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BULLETIN OF THE NATIONAL BIOSAFETY FRAMEWORK PROJECT - LEBANON.

EDITORIAL

In the MENA region, biotechnology has been and is still facing some political, financial, institutional, social and cultural challenges as revealed during the regional consultation meeting convened last month by the International Development Research Center (IDRC) in Egypt. Internationally, the debate is crystal clear on GMOs uses, impact of release and effect on economic growth. Will scientific communities be able to seed peace in societies vis-à-vis GMOs use? Will risks be well managed to avoid impact on environment and/or health? The meetings held at two locations across the Mediterranean Basin underpin the need for a network that would open the ground for discussions between scientists, decision-makers, and world citizens as well as marginalized groups. It also stressed the importance of promoting and strengthening cooperative programmes between research institutions and initiating awareness programmes to disseminate the knowledge and assess opinion polls on GMOs transfer and uses. In the Egypt meeting, ethical issue was strongly highlighted when the ground was opened for CENESTA (An Iranian NGO) that reminded the international, regional and national communities on the importance of respecting the law of nature! Do we know if MENA societies are ready or want to have GMOs in the region or do they want to preserve it and label it "MENA Island Free of GMO"? Do we need national and regional opinion polls before finalizing NBFs and taking a communal decision? What is obvious is that building bridges between the different stakeholders; the awareness on GMOs, their impacts and uses; on the Cartagena Protocol and on trade agreements are essential first steps before it would be too late and NBFs end up frozen. This issue of the project newsletter brings briefings on major points raised at the above mentioned international workshops, two texts on the precautionary principles and LMOs for Food or Feed or for processing (LMOs-FFP) as well as summary on the 2nd national workshop held in Lebanon ✨

DR. E. J. SATTOUT - IBSAR-AUB



BRIEF OVERVIEW ON THE 8TH INTERNATIONAL SYMPOSIUM ON BIOSAFETY OF GMOs

Ms. D. KLAIMI, BIOSAFETY FOCAL POINT, MINISTRY OF ENVIRONMENT - LEBANON.

Promoting scientific assessment of potential risks associated with GMO's was the major theme of the 8th International Symposium on Biosafety of Genetically Modified Organisms (ISBGMOs). Around 300 participants from 50 countries gathered last month to attend the 8th ISBGMOs. The Meeting was held in Montpellier-France from 26 to 30 September, 2004, two years following the last meeting that took place in Beijing, China (October 10 -15, 2002) and which witnessed an incomparable participation (approximately 1000 participants). This event was organized by the newly established International Society for Biosafety Research (ISBR), Institut National de la Recherche Agronomique (INRA), and Centre de Cooperation Internationale en Recherche Agronomique pour le Developpment (CIRAD).

Participants came from a large number of fields of expertise; presentations were given by biotechnology specialists, ecologists, industrial company experts, international organization representatives, policy makers, regulators, legislators, lawyers, national committee representatives, national focal points, journalists, students and NGO's. A total of 60 posters were displayed to be viewed by participants. It is also worth noting that Lebanon was the sole Arab country represented. Additionally, the last day of the event was marked by Green Peace protestors to GMO's at the doors of the 'Le Corum', where the meeting was held.

Nearly 65 presentations were conferred tackling various subjects of Biosafety. The commercialization and Biosafety aspects of Bt and other insecticidal crops as well as Biosafety aspects of virus-resistant transgenic crops in China, USA, and Hungary were emphasized the first day. Results of risk assessments proved to be satisfactory regarding the environment in each of the cases. The effect of insect resistant crops on non-target organisms in Denmark, India and Switzerland yielded the need for harmonization of Biosafety guidelines to facilitate trans-boundary movement of GMOs. Likewise, results of several papers also showed that effects of GM plants on the soil and rhizosphere microbial communities were analogous to the changes caused by other conventional plant crops.

The second day was confined to a North-South workshop between developed and developing countries. A short session was paneled by Representatives of the CBD, Cartagena Protocol (CP), UNEP-GEF projects on capacity building, EU risk assessments research on Biosafety, followed by a much longer session that emphasized the impacts of plant-to-plant gene flow and the non-harmful effects of Bt crops on insects. An evening session was assigned to cover to the methods of conducting an environmental risk assessment taking into account Biosafety measures to ensure proper harvest of biotechnology benefits.



At the third day, Biosafety issues of the next generation were discussed. This means the production of viral replicons and proteins for industry, the production of pharmaceuticals and vaccines from plant crop (Bio-pharming) and the use of GMO's to improve nutritional aspects of crops. There seemed to be a particular concern and reservation in that regard due to the highly publicized incidents of pharmaceutical crop seed mixing with edible crops.

Risk management was addressed elaborately through a series of papers on strategies for biological containment in plants, notably: Transgene containment via material inheritance (chloroplast transformation) and male sterility. In addition modern technologies were revealed on how to successfully mitigate transgenic flow such as GURT (sterile seeds) and APO MIXIS (asexual) technologies. Furthermore, there is a need for other Environmental Containment Management Systems such as ISO 14001, CACCP (for physical containment of pharm crops to judiciously manage activities related to GMO's).

Regulations adopted worldwide was the topic of the 5th day and discussions gave rise to a strong verbal argument between scientists who attacked the CP on one hand and a well reputed UK biotechnology lawyer, Julian Kinderlerer, who managed to defend the grounds of the CP and what it stands for and succeeded in bringing the discussion to a satisfactory balance. It is worthy to note that one of the success stories brought forward was a case in Denmark where scientists were able to develop Biosafety regulations on Co-Existence between conventional agriculture, organic farming and GM crops.

On the other hand, when dealing with commercialization of GM fish, other categories of ecological issues emerge such as size incompatibility with respect to bird predators. Thus there was a need to study their Biosafety and containment aspects.

Finally, a systems approach in Biosafety debates and Biosafety communication was discussed and there was a general agreement on the fact that the problem lied in the lack of contact between biotechnology scientists and the public community and hence there is an urgent need to develop an understandable system of communication such as the creation of accessible technical websites. To conclude, a biotechnology philosopher was given the opportunity to openly state her partial point of view on GMO's and their potential risks on earthly species, followed by the presentation of the symposium results to the public



CAIRO: BIOTECHNOLOGY IN MENA REGION

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Dr. E. J. Sattout, National Project Coordinator, IBSAR-AUB, Lebanon.

Building up a regional network and a platform for information exchange and dissemination in both agricultural and health biotechnology fields was one of the major points raised during a regional consultation meeting held on 29th & 30th of September 2004 in Cairo, Egypt. The workshop, organized by IDRC, gathered participants from Eastern Mediterranean and North African countries. The diversity in the participants' background has contributed to open the ground for a multifaceted debate addressing technology, policies, regulations, legislations and public participation as well as ethics. Participants, delegated from academic institutions, research centres, private business firms, law firms and media, were invited to discuss two concepts papers on Biotechnology and agriculture presented by *Dr. M. Baum* (ICARDA, Syria) and biotechnology and health presented by *Dr. D. Fathallah* (Institut Pasteur de Tunis).

Dr. R. Talhouk, workshop coordinator, divided the problems facing the region into two categories: one that could be potentially solved by biotechnology (low food security, environmental problems, health problems, water crisis, etc.) and the other category comprises problems such as lack of governmental funding and capacity and political instability. He added that however, biotechnology in the Eastern Mediterranean and North African countries cannot provide a sustainable pattern of development as it faces some political, financial, institutional, social and cultural challenges.

Among many important issues raised; there were building up a biotechnology related database, initiating research on risk assessment and risk management and transfer of the knowledge to the public to gain their trust, lack in cooperation and collaboration between the different countries, property rights issues, etc. One of the questions raised was ***Do we want GMOs in the region or not?***



LEBANON: SITUATION ANALYSIS IN LEBANON PRESENTED AT 2ND NATIONAL WORKSHOP

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Dr. E. J. Sattout, NPC, IBSAR-AUB

Situation analysis on the status of biotechnology, Genetically Modified Organisms, related legislation and regulations, etc - done under the Development of National Biosafety Framework for Lebanon project - was presented at the 2nd national workshop. The workshop was held on July 30, 2004 in the College Hall at the American University of Beirut and gathered participants from different sectors of the societies; private firms, state agencies as well as Non Governmental Organizations.

The findings reflected the national gaps, needs and priorities to be taken in consideration for the effective and successful implementation of the NBF for Lebanon. The workshop was launched by Dr. S. N. Talhouk who welcomed the participants and presented among other things the profile of IBSAR team experts working on the project. The UNDP was represented by Ms. Dr. Al-Khatib, the opening speech of the MOE was given by Ms. D. Klaimi, Biosafety National Focal Point. Following her opening speech, she presented the different conventions and agreements falling under the World Trade Organization related to biotechnology. Dr. E. J. Sattout, National Project Coordinator, recalled briefly on the project objectives and activities and gave a detailed update on its activities. She opened the ground for the following session on survey findings. Dr. A. Al-Khatib presented the steps followed for data collection. This has been followed by 4 presentations to draw on the results on biotechnology status in Lebanon, cooperative programmes in application of biotechnology, current status of LMOs and commercial products, review of existing legislations that may impact the use of biotechnologies, and risk assessment and risk management. These presentations were given respectively By Dr. R. Talhouk, Dr. H. Mouhtasseb, Dr. A. Al-Khatib (On behalf of R. Baalbaki), Mr. W. Nasser & Dr. D. Jamali from IBSAR-AUB.

The third session aimed at defining the future directions and needs for the various stakeholders' profile including scientists, NGOs, cooperatives, syndicates and government, and those working on legislations and policies.

Many points have been raised by the participants such as the importance of risk assessment on wild relative crops as Lebanon is located at the heart of the Center of origins of many crops, the consideration of the opinion of the religious communities, the importance of regulations and legal aspects, national opportunities for biotechnology development, etc...

PRECAUTIONARY PRINCIPLES: CONCEPT & THE CARTAGENA PROTOCOL

Dr. E. J. Sattout, NPC, IBSARAUB

While the precautionary principle has taken center stage in a number of recent international discussions on trade, the environment, and human health, it has stirred many criticisms and interests. Recent negotiations around the precautionary principle at the CBD and the WSSD were surrounded by strong sentiments. The principle has been at the core of series of disputes in the WTO arena.

The first times the precautionary principle concept aroused in environmental issues was in the 70's in Europe, when Germany discovered that its forests were suddenly dying. Even though, there was not yet scientific proof that acid rain was the main cause, the government proceeded to reduce power-plant emissions acting as per the principle of "Vorsorge" or "forecaring". Soon, the "forecaring" or precautionary principle - became an axiom in German environmental law. Since then, Germany's approach has gone international. Precautionary principle has emerged in the preamble of the U.N. Treaty on Biodiversity and was incorporated into protocols and rules issued by the European Union in the 90's.

The European Commission Communication on the Precautionary Principle (February 2, 2000) notes: "The precautionary principle applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU."

The precautionary principle is a key element of the Cartagena protocol on Biosafety and it is put into operation in decision-making. The articles 10 & 11 of the protocol state that parties are permitted to adopt precautionary approaches to avoid risks which can arise from the transfer, handling and use of LMOs. This is applicable even when there is lack of scientific certainty regarding the extent of harm that might occur. In the absence of scientific certainty, a party should err on the side of caution and could restrict or ban the import of GMOs on account of their potential adverse effects. The protocol also establishes the principle of prior informed consent with regard to the import of GMOs and preserves the right of a country to reject applications for the import of GMOs.

The Cartagena Protocol on Biosafety states:

"Lack of scientific certainty due to insufficient relevant scientific information . . . shall not prevent the Party of import, in order to avoid or minimize such potential adverse effects, from taking a decision, as appropriate, with regard to the import of the LMO in question."

Thus the importing countries are all in need to have clear guidelines for applying a precautionary approach to particular LMOs.

Recently, the council of the EU formalized a moratorium on GMO approval by recommending to the EC an amendment to the Directive 90/220/EC. The provisions included recommendations that the EU should adopt a precautionary principle with regard to further approval of the GMOs. 🌱

What is the Precautionary Principle?

The precautionary principle or precautionary approach is a response to uncertainty, in the face of risks to health or the environment. In general, it involves acting to avoid serious or irreversible magnitude, or causation of that harm. Precaution is now an established principle of environmental governance, prominent law, policy and management instruments at international, regional and domestic level across such diverse areas as pollution, toxic chemicals, food and phytosanitary standards, fisheries management, species introductions and wildlife trade.

🌱 Whether GMOs are fully safe, policy makers and consumers in the EU seem to agree that there is a need to control the role of biotechnology in the food industry and to use the precautionary principle until more is known about the potential risks associated with GMO products.

When applying the precautionary principle approach to LMOs, the points to be considered are the nature and extent of potential harm as well as the standards to be used to measure harms. Precautionary approach should pay particular attention to impacts that are widespread, long-term, not reversible, and/or accumulative.

Implementing the protocol provisions will require analysis of the causes and extent of uncertainty, and careful evaluation of the evidence used to demonstrate safety. The factors to be considered are the error bias where in most cases, detection and evaluation of the adverse effects of LMOs on biodiversity will require experiments and monitoring procedures that are designed specifically for this purpose. The concluded results from tests designed for other purposes or poorly designed trials may indicate, or result in, a bias toward showing safety; that is, a bias toward concluding LMOs pose no adverse effects when in fact they may.

The other factor is the weight of evidence. While laboratory experiments and controlled field trials reveal the potential impacts of LMOs, these methods are not expected to predict accurately the effects of unconfined, global release over long periods of time. Consequently, a broader range of evidence must be gathered and weighed. These include interdisciplinary investigations (e.g. combining ecology, evolutionary biology, sociology, ethics and economics); local knowledge (e.g. traditional ecological and agricultural knowledge); case studies (e.g. documented experiences of people who have used the technology); and correlation to other similar technologies or activities (e.g. release of non-indigenous organisms).

The third factor is participation and transparency. Despite attempts to acknowledge and reduce uncertainty, conclusions about the potential effects of LMOs and decisions about their use will always involve an element of informed judgments. Such judgments will be better informed if all stages of the research and decision-making process are open and transparent. Therefore

"Participatory procedures are not only more democratic, but are also likely to yield more robust and appropriate evidence upon which to base decisions" 🌱

Sources:

Jonathan H. Adler - Earthlink.
Katherine Barrett Science and Environmental Health Network and Eco-Research. Faculty of Law-University of Victoria, Canada
Nancy Myers, SEHN Organization.
Michael Pollan, The New York Times Company.
Rosie Cooney, Fauna & Flora organization, UK.

"The Cartagena Protocol on biosafety is the legally binding agreement for handling, transport, packaging and identification of LMOs (basic rules sets in article 18) not only in the specific countries' legal system that have ratified, approved, accepted or acceded to it but also in the international legal system. It establishes the foundations of international law on the regulation of handling, use and transfer of GMOs and addresses the fact that GMOs may have biodiversity, human health and socio-economic impacts, and that these impacts need to be risk assessed".

Food containing genetically engineered grain is a GMO intended for direct use as food or feed, or for processing. These are commonly referred to as LMO-FFPs and have to be regulated by the Biosafety protocol, particularly with regard to its import and export. Processed foods, such as maize meal, soy flour, cornsoy blends and vegetable oils, are not regulated under the Biosafety Protocol. The article 18(2)(a) specifying the documentation requirements for LMO-FFPs temporarily avoids clear identification requirements by stipulating that documentation accompanying LMO-FFPs must clearly identify that the shipment "may contain" LMOs and are not intended for intentional introduction into the environment. It must also provide a contact point for further information.

However, due to the difficult negotiations, the Protocol eventually excluded food or feed, or for processing from the AIA procedure as well as GMOs in transit and for contained use. For LMO-FFPs, Article 11 of the Protocol only foresees a multilateral information exchange system facilitated by the Biosafety Clearing House (BCH), administered by the CBD Secretariat.

Thus, the obligation is on a potential importing Party to check the BCH for information on new LMO-FFP that may enter international trade, and if it wishes to subject them to domestic regulation.

However, the Protocol preserves the right of Parties to take a decision on the import of LMO-FFP according to its domestic regulatory framework.

Article 11(4) asserts the right of Parties to subject imports of LMO-FFPs to independent, prior risk assessment and approval. The importing Party's domestic regulation could, for example, trigger procedures for LMO-FFPs requiring prior notification, risk assessment and explicit written approval.

In the absence of a domestic regulatory framework, a developing country Party or a Party with an economy in transition can still take a decision on an LMO-FFP in accordance with a prior risk assessment and within a specified timeframe, provided that this intention has been previously declared through the BCH. Any failure to communicate a decision within the stipulated timeframe does not imply consent or refusal to import the LMO-FFP.

The Precautionary Principle applies in any cases to decision-making regarding the import of an LMO-FFP. In the absence of scientific certainty on the potential adverse effect of that LMO-FFP, a country can take an appropriate decision in order to avoid or minimize the potential effects. Parties could decide either restriction (e.g. a request that the grain be milled to prevent planting and potential adverse environmental impacts) or banning.

Exporting countries can further design legislation that places obligations on its own exporters. For example, the EU in its Regulation on transboundary movement on GMOs removes the ambiguity related to the "may contain" declaration, by requiring its exporters to clearly identify that a shipment of GMOs intended for direct use as food or feed, or for processing contains or consists of GMOs. Non-Party exporters, although not bound by the Protocol, should ensure their actions do not contradict the Protocol's objectives nor result in a lower level of protection.

They should also provide relevant information to the BCH.

In all cases, decisions made about the import of an LMO-FFP should be based on a prior risk assessment and the Precautionary Principle. In the absence of national legislation, a risk assessment can still be required prior to the first import of an LMO-FFP, as provided for under the Biosafety Protocol 🌻

Sources: Lim Li Ching, Third World Network & CBD website & UNEP biosafety website.

A Party making a decision regarding domestic use must provide, at a minimum, some information on that LMO-FFP. Among other things, this includes information on the GMO, the genetic modification, the donor and recipient organisms, and a risk assessment report. This is the extent of the obligation of the potential exporting country. It does not have to provide any notification or information directly to the importing Party, although once the decision is placed on the BCH, any Party can request additional information from the authority making that decision.

Source: *agbios*, 2002

RESOURCES

UNEP TOOLKIT MODULE ON THE FORMULATION OF THE REGULATORY REGIME

Downloadable online at:

<http://www.unep.ch/biosafety/development/devdocuments/ToolkitBSE3EN.pdf>

GMOS & BIOSAFETY: A BACKGROUND PAPER FOR DECISION-MAKERS AND OTHERS TO ASSIST IN CONSIDERATION OF GMO ISSUES :

BY T. YOUNG, 2004 - IUCN, GLAND

Downloadable online at:

<http://iucn.org/dbtw-wpd/edocs/PGC-001.pdf> (English)

http://iucn.org/dbtw-wpd/edocs/PGC-001_Fr.pdf (French)



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