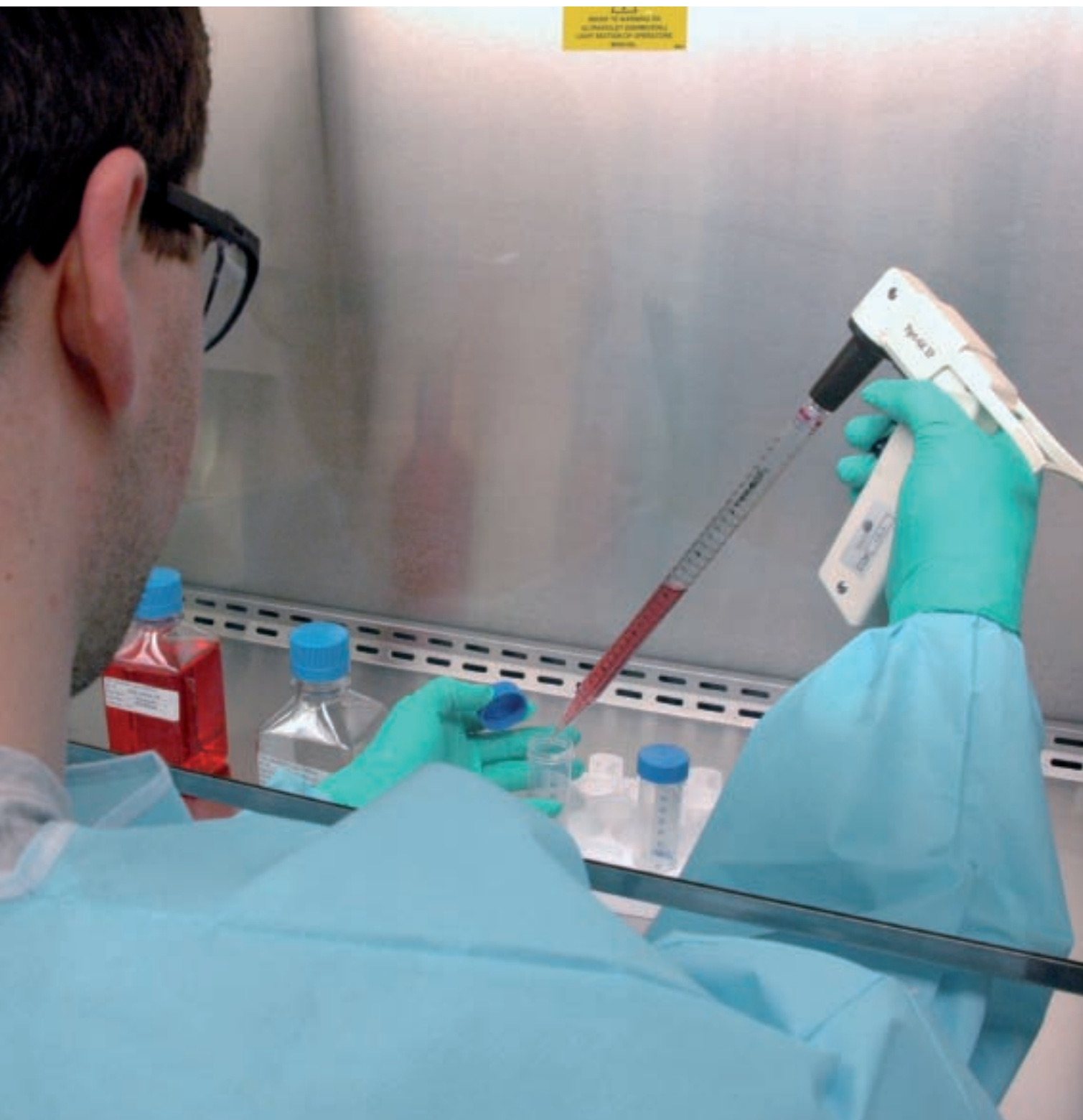


# Biosafety of Biotechnology Products

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## I. INTRODUCTION: WHAT ARE BIOTECHNOLOGY PRODUCTS?

Biotechnology is the science and application of “biological entities” to provide goods and services for human welfare. “Biological entities” refers to plants, animals, microorganisms and their sub-cellular components. As such, biotechnologies have been exploited by humans since ancient history for the production of food, fibres, drugs and many products such as bread, cheese and various fermented foods and goods.

Although the genetic material of all living beings is essentially similar in chemical nature, it is distinctive to each individual type (strains or varieties) of each species. While different living beings may live together in the same ecosystem, the exchange of their similar genetic material is strictly limited to individuals within the same species. Living beings have a precise system which recognizes any foreign genetic material which may gain access to the cell, and subsequently destroys it. This natural genetic barrier helped maintain the basic unique properties and characteristics of each species over millennia, while allowing the development of vast diversity within each species.

In 1971 this natural barrier was broken in the laboratory when genetic material from one species of bacteria was incorporated permanently in another species of bacteria and was “expressed” in the host, imparting novel properties to it as a result of creating a laboratory genetic hybrid possessing properties derived from two incompatible species. This laboratory technique was termed “genetic engineering.” Soon, the human genetic material responsible for producing the hormone insulin (that was not then available as a drug) was incorporated into a bacteria which was grown industrially to produce human insulin for diabetic persons in unlimited quantities. More applications followed in the healthcare field and later in crops. Thus the bacterial genetic material responsible for the production of substances which kill certain insects was incorporated into crop plants making them toxic to, and hence resistant to attack by, these insects. New techniques of biotechnology are being developed continuously and offer a potential for the provision of novel services and goods for human well being limited only by human imagination!

## II. THE ORIGIN OF CONCERN FOR BIOSAFETY OF BIOTECHNOLOGY PRODUCTS

The novelty of genetic engineering raised a number of concerns including ethical concern with intervention with “God’s creations.” The environmental concern focused on the possibility of escape from laboratories of exotic, possibly harmful, organisms developed deliberately or accidentally during experimentation. The concern was that such organisms did not develop in harmony with nature; hence their behaviour in a natural ecosystem is unpredictable and could cause risks to humans and other beings which would be difficult or impossible to contain. While the interaction between naturally occurring living beings following rules of natural biology has been tested over millennia, interaction with genetically engineered beings where such rules have been violated in the laboratory will not be predictable.

Over time, the scare of an escape from laboratories of monster living beings became muted and more confidence crept into public opinion, catalyzing the commercialization of many biotechnology products on a wide scale. Such “open environment release” of genetically engineered products, however, raised a new alarm: what influence could this massive “invasion” have on natural biodiversity? Agenda 21 of the Rio Summit of 1992 (para 16.29) recognized the potential benefits and risks associated with biotechnology. This coincided with the negotiation and drafting of the Convention on Biological Diversity (CBD) in 1992; two articles of the CBD touched specifically on the issue:

- Article 8(g) which states that each Party “*shall establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.*”
- Article 19(3) which states that “*The parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling*



*and use of any living modified organism resulting from biotechnology that may have adverse environmental effect on the conservation and sustainable use of biological diversity.”*

### III. THE VALUE OF BIODIVERSITY

Biodiversity is the total genetic make up of all living beings in all ecosystems on the planet, and covers the diversity between and within species. Biodiversity was influenced not only by the changes which the planet encountered throughout its history, but also by human activity: that is, by humans favouring, developing and manipulating certain varieties of species which better served their needs (using natural biological phenomena) while neglecting others. Perhaps more importantly, humans developed land use systems which destroyed entire ecosystems (and their biodiversity) replacing them with novel ecosystems such as monoculture used in agriculture and animal production systems.

Over thousands of years, but especially in the last few centuries, biodiversity was eroded. Concerns

over a continuation of these trends were expressed and calls for remedial action were raised by different groups of nature lovers. To them, maintaining biodiversity and natural ecosystems are important. Those responsible for breeding so-called “economic species” on which further human development depends for food, fibres and drugs looked at it differently: breeding programs required parental breeding varieties and strains obtainable only from traditional farming and wild ecosystems which came to be called genetic resources. Modern biotechnologists too needed all kinds of natural genetic material since they could not “invent” synthetic genetic material. These various interests merged in the launching of the CBD which was drafted in 1992 and came into force in 1994. Presently, over 190 states are Parties to the CBD. Many industrial interests, especially in the drug industry, felt that there is an un-exploited potential wealth of drugs and industrial products in biodiversity which warrants its conservation and sustainable use. Since developing countries are home to most such natural biodiversity they added a third objective to the CBD: benefit sharing between the developer and the provider of sustainably exploitable biodiversity.

TABLE 1 BASIC DATA ON INTERACTION BETWEEN ARAB COUNTRIES AND THE CPB

Country	CPB party since (dd/mm/yy)	National focal point at	Competent national authority	Nbf signed	Bch project signed
<b>Algeria</b>	3/11/2004	Environment Division, Ministry of Science	Not designated	No	Yes
<b>Bahrain</b>	Has not signed	Environment Department	Not designated	No	No
<b>Comoros</b>	Has not signed	Environmental Section, Ministry of Agriculture, Forestry, Industry and Environment	Not designated	2/12/2002	No
<b>Djibouti</b>	11/9/2003	Environment Department, Ministry of Human Settlements and Environment	Same as NFP	1/4/2003	Yes
<b>Egypt</b>	21/3/2004	Egyptian Environmental Affairs Agency, Ministry of State for Environmental Affairs	Same as NFP	1997/1999 (concluded)	Yes
<b>Iraq</b>	Has not signed	Embassy of Iraq, Ottawa, Canada	Not designated	No	No
<b>Jordan</b>	9/2/2004	Biodiversity Division, Ministry of Environment	Not designated	16/06/2002 Concluded 15/08/2004	Yes, 2007
<b>Kuwait</b>	Has not signed	Environment Public Authority	Not designated	No	No
<b>Lebanon</b>	Has not signed <sup>(1)</sup>	Department of Conservation of National Wealth, Ministry of Environment	Not designated	10/06/2003 Concluded 1/02/2006 <sup>(2)</sup>	Yes
<b>Libya</b>	12/9/2005	Environment General Authority	Not designated	No	Yes
<b>Mauritania</b>	20/10/2005	International Convention Affairs, Prime Minister's Office	Not designated	No	Yes
<b>Morocco</b>	Signed only 25/05/2000	Department of Environment, State Secretary of Water and Environment	Not designated	5/2/2004	Yes
<b>Oman</b>	11/9/2003	Nature Conservation, Ministry of Regional Municipalities, Environment and water	Same as NFP	No	No
<b>Palestine</b>	Has not signed	Not defined	Not designated	No	No
<b>Qatar</b>	12/6/2007	Supreme Council for Environment and Natural Resources	Same as NFP	No	No
<b>Saudi arabia</b>	7/11/2007	King Abdul Aziz City for Science and technology	Not designated	No	No
<b>Somalia</b>	Has not signed	Ministry of Foreign Affairs	Not designated	No	No
<b>Sudan</b>	11/9/2005	Higher Council for Environment and Natural Resources, Ministry of Environment and Physical Development	Ministry of Science and Technology	14/11/2002	Yes
<b>Syria</b>	30/06/2004	General Commission for Environmental Affairs, Ministry of Local Administration and Environment	Ministry of Agriculture and Agric. Reforms <sup>(3)</sup> Ministry of Economy and Trade <sup>(4)</sup>	30/09/2003	Yes
<b>Tunisia</b>	11/9/2003	Ministry of Environment and Sustainable Development	Not designated	1997/1999 Concluded	Yes
<b>Uae</b>	Has not signed <sup>(5)</sup>	Federal Environmental Agency	Not designated	No	No
<b>Yemen</b>	1/3/2006	Environmental Protection Agency	Not designated	27/06/2003	Yes

(1) According to the records of the CPB. According to the response to the questionnaire, Lebanon is a party  
(2) UNDP was involved along with UNEP

(3) For microorganisms and Plants  
(4) For Handling, identification, import/export and human health  
(5) According to the records of the CPB. According to the response to the questionnaire, UAE is a Party

#### IV. THE SCOPE OF RISKS POSED BY BIOTECHNOLOGY APPLICATIONS

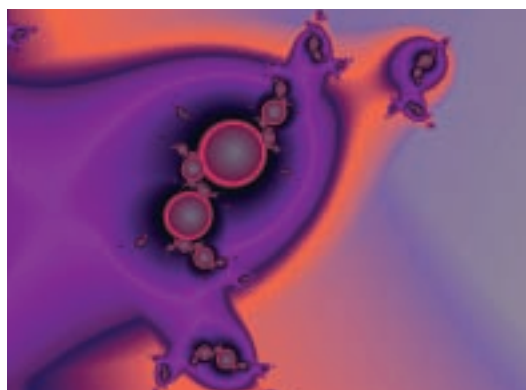
As mentioned above, the main risk is erosion or contamination of natural biodiversity. However, because of the short experience humanity had had with biotechnology products there was concern that human health too could be negatively impacted upon, hence a reference to this aspect in Article 8(g) of the CBD. Negotiations for the protocol referred to in Article 19 of the CBD started in 1995 and ended with the approval by the Parties to the CBD of the Cartagena Protocol on Biosafety (CPB) regulating trans-boundary movement of Living Modified Organisms (LMOs, another term for Genetically Modified Organisms, or GMOs) in 2000. The protocol came into force in 2003 and currently 141 Parties to the CBD are Parties to the Protocol. Three Meetings of the Parties were convened in 2004, 2005 and 2006 where two unsettled issues were discussed:

1. Article 18 on documentation necessary for transport of LMOs; and
2. Article 27 on “international rules and procedures” for liability and redress for damage resulting from trans-boundary movement of LMOs

The 4<sup>th</sup> Meeting of the Parties is planned for May 2008.

The main thrust of the protocol, in line with Article 19 of the CBD, is to regulate trans-boundary movement of LMOs in such a way that a state accepts shipment of LMOs only after *explicit* Advance Informed Agreement (AIA) procedures have been applied. Decision by an importing country on whether to receive a shipment relies on the provision of certain information by the exporter which makes it possible for the National Competent Authority (NCA) of the country of import to decide, based on risk assessment (RA) in the receiving environment. Decision-making may take into account socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biodiversity, “especially with regard to the values of biodiversity to indigenous and local communities” (Article 26).

During the negotiations, it was recognized that the Protocol would have serious implications for



international trade, especially for GMO commodities. The Preamble of the Protocol, while clearly “reaffirming the Precautionary Approach contained in Principle 15 of the Rio Declaration on Environment and Development,” also recognized “that trade and environment agreements should be mutually supportive with the aim of achieving sustainable development,” and emphasized that the Protocol “shall not be interpreted as implying a change in the rights and obligations of a party under any existing international agreements” but expressed the understanding that “this is not intended to subordinate this Protocol to other international agreements.”

Finally, while the Protocol deals only with trans-boundary movement of LMOs, Article 2 dictates that “each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.” Simply stated, this requires each Party to formulate national legislation which makes compliance with Protocol obligations possible. The Protocol also established a Biosafety Clearing House (BCH) to facilitate the exchange of information and experiences and to make national information available, if applicable.

#### V. THE ROLE OF ARAB STATES IN THE NEGOTIATION OF THE PROTOCOL

Although the Arab League enjoys a formal status at the United Nations, the Arab world is not recognized as a region and is split between the African and the Asia-Pacific regions. During the negotiations for the Protocol (1995-2000) the Asia-Pacific group was not very effective except through the *Group of 77 and China* which in fact re-formed as the Like-Minded Group (LMG) due

TABLE 2 INFORMATION AVAILABLE<sup>(1)</sup> ON ARAB COUNTRIES ON THE BCH<sup>(2)</sup>

Country	Designate CNA	Experts listed in Roster	Capacity needs defined	Formulate NBF	Formulate National legislation	URL for NFP	Submit Interim National Report	Submit First national Report
<b>Algeria</b>	No	2	No	No	No	No	Yes	No
<b>Bahrain</b>	No	1	No	No	No	No	No	No
<b>Djibouti</b>	Yes	None	No	No	No	No	No	No
<b>Egypt</b>	Yes	7	Yes	Yes	Draft, 30/12/06	www.egbch.com	Yes	Yes
<b>Lebanon</b>	No <sup>(3)</sup>	6	No	Yes <sup>(4)</sup>	No	www.biosafety.moe.gov.lb	No	No
<b>Mauritania</b>	No	None	Yes	No	No	No	No	No
<b>Morocco</b>	No	19	No	No	No	No	No	No
<b>Oman</b>	Yes	None	No	No	No	No	No	No
<b>Qatar</b>	Yes	None	No	No	No	No	No	Yes
<b>Saudi Arabia</b>	No	2	No	No	Yes <sup>(5)</sup>	No	No	No
<b>Sudan</b>	Yes	2	Yes	Yes <sup>(4)</sup>	No	www.biosafety.gov.sd <sup>(6)</sup>	No	Yes
<b>Syria</b>	Yes	4	No	No	No	No	No	Yes
<b>Tunisia</b>	No	7	No	No	No	No	No	No

(1) The following countries only reported designation of NFP: Comoros, Iraq, Jordan, Kuwait, Libya, Somalia, UAE, Yemen. All countries listed in the table designated NFP. No decisions were reported by any of the countries listed, except for one by Syria relating to non-recognition of Israel. Palestine is not listed on the BCH

(2) www.bch.cbd.int/default.asp

(3) This is in contradiction of the response to the questionnaire

(4) Preliminary, to be finalized.

(5) No details are available

(6) Covers the NBF project only.

to conflicting positions of a few members (notably Argentina and Uruguay) with the rest of the group. Arab states belonged to the LMG in which the African bloc exercised significant influence. Coordination among Arab states was occasionally catalyzed by a representative from the Arab League but this was not particularly effective or consistent. Within the African group, Egypt exercised significant influence mainly because it was the only Arab country where the same representative was present in all negotiation sessions. Informally, there was a degree of concerted action between Asian and African Arab representatives.

## VI. CAPACITY BUILDING UNDER THE PROTOCOL

Capacity building is covered by Article 22 of the Protocol which encourages efforts to enhance the capacity of developing countries towards meeting their obligations under the Protocol. The financial mechanism established under Article 28 of the Protocol is the same as that established under Article 21 of the CBD. Multilateral capacity building efforts were accordingly funded by the Global Environment Facility (GEF) established

in 1991 as the financial mechanism for activities in developing countries “which protect the global environment.” GEF placed emphasis on 6 “focal areas,” including biodiversity to which it allocated \$1.89b in 1991-2004. Its “strategy for biodiversity” (with 4 strategic objectives) includes – within its Strategic Objective No. 3 – an “initial strategy for biosafety” supporting the implementation of the CPB through national, sub-regional and regional projects aiming at establishment of:

- National coordination mechanisms;
- Effective regulatory policy frameworks;
- Administrative frameworks;
- Capacity to conduct risk assessment including standardized regional methodologies;
- Workable and up-dated biosafety clearing house (BCH) participation including regional cooperation.

GEF funded a pilot project in 1997-1999, even before the Protocol became operational, to test the feasibility of developing a framework for Biosafety (NBF) in each of 18 countries – including 2 Arab states: Egypt and Tunisia. The project was expanded, in June 2001, to cover some 139

developing countries, including an additional 8 Arab states. This was complemented with small grants to also develop capacity to interact with the BCH in the same countries. GEF also funded a number of medium-sized projects in a few countries to develop the full implementation phase of the NBFs, and this included projects in Egypt and Tunisia.

Development of NBFs includes: information gathering, analysis, consultation, training and preparation of a draft NBF (draft legal instruments, administrative systems, risk assessment procedures, systems for public participation and information). Regional workshops will: increase understanding of the Protocol and assess implications for risk assessment and decision-making at national levels, while sub-regional workshops aim to identify: capacity building needs, opportunities for collaboration, mechanisms for sharing of risk assessment and management experiences, coordination of capacity building activities and networking to share lessons and experiences. The total cost of the project is \$38.4 million. This is funded by a contribution of \$26.1 million from GEF, with co-financing of \$12.3 million from UNEP and participating countries. These countries contribute one third of the costs of their national projects, in cash and/or in kind.

## **VII. THE STATUS OF IMPLEMENTATION OF THE PROTOCOL IN ARAB STATES**

Thirteen Arab states are presently Parties to the Protocol and an additional state (Morocco) only signed it, while seven neither signed nor ratified (Table 1). Thirteen Arab countries are eligible for GEF funding and the GEF pilot project assisted two of them (Egypt and Tunisia) draft NBF in 1997-1999. Within the full scale project eight additional Arab countries were supported. While 95 countries concluded their projects, only three Arab countries finalized theirs: Egypt, Jordan and Tunisia. This effort was largely done with technical support from the United Nations Environment Program (UNEP). The project produced three toolkits (none in Arabic) for (i) starting the project; (ii) taking stock; and (iii) consultation and analysis.

Another toolkit on drafting the NBF was produced in Arabic with two components: formu-

lation of the regulatory regime and design of the administrative system for handling applications and notification. No regional or sub-regional workshops were conducted either in or for Arab countries.

The “add on” activity, aiming at establishing national BCH nodes in each of the countries funded, aimed at “building capacity for effective participation in the BCH” of the CPB. It was signed with 12 Arab countries but none have been concluded as yet (Table 2). The project designated 47 “regional advisors” including four from Arab countries of which only three can speak Arabic. The project also offers free software solutions for BCH nodes developed by the United States, Canada and Switzerland. No Arab country seems to have made use of this offer.

## **VIII. INTERACTION BETWEEN ARAB STATES AND THE BCH OF THE PROTOCOL**

The BCH presents information which is voluntarily provided by Parties and non-Parties. The information provided by each of the Arab states is presented in Table 2. Only one Arab country (Egypt) has a national site linked to the central portal of the BCH with 2 others (Lebanon and Sudan) linking their sites for the GEF NBF projects only.

## **IX. RESPONSE OF THE NATIONAL FOCAL POINTS IN ARAB STATES TO A QUESTIONNAIRE**

In early September 2007, a questionnaire was emailed to the NFP of each of the Arab countries along with a covering letter explaining the purpose of the questionnaire. Two appeals for speedy responses were sent two weeks apart afterwards. The information received in nine responses is presented in Table 3. Since several countries did not respond, information was retrieved from the records of the BCH site as well as those of GEF, UNEP, UNDP, and the International Center for Genetic Engineering and Biotechnology (ICGEB) – all of which maintain records of biosafety activities – and this information was incorporated in Tables 1 and 2. Whenever a URL for the national agency respon-

TABLE 3 INFORMATION ON ARAB COUNTRIES RESPONDING TO QUESTIONNAIRE <sup>(1)</sup>

Country	Egypt	Jordan	Lebanon	Libya
NBF in place	Yes	Yes	Yes	Near completion
Capacity needs defined	RA/RM <sup>(2)</sup> Detection, Administration	Not defined	RA/RM Administration, Detection, Interagency coordination	RA/RM Detection, Law enforcement, Public awareness
National legislation status	Draft Approved by Ministry of Justice	"launched" October 2006	Draft by Ministry of Environment	Chapter 10 of Law 15-2003 on environment
NCA designated	Ministry of Environment			Yes, EGA
Detection facilities available	Yes	No information	Yes	No
Risk assessment capability	Yes	No	Yes	No
Requirements for shipping documents	No	No information	Yes	Under preparation
Liability and redress arrangements	No	No	Yes	Yes
BCH site operative	Yes		Yes	No
GMO shipments received	Not legally	No information	Not known	Not known
Regional approach	Useful	Useful	Useful	Useful

(1) Only Egypt and Tunisia signed implementation projects  
 (2) RA/RM: Risk assessment/ risk management

sible for implementation of the Protocol was indicated in the records, it was consulted and relevant information too was incorporated in Tables 1 and 2.

## X. ANALYSIS OF THE STATUS OF BIOSAFETY AND PROTOCOL IMPLEMENTATION IN ARAB COUNTRIES

A paucity of information on environmental activities, taking a holistic concept for the environment, is common in developing countries. Thus the concept of environmentally sustainable development, for example, is not fully appreciated or understood by decision-makers and by the public. Reasons often cited include: pressing economic and political issues and weak civil society. The environment thus largely remains a genuine concern only for the elite and a few scientists. Only when qualities of air and water deteriorate, along with accumulation of domestic wastes – elements of classic pollution – becoming a health hazard does the public get involved. Arab countries, even the affluent ones, are no exception. Many environmental issues draw the concern of decision-makers and the public as a result of "environmental agitation" in developed coun-

tries, especially when their impact on the global environment necessitates international action. Issues of climate change are a case in point. This is especially true with the current advances in communication and closer contact between different peoples and cultures. Interest in biosafety, and even in the broad area of biodiversity, in Arab countries typically reflects the observations made above.

Analysis of the information presented above suggests the following:

### ***Achieving inter-agency cooperation on inter-sectoral environmental issues***

The environmental dimension impacts practically all human activities and hence needs to be tackled by joint team action of several actors. Such team action requires both a political will and strong public pressure to force the isolated islands of governance to cooperate. The political and popular (and possibly even cultural) environments in Arab countries do not seem to be conducive to this approach of inter-agency team work. In fact, different government agencies tend to deal with their environmental concerns separately and individually, if not with some inter-agency rivalry, regarding the environmental

Morocco	Qatar	Syria	Sudan	UAE
No	No			No
Technical & financial support	RA/RM Detection, Legislation	RA/RM, BCH, Legislation Administration	RA/RM Detection, Training Biosafety research	Technical support, Training, Public participation
Draft by Dept. of Environment	Under discussion at NFP	Being drafted	Law being discussed	Only Federal Law 24/1999 on Environment
No information	No	No	Yes	No
No information	No	Limited	Yes	Yes
No	No	Only in the Draft Law	Yes	Yes
No	No	Being drafted	Yes	Yes
No	No	No	Yes	No
No	No	No	No	No
Useful	Urgently needed Workshops planned	Not practical	Useful	Useful

dimension as a hindrance and exhibiting a desire to protect their little empires! Needless to say, each agency has a primary clientele with interests focused on the main sector rather than inter-sectoral approaches and concerns, such as the environment. The establishment of a coordinating national environmental agency did not prove to effectively outwit this attitude and ministries of environment in Arab countries did not present novel mechanisms for the environment to escape sectoral emphasis and rivalry.

In developed countries, mechanisms, expertise and resources exist for achieving coordination between agencies and each is held accountable for inability to respond to needs for coordination.

### **Public attention to and involvement with the issues of biosafety and biodiversity**

In Arab countries, common citizens are often preoccupied with concerns of immediate everyday impact (such as how to make a decent living) that over-shadow concerns for the medium or distant future. Biodiversity by its nature is a long term concern, obscuring the direct benefits to the individual of supporting it. Surprisingly, and because of the reflection of the hot international

debate on biosafety in the local media, certain aspects of biosafety (mainly health implications) attracted some public attention. The safety of food produced by biotechnology caught the attention of certain media actors, and hence furnished the public with (mostly inaccurate) claims. Thus GMOs were blamed for food poisoning, reduced flavour of vegetables and fruits, causing cancer etc, elements in which GMOs are in fact not implicated (see also chapter 10). As a result, food biosafety acquired a much larger sector of the public debate in Arab media than the most important concern which is impact on biodiversity. In public discussions the impact of GMOs on biodiversity was consistently overshadowed by the health impacts. The conspiracy theory was quickly recalled accusing GMOs of being a hazardous product to be tested on peoples from developing countries using them as guinea pigs. However, genuine socio-economic considerations were often raised too.

In developed countries, concern for biosafety was raised, as early as 1971, by scientists, environmentalists and religious leaders. Wider spread concern was strongly evident during the negotiation stage of the CBD in 1992 and this was reflected in Articles 8(g) and 19. The debate continued in developed countries and inter-agency

## THE CASE OF EGYPT

The case of Egypt is illustrative of the general sluggishness of progress in the Arab region: despite a head start and obvious enthusiasm, not much has progressed to its logical conclusion in practice. Thus, while technical expertise in biotechnology allowed laboratories in Egypt to become affiliates of the ICGEB as early as 1983, to date, biosafety research publications are scarce. Egypt's effort to address biosafety was set in motion in 1992 by the terms of collaboration between Agricultural Genetic Engineering Research Institute (AGERI) and the Agricultural Biotechnology Support Project (ABSP). A biosafety system was formally instituted by the Ministry of Agriculture through two ministerial decrees: No. 85 (January 25, 1995) establishing a Biosafety Committee, later re-designated National Biosafety Committee (NBC); and No. 136 (February 7, 1995) adopting biosafety regulations and guidelines under the Central Administration for Seed Testing and Certification of the Ministry. This, rather than the much more relevant Law 4 of 1994 on the environment, was the umbrella law for the decrees, for reasons related to the activity being initiated by the Minister of Agriculture (to cater for specific research activities by the Ministry) rather than by a concerted decision of the government as a whole. In fact, other ministries (such as those responsible for scientific research, higher education, environment, health, trade, finance, justice, foreign affairs etc) were neither consulted nor informed in advance of the Decrees.

These described the modalities of use, handling, transfer, and testing of *all* GMOs – but in fact were designed for seed certification. They addressed laboratory practices, greenhouse containment, and small-scale field testing including conducting risk assessments and issuing permits, and called for establishment of Institutional Biosafety Committees at *all* institutions conducting recombinant DNA research. In practice, no functional institutional biosafety committees



were established. The NBC does not meet on a regular basis but rather occasionally (at best once or twice a year) and has to deal with tens of applications for field testing of GMO seeds as well as for other research on GMOs, within a couple of hours. It has no secretariat, government financial resources or a technical-administrative system to screen information provided by the applicant – which is often a open-page resume. No formal signed permits are issued: only a decision is recorded in the minutes of the committee meeting. The NBC does not experimentally check the claims made by the applicant or conduct risk assessment. The NBC did not constitute the sub-committees (on health, agriculture, industry and environment) it decided will screen applications or examine those referred to it by the NBC. The contradiction was evident when the Ministry of Health issued Decree No. 242 in 1997 prohibiting the import of any foodstuff produced through the use of GMOs “unless safety is confirmed” and requiring that any imported seeds be accompanied by a certificate from the country of origin confirming that these seeds were not produced from “untested GMO crops.” This Decree too did not specify procedures, responsibilities, enforcement or penalties and did not mention how to deal with locally produced foodstuff or seeds.

discussions were initiated, along with public consultation, in order to formulate positions. The public was heavily involved in the debate which was often influenced by interest groups, business, NGOs and a general mistrust of scientists and regulators after the mad cow disease fiasco. By the late 1990s, when negotiations for the Protocol were approaching their conclusion, consensus was established and genuine positions of developed countries gelled – often reflecting popular demands aired by voters. Biosafety became a political issue.

A somewhat similar approach developed in those developing countries where the political environment allowed it, such as in India and some Latin American countries. This did not take place in any Arab country, and the issues only trickled into the media as a ripple effect of the actual negotiations for the Protocol. Governmental consideration was limited, at best, to following positions of others during the negotiations. This explains the fact that, to date, not a single Arab country party to the Protocol has the national legislation, called for in Article 2, which is necessary for implementation while several other developing countries already have legislation and operative regulatory systems in place.

### **The importance of political will**

A notable observation in the above tables is that country preparedness is not seriously influenced by the level of affluence or availability of expertise, a reflection of the fact that lack of political will is a more decisive factor in the state of affairs of biosafety in Arab countries. Thus, none of the eight affluent Arab countries which do not qualify for GEF financial support sought technical assistance of relevant UN agencies to develop an NBF or relied on national expertise for this purpose. A related observation is that countries which received financial support to develop an NBF, and concluded or are close to concluding it, did not then fully develop national mechanisms for implementation but sought or are seeking further financial support for implementation, despite the fact that the cost of development and approval of appropriate legislation is minimal.

Some contradictions within the responses of some countries to the questionnaire were recorded, which again reflect a lack of political will and

coordination rather than resources. Thus, while some countries reported availability of “GMO detection facilities” and “risk assessment capability,” the same countries reported that it is not known whether shipments of GMOs have been received or not. In some ways, this also applies to reporting availability of liability and redress provisions and the requirement of special shipping documentation for GMO products by some countries which in fact reported lack of legislation regulating the handling and release of such products. Similarly, most Arab countries did not notify the Protocol Secretariat of their capacity building needs, in response to a request to this effect made in 2005, while an expression of such needs was made in responses to the questionnaire.

In the example of Egypt, and in general, one can detect a level of *personification* rather than *institutionalization* of actions relating to biosafety in Arab countries. In many cases, one can conclude that the basic question of who takes responsibility for implementation of relevant regulations is still not settled. In almost all countries, primary responsibility is entrusted to an office responsible for environmental concerns (probably because the mother treaty, the CBD, is an environmental treaty). However, when it comes to implementation which necessarily also touches on health, agriculture, trade, scientific research etc, the question becomes more difficult to answer. One interesting example is in Syria which designated three (in some reports even four or five) independent CNA for the protocol despite the obvious fact that relevant decisions will have to take *all* interests into consideration with a coordinating mechanism based in the environmental agency – as is the case with the vast majority of parties to the Protocol. This is also an example of lack of political will hindering development of effective coordination mechanisms to deal with biosafety.

### **Positive signs for the future**

Despite these negative observations, it is safe to conclude that the international debate on biosafety along with the initiation of GEF-supported activities in several Arab countries has catalyzed action by government agencies and are encouraging the question of national coordination to be considered and settled. The surveys and workshops conducted during the course of

the GEF projects raised both governmental and public awareness of the issues. Even some countries which did not qualify for GEF support carried out somewhat similar activities on their own which were instrumental in satisfying similar objectives. Some more are being planned. The Arab League organized a workshop to review the status of implementation of both the CBD and the CPB in 2006 and a network for concerted action was proposed to be hosted by the Arab Center for Semi-Arid Dry-lands (ACSAD) but did not yet effectively operate. In September 2007, a preparatory meeting was convened by UNEP, FAO and ICARDA (The Regional Consultation on Biotechnology and Biosafety for Agriculture and Environment in the West Asia and North Africa Sub-region), which included also certain non-Arab countries of the region, to draft a regional project on biosafety to be submitted to GEF. The objective of this workshop was “to develop, through a participatory approach, a proposal for an integrated regional framework on biotechnology and biosafety involving major stakeholders.” Biosafety regulation is recognized here as “an integral part of the development of any transgenic variety.”

In a number of countries, there are strong influences of trade partners and foreign interests with their own positions on biosafety issues. This is evident from the unexplainable delays in taking national actions which at one point seemed to be sailing through. It is known, for example, that the USA, which is by far the biggest producer of biotechnology commodities and seeds, took the European Union members to the World Trade Organization with claims for damages resulting from an EU de facto moratorium on approval of GMOs, since the two trade giants hold opposing views on the regulation of GMOs. At one point, one Arab country announced it would file suit on the side of the USA, and this was denied by higher authorities only after the EU expressed serious displeasure.

### ***The Arab countries' positions on GMOs***

Except for a few products for health care, none of the Arab countries currently produce their own biotechnology products – especially commodities. Some have active research programs for developing such products, but, unlike countries such as Brazil, China, India and South Africa,

there are no indications that such production could take place in the near future, say the next five to ten years. Thus, apart from the health care field, Arab countries are potential importers rather than exporters of biotechnology products. In fact, the position of the Arab world (being a major world importer of food, especially cereals) on GMO wheat was instrumental in convincing the wheat industry in North America to delay commercialization of GMO wheat in 2004 and until now. With the recent sharp rise in the prices of cereals and vegetable oils in world markets, as a result of moves to use them for producing bio-fuels, the situation may in fact change. On the other hand, some Arab countries export certain agricultural products such as vegetables and fruits, especially products of organic farming, to the EU which maintains strict biosafety regulations. Since these exports represent significant components of the balance of payment for these countries, they are careful to institutionalize national regulations in conformity with those of the importers.

Independent studies indicated that several imported GMO commodities are in the markets of Arab countries, un-declared and un-labeled. These include corn and maize (sometimes containing the Starlink variety which is not approved for human consumption), long grain rice (which was contaminated with a variety not approved for commercialization) and soybean seeds, oil and cake.

## **XI. CONCLUSIONS**

- 1- Biosafety is still not a major public or policy-makers issue in Arab countries, except from a food safety perspective.
- 2- Biosafety is essentially entrusted to the environmental agencies but with several other actors intervening rather than cooperating.
- 3- Arab countries are potential importers, rather than exporters, of most biotechnology products and this situation is not likely to change in the near future, especially in field of commodities.
- 4- Despite financial and technical support to developing Arab countries all still lack legal regulatory mechanisms in place and their participation in the Protocol's BCH is extremely weak.



- 5- Some GMOs commodities gain access to Arab countries un-declared and un-labeled due to lack of legislation, enforcement mechanisms and appropriate administrative structures.
- 6- Directing resources to the areas of biotechnology development and public communication will basically means that skills in areas such as risk assessment, which is essential for importing countries to be able to make informed decisions under the AIA procedure of the Protocol, would not be well developed. Without external assistance, capacity in risk management would be overlooked and Arab countries would not be able to effectively manage risks to the conservation and sustainable use of biodiversity within their territory or protect their trade interests.
- 7- Other efforts needed are: training of the representatives of different ministries and customs staff in the field of GMO identification, AIA procedures, risk management, producing manuals for private companies, which detail their obligations under the biosafety legislation, and building scientific capacity to monitor longer-term impacts on environment, human health and biodiversity through a risk management program;
- 8- Activation of biosafety issues must await political will and a role for civil society. Unless this takes place, biosafety activities in Arab countries will not be sustainable and they will continue to receive biotechnology products un-declared and un-labelled. Negative impacts on development of indigenous biotechnology, biodiversity, competitive trade advantages, socio-economic norms and health would be significant.

## REFERENCES / FURTHER READING

Mackenzie, Ruth, Françoise Burhenne-Guilmin, Antonio G.M. La Viña and Jacob D. Werksman. *An Explanatory Guide to the Cartagena Protocol on Biosafety* IUCN Environmental Law Paper No. 46. Cambridge, UK: IUCN Environmental Law Center, 2003.

"The Cartagena Protocol on Biosafety: A record of the negotiations." Secretariat of the Convention on Biological Diversity, United Nations Environment Programme. September 2003. [www.biodiv.org/doc/publications/bs-brochure-03-en.pdf](http://www.biodiv.org/doc/publications/bs-brochure-03-en.pdf) (accessed March 8, 2008).

### **In addition, the following websites contain valuable information on the topic of biosafety and biotechnology:**

"Biosafety home page." United Nations Environment Programme (UNEP) Home Page. <http://www.unep.org/biosafety/> (accessed October 15, 2007).

"Biosafety Information Network and Advisory Service." UNIDO. <http://www.binas.unido.org/binas> (accessed October 12, 2007).

"Egyptian Biosafety Clearing-House." Egyptian Biosafety Clearing-House (EG-BCH). <http://www.egbch.com> (accessed October 15, 2007).

"Global Environment Facility." Global Environment Facility (GEF). <http://www.gefweb.org/index.html> (accessed November 23, 2007).

"Homepage - Biosafety Lebanon 2005." Biosafety Lebanon, Lebanon Ministry of Environment. <http://biosafety.moe.gov.lb/> (accessed December 3, 2007).

"ICGEB - Home." The International Centre for Genetic Engineering and Biotechnology. <http://www.icgeb.org> (accessed December 3, 2007).

"Lebanese national biosafety framework project" <http://www.undp.org.lb/programme/environment/> (accessed November 17, 2007).

"Nuffield Council on Bioethics - Home." Nuffield Council on Bioethics. <http://www.nuffieldbioethics.org> (accessed October 18, 2007).

"Sudanese national biosafety framework project." <http://www.biosafety.gov.sd> (accessed October 28, 2007).

"The Biosafety Clearing-House (BCH) Central Portal." The Biosafety Clearing-House. <http://bch.cbd.int/> (accessed November 3, 2007).

"UNDP - GEF." United Nations Development Programme. <http://www.undp.org/gef/> (accessed March 6, 2008).

"Union of Concerned Scientists." Union of Concerned Scientists. <http://www.ucsusa.org> (accessed March 6, 2008).