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BIOTECH TRADE POLICY EDUCATION AND CAPACITY-BUILDING: WTO OUTREACH AND KENYA CASE STUDY

RAISE SPS DIAGNOSTIC REPORT #38

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Biotech Trade Policy Education and Capacity-Building: WTO Outreach and Kenya Case Study

The original purpose of this activity was to conduct outreach to foreign officials with an interest in issues related to trade in products of agricultural biotechnology. At the request of USAID, we focused in particular on compatibility of international agreements and domestic legislation with the rules of the World Trade Organization. Much of our effort was directed towards trade ministry officials who understood WTO obligations and the importance of WTO disciplines, but who were unfamiliar with biotech trade issues.

The project had two phases. The first five activities took place in Geneva and the last three in Nairobi.

The pace of the Geneva phase and the approach were affected by the WTO negotiating calendar. We began by organizing seminars on biotech-related trade issues. As the frequency of negotiating sessions in Geneva increased, making it difficult for negotiators to set aside several hours for a seminar, we began to meet individually with officials from key countries.

The success of this phase of the project can be measured in the attitudes of Geneva-based officials regarding biotechnology. When we first began most Geneva-based officials were only vaguely familiar with the technology and the trade issues associated with it. Many of them questioned the applicability of the WTO *Agreement on the Application of Sanitary and Phytosanitary Measures* (the SPS Agreement) to products of biotechnology. Some key delegates worried that the technology was so controversial that any attempt to use WTO rules to pressure domestic regulators would have serious negative consequences for the WTO. Others believed that biotech was so new and so poorly understood that it might require extraordinary regulatory oversight.

We used the seminars and private meeting to provide information on the technology, to discuss its potential benefits, especially for developing countries, and to explain how it could be regulated in a WTO-consistent manner. For officials from countries that were not yet producing or exporting biotech products, we illustrated the potential consequences of illegitimate biotech-related trade restrictions by drawing parallels to other current trade issues. We produced analyses of the potential conflicts between the *Cartagena Protocol on Biosafety* and the WTO and worked to get trade officials more involved in the negotiation and implementation of that agreement.

Trade officials around the world, especially those in Geneva, are more familiar with biotechnology than they were in 2004 – in part, we hope, due to our efforts. It is rare now to hear anyone make the argument that the SPS Agreement does not apply to biotech. (Indeed, the U.S. recently won a biotech-related dispute settlement case against the EU involving claims under the SPS Agreement, and the outcome caused very little controversy.) Moreover, most key officials recognize that it is in their interest to see WTO disciplines fully respected with respect to trade in biotech products, even if they do not yet produce or export those products. However, we had limited success in persuading trade ministry officials to take a more active role in the development of WTO-consistent domestic regulations. Accomplishing that goal would require a more prolonged and sustained effort and would ideally involve work in key capitals.

By late 2005 the pace of the Doha Round of WTO negotiations became so intense that it became difficult to continue with our work in Geneva. As a result, USAID asked us to refocus our efforts on Kenya. The Kenyan government was in the process of developing its regulatory framework for biotech products. We were asked to work with Kenyan officials and private sector stakeholders to try to ensure that the legislation was effective, minimally trade-disruptive, and WTO-consistent. We prepared detailed comments on the draft bill and traveled to Nairobi three times for meeting with key Kenyan officials and private sector stakeholders. We also worked between visits with stakeholders to help them develop a lobbying strategy.

The results of the activity were mixed. The current draft of the bill, which is new before the parliament, incorporates nearly half of our proposed amendments. However, many of the most significant problems remain. It may be possible to address those problems during the drafting of implementing regulations.

GENEVA ACTIVITIES:

Deliverable #1: Geneva Symposium (May 27, 2004)

In May 2004 the WTO organized a symposium for non-governmental organizations (NGOs), the press and delegates from WTO member countries. Six weeks prior to the symposium DTB Associates learned that Friends of the Earth was putting on a workshop at the symposium entitled "*The GMO dispute — rules, risks and reality*". Since the first meeting of the WTO panel that was adjudicating the dispute between the U.S. and the EU regarding biotech imports was scheduled to take place the week after the symposium, we were concerned that the Friends of the Earth program would affect the press climate as well as the attitudes of representatives from key countries. When we protested what we believed would be a one-sided presentation by Friends of the Earth, the WTO offered us an opportunity to organize a session of our own. We did so, using RAISE funds. Below is the program for our session.

Session Title: Trade, Technology and Development

Moderator: Julian Morris, International Policy Network

Speakers:

- Johan Norberg – author of "In Defence of Global Capitalism"
- Margaret Karembu – University of Nairobi
- Andrew Shoyer – partner, Sidley Austin LLP

Julian Morris and Johan Norberg addressed the general topic, focusing on the negative effect of regulatory barriers on transfer of technology to developing countries. Margaret Karembu and Andy Shoyer discussed ag biotechnology as the prime example of the problem. Karembu talked about biotech applications in developing countries and the difficulties that trade problems are causing for developing countries that want to use the technology. Shoyer discussed relevant WTO rules governing, e.g., pre-market approval, labeling, traceability, etc.

We also organized on the day of the session a lunch with the Geneva press corps. Eleven journalists attended, including the core of the international trade press – Reuters, Bloomberg, BNA, Washington Trade Daily, etc. – and journalists from a number of key WTO member countries. The presenters from our symposium session attended, as did John Weekes of Sidley Austin, Helen Disney of the Stockholm Network and Craig Thorn of DTB Associates.

The purpose of the lunch was to provide information and analysis regarding the application of WTO rules to trade in biotech products in order to counter in advance the misinformation that would come out of the Friends of the Earth session. We also wanted to give reporters a context for their reporting the following week on the first meeting of the panel in the EU moratorium case. Andy Shoyer summarized the arguments made by the U.S., Argentina and Canada in their first submissions to the panel (his written summary is attached in Annex 1), and he and the other presenters answered journalists' questions. Margaret Karembu was particularly effective in explaining the extent to which EU actions regarding biotech have affected developing countries and the reasons why those countries have an interest in the proper application of WTO rules.

The symposium session was attended by around 30 participants. Unfortunately, many of the Geneva-based delegates from WTO member governments that we have been working with on biotech issues were involved that day in an important informal joint meeting of the Cairns Group and the G-20 and were therefore unable to attend. The presentations were excellent and the questioning was lively.

**Deliverable #2: Seminar on Biotech Labeling for WTO Delegates
(November 30, 2004)**

In September 2004 USAID organized a meeting to discuss our project and invited officials from various interested agencies. That group identified biotech labeling as a top priority. On November 30, 2004, DTB Associates held a seminar in Geneva entitled "Labeling, Traceability and Trade." Attached (Annex 2) is the invitation to the event and the list of invitees. Presentations by the speakers have been forwarded separately.

Ten delegates from eight countries, along with officials from the World Trade Organization, the World Intellectual Property Organization, and several Geneva-based non-governmental organizations attended. Nearly all of the attendees stayed for the entire three-hour session, and we received a number of favorable comments about the quality of the presentations.

Julian Morris of the International Policy Network spoke about labeling and traceability as trade barriers and the need for international disciplines. He drew the link between current legislation in some countries pertaining to biotech products and potential requirements that would directly affect many developing countries – e.g., labeling for labor or environmental standards or animal welfare practices. Professor Dermot Hayes of Iowa State University explained to the group his research on the

economics of biotech labeling and the effects of negative information on consumer perceptions and choices. Barun Mitra talked about the potential benefits of biotechnology in India and other developing countries, and the effect that labeling and traceability requirements could have on the ability of those countries to take advantage of those benefits. Victor Bradley, a former colleague of many of the attendees, spoke about the WTO rules governing labeling and traceability and the history of discussions of the issue under the auspices of the Agreement on Technical Barriers to Trade. A 90-minute discussion followed the presentations.

**Deliverable #3: Seminar on the WTO and the Biosafety Protocol for WTO Delegates
(February 23, 2005)**

On February 23, 2005, DTB held the third in our series of biotech-related seminars for WTO delegates in Geneva. The topic of the seminar was the relationship between the WTO Agreements and the Cartagena Protocol on Biosafety (BSP). The invitation to the event is attached (Annex 3). Presentations by the speakers have been forwarded separately.

Klaus Ammann, the Director of the Botanical Garden at the University of Bern, spoke about biotech applications, with a focus on the developing world, and the effect that regulatory barriers are having on countries' ability to exploit the technology. Laura van der Meer, a Brussels-based lawyer who specializes in biotech trade issues, discussed the status of BSP implementation and emerging problems. Craig Thorn of DTB Associates presented a paper on the legal relationship between the WTO and the BSP. Julian Morris led a discussion among attendees regarding the sharing of biotech-related information in Geneva.

Unfortunately, attendance at the event was well below expectations due to multiple conflicts with meetings related to the Doha Round of WTO negotiations. As a result, we changed our approach for subsequent activities. Given the pace of the Doha Round negotiations, we believed it would be difficult to get WTO delegate to devote a half day to a subject that is not directly relevant to their negotiating responsibilities. We therefore decided to focus on future visits on meetings with individual delegates.

**Deliverable #4: Meetings with WTO Delegates
(April 7 & 8, 2005)**

DTB organized a visit to Geneva of biotech experts and industry representatives on April 7 & 8. We held seven meetings with Geneva-based diplomats and officials from the WTO Secretariat. Members of the visiting group were Tim Jacob – Dupont, Brian Lowry – Monsanto, Margaret Gadsby – Bayer CropScience, Laura van der Meer – International Environmental Resources, and Craig Thorn – DTB Associates.

The main purpose of the visit was to discuss Biosafety Protocol implementation problems with officials responsible for WTO negotiations on agricultural and environmental issues. We found that many of those officials were not well informed about the status of BSP implementation, but that all were interested in receiving information. They recognized the potential implications of the BSP for international trade and WTO trade rules. Most of them offered useful suggestions for future outreach and several promised to follow up with officials in capital.

We also had a discussion at each meeting of access and benefit sharing (ABS) and the related initiation of a “Development Agenda” at World Intellectual Property Organization (WIPO). There was keen interest in that subject as well, in part because it had recently become more prominent on the WTO negotiating agenda. We found the officials with whom we spoke to be open and receptive on the issue. Some officials expressed concern regarding potential for these IPR issues to work their way into the Doha Round as last minute negotiating items. Specific concern was expressed that the EU could form an “unholy alliance” on the issue with certain developing countries in order to advance its agenda on other fronts.

We provided each person with a summary of discussion points on the WTO and the BSP and an analysis of the relationship between the BSP and the WTO, both of which are attached in Annex 4. Also attached are a set of talking points used by the group.

Below are the key points from each of our meetings.

U.S. – Ambassador Linnet Deily, David Shark, Mary Revelt, Gregg Young, Henry Schmick

- According to Ambassador Deily, while Geneva meetings are useful, top-level trade officials in most countries can best be influenced through meetings in capitals.
- Certain countries – e.g., Korea, Egypt and Ethiopia – have new trade ministers who could potentially be helpful. Ambassador Deily

suggested we might be able to meet with those Ministers during their frequent Washington visits.

WTO Secretariat – Doaa Abdel Motaal

- We asked about the low profile of the WTO at BSP meetings. Abdel Motaal said the Secretariat was considering putting on a side event at the upcoming BSP COP/MOP meeting to explain WTO rules relevant to the Protocol. We encouraged her strongly to organize such an event and to participate personally. (She would be a particularly effective spokesperson.)
- WTO officials are also available on request to make presentations at regional capacity-building conferences. She suggested we consider organizing such events. WTO participation can be funded by private industry.
- Unlike many of the officials with whom we spoke, Abdel Motaal said she believed we should not discount the possibility that the negotiations on the relationship between the WTO and multilateral environmental agreements (MEAs) could yield a concrete outcome, especially if the EU insists, as it did in Doha at the launching of the Round, that such an outcome be part of the final Doha Round package. She expects the negotiations to develop slowly this year and to accelerate after the Hong Kong Ministerial Conference at the end of the year. The outcome could take the form of a set of principles to guide interpreters of both sets of agreements.

Australia – Ambassador David Spencer and George Mina

- Ambassador Spencer was particularly concerned about the difficulty of influencing the decision making process at the COP/MOP. We discussed the role that New Zealand could play at the meeting. He offered to contact New Zealand trade officials to ensure that they were involved in the development of that country's positions.
- Spencer also promised to contact officials in Canberra regarding the Australian position and report back to us on the results. (We have already received that report.)

Canada – Pamela Cooper

- Cooper chaired a recent seminar on the BSP held on the margins of a meeting of the Committee on Sanitary and Phytosanitary (SPS) Measures. The seminar was a U.S. initiative organized jointly with Canada. (USTR promised to hold the event following a series of meetings in Washington with DTB and industry representatives.) The

U.S. and Canadian representatives to the SPS Committee made presentations on BSP implementation issues and potential conflicts with WTO rules.

- Many of the 30+ participants were trade and agriculture ministry officials from Latin American capitals. Funding for the travel of those officials came from the Inter-American Institute for Cooperation in Agriculture (IICA). In order to receive that funding, officials must implement a process of inter-agency coordination. Those officials should therefore be in a good position to promote coordinated positions on BSP issues. (We later received a list of attendees from the U.S. Mission for follow up contacts.)
- Cooper expressed concern about US initiatives to dialogue separately with the EU, Australia, Brazil and India on issues related to the Doha Round negotiations on agriculture.
- Cooper recommended that we follow up with Paul Haddow, Canada's SPS Committee representative, in Ottawa and with Cameron MacKay, who is responsible for intellectual property issues in Geneva.
- She said that developing countries such as Argentina that understand BSP issues and that have been successful in coordinating BSP negotiating positions between agencies could potentially influence trade ministry officials from other developing countries to get involved in the issue. She suggested that we help persuade Argentina and others to play that role.

Argentina – Ernesto Martinez Gondra, Deputy Chief of Mission

- Gondra was initially skeptical about discussing the BSP in Geneva. He was clearly concerned that such a discussion could complicate negotiations on other issues and open the door to mischief on the part of the EU. He became less defensive when we explained that our purpose was not to promote negotiations on the BSP in Geneva, but to encourage trade and ag ministry officials to be more involved in the BSP implementation process. He also recognized that there was less potential for the EU and others to cause mischief in the WTO/MEA negotiations if negotiators from agricultural exporting countries were well informed about potential BSP problems.
- Gondra said that Argentina and other ag exporting countries were still suffering from the lack of industry involvement in the early stages of the negotiation of the BSP.
- The change in the Brazilian position was due in large part to contacts between the Argentine and Brazilian ministers of agriculture. Gondra said he believed that Uruguay and Paraguay were also potential allies

and recommended that we work on both, focusing especially on the agriculture ministries.

- Gondra was unaware of the departure of Argentine trade officials responsible for BSP matters. He promised to contact Buenos Aires to find out who would be replacing those officials.
- Gondra said that we could expect certain developing countries to push ABS in the negotiations in the WTO TRIPS Council. He drew a distinction between TRIPS Article 27 (what is patentable) versus Article 29 (supplemental documentation in conjunction with patent applications), indicating that Argentina would strongly resist opening #27, but that Article 29 may be an area of compromise.

Chile – Carmen Dominguez and Sebastian Herreros

- Dominguez and Herreros admitted that they were not well informed regarding the BSP, said they appreciated our visit. They took careful notes during the meeting and offered to follow up with their colleagues in Santiago.
- They said that the informal “Friends of Biotech” meetings that the U.S. held on a regular basis on the margins of the Agriculture Committee meetings until about a year ago had been a useful source of information on biotech issues, and they recommended that they be resumed. They suggested that the meetings be held between major meetings when negotiators from capitals are not in Geneva.
- They also recommended working with Washington embassies of potentially friendly countries whose embassies are staffed with officials from various government ministries. They said it would be helpful to them for those officials to send reports on BSP issues to their ministries. They suspected that the same would be true for other countries.

India – Rajesh Aggarwal

- Aggarwal admitted that the government was under considerable pressure from activists, but said that India must take advantage of biotechnology in order to feed its population.
- Aggarwal invited us to be frank regarding India’s position in the BSP negotiations and the level of trade ministry involvement. He offered to make the case with his ministry for greater involvement and asked that we prepare for him a summary of issues. He also requested information on biotech developments in India.
- He said that Geneva delegates were interested in biotech and other regulatory issues, but were so busy with negotiating responsibilities that they could not keep up with developments. Industry could play an

important role by providing regular, comprehensible information on WTO-relevant issues.

**Deliverable # 5: Meetings with WTO Delegates
(September 19-20, 2005)**

DTB organized another visit for a group of biotech experts September 19 & 20. Participants included Steve Daugherty, Pioneer/Dupont; Claire Miller-Carlton, Bayer CropScience; Val Giddings, BIO; Laura van der Meer, International Environmental Resources; and Craig Thorn, DTB Associates. This visit was similar to one in April 2005, and we used it in part to follow up on contacts we made on that trip.

We met on this trip with delegates to the WTO from 13 countries, selected from the list of priority outreach countries identified by the Global Industry Coalition, an industry group that is active on Biosafety Protocol (BSP) implementation issues. We provided background on the BSP and an update on current implementation issues, emphasizing the implications for their countries' trade interests and for the WTO. Attached (Annex 5) are two papers we left behind at each meeting.

Many of the officials we met with had a general familiarity with the BSP, but none of them were following the implementation process in any detail. The large majority was very interested in the subject and appreciative of the information provided. They recognized the potential negative implications of developments in the BSP for WTO principles that their countries have defended in Geneva. Most of them admitted that there was a serious need for better interagency coordination within their countries.

In general, these delegates were a friendly and receptive audience, even those from countries with which we have had disagreements in the BSP context. We delivered hard messages to certain officials regarding the positions their country representatives have taken in the BSP talks, but no one reacted defensively. (It seems clear in those cases that the positions taken by the representatives of those governments on BSP implementation are more a reflection of individual beliefs and personalities rather than coordinated government policies.) All officials said they would welcome follow-up information, and several promised to contact their home ministries.

In follow-up, we sent to each official, as appropriate, 1) information on biotech research and commercialization in their countries; 2) the IPC study on the economic effects of proposed documentation requirements;

and 3) further analysis of implications for WTO rules. Other follow-up items for specific countries are noted below.

Following is a summary of specific points raised in the meetings, along with some observations.

U.S. (Rachel Shub & Henry Schmick) and Canada (Cameron MacKay)

- Both countries seem anxious to do their part, within the constraints of a busy negotiating schedule, to help educate Geneva delegates and promote more trade and agriculture ministry involvement.
- They organized jointly a seminar on the BSP on the margins of the March meeting of the SPS Committee, and were planning to do the same thing again in October. However, the October meeting has been cancelled, along with most other routine meetings, because of preparations for the Hong Kong Ministerial meeting. The next opportunity will be the SPS Committee meeting scheduled for January 30 & 31.
- They expressed some concern about an apparent shift in the Brazilian position in the negotiations on the relationship between the WTO and multilateral environmental agreements (MEAs). At a recent negotiating session, Brazil argued for maintaining the focus on that issue.

Follow-up: We provided a list of non-industry (e.g. independent) speakers and target countries for January seminar.

Brazil (Guilherme Patriota)

- Patriota dealt with the BSP in a previous position and is well-informed regarding domestic Brazilian policies on biotech. He said he had recommended against Brazil ratifying the BSP because he thought it would be too difficult to implement.
- Nevertheless, he was less receptive than most and expressed some concern that Brazil had taken a leadership role at the last COP/MOP meeting.
- He was coy regarding Brazil's shift in position in the MEA negotiations, saying only that Brazil believed the subject needed more discussion.

Malaysia (Zulkafli Bin Abdul Karim & Hairil Yahri)

- Zulkafli attributed the Malaysian position in the BSP to a lack of interagency coordination. He seemed somewhat skeptical of the

ability of the trade ministry to influence the environment ministry, which has responsibility for the BSP.

- He recommended that U.S. industry representatives contact the environment minister directly to make him aware of the positions Malaysia was taking and point out their consequences.
- Both Zulkafli and Hairil are new to Geneva. Their predecessors, who were active defenders of SPS and TBT disciplines during their time in Geneva, are dealing with WTO issues in Kuala Lumpur. Zulkafli recommended that we also contact them.

Follow up: We sent a letter to Environment Minister and contacted officials in trade ministry in KL.

Chile (Carmen Dominguez), Colombia (Marta Olga Gallón) & Peru (Milagros Miranda)

- All were receptive and interested in getting further information. Dominguez requested copies of industry submissions to future meetings.
- Gallón also expressed interest in developments in Colombia's domestic biotech policies.

Follow-up: We sent copies of industry submissions to Dominguez and information on Colombian policies to Gallón.

Philippines (Jose Antonio Buencamino & Maria Alberto)

- Both officials seemed to appreciate the importance of the issue.
- They were surprised and concerned to hear about the Malaysian positions. They were familiar with the efforts of the Third World Network and other NGOs to influence biotech policy in Asia.
- We pointed out that the Philippines might be able to influence the Malaysian position through government to government contacts. They promised to consider the idea.
- Alberto, who is from the Department of Agriculture, promised to contact her Department.

South Africa (Solveig Crompton) and New Zealand (Rebecca Berendt)

- Both said that their countries had ratified the BSP for similar reasons – to provide a voice of reason from within.
- Crompton was concerned but not surprised by the position taken by her government on liability.

- Berendt pointed out that her government was “walking a fine line” in the BSP, given its domestic political pressures. She indicated that a change in the composition of the government could affect the ability of the New Zealand representatives to maintain their firm line.

Egypt (Bahaa Elattar & Mohamed Ahmed)

- Both were familiar with the Egyptian spokesman in the BSP. They admitted to problems of coordination between ministries. They promised to contact their trade ministry to recommend better coordination.
- Elattar recommended contacting the agricultural attaché at the Egyptian Embassy in Washington.

China (Huang Rengang)

- Huang was frank about China’s failing regarding interagency coordination and implementation of SPS commitments. He talked about the need for technical assistance to regulatory officials.
- He offered to put us in contact with his colleague who is responsible for the Committee on Trade and Environment.

Mexico (Juan Antonio Dorantes & staff member)

- Dorantes was well informed and showed considerable interest in the subject. He said our visit was timely and assured us that his ministry (Ministry of Economy) would not hesitate to intervene if they believed that important WTO issues were at stake.
- He promised to check with his capital regarding the Mexican position on liability. If it turns out that there are substantive reasons for the Mexican position, he said, it may be possible for industry to provide alternatives.
- Before coming to Geneva he was Deputy Director-General in the Ministry of Economy, and his responsibilities included coordinating interagency positions on issues such as this one. He gave us the name of his successor (Dra. Luz Maria de la Mora) and encouraged us to contact her.
- Dorantes pointed out that delegates in Geneva were sensitive to the problem of agreements negotiated in other international organizations undermining WTO disciplines. He and others are currently concerned about an agreement on cultural diversity being negotiated in UNESCO that would in its current draft give countries the right to ignore certain WTO obligations.

KENYA ACTIVITIES:

Deliverable #6: Biosafety Roundtable and Meetings with Kenyan Government Officials (April 11 & 12, 2006)

Roundtable, April 11

The purpose of the Roundtable was to raise with key Kenyan government officials issues related to the development of biosafety legislation. The event was a success. It was attended by representatives of the following government agencies: Office of the President, Ministry of Agriculture, Kenya Plant Health Inspectorate Services (KEPHIS), Ministry of Environment, Ministry of Trade and Industry, Ministry of Health, Ministry of Science and Technology, Kenya Bureau of Standards, Kenya Agricultural Research Institute and the National Council of Science and Technology. A list of participants is attached (Annex 6). The event lasted one-half day and was followed by a lunch.

The presentations by two government officials and five experts covered a broad range of topics related to the adoption of biosafety legislation, with a particular emphasis on avoiding unnecessary trade disruption. (Presentations forwarded separately.) Discussion was lively. On several subjects (e.g., current authority for approval of imports of biotech commodities) it was evident that agency responsibilities were not clearly delineated. It was also clear that some of the people in the room were becoming aware of potential trade problems for the first time. U.S. participants felt that the discussion had promoted dialogue among the agencies present.

It became clear during the discussion that the draft Kenyan biosafety law, which was circulated early in 2005, had, to a certain extent, been overtaken by events. Kenyan officials told us they were busy drafting a biotech policy which was to serve as the basis for legislation and regulations. (In the end, however, the final version of the Biosafety Bill was based quite closely on the 2005 draft.)

Meetings with Kenyan officials, April 12

Josette Lewis (USAID), Tanuja Rasogi (State), Kyd Brenner (DTB), Sarah Lukie (McKenna Long & Aldridge), Ramon Clarete (Nathan Associates), Craig Thorn (DTB) and various Nairobi-based U.S. officials met the next day with high-level Kenyan officials at the Ministry of Agriculture, the Ministry of Science and Technology and the Bureau of Standards.

Ministry of Agriculture: The group met with Permanent Secretary Romano Kiome. Kiome was well-informed on biotech issues and receptive to the points the group made. He said he believed it would be 1 to 2 years before the Kenyan biosafety law is in place. He therefore believes that Kenya will need interim measures to govern trade in biotech products in the meantime and to facilitate a smooth transition when the biosafety law is finally implemented. He said that the government needed a cabinet-level debate on the issue. The interim policy could then take the form of a cabinet memorandum. Kiome said he believed that Kenya could not survive overly-strict biotech regulations.

Ministry of Science and Technology: The group met with Permanent Secretary Geoffrey Kiamba. Science and Technology is the lead ministry on biotech issues. Like Kiome, Kiamba was well-informed and receptive. He said biotech was too important for Kenya to ignore. He said that the Cabinet would discuss Kenyan biotech policy before the end of the financial year and then the Parliament would consider legislation. Lewis asked about Kenya's policy on importing whole corn from countries using biotech. (Kenya currently allows the import of corn from the U.S. for food aid only after it has been milled.) She said she hoped that it would be possible to work out a solution to the problem quietly.

Kenyan Bureau of Standards: The group met with Eva Oduor, General Manager, and Margaret Aleke, Head of Department. Since this meeting involved lower-level officials, the group was able to have a more detailed discussion. The group raised several issues related to the original draft Kenyan biosafety law – 1) the failure to differentiate between imports of biotech products as commodities and as seed; 2) the importance of transition measures (e.g., temporary approval of products already on the market at the time when law comes into force) to avoid trade disruptions; and 3) the utility of Codex standards for biotech risk assessments.

**Deliverable #7: Meetings with Kenyan Private Sector Stake Holders and Government Officials
(September 18-21, 2006)**

Craig Thorn of DTB traveled to Kenya, together with Sarah Lukie, who chairs the Global Industry Coalition, to meet with Kenyans from government and the private sector to discuss the draft Kenyan biosafety bill. The trip was pulled together at the last minute when it looked as though the bill was about to be taken up by the Kenyan Parliament.

We met first with a consortium of Kenyan non-governmental organizations interested in the advancement of agricultural biotechnology. Representatives of three organizations – Africa Harvest, the Agriculture Biotechnology Stakeholders Forum (ABSF) and the International Service for the Acquisition of Agri-biotech Applications (ISAAA) – attended, along with embassy staff from the USAID and USDA offices. At that meeting, which lasted over three hours, we went through the draft bill line-by-line, discussed problems and offered suggestions for possible changes.

We agreed that proposals for amendments stood the best chance of being accepted if they were offered by the Kenyans at the meeting. Therefore, we promised to prepare a redline version of the draft with proposed amendments, along with comments on those amendments, and to send them to the Kenyan groups. Copies of those documents are attached (see Annex 6). We discussed the proposed amendments with Josette Lewis of USAID and Tanuja Rastogi of the State Department before sending them to the Kenyans.

We also met with officials from the Kenyan Plant Health Inspection Service, the National Environmental Management Agency, the Kenyan Bureau of Standards and the Kenya Agricultural Research Institute. At each of those meeting we discussed issues related to the draft bill. We received a sympathetic hearing in every meeting. We got the impression that the regulators with whom we met understood the problems and were interested in helping to find solutions. However, none of the officials seemed confident of his/her ability to influence the drafting process.

**Deliverable #8: Meetings with Private Sector Stake Holders and
Government Officials
(April 18-20, 2007)**

Craig Thorn of DTB traveled to Kenya, together with Sarah Lukie of BIO, who chairs the Global Industry Coalition and Jeff Stein of the Danforth Center, who runs Africa programs for USAID's Program for Biosafety, to meet with Kenyans from government and the private sector to discuss the draft Kenyan biosafety bill. The purpose of the trip was to provide technical comments of the draft bill prior to its publication. At the time, observers expected the bill to be published soon. Publication was to be followed by a twenty-day period for public comment and then a first reading in the Parliament. If the bill was designated as a priority, observers believed it could become law before the end of the year. If not, it would join the queue behind more than twenty other bills, and passage would

likely be delayed for at least a year due to elections in early 2008. (As it turned out, the bill was published about six weeks later, in mid June.)

We met with Margaret Aleke, Alice Onyango and Immaculate Odwori from the Kenyan Bureau of Standards (KEBS); Harrison Macharia, from the National Council for Science and Technology; Felix Mmboyi and staff from the African Biotechnology Stakeholders Forum (ABSF); Florence Wambugu and James Okeno from Africa Harvest; Margaret Karembu from the International Service for the Acquisition of Agri-biotech Applications (ISAAA); James Ochanda from the University of Nairobi; Allen Fleming, USAID Office Director; and Kevin Smith and staff from the USDA/FAS office. Silas Obukosia of the USAID office accompanied us to all of those meetings. We also met informally with Kinyua M'Mbijjewe from the Monsanto office in Kenya.

On our last visit to Kenya in September 2006 we discussed the draft bill in detail with private sector stakeholders. We agreed to prepare detailed comments on and suggest amendments to the draft. We prepared those comments and amendments and forwarded them to the private sector coalition shortly after our trip (see Annex 7). We held a teleconference with the stakeholders to discuss the comments and to develop a strategy for getting the proposed amendments to the responsible officials.

In the months following our visit, it became clear that only one of the groups, Africa Harvest, was actually working to carry out the strategy. Okeno met several times with Macharia and with Rachel Shibalira from the Attorney General's office, the drafter of the bill, to go over the proposed amendments. He reported some progress, but it was not clear to what extent the draft had been changed.

When we arrived for this visit, we discovered disarray among the stakeholders. The ABSF staff members with whom we met were unaware of the comments we sent in October and the issues we had identified, and their views on certain issues – e.g., labeling – were somewhat alarming. They told us they would be coordinating private sector comments on the draft after it is published. Karembu and Ochanda were reluctant to meet with us because they said they opposed any changes in the draft. They also opposed our meeting with Macharia. When we decided (on the basis of advice from Okeno, Obukosia and the USAID and FAS offices) to go ahead with the meeting, Karembu and Ochanda insisted on attending, even though the original plan was for only Okeno to be there. (Okeno attended the entire meeting. Karembu and Ochanda were there for the second half.) Shibalira was also supposed to attend

the meeting, but Karembu and Ochanda apparently convinced her not to come.

The first half of the meeting with Macharia went well. We discussed several of our proposed amendments in detail and seemed to be making progress on a couple of key issues. For example, Macharia seemed to understand the need for a transition period and reasons why it was unnecessary and unworkable to require a full regulatory approval each time a product was placed on the market. He asked us to send him our suggestions for language changes. Okeno and Obukosia provided useful input.

However, the meeting deteriorated in the second hour after Karembu and Macharia arrived. They argued strongly that the bill should not be changed, even if the changes did not delay its publication and passage. They expressed the view, for example, that it was perfectly normal and appropriate to require a full regulatory review each time a product was placed on the market because of the possibility that products could vary from shipment to shipment. We think we made some progress in the meeting in explaining the issues, but we are not certain where we came out with Macharia.

The meeting with KEBS went well. We discussed the proposed amendments with the bill having to do with food safety, KEBS's area of responsibility. They seemed open to input. They asked us for a list of food safety-related amendments and comments (which we have since provided through Okeno), and they said they would consider submitting comments on the draft during the comment period.

At the end of the visit, we agreed with Okeno and Obukosia that we would send to them a full set of proposed amendments and comments, which they would pass to Macharia; a subset of food safety-related amendments which they would pass to KEBS; a subset of plant health-related comments which they would pass to the Kenyan Plant Health Inspection Service; and a subset of comments on contained use which they would pass to the Kenyan Agricultural Research Institute. Africa Harvest will also use the documents in the preparation of its comments on the draft bill when the draft is published.

(Note: In the end, Kenyan officials incorporated nearly half of our proposed amendments. Unfortunately, they ignored many of the more important ones. We are currently working with Kenyan regulators to try to accomplish in the implementing regulations what we were unable to do in the legislation.)

ANNEX 1

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Summary of Complainants' Claims in *European Communities – Measures Affecting Biotech Products* (WT/DS291, 292, and 293)

“Since 1998 there has been a de facto moratorium on the use of genetically modified organisms (GMOs) in the European Union. Accordingly, all this time no new marketing of GMOs has been authorised.”

- Press Release by Belgium, Presidency of the Council of the European Union, December 3, 2001

“The use of more precise technology and greater regulatory scrutiny probably make [agricultural biotech products] safer than conventional plants and foods.”

- Press Release by Research Directorate-General, European Commission, October 8, 2001

The WTO dispute initiated by Argentina, Canada and the United States challenges the European Communities' “de facto” moratorium on the approval of new agricultural products of biotechnology. The Complainants also are challenging the national marketing and import bans imposed by six EC member States. As the Complainants have detailed in their April 21, 2004 submissions to the Panel, the EC “de facto” moratorium, as well as bans maintained by several member States, are inconsistent with the EC's obligations under the SPS Agreement and other WTO provisions. The EC's measures are entirely without scientific justification. Even the EC's scientific authorities have concluded that agricultural biotech products, as a class, are not unsafe, and the EC itself has approved at least 10 biotech products. These unjustified measures thus constitute a threat to the interests of all WTO Members that depend on science-based regulation of agricultural trade.

To end the moratorium and fulfill its obligations under the WTO, the EC must permit applications to move through the defined EC approval procedures to their completion without undue delay and the EC member state bans on biotech products must be brought to an end. It is important to note that the complaint is *not* a challenge to the right of a Member to maintain pre-marketing approval

procedures for agricultural products (indeed, all three Complainants have them). Nor are the Complainants challenging the underlying EC's regulations themselves.

EC MEASURES VIOLATE SPS AGREEMENT

- **Description of EC measures.** The measures in dispute include the following: (i) the EC's failure to operate its own domestic approval procedures, without undue delay, through to completion for any and all agricultural biotech products since October 1998 (i.e., the moratorium); (ii) the EC's failure to operate these approval procedures for particular agricultural biotech products with applications pending under the EC's approval regime, without undue delay; and (iii) the national marketing and import bans maintained by six EC member States on several agricultural biotech products that were approved by the EC before the moratorium was imposed. Each of these measures is within the scope of the SPS Agreement, as the "purpose" of each was to protect human, animal, and plant life or health from risks enumerated in the SPS Agreement and each of these measures affects international trade.
- **Summary of violations.** The EC's measures restrict trade in biotech products and are not based on scientific evidence and risk assessment. In addition, these measures have caused an undue delay in the approval for agricultural biotech products. Moreover, the EC has set a level of SPS protection for agricultural biotech products that is arbitrarily and unjustifiably strict as compared to the level set for other products with comparable risks, resulting in a disguised restriction on trade. Alternatively, if EC argues that its chosen level of protection is not as strict as the challenged measures imply, then those measures are more trade-restrictive than necessary to achieve that defined level of protection.
- **Not based on scientific evidence or risk assessment.** The measures at issue violate the requirements of Articles 2.2 and 5.1 that all SPS measures be based on scientific principles, that sufficient scientific evidence support a measure and that all such measures be based on risk assessments. There is no indication that the EC's moratorium on all agricultural biotech products, its failure to operate its own approval procedures for particular products, or the EC member State marketing and import bans are based on scientific evidence or risk assessments.
- **Undue delay in approval of biotech products.** The EC's failure to operate its own approval procedures for any and all agricultural biotech products as well as for products with applications pending violates the SPS Agreement requirement under Article 8 and Annex C(1) that SPS approval procedures be carried out without "undue delay." The ordinary meaning of "undue delay" requires that there not be an "excessive" or "unjustifiable" hindrance in the undertaking of an SPS approval procedure. The delay caused by the EC's measures is both "excessive" and "unjustified." It is "excessive" because, as of the time the Panel was established, the "de facto" moratorium on all biotech products had been in effect for *five years* and many individual applications had been delayed even longer. It is "unjustified" because the EC's measures were imposed disregarding the fact that many products had had positive scientific risk assessment under the EC procedures.
- **Disguised (or unnecessary) restriction on trade.** The EC's measures also violate Articles 2.3 and 5.5, which require Members to avoid arbitrary or unjustifiable distinctions in levels of SPS protection in comparable situations if such distinctions result in discrimination or a disguised restriction on international trade. The EC's implied level of protection for new

agricultural biotech products is zero risk, as reflected by the *de facto* ban on such products, whereas the level of protection for other

- products with comparable risks, *e.g.*, conventionally bred products and products made with biotech processing aids, which are allowed to enter the EC market, is substantially lower. Alternatively, if the EC argues that it has set a high but not zero-risk level of protection, then the *de facto* ban is more trade-restrictive than necessary to achieve that level of protection in violation of Articles 5.6 and 2.3.
- **Other SPS violations.** The EC has violated its obligations under Article 7 and Annex B:1 of the SPS Agreement to publish and notify its moratorium as an SPS measure. In addition, the EC moratorium is incompatible with the EC's obligation under Article 10.1 to "take account of the special needs of developing country Members."
- In the alternative to their SPS claims, Complainants argue that the EC's measures are inconsistent with the Agreement on Technical Barriers to Trade, as the measures are more trade restrictive than necessary to fulfill their objectives, and are not completed as expeditiously as possible.

EC MEASURES ALSO VIOLATE GATT 1994

- **EC measures violate GATT 1994 Articles III and XI.** The EC's failure to operate its approval procedures for particular biotech products with applications pending in the EC, as well as the member State bans, violate the obligation in Article III:4 to treat imported products no less favorably than like domestic products. In addition, the import ban imposed by Greece violates Article XI:1's prohibition on quantitative restrictions on imports.

* * *

In summary, the moratorium and member State bans, which have blocked the marketing of new agricultural biotech products for more than five years, are not supported by scientific evidence or risk assessment. And there is no end in sight. As EC Environment Commissioner Wallström stated in October 2002, "I have stopped guessing when the moratorium would be lifted. . . . but some member states are opposed to GMOs and they will try to move the goal posts."

ANNEX 2



invite you to a roundtable seminar to discuss

Labelling, Traceability and Trade

Government requirements that goods – such as food and agricultural products – be labelled and/or traceable as to their origin presents a challenge to the producers of those goods, especially in poorer countries, where the costs of instituting such a regime may be very high relative to the value of the goods. This workshop will discuss the merits and drawbacks of such labelling and traceability schemes, evaluating them in the context of WTO rules. Speakers include:

Victor Bradley

Consultant, Former Canadian Trade Policy Official &
Canadian Representative to the Committee on Technical Barriers to Trade

Dermot Hayes

Professor, Department of Economics, Iowa State University, USA

Barun Mitra
Director, Liberty Institute, New Delhi, India

Julian Morris

Director, International Policy Network, London, UK

Dan Lewis
Director of Environmental Affairs, Stockholm Network (Chair)

Tuesday 30 November, 2004

2.00 for 2.15pm until 5.30pm

The meeting will be followed by an informal drinks reception.

, Geneva, Switzerland

RSVP: Anne Jensen
Acceptances Only Please

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anne@stockholm-network.org

Invitation List

- Argentina** Mr. Eduardo Tempone
(biotech, TBT/labeling issues)
Mr. Gabriel Taboada
(agriculture, SPS)
Permanent Mission of Argentina to the WTO
Route de l' Aéroport 10
1216 Geneva
- Australia** Mr. David Spencer
Ambassador
Mr. Tim Yeend
Minister and Deputy Permanent Representative
Permanent Representation of Australia to the WTO
Chemin des Fins 2
1209 Geneva
- Brazil** Ms. Maria-Rita Fontes
(TBT issues)
Ms. Maria Izabel Vieira
(ag, SPS)
Permanent Representation of Brazil to the WTO
Ancienne Route 176
1218 Grand Saconnex
- Canada** Ms. Pamela M. Cooper
(ag, SPS)
Mr. Tobias Nussbaum
(TBT)
Permanent Mission of Canada to the WTO
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- Chile** Ms. Carmen Dominguez
(TBT)
Mr. Sebastian Herreros
(ag, SPS)
Permanent Mission of Chile to the WTO
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1209 Geneva
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Deputy Chief of Mission
Mr. Wang Xiaodong
(ag)
Mr. Xia Jianmin

(ag)
Permanent Representation of the People's Republic of China to the WTO
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1292 Chambesy

- Colombia** Ms. Olga Lucia Lozano
Deputy Chief of Mission
Ms. Marta Olga Gallon
(ag)
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1202 Geneva
- Costa Rica** Mr. Ronald Saborio
Ambassador
Permanent Mission of Costa Rica to the WTO
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1202 Geneva
- Egypt** Dr. Magdi Farahat
Minister Plenipotentiary
Mr. Ahmed Maghawry Diab
Third Secretary
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- India** Mr. Rajesh Aggarwal
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1202 Geneva
- Indonesia** Mr. Bagas Hapsoro
(ag)
Permanent Mission of Indonesia to the WTO
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1203 Geneva
- Japan** Mr. Makoto Osawa
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Mr. Hiroyoki Yanaguchi
(ag)
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Mr. Mauricio Garcia Velasco
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(ag)
Mr. Gregg Young
(ag)
Ms. Rachel Shub
(TBT, environment)
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WTO

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Director, Agriculture Division
Ms. Gretchen Stanton
Agriculture Division
Ms. Maria Perez Esteue
Agriculture Division
Ms. Doaa Abdel Motaal
Environment Division (also does labeling)
Mr. Erik Wijkstrom
TBT Division

Centre William Rappard
Rue de Lausanne 154
1211 Geneva 21

ANNEX 3



AND



Invite you to a roundtable seminar to discuss

The WTO and the Biosafety Protocol

The aim of this workshop is to examine the relationship between the WTO and multilateral environmental agreements, in particular the Cartagena Protocol on Biosafety. Speakers will discuss the status of the implementation of the Cartagena Protocol and the potential for commercial and international legal disputes. They will also present information on the development of biotech applications of interest to developing countries.

Speakers include:

Dr. Klaus Ammann

Director, Botanical Garden, University of Bern, Switzerland

Laura van der Meer, Esq

International Environmental Resources, *sprl*, Brussels, Belgium

Julian Morris

Director, International Policy Network, London, UK

Craig Thorn

Partner, DTB Associates, LLP, Washington, USA

Dan Lewis
Director of Environmental Affairs, Stockholm Network, London, UK (Chair)

Wednesday 23 February, 2005

2.45 for 3.00pm until 6.00pm

The meeting will be followed by an informal drinks reception.
Hotel President Wilson, Quai Wilson, 1211 Geneva, Switzerland

RSVP: Anne Jensen
Acceptances Only Please

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SUMMARY OF DISCUSSION POINTS:
WTO AND THE CARTAGENA PROTOCOL ON BIOSAFETY

- We are aware that many Geneva delegates are concerned that trade-related provisions of MEAs could be used to justify trade barriers and undermine WTO rules. We share those concerns, and we encourage you to resist any outcome to the negotiations under paragraph 31(i) of the Doha Ministerial Declaration that would give MEAs automatic precedence over the WTO.
- The implementation of one MEA, the Cartagena Protocol on Biosafety, poses significant potential problems. Even though the Protocol as written could be implemented in a WTO-consistent manner, some of the Parties to the Protocol who are also WTO members are arguing strongly in favor of interpretations of the agreement that would clearly be WTO-inconsistent.
 - Documentation: Article 18.2 of the Protocol establishes rules on documentation of biotech products and sets up a negotiation on more detailed requirements. Some countries are advocating requirements that would be burdensome, costly, and trade-disruptive. Depending on decisions made by the Parties, implementation could require fundamental changes in the way commodities are produced, handled and shipped. Much of the cost of such changes would be passed on to importing developing countries. There has been little discussion of the potential cost of the requirements under consideration, or their consistency with the WTO.
 - Method of production is not a sufficient justification under WTO rules for imposing restrictions on identification, handling, packaging or transport of a product. Measures maintained for SPS-related purposes must be, *inter alia*, based on a proper risk assessment and supported by sufficient scientific evidence. Moreover, WTO rules do not permit members to discriminate between like products. If the products in question have been examined and approved for use, and there is no scientific reason to restrict their use, special documentation requirements would be inconsistent with WTO rules.
 - Liability and redress: Article 27 of the Protocol tasks Parties with elaborating “international rules and procedures in the field of liability and redress for damage resulting from transboundary movements” of products of biotechnology. The Conference of Parties has established a process aimed at fulfilling this mandate. Some participants in this process are proposing establishing insurance requirements and mandating the deposit of funds for any activities involving biotech products. The cost of such rules could be prohibitive for producers of biotech products. Again, Parties have made little effort to take into account relevant WTO rules.
 - Liability rules of the type being considered would be subject to the disciplines of the WTO SPS Agreement. An across-the-board requirement for liability insurance for biotech products, one that is based purely on the method of production and not related to the risks associated with a particular product, would almost certainly violate SPS rules.
 - Socio-economic considerations: Article 26 of the Protocol permits parties to take into account in their regulatory decision making process, in a manner consistent with their

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international obligations, “socio-economic considerations arising from the impact of [biotech products] on . . . biological diversity.” Parties to the protocol have made this issue a major area focus in their early work on implementation. Agricultural exporting countries are concerned that the provision may be interpreted broadly, without regard to WTO rules.

- WTO members must base SPS measures on a scientific assessment of risk. Members are to take economic issues into account in the context of the overall objective of minimizing the negative trade effects of measures taken.
- We all have an interest in preserving the disciplines of the SPS and TBT Agreements. It is important for trade officials to be involved in COP/MOP process in order to ensure that the BSP does not undermine WTO disciplines. It is equally important, for similar reasons, that trade officials be involved in the development of national biosafety legislation.

The WTO and Biosafety Protocol
Talking Points for Geneva Visit
April 2005

Objectives

To inform WTO delegates about emerging conflicts between the Biosafety Protocol and the WTO and encourage more involvement by trade ministry officials in BSP implementation, and to lay a foundation for future work on other issues.

Talking points

- We have been following with interest the ongoing work of the Trade and Environment Committee, in particular the negotiations on the relationship between multilateral environmental agreements and the WTO.
- We are aware that many Geneva delegates are concerned that trade-related provisions of MEAs could be used justify trade barriers and undermine WTO rules. We share those concerns, and we encourage you to resist any outcome that would give MEAs automatic precedence over the WTO.
- The implementation of one MEA, the Biosafety Protocol, poses significant potential problems. Even though the Protocol as written could be implemented in a WTO-consistent manner, some of the Parties to the Protocol who are also WTO members are arguing strongly in favor of interpretations of the agreement that would clearly be WTO-inconsistent.
- [Short discussion of implementation issues – *e.g.*, documentation/labeling, socio-economic considerations, liability, risk assessment, public participation, precautionary principle – and preparations for COP/MOP 2.]
- We all have an interest in preserving the disciplines of the SPS and TBT Agreements. It is important for trade officials to be involved in COP/MOP process in order to ensure that the BSP does not undermine WTO disciplines. It is equally important, for similar reasons, that trade officials be involved in the development of national biosafety legislation.

Background

Current WTO rules should offer effective protection against unfair, arbitrary and protectionist restrictions to biotech trade. However, the EU, its allies and a number of NGOs are pursuing a strategy designed to weaken those rules – in international fora such as the BSP implementation discussions and the Codex, and through formal and informal outreach efforts to various developing countries. Moreover, regulators in many of the countries now developing domestic regulatory frameworks know little about their countries' WTO obligations.

Most Geneva based diplomats and their colleagues in capitals understand the value of WTO rules on regulatory practices, but many are paying little attention to biotech-related issues and do not fully understand the implications of those issues for the WTO.

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This is true even though they are involved in negotiations that have important implications for the implementation of the BSP. As a part of the WTO Doha Round of multilateral trade negotiations, WTO member countries are engaged in talks on the “relationship between existing WTO rules and specific trade obligations set out in multilateral environmental agreements (MEAs).” This negotiation was included in the Doha Round mandate at the insistence of the EU over the vehement objections of a number of countries. As a result, the U.S. and its allies (most of the world outside of Europe) have worked to limit the scope of the negotiation in order to limit the possibilities for European mischief.

There is certainly good reason to be concerned about Europe’s intentions. In a submission to the Committee on Trade and Environment (CTE), where the negotiations on MEAs take place, Switzerland made clear that its goal is to give MEAs precedence over the WTO in cases where the agreements overlap:

As Switzerland has pointed out in previous statements and submissions, the fact that an STO [specific trade obligation] is set out in an MEA clearly shows that the Parties to this MEA considered the relevant trade measures to be necessary to achieve the objectives of the Agreement. It would, therefore, in our view, not be adequate if the necessity of a specific trade measure based on an STO set out in an MEA could be examined again within the WTO. There has to be a presumption that any such measure, if it is covered by an STO, is necessary to achieve the objectives of the MEA. This presumption does mean that if a party is able to show that its trade measures are covered by the provisions of an MEA, the necessity of this measure cannot be objected any more under Article XX of GATT. It would still be possible to examine the question of whether a specific measure is applied in a manner that constitutes a means of arbitrary or unjustifiable discrimination or a disguised trade restriction. If it cannot be proved that a measure constitutes a mean of arbitrary or unjustifiable discrimination or a disguised trade restriction, this measure has to be considered to be in conformity with Article XX of the GATT. (TN/TE/W/32 of May 13, 2003, paragraph 13)

Essentially, Switzerland is proposing to throw out the WTO SPS and TBT Agreements with respect to measures that a country implements pursuant to its obligations under an MEA. A party taking a complaint under the WTO against such a measure would not be able to argue that the measure violated WTO rules because, for example, it was not based on scientific evidence or it was more trade restrictive than necessary to fulfill a WTO-specified legitimate objective. The only relevant WTO discipline would be the chapeau of GATT Article XX, which says that measures should not discriminate between WTO members and should not be disguised trade restriction.

EU officials do not go quite as far in their most recent submission, but they are clearly leaning in the same direction:

This state of affairs is fundamentally based on the so-called “deference” principle: both WTO and MEAs should remain responsible and competent for issues falling within their respective primary areas of competence and expertise. While MEAs are responsible for environmental policy making, the WTO is competent for ensuring that

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the national implementing measures are not protectionist; i.e. constitute a means of arbitrary or unjustifiable discrimination or disguised restrictions on international trade.

Mutual supportiveness, therefore, essentially lies in the recognition of the very existence and competence of each other, and in the development of substantive linkages which recognize this inter-connectedness without indicating hierarchy. (TN/TE/W/39 of March 24, 2004, paragraphs 30 & 31)

The U.S. and its allies (including most other countries that are friendly to biotechnology) on this issue have adopted a defensive posture, trying to limit the scope of the negotiations by arguing that the potential for conflict between the WTO and MEAs is minimal. As a result, they have avoided discussion of trade problems arising from the implementation of the Biosafety Protocol (BSP).

A recent U.S. paper examines the negotiation and implementation of three MEAs with trade-related provisions – the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES); the Stockholm Convention on Persistent Organic Pollutants (POPs); and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (PIC) – and concludes that “the MEA/WTO relationship is working quite well.” The reason, according to the paper, is that countries are working on a national and international level to coordinate positions between officials responsible for trade agreements and those responsible for MEAs in order to avoid conflicts between trade and environmental interests.

The U.S. experience . . . suggests that there have been tremendous efforts to work together to craft STOs in a manner that takes into account the specific objectives of the MEA, the nature of the environmental harm to be prevented, other types of control obligations set out in the MEA (e.g., production and use restrictions), the concerns and needs of all participating countries and relevant trade rules and trade implications. (TN/TE/W/40 of June 21, 2004, paragraph 21)

Other countries have followed the U.S. lead. Australia recently submitted a similar paper on national coordination.

In addition, the U.S. and its allies have attempted to limit the scope of the negotiations by arguing that the ministerial mandate is narrow. The Doha Ministerial Declaration refers to “specific trade obligations” (STOs) in MEAs. The U.S. has argued that STOs are provisions that *require* action. (Switzerland and the EU argue that the negotiations should cover not only measures that are *required* under MEAs, but also those that are *authorized*.) A number of countries have argued that the BSP authorizes but does not require trade restrictions.

We have argued that the U.S. negotiating position ignores the very real problems of BSP implementation. As a result, U.S. arguments are misleading to the point of being dangerous. They have undoubtedly led some important officials in potentially helpful countries to believe that the BSP has minor trade implications.

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U.S. negotiators are unlikely at this point to change their negotiating strategy. They have, however, at our urging, begun to address the BSP in other contexts in Geneva. On the margins of the March meeting of the Committee on Sanitary and Phytosanitary Measures, the U.S. and Canada hosted jointly a discussion of the BSP and its implications for the WTO. Over thirty people attended, most of whom were SPS Committee delegates from Latin America.

**THE CARTAGENA PROTOCOL ON BIOSAFETY AND
THE WORLD TRADE ORGANIZATION:
Implementing a WTO-Consistent Biosafety Regulatory Framework**

Craig Thorn
DTB Associates, LLP

Kevin Brosch, Esq.
DTB Associates, LLP

ABOUT THE AUTHORS

Craig Thorn

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Kevin Brosch

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1. The Cartagena Protocol on Biosafety (“BSP”), a supplementary agreement to the Convention on Biological Diversity (“CBD”), was adopted in January 2000 and entered in to force on September 11, 2003. As of this writing, the BSP has been ratified by 110 countries, and many of these countries are now considering implementing legislation.

2. A large majority of countries that are party to the Biosafety Protocol are also members of the World Trade Organization (“WTO”). Since several WTO agreements contain disciplines that are relevant to trade in products of agricultural biotechnology, those countries will need to take both sets of obligations into account as they develop implementing legislation. The purpose of this paper is to examine the trade-related provisions of the BSP, together with relevant WTO obligations, and to suggest WTO-compliant approaches to establishing a biosafety regulatory framework.

The WTO and Multilateral Environmental Agreements

3. The relationship between the WTO and multilateral environmental agreements (“MEAs”) such as the Biosafety Protocol has received a great deal of attention in recent years. In 1994 at the Marrakesh Ministerial Conference marking the end of the Uruguay Round of trade negotiations, trade ministers from WTO member countries established a special Committee on Trade and Environment. The first item on the work program of the Committee was to examine “the relationship between the rules of the multilateral trading system and the trade measures contained in multilateral environmental agreements, and between their dispute settlement mechanisms¹.” Ministers empowered the Committee to examine issues and make recommendations, but did not give it a mandate to conduct negotiations. The Committee focused mainly on establishing institutional links between the WTO and the secretariats of various MEAs.

4. At the fourth Ministerial Conference of the WTO – which took place in Doha, Qatar, in November 2001 – WTO members launched the Doha Development Agenda, a new round of trade talks aimed at lowering trade barriers and strengthening multilateral trade rules. As a part of the mandate adopted at Doha, trade ministers agreed to negotiations regarding “the relationship between existing WTO rules and specific trade obligations set out in multilateral environmental agreements.”² The negotiating mandate included a number of qualifications that indicate the trepidation with which many member countries approached negotiations on this subject:

- Ministers agreed to negotiations “without prejudging their outcome”.³

¹ Work Programme of the Committee on Trade and Environment, http://www.wto.org/english/tratop_e/envir_e/cte00_e.htm

² Ministerial Declaration, Ministerial Conference, Fourth Session, Doha, 9-14 November, 2001, WT/MIN(01)/DEC/1, http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.pdf, paragraph 31 (i).

³ Ibid, para. 31.

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- The negotiations were to be “limited in scope to the applicability of such existing WTO rules as among parties to the MEA in question” and were not to “prejudice the WTO rights of any Member that is not a party to the MEA in question”.⁴
- Any outcome of the negotiation 1) had to be “compatible with the open and non-discriminatory nature of the multilateral trading system”; 2) could “not add to or diminish the rights and obligations of Members under existing WTO agreements, in particular the Agreement on the Application of Sanitary and Phytosanitary Measures”; 3) could not “alter the balance of [those] rights and obligations”; and 4) had to “take into account the needs of developing and least-developed countries.”⁵

5. Many of delegates at the Doha Ministerial Conference, in particular those from developing countries, expressed concern that trade provisions in MEAs might be used to legitimize new forms of protectionism. That same concern has been evident thus far in the negotiations, which have progressed slowly. The majority of participants have argued in favor of keeping the scope of work for the negotiating committee narrow, in an effort to avoid an outcome that would undermine WTO disciplines or otherwise change the balance of rights and obligations under the WTO agreements. The BSP is one of the six MEAs most often mentioned as containing “specific trade obligations” that should be examined in the course of the negotiations.

Savings Clause

6. The Doha Round negotiations may eventually produce an outcome that clarifies definitively the relationship between MEAs and the WTO agreements. In the meantime, interpretation will be guided by the language of the agreements themselves, by other relevant international legal instruments, and by legal precedent.

7. The negotiators of the CBD and the BSP were aware of the possibility that those agreements might overlap with other international agreements, especially trade agreements. CBD negotiators dealt with the issue explicitly by including a “savings clause” in Article 22(1):

The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.

8. The inclusion of a similar clause in the BSP became of a matter of some controversy and was among the last issues decided by negotiators. The language that was finally accepted appears in the preamble and is clearly the result of compromise:

The Parties to this Protocol,

⁴ Ibid, para. 31(i).

⁵ Ibid, para. 32.

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...

Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements, . . .

9. These provisos are important to an analysis of the legal relationship between the BSP and the WTO. The WTO Appellate Body has stated that WTO rules cannot be “read in clinical isolation from public international law”⁶ and has cited frequently the Vienna Convention on the Law of Treaties when interpreting WTO agreements in the context of formal trade disputes. Article 30 of that Convention⁷, which pertains to the application of successive treaties relating to the same subject matter, reads in part as follows:

2. When a treaty specifies that it is subject to, or that it is not to be considered as incompatible with, an earlier or later treaty, the provisions of that other treaty prevail.

3. When all the parties to the earlier treaty are parties also to the later treaty but the earlier treaty is not terminated or suspended in operation under article 59, the earlier treaty applies only to the extent that its provisions are compatible with those of the latter treaty.

10. The CBD savings clause places that agreement, in all but the most critical circumstances, in the category described by paragraph 2 above. The CBD must be interpreted in a manner consistent with WTO rights and obligations pertaining to trade, except in cases where biological diversity is threatened. The comparable language in the BSP is more equivocal, and it appears in the preamble rather than in the text of the agreement itself. Nonetheless, it seems to provide a valid basis for WTO panels and the Appellate Body to conclude that negotiators of the BSP did not intend for that agreement to supercede automatically WTO rules.

11. There is certainly no ambiguity regarding the rights and obligations of WTO members who are not parties to the BSP. Article 30.4(b) of the Vienna Convention reads:

4. When the parties to the later treaty do not include all the parties to the earlier one:

...

⁶ [Appellate Body Report on US – Gasoline](#), p.17.

⁷ Article 30 has never been used as a basis for a dispute settlement finding by a WTO panel or the Appellate Body, but it has been cited as a defense by at least one Member. See [Appellate Body Report on EC – Poultry](#), para. 79.

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(b) as between a State party to both treaties and a State party to only one of the treaties, the treaty to which both States are parties governs their mutual rights and obligations.

In other words, trade relations between parties to the BSP that are WTO members and non-parties that are WTO members are governed exclusively by the WTO agreements.⁸ Most current exporters of products of biotechnology are not parties to the BSP.

Implementation Issues

12. Fortunately for countries that are Parties to the BSP as well as WTO Members, it is possible to avoid conflict between WTO rules and the trade-related provisions of the BSP by implementing the BSP in a manner that is fully consistent with WTO obligations. In the section below we list each of the provisions of the BSP that could affect trade, cite relevant WTO rules, and suggest WTO-compliant approaches to implementation. Relevant excerpts from the text of the BSP can be found in the annex, listed in the order in which they are discussed below.

13. There is a fundamental difference in orientation between the BSP and WTO rules that policy makers must consider in developing a WTO-consistent biosafety regime. The BSP is essentially a process-based agreement – *i.e.*, it regulates a category of products simply because they have been produced using a particular production method. WTO rules are, for the most part, product-based – *i.e.*, they focus on the end product rather than the production process. The WTO does not expressly prohibit the regulation of particular production methods; rather, it requires that decisions taken under such a regulatory regime be justified on the basis of the characteristics of the end product.

Advance Informed Agreement (“AIA”) Procedure

14. **Article 7.1** of the BSP provides that an “advanced informed agreement procedure . . . shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.” The AIA procedure is set out in various provisions of **Article 8, 9 and 10** (see annex). Living modified organisms (“LMOs”) are defined in the agreement as “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology (**Article 3.g**).” AIA does not, however, apply to LMOs moved across borders for direct use as food or feed, or for processing. (That category of products is subject to the requirements of **Articles 7.3 and 11** – see below.) In other words, the AIA requirement applies, for example, to seeds for planting, LMOs used for environmental remediation or industrial applications, transgenic animals and certain veterinary medicines.

15. There is nothing inherently WTO-illegal about the AIA requirement. In fact, the *Agreement on the Application of Sanitary and Phytosanitary Measures* (“SPS Agreement”) and

⁸ This is true despite the fact that BSP Article 24 requires trade in living modified organisms between a Party and a non-Party to be “consistent with the objective” of the Protocol. A WTO dispute settlement panel would be likely to interpret Article 30.4(b) of the Vienna Convention as giving precedence to WTO rights and obligations in cases where the two countries concerned were both WTO Members.

the *Agreement on Technical Barriers to Trade* (“TBT Agreement”), two of the relevant WTO agreements⁹, implicitly permit pre-market approval procedures, subject to certain conditions – *e.g.*, that decisions be taken “without undue delay” and that measures taken under the procedures be consistent with other provisions of the Agreement (see SPS Agreement, Article 8 and Annex C; and TBT Agreement, Article 5). However, certain features of the AIA procedure could cause WTO problems if improperly applied.

16. **Article 8** requires exporting Parties to notify, or to ensure that the exporter notifies, the importing Party prior to the first shipment of LMOs for intentional introduction into the environment. Nothing in the WTO agreements would prevent an exporting Member from voluntarily taking on such an obligation. However, WTO rules aim at minimizing government involvement in international commercial decisions. A requirement by an importing country that the government of an exporting country, as opposed to a private exporter, take on the responsibility for issuing the notification and ensuring the accuracy of the information provided could in itself become a barrier to trade, since it could force governments of exporting countries to establish official controls especially for that purpose. Annex C of the SPS Agreement requires members to ensure, *inter alia*, that “information requirements [be] limited to what is necessary for . . . appropriate approval procedures.”

17. Fortunately, this Article does not place any obligation on the importer with regard to the notifier. An importing country could fulfill its obligations under the BSP and avoid potential WTO problems by following normal practices for product approvals and allowing private parties to submit notifications.

18. **Articles 9.4 and 10.5** of the BSP imply that a party to the BSP could ban the import of a product indefinitely simply by failing to reply to a notification or render a final decision. While neither the SPS Agreement nor the TBT Agreement puts an absolute time limit on pre-market approval procedures, both agreements require prompt action. The SPS Agreement stipulates that approval procedures must be “completed without undue delay” (SPS Annex C.1.a), and the TBT Agreement says they must be “completed as expeditiously as possible” (TBT 5.2.1).

19. Some participants in the BSP negotiations describe **Article 10.6** as an expression of the “precautionary principle.” Certain agricultural exporting countries resisted strongly the inclusion of the paragraph during the negotiation, in part because of a fear that it would undermine WTO disciplines.

20. The precautionary principle has been a frequent topic of discussion in the WTO, having been raised both in the Committee on Sanitary and Phytosanitary Measures and in the context of the Doha Development Agenda negotiations on agriculture.¹⁰ However, in both contexts the majority of WTO members opposed amending or interpreting WTO rules to

⁹ The SPS Agreement applies to all sanitary and phytosanitary measures that may affect international trade. SPS measures are defined in Annex A of the Agreement as any measure applied to protect human, animal or plant life or health from certain specified risks. The TBT Agreement applies to all technical regulations and standards that are not covered by the SPS Agreement (see TBT Agreement, Article 1.5). Most measures designed to implement the BSP are likely to be covered by the SPS Agreement.

¹⁰ See WTO document G/SPS/GEN/168, *Communication from the Commission on the Precautionary Principle*, 14 March 2000.

incorporate such a broad, open-ended principle.¹¹ Moreover, when one WTO member invoked the precautionary principle as a defense in a dispute settlement case, the Appellate Body declined to recognize it as a general principle of international law and stated that the principle could not override obligations under SPS Agreement.¹²

21. The WTO SPS Agreement does incorporate important elements of precaution. Article 5.7 of the SPS Agreement contains language that is similar in some respects to BSP **Article 10.6**:

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

22. Like BSP **Article 10.6**, SPS Article 5.7 permits members to adopt provisional measures in cases where information is incomplete. However, this right under the SPS Agreement is accompanied by clear obligations, as described by the WTO Appellate Body below:

Article 5.7 of the SPS Agreement sets out four requirements which must be met in order to adopt and maintain a provisional SPS measure. Pursuant to the first sentence of Article 5.7, a Member may provisionally adopt an SPS measure if this measure is:

- (1) imposed in respect of a situation where ‘relevant scientific information is insufficient’; and
- (2) adopted ‘on the basis of available pertinent information’.

Pursuant to the second sentence of Article 5.7, such a provisional measure may not be maintained unless the Member which adopted the measure:

- (1) ‘seek[s] to obtain the additional information necessary for a more objective assessment of risk’; and
- (2) ‘review[s] the ... measure accordingly within a reasonable period of time’.

These four requirements are clearly cumulative in nature and are equally important for the purpose of determining consistency with this provision. Whenever one of these four requirements is not met, the measure at issue is inconsistent with Article 5.7.¹³

¹¹ See WTO document G/SPS/R/18, *Summary of the Meeting Held on 15-16 March 2000*, Committee on Sanitary and Phytosanitary Measures, 18 April 2000, page 1.

¹² Appellate Body Report on *EC – Hormones*, para. 123.

¹³ [Appellate Body Report on *Japan – Agricultural Products II*](#), para. 89.

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23. Other elements of precaution in the SPS Agreement are also carefully circumscribed and balanced with reasonable obligations. Article 8 permits pre-market approval requirements for certain products, but Annex C lays down standards that such a system must meet. Article 3.3 allows a member to adopt measures that are stricter than relevant international standards, but requires that member to provide a scientific justification.

24. The right to act under BSP **Article 10.6** is less qualified. BSP **Article 12** permits but does not require a review, in light of new scientific evidence, of decisions taken under **Article 10**. Nevertheless, nothing in the BSP prevents WTO members from implementing AIA procedures that comply fully with WTO limits on the use of precautionary measures.

Procedure for Living Modified Organisms Intended for Direct Use as Food or Feed, Or For Processing (“LMO-FFPs”)

25. **Article 7.3** and **Article 11** (see annex) govern LMO-FFPs. These provisions apply to the large majority of trade in LMOs, which is in the form of bulk commodity shipments.

26. The BSP does not require advanced informed agreement for the export of LMO-FFPs. Instead, **Article 11.1** requires governments that make a final decision on LMOs for domestic use that may be subject to transboundary movement for direct use as food, feed or for processing, to notify other Parties of that decision through the Protocol’s Biosafety Clearing House (“BCH”). However, under **Article 11.4 and 11.6** Parties may elect to subject the first import of an LMO-FFP into their country to advanced decision-making. If a Party decides to take this step, it can take a decision under its domestic legislation or, if it has no such legislation, on the basis of a risk assessment in conformity with BSP procedures and requirements.

27. As indicated above, such pre-market approval requirements are permitted under the WTO, subject to certain conditions. Potential conflicts between specific features of the BSP procedures for LMO-FFPs and WTO rules are detailed below.

28. **Articles 11.4 and 11.6** may be applied in a manner that is consistent with WTO rules if BSP Parties take into account the additional requirements contained in the WTO. The SPS Agreement requires that a measure be “based on” a risk assessment (SPS 5.1) – that is, there must be a “rational relationship between the measure and the risk assessment.”¹⁴ In addition, a measure must comply with the other requirements laid down in the Agreement – *e.g.*, sufficiency of scientific evidence (SPS 2.2); necessity (SPS 5.6, TBT 2.2, Article XX of the *General Agreement on Tariffs and Trade* (“GATT”)), and non-discrimination (SPS 2.3, TBT 2.1, GATT III.4).

29. **Article 11.5** requires that “national laws, regulations and guidelines” applicable to the import of LMO-FFPs be notified to the BCH. Such measures must also be notified to the WTO (see SPS 7 and Annex B, TBT 10).

30. **Article 11.7**: See paragraph 18 above.

31. **Article 11.8**: See paragraphs 19-24 above.

Bilateral, Regional and Multilateral Agreements

¹⁴ [Appellate Body Report on EC – Hormones](#), para. 193.

32. WTO rules do not prohibit special arrangements between or among members on regulatory matters, as permitted in **Article 14.1** of the BSP. However, the SPS Agreement requires members to “ensure that their [SPS] measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members” (SPS 2.3). This provision is an elaboration of the “most-favored-nation” principle, the cornerstone of WTO law. The GATT requires that, with respect to all laws, regulations and requirements affecting trade:

any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.

33. If a BSP party that is a WTO member reaches an agreement under **Article 14.1** to grant special treatment to another country, that party is obliged under WTO rules to grant the same treatment to any other WTO member that can meet the same standard as the country to which special treatment has been granted.

34. **Article 14.1** is one of several BSP provisions that approach regulatory restrictions from a point of view opposite that of the WTO. **Article 14.1** stipulates that special arrangements between countries may not result “in a lower level of protection than that provided for by the Protocol.” WTO rules require that measures be no more trade restrictive than necessary to fulfill their objective (see SPS 5.6, TBT 2.2, GATT XX). In a sense, the BSP defines the *minimum* permissible amount of regulation, while the WTO rules define the *maximum*.

Risk Assessment

35. The risk assessment provisions in **Article 15.1** and **Annex III** of the BSP are broadly consistent with the rules of the SPS Agreement (see SPS 5). A risk assessment carried out in accordance with BSP guidelines would in all likelihood meet the standard established in Article 5.2 of the SPS Agreement. WTO members should be aware that there are some limits on the amount and type of data they can demand from notifiers. The SPS Agreement requires members to ensure that “information requirements are limited to what is necessary for appropriate control, inspection and approval procedures” (SPS Annex C.1.c; see also TBT 5.2.3).

36. Requiring the exporter or the notifier to carry out a risk assessment, as provided for in **Article 15.2**, is permissible under WTO rules, so long as the requirement is non-discriminatory – *i.e.*, all notifiers, foreign and domestic, are subject to the same requirement – and consistent with a country’s approach to regulating similar risks. In practice, most countries that regulate biotechnology require that the company or organization submitting the notification supply data along the lines of those specified in **Annexes I and III**. Moreover, it is normal for products being produced commercially and traded internationally to undergo a safety evaluation in at least

one country. Both the BSP and the SPS Agreement permit countries to make their regulatory decisions based on risk assessments performed by another party.¹⁵

37. **Article 15.3** allows BSP parties to require notifiers to pay the cost of a risk assessment. Under WTO rules, any such fees may not exceed the cost of services rendered and must be equitable in relation to fees charged for similar services for like products of domestic origin (SPS Annex C.1.f; TBT 5.2.5; GATT III.1 and II.2.c and VIII).

Risk Management

38. **Article 16.1** obliges BSP parties to regulate the “use, handling and transboundary movement” of all LMOs. As indicated above (para. 13), WTO rules do not permit a member to restrict imports of a product simply because it has been produced by a particular process. An SPS measure must be based on an identifiable risk related to the particular product (SPS 5.1), and must conform to the other disciplines laid down in the SPS Agreement and the GATT. If a WTO member decides to control trade in an LMO, it must base that decision on the characteristics of the end product.

39. Like **Article 14.1**, **Article 16.2** defines the minimum permissible amount of regulation, viewed from the perspective of biosafety. Nothing in the SPS Agreement prevents countries from safeguarding biosafety. In fact, the SPS Agreement explicitly permits members “to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health” (SPS 2.1). However, under the SPS Agreement risks, once they are identified, must be managed without unnecessary trade distortions. SPS Article 2.2 requires that SPS measures be “applied only to the extent necessary to protect human, animal or plant life or health” (see also SPS 5.3 through 5.6). A science-based regulatory decision should have no trouble conforming to both BSP and WTO rules.

Handling, Transport, Packaging and Identification (Article 18)

40. As indicated above, method of production is not a sufficient justification under the SPS Agreement for imposing restrictions on handling, packaging and transport of a product. Measures maintained for SPS-related purposes must be, *inter alia*, based on a proper risk assessment and supported by sufficient scientific evidence. Moreover, WTO rules do not permit members to discriminate between like products (GATT III.4, TBT 2.1). If the LMOs in question have been examined and approved for use, and there is no scientific reason to restrict their use, special handling, packaging and transport requirements would be inconsistent with WTO rules.

41. Labeling for consumer information purposes, as opposed to labeling for a health or environmental risk, is permissible under WTO rules. However, the TBT Agreement requires, *inter alia*, that such labeling be non-discriminatory and “no more restrictive than necessary to

¹⁵ The WTO Appellate Body addressed this issue in their finding in the *EC – Hormones* dispute settlement case “Article 5.1 [of the SPS Agreement] does not insist that a Member that adopts a sanitary measure shall have carried out its own risk assessment. It only requires that the SPS measures be ‘based on an assessment, as appropriate for the circumstances ...’. The SPS measure might well find its objective justification in a risk assessment carried out by another Member, or an international organization.” [Appellate Body Report on EC – Hormones](#), para. 190.

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fulfil a legitimate objective” (TBT 2.2). Mandatory labeling of LMOs for food, feed and processing for consumer information purposes can be burdensome and costly. On the other hand, a system that allows voluntary labeling of non-LMO products can provide the same information to consumers in a much less trade-restrictive manner.

Confidential Information

42. The WTO lays down rules regarding the protection of undisclosed information that are somewhat more protective of the rights of the notifier than those contained in **Article 21** of the BSP. The SPS and TBT Agreements require that information provided in the course of an approval process be “respected in a way no less favourable than for domestic products and in such a manner that legitimate commercial interests are protected” (SPS Annex C.1.d and TBT 5.2.4). Article 39 of the *WTO Agreement on Trade-Related Aspects of Intellectual Property Rights* contains more detailed obligations:

1. In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices[*] so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

*For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

Socio-Economic Considerations

43. As indicated above, WTO members must base SPS measures on a scientific assessment of risk. Members are to take economic issues into account in the context of the overall objective of minimizing the negative trade effects of measures taken (SPS 5.3 and 5.4).

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The BSP implicitly recognizes these conditions by requiring that socio-economic considerations be taken into account in a manner “consistent with . . . international obligations.”

Liability and Redress

44. **Article 27** tasks BSP Parties with elaborating “international rules and procedures in the field of liability and redress for damage resulting from transboundary movements” of LMOs. The Conference of Parties has established a process aimed at fulfilling this mandate. Some participants in this process are proposing establishing insurance requirements and requiring the deposit of funds for any activities involving LMOs. Such requirements would be considered SPS measures under WTO rules and would therefore be subject to the disciplines of the SPS Agreement. An across-the-board requirement for liability insurance for LMOs, one that is not related to the risks associated with a particular product, would almost certainly violate those SPS rules.

WTO AND CARTAGENA PROTOCOL ON BIOSAFETY

Summary of Discussion Points on Protocol Implementation Issues

We are aware that many Geneva delegates are concerned that trade-related provisions of multilateral environmental agreements (MEAs) could be used justify trade barriers and undermine WTO rules. We share those concerns, and we encourage you to resist any outcome to the negotiations under paragraph 31(i) of the Doha Ministerial Declaration that would give MEAs automatic precedence over the WTO.

The implementation of one MEA, the Cartagena Protocol on Biosafety, poses significant potential problems. Even though the Protocol as written could be implemented in a WTO-consistent manner, some of the Parties to the Protocol who are also WTO members are arguing strongly in favor of interpretations of the agreement and additional implementation requirements that would clearly be WTO-inconsistent. The following describes possible outcomes of the next implementation talks that would preserve the possibility for countries to meet their obligations under both agreements.

Current Implementation Work should Focus on Bringing All Parties into Compliance

- Biosafety Protocol implementation work should focus first and foremost on the development of the capacity of all Parties to ensure compliance with the Protocol. The creation of new obligations should only be considered after compliance is achieved.
- Due care should be taken in the development of any new requirements to carefully balance the need for biosafety in connection with living modified organisms (LMOs) with trade considerations and the goal of ensuring the continue availability of the technology to those who wish to benefit from it.

Documentation Requirements for LMO-FFPs should not Disrupt World Trade

- In order to avoid trade disruptions and to promote consistency in the implementation of the Protocol in international commerce, the provisions of the Trilateral Arrangement negotiated by Mexico, United States and Canada should be the basis for commercial transactions between exporters and importers on all LMO-FFP shipments to all Parties, unless domestic regulations of the importing country demand otherwise.
- This arrangement is designed to fulfill the Protocol's objectives without unnecessarily disrupting international commodity trade. It incorporates many of the recommendations of the grain trade industry, including: continued use of the "may contain" language for all transboundary shipments of LMO-FFPs where an LMO of that commodity species is authorized in or sold from a country of export except when the exporting country does not have in commerce any LMO of that species; an exemption from the documentation requirements for shipments where the exporter and importer have contractually defined a "non-LMO shipment"; and support for the position that adventitious presence of LMOs in a non-LMO shipment should not be considered a trigger for the "may contain" documentation.

Biotech-specific Liability Regime Threatens Trade and Development Opportunities

- Some developing countries are advocating a biotech-specific liability regime under the Protocol that would hold technology companies strictly liable for a wide variety of vague and unquantifiable “harms” unrelated to the protection of biodiversity and without the defenses, caps and time limitations necessary for insurability. If put in place, such a regime could have a serious negative impact on trade with any Party to the Protocol because it would create too much legal and financial uncertainty. It also could be expected to erode the building blocks of trade in developing countries including public sector research, commercial development, and technology transfer, contrary to the objectives and commitments of Agenda 21, the Convention on Biological Diversity, and the Millennium Development Goals.
- Negotiation of an international liability regime specifically for LMOs is unnecessary because existing civil liability laws already in place would also apply to any potential damage alleged to be caused by LMOs. To the extent additional coverage is necessary for environmental harms, the most prudent course would focus on national capacity building to create general environmental liability laws that would cover all damage to biodiversity, regardless of source, and development of any necessary new international rules under the Convention on Biological Diversity.

Existing Documentation for Research and Release should be Maintained

- Parties should continue to accept and insist upon use of standard commercial and shipping documentation (e.g. invoices or proforma invoices) in conformity with existing Protocol guidance for LMOs for contained use (e.g. for approved research activities in laboratories) and intentional introduction into the environment (e.g. importation pursuant to commercial planting or permits for planting). Initiatives to create new stand alone documentation and/or additional requirements threaten to disrupt ongoing trade which fully complies with the Protocol.

Existing Risk Assessment Models and Guidance meet Needs

Existing guidance materials and models on risk assessment can be integrated effectively into the Protocol risk assessment process to facilitate decision-making on LMOs, obviating the need for development of new guidance or systems under the Protocol. These include those developed under the International Plant Protection Convention and the Codex Alimentarius, both recognized as the standard setting bodies in their fields. Other useful guidance and materials is available from the OECD, UNEP and national regulatory systems (e.g., EU, Canada, U.S.).

Conclusion:

We all have an interest in preserving the disciplines of the SPS and TBT Agreements. It is important for trade officials to be involved in COP/MOP process in order to ensure that the BSP does not undermine WTO disciplines. It is equally important, for similar reasons, that trade officials be involved in the development of national biosafety legislation.

**TRADE CONCERNS IN
BIOSAFETY PROTOCOL IMPLEMENTATION TALKS
MERIT ATTENTION FROM GENEVA-BASED OFFICIALS**

A number of issues arising from the ongoing implementation of the Cartagena Biosafety Protocol warrant the attention of WTO member country trade officials. In preparation for the Third Meeting of the Parties to be held 13-17 March 2006 in Curitiba, Brazil (“MOP-3”), **the private sector users and developers of biotechnology respectfully request that Geneva-based trade delegations work with their respective in-capital officials to ensure that country positions are consistent with national trade and development interests.**

For each key implementation issue, this paper provides information on the status and next steps following the Second Meeting of the Parties in June 2005 (“MOP-2”), potential trade and development concerns related to each, and a summary of positions taken by countries to date.

I. CURRENT IMPLEMENTATION ISSUES OF CONCERN

A. Documentation – Commodities Shipments

Issue: Article 18.2 of the Protocol establishes rules on documentation of biotech products (or “living modified organisms (LMOs), as they are known in the Protocol) and sets up a negotiation on more detailed requirements.

Status: At MOP-2, the Parties were obliged to decide on “detailed requirements” for the Protocol mandate that shipments of LMOs for direct use as food, feed or processing (LMO-FFPs) are accompanied by documentation that states that the shipment “may contain” LMOs. Consensus could not be reached on a Swiss compromise proposal, however, and no detailed requirements were agreed. The status quo (accompanying documentation must reflect that the shipment “may contain” LMOs, permitting potential importers to review data on commercialized LMOs that may be present via the Biosafety Clearing House) therefore is preserved until the issue is resolved at MOP-3 or thereafter.

Next Steps: Questions surrounding LMO-FFPs identification and documentation will be a central focus of MOP-3, with the Swiss compromise proposal serving as a potential starting point for discussions.

Concerns: Some countries are advocating detailed documentation requirements that would be burdensome, costly, and disruptive to world commodity trade and access to basic food supplies. These proposals are potentially trade-disruptive because they would require fundamental changes in the way commodities are produced, handled and shipped to create the level of segregation necessary to implement the detailed documentation requirements. The creation of such a highly segregated system is inconsistent with current, economically balanced bulk commodity production and trade practices. Instead, current practice requires those that seek to gain higher

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returns from specific products (e.g., organic products) to take the necessary steps to handle those products outside the commodity stream.

Some of the changes required by these proposals for detailed documentation accompanying commodity shipments may not be feasible at all. Further, the costs for those changes that could be made would be passed on to importing developing countries.

Moreover, method of production is not a sufficient justification under WTO rules for imposing restrictions on identification, handling, packaging or transport of a product. Measures maintained for SPS-related purposes must be, *inter alia*, based on a proper risk assessment and supported by sufficient scientific evidence. Moreover, WTO rules do not permit members to discriminate between like products. If the products in question have been examined and approved for use, and there is no scientific reason to restrict their use, special documentation requirements would be inconsistent with WTO rules.

There has been little discussion of the potential costs of the various proposals under discussion or their consistency with the WTO.

Positions:

- **African Group:** Insist that documentation and other systems must prevent any trace of unapproved LMOs from being included in commodity shipments.
- **New Zealand:** Objected to reference to thresholds in proposed compromise on documentation requirements.
- **Brazil:** “Gravely” concerned about trade implications of a rushed “compromise” decision.
- **Peru, Mexico and Australia:** Oppose onerous requirements for commodity documentation.

B. Documentation – Research and Releases

Issue: Article 18 of the Protocol sets forth certain documentation and identification requirements for shipments of LMOs destined for contained (laboratory) use or for release into the environment (whether for experimental or commercial use).

Status: MOP-2 agreed to continue applying documentation requirements for LMOs for contained use and for release into the environment using existing commercial invoices as decided at MOP-1.

Next Steps: Documentation and identification requirements for research and release into the environment will be considered again at MOP-3.

Concerns: Outstanding proposals from MOP-1, which are likely to be re-presented at MOP-3, advocate the creation of new stand-alone documentation requirements to replace current commercial invoices. They also propose to add further details beyond what is required by the Protocol without scientific justification in potential violation of WTO member obligations under

the SPS Agreement. New formats that differ from widely known and accepted existing commercial invoices, not only would increase costs but could be designed and implemented in such a way as to create an additional barrier trade that may conflict with the disciplines of the TBT Agreement, particularly where these requirements raise questions that could result in delay or rejection of shipments. New requirements to include more detailed information for LMOs for contained use may also risk exposing confidential business information which is extremely sensitive in the research and development phase.

Positions:

- **Norway:** Insists on use of a stand-alone document developed by the Norwegian government as the only means possible to implement Article 18.2(b) and (c).
- **The African Group, India, Iran, Oman and Ireland (for the EU):** Support Norway and advocate strongly for stand-alone, government-issued document.
- **U.S., Canada, Australia, Japan, Brazil, Mexico, Uruguay, Argentina and Nicaragua:** Oppose the use of stand-alone documentation and favor use of existing documentation, either commercial invoices or other documents already in commercial use.

C. Risk Assessment and Risk Management

Issue: The Protocol requires science-based risk assessment in conformity with guidance set forth in an annex and obligates countries to undertake certain risk management measures.

Status: MOP-2 was unable to decide whether additional work should be undertaken pursuant to the Protocol on risk assessment and, if so, whether it would be limited to create guidance materials based on existing approaches and document or, on the other hand, further elaborate existing principles (i.e., those contained in the Protocol) for risk assessment and risk management. Related to this issue was whether a new technical body should be created to undertake such work.

Next Steps: A Technical Experts Group will meet in **15-18 November 2005** in Italy to consider the nature and scope of existing risk assessment approaches, identify gaps, capacity building needs identified by Parties, etc. and report to MOP-3 for further consideration of this issue.

Concerns: The concern is that development of new material under the Protocol – rather than use of the ample guidance already available from, *inter alia*, the International Plant Protection Convention (IPPC), Codex Alimentarius, OECD, UNEP and national systems – may undermine the Protocol's current science-based approach to risk assessment in direct conflict with the disciplines of the SPS Agreement. The creation of yet another regime of scientific or technical assessment increases the risk of WTO members being placed in a position of impossibility of compliance. That is to say, a member's effort to satisfy the disciplines of the SPS Agreement could be frustrated by that member's attempts to meet a set of differing requirements proposed to be established under the Protocol and place that member in a position of non-conformance.

The concern about the establishment of a subsidiary body to do this and other work is that doing so risks diverting attention and resources from bringing existing Parties into compliance with

their basic Protocol obligations. New bodies inevitably result in the creation of additional work programs and not only threaten to create additional requirements and hurdles as a result, but increase costs for everyone.

Positions:

- **Ethiopia (for Africa), Norway, Panama, Malaysia, Cuba and other developing countries:** A technical group should be established to immediately begin work on risk assessment guidance.
- **Mexico, Japan, India, New Zealand and Ukraine:** Formation of a technical group would be premature.
- **Brazil:** Any work should await analysis to determine if there is any need.

E. Liability

Issue: Article 27 of the Protocol tasks Parties with elaborating “international rules and procedures in the field of liability and redress for damage resulting from transboundary movements” of LMOs. The Conference of Parties has established a process aimed at fulfilling this mandate.

Status: The first meeting of the Liability Working Group (May 2005) gave little attention to highly critical threshold issues, including analysis of how existing legal systems would apply and whether there is any need for any new international rules and procedures. Instead, the Working Group focused on the further development of possible elements of a legally binding regime, adding more ideas to a pre-existing list.

Next Steps: Countries are invited to submit comments and textual proposals on the list of potential elements of a liability regime by **13 November 2005**. These submissions will form the basis of negotiations in the Liability Working Group meeting from **13-17 February 2006** in Montreal. The outcome of that meeting will be reported to MOP-3 where the Parties will give further direction to the Working Group.

Concerns: Of greatest concern are proposals for an extremely broad scope for liability rules that would hold technology companies, in particular, strictly responsible for social, economic and other unquantifiable and unpredictable “harms.” Further, some participants in this process are proposing establishing insurance requirements and mandating the deposit of funds for any activities involving biotech products. The cost of such rules could be prohibitive for producers of biotech products. In addition, very little consideration is being given to:

- The workability of proposals (including insurance requirements that may be unattainable in the marketplace);
- Whether the proposed system would be fair (proposals for strict liability fail to take into account fault of other actors); or
- Whether the objective of the Biosafety Protocol (conservation and sustainable use of biodiversity) would be advanced.

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- Many advocating a broad and strict liability regime have not considered the negative impact it would have on their own public research, local companies, technology transfer, trade or the attraction of foreign investment.

As with other Protocol implementation issues, Parties have made little effort to take into account relevant WTO rules even though liability rules of the type being considered would be subject to the disciplines of the WTO SPS Agreement. For example, an across-the-board requirement for liability insurance for biotech products, one that is based purely on the method of production and not related to the risks associated with a particular product, would almost certainly violate SPS rules.

Positions:

- **The Philippines:** Reminded countries that biotech products will be produced by developing as well as developed countries and that any liability rules created under the Protocol also will apply to them.
- **Morocco:** Reminded Parties that biotechnology brings economic and social benefits that need to be considered in the liability discussion.
- **Colombia, supported by South Africa, Mexico and Ukraine:** Asserted that “cultural and moral damage” should be included in the scope of a regime. Others proposed additional coverage including cultural heritage and damage to agricultural “subgroups” with traditional lifestyles (**Estonia**), spiritual damage (**Senegal**) damage to farmers’ skills and independence (**Botswana**), damage to livelihoods of indigenous communities (**Thailand**).
- **Argentina:** Socio-economic damage is outside the scope of the Protocol.
- **Cote d’Ivoire and the European Union:** Issues concerning human health should be dealt with at the national level and not included in the scope of any rules.
- **India, Malaysia, Cuba, and Senegal:** Supported a strict liability regime
- **Canada and the United States:** Strict liability is reserved for ultra-hazardous activities and that transboundary movements of LMOs are not themselves hazardous.
- **Malaysia and Egypt:** Opposed inclusion of the “permit” and “state of the art” defenses.
- **European Union:** Insisted that “permit” and “state of the art” defenses remain on the list of excluded defenses to liability.
- **The Philippines, Canada, New Zealand, and the United States:** Emphasized the need for limitation periods after which claims could not be brought.
- **Colombia, Malaysia and Uganda:** supported the establishment of a fund with contributions from the biotech industry to provide financial guarantees.
- **Canada and Australia:** fund is unworkable as the broad scope of damage being discussed would mean that insurance would not be available and that funds only operate as a second layer of protection after insurance coverage is exhausted.
- **Switzerland:** did not support the creation of a fund because it is not consistent with the polluter pays principle.
- **Senegal, Trinidad & Tobago, Cuba, Uganda, Venezuela, Zambia, El Salvador and India:** the liability process must result in a legally binding instrument.

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- **New Zealand** asked for the inclusion of “no new instrument” as an alternative option.
- **Brazil and Canada** insisted that all options remain open at this stage and the
- **European Union** warned that the group must consider alternative ways to meet their objectives in light of the fact that so few international liability regimes have gained acceptance.

All countries recognized the critical importance of capacity building in this context. **Mexico and Brazil** emphasized the importance of developing national liability legislation. **Colombia, supported by Uganda, Jordan, Mali, Syria, Malaysia, Cuba, Iran, Senegal, Tanzania and Cameroon**, insisted that any capacity building received must not replace efforts to develop an international liability regime.

* * * * *

ANNEX 6
AFRICA HARVEST - USAID ROUND TABLE DISCUSSIONS - 11/4/06 -
PARTICIPANTS

	NAME	ORGANISATION
1	Dr. Geoffrey Muluvi	Kenyatta University
2	Dr. Silas Obukosia	USAID-Kenya
3	D .A. Smith	USAID-Kenya
4	Allen Fleming	USAID-Kenya
5	Sarah Lukie	McKenna Long & Aldridge
6	Kyd Brenner	DTB Associates
7	Dr. Mike Hall	USAID-Redso
8	Dr. James Okeno	Africa Harvest
9	Prof. G. Kingoriah	National Council of Science & Technology
10	Mary Onsongo	US Embassy - Depart. Of Agriculture
11	Mr. Kevin Smith	US Embassy - Agricultural Attache
12	Philip Tarus	Office of the President - Special Programmes
13	Margaret Aleke	Kenya Bureau of Standards
14	Josette Lewis	USAID
15	Tanuja Rastogi	State Dept. - USA
16	Craig Thorn	DTB Associates
17	Dr. Francis Nang'ayo	African Agricultural Technology Foundation
18	Cecilia Nzau	Dept. of Research, Ministry of Science & Technology
19	Gathama S.K.	Pioneer Seeds - Kenya
20	Harrison Macharia	National Council of Science & Technology
21	Kepha M. Ombacho	Ministry of Health
22	Dr. Stephen Mugo	CIMMYT
23	Jane Otadoh	Ministry of Agriculture
24	Simon Gichuki	Kenya Agricultural Research Institute Biotechnology Department
25	Ramon Clarete	Economic Modernization through Efficient Reforms and Governance Enhancement
26	Nduati Kariuki	Kenya National Federation of Agricultural Producers
27	Lucy Mwangi	Kenya National Federation of Agricultural Producers
28	Kilinda Kilei	Ministry of Health
29	Janet Abilla	Ministry of Trade & Industry
30	Janet Mutiso	Ministry of Environment
31	Ann Njoki Kingiri	Kenya Plant Health Inspectorate Services (KEPHIS)
32	Dr. Florence Wambugu	Africa Harvest
33	Daniel Kamanga	Africa Harvest

THE BIOSAFETY BILL

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2— interpretation

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5—Establishment of Authority

6—Composition of Authority

- 7—Function of the Authority
- 8—Conduct of Business of the Affairs or the Board
- 9—Delegation of powers of the Authority
- 10—Remuneration of Board Members
- 11—The Chief Executive Officer
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- 13—Protection from Personal Liability

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20—Withdrawal of Application.

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THE BIOSAFETY BILL

A Bill

For

An Act of Parliament to make provision for the establishment of a National Biosafety Authority, to regulate modern biotechnology and for connected purposes.

ENACTED BY the Parliament of Kenya as follows-

PART I – PRELIMINARY PROVISIONS

Short title and commencement.

1. This Act may be cited as the Biosafety Act 2006 and shall come into operation within six months of assent by notice in the Gazette.

Interpretation.

2. In this Act, unless the context otherwise requires-

"applicant" means a person submitting an application pursuant to the provisions of this Act;

"Authority" means the National Biosafety Authority established under section 5 of this Act;

"Biosafety" means the avoidance of risk to human health and safety to the conservation of the environment, as a result of the use for research and commerce of genetically modified organisms;

"biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

"contained use" means any activity undertaken within a facility, installation or other physical structure which

involves genetically modified organisms that are controlled by specific measures;

"genetically modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques;

"Minister" means the Minister for the time being responsible for matters relating to science and technology,

"modern biotechnology" means the application of-
(1)in-vitro nucleic acid techniques including the use of recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or

(2)fusion of cells beyond the taxonomic family, that overcome natural physiological, reproductive and recombination barriers and which are not techniques used in traditional breeding and selection;

"placing on the market" means making a genetically modified organism available for sale;

"Regulatory agency" means a regulatory agency as set out in the First Schedule to the Act.

Scope of Act.

3. (1) The requirements of this Act are in addition to the requirements imposed by any other Act.

(2) This Act shall not apply to genetically modified organisms that are pharmaceuticals for human use.

Objectives of the Act.

4. The objectives of this Act are-

(a) in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, to ensure an adequate level of protection in the field of safe transfer, handling and use of

genetically modified organisms resulting from modern biotechnology that may have an adverse effect on the environment; and

(b) to establish a transparent, science-based and predictable process to review and make decisions on such genetically modified organisms and related activities.

PART II- ADMINISTRATIVE PROVISIONS.

Establishment of an Authority.

5. (1) There is hereby established an Authority to be known as the National Biosafety Authority.

(2)The Authority shall be a body corporate with perpetual succession and a common seal and shall in its corporate name be capable of-

(a)suing and being sued;

(b) taking, purchasing or otherwise acquiring, holding, charging or disposing of moveable and immovable property;

(c) borrowing and lending money, and

(d)doing or performing all other things which may lawfully be done or performed by a body corporate.

Composition of Board.

6. The Authority shall be managed by a board that shall consist of-

(a)a chairman, who shall be an eminent scientist, appointed by the Minister;

(b)three other members comprising experts in each of the following sciences, namely biological, environmental and social sciences,

appointed by the Minister;

(c)the Permanent Secretary in the Ministry for the time being responsible for Science and Technology or his representative nominated in writing;

(d)the Permanent Secretary in the ministry for the time being responsible for finance or his representative nominated in writing;

(e)the Director-General, National Environment Management Authority or his representative nominated in writing;

(f)the Managing Director, Kenya Bureau of Standards or his representative nominated in writing;

(g)the Managing Director, Kenya Plant Health Inspectorate Services, or his representative nominated in writing;

(h)the Director, Department of Veterinary Services or his representative nominated in writing;

(i)the Secretary, National Council for Science and Technology or his representative nominated in writing;

(j)the Chief Public Health Officer or his representative nominated in writing;

(k)the Director of Agriculture or his representative nominated in writing;

(l)one person appointed by the Minister as representing the interests of the consumers;

(m) one person nominated by farmers and appointed by the Minister.

(2) The chairman and members of the Board shall hold office for a period of three years but shall be eligible for reappointment for a further term of three years.

(3) The names of all the appointed members shall be published by notice in the Gazette.

Functions of the Authority.

7. The Authority shall-

(a) receive, respond to and make decisions on applications under and in conformity with this Act;

(b) establish administrative mechanisms to ensure the appropriate handling and storage of documents and data in connection with the processing of applications and other matters covered by this Act;

(c) establish contact and maintain liaison with other countries and organizations dealing with Biosafety;

(d) establish a database for the purpose of facilitating collection and dissemination of information relevant to Biosafety;

(e) identify national requirements for manpower development and capacity building in Biosafety;

(f) maintain a directory of experts in biotechnology and Biosafety;

(g) keep a record of biotechnology and Biosafety activities in Kenya;

(h) advise institutions and persons on mitigation measures to be undertaken in case of an

accident;

(i) promote awareness and education among the general public in matters relating to Biosafety; and

(j) performing such other functions as may be necessary for the proper administration of this Act.

Conduct of business and affairs of the Board.

8. The conduct and regulation of the business and affairs of the Board shall be as provided in the Second Schedule to this Act.

Delegation of powers of the Authority.

9. Subject to this Act, the Authority may either generally or in any particular case delegate to any committee of the Board or to any member, officer, employee or agent of the Authority, the exercise of any of the powers of the Authority under this Act.

Remuneration of Board members.

10. The Authority shall pay to its Board members such remuneration, fees or allowances for expenses as it may determine with the approval of the Minister.

The chief executive officer.

11. (1) There shall be a Chief Executive Officer of the Authority who shall be appointed by the Board and whose terms and conditions of service the Board in the instrument of appointment shall determine.

(2) The Chief Executive Officer shall hold office for a period of five years.

(3) The Chief Executive Officer shall, subject to the directions of the Board, be responsible for the management of the affairs of the Authority and shall be the secretary to the Board.

Staff of the Authority.

12. The Authority may appoint such officers and other staff as are necessary for the proper discharge of its

functions under this Act, upon such terms and conditions of service as the Authority may determine.

Protection from personal liability.

13. No matter or thing done by a member of the Board or by an officer, employee or agent of the Authority shall, if the matter or thing is done bona fide for executing the functions, powers or duties of the Authority, render the member, officer, employee or agent personally liable to any action, claim or demand whatsoever.

PART III HANDLING REQUESTS FOR APPROVALS.

Application for contained use.

14. (1) No person shall conduct any contained use activities involving genetically modified organisms without providing advance written notice to the Authority.

(2) Such notice shall include-

(a) the information set out in the Third Schedule and in the regulations to this to this Act; and

(b) any additional information that the applicant or the Authority may deem necessary to an assessment of the potential risk and benefits of the requested activity.

(3) If the applicant receives no response within sixty days of the submission of the notification, the proposed activities may commence.

(4) In response to the submission of a notification, the Authority may request in writing additional information. Where additional information is sought by the Authority, a final written decision as to whether the proposed activities may proceed shall be provided by the Authority no later than sixty days following the receipt of the additional information. In the event that

the proposed activities are not permitted as requested in the notification, the Authority shall include in its final decision the reasons for the prohibition or any limitations or conditions that may be placed on the proposed activities.

Application to introduce into the environment.

15. (1) No person shall introduce into the environment a genetically modified organism unless it is covered by a written approval of the Authority granted in conformity with this section.

(2) A person wishing to introduce a genetically modified organism into the environment for the first time shall submit to the Authority an application describing the activity for which the approval is sought.

(3) An application to introduce a genetically modified organism into the environment shall include –

(a) the information set out in the Fourth Schedule and in the regulations to this Act;

(b) a risk assessment as set out in the Fifth schedule and in the regulations to this Act; and

(c) any additional information that the applicant or the Authority may deem necessary to an assessment of the potential risks and benefits of the requested activity.

Application for
importation .

Application for
placing on the
market.

17. (1) No person shall place on the market a genetically modified organism unless it is covered by a written approval of the Authority granted in conformity with this section.

(2) An application to place on the market a genetically modified organism shall include –

(a) the information set out in the Fourth schedule and in the regulations to this Act;

(b) a risk assessment as set out in the Fifth schedule and in the regulations to this Act; and

(c) any additional information that the applicant or the Authority may deem necessary to an assessment of the potential risks and benefits of the requested activity.

Genetically modified organisms in transit.

18. (1) A person transporting through Kenya genetically modified organisms which are not covered by a written approval of the Authority in granted conformity with this Act and which are not destined for use in Kenya shall-

(a) provide advance written notice of such transportation to the Authority; and

(b) ensure that the genetically modified organisms are properly packaged and transported in accordance with the regulations and international standards.

(2) Detailed procedures for handling and tracking such genetically modified organisms shall be as prescribed in the regulations.

Application to export.

19. A person intending to export a genetically modified organism shall provide the Authority with a written advance informed agreement of the competent authority of the importing country.

Withdrawal of application.

20. An applicant may withdraw his application at any time prior to the issuance of a final decision by the Authority.

Confidential information.

21. (1) The Authority shall –

(a) allow an applicant to identify information provided to the Authority in accordance with the requirements of this Act and any regulations made hereunder, that is to be treated as confidential, with justification for claims of confidentiality to be provided upon request;

(b) decide whether it accepts as confidential the information designated by the applicant;

(c) inform the applicant of any rejection of the claim of confidentiality, providing reasons on

request, as well as an opportunity for consultation; and

(d) in the event that an applicant withdraws an application, respect the applicant's claims of confidentiality.

(2) The Authority shall not use confidential information for any purpose not authorized under this Act and shall ensure that such information is protected by any person involved in handling applications under this Act.

Acknowledgement
of application.

22. (1) Upon receipt of an application, the Authority shall screen the application for completeness and shall within thirty days of the receipt, acknowledge in writing, receipt of the application.

(2) Where an application is not complete, the Authority shall request the applicant to submit additional information.

(3) Where the Authority requests for additional information from the applicant, the authority shall not include the time taken before getting the information, in calculating the time frame for making a final decision.

Authority to
publish notice

23. (1) The Authority shall publish in the Kenya Gazette and in at least two newspapers of nationwide circulation, notice concerning any application for release into the environment of a genetically modified organism, for the general information of the public.

(2) The public may, within thirty days of the notice, respond to the notice and the Authority shall address appropriately any relevant concerns raised by the public.

(3) Upon request, the Authority may, on payment of its reasonable costs, avail to any person portions of any application that do not qualify as confidential information.

24. (1) Where the application has been screened and found to be complete, the Authority shall undertake a risk assessment as set out in the Fifth Schedule to this Act.

(2) Risk assessment shall be carried out taking into account available information concerning any potential exposure to the genetically modified organism.

(3) Risk assessment shall be carried out on a case-by-case basis, meaning that the required information may vary depending on the type of the genetically modified organisms concerned, their intended use and the potential receiving environment, taking into account, *inter alia*, genetically modified organisms already in the environment.

(4) Food safety assessment shall include a comparison between the food derived from modern biotechnology and its conventional counterpart, focusing on determination of similarities and differences. Where appropriate, the results of a risk assessment undertaken by other regulatory authorities may be used to assist in the risk analysis and avoid duplication of work.

(3) The Authority shall conduct a risk assessment as required and shall audit risk assessment information submitted by the applicant.

(4) Upon completion of the risk assessment, the Authority shall make a report giving its decision, including justification on the determination of the application and indicate any measures to be taken to ensure the safe use of the genetically modified organism.

(5) The Authority shall liaise with the appropriate regulatory agency to ensure that measures are in place to manage and control risks identified during the risk

assessment process.

Risk assessment may be omitted.

25. The Authority may decline to undertake a risk assessment in accordance with section 14, 15 or 16, where it determines that sufficient experience or information exists to conclude that the genetically modified organisms or activities concerned do not pose a significant risk to the environment.

Determination of the application.

26(1) In reaching a final decision, the Authority shall take into account-

- (a) information submitted by the applicant;
- (b) information and conditions submitted by the relevant regulatory agency;
- (c) the risk assessment report;
- (d) any relevant comments submitted by the public; and
- (e) socio-economic considerations arising from the impact of the genetically modified organism on the environment.

(2) The Authority shall be the body responsible for issuing of approvals in matters relating to activities involving genetically modified organisms.

(3) The Authority shall, prior to determining an application, liaise with the relevant regulatory agency and the regulatory agency shall submit to the Authority any conditions that the regulatory agency deems appropriate to be attached to the approval.

Communication of decision.

27. (1) The Authority shall communicate its final decision of approval or rejection of the application, to the applicant within one hundred and fifty days of the receipt of the application.

(2) An approval shall clearly set out any specific conditions, related to the approval, including any conditions given by the appropriate regulatory agency.

(3) The approval shall be specific to the activity authorized as set out in the decision document.

(4) The rejection shall clearly set out the reasons for rejection of the application.

Authority to
maintain a register.

28.The Authority shall maintain a register, which shall contain the following information –

(a) a copy of every application;

(b) a copy of the risk assessment report;

(c) a copy of the decision document;

(d) a copy of the approval; and

(e) any other information the Authority may deem necessary or expedient to preserve.

PART IV- REVIEW AND APPEALS

Review of
approval.

29. (1) The Authority may review a decision made under section 25 at any time upon obtaining significant new scientific information relating to Biosafety of the genetically modified organism or activities involved.

(2) A regulatory agency or an applicant may request the Authority to review its decision with respect to an activity conducted by the applicant where the applicant considers that -

(a) a change in the circumstance has occurred that may have a material effect on the outcome of the risk assessment upon which the decision

was based; or

(b) additional scientific or technical information has become available that may have a material effect on the decision or any conditions, limitations or requirements imposed under a decision.

(3) If upon review the Authority is satisfied that a change is warranted, the Authority shall issue a substitute approval.

(4) The Authority shall make a decision on a review within one hundred and fifty days from the date of request for the review and shall set out the reasons for its decision.

(5) Where the Authority has knowledge that an activity poses a threat to Biosafety, the Authority shall take immediate action to put necessary measures in place.

(6) The Authority shall give special consideration for review requests from a regulatory agency.

Offence of withholding information.

30. Where an applicant withholds information that has become available to him after the approval of his application and the information could reasonably be expected to change the evaluation of the risk posed by the applicant's intended activity, the applicant commits an offence and is liable on conviction to a fine of two million shillings or imprisonment for ten years.

Appeal from decision.

31. (1) There is hereby established an Appeals Board which shall consist of-

(a) a chairman, nominated by the judicial service commission, who shall be an advocate of the High Court qualified for appointment as a judge of the High Court of Kenya, and appointed by the Minister;

(b) three persons, each with qualifications in biological, environmental or social sciences, appointed by the Minister.

(2) All appointments to the Appeals Board shall be by gazette notice issued by the Minister.

(3) The members shall hold office for three years.

(4) Any person who is aggrieved by-

(a) a refusal to grant an approval under this Act;

(b) the imposition of any conditions on an approval under this Act;

(c) the revocation, suspension or variations of an approval under this Act;

(d) a refusal to treat an application as confidential;

may within thirty days of being notified of the relevant decision of the Authority, appeal to the Appeals Board in the prescribed manner.

(5) Any person aggrieved by a decision of the Appeals Board may within thirty days of the decision, appeal against the decision to the High court.

(6) The decision of the High court on any appeal under this section shall be final.

Power of Appeals
Board

32 (1) On hearing an appeal the Appeals Board shall have the powers of a court to summon witnesses, take evidence upon oath or affirmation and to call for the production of books and other documents.

(2). Where the Appeals Board considers it desirable for the purpose of avoiding expense or delay or any other

special reason so to do, it may receive evidence by affidavit and administer interrogatories and require the person to whom interrogatories are administered to make full and true reply to the interrogatories within the time specified by the Appeals Board.

(3) In its determination of any matter, the Appeals Board may take into consideration any evidence which it considers relevant to the subject of an appeal before it, notwithstanding that such evidence would not otherwise be admissible under the law relating to evidence.

(4) The Appeals Board shall have the power to award the costs of any proceedings before it and to direct that costs shall be taxed in accordance with any scale prescribed.

(5) All summonses, notices or other documents issued under the hand of the Chairman of the Appeals Board shall be deemed to be issued by the Appeals Board.

(6) Any interested party may be represented before the Appeals Board by an advocate or by any other person whom the Appeals Board may admit to be heard on behalf of the party.

Conduct of business and affairs of the Appeals Board.

33. The conduct and regulation of the business and affairs of the Appeals Board shall be as provided in the Sixth Schedule to this Act.

PART V- ROLE OF REGULATORY AGENCIES

Duties of regulatory agencies.

34. (1) The Authority shall coordinate all activities involving genetically modified organisms and in carrying out its role of coordination, the Authority may require the regulatory agencies to carry out an additional function, under their respective mandates, of monitoring, inspecting and evaluating activities involving genetically modified organisms.

(2) Regulatory agencies shall, where appropriate, monitor an applicant's activities to ensure that these activities comply with the requirements of this Act and any conditions imposed in connection with an approval under this Act.

(3) Where a regulatory agency becomes aware of any significant new scientific information indicating that approved activities with genetically modified organisms may pose potential Biosafety risks not previously known, the regulatory agency shall immediately inform the Authority of the new information and of the measures proposed to be put in place to ensure the continued safe use of the genetically modified organism.

Unintentional
release into the
environment.

35. (1) A regulatory agency with knowledge of an unintentional or unapproved introduction into the environment of a genetically modified organism that is likely to pose Biosafety risks shall, within twenty-four hours of when the regulatory agency first knew of the introduction, notify the Authority of the occurrence.

(2) A notification shall include adequate information for the Authority to undertake a risk assessment.

(3) The Authority in consultation with the regulatory agency shall determine whether any action is necessary to minimize any Biosafety risks.

PART VI – RESTORATION AND CESSATION ORDERS

Environmental
restoration order.

36. The Authority may issue and serve on any person a restoration order in respect of any matter relating to release of a genetically modified organism into the environment.

(2) An environmental restoration order issued under subsection (1) shall be issued to-

- (a) require the person on whom it is served to restore the environment as near as it may be to the state in which it was before the release of a genetically modified organism;
- (b) levy a charge on the person on whom it is served which in the opinion of the Authority,, represents a reasonable estimate of the costs of any action taken by an authorized person or organization to restore the environment to the state in which it was before the release of a genetically modified organism.

Content of
restoration order.

37. An environmental restoration order shall specify clearly and in a manner which may be easily understood-

- (a) the activity to which it relates;
- (b) the person to whom it is addressed;
- (c) the time at which it comes into effect;
- (d) the action which must be taken to remedy the harm to the environment and the time, being not more than thirty days or such further period as may be prescribed in the order within which the action must be taken; and
- (e) the penalty which may be imposed if the action specified is not undertaken.

Cessation Orders.

38. (1) The Authority, in consultation with the relevant regulatory agency, may issue an order for the immediate cessation of an approved activity or for the immediate imposition of additional Risk Management measures with respect to such activity, if the Authority, in consultation with the relevant regulatory agency,

determines that there is imminent danger posed to the conservation and sustainable use of biological diversity taking into account risks to the human health on the basis of-

(a) one or more tests conducted and evaluated in a manner consistent with acceptable scientific procedures;

(b) other validated scientific evidence.

(2). The Authority may issue a cessation order upon the failure of any person issued with an approval to demonstrate compliance after a reasonable period of time with respect to an approval under this Act, when there exists a violation of any provisions of this Act or regulations made under this Act.

(3). A cessation order issued under this Act may be withdrawn once the Authority determines that sufficient information exists to permit the activity to resume or to resume in the absence of additional risk management measures without posing a significant risk to the conservation and sustainable use of biological diversity, also taking into account risks to human health.

PART VII – INSPECTION AND MONITORING

Appointment of Biosafety inspectors.

39. The Minister shall, by Gazette notice, appoint duly qualified persons whether by name or by title of office, to be Biosafety inspectors of the Authority, for such jurisdictional units as shall be specified in the notice appointing them.

Powers of inspectors.

40. (1) A Biosafety inspector may, in the performance of his duties under this Act, at all reasonable times and without a warrant –

(a) enter any premises, facility, vessel or property which the inspector has reason to believe it is necessary for him to enter in order to

ascertain whether the requirements of this Act or any approval under this Act are being complied, with and may take with him any person duly authorized by the Authority;

(b)take with him any equipment or material required for any purpose for which the power of entry is being exercised;

(c)carry out such tests and inspections and make such recordings as may in the circumstances be necessary;

(d)direct that any part of premises which he has power to enter, or anything in such premises shall be left undisturbed for so long as is reasonably necessary for the purpose of any test or inspection;

(e)take appropriate samples of any organisms, articles or substances found in any premises which he has power to enter for analysis or any other relevant purpose under this Act;

(f)in the case of anything found in the premises which he has power to enter, which appears to him to contain genetically modified organisms which pose Biosafety risk, cause it to be dismantled or subjected to any process or test but not so as to damage or destroy it, unless it is necessary;

(g) require the production of any records which are required to be kept under this Act.

(2)When exercising his powers under this Act, the Biosafety inspector shall suitably identify himself.

Functions of
Biosafety
inspectors.

41. A Biosafety inspector shall-

(a) monitor compliance with this Act and regulations made this Act;

(b) submit inspection reports to the Authority;

(c) perform such other functions as may be required under this Act or under the Gazette Notice appointing the inspector.

PART VIII - FINANCIAL PROVISIONS

Funds of the Authority.

42. The funds of the Authority shall comprise –

(a) such moneys as may be appropriated by Parliament for the purposes of the Authority;

(b) such moneys as may accrue to or vest in the Authority in the course of the exercise of its powers or performance of its functions under this Act; and

(c) all moneys from any other source provided for, donated or lent to the Authority.

Investment of funds.

43. (1) The Authority may –

(a) invest any of its surplus funds in government securities; or

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(b) place on deposit with any bank quoted on an approved securities exchange in Kenya any moneys not immediately required for its purposes.

(2) In this section “approved securities exchange,” means a securities exchange approved under the capital Markets Authority Act.

Financial year. **44.** The financial year of the Authority shall be the period of twelve months ending on the thirtieth of June in each year.

Annual estimates. **45.** (1) Before the commencement of each financial year, the Authority shall cause to be prepared estimates of revenue and expenditure of the Authority for that financial year.

(2) The annual estimates shall make provision for all the estimated expenditure of the Authority for the financial year concerned and in particular, shall provide for -

(a) the payment of salaries, allowances and other charges in respect of the staff of the Authority; or

(b) the payment of pensions, gratuities and other charges in respect of retirement benefits which are payable out of the funds of the Authority;

(c) the acquisition, maintenance, repair and replacement of the equipment and other moveable property of the Authority.

Accounts and audit. **46.** (1) The annual estimates shall be approved by the Authority before the commencement of the financial year to which they relate:

Provided that once approved, the sum provided in the estimates shall not be increased without the prior consent of the Authority.

(2) The Authority shall cause to be kept all proper books and records of account of the income, expenditure, assets and liabilities of the Authority.

(3) Within a period of four months from the end of the financial year, the Authority shall submit to the

Controller and Auditor-General the accounts of the Authority together with -

- (a) a statement of the income and expenditure of the Authority on the last day of that year; and
 - (b) a statement of the assets and liabilities of the Authority on the last day of that year.
- (4) The accounts of the Authority shall be audited and reported upon in accordance with the Public Audit Act.
- (5) The Authority shall keep the public informed of its activities and operations through regular publications and such activities and operations shall be accessible to the public unless there are reasons of commercial confidentiality or security justifying exclusions.

PART IX – MISCELLANEOUS PROVISIONS

Packaging labeling of genetically modified organisms.

and of

47. Any person manufacturing or importing any genetically modified organisms shall package and label such genetically modified organism in the prescribed manner.

Liability redress.

and

48. Liability and redress for any damage that occurs as a result of activities subject to this Act shall be addressed by the general Law of Tort.

Authority's power to make Regulations.

49. The Authority may, with the approval of the Minister, make regulations for the better carrying out of its functions under this Act and in particular for prescribing-

- (a) anything required by this Act to be prescribed;
- (b) procedures for conducting contained use activities involving genetically modified organisms;

- (c) procedures for release of genetically modified organisms into the environment;
- (d) procedures for importation of genetically modified organisms;
- (e) procedures for exportation of genetically modified organisms;
- (f) procedures for genetically modified organisms in transit;
- (g) procedures to be adopted by the Appeals Board in hearing the appeal and the records to be kept by the Appeals Board;
- (h) the manner in which an appeal shall be made to the Appeals Board and the fees to be paid in respect of an appeal;
- (i) the manner in which the Appeals Board shall be convened and the places where and the time at which the sittings shall be held;
- (j) the scale of costs which may be awarded by the Appeals Board;
- (k) procedure for packaging and labeling of genetically modified organisms;
- (l) forms to be used for applications for approvals;
- (m) schedules of fees to cover administrative costs of processing applications and notices.

Offence penalties.

and **50.** Any person who-

- (a) makes contained use of, releases into the

environment, places on the market, imports or exports a genetically modified organism without the approval of the Authority;

(b) contravenes any conditions attached to an approval under this Act;

(c) fails to furnish any information as required by this Act;

(d) uses any confidential information for any purpose not authorized under this Act;

(e) uses a genetically modified organism for mischievous or unethical purposes;

(f) obstructs or fails to assist the Authority or officers of the Authority in the performance of their duties under this Act;

(g) contravenes any of the provisions of this Act;

commits an offence and is liable on conviction to a fine not exceeding one million shillings or to imprisonment for a term not exceeding three years.

Restrictions
institution
proceedings.

on
of

51. (1) No proceedings for an offence under this Act shall be instituted without the written sanction thereto of the Attorney-general.

(2) proceedings for an offence under this Act maybe taken against a body corporate at any place at which the body corporate has a place of business, and against any other person at any place at which the person has a place of business or is for the time being resident.

Public awareness
and participation.

52. (1) The Authority shall promote public awareness and education of the public and those conducting the activities subject to the Act concerning Biosafety

matters through the publication of guidance documents and other material aimed at improving the understanding of Biosafety.

(2) The Authority shall publish notices of final decisions concerning all applications.

(3) Upon request, the Authority shall make available to any person portions of any application that do not qualify as confidential information.

(4) Any person may submit written comments on a proposed decision for any application for placing a genetically modified organism on the market, within thirty days from the date the notice is posted.

Transitional provisions.

53. (1) Any application made under the Science and Technology Act to the National Council for Science and Technology and which was not finally determined as at the date of the entry into force of this Act shall be deemed to be an application for approval under this Act and be dealt with accordingly.

(2) An approval of the National Council for Science and Technology, which as at the date of entry into force of this Act was in force under the Science and Technology Act, shall be deemed to be an approval of the Authority under this Act.

(3) An applicant who was granted an approval under the Science and Technology to handle a genetically modified organism by the National Council for Science and Technology shall within thirty days of the entry into force of this Act, lodge an application for review under this Act.

(4) By way of derogation from Section 17, products falling within the scope of this Section which have been

lawfully placed on the market in Kenya before the date of application of this Act may continue on a temporary basis to be placed on the market, used and processed provided that the operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Act, notify the Authority that the products were placed on the market in Kenya before the date of application of this Act. The notification shall be accompanied by an application for permanent approval as laid down in Section 17, paragraph 2.

FIRST SCHEDULE (Sec 2)
REGULATORY AGENCIES

1. Ministry of Health.
2. Department of Veterinary Services.
3. Kenya Bureau of Standards.
4. Kenya Plant Health Inspectorate Services.
5. Kenya Industrial Property Institute.
6. Kenya Wildlife Service.
7. Pest Control Products Board.
8. National Environment Management Authority.

SECOND SCHEDULE (Sec 8)

**PROVISIONS AS TO THE
CONDUCT OF BUSINESS AND
AFFAIRS OF THE BOARD**

Committees and
co-opted
advisors.

1.(1) The Board shall establish such committees as it may deem appropriate to perform such functions and responsibilities as it shall determine, but all findings of such committees shall be presented to the Board for its consideration and determination.

(2) The Board may at its discretion, at any time and for any length of time, invite any person to attend any of its deliberations but such person shall not be entitled to vote on any matter at any meeting of the Board.

Meeting of
Board.

2. (1) The Board shall meet at least four times in every financial year.

(2) The chairman shall preside at every meeting of the Board at which he is present, but in his absence, the members shall elect one of their number who shall, with respect to that meeting and the business transacted

thereat, have all the powers of a chairman.

(3) Unless an unanimous decision is reached, a decision on any matter before the board shall be by a majority of votes of the members present and in the case of an equality of votes, the chairman shall have a casting vote.

(4) all the members of the Board must be present to form the quorum of the transaction of the business of the Board.

Vacation of
office.

2.(1) A member of the Board other than an ex-officio member shall vacate office on any of the following grounds-

(a) upon the expiry of his appointment;

(b) upon his death;

(c) if he is adjudged bankrupt;

(d) if he is sentenced for any offence against any written law to a term of imprisonment of six months or more;

(e) if he is convicted of an offence involving fraud, dishonesty or moral turpitude;

(f) if he is absent, without permission of the Board from three successive meetings of the Board of which he has received notice;

(g) upon notice in writing of his intention to resign his office,

(h) if in the opinion of the Board, he becomes by reason of mental or physical infirmity incapable of performing his duties as a member of the Board; or

(i) upon the commission of an offence under this Act.

Disclosure of interest.

4. If a member of the Board has any interest direct or indirect in any application or other matter which is the subject of consideration at a meeting of the Board, the member shall at the meeting, disclose the fact to the Board and shall take no part in the consideration or discussion of or vote on any question with respect to the application or the other matter.

THIRD SCHEDULE

(Sec 14)

**PROVISIONS AS TO THE INFORMATION
REQUIRED IN APPLICATIONS FOR CONTAINED
USE.**

1. The name and contact address of the applicant,
2. The location where contained use activities are to be undertaken
3. The nature and identity of genetically modified organisms to be involved.
4. The nature and purpose of the activities including such activities as storing, transporting, producing, processing, disposing or using the genetically modified organisms in any other way.
5. A description of the containment measures to be provided and the suitability of those measures for the genetically modified organisms and activities to be undertaken.
6. A description of any potential risks associated with the genetically modified organisms or the activities to be undertaken, and
7. A description of remedial measures to be undertaken in the event of any accident.
8. A sworn declaration by the applicant that the above information is factually correct.

THE FOURTH SCHEDULE

(Sec 15, 16)

PROVISIONS AS TO THE INFORMATION REQUIRED IN APPLICATIONS FOR RELEASE, IMPORTATION AND PLACING ON THE MARKET OF GENETICALLY MODIFIED ORGANISMS.

1. Name and identity of the genetically modified organism as well as the domestic classification, if any, of the Biosafety level of the genetically modified organism in the country of export.
2. Taxonomic status, common name, point of collection or acquisition and characteristics of the recipient organism or parental organism related to Biosafety.
3. Center of origin and center of genetic diversity if known, of the recipient organism and the parental organism and the description of the habitat where the organism may persist.
4. Taxonomic status, common name, point of collection or acquisition and characteristics of the modification introduced, the technique used and the resulting characteristics of the genetically modified organism.
5. Scale of release, *e.g.*, field test or large scale.
6. Intended use of the genetically modified organism.
7. Suggested methods for the safe handling, storage, transport and use.

8. For the food safety assessment, information regarding:
 - a. expressed substances (non-nucleic acid substances);
 - b. compositional analyses of key components;
 - c. evaluation of metabolites ;
 - d. food processing; and
 - e. nutritional modification.

9. A sworn declaration of the applicant that the above mentioned information is factually correct.

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FIFTH SCHEDULE

(Sec 15, 16)

RISK ASSESSMENT

- | | |
|-------------------------------|--|
| Objective of risk assessment. | 1. The objective of the risk assessment is to identify and evaluate the potential adverse effects of genetically modified organisms on the environment. |
| Use of risk assessment. | 2. The risk assessment shall be used by the Authority to make informed decisions regarding genetically modified organisms. |
| General principles. | <p>3. The general principles guiding risk assessment are-</p> <ul style="list-style-type: none">(a) Risk assessment shall be carried out in a scientifically sound and transparent manner and may take into account expert advice and guiding principles developed by relevant organizations.(b) Lack of scientific knowledge or scientific consensus shall not necessarily be interpreted to indicate a particular level of risk, an absence of risk or an acceptable risk.(c) Risk associated with genetically modified organisms shall be considered in the context of the risks posed by the genetically modified organisms recipient or the parental organisms in the likely potential receiving environment. |
| Methodology. | <p>4. To fulfill its objective, the risk assessment shall entail the following steps-</p> <ul style="list-style-type: none">(a) An identification of any genotype and phenotypic characteristics associated with the genetically modified organisms that may have adverse effects on the environment or on human health,(b) An evaluation of the likelihood of these |

adverse effects being realized, taking into account the level and the kind of exposure of the likely potential receiving environment of the genetically modified organisms,

(c) An evaluation of the consequences should these effects be realized,

(d) An estimation of the overall risk posed by the genetically modified organisms based on the evaluation of the likelihood and consequences of the identified adverse effects being realized,

(e) A recommendation as to whether or not the risks are acceptable or manageable, including identification of strategies to manage these risks, and

(f) Where there is uncertainty regarding the level of risk, the Authority may request for further information on the specific issues of concern or may recommend implementing appropriate risk management strategies and monitoring the genetically modified organisms in the receiving environment.

Points to consider.

5. Risk assessment shall take into account the relevant technical and scientific details regarding the characteristics of the following subjects-

(a) recipient organism or parental organism.

The biological characteristics of the recipient organism or parental organism including taxonomic status, common name, origin, centers of origin and centers of genetic diversity and a description of the habitat where the organism persists

(b) donor organism

taxonomic status and common name, source and the relevant biological characteristics of the donor organisms.

(c) vector

characteristics of the vector including its identity and the sources of origin and host range.

(d) insert and characteristics of modification.

Genetic characteristics of the inserted nucleic acid and the function it specifies and characteristics of the modification introduced.

(e) genetically modified organisms.

identity of the genetically modified organisms and the differences between the biological characteristics of the genetically modified organisms and those of the recipient organism or parental organism.

(f) detection and identification of genetically modified organisms.

suggested detection and identification methods and the specificity, sensitivity and reliability.

(g) information relating to the intended use.

Information related to the intended use of the genetically modified organisms including new or changed use

compared to the recipient organism or parental organism.

(h) receiving environment.

Information on the location, geographical, climatic and ecological characteristics including relevant information on biological diversity and centers of origin of the likely potential receiving environment.

SIXTH SCHEDULE

(Sec 8)

PROVISIONS AS TO THE CONDUCT OF BUSINESS AND AFFAIRS OF THE APPEALS BOARD.

Vacation of office. 1(1) A member of the Appeals Board other than an ex-officio member shall vacate office on any of the following grounds-

- (a) upon the expiry of his appointment;
- (b) upon his death;
- (c) if he is adjudged bankrupt;
- (d) if he is sentenced for any offence against any written law to a term of imprisonment of six months or more;
- (e) if he is convicted of an offence involving fraud, dishonesty or moral turpitude;
- (f) if he is absent, without permission of the Appeals Board from three successive meetings of the Appeals Board of which he has received notice;
- (g) upon giving notice in writing of his intention to resign his office,
- (h) if in the opinion of the Appeals Board, he becomes by reason of mental or physical infirmity incapable of performing his duties as a member of the Appeals Board; or
- (i) upon the commission of an offence under this Act.

Meeting of
Appeals Board.

2. (1) The Appeals Board shall meet at least four times in every financial year.

(2) The chairman shall preside at every meeting of the Appeals Board at which he is present, but in his absence, the members shall elect one of their number who shall, with respect to that meeting and the business transacted thereat, have all the powers of a chairman.

(3) Unless an unanimous decision is reached, a decision on any matter before the Appeals board shall be by a majority of votes of the members present and in the case of an equality of votes, the chairman shall have a casting vote.

(4) all the members of the Board must be present to form the quorum of the transaction of the business of the Board.

Disclosure of
interest.

3. If a member of the Appeals Board has any interest direct or indirect in any application or other matter which is the subject of consideration at a meeting of the Appeals Board, the member shall at the meeting, disclose the fact to the Appeals Board and shall take no part in the consideration or discussion of or vote on any question with respect to the application or the other matter.

THE BIOSAFETY BILL

Comments Regarding Proposed Amendments

Section 2, page 4: Delete “*living or non-living*” from definition of “Genetically Modified Organism.”

Comment: The original formulation is overly broad. Taken literally, it would mean that all products derived from or produced with genetically modified organisms – e.g., processed foods, vegetable oils, beer, wine, cheese, cotton textiles – would have to undergo a full safety evaluation before they could be marketed in Kenya.

Section 4(a): Replace “*principle*” with “*approach contained in Principle 15 of the Rio Declaration on Environment and Development*”

Comment: “Precautionary principle” is a controversial and ill-defined term. The new formulation is clearer.

Section 4(b): Insert “*science-based*”

Comment: This change is self-explanatory.

Section 14: Various amendments to change the requirement from written approval for contained use into a requirement for written notification.

Comment: A requirement for written approval for materials for contained use would hamper Kenyan research unduly. Other countries with active research programs – i.e., the U.S., the EU, Canada – regulate the facilities engaged in such research rather than requiring prior approval for moving research materials. The approach we suggest is somewhat stricter than the one those countries employ. It would require researchers to provide advance written notice, and then give regulatory authorities an opportunity to either prohibit the proposed activities or impose conditions. Kenyan officials would be free to regulate research facilities as well.

Section 15: Various amendments to make clear that the requirement for written approval applies only to the first time a new biotech event is introduced into the environment.

Comment: We assume that the amended version is consistent with the intent of the drafter. No other country requires written approval each time a biotech product is introduced into the environment or placed on the market. Such a requirement would essentially make it impossible to market biotech seeds for planting in Kenya. It would also almost certainly violate Kenya's WTO obligations, since there is no scientific justification for such a requirement (see Articles 2.2 and 5.1 of the WTO SPS Agreement).

Section 16: Delete entire section.

Comment: The level and type of regulatory scrutiny for a given biotech product should be based on the USE to which that product will be put, not the ORIGIN of the product. If an imported product is destined for introduction into the environment, it should be subject to the requirements of Section 15. If it will be placed on the market for use as food or feed or from processing, it should be subject to the requirements of Section 17. WTO rules require that countries not discriminate between imported products and products of domestic origin (see Article 2.3 of the SPS Agreement).

Section 17: Various amendments to make clear that the requirement for written approval applies only to the first time a new biotech event is placed on the market.

Comment: See comment above regarding Section 15.

Section 18.1: after "*genetically modified organisms*", insert "*which are not covered by a written approval of the Authority in granted conformity with this Act and*".

Comment: This amendment makes clear that any measures to monitor or control GMOs in transit apply only to events that have not been previously approved for marketing in Kenya.

Section 18.1(a) and 18.2: Replace "*apply for written approval*" with "*provide advance written notice*". Replace "*an application to transport genetically modified organisms through Kenya*" with "*detailed procedures for handling and tracking such genetically modified organisms*".

Comment: A requirement for written approval for GMOs in transit is disproportionately strict. It would cause international grain shippers to avoid using Kenyan ports whenever possible and could lead to serious delays in essential food shipments. KEPHIS already has an effective system in place for tracking shipments in transit. A prior notice requirement would enhance the effectiveness of the current system.

Section 22: Replace “*one hundred fifty days*” with “*thirty days*”.

Comments: One hundred fifty days is much longer than any agency needs to review and acknowledge receipt of an application. WTO rules require that applications for pre-marketing approval be processed “without undue delay” (see SPS Agreement, Annex C.1(a)).

Section 24, new paragraphs 3 and 4: Insert two new paragraphs on risk assessment.

Comment: The risk assessment and risk management guidelines in the draft bill focus almost exclusively on environment issues. They make no distinction between seeds for planting and commodities intended for food, feed or processing. These new paragraphs are intended to make clear that regulators should, where appropriate, examine food safety issues as well as environmental issues and adapt their risk assessments to take into account the intended use of the product in question.

New paragraph 3, which was adapted from a provision in an EU directive, instructs regulators to assess risk on a case-by-case basis and to adjust their approach to take into account various factors, including end use. (See EU Directive 2001/18, Annex II, section B (Official Journal L 106 of 17/4/01, page 19).)

New paragraph 4, which was adapted from guidelines developed by the Codex Alimentarius, establishes general principles for food safety assessments. (See “Principles for the Risk Analysis of Foods Derived from Modern Biotechnology,” Codex Alimentarius, CAC/GL 44-2003, paragraphs 10 and 6.)

Section 53, new paragraph 4: Insert new paragraph regarding a transition mechanism for biotech products already on the market in Kenya.

A number of biotech products are already being imported and consumed in Kenya – e.g., products of maize and soybeans, cotton and cotton textiles. Under the current draft, all of these products would be illegal on the date of entry into force of the legislation. At the same time, there is no mechanism that would allow producers or importers of those product to apply for approval in advance of entry into force. Other countries in similar situations have included in their legislation provisions intended to facilitate an orderly transition. This paragraph was adapted from recent EU legislation on GM food and feed. (See EU Regulation 1829/2003, Articles 8 and 20 (Official Journal L 268 of 18/10/03, page 9 and 15).)

Fourth Schedule: Delete first, second, fourth and ninth bullets – “*Name, address and contact details of the exporter*” ; “*Name, address and contact details of the importer*” ; “*Intended dates of the trans-boundary movement*” and “*Quantity or volume of the genetically modified organism to be transferred.*”

Comment: The information in the application for pre-marketing approval should pertain to the characteristics of the new biotech event in question rather than to specific commercial transactions. An applicant for approval of a new event (e.g., a Kenyan research institute or a foreign biotech firm) would not be able to provide the information requested in the deleted bullets because he or she would normally apply before commercial activity takes place.

The information requested in the four delete bullets implies a requirement for a shipment-by-shipment approval. The requirement for approval should apply only to the first time a new biotech event is entered into the environment or placed on the market (see comments on Sections 15 and 17).

Fourth Schedule, new paragraph 5: Insert “*Scale of release, e.g., field test or large scale.*”

Comment: Under the current draft there is no differentiation between the level of scrutiny required for an application for a controlled field test and that required for an application for large-scale release. This creates a problem, since in-country field tests are often necessary for gathering data for an application for large-scale release. This language would make clear that applications for field tests would not be subject to a full risk assessment.

Fourth Schedule, new paragraph 8: Insert language on food safety assessment.

Comment: As indicated above, the current draft focuses almost exclusively on environmental issues. This language, which was adapted from guidelines developed by the Codex Alimentarius, would require applicants to provide information relevant to a food safety assessment. (See “Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants,” Codex Alimentarius, CAC/GL 45-2003, paragraph 18.)

Fifth Schedule, paragraph 4: Insert “*or on human health.*”

Comment: The guidelines for risk assessment in the Fifth Schedule are basically sound. This addition simply makes clear that regulators should take into account food safety issues as well as environmental issues in performing a risk assessment. In fact, in some cases – i.e., applications for approval for food, feed or processing – food safety issues should be the principle focus of the assessment.