future prospective - Zambia

The collaboration with NISIR has had a positive start where much has been achieved during the one year pilot project. The exchange program via Fredskorpset is the first initial practical cooperation, in a hopefully, long lasting research collaboration between the two institutions.

The first main challenge to be solved in order to achieve the objective will be to secure the initial needed 5 year funding for NISIR to establish the Gene Ecology Institute of Southern Africa (GEISA) and develop it into a regional biosafety research institute of excellence. National support and prioritisation from relevant Ministries and the Government are necessary to achieve this goal. So far MSTVT has given support in refurbishing the facilities of the new laboratory at NISIR, and Norway has funded the purchase of necessary laboratory equipment and instruments for GMO detection and research. It is not expected that Zambia and NISIR will manage to build the GEISA institute without external support and funding from Norway, or other western countries with bilateral collaboration with Zambia. Due to this situation it is important that a new biosafety project application from Zambia, that is intended to be finalised in the late spring of 2006, is met with realistic economical frames and support to enable the establishment of the GEISA at NISIR.

There are also some preliminary plans for exchange of researchers and technical staff between Gateways Institutes south-south, especially between the future GEISA institute and the Nanjing Institute of Environmental Science (NIES) in China. This will most probably be initiated in the near future through an application under the south-south program of the Norwegian Fredskorpset.

2. Ethiopia

2.1. Meetings in Ethiopia to facilitate a future Gateway Research Institute in Ethiopia.

During the mission to Africa in April 2005 the group from GenØk, and the representative from GTZ, had meetings with the Ethiopian Environmental Protection Authority (EPA) and the Norwegian Embassy in Addis Ababa.

Meeting with the Environmental Protection Authority (EPA).

The meeting with EPA took place at their premises in Addis Ababa where the Executive Director informed about EPA's role as a policy making and implementing authority. EPA is the focal point for the Cartagena protocol in Ethiopia and reports directly to the Parliament and the Prime Minister. Ethiopia has ratified the protocol and has also developed a National Biosafety Framework (NBF), and a draft biosafety law is due to be debated in Parliament.

The newly installed laboratories at EPA, which are used for federal environmental monitoring tasks, were also visited. The respective legal framework for environmental monitoring was created two years ago, followed by setting up national norms and standards. The laboratories with its 10 employees are functional and provide sufficient space for many working places. The analytical instruments are

modern and cover a broad range of methodology. The laboratory has no trained staff in biosafety research and detection analysis, nor any equipment to perform standard gene and protein analysis needed for biosafety research and detection of GMOs.

In the meeting GenØk presented the Gateways initiative and highlighted important perspectives linked to the research field of Gene Ecology, and the philosophy behind the initiative. EPA had received a copy of the draft Gateways Institutes Program (GIP) document, and from the discussions it was clear that EPA was interested in establishing a regional Gateways Institute in Ethiopia. A Gateways Institute taking a holistic approach towards biosafety should be as independent as possible, but can for example be located linked to a multidisciplinary university. A Gateways Institute should not directly be subordinated a governmental body, which may exclude e.g. EPA as a host institution. GMO detection laboratories, which are used for monitoring tasks by authorities, may although be located in governmental laboratories.

During the meeting two alternatives for the host of a possible future Gateways institute were discussed; the University of Addis Ababa and the Mekelle University. The Mekelle University had already received the draft GIP plans and gave a written response linked to a possible Gateways Institute at their University. The Mekelle University is one of the youngest universities in Ethiopia, has a good research record and an extensive experience in bilateral and multilateral cooperation. It also seems to be the most suitable with its agricultural, biological and social sciences. It was therefore also suggested by the Executive Director of EPA that the Mekelle University most probably was the best alternative of the two universities. An institute linked to the laboratory facilities of EPA should although not be completely excluded.

2.2. *Meetings with the Norwegian Embassy in Addis Ababa*

At the meeting with the Embassy Secretary of the Norwegian Embassy, GenØk presented the Gateways initiative, the pilot project funded by the Norwegian Ministry of Foreign Affairs, and the issues discussed at the preliminary meeting with EPA. GenØk also received information about the Norwegian official presence and collaboration in Ethiopia. The Embassy had a positive impression of the Mekelle University, a university that was well known by the Embassy and has received several research and training grants from Norway.

2.3. *Possible collaboration with GTZ and the African Union in Ethiopia.*

GTZ has an office in Ethiopia and ongoing collaboration with the African Union (AU) regarding biosafety capacity building, especially connected to detection of GMOs. It was therefore also discussed the possibility of joint effort and co-operation between the Gateways initiative and a future German technical project linked to laboratory detection of GMOs in Ethiopia. The common methodological concepts, biosafety training and capacity building, including financial considerations, clearly favour an approach that combines future collaboration between a Gateways Institute and the GTZ initiatives in Ethiopia.

At a short meeting with a representative from the secretariat of the AU it was informed about the Gateways Institutes initiative in Africa and the possible collaboration between GTZ and GenØk in this regard. During the discussion it became quite clear that support for this biosafety capacity building initiative in Africa was highly requested from the AU, and that a letter of recommendation was a possible outcome of the meeting. Unfortunately it has recently become clear that the representative from the AU secretariat has stopped working with the AU, and the request has therefore most probably not been dealt with.

The issue of future collaboration between GenØk and GTZ, and also other European donor implementing agencies and research institutions, is discussed later in the conclusion of the report under point 4.4, page 15.

2.4. Meeting in Norway with the vice-chancellor of the Mekelle University.

In connection with a visit at the University of Trondheim in November 2005 by the vice-chancellor of the Mekelle University, it was arranged a meeting with two representatives from GenØk. GenØk received comprehensive information about the Mekelle University, its historical background, educational system, faculties and to some degree research activities. GenØk informed about the GenØk foundation, the ongoing research and capacity building activities, the Gateways Institute initiative in Zambia and China, and the discussions we had at the meetings with EPA in Ethiopia.

2.5. Conclusions - Ethiopia:

It was planned a visit to the Mekelle University by two representatives from GenØk in November 2005, but unfortunately due to busy schedules this was not possible to realise. The Mekelle University is going to make a revised draft plan for a future Gateways Institute at the university in lines with the comments received from GenØk and EPA. When the draft plans are finalised it is expected that representatives from GenØk will visit EPA and the Mekelle University in order to discuss future plans of collaboration.

3. China

3.1 Meetings in China to facilitate a future Gateways Institute in China and research collaboration between the Nanjing Institute and GenØk.

During the mission to China in October 2005, it was arranged two meetings with the State Environmental Protection Administration (SEPA) and several meetings with the Nanjing Institute of Environmental Sciences (NIES). It was also arranged an information meeting with the Norwegian Embassy in Beijing and a discussion meeting with the Science and Technology Counsellor. The meetings in China were organised back-to-back with a Chinese biosafety workshop where three representatives from GenØk gave presentations.

Meetings at the State Environmental Protection Administration (SEPA)

At the first meeting with SEPA, where also representatives from NIES were present, GenØk gave an overall presentation of the institute's activities, the Biosafety Capacity Building Program and the Gateways Institute Program (GIP). SEPA presented information about their environmental responsibilities as an authority and especially the activities of the department of Nature and Ecology Conservation, which was the host of the meeting. At the meeting the institutions entered fast into initial discussions on the possible future cooperation between SEPA, NIES and GenØk regarding establishment of a Gateways Institute of Gene Ecology in China. NIES was seen as one of the most probable candidate to host such a new institute. All institutions expressed strong interest in exploring the possibility of cooperation. The in-depth discussions between the institutes were undertaken at two meetings in Nanjing.

During the workshop in Nanjing it was arranged a second meeting with SEPA where the Director General of SEPA was present. The discussion that was started at SEPA in Beijing on possibilities of the establishment of a Gateways Institute of Gene Ecology within NIES was elaborated and received full support. It was agreed to enter into a MoU between SEPA, NIES and GenØk.

Meetings at the Nanjing Institute of Environmental Sciences (NIES)

At the meeting at NIES, where the Director and the Deputy Director were present, we were provided with the detailed information on the institutional structure, personnel, research activities, the newly

build laboratory facilities and their national and international cooperation. The role of NIES is e.g. to provide technical support to SEPA and to participate in environmental negotiations. NIES is also appointed the National Focal Point for the Cartagena protocol in China and the biosafety laboratory at NIES is a key-laboratory for SEPA in this regard.

GenØk provided information on its institutional structure, biosafety capacity building and research activities. Both SEPA and NIES expressed a wish to join the Gateways Institute Program (GIP) through the establishment of a Gateways Institute of Gene Ecology at NIES. NIES proposed 3 types of activities for a possible future Gateway Institute; i) Scientific studies on biosafety, ii) Biosafety training, and iii) Expertise cooperation and exchange.

3.2. *Meetings with the Norwegian Embassy in Beijing*

The meeting with the Counsellor of Science and Technology from the Norwegian Embassy took place just after the first meetings with SEPA and NIES in order to inform about the possible cooperation between SEPA, NIES and GenØk. It was therefore important to receive the Counsellors perspective and opinions regarding different relevant scientific institutions in China, with the intention to find appropriate partners for future collaboration with GenØk. It was suggested that NIES might be an appropriate partner for collaboration under a possible future Gateways network in China. At the meeting with the Embassy general exchange of information took place, where GenØk informed about the Biosafety Capacity Building Program (funded by NORAD) and the Gateways Institute Program (pilot project funded by MFA). The representatives from the Embassy gave a comprehensive introduction to the relevant collaboration between China and Norway. The issues of China as a developing country, but with many recourses and high capability to take care of national problems, were discussed in the context of a possible future Norwegian support for a Gateways project at NIES. It was not seen any possibilities for this type of project within the Embassies economy and framework for cooperation in China today. A possible support for a future gateways project will therefore have to be prioritised and generated directly via MFA or NORAD. Although it might be relevant for the Embassy to supervise and implement the project if funding is received.

3.3. *Conclusion and action plan developed after the meetings in China*

GenØk invited SEPA and NIES to visit Norway in May 2006. It was agreed that a MoU between SEPA, NIES and GenØk could possibly be signed in Tromsø, May 2006. It was also suggested an internal workshop between the institutions for closer discussions on cooperation and to write request for economically support from the Norwegian Government during the spring of 2006.

There is an existing MoU between SEPA and the Norwegian Ministry of Environment. It is therefore a possibility, if all parties agree to such an approach, to link the MoU between NIES and GenØk to this already existing MoU.

GenØk will initiate an application to the Norwegian Fredskorpset for a grant under their program for exchange of researchers between GenØk and NIES, but also between NIES and NISIR of Zambia. Possible candidates for the reciprocal exchange will be chosen by the three institutions if the project application is granted.

GenØk will accept 1-2 participants from SEPA or NIES to attend the annual international biosafety course in Tromsø summer 2006.

3.4. *Meeting with representatives from the Embassy in Bangkok, Thailand.*

At the way back from China to Norway, two representatives from GenØk undertook an information exchange meeting with representatives from the Norwegian Embassy in Bangkok and one visiting representative from NORAD. The reason for this meeting was the need to learn more about possible institutions for future biosafety collaboration in the region. It was also conducted in order to inform the Embassy of the activities under the Gateways program, and the other capacity building initiatives of GenØk.

GenØk presented the general problems with biosafety in developing countries and explained the initiatives and plans for collaboration with China, Zambia and Ethiopia. The then planned biosafety training course that took place in Indonesia in January 2006, was also an issue that was discussed. The need for biosafety support regarding training, management, research and detection of GMOs connected to the implementation of the Cartagena protocol within the South-East Asian region was explained, including GenØk's possible roles and function linked to the Gateways initiative in this regard. The representatives from the Embassy presented their views on possible collaboration with the Embassy and asked questions regarding biosafety capacity building needs in general. At the moment the Embassy had no relevant programs going on within the region that could take on board biosafety capacity building, but the impression was clearly that it was possible in the future to collaborate with GenØk to take initiatives in the region if funding was made available.

3.5. Meetings in Oslo and Tromsø 7th to 11th May 2006.

The delegation with four representatives from SEPA and NIES arrived in Norway on 7th May 2006 to continue discussions that took place in China in the fall of 2005. It was arranged a meeting in Oslo between the delegation, the Ministry of Environment (NME), the Ministry of Foreign Affairs (MFA) and GenØk. At the meeting hosted by the NME general information about the two Chinese institutions was provided in the context of biosafety responsibilities, biosafety and biotechnology activities in China. Representatives from the ministry of Environment gave an overview of the Norwegian Gene Technology Act and the implementation of the Cartagena Protocol in Norway. A clear support for a MoU and future collaboration between NIES/SEPA and GenØk was stated by the NME. It was a clear understanding that future collaboration between the NME, MFA and SEPA, regarding biosafety issues, was a possibility that may be elaborated.

It was also arranged a meeting with the Norwegian Biotechnology Advisory Board in Oslo where the mandate, tasks and responsibilities of the board were presented. The delegation went for a 3-day visit to GenØk in Tromsø. In addition to the in-depth discussions at GenØk the Chinese delegation had meetings with the Chancellor of University of Tromsø, several institutes at the University and the Polar Environmental Centre.

The outcome of the meetings with GenØk was a signed MoU between NIES/SEPA and GenØk (Attachment IV). In addition to the MoU it was made a short strategy plan for the future collaboration. This encompasses a workshop that is planned to be held in China in October 2006. The main objective of the workshop is to elaborate the content of the research collaboration and the exchange and training of the personnel. It will also be taken initiatives for applications of an exchange program under *Fredskorpset*.

4. The Gateways Institute Program (GIP)

4.1. The present situation

On the basis of the inquiries GenØk has received, and the meetings that have been arranged regarding the Gateways Institute Program during the year of the pilot project, it has become quite clear that there is an extensive international interest for the program. This should be seen in light of the a global development linked to gene technology, export, import and marketing of GMOs, when at the same time essential scientific concerns for environment and health safety has not been properly solved.

The number of parties to the Cartagena Protocol has rapidly increased. Today 132 countries have ratified the protocol. The need for capacity building as a follow up on implementation of the protocol in developing countries is seen as one of the major obstacles for a successful functioning protocol. Lack of legal frameworks and regulations, as well as trained and educated staff among national authorities, are still areas of concern, although many developing countries have made National Biosafety Frameworks and some have implemented laws and regulations. Control and management

requirements for handling and stopping illegal import, but also to prevent the possibility of exporting GMOs illegal to other countries, are of major concerns. So are also the lack of knowledge regarding the possible effects on environment and health at the national and regional levels from these activities.

Different issues covered in the draft Gateways Institute Program document, e.g. i) development of biosafety research institutions and competence, ii) training in biosafety research and detection methodologies, iii) building of laboratories, iv) need for instruments and training in proper usage, and v) research collaboration regional, south-south and south-north, are still some of the highest priorities among developing countries.

4.2. *Future collaboration and development of institutions under the Gateways initiative*

Preferably it should be one to two Gateways Institutes within each of the UN regions. At the moment it is one institute in Norway (GenØk) and in New Zealand (NIZIGE), one under establishment in Zambia (GEISA), hopefully one in China soon, and possibly one in Ethiopia not too far into the future. There are plans for initiating new institutes in South and North America, where the need for Gateways collaboration is seen to be very important due to the fast development and use of GMOs in this part of the world.

GenØk has also had preliminary discussions with a Saudi Arabian Governmental research institution, who expressed a clear interest in research collaboration within the Gateways network. After discussions and meeting with a representative from a research institution at the Solomon Islands, the Environmental Minister from the Solomon Islands wrote a letter to the Executive Director of UNEP, stating their supporting for the Gateways network and their interest in building a Gateways institute for the Pacific Islands region at the Solomon Islands. At the moment there are no further discussions with the Solomon Islands. Future research cooperation is planned with the Saudi Arabian research institution, but whether this activity will take place under the Gateways initiative will still have to be discussed with representatives from the institute and the Saudi Arabian authorities.

4.3. *Planned educational possibilities linked to the future Gateways network*

GenØk is localised with the head office at the premises of the Science Park in Tromsø and have both its origin and its laboratories at the University of Tromsø. It is therefore a formalised and close collaboration with the University, especially with the Institute of Medical Biology and the Institute of Pharmacology at the Medical Faculty, as the closest collaborating institutes. Future plans within the Gateways network include education of students at the Master and PhD levels in biosafety. This education will take place through a planned new curriculum in close collaboration with the Tromsø University. In this regard it is also an on-going collaboration with the Global Virtual University (GVU) at GRID Arendal and the United Nations University (UNU) in Tokyo. Hopefully students from different parts of the world can start education in the "holistic biosafety approach" under this new curriculum from year 2007, including the teaching supervisors from GenØk and other institutions within the Gateways network.

4.4. *Collaboration with institutions in Europe*

As outlined in chapter 2, GenØk has started a preliminary collaboration with GTZ, especially linked to possible detection laboratories for GMOs in Africa. In this respect a representative from GTZ was invited to participate at the first meetings in Ethiopia and Zambia. In the future this collaboration may be formalised and also extended to other countries and regions in the world where a Gateways Institute initiative may take place, e.g. China where GTZ already have many activities.

During the autumn of 2005, GenØk and representatives from GTZ and the German BMZ initiated the workshop "European Responsibility for Biosafety Cooperation" that was arranged in Königswinter near Bonn from 8-9th November 2005.

The workshop had representatives both from the EU Commission and Austria, which at the moment hold the Presidency of the EU countries. There were also representatives from research groups,

authorities and institutions involved in capacity building from Switzerland, Germany, United Kingdom, Denmark, Finland and Norway. Some of the representatives are also cooperating with GenØk as presenters and resource persons at the International Biosafety Course in Tromsø, and others have research collaboration with scientists at GenØk.

Representatives from relevant biosafety research projects including capacity building programs and projects for developing countries and the Gateways Initiative were presented at the workshop.

The following 5 points were the major conclusions from the workshop:

1. The participants of the meeting agreed to form a "European Network on Biosafety Research and Capacity Building" for creating better synergies between the existing and future efforts in biosafety research and capacity building in the developing countries. The areas of cooperation within the "European Coalition on Biosafety Research and Capacity Building" should be defined by commonly identified knowledge as well as policy gaps and mapping our own resources.
2. In 2006, GenØk will coordinate the activities of the Network. The internet-based Biosafety Clearing-House should be used to retrieve and disseminate information about cooperation and projects as well as assessment of need and priorities settings.
3. The "Königswinter Workshop" is recommended to be convened once a year. The next workshop is envisaged for May 2006 with the aim to foster the dialog between researchers, implementing organisations and donors.
4. Programmes and projects with developing countries should take into account the recommendations of the "Königswinter Workshop" on scientific research and risk assessment, public participation in risk assessment & decision making, and socio-economic considerations.
5. The "European Network on Biosafety Research and Capacity Building" will provide their respective national administrations with ideas and recommendations regarding biosafety research and capacity building in the developing countries on following issues:
 - a) Review of the Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety
 - b) Questionnaire for the Comprehensive Review of the Action Plan
 - c) Decision documents for COP-MOP-3.

This information can also be brought to the attention of the incoming Austrian Presidency, respectively the European Commission.

The report from the workshop is attached as annex III. BMZ sent the report to the secretariat of the Cartagena protocol and the report was available at COP/MOP 3, as document UNEP/CBD/BS/COP-MOP/3/INF/10.

The next meeting of the new established "European Network on Biosafety Research and Capacity Building" is scheduled to take place in May-June 2006. The intention is especially to invite representatives from the donor institutions of Europe, with the main objective to find common grounds for biosafety initiatives and collaboration connected to biosafety research and capacity building in developing countries.

4.5. Conclusions – The Gateways Institutes Program

The pilot project "the Gateways Institutes Program" started in Mars 2005, has had high activity, and from GenØks point of view, satisfactory results. The need for biosafety research activities and collaboration between developed and developing countries is increasing. In this regard the need for capacity building has never been more urgent than today, both due to lack of necessary biosafety knowledge and the rapid development and dissemination of gene technologies and GMOs worldwide.

This situation is the ultimate cause for both the development of the Gateways Institutes and the need for expanding the initiative to the other parts of the world as fast as possible, e.g. the South East Asia, the Pacific region, the Arabian Peninsula, South and North America. In most regions there are appropriate scientific institutions and scientists that are willing to host a new Gateways Institute. Many

developing country authorities and Governments will most probably entail collaboration linked to *future biosafety research as the basis for comprehensive and effective implementation of the Cartagena Protocol*.

It is also a need for future cooperation with other research institutions in Norway linked to the Gateways initiative. This cooperation can take many directions, e.g. involvement in training of researchers and staff from the Gateways Institutes, and/or direct collaboration connected to research projects.

The start of “The European Network on Biosafety research and Capacity Building” is a positive development that may benefit biosafety initiatives and capacity building in developing countries in the future, and therefore also the Gateways initiative. It is crucial to bring other donor institutions of Europe into a closer cooperation connected to biosafety initiatives, including the Gateways initiative. The National donor institutions of Europe will therefore be especially invited to the next network meeting.

All the activities and initiatives linked to the Gateways program, also the European network initiative, are today completely dependent on GenØk as the steering and driving force. A consequence of this is that the whole Gateways Institutes Program is very vulnerable without a solid basis at, and a comprehensive involvement by, GenØk. This involvement includes appropriate and sufficient work capacity and a secure economic situation for GenØk. The same will be the situation for the future individual National Gateways Institutes within the different developing countries. Without clear support and priority from their relevant authorities, ministries and Governments, will most probably any initiations of new regional Gateways Institutes fail. The same will be the situation if not sufficient initial funding from donor partners of Europe is made available for new Gateways Institutions.

5. Economy and Financing

5.1. Future Economy and budget needs

The realisation of the Gateways pilot project was entirely dependent on funding from The Norwegian Ministry of Foreign Affairs. It can also be stated that the support from NORAD, for the biosafety capacity building program at GenØk that is now going on for the fourth year, was an initial economic trigger also entailing the fundament that the Gateways initiative is resting on.

If future plans and progression of the Gateways Institutes Program (GIP) shall be realised, it will depend on two initial sorts of finances, National economic support in the recipient country and the possibility for external donor financing. The funding will most probably be dependent on National Governmental prioritisation and the economy of the research institution initiating and hosting the Gateways Institute. Varying possibilities of national economic contribution is expected. The need for external donor finances is therefore also something that is expected to vary between countries when building a regional Gateways Institute. The initial research capacity, necessary facilities and infrastructure, including the general status of the hosting institution in question, will also influence the level of needed contribution.

Future initiatives in Ethiopia have been postponed due to GenØks lack of capacity. The same is the situation with new Gateways initiatives in other countries or regions, which will have to be discussed and planned at a later stage of the Gateways development.

5.2. *Expected needs for financial support to NISIR in Zambia*

Of the ongoing described Gateways initiatives in this report, it is expected that NISIR in Zambia will be the first institution to need financial support from Norway. In accordance with the calculated budget in the draft GIP document this will require approximately 20 mill NOK for an initial period of 3-5 years. After this initial period it is expected that the need for support will fall due to finances generated through the institutes own activity at the national, regional and international level, especially through the Gateways network collaboration. It is therefore difficult to plan for a longer period than 5 years. As described in chapter 1 regarding Zambia, a request for financial support in spring 2006 connected to the continuation of the ongoing biosafety project will include a proposal for establishment of the GEISA institute at NISIR.

5.3 *Expected needs for financial support to NIES in China*

The Nanjing Institute for Environmental Science (NIES) is a well-established Governmental research institute under SEPA that has recently build new laboratories appropriate for biosafety research. China has also a high ongoing research and development activity connected to production of GMOs, including release of different GM-plant species and varieties into the environment as field experiments. It is almost no biosafety research activity going on in connection with these experiments. It is therefore a comprehensive potential and a need for relevant biosafety studies in China.

A Gateways Institute at NIES is expected to need financial support during the initial phase of 3-5 years. The support is needed in order to purchase necessary instruments and equipment, but also to initiate biosafety research projects at the institute. To build up a Gateways Institute at NIES that have 15-20 employees after a period of 5 years, is expected to need approximately 7-10 mill NOK in support. It is expected that China will be able to carry much of the initial costs involved, and they also have a better starting point than many other developing countries when it comes to relevant education, training and research facilities.

6. Final conclusions and recommendations

6.1. *Recommendations for the future of the Gateways initiative*

This report shows clearly the potential and clear need for the Gateways Institutes Program as a capacity building initiative where the following 9 points can be seen as the major recommendations for further activities:

- The pilot Gateways project to be converted into a continuing program of biosafety capacity building and research cooperation. The establishment of Gateways institutions in a south-south and south-north collaborating network, in line with the intentions of the draft Gateways Institutes Program document, is the main objective.
- To elaborate the possibilities of the support to the Gateways Institutes of NISIR and NIES for the period from 2006 to 2011.
- Meetings and discussions regarding a possible Gateways Institute in Ethiopia to take place later in 2006.
- Further initiatives, e.g. in China, linked to the exchange programs of the Norwegian Fredskorpset to be envisaged.
- An official initiative to request support from other collaborating donor institutions in Europe, in order to establish regional Gateways Institutes e.g. in other parts of the world to be undertaken
- The collaboration with GTZ that may also support new Gateways institutes in the future to be continued.

- The capacity building network and research collaboration linked to relevant European donor and research institutions to be further expanded and elaborated.
- A “secretariat” with the main function to administrate and coordinate the Gateways network, including the collaboration between GenØk and the Gateways Institutes and other cooperating partners, to be established at GenØk in due time.
- A clear “mandate”, which includes description of roles, philosophy, principles and research programs, to be made with regard to how the Gateways Institute collaboration and network should best function in the future. This may be developed at a meeting or workshop where representatives from all relevant Gateways Institutes take part.

Capacity building through technology transfer, education, training and collaboration are essential issues for safer management of gene technology, development and usage of GMOs in the future. The future Gateways Institutes will aim and work towards resolving these issues by becoming independent and unbiased research centres of excellence within biosafety. The further development of the initiative will follow the objectives of the draft GIP document, and will in all respect support the capacity building intentions of the Cartagena Protocol on Biosafety.

THE GATEWAYS INSTITUTES OF GENE ECOLOGY (DRAFT)

**Portals to Holistic, Independent Research and Biosafety Competence Related to
Genetic Engineering (GE) and Genetically Modified Organisms (GMOs) in
Developing Countries.**

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1. Introduction

The Cartagena Protocol (CP) on Biosafety to the Convention on Biological Diversity entered into force 11th September 2003. By 14th March 2005, 116 countries have ratified the protocol, and amongst those developing countries are making up the majority. The need for capacity building in these countries is well documented in workshops and documents connected to the Cartagena Protocol. A major issue in connection with the protocol is appropriate capacity building and technology transfer that enables developing countries to fulfil their obligations under the protocol. This is a challenge that will require cooperation at national, regional and even the international levels, including a high standard of teaching, training and methodology transfer from countries with institutions experienced in handling safety in relation to modern biotechnology. At the moment many developing countries are developing and some implementing their national biosafety policy, regulations and management systems as a part of the ongoing UNEP/GEF biosafety projects. This will enable the countries to build up a system of regulations and management to a certain degree, however the necessary scientific and social-scientific risk-related knowledge and institutional capacity to support governments and authorities would still be lacking.

Economic analysts have predicted that by year 2025, 70% of the global industry and 40% of the total world economy will be based on modern biotechnology, and thereby GMO related production lines. A number of the conceived but still hypothetical hazards and harms may display qualitative and quantitative variation due to the influence of local or regional environmental and social factors. Hence, relevant risk research and governance must be carried out locally within a precautionary, holistic context combining ecological, ethical, socio-economical, health, cultural and legal issues. The ecosystems and societies in the South are, for various reasons, the most vulnerable with regard to many of the putative risks.

In addition to the transgenic modification techniques that have been applied so far, products being, or containing molecules derived from, so-called *nanobiotechnology* and/or *RNA interference*, may be marketed in a not too distant future. These new techniques and their practical applications represent opportunities for better predictions, prevention and treatment of ecosystem, human and animal health problems. But they also imply new putative risks adding to those related to the now traditional transgenic techniques. Furthermore, new and enhanced risk issues connected to transgenic applications will be conceived as “molecular pharming” and animal transgenic “bioreactors” become realities.

The issue of uncertainty and lack of knowledge regarding potential hazards and risks of biotechnology, together with strengthening capacity building, is elaborated in the report by the UN Secretary General “Promoting the application of science and technology to meet the Development Goals contained in the Millennium Declaration” (UN, Economic and Social Council, E/CN.16/2004/2. 7 April 2004). The report states that many developing countries lack scientific and administrative expertise and that implementation of safety regimes may encounter difficulties due to lack of technical capacities. It is further proposed that one possible way forward is to build regional capabilities to oversee the implementation of safety regimes, and that countries could pool resources together on a regional basis to develop regional scientific and administrative capabilities for the implementation of safety regimes. This is consistent with Principle 9 of the Rio Declaration on Environment and Development which says that: “States should cooperate to strengthen endogenous capacity-building for sustainable development by improving scientific understanding through exchanges of scientific and technological knowledge, and by enhancing the development, adaptation, diffusion and transfer of technologies, including new and innovative technologies”.

As stated by important UN documents very few developing countries have the capacity to *conduct risk-related research and appropriate risk assessments connected to new applications of GMOs for deliberate or experimental release*. This applies also for LMOs in containment

intended for research or production purposes. There is also a lack of knowledge and capacity regarding how to test, identify and control GMOs that may be imported together with conventional seeds, food and feed, and in this regard enable governments to prevent import that may violate national regulations or obligations under the Cartagena Protocol. Underlying this is the global challenge of developing modern biotechnology in a sound and transparent manner without negative ecosystem and human health effects, within the framework of sustainable development aiming towards equal sharing of the future benefits from modern biotechnology.

The Gateways Institutes Program is an initiative for supporting countries that wish to fulfil their obligations under the Cartagena Protocol. The Gateways Institutes constitute a network of applied and basic research institutions intended to operate within national and regional frameworks, to serve as centres for coordination of biosafety research and implementation in their regions, and to train researchers and other personnel categories necessary to fill knowledge gaps and improve GE/GMO related biosafety. Each Institute is to be supported by the network through exchanges of staff and open communication of techniques and knowledge, and combining their efforts at raising the profile of biosafety nationally and internationally.

This document presents the basic concepts behind the Gateways Institutes and their intended roles in supplying host societies with the necessary biosafety capacity required by the Cartagena Protocol. It must, however, be emphasized that the research programs of the Institutes will be of general interest and importance, supplying the international society with badly needed research results. That capacity is synonymous with skills for detecting, preventing and treating new diseases, securing intellectual property rights and monitoring environmental threats and harms of all kinds. Under the Gateways banner, the ultimate goal of research is applied biosafety, i.e. being able to take out the benefits of GE/GMO applications in safe ways. Those countries that are flying the Gateways flag will be in the first world for biosafety.

2. The Gateways founding and first member institutes

The name "Gateways Institutes" derives from the history and geography of the first two Institutes of Gene Ecology, located in Tromsø, Norway (Norwegian Institute of Gene Ecology - GenØk) and Christchurch, New Zealand (New Zealand Institute of Gene Ecology - NZIGE). The name was chosen to reflect the historical fact that Christchurch, and Tromsø, were the respective "gateways" to the South and North Poles, the last ports before the explorers entered their final legs towards the South and the North Poles. When discussing a common name for the family of gene ecology institutes, the directors of the two gene ecology institutes realized that the "Gateways" concept was ideal for the present purpose, i.e. establishing institutes that would be "gateways" for access to independent, integrated, and innovative competence building and research within the novel research field of gene ecology.

An explicit goal of the Institutes is to have them grow into facilities that serve to build global capacity in biosafety, converting research and training in biosafety into enlightened regulation and policy throughout the world. The commitment and ability to deliver on this critical goal has already been demonstrated by the launch of the international GE/GMO Biosafety Course and Biosafety Forecast Service, along with numerous research grants operating out of GenØk and the NZIGE, pending research initiatives, and the series of recent research articles in high-impact international science journals.

Gene Ecology is a new interdisciplinary scientific field that is unique in its combination of genetics and biochemistry with bioethics, the philosophy of science, and social studies of science and technology. It builds on innovative work in the areas of genomics, proteomics, food science, ecology, evolution, intellectual property, indigenous rights, participatory

technology assessment, and globalization. This synthetic approach reverses the trend toward the more reductionist qualities of some of the component sciences. Gene Ecology is rapidly becoming a central discipline for drug design and for the comprehensive evaluation of gene-based technologies.

From a scientific point of view, GenØk and NZIGE are complementing each other within the total framework of disciplines and research areas relevant to gene ecology.

3. The idea and philosophy behind the Gateways Institutes

Biosafety research is not a hobby. Effective and reliable biosafety research requires personnel with cutting-edge skills in a variety of disciplines and the right kind of environment in which to apply those skills. Critical to the achievement of a performing biosafety sector is the creation of institutions that have no interests or bias that could undermine a commitment to research guided by the precautionary principle and the public good. Every Gateways Institute must offer long-term security and competitive career pathways for dedicated “biosafety engineers”; it must attract and retain the highest possible research talent and build prestige and pride among colleagues that grows interest and innovation in biosafety outcomes locally and internationally.

In most cases the physical starting point of a Gateways Institute would preferably and ideally be an already existing research facility. Both the founding institutes emerged from a university department, but other types of publicly funded research institutions, i.e. National Institutes of Health or Environmental Research Institutes, may represent good logistic starting points. However, to find a suitable institutional platform for indisputable independence should be the most important issue, during the initial phases as well as the long-term activities of a Gateways Institute. It may be suggested that national research and competence-building foundations, based on the model regulations provided by GenØk and affiliated, or engaged in collaborative research work, with regional, global or supra-national organization, may be the best way to go.

It is important that the researchers and the staff are devoted to the research activity and to the application of biosafety at the highest standard possible, have backgrounds or dispositions that ensure their abilities to collaborate across traditional discipline boundaries, and have an ongoing commitment to work in the public interest. The development of crosscutting activities in both social and natural sciences will build capacity to handle issues linked to GMOs and molecular genetics, ecology, access and utilization of genetic resources, risks and benefits in a real-world (i.e., social) context. The intention of these “holistic” approaches is to gain highly needed scientific (including social-scientific) knowledge that will support governments and authorities in taking decisions related to GMOs and genetic engineering applications in the future.

There are good reasons to be particular with regard to the genuine independence of risk-related research and competence building:

- The public, consumer organizations, green NGOs etc will not accept that scientific results obtained by the GE/GMO producers themselves, or producer-associated research groups, form the basis for the risk management of their countries and societies.
- University research institutes with relevant competence are increasingly made dependent on corporative support.
- The independent research groups base their starting hypotheses and their project designs on the Precautionary Principle. This in its turn leads to research substantially

unequivocal to approaches starting with assumptions of safety and “substantial equivalence”.

The direct and indirect spin-off effects of the Gateways Institutes Program include:

- Universally important research otherwise not performed.
- Development of generally applicable sampling and analysis methods otherwise not developed.
- Avoidance of economic losses due to export product GMO contamination detected by recipients.
- Capacity and know-how to implement bio-prospecting (“gene hunting”) in own ecosystems, and secure maximal benefits for local and national interests.

The Gateways Institutes Program will help provide support to young National Biosafety Frameworks (NBF). Gateways Institutes will be centers of biosafety capacity building through ongoing research on biosafety and knowledge/skill transfer within their regional homes. Through these activities, the Gateways Institutes will support authorities and decision-makers with highly needed scientific and social information necessary to make appropriate decisions in accordance with the provisions of the Cartagena Protocol. Furthermore, the Gateways Institutes will contribute to filling the universal void in knowledge concerning the characteristics and consequences of any transgenic construct or organism under all the different ecological and socioeconomic conditions where it will conceivably be used. This knowledge void is the core in many unsettled controversies between the different stakeholders all over the world.

4. Organization and Management

All institutes should be totally independent and run/directed by local/regional resource persons. At the same time all efforts and activities should be coordinated so that all knowledge and competence obtained by one of the members will be instantly shared with the others. The best organizational basis for obtaining these goals would be non-profit, national/regional Gateways foundations with a coordinating umbrella “the Gateways Institute Coordination Center”.

Each foundation should be a legal subject with a responsible Board and a local administration. The regulations and management rules of GenØk may be used as a template for working out regulations according to the specific requirements of each institute.

The secretariat and the Executive Director of the Gateways Institutes will be located at the Gateways Institute Coordination Center.

5. Training, equipment and research needs Salient features of the Gateways Institutes.

Some of the important issues regarding appropriate laboratory equipment, training of staff in research methodologies and technologies, and collaboration for support of applied cross-cutting research activities in the new Gateways institutes, are summarized in the following points:

- *Practical teaching of methodologies and techniques needed at the Gateways institutes, to increase knowledge and research activities connected to environmental and health biosafety issues, shall be conducted as a part of the Gateways cooperation programs.*
- The Gateways institutes will need up-to-date facilities and laboratory equipment to conduct the necessary research activities in scientifically appropriate ways.

- It is necessary that resource personnel and staff participate in both practical and theoretical courses and training programs. *The coordination of such activities will be an important part of the integrated Gateways Institutes network and collaboration.*
- Identification of the practical research needs has to be performed at the national and regional level, in collaboration with governments, authorities, Gateways members or other cooperating research institutes. The aims of such processes are to conceive and capture local and regional research challenges with regard to knowledge gaps concerning possible ecosystem and human health impacts of present and future GE/GMO applications.
- The Gateways Institutes will make joint research efforts, support specific projects of any member institute, and carry out confirmatory testing when required. The Gateways Institutes will cooperate with any relevant research group in order to obtain robust answers to important questions. GENØK and NZIGE are already cooperating with a number of high competence institutions all over the world.
- Competence Building will be achieved through PhD students and Post-doctorates, with rotation periods between Gateways Institutes built into their curricula. The long-term result will be "adult" researchers with more precautionary, holistic and broad-minded scientific starting points for their research hypotheses, questions and designs.
- *Additional roles of the founding Gateway Institutes will be development of specialized M.Sc. courses.*

The founding Gateways Institutes (GenØk and NZIGE) will serve as mentoring and training foci for Institutes as they come on line, and as ongoing partners in the network. The work at these centers will include research on organizational structures that promote independence, transparency and responsiveness to public research needs.

Online Master of Science Program

GenØk/NZIGE in cooperation with the University of Tromsø and the University of Canterbury are at the moment developing a specialization in the Master of Science Program under The Global Environment and Development Studies (GEDS) called "Gene Ecology and Holistic GE/GMO Risk Assessment" in cooperation with the United Nations University/Global Virtual University (UNU/GVU).

The courses/study material that GenØk and NZIGE already has available will be combined with the e-learning pedagogical expertise at the Global Virtual University and made available as an online Master of Science Program for potential students all over the world.

The target group will be policy-and decision-makers, both at administrative and political levels; persons working in management positions at the state, regional and municipal levels, as well as students in the area of ecology, environment, environmental law and agriculture, social sciences, medicine and journalism/mass media. Prerequisites will be a bachelor's degree in a relevant area of study (see annex 1 for further information).

Annual Biosafety Course Program

GenØk and NZIGE have already initiated and launched a biosafety course with financial support from the government of Norway, and in kind support as well as volunteers from New Zealand and Malaysia. This annual biosafety course is also one of the items embraced by the Memorandum of Understanding (MoU) between UNEP and GenØk. The first course was launched in Tomsø in 2003 and had 49 participants from 41 countries, and the second course in 2004 had 51 participants from 42 countries. The number of lecturers and resource persons

attending was 29 the first year and 22 the second. The “raison d’être” for the course is illustrated by the 2004 application data: 376 very highly qualified applicants from nearly 120 countries. The capacity of the laboratory exercises of the course restricts the number of participants to 50, and hence the course should be repeated 1-2 times each year.

The biosafety course is designed to provide high-level policy makers, regulators, scientists, and representatives from NGOs and civil society, especially from developing countries, countries with economies in transition and small island states, with knowledge and training in crucial genetic engineering and GMO issues. Through lectures, laboratory hands-on exercises and demonstrations, group work on case studies and moderated discussions, biosafety capacity building within a holistic framework is offered. The intention is that the course will be followed up by local and/or regional courses organized by the course alumni and staff from within the Gateways Institutes network, and an alumni network service will be established in order to secure continued exchange of information and new scientific knowledge. The participant evaluations have been highly favourable both years. An expert evaluation committee assigned by the Norwegian Ministry of Foreign Affairs gave the course a very high rating, and recommended that it be made into an annual core event, accompanied by regional and local courses.

Development of a Handbook/CD-ROM on Biosafety

In connection with the course an initiative has been taken to develop a Book/CD-ROM with the working title, “Foundations of Gene Ecology and Holistic Approaches to Risk Assessment of Genetic Engineering”. The book is being developed as a text for a course designed to train, or augment the training of, those involved in risk assessment procedures or who must understand how risk assessments are done. Using the important example of genetic modification as a case topic, the book is intended to serve as an introduction to the technical issues of risk assessment. The technical issues range from cultural and social, through economic and political, to molecular, food and environmental sciences. The book would aim for the Scientific American level reader, thus suiting undergraduate and graduate students in any of the relevant disciplines, or university academics and other professionals looking for an introduction to topics outside their immediate expertise. The Book/CD-ROM will be automatically updated and re-edited regularly during the course preparatory activity period.

The practical component of the course guide would detail the design of laboratory-based experiments in molecular genetic techniques. Thus, students using this book as a text would have their theory grounded in experience. The experiments would be suited to those with no prior laboratory experience, and thus could be used to teach in a variety of university, community outreach, and professional courses. Some students interested in such a course would undoubtedly already have advanced training in molecular techniques. Such students may substitute the laboratory component with projects that extend their knowledge in economics or the social sciences.

6. National, regional and international cooperation

The need for global cooperation within the field of biosafety is obvious, and is the main reason behind the strong focus on biosafety issues within the Convention on Biodiversity, including the mandate and the negotiation of the Cartagena protocol. As an example, in Europe biosafety cooperation has been implemented between the EU countries and the research institutions of the EU Commission, e.g. Joint Research Center (JRC). Biosafety research collaboration is also exerted under various EU research programs. The aim of this research is e.g. to increase knowledge regarding biosafety issues linked to GMOs, to monitor GMOs, and to develop better methods for detection and identification of GMOs and GM-products. This research and collaboration activity serves as a means towards appropriate management and handling of GMOs and GM processed products in accordance with the

different EU directives and regulations concerning biosafety, and will enable the European countries to fulfill their obligations under the Cartagena Protocol.

Provision of a Biosafety Forecast Service

Developing countries have the same needs for independent biosafety research and information collaboration as EU. The Gateways Institutes will contribute to this end through network building, training and cooperation resulting in increased knowledge, and serve their governments, authorities and society with updated relevant research and information connected to biosafety issues and modern biotechnology in general. It is important to emphasize that results obtained in one part of the world cannot be used to directly extrapolate how a given GMO and transgene will behave in another part of the world. Consequently, studies performed in ecosystems/models specific for any locality or region is important for the whole world.

As a part of the collaboration between GenØk and NZIGE a “Biosafety Forecast Service” is now being implemented. It will be a free-to-the-public database devoted to the dissemination of information from the elite scientific and technical literature to policy and regulatory officials in government, NGOs and the interested public, and specialist researchers in academia and industry. The Forecast Service will be accessible to those of all training and knowledge backgrounds and assist the user in finding the research relevant to their specific needs.

So far in the history of GE/GMO applications, risk-related research has been lagging significantly behind product development and commercialization. That is why the Forecast Service is not simply a passive guide to complex literature, but provides support for assessing generic and specific issues of risk in applying GMOs. An associated goal of the Forecast is to identify areas of uncertainty and potential risk issues in emerging areas of biotechnology. This may lead to relevant risk issues being raised long before social or commercial investment in development conflict with risk assessment. This should be in the best interest of all stakeholders, included the biotech industry.

Holistic and multi-disciplinary scientific competence is of critical importance when assessing the risks associated with genetic engineering. Countries need to be able to conduct scientific risk assessment and management generally, and also specifically for their special environmental, medical and security needs. Moreover, they need to place these bio-applications, conducted in their countries, or imported purposely or accidentally from others, into the context of their special social, cultural, ethical and regulatory frameworks. In this regard, the GE Biosafety Forecast Service is much needed and timely. For developing countries in particular, this Service will provide a resource to augment the capacity of the existing research and regulatory communities (see annex 2 for further information).

7. Time scale and development plan for launching the Gateways Institutes

As far as we are aware, there are no other research institutions approaching GE/GMO biosafety issues from a holistic scientific perspective, and hence the Gateways Institutes are needed in all regions of the world.

At the moment the two founder institutions of gene ecology, GenØk and NZIGE, constitute the Gateways Institutes. It is therefore of paramount importance to ensure that they receive an appropriate and predictable annual baseline funding. This is an absolute prerequisite for maintaining and expanding the course and training activities, the Biosafety Forecast Service, network building, and as a starting platform for long-term, high-quality local and regional research programs. The research programs must be at a quality level that makes them attractive to first-line international research groups, as well as to granting agencies.

Ideally there ought to be 2-3 Gateways Institutes within each of the developing south regions of the world during the next 3-6 years. At the present time initiatives have been taken to establish a Gateways institute for South-East Asia, for the Southern part of Africa and for the Pacific island nations. It is also a wish and a need to take initiatives in Central-Africa, North Africa, North-West Asia, Central America and South America. We are then speaking about a total of 10-12 Gateways institutes globally. This goal ought to be achievable within 3-6 years if governments, relevant authorities, donor countries, UN and other international organisations support it.

Briefly, there are two existing Gateways Institutes, and in addition three countries where preparatory initiatives have been implemented. In some other regions scientists and regulators have asked for support to start a Gateway initiative. It should therefore be a realistic goal to have 9 functional Gateways Institutes within the first 5 years, as listed below:

1. Norwegian Institute of Gene Ecology (GENØK).
2. New Zealand Institute of Gene Ecology (NZIGE)
3. The Gene Ecology Institute of Southern Africa (GEISA) in Lusaka, Zambia (Initiative is taken in cooperation between the National Institute for Scientific and Industrial Research (NISIR) and the Ministry of Science, Technology and Vocational Training (MSTVT)).
4. The Gene Ecology Institute of Northern and Central Africa (Discussions has started in cooperation with the Ethiopian Environmental Protections Authority in Addis Ababa, Ethiopia).
5. The Gene Ecology Institute of Pacific Island Nations (GEIPIN) on Solomon Islands (Private foundation located at Solomon Islands. Initiative has been taken and has support from Solomon Islands Head of Government (PM)).
6. The Gene Ecology Institute of Southeast Asia (GEISEA) in Manila, the Philippines (Private foundation to be located at the National Institute of Health (NIH), Manila, the Philippines. Intentional agreement and legal requirements are under preparation).
7. The Gene Ecology Institute of North America (GEINA) (to be initiated)
8. The Gene Ecology Institute of Latin America (GEILA) (to be initiated)
9. The Gene Ecology Institute of Northeast Asia (GEICA) in China (to be initiated)

8. Resources and Funding Needed for Launching the Gateways Institutes

In the following sections and the attached annex 3, an evaluation of the resources and funding needed to launch the Gateways Institutes is conducted. The calculations performed below do **not** include all the already initiated Gateways projects and activities, like the core and regional courses, Biosafety Forecast Service, Book/CD-ROM, M.Sc. studies, estimated to an annual total USD 1 mill. It should however cover all new activities, such as the surveillance, monitoring, diagnostic services and research activities, to be started up. After the first 3-4 years each institute should be able to compete favourably for international grants, alone, together with the Gateways family members and/or other research institutions.

GENØK, NZIGE and The Six Regional Founding Institutes:

Staff: For each of these institutes it is necessary to secure a minimum staff of 20 for the next 5 years:

- Five administrative positions: 1 Research Director; 1 General Manager; 1 Executive for Capacity Building and Education; 1 Executive for Research Cooperation and Grant Applications; 1 Secretary.
- Five Senior Researchers: 3 ecology/molecular biology/biosafety engineers; 2 social scientists.
- Ten Junior Researchers/Technicians, to be allocated to the respective seniors/research fields.

Equipment:

- Genøk and NZIGE will need an annual budget of approx. USD 150 000 each to replenish existing infrastructure and add/buy access to heavy instruments/ new logistics.
- The Regional Founding Institutes will need a one-time investment of approximately USD 500 000, and then approx. USD 100 000 for each following year. The first year investment includes all general purpose laboratory equipment, plant and animal cell cultivation equipment, bacterial cultivation equipment, laboratory construction and office and computer equipment.

Supplies and Running Costs:

- Reagents, chemicals, culture media, office and travel expenses etc. A thumb rule is approx. USD 30 000 per scientific and 10 000 per administrative position.

(See annex 3 for preliminary budget calculations).

Annex 1

Preliminary synopsis: Master of Science studies with majors in Gene Ecology and Holistic GE/GMO Risk Assessment.

Background.

Capacity building in biosafety is urgently required, particularly now that the Cartagena Protocol on Biosafety has been adopted. Countries, many of which are in the process of ratifying the Biosafety Protocol, will need to be able to implement it nationally. This requires, among others, scientific and technical capacity for biosafety assessment and regulation.

Developing countries are most vulnerable to the socio-economic and ecological impacts of genetic engineering and its products. As the main centres of genetic diversity and crop origin, developing countries face the biggest ecological risks with the introduction of genetically engineered crops, seeds and other products of genetic engineering.

Developing countries are primarily importers of GMOs. Public and consumer rejection in Europe and many other parts of the world of genetically engineered food and crops is also intensifying. Most developing countries have yet to formulate or implement biosafety regulation domestically. They thus also face a real threat of becoming a dumping and testing ground for GMOs.

Holistic and multi-disciplinary scientific expertise is of critical importance when assessing the risks associated with genetic engineering. Countries need to be able to conduct scientific risk assessment and risk management, and address other technical biosafety regulation needs. In this regard, the proposed M.Sc. studies are much needed and timely. For developing countries in particular, this scientific competence and understanding is even more crucial, given their vulnerability.

The students selecting the GE/GMO specialisation should apply to become enrolled as GUV students, attending the first semester as described in the GEDS study programme. The second semester they will proceed to study the theoretical specialisation, mainly online, under the auspices of GenØk/ University of Tromsø or NZIGE/ University of Canterbury. The third semester will be some online theory, combined with some practical work in the field, while the fourth semester mainly will be writing up of a Master of Science thesis. GenØk/University of Tromsø and NZIGE/University of Canterbury will provide the subject expertise and tutors, who in cooperation with the e-learning pedagogues at the GUV will build up a good learning environment.

The Curriculum of the M.Sc. studies.

The following specially tailored, credit-achieving courses are already established:

1. *Holistic Risk Assessment of Genetic Engineering (GE) and Genetically Modified Organisms (GMO).* This course is part of the GenØk/UNEP GE/GMO Biosafety Capacity Building Program. The course is based on hands-on laboratory work/demonstrations, case-based seminars and lectures by an international specialist faculty (20 ECTS - European Community Course Credit Transfer credits).
2. *Ethical, legal and social aspect of biotechnology.* This is a course in bio-ethics problems related to applications of GE/GMOs in cooperation with the Functional Genomics Program at the Research Council of Norway and the Norwegian

Biotechnology Board. The course is based on case-based seminars and lectures by an international specialist faculty (7,5 ECTS).

In addition, it will be possible to select from a wide range of relevant courses organized by the Schools of Medicine and Science, as well as the Norwegian College of Fishery Science, e.g.:

- JUR-3650 Indigenous Peoples rights
- SOA-2007 Indigenous Resource Management General
- Bio-100C Cell biology/genetics
- Bio-104 Medical Biology
- Bio-106 General Microbiology
- Bio-115/116 Aquatic and Terrestrial Biodiversity
- Bio-252 Molecular Cell Biology
- Bio-322 Evolutionary Ecology
- Bio-346S Mammalian Cell Culture
- Bio-352BS Biotechnological Laboratory Methods
- Bio-355S Introduction to Bio-informatics and Bio-structure
- Bio-453 Molecular genetics
- Bio-456 Biotechnology
- Bio-363 Virology

Including a number of other alternative courses.

Scientific thesis.

GenØk can offer M.Sc. projects related to our research portfolio:

1. Feeding experiments to investigate potential health risks related to genetically modified food/feed.
2. Epidemiological studies related to respiratory/gastrointestinal exposure to genetically modified food.
3. Interdisciplinary analysis of impacts on local small scale farming systems by introductions of trans-genetic crops – case study of Bt-maize in the Philippines.
4. Horizontal transfer and biological effects of foreign DNA within an aquatic food web model.
5. Variation in transgene stability and gene expression patterns for GM and unmodified plants.
6. The effects and faith of DNA vaccines in salmon.
7. Ecological and health risks related to GM poxviruses as vaccine vectors for humans and domestic animals.
8. Risk governance of GMOs, with focus on employment of ethical principals and public participation.

In addition, through our established cooperating network, we can offer more specialized projects at the Institutes of Medical Biology, Biotechnology and Pharmacy, as well as the Norwegian College of Fishery Science at the University of Tromsø; The Norwegian Agricultural University at Ås, Norway; NZIGE/Canterbury University, Christchurch, New Zealand; University of California at Irvine, USA; University of the Philippines in Manila.

Annex 2

The GE Biosafety Forecast Service

What is it?

The Biosafety Forecast is a free-to-the-public database devoted to spreading information from the elite scientific and technical literature to policy and regulatory officials in government, NGOs, the interested public and specialist researchers in academia, government and industry. The Forecast Service will be accessible to those of all training and knowledge backgrounds and assist the user in finding the research relevant to their specific risk assessment and management needs.

The Forecast is funded by the Norwegian Government as part of the Memorandum of Understanding between the United Nations Environment Programme and GENØK with the cooperation of the New Zealand Institute of Gene Ecology/University of Canterbury.

Why do we need it?

In short, because the Cartagena Protocol on Biosafety requires that the trans-boundary movement of living modified organisms be done safely or not at all.

Multi-disciplinary scientific and social scientific competence is of critical importance when assessing the risks associated with genetic engineering. Each country need to be able to conduct scientific risk assessment and management generally, and also specifically for their special environmental, medical and security needs. Moreover, they need to assess LMOs developed in their countries, or imported purposely or accidentally from others, into the context of their special cultural, ethical and regulatory frameworks.

In this regard, the GE Biosafety Forecast Service is much needed and timely. For developing countries in particular, this Service will provide a resource to augment the capacity of the existing research and regulatory communities.

The demands on countries for competence in key implementation areas of the Cartagena Protocol are expected to be extremely high. Competence requires both access to personnel with appropriate training and the ability to extract information of relevance to the needs of each ratifying country. The Forecast will therefore also support the research and assessment activities of researchers from each "Cartagena Protocol country" who reside and work in their home country or region.

Special issues for developing countries, economies in transition and small island developing states:

Developing countries are most vulnerable to the ecological, health and socioeconomic impacts of genetic engineering and its products.

As the main centers of genetic diversity and crop origin, developing countries face the biggest ecological risks with the introduction of genetically engineered crops, seeds and other products of genetic engineering.

Bio-rich states are also the most vulnerable to the loss of intellectual property to the North. By building the capacity called for under the Cartagena Protocol, developing countries will simultaneously build the capacity needed to catalog and harness their own biological resources and identify those resources if they have been illegally moved overseas.

Failure to develop the capacity to detect and monitor transboundary movements of LMOs may create new trade risks for developing countries. Wealthier nations are investing in technologies that more stringently evaluate food imports. Any indicator that a component of the material is uncharacterized can cause shipments to be rejected. Genetic engineering creates genes and gene products, which for proprietary reasons, are not publicly described. These can trigger responses from monitoring agencies, for example, as has happened in a shipment of bread with a genetically engineered enzyme to Japan from New Zealand in October 2003. Small economies could suffer significantly from events of this type.

How does it work?

The full Forecast will provide briefings on science, social/cultural, ethical and security risk assessments. We categorize these components as Biosafety, Social and Threat Forecasts. In this first pilot year, the Forecast will produce material of immediate practical value for evaluating applications to approve imports of LMOs.

Research relevant to biosafety is of course coming from all areas, not just the scientific literature. Specialists will be searching the literature and other sources of knowledge to assemble comprehensive views of impact. Important knowledge with practical implications is now frequently encoded in the language of mathematics and DNA sequences, making it even less accessible to the regulatory community. In time, we would like to develop a bioinformatic component into the Forecast, to help countries design specific surveillance tools for detecting genetically engineered material that may be crossing national boundaries or contaminating food.

The pilot year:

The Forecast will begin development in October of 2004 from its current base at the University of Canterbury in Christchurch, New Zealand.

In the initial set-up phase, Forecasts will be drafted explicitly for the regulatory and decision-making sector of governments, but with an intention that they be useful and relevant to other sectors such as the scientific community and NGOs. We hope to recruit volunteers from these sectors of developing countries to guide our development of Forecasts. We have in mind to invite approximately 10 reviewers drawing largely from the participants of the International Biosafety Course (UNEP-GENØK). These reviewers would be asked to comment on content, readability, utility and relevance, as well as invited to suggest additional topic areas. The Forecast will first be offered over the World Wide Web, so reviewers will be asked to comment on the ease of use in that format. Eventually, we hope to be able to deliver the Forecast by means more suited to the infrastructure of the full client base.



MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (herein referred to as ("MoU")) is concluded

BETWEEN:

The Norwegian Institute of Gene Ecology, an independent, non-profit research foundation funded by the Norwegian Ministry of Environment, the Norwegian Ministry of Health and Care, the Norwegian Ministry of Foreign Affairs, NORAD and the Research Council of Norway, and having its registered office at the Science Park, P.O. Box 6418, 9294 Tromsø, Norway. (Hereinafter referred to as "**GENØK**" of the one part.)

AND

The National Institute for Scientific and Industrial Research, a body incorporate, established under regulation three (3) of the Statutory Instrument No. 73 of 1998 following the repeal of the NCSR Act under Section twenty-three (23) of the Science and Technology Act of 1997, and having its registered office at International Airport Road, P.O. Box 310158, Chelston, 15302 LUSAKA, ZAMBIA. (Hereinafter referred to as "**NISIR**" of the other part).

GENØK and NISIR shall be collectively referred to as "**the Parties**" and individually as "**the Party**".

WHEREAS

- A. GENØK, a capacity building research institute devoted to handling issues linked to biosafety, GMOs and molecular genetics, ecology, access and

utilization of genetic resources within a holistic framework.

- B. NISIR, a Zambian Statutory Body established to conduct and promote basic and applied research in Zambia.

NOW, THEREFORE, the Parties hereby agree on the terms of understanding as follows:

PART 1 OBJECTIVE

- 1.1 The principal objective of this MOU is to promote co-operation between the Parties in the following activities:
- a) Take necessary measures towards the establishment of the Gene Ecology Institute of Southern Africa (GEISA) as a member of the Gateways Institute Network (*Annex 1*).
 - b) Training and education of Zambian scientists at M. Sc and PhD levels;
and
 - c) Exchange of scientists between GENØK and NISIR, and the other Gateways institutes within the Network.

PART 2 IMPLEMENTATION

- 2.1 The co-operation, pursuant to this MOU, will be managed by a Steering Committee consisting of at least two (2) representatives from each Party.
- 2.2 The Steering Committee shall review twice a year the progress of technical co-operation under this MOU.

PART 3
DURATION

- 3.1 The MOU shall take effect from the date of its signature by the Parties and shall continue in effect until 31 December 2010, unless it is terminated pursuant to paragraph 3.2 below.
- 3.2 This MoU may be terminated by either party before the expiry date of the MoU by giving notice in writing to the other party. The period of notice shall be 60 days.

Signed on behalf of GENØK
Tromsø, 23 August 2005

Signed on behalf of GENØK
Tromsø, 23 August 2005

.....
Olga Goldfain
General Manager
Norwegian Institute of Gene Ecology

.....
Mwananyanda Mbikusita Lewanika
Executive Director
National Institute for Scientific and
Industrial Research

and

and

.....
Terje Traavik
Scientific Director
Norwegian Institute of Gene Ecology

.....
Henry Medza Mwenda
Board Chairman
National Institute for Scientific and
Industrial Research

Annex 1: The Gateways Institute document.

European Responsibility for Biosafety Cooperation

- Report -

**7 & 8 November 2005
Königswinter/Germany**

Chairpersons: Olga Goldfain, GenØk & Hartmut Meyer, GTZ



Deutsche Gesellschaft für
Technische Zusammenarbeit (GTZ) GmbH



Bundesministerium für
wirtschaftliche Zusammenarbeit
und Entwicklung



Norwegian Institute of Gene Ecology

SUMMARY

Background

Recent discussions at the 2nd Meeting of the Parties to the Cartagena Protocol in June 2005 revealed a lack of a coordinated European agenda on biosafety research and capacity building. Many European donors fund some capacity building measures indirectly through their contribution to the multilateral donor organisation Global Environment Facility (GEF), but only few have set up own policies and initiatives to support a broader range of activities. Most critically, the effective implementation of the Cartagena Protocol and the establishment of a comprehensive national framework also require other types of expertise which can not or only be partially developed in the GEF projects. For example, expertise has to be built up in the fields of:

- independent science that takes into account local environmental conditions and health-related issues, thus supporting the national authorities in risk assessments;
- public information and participation in developing national biosafety legislation and in decision-making;
- environmental monitoring of GMOs;
- segregation of GMO and non-GMO commodities;
- co-existence of GMOs with non-GMOs;
- socio-economic considerations in decision-making.

The "Königswinter workshop"

This workshop convened by the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH, Germany, the Federal Ministry for Economic Cooperation and Development (BMZ), Germany and the Norwegian Institute for Gene Ecology (GenØk), brought together European researchers, regulators and donors who already work on or can contribute significantly to initiatives supporting research and capacity building measures in the developing countries aiming at implementing the Cartagena Protocol on Biosafety under the Convention of Biological Diversity.

During the two-day workshop several resource persons gave presentations of examples of scientific research and capacity building projects addressing biosafety issues. The position and activities of the EU Member States concerning biosafety capacity building with regard to next meeting of the Cartagena Protocol (COP-MOP-3) and the bilateral biosafety cooperation projects of the European Commission were also presented.

The workshop discussed the specific requirements for coordination of biosafety research and capacity building, possible linkages between detection capacity, segregation & labelling and environmental risk assessments as well as scientific research and risk assessment, public participation, and socio-economic considerations as necessary preconditions to ensure informed consent in GMO decision making. This report has been compiled by the two chairpersons as their record and summary of the discussion.

Conclusions

In order to reinforce and create better synergies between the existing and future efforts in supporting biosafety research and capacity building in the developing countries the participants agreed to form a "European Network on Biosafety Research and Capacity Building". The Network aims to provide, based on its current involvement and expertise, the respective national administrations ideas and recommendations regarding biosafety research and capacity building in the developing countries on the issues of the review of the Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety, the questionnaire for the comprehensive review of the Action Plan, and the decision documents for COP-MOP-3. This information can also be brought to the attention of the incoming Austrian Presidency, respectively the European Commission.

Input by resource persons

(The presentations can be downloaded at <http://www.genok.org/>)

The Cartagena Protocol on Biosafety - COP-MOP decisions on capacity building - International coordination and activities

- a) **Hartmut Meyer (GTZ/Germany & Chairperson of the Coordination Meeting Steering Committee)** on the Coordination Meeting for Governments and Organisations Implementing or Funding Biosafety Capacity-Building Activities
- b) **Jan Husby (GenØk/Norway)** on the provisions on biosafety research and capacity building in the COP-MOP decisions and other United Nations documents

Examples of scientific research and capacity building projects addressing biosafety issues

- c) **Helmut Gaugitsch (Federal Environment Agency/Austria)** on the assessment of GE crop & food application dossiers to the EU with regard to the information on toxicology and allergenicity provided by the applicants, and on suggestions for capacity building in developing countries with respect to independent health risk assessment of GE crop & applications
- d) **Angelika Hilbeck (Swiss Federal Institute of Technology Zurich/Switzerland)** on the GMO Guidelines (now GMO ERA) Project developing and applying scientific field and laboratory methods for GE crop environmental risk assessment in Kenya, Brazil, and Vietnam
- e) **Gavor Lövei (Danish Institute of Agricultural Sciences Flakkebjerg/Denmark)** on Biosafety Capacity Building in East Africa: the DANIDA-supported BiosafeTrain Project
- f) **Broder Breckling (University of Bremen/Germany)** on an EU project about modelling landscape effects of GE plants and biosafety implications on different scales based on examples from Northern Germany
- g) **Bryan Wynne (University of Lancaster/UK)** on the necessity of public participation for UN Biosafety Protocol Risk Assessment
- h) **Alexandra Müller & Hartmut Meyer (both GTZ/Germany)** on bilateral German biosafety capacity building projects in China and Algeria focussing on public information and participation, and on the BMZ/AU-project for biosafety capacity building in Africa focussing on regional policy issues
- i) **Terje Traavik (GenØk/Norway)** on Gateways - Portals to Holistic, Independent Research and Biosafety Competence Related to Genetic Engineering and Genetically Modified Organisms in Developing Countries

Is biosafety capacity building and research a topic in the European development cooperation? Discussions on and propositions for national and European approaches and collaboration

- j) **Matthias Buck (DG Environment - European Commission/Belgium)** on examples of relevant EC bilateral cooperation projects
- k) **Helmut Gaugitsch (Federal Environment Agency/Austria)** on positions and activities of the EU concerning biosafety capacity building and research with regard to COP-MOP-3

Result of the discussions of the workshop

1) Specific requirements of coordination of biosafety research and capacity building

The participants of the workshop identified necessary additional features of coordination besides the broadly recognized elements like enhancing information exchange, promoting synergies between activities etc.:

- coordination of scientific research should be undertaken by coordinative bodies involving a broad range of stakeholders, the coordination through purely scientific bodies - often consisting of potential applicants for grants - contravenes the necessary diversity of disciplines, approaches and methodologies;
- coordinative bodies should ensure:
 - that a diverse range of governmental and civil society organisations have access to and can participate in biosafety capacity building programmes;
 - that regulatory systems are developed accommodating existing public demands and that possibly can anticipate future public demands;
 - that regulatory systems show enough flexibility to react to changing public demands.

2) Relationship between economics and the ecological risks of GMOs

The participants of the workshop discussed possible linkages between segregation, labelling and environmental risk assessments. They described the current situation as follows:

- the Cartagena Protocol and European Union GMO legislation limit the scope of risk assessment on environment and health aspects, an European Union legislation for assessing socio-economic risks and taking them into account in decision making does not exist;
- many developing countries see the economic risks of GMOs in agriculture and food production in the context of access to those markets that demand segregation and labelling; market-oriented considerations are seen as essential elements of biosafety systems and risk assessments, European countries are asked for appropriate support in research and capacity building;
- the new European GMO legislation, based on the precautionary principle, takes into account the issues of uncertainty in risk assessments to provide provisions for post-marketing measures like monitoring, limited approval timeframes, or registers for field trials.

To find a way forward with regard to support developing countries in economic and environmental risk assessments the following considerations should be taken into account:

- decisions under the Cartagena Protocol should be based on the precautionary principle;
- the Cartagena Protocol states that Parties may take into account biodiversity-related socio-economic considerations in decision-making within the scope of the protocol;
- outside of the scope of the Cartagena Protocol, States may adopt post-marketing measures reflecting the inherent uncertainty in risk assessments;
- the methodology of risk assessments under the Cartagena Protocol itself links scientific uncertainty with post-marketing measures such as monitoring.

3) Necessary preconditions to ensure informed consent in GMO decision making

The discussion covered three topics that have been identified as highly relevant for GMO decision-making: scientific research and risk assessment, public participation, and socio-economic considerations. The following recommendations were made:

a) Scientific research and risk assessment

- Secure independent biosafety-related research
- Separate the promotion of modern biotechnology from biosafety issues
- Engage diverse expertise in research and risk assessment
- Base risk assessment on experimental work that follows good scientific practice and reporting rather than on assumptions
- Identify and mobilize expertise existing in developing countries
- Create "problem and needs" orientated research and training opportunities
- Develop (sub)regional biosafety capacity including GMO detection and identification capacity

b) Public participation in risk assessment and decision-making

- Engage non-scientific experts carrying relevant local knowledge (eg. farmers, indigenous groups) in the risk assessment procedures
- Develop communication tools that take into account language barriers and illiteracy
- Effective public participation requires unrestricted access to public information and should build upon existing models of public participation
- Develop capacity that can deal with the consequences of the decisions made

c) Socio-economic considerations

- Collect and analyse existing studies on socio-economic impacts
- Plan and undertake field studies concerning socio-economic issues covering Art. 26 of the Cartagena Protocol and other emerging socio-economic issues

4) Coordinating biosafety research and capacity building activities in the developing countries

The participants suggested the following critical elements when planning and pursuing joint biosafety research and capacity building activities in developing countries:

a) Planning and coordinating of joint activities:

- Create synergies with existing biosafety research and capacity building activities in the developed and the developing countries
- Sustain independence of research and capacity building activities
- Specifically consider and avoid conflicts of interests
- Coordinate short and long term training opportunities
- Undertake regular evaluation of biosafety research and capacity building activities

b) Pursuing the cooperation in the developing countries:

- Create interdisciplinary multi-level expertise
- Ensure access to complete information on existing GMO risk assessments
- Promote South-South networks
- Integrate communication training in biosafety research and capacity building activities
- Transfer technology and methodology that work under local conditions
- Develop infrastructure in the developing countries, e.g. laboratory facilities, training facilities
- Develop a transition plans to support sustainability of research and capacity building activities
- Make efforts to create appropriate employment opportunities after training

c) Recommendations for project applications:

- Provide the potential donor with an analysis of the existing biosafety projects in the recipient country and make sure that projects fit into the "biosafety landscape" of the recipient country
- Document the interest of national stakeholders of projects
- Discuss co-funding opportunities and consortium-building
- Create and demonstrate strong ownership incentives (eg. through matching funding from the recipient country)
- Ensure that the project is in line with the MOP decisions and the donor's country priorities; if the project supports the achievement of the Millennium Development Goals highlight and explain it

Conclusions of the workshop

1. The participants of the meeting agreed to form a "European Network on Biosafety Research and Capacity Building" for creating better synergies between the existing and future efforts in biosafety research and capacity building in the developing countries. The areas of cooperation within the "European Coalition on Biosafety Research and Capacity Building" should be defined by commonly identified knowledge as well as policy gaps and mapping our own resources.
2. In 2006, GenØk will coordinate the activities of the Network. The internet-based Biosafety Clearing-House should be used to retrieve and disseminate information about cooperation and projects as well as assessment of need and priorities settings.
3. The "Königswinter Workshop" is recommended to be convened once a year. The next workshop is envisaged for May 2006 with the aim to foster the dialog between researchers, implementing organisations and donors.
4. Programmes and projects with developing countries should take into account the recommendations of the "Königswinter Workshop" on scientific research and risk assessment, public participation in risk assessment & decision making, and socio-economic considerations.
5. The "European Network on Biosafety Research and Capacity Building" will provide their respective national administrations with ideas and recommendations regarding biosafety research and capacity building in the developing countries on following issues:
 - a) Review of the Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety
 - b) Questionnaire for the Comprehensive Review of the Action Plan
 - c) Decision documents for COP-MOP-3This information can also be brought to the attention of the incoming Austrian Presidency, respectively the European Commission.

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