

**Secretariat Gef**  
Sent by: Nimanthi A.  
Attapattu

Subject: German and Norwegian Comments to West African Regional  
Biosafety Project

09/10/2007 10:34 AM

Dear Maria and Erik,

Thank you for your comments on the West African Regional Biosafety project. Please find attached a note, elaborated by the World Bank, which in our staff's opinion addresses all the questions you have raised before. Regarding the concerns raised by COPAGEN, the World Bank is currently working on them. A response will be sent directly by the World Bank to the NGO coalition, and will be shared with GEF Council members.



WARBP.Answer.Germany04-09.doc

With best regards,

Monique

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August 30, 2007

## **World Bank's response to comments by Germany on the West African Regional Biosafety Project**

**Comment:** *“The proposal lacks a clear strategy on how to tackle the noted non-existence of weak national biosafety capacities (para 5, p. 5). Instead of evaluating the reasons for the low performance of the national NBF programmes and developing strategies to improve national approaches to set up and implement biosafety frameworks, the project suggests to develop an additional supra-national layer of biosafety regulation beside the Cartagena Protocol. It is not clear why this approach should be more successful in implementing the Cartagena Protocol than the UNEP/GEF NBF projects.”*

**Response:** The program does not develop an additional supra-national layer of biosafety regulation *beside* the Cartagena Protocol on Biosafety (CPB), as stated above – the regulation is put in place precisely to enable recipient countries to fully implement the CPB. Nor does the program put in place an “additional layer,” different from the national biosafety frameworks (NBFs): the regional biosafety framework will encompass and standardize the existing NBFs.

**Comment:** *“In general the effectiveness of the project rationale to develop a regional biosafety law BEFORE the Member States have set up functional NBFs and national biosafety legislation remains highly doubtful. This approach has always been repeatedly dismissed as inappropriate, most recently at the THIRD COORDINATION MEETING FOR GOVERNMENTS AND ORGANIZATIONS IMPLEMENTING OR FUNDING BIOSAFETY CAPACITY-BUILDING ACTIVITIES in February 2007 in Lusaka/Zambia.”*

**Response:** A regional biosafety law will be developed *during* the implementation of the National Biosafety Frameworks (NBFs). Since the RBF will take two years to be put in place, the Program will support through the first subcomponent (C1) intermediary measures for the implementation of the existing National Biosafety Frameworks in the countries that have already started field trials, such as Burkina Faso. This is to ensure that the recipient countries have biosafety legislation in place during the duration of the program, whether national (at the beginning) or regional (once the RBF is set up).

**Comment:** *“Germany still is of the opinion that a better approach to secure the full and effective implementation of the CPB would be achieved by amending the project plan by a stock taking activity at national level. This activity should analyse the NBF processes and give recommendations for a more promising development of NBFs. Only when all project member states have developed NBFs and adopted national biosafety laws, a reasonable gap analysis and subsequent development of a regional biosafety law appears to be possible, justified, and promising.”*

**Response:** In fact, a stocktaking assessment evaluating the existing biosafety laws – including the national biosafety frameworks (NBFs) – *has* taken place as part of program preparation. The evaluation of these NBFs through the stocktaking assessment was a factor in the decision by the recipient countries to institute a *regional* biosafety framework.

**Comment:** *“In our opinion, the statement that all participating countries simply agreed to lift the unsuccessful national attempts to build NBFs on the regional level does not at all assure that the existing difficulties in implementing a supranational biosafety law are overcome.”*

**Response:** The participating countries have not “simply agreed” to stop all efforts to build an NBF in exchange for the program. To the contrary, in fact, the program will strengthen the NBFs in the first two years<sup>1</sup>, until the overarching regional biosafety law is completely developed and implemented. This will be done to avoid a time gap in which the national legislation is discontinued before the regional framework and legislation is put into place.

**Comment:** *“As a reaction on our comments concerning the role of the private sector in and its benefits from the project, the proposal has been changed accordingly. While the text now implies that the private sector plays no official role in the project implementation, the budget shows that it still provides 5,000,000 USD to support the project activities (1d, page 3). The text states that non-named entities of private sector contribute “\$0.7 million through cost recovery mechanisms” (para 15, p.5). The purpose of the remaining sum of 4,300,000 USD remains unclear. Germany would like to be fully informed about the financial engagement of the private sector in this biosafety project.”*

**Response:** The table on page 1d) of the Request for CEO Endorsement does not state that the private sector provides US\$5 million to the program at CEO endorsement. Indeed, this table clearly indicates that at CEO endorsement, the private sector will provide *no* funds to the project – neither to the GEF-eligible nor to the non-GEF eligible countries. The mention of US\$5 million from the private sector refers to the work program entry column, which is over-ridden by the following two columns of “at CEO endorsement.” Please refer to the Request for CEO Endorsement, table 1d, page 3. The cost recovery mechanism (charge for the reference laboratory’s services) extends only to the abovementioned US\$0.7 million and no further: please refer to Annex 5 of the program document for the complete description of program and project financiers as well as to Annex 9: Economic and Financial Analysis. For more information about why the private sector is not involved in the program beyond cost recovery mechanisms, please refer to the Request for CEO Endorsement and page 25 of GEF document entitled “Responses from the Implementing and Executing Agencies and the GEF Secretariat to Issues Raised by Council Members When Requesting Consideration of Proposed Project Proposals at the Special Council Meeting to be Convened in August 2006.”

**Comment:** *“The project proposal states that due to a series of consultations, the initial civil society resistance against the project could be overcome. This was achieved by shifting the project focus from supporting modern biotechnology, especially Bt cotton to supporting the development of biosafety systems. To ensure that this shift is correctly reflected in the project implementation it will be crucial to involve experts and staff that have a proven record to*

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<sup>1</sup> The **Article 10** from the “Règlement N003/2007/CM/UEMOA” adopted by the Council of Ministers in April 2007 states that : « En attendant la mise en oeuvre effective des dispositions du présent Règlement, les Etats membres sont chargés de prendre des mesures conservatoires telles qu'édictées par le Protocole de Cartagena sur la prévention des risques biotechnologiques relatif à la Convention sur la Diversité Biologique, en vue de se prémunir des risques liés à l'introduction des Organismes Vivants Modifiés (OVMs) et des produits dérivés. »

*support the full and effective implementation of the Biosafety Protocol and are not actively involved in developing and promoting GMOs.”*

**Response:** None of the current or future staff and experts actively involved in program preparation or implementation are or will be concurrently involved in developing and promoting GMOs, as this would involve obvious conflicts of interest.

**Comment:** *“We are in general of the opinion that a 15 M project proposal which is not available in the common language of the project countries is not helpful to create trust in the project, especially in the current situation when the project is met with public scepticism and resistance. All project information should be available in French as well as in English.”*

**Response:** Please note that the project document is currently being translated into French to address and allay such concerns and to encourage transparency and public participation in the project. Most recently, during the first meeting of the Steering Committee in July 2007, the Regional program coordinator presented in French an overview of the program. The program components and other relevant details are also explained in the “Réglement N003/2007/CM/UEMOA” adopted by the Council of Ministers in April 2007 and the 2007 WAEMU Regional Biosafety Program, both of which are in French. Earlier presentations in French occurred during the consultations conducted in 2006 in the program countries; please refer to Annex 10 of the project document for more information on this process.

**Comment:** *“With respect to the necessary transparency of the project, it must be secured that the establishment of a functional regional BCH presenting all relevant information on the project activities and outcomes is guaranteed right at the beginning of the project. Moreover it is still unclear how this BCH will relate to the UNEP BCH. The proposal only speaks of “cooperation”. The World Bank should be in a position to give more detailed information of what cooperation with another GEF Implementing Agency would look like. Besides, our question of the value added of an additional BCH has not been answered yet.”*

**Response:** The Biosafety Clearing House (BCH) will be operational at the beginning of the program. National BCH funding will be from the GEF-UNEP project; the “financing rule” for activities of the observatory is in Annex 4 of the Project Document. At the Cotonou meeting<sup>2</sup> of the technical and financial partners of the WARBP held in September 2006, UNEP stated that it will implement BCH activities for the eight WAEMU countries through the GEF regional BCH program (*Building Capacity for the Effective Participation of Countries in the Biosafety Clearing House*). The program will coordinate its activities with this UNEP-GEF: namely, the regional biosafety clearing house will manage, coordinate, and facilitate cooperation and information sharing between all of the national BCHs, including such items as registers, dossiers, trial data and other related information required by the CPB. Without the program, the eight separate national BCHs would operate without the assistance of a regional clearing house to coordinate and deal with regional issues, which would lead to inefficiency, poor information management, and redundancy of efforts by all the national BCHs.

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<sup>2</sup> Final synthesis of the *Réunion de concertation et des partenaires techniques et financiers sur le projet régional de biosécurité en Afrique de l’ouest*, Cotonou, Bénin, September 20-22, 2006.

**Comment:** *While the project proposal recognized the need to cooperate with the biosafety policies and approaches which are under development at the ECOWAS level, it is ignorant of the Pan-African biosafety policies and approaches under development by the African Union and NEPAD which for example have been presented by the AU at the above mentioned biosafety capacity building meeting in Lusaka.*

*In November 2006, the EXTRAORDINARY CONFERENCE OF THE AFRICAN MINISTERIAL COUNCIL ON SCIENCE AND TECHNOLOGY (AMCOST) committed itself to working together to develop a 20 year African Biotechnology Strategy with specific regional technology goals to be implemented through our Regional Economic Communities (RECs) and to develop and harmonize national and regional regulations that promote the application and safe use of modern biotechnology. Meanwhile the African Union in collaborated with NEPAD, the African NFP for the Cartagena Protocol, the National Science & Technology Experts, and relevant African stakeholders from industry and civil society works on the revision of the African Model Law on Safety in Biotechnology. This activity is a first step towards the announced 20-year strategy. The process working through AU and AMCOST consultations on the Panafrican and regional level is expected to lead to a revised Model Law that will be presented for adoption to a summit of African Heads of State and Government in 2008. The development of a regional biosafety law by the WB project should be linked to this Panafrican process and use the Model Law when it is adopted. A separate approach to develop a regional Model when there is a Panafrican Model under work appears to be ineffective and counterproductive with respect to the harmonization of African biosafety approaches.*

**Response:** It has never been said that the WARB Program would not capitalize on the African Model Law on Safety in Biotechnology in its formulation of the regional framework. The Model Law itself is meant to adapt to the context of the countries that wish to adopt it: it is not obligatory for the WAEMU countries to do so. It was clearly announced in the program document that the regional framework would be based on other existing laws, which include, among others, the African Model Law and the framework convention of the CILSS. The WAEMU regional biosafety framework and legislation, once it is completed and implemented, will apply to all eight countries of the union. This regional approach will allow WAEMU to benefit from economies of scale (in terms both of procedures and the time needed to implement the framework). It should be stressed that the WAEMU countries are currently working in a legal vacuum when it comes to biosafety and biotechnology – the program aims to remedy this, and encompass the Model Law as needed.

It should also be noted that the WARB Program is very strongly supported by the countries of the West African Economic and Monetary Union (WAEMU), as indicated in the Bamako Declaration by the Ministers of Environment of WAEMU (November 2006) and the “Réglement N003/2007/CM/UEMOA” adopted by the Council of Ministers in April 2007.

**Comment:** *“Furthermore, the question arises why the project has to support the involvement of international lawyers when African countries have been supported since many years and with numerous projects to develop national biosafety regulations. In the light of cost effectiveness and necessary ownership of the project results it appears to be advisable to engage African lawyers to develop an African regional biosafety law. The AU might be one useful source of information on appropriate experts.”*

**Response:** Please note that the terms “international lawyer” and “African lawyer” are not mutually exclusive: the project document’s reference to international lawyers could very well include lawyers from various West African countries. In fact, it is expected that the program will make extensive use of the services of West African lawyers.