ACB BRIEFING PAPER No. 7, 2009

Comments on the Biosafety Bill, 2008, of Kenya

Mariam Mayet, April 2009

PO Box 29170, Melville 2109, South Africa
www.biosafetyafrica.net

Contents

Introduction

Genetically Modified crop plants continue to be offered to Africa as a solution to alleviate poverty and stave off hunger. It is a trite observation that hunger has little to do with how efficiently food is produced or how much food is available for consumption. Indeed, hunger is rooted in socio-economic realities which limit the ability of people to access food on the market or land; the means to acquire food and other resources to produce food; access to a clean and healthy environment' health care and education and so forth. Nevertheless, several countries in Africa, especially Kenya, are hell bent on adopting GMOs into their agricultural systems. During February 2009, Kenya's President Mwai Kibaki signed the country's heavily contested Biosafety Bill.[i] A year earlier, the NGO 'Africa Nature Stream' approached the Kenyan courts to intervene and stop the promulgation of a previous version of the Bill (Biosafety Bill 2007), on the grounds that GMOs cause unacceptable risks to human health and the environment.[ii] However, this legal intervention proved to be futile as did other forms of resistance on the part of Kenyan activists. Indeed, no amount of opposition by activists in Kenya could have changed the course of history because the US government had the entire regulatory process all wrapped up. The United States Agency for International Development (USAID)'s Program for Biosafety Systems (PBS) has played a pivotal role in the development of the Kenyan biosafety law and ensuring its safe passage into the Kenyan statute books. In its document titled 'PBS Helps Set the Stage for Biosafety Legislation'[iii] it is upfront about having helped prepare the Kenyan Biosafety Bill for enactment by participating in consultations to revise the bill, educating members of Parliament on the bill, countering misleading information and preparing briefing documents for policy makers and the media. PBS is so far ahead of the game that while the Kenyan government is still in the process of putting in place the necessary biosafety administrative systems to implement the Biosafety law, PBS has already prepared the regulations to implement the Bill, on such issues as "contained use" and "deliberate release." [iv]

The main imperatives underpinning the legislation appear to be the implementation of the Cartagena Protocol on Biosafety, to which Kenya is a Party, and the legal mechanism to allow the commercial growing of GM maize and cotton in Kenya, with the hope that this will open the doors for further expansion into the rest of the Common Market for Eastern and Southern Africa (COMESA). Indeed, upon hearing the news that the Kenyan Biosafety Bill had been enacted, COMESA praised the move as " …a major milestone because of the strategic importance of Kenya in the COMESA region…"[v] It must be noted that Kenya does not need a Biosafety law to authorize field trials involving GMOs nor to sanction the importation of GM food/ food aid. Kenya has allowed field trials involving GM sweet potato (which failed spectacularly) as long ago as 2003/4 and thereafter, GM cotton and maize. It has also accepted US maize and soyamilk food aid in 2001, during the Southern African food crisis, without restrictions, when many other Southern African countries were imposing various restrictions on food aid to prevent the ingress of GMOs in their agricultural systems by way of contamination or inadvertent planting Indeed, Kenya has continued to import several thousand tons of food aid form the US, which in all likelihood consists of GMOs.[vi]

In this paper, we provide a brief analysis of the Kenyan Biosafety Bill for the benefit of Kenyan activists in order to contribute in a small way, to their onward battle against GMOs.

Summary of Biosafety Bill

The Biosafety law establishes a GMO permitting system, which the regulatory Body, the National Biosafety Authority (Authority), administers. This is comprised of a mixture of government officials, experts and civil society representatives; thus farmers and consumer groups are represented on the Authority, together with an industry representative. Nevertheless, the provisions dealing with public participation and access to information do not give the Kenyan public the right to participation, but merely an opportunity to make input with regard to GM applications concerning field trials and commercial releases. The notification procedures to inform the public of such applications appear to be inadequate and may have little impact.

Too much discretion is given to both the applicant and Authority to decide on the question of confidentiality regarding the information that is available to the public. This can easily lead to the abuse of power and defeating the public's rights to meaningfully engage with the process and making representations.

Generally speaking, the law exhibits an extreme reluctance to place clear and precise biosafety obligations on the applicant. Provisions dealing with applications to introduce GMOs into the environment are meager in terms of their biosafety content and a discretion is conferred on an applicant to decide on the overall scope of the information it needs to furnish to the Authority, in order to allow the latter to make complete risk evaluation of the potential risks.

The most worrying provisions are those dealing with exemptions from risk assessments for applications for contained use, introduction into the environment and import. These mean that the Authority can do away with case-by-case assessments and exempt such applications from the permitting requirements of the law. It will be able to do so, by arguing that it has relied on information shared by the regulators from countries that have a longer history with GMOs, such as the US or South Africa, that the GMO and activity in question are safe.

Unintentional and unapproved releases (such as illegal imports of GMOs, contamination incidences) are dealt with in a like restrictive manner and do not immediately attract intervention, including cessation of the activity. Instead, the intervention contemplated is one of consultation at the government level to decide whether any action is necessary to minimize any biosafety risks. Indeed, the Biosafety law does not readily allow the Authority to over-turn an approval, once granted. Cessation orders can only be issued when there is non compliance. In the event of an imminent danger to biodiversity and human health, the Authority is only able to issue a cessation order if one or more scientific studies calls for this. If these studies take a year to produce, then despite the imminent threat of damage, the Authority will not be able to issue a cessation order.

Decision making on the part of the Authority may only take socio-economic considerations into account when these are linked to negative environmental impacts. Arguably, negative socio-economic impacts that arise in the context of food security will not be taken into account? These provisions are also linked to consultation with the Biosafety Clearing House (BCH) and conditions imposed by the BCH. This is difficult to understand since the BCH

is nothing more than an internet-based clearing house or repository of biosafety related information, and thus cannot take decisions, consult or impose conditions.

The provisions dealing with decision-making do not make any explicit reference to the precautionary principle. What has thus been lost is an opportunity for the Authority to take measures to prevent harm; look for alternatives, place the burden of proof on the applicant to prove safety and the use of democratic processes to carry out and enforce the principle.

There is nothing in the Bill that places a clear and unequivocal responsibility on the applicant to take risk management measures to ensure that monitoring of the activity continues after approval has been granted. Such responsibility may or may not form part of permit conditions.

The provisions dealing with liability and redress are perhaps the most interesting. The Authority is held liable to pay compensation or damages to any person for any injury suffered as a result of the exercise of any power by the Authority in terms of the Biosafety law. It also holds a whole range of people strictly liable for any harm and has good provisions on access to justice, legal standing and so forth. These provisions seem to have been added in at the last minute, perhaps as a compromise in order to expedite the safe passage of the law through Parliament.

The law does require environmental impact assessments and does not deal with labeling of GMO food.

A great deal of work is still required in the drafting of regulations to fill in gaps, close some loopholes and bring about greater legal certainty. Civil society groups should ensure that they are part of this process.

Institutional Arrangements

(a) National Biosafety Authority

The legislation establishes a GMO regulatory body called the National Biosafety Authority ("Authority"), to be managed by a Board consisting of 13 people. Five members are high ranking officials from various government departments namely, science and technology, agriculture, the environmental management authority, bureau of standards and a scientist appointed by the President who will serve as chairperson. In addition, the Board will consist of a chief executive officer appointed by the board and six persons appointed by the Minister of Science and Technology. Of these six persons, one person represents consumers, two represent the interests of farmers and one represents the interests of the biotechnology industry, with two members being experts in the biological, environmental and/or social science fields. Thus, of the 13 members, at least 3 from civil society will have immediate access to the process and the applications for GMO activities, and can influence decision-making. The law is silent on whether the 2 experts should be independent experts; what expertise the chairperson needs to have; and whether this person will come from government, industry or will be an independent expert. It is also unknown what special

expertise the CEO will need to have. The members will serve for a period of three years, renewable for a further period of three years. It is hoped that every effort will be made to ensure that the majority of the members of the Board will bring meaningful biosafety capacity to its functioning.

(b) Regulatory Agencies

Regulatory agencies refer to nine departments within the Kenyan government: public health; veterinary services; bureau of standards; plant health inspectorate services; industrial property institute; wildlife service; pest control products board; the national environmental management authority and council for science and technology. The Authority is obliged to co-ordinate all activities involving GMOs with the relevant regulatory agency but has a discretion to consult with such agency. Nevertheless, regulatory agencies have the obligation to monitor any approved activity involving a GMO to ensure compliance with conditions that may have been imposed. Regulatory agencies also have a role to play in the review of decisions linked to its monitoring function (see below under review of decisions).

Scope

Section 3 of the legislation is titled 'scope' yet it does not set out the scope of the law. Instead, it sets out what the law will not apply to, namely, GMOs that are pharmaceuticals for humans. It is difficult for us to comment on the adequacy of existing legislation in Kenya for the regulation of GMOs that are pharmaceuticals for humans, save to point out that from the South African experience, the regulation of such GMOs fall within the scope of the GMO Act, administered by the Department of Agriculture and used predominantly to deal with GMOs in food and farming. In addition, because these GMOs are also medicines (e.g. GM vaccines), they also fall under the Medicines and Related Substances Control Amendment Act, which is administered by the Department of Health. The difficulties regarding the South African situation concerning GM vaccines, is dealt with in detail in an ACB publication titled, GM human vaccines in South Africa: a case for the precautionary principle.[vii]

The preamble to the Bill gives some detail as to the scope of the legislation, but a preamble is not regarded as being part of the operative part of legislation. The preamble describes the law as "an Act of Parliament to regulate…..the development, handling, transfer, use, release and disposal of materials, products, processes and organisms resulting from modern biotechnology…." When reading the section dealing with the objectives of the law (section 4(c)) and section 7 dealing with the objectives and functions of the board, one may come to the conclusion that the law intends to regulate the transfer, handling and use of GMOs. None of these activities have been defined, and regulations should be drafted to do so, in order to bring about legal certainty.

Notwithstanding these uncertainties, it is clear that the Biosafety law sets up a permitting system as the central mechanism to exercise regulatory control over specific GMO activities in Kenya. Activities involving GMOs under contained use conditions, field trials, commercial releases, placing on the market, and import and export, will require a permit to be issued authorizing such activities. This permit must be obtained from the Authority. Thus, for each of these activities, an application for a permit must be made to the Authority, in accordance

with the provisions of the Act. Although the preamble makes specific reference to products resulting from modern biotechnology, the legislation does not make special provisions for the regulation of products of GMOs.

Application for Contained Use

Whist the legislation has a fairly good definition of contained use, the facilities, installations or physical structures where contained use activities will be conducted are not dealt with at all in the legislation. A registration or certification system for these activities needs to be provided for, as well as an appropriate government agency to monitor the activities of these institutions. This system should be accessible to the general public. Section 24 deals with an application for permission to conduct a contained use activity, and requires the applicant to furnish the information as set out in the Third Schedule to the legislation, which contains 8 basic requirements. It is highly recommended that standards for contained use be developed for GMOs specifically, and that this task be one of the priorities for the Authority. However, as already mentioned, this task that should fall to the Authority has already been usurped by USAID's PBS.

Application for Introducing a GMO into the Environment

Section 25 deals with an application to introduce a GMO into the environment and requires that an applicant furnish the information as set out in the Fourth Schedule to the law. However, the Fourth Schedule also appears to deal with the information that must be furnished for an application for importation and placing on the market of a GMO. This Schedule sets out 10 rather basic requirements, taking into account that these pertain to an application to introduce a GMO into the environment for the purposes of conducting either field trials or for a commercial release of a GMO. The regulators have placed few mandatory requirements on an applicant who intends to release a GMO into Kenya's environment. The law has preferred to give an applicant the discretion to decide what other information it may deem necessary to enable the assessment of the potential risks or benefits of the introduction of a particular GMO into the environment. (Section 25(3)(ii)).

It is not satisfactory to have 10 rudimentary requirements pertaining to very different activities involving GMOs. Ideally, specially tailored requirements should pertain to the different activities and special attention should be given to what information an applicant should be providing for field trials and these should be more fully expanded and linked to an application for the commercial release of a GMO. For example, an applicant who intends to conduct a field trial, should furnish at a minimum base line information pertaining to the ecology and environment where a GMO is intended to be introduced; information pertaining to similar field trials conducted elsewhere in the world including approvals, rejections and conditions imposed by other authorities; information pertaining to a previous field trial conducted in Kenya and ensuring that field trials are differentiated from seed bulking activities, and so forth. We set these examples out to illustrate why we say the information set out in the Fourth Schedule is extremely flimsy and should be supplemented by specially tailored regulations.

Transport vs Transit

Although the Biosafety Protocol deals specifically with transit, the Kenyan Biosafety law deals with 'transport through Kenya which is not destined for use in Kenya'. A person wishing to transport GMOs through Kenya will need a permit and will have to ensure that GMOs are packaged and transported in accordance with regulations to be prescribed and any applicable international standards. The Authority will have to ensure that regulations are promulgated to bring this section into effect and should clearly make reference in such regulations, to international standards that should be complied with. The question that arises is what laws will apply to GMOs being transported through Kenya, that are not intended for use in Kenya but are being milled in Kenya (in the case of GMOs that are food aid for example) for distribution to countries in the region? Where the GMO in question has not been approved in Kenya, the Kenyan government should adopt a zero tolerance for unapproved GMOs and should not permit such GMOs to be milled in Kenya, because contamination is likely to occur even if risk management and containment measures are taken. In any event, special measures should be put in place to deal with consignments of GMOs transiting through Kenya without being milled. Regard could be had to the 'Policy on GMO consignments in Transit' issued by South Africa's Department of Agriculture, as compiled by the Executive Council, Genetically Modified Organisms.

Risk Assessment/ Risk Evaluation

The Authority receives and screens all applications to ensure that these are complete and if not, is entitled to request further information from the applicant. The Authority then in terms of section 33, undertakes a risk assessment in terms of the provisions of the Fifth Schedule to the law as well as auditing the risk assessment information submitted by the applicant. The Fifth schedule is closely based on annex III of the Biosafety Protocol dealing with risk assessment –the risk assessment that must be conducted on the part of an applicant, and these have now been used to guide the Authority in conducting a 'risk assessment'. Section 33 is thus quite confusing as typically it is really not the Authority that conducts a risk assessment in global biosafety practice, but the applicant does the risk assessment and the Authority will merely conduct a desk top evaluation of the information and data, including the risk assessment data produced by the applicant. It appears as if this section and the annex has been drafted to deliberately confuse the lay person into believing that for each and every application submitted, the Authority will be conducting an independent biosafety risk assessment.

Once the Authority had completed its biosafety evaluation of the application and risk assessment data, then it is obliged to make a report on its findings. The applicant or the importer is responsible for paying the costs incurred for the risk assessment. It is thus not clear whether the applicant will pay for its own risk assessment and/or the costs incurred by the Authority in processing and evaluating the application containing the risk assessment produced by the applicant.

Regulations should pay attention to clarifying the different roles and responsibilities with regard to risk assessments and risk evaluations.

Exemptions from Risk Assessments

Section 34 contains provisions that will have far reaching implications. It provides that the Authority may opt not to undertake a risk assessment for purposes of contained use, introduction into the environment, or import of a GMO, where it determines that sufficient experience or information exists to conclude that the GMO or contained use activity concerned does not pose a significant risk. What exactly does this mean and what are its implications?

It means that the Authority can do away with case-by-case assessments and exempt any application for contained use, import and introduction into the environment from the permitting requirements of the law. It can do so by arguing that it has relied on information shared by the regulators from countries that have a longer history with GMOs such as the US or South Africa to the effect that the GMO and activity in question are safe. In other words, if South Africa has approved Monsanto's GM maize MON 810 for commercial growing as far back as 1997, and if the South African regulators have concluded that the GMO poses no significant risk because MON 810 has been in commercial production for a number of years, the Authority will then invoke the provisions of section 34 and approve an application for introduction into the environment without even glancing at the application. It is a mystery as to how the Authority will determine a significant risk to the health of Kenyans and the environment in Kenya other than by conducting a case-by-case assessment.
Decision-making

Leaving aside section 34 for the moment, the Authority in coming to a decision, must take into consideration all the information submitted by an applicant; information and conditions submitted by a relevant regulatory agency; its own risk assessment report, submissions made by members of the public, and socio-economic considerations arising from the impact of the GMO on the environment, where a decision relates to an application under section 19 of the Act. Section 19 deals with the Biosafety Clearing House and provides that "the Biosafety Clearing House shall serve as a means through which information is made available for the purposes of this section." Socio-economic considerations can thus only be taken into account if these relate directly to the impact of a GMO on the environment. Thus, negative socio-economic impacts that arise in the context of food security and food sovereignty will not be taken into account. We do not understand the reference to section 19, because our version of the Bill relates to the Biosafety Clearing House. Section 35(2), however, stresses that "the Authority shall, prior to determining an application, liaise with the Biosafety Clearing House …. and the Biosafety Clearing House… shall submit to the Authority any conditions it considers appropriate to attach to the approval." We are completely at a loss as to what these provisions mean because the BCH is merely an internet based clearing house or repository of information. It does not process information or provide feedback.

Criteria will have to be established to provide guidance for socio-economic assessments; the terms of reference for such assessments; issues concerning the public's right to access to this information and the participation of the communities affected. Clarity should also be provided for the role of the BSC via-a-vis decision making.

Neither section 34 nor 35 dealing with decision - making, make any explicit reference to the precautionary principle. The Fifth Schedule to the law dealing with 'Risk Assessment'

contains a watered down, weak and scientifically flawed version of the precautionary principle, which is articulated as follows: “Lack of scientific knowledge or consensus on the safe use of genetically modified organisms shall not be interpreted as indicating a particular level of risk, an acceptable risk or an absence of risk.” This effectively means that lack of scientific knowledge or consensus on the safe use of GMOs is not relevant, or should not be taken into account in the assessment of the risk. In other words, lack of scientific knowledge or consensus is neutral.

What is required is decision-making based on the precautionary principle that allows for the taking of measures to prevent harm; looking for alternatives; placing the burden of proof on the proponent of the activity to prove safety; and most importantly, using democratic processes to carry out and enforce the principle. An applicant should thus be required to demonstrate through an open and transparent process, that the GMO and the activity proposed are safe and necessary and that no better alternatives are available. The precautionary principle in this context should not be a reactive measure but should focus on prevention rather than cure.

Interestingly, the law holds the Authority liable to pay compensation or damages to any person for any injury to that person, his or her property or any of his or her interest, caused by the exercise of any power in terms of the Biosafety law, or any other written law or by the failure, wholly or partially, of any works. This is quite a far–reaching set of provisions, particularly in the light that the law also holds several people strictly liable for damage caused, as discussed later (see paragraph on liability and redress.)
The law is silent on the practicalities of how decisions will be taken: will this be on the basis of consensus or by my majority vote?

Monitoring

The hallmark of all responsible safety legislation is that it provides for risk management measures to ensure that monitoring of the activity continues after approval has been granted. The objective of risk management is to identify risks and regulate them, with the aim of avoiding the risk. There is nothing in the Bill that places a clear and unequivocal responsibility on the applicant to take such measures. It is unknown whether these will form part of the permit conditions. Nevertheless, Article 16 of the Biosafety Protocol sets out the risk management measures that a Party must put in place, and these can form a guide to the regulators when they draft regulations. When doing so, attention should also be given to the need for and modalities for testing in the fields, bulk shipments of GMOs and products on the market.

In any event, section 33(4) of the Biosafety law places monitoring duties on the state and requires the taking of risk management measures on the part of relevant regulatory agencies, but the parameters of what these will entail is not provided by the law. The key question is whether regulatory agencies will have the necessary monitoring capacity in order to reliably assess the degree of environmental and food safety risks posed by transgenic crops. Monitoring is closely linked to possible direct, indirect, immediate or delayed effects identified in the risk assessment. At the same time, monitoring should include general surveillance (routine observations) to detect possible unforeseen adverse effects that were

not predicted in the risk assessment. There is a significant gap in current knowledge of the potential and real nature and extent of the environmental risks and adverse impacts on the environment posed by transgenic crops. In drafting monitoring protocols, regulators should pay attention to the following:

In relation to herbicide tolerant crop plants, the following should be investigated:
- Increased weediness of wild relatives of crops through gene flows;
- Development of herbicide tolerant weed populations through avoidance and selections;
- Development of herbicide tolerant 'volunteer' crop plants; and
- Negative impacts on wildlife populations through reduction of food supplies.

In relation to virus resistant crop plants, the following should be investigated:
- Increased weediness of wild relatives of crops through gene flow;
- Disease promotion among plant neighbours of virus-resistant crops through plant alteration; and
- Development of more virulent and more difficult to control viruses through virus alternation.

In regard to insect resistant GMOs, the following should be investigated:
- Increased weediness in wild relatives of crops through gene flow;
- Development of resistant insect populations; and
- Toxicity to non-target organisms and beneficial insect and soil microorganism populations.

Access to Information

(i) Biosafety Clearing House

Article 20 of the Biosafety Protocol establishes a means for information sharing through the Biosafety Clearing House (BCH). The BCH is a key mechanism in the implementation of the Protocol and is meant to ensure that an up-to-date repository of information on LMOs and biosafety exists, principally to assist decision makers and provide information to the general public. Following on from the Biosafety Protocol, section 18 of the Kenyan Biosafety law establishes a Biosafety Clearing House to function as a repository of information and mechanism of information exchange. Section 19 has a curious clause obliging each importing and exporting Party to make available to the Biosafety Clearing House information such as bilateral, regional and multi-lateral agreements and arrangements, summaries of risk assessments etc. 'Party' probably refers to a Party to the Biosafety Protocol. Kenyan law is not able to bind Parties to the Protocol, thus casting a dubious shadow over this awkward provision.

Neverthless, what the Biosafety law fails to provide for is clear legal obligations on the Authority to itself ensure that Kenya's obligations under the Protocol with regard to the Biosafety Clearing House is implemented. More curious is section 22, which provides that "the decision of the Biosafety Clearing House regarding the importation or release of living modified organisms shall be put into consideration whenever the Authority is making a decision regarding a GMO issue."

We point out that from the South African experience, that to date the government has made only 18 postings on its Biosafety Clearing House (http://bch.cbd.int/about/countryprofile.shtml?country=za), despite the South African government having granted well over 2000 permits since 1999. In addition, the link to the South African Biosafety Clearing House on the Department of Agriculture's site is not functional.

Of particular concern to the ACB regarding South Africa's lack of compliance, includes the following:

1. Decisions are not being posted regularly and in a timely manner, leaving decision makers and civil society entirely in the dark (
2 .Not a single risk assessment has been posted to date as required; and
3. Maize seed exported to Kenya from South Africa was found to be contaminated with MON810 in early 2008. This variety is not approved in Kenya. The contamination was not posted to the BCH as required.

(ii) Public input vs Public participation

Public participation is an integral part of an open, transparent and accountable government and leads to better and more informed decisions. The Kenyan public does not appear to have the right to participation but merely an opportunity to make input with regard to GM applications concerning field trials and commercial releases. It is not clear whether imports for the purposes of direct use as food, feed and processing will qualify as a release into the environment. Nevertheless, section 69(4) creates the right on the part of any person to submit written comments on a proposed decision for any application for placing on the market of a GMO, within thirty days from the date the notice is posted.

The Biosafety law places an obligation on the Authority to publish in the Gazette, in at least 2 newspapers with nationwide circulation and in electronic media, a notice concerning any application for release of a GMO into the environment. It is not known whether this notice will be in the form of an invitation to the public to respond to an application. It is also not known how much information will be contained in this notification to enable the public to react, which languages such notice will be published in and so forth. These issues can and should be dealt with in the regulations. However, the central concern is whether these efforts are sufficient so as to reach and notify illiterate or poorly educated members of local communities that may be affected by a release. It does appear as if oral representations prior to decision-making are not included and should be provided for in regulations.

A study done for South Africa's National Environmental Advisory Forum (NEAF) title 'Public Participation in the context of the Regulation of Genetically Modified Organisms in South Africa' has made the following recommendations for legal reform of South Africa's GMO regime, based on the consensus reached by the relevant stakeholders in that country. These include the following:

- Publishing notices of permit applications on an up-to-date, dedicated website;
- Emailing notices to stakeholders registered on the database;
- Publishing notices in national and local newspapers;
- Copies of the full non-CBI version of the permit application and supporting documentation should be made available to stakeholders at the inception of the

permitting process and be posted on a dedicated website as soon as the application is received (perhaps on the BCH); and
- Publication of any report given by an independent biosafety advisory committee/ body as well as the decision made in respect of the application, together with all recommendations and conditions.

This experience can inform the drafting of regulations in Kenya.

Section 69 deals with public awareness and participation and places an obligation on the Authority to promote public awareness and education of the public on biosafety matters through publication of guidance documents and other materials aimed at improving the understanding of biosafety. The Authority is also obliged to give notice in the Gazette of all decisions made regarding applications for approval. Publication in the Gazettle is not an effective mechanism to raise the awareness of the public. The Authority is also obliged to make available to any person, upon payment of a fee, copies of records kept in regard to an application, including details of any application that do not qualify as confidential information. This provision is welcome.

Confidential Information

Section 31 allows an applicant to identify information that it provides to the Authority as being confidential information. It is up to the Authority to decide whether it accepts as confidential, the information designated by the applicant. The Authority has the right to reject a claim of confidentiality, provided that it furnishes the applicant with reasons for such rejection. Confidential information is an extremely broad concept, and goes beyond what the legislation should protect, namely the bona fides, confidential business information of the applicant. Too much discretion is given to both the applicant and the Authority to decide on the question of confidentiality, which can easily result in the abuse of power and undermining the rights of the public to information and defeating their ability to meaningfully engage with the process and make representations. The regulations should set out the grounds upon which confidential business information should not be refused and this could include information relating to human, animal and environmental testing, or other investigations supplied by the applicant.

Offence of Withholding Information

Section 39 makes it incumbent upon a person to furnish available information before and after an approval that could reasonably be expected to change the evaluation of the risk posed by the person's activity. Where such information is withheld, the person commits an offence and is liable on conviction to a fine or imprisonment of ten years or both. This provision is most welcome.

Appeals

The Bill provides procedures for appeals as well as for the establishment of an appeals board but does not provide any mechanisms for a member of the public to appeal against a decision. No provision is made for the communication of a decision by the Authority to persons who have made submissions in order to enable them to access the appeal procedures. An appeal has to be lodged with the Appeals Board within thirty days from the date of the decision. A person who makes a submission will not be able to lodge an appeal within this period of time if he or she does not know of the decision. However, regulations can cure these defects by ensuring that, at the very least, persons who make submissions should be notified timeously of the decision of the Authority and be given reasons therefore, as well as being advised that they have the right to appeal to an appeals board etc.

Unintentional and Unapproved Releases

Unintentional and unapproved releases are also dealt with in a restrictive manner. When these occur, the bill does not contemplate the taking of immediate and emergency measures to ensure that such releases cease. Instead, the bill requires that where such releases pose biosafety risks, the regulatory agency who has knowledge of such releases must notify the Authority within 24 hours of obtaining such knowledge whereupon, in consultation with the Authority, they will determine whether any action is necessary to minimize any biosafety risks.

The Biosafety Protocol by contrast, in Article 25 dealing with illegal transboundary movements, compels Parties to adopt domestic measures aimed at preventing and penalizing unapproved releases that originate from a transboundary movement. It goes further and requires an affected Party to request the Party of origin to dispose of the GMO at its own expense by way of repatriation or destruction.

It is ironic that the Kenyan Biosafety Bill places a great deal of emphasis on the Biosafety Clearing House, and yet, fails to implement its obligations in terms of Article 25(3) of the Protocol which requires Parties to make available to the BCH, information concerning cases of illegal transboundary movements. Regulations should be drafted to close this omission.

Review of Decision

Section 38 provides several opportunities for the Authority review its decision. This it can do when it obtains significant new scientific information relating to the biosafety of a GMO or contained use activity involved. The word ‘obtains’ seems to convey the notion that the information pertains to that which the Authority seeks out as opposed to information that it is given or it receives for example, by members of the public or an independent scientific body etc. A regulatory authority is also able to request the Authority to review its decision, where the regulatory authority or the applicant considers that a change in circumstances

has occurred that may have a material effect on the outcome of the risk assessment upon which the decision was made. It may also do so where additional scientific information has become available that may have a material effect on the decision or any conditions, limitations, or requirements imposed by a decision. In all of these circumstances, the Authority still has a discretion whether to review its decision and even if it does review its decision, the Bill does not allow the Authority to overturn its earlier decision and issue a rejection or a 'taking back' of the approval. It only allows the Authority to substitute its earlier approval with yet another approval- taking into account a change in circumstances. The Authority has up to 180 days to make a decision on review, although the Bill does allow for the taking of immediate measures where the activity in question poses a threat to biosafety.

Section 38 does not make any provision for members of the public to request the Authority to review its decision, but nor does it preclude the public from making such requests either. Section 38(6) does provide that the Authority shall give special consideration for review of requests from a regulatory agency. Thus, it appears that if a member of the public would like to approach the Authority to review a decision, it should first make representations to a regulatory agency and convince such agency to approach the Authority to review a decision.

The regulatory agency also has the duty to immediately inform the Authority of any significant new scientific information that indicates that an approved activity may pose potential biosafety risks not previously known. In addition, the regulatory authority is required to provide the measures that ought to be taken to continue the safe use of the GMO. There is no provision to the effect that such measures should also include the cessation of the activity. It does appear to be quite strange that where an activity has the potential to pose a significant risk, that this activity should be allowed to continue and somehow, safety measures have to be conjured up on the part of the Authority.

Restoration of the Environment and Cessation Orders

Section 45 sets out provisions for the issuing of restoration orders on the part of the Authority to any person for restoration of the environment as near to the state in which it was before the release of the GMOs, or a payment for the restoration of the environment. Section 45 does not refer to the circumstances in which such restoration orders may be issued and no cross references are made to any other section of the Bill or to the monitoring and reporting functions of the regulatory agencies.

Section 47 deals with cessation orders, and it provides that the Authority, in consultation with the relevant regulatory agency, may issue a cessation order or the imposition of risk management measures under certain circumstances. These are: "…there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking into account the risks to human health ON THE BASIS OF one or more tests conducted and evaluated in a manner consistent with acceptable scientific procedures, and other validated scientific procedures." Thus, the grounds for issuing the cessation orders are severely constrained even in the face of imminent danger because scientific tests would first have to be conducted!! These provisions are highly irregular!

Cessation orders may also be issued where there is failure to comply with permit conditions or with the provisions of the Act and regulations.

Section 47(3) provides for the withdrawal of a cessation order once the Authority determines that sufficient information exists to permit the activity concerned to resume or to resume once risk management measures are taken that do not pose a significant risk to human health or the environment. It appears as if the regulators have placed severe restrictions on the Authority when it comes to its powers to issue cessation orders and every attempt is made to ensure that once approval is granted, that approval cannot be taken back.

Liability and Redress

The legislation holds the person who imports, makes contained use of, releases or places a GMO on the market or a product of a GMO, strictly liable for any harm caused by such GMO and to fully compensate for the harm caused. However, it also attaches liability to the person responsible for the activity which results in the damage, injury or loss as well as to attaching such liability to the provider, supplier or developer of a GMO or product thereof. Such liability is to be borne jointly and severally. Compensation for harm to the environment or biological diversity shall include the costs of reinstatement, rehabilitation or clean-up measures which have been or are being incurred and where applicable, the costs of preventative measures. Interestingly, liability is to extend also to harm or damage caused directly or indirectly by the GMO or product to the economy or social or cultural conditions, the livelihood or indigenous knowledge systems or technologies of a community or communities, or incidents of public disorder triggered by the GMO or product. Incidents include disruption or damage to production systems, agricultural systems, reduction in yields, soil contamination,damage to biological diversity, the economy of an area or community or any other consequential disorder. The time frame given for the right to bring an action is a reasonable period of time from the date on which the affected person or the community could reasonably be expected to have learned of the harm, taking into account the time the harm may take to manifest and the time it may reasonably take to correlate the harm with the GMO or product, having regard to the situation or circumstance of the person or community. Any person, group of persons or state organizations are entitled to bring a claim and seek redress in respect of the breach or threatened breach of any provision relating to damage to the environment, to biodiversity, human health or socio-economic conditions whether in that person's interest, on behalf of someone else, in the interests of a group or class, the public interest or in the interests of protecting the environment or biodiversity, provided that the action is not frivolous or vexatious, and an abuse of the court process. Furthermore, drawing on the South African legislation (National Environmental Management Act), the biosafety law provides that no costs shall be awarded against a person who fails in any action if the action was instituted reasonably out of concern for the public interest of protecting human health, biodiversity, and in general, the environment or biological diversity. Compensation for damage to human health is to include medical expenses, disability suffered and loss of life. All of these provisions are most welcome.

Handling, Packaging, Identification and Transportation of GMOs

Section 65 obliges any person manufacturing or importing any GMO to ensure that the handling, packaging, identification and transportation of a GMO are done in the prescribed manner. In drafting regulations, we point out that special attention should be given to the 'identification of GMOs' in that legal responsibilities should be placed on an applicant to: (i) protect the integrity of non GM shipments from contamination; (ii) ensure zero tolerance for unapproved GMOs; and (iii) develop modalities for sampling and detection techniques. Civil society should also be aware that a central issue is the establishment of thresholds for inadventitious GM content in non GM shipments. Industry will push for a 5% threshold level. Several countries have settled on a 0.1% threshold.

Regulations

Section 66 gives the Minister the power to make regulations in consultation with the Authority for the better carrying into effect of the provisions of the Act, and in particular, procedures for conducting contained use activities involving GMOs, procedures for the release of GMOs into the environment, procedures for importation and exportation and for applications for approvals of GMOs.

What the Biosafety Law does not deal with:

Environmental Impact Assessments

Kenya's Biosafety law does not make any provision for the conducting of environmental impact assessments for GMOs that are introduced into the environment. EIAs can play a key role in ensuring that the state takes reasonable legislative measures to ensure inter-generational equity, prevent pollution and ecological degradation, promote conservation and so forth. It appears as if an important ecological safeguard has been sacrificed in favour of expediting the introduction of GMOs into Kenya's agricultural systems.

Labelling and the Right to Know

The labelling of GM food is one of the most important ways of upholding the right of consumers to choose what they wish to consume. It is also a way to trace GMOs through the food chain from farm to plate, and is important for risk management and monitoring, product recall in the event that something goes wrong and concomitant issues of liability and redress. Even South Africa has adopted mandatory labelling provisions in the Consumer Protection Bill and associated liability and redress provisions for product liability.

Conclusion

Kenyan civil society has mounted a courageous and sustainable battle against the introduction of GMOs into their country. They have put a great deal of energy into ensuring good biosafety legislation is passed and in doing so, they have raised the profile of the issue, and have contributed substantially to the public discourse in Kenya and the region. Now that the legislation has been finalised, different strategies, mechanisms and capacities will be required. South African activists have at least ten years worth of experience in opposing GMOs. They have engaged extensively with legislation, legislative processes, case-by-case GM applications and the biosafety discourse in general. This experience is at the disposal of Kenyan civil society.

References

i. Henry Neondo All Africa Science News (http://africasciencenews.org), via AgBioView. https://www.truthabouttrade.org/content/view/13344/54/lang,de/
ii. Body goes to court over Kenya's Biosafety Bill, 10 February, 2008. http://www.africaconservation. Org/cgi-bin/dcforum/dcboard.cgi
iii. Program for Biosafety Sytsems A partnership program for biosafety capacity development. (2007).
iv. Program for Biosafety Sytsems A partnership program for biosafety capacity development. (2007).
v. John Oyuke. Comesa commends Kenya for Biosafety law. The Standard Online. http://www.eaststandard.net/print.php?id=1144008369&cid=14
vi. Shenaz Moola and Victor Munnik. (2007). GMOs in Africa: food and agriculture: Status report 2007. African Centre for Biosafety., Biosafety, Biopiracy and Biopolitics Series: 4.
vii. African Centre for Biosafety. (2008) GM human vaccines in South Africa: a case for the precautionary principle. Biosafety, Biopiracy and Biopolitics series