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Regulation of Genetically Modified Organisms Trade and Utilization in Developing Countries

Lenjisa Direba Balcha*
Ethiopian Institute of Agricultural Research, Debre Zeit, Ethiopia

Abstract

Crops improved through biotechnology have been widely adopted by farmers around the world wherever farmers have been able to secure access to the seeds and where they do not fear the loss of export markets. However, governments in some regions have created significant impediments to farmers' use of GMO-improved seeds, most conspicuously in Europe, which has exported restrictive regimes wherever they can, with particular success in sub-Saharan Africa. African farmers' access to biotech-improved seeds has been severely and directly limited by threats from Europe to close their access to export markets; and by regulatory barriers to innovation erected through a global effort by EU and member states to create regulations in other countries that block farmers' access to biotech-improved seeds. And on top of that, a wide array of NGOs, more interested in pursuing an anti-corporate agenda than a pro-development agenda, have worked to convince nations to ban or otherwise limit productivity-enhancing GMOs. Consequently, in most cases, seeds for GM versions of African crops simply don't exist. Even in the few cases where biotech-improved seeds do exist, it is difficult or impossible for farmers to gain access. Despite the strongly positive track record of biotech-derived crops for farmers, consumers, and the environment, unexploited opportunities for additional, widely shared benefits are considerable. We estimate the economic value forgone in Africa from restrictive regulation at $1 billion in 2013. If such regulations continue to restrict and suppress innovation in agriculture, the cumulative costs to low- and lower-middle-income countries worldwide will be approximately $1.5 trillion by 2050. Because of the unprecedented demands to increase agricultural production and productivity over the next 30 years, such restrictive regimes must be rolled back everywhere as rapidly as possible.

Keywords: Genetically Modified Organism; Trade; Regulation; Developing Country

Introduction

Background

Genetically modified organisms (GMOs) are defined as organisms (plants, animals, or microorganisms) in which the genetic material (deoxyribonucleic acid or DNA) has been altered so that it does not occur naturally by mating and/or by natural recombination. They are produced as a result of genetic engineering technology, also known as 'modern biotechnology' or 'recombinant DNA technology, which allows the transfer of selected individual genes from one organism to another as well as between organisms of non-related species such as the transfer of genes from bacteria to a plant (Ibid.) [1].

According to Richard B. Stewart, Commercial adoption of genetically modified (GM) foods and crops (also called "genetically modified organisms" or "GMOs") created through recent innovations in agricultural biotechnology has triggered widespread controversy over the environmental and economic benefits and risks of GMOs as well as a wider range of social, cultural, and ethical values. Differences among nations in their assessments of GMO cost and benefits and their interests and values have led different countries to adopt quite different environmental health and safety (EHS) regulatory programs for GMO foods and crops [2]. These differences in turn have produced sharp trade conflicts. GMO agricultural exports from countries that favor GMO technologies, such as the U.S., have been blocked by GMO regulations in jurisdictions, such as the EU, that oppose or are skeptical regarding GMOs. Moreover, the advent of domestic labeling and traceability requirements for food imports, such as those recently adopted by the EU, may seriously inhibit the use of GM crops in exporting countries even where those crops are consumed internally or exported to third countries. The advent of dramatically higher food prices has enhanced the interesting use of GMO crop varieties and led to some softening of regulatory restrictions and consumer attitudes in Europe and some developing countries, but sharp differences and conflicts among states over GMOs remain. Such conflicts have posed a severe challenge to the various international authorities including the WTO, international environmental and health standard-setting bodies such as the Codex Alimentarius Commission, and the Biosafety Protocol – that deal with GMO trade and regulation

In analyzing this challenge, this paper focuses particular attention on its implications for developing countries. Unlike many international environmental issues, the divide on GMOs is not North/South. There are sharp differences in GMO policies and regulations among developed countries most notably between the US and Canada on the one hand, and Europe, Japan, and South Korea on the other. There are also sharp differences among developing countries; several important countries have, with varying degrees of caution, embraced GMO crops, but many developing countries are on the fence and a few are strongly opposed. In Africa, South Africa and Egypt are the only countries with authorized commercial plantings of GM crops; South Africa, in particular, is regarded as a leader in GM crop issues in Africa [3]. In 2006 South African farmers planted GM crop varieties on 1.4 million hectares, making the country the eighth in the world in GM acreage. GM varieties accounted for 92 % of South Africa's cotton, 44% of corn, and 59% of soybeans. There is, however, domestic opposition to GMOs

***Corresponding author:** Lenjisa Direba Balcha, Ethiopian Institute of Agricultural Research, Debre Zeit, Ethiopia, Tel: +251910453422; E-mail: lenjisa1@gmail.com

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from environmental and church groups. The government is taking a rather cautious regulatory approach to GMOs; it recently denied approval for GM sorghum and cassava for food and for GM corn to produce biofuel because of concerns over the containment of gene flow to non-GM varieties. Eight other African countries, including Burkina Faso, Kenya, Morocco, Senegal, Tanzania, Uganda, Zambia, and Zimbabwe, have conducted field trials of GMO crops. 20 countries have some form of GMO R&D program. There is, for example, a marked degree of emerging interest in GMOs in Zimbabwe [4]. And even countries that remain unwilling to plant GMOs have become more amenable to the prospect of importing such crops; Kenya's agriculture minister, for instance, announced in August 2008 that Kenya would begin importing genetically modified foods in response to food shortages. There is, however, significant opposition in many countries to GMOs on economic and environmental health and safety (EHS) grounds as well as out of concern that GM crops would threaten traditional agriculture. Zambia, for example, has maintained implacable opposition to the commercial use of GM crops despite calls for a group of scientific, agricultural, and non-governmental organizations to use GMOs to reduce poverty and hunger. At the same time, unauthorized plantings of GM crops may be occurring in Southern Africa as GM seeds can easily cross borders.

Developing countries, however, have much more at stake in resolving these conflicts than do developed countries. The potential economic and environmental benefits and risks are often greater for developing than for developed countries [5]. GMO crop varieties can potentially meet the food security needs of developing countries and enhance crop exports. They can also address the challenges of droughts and other impacts of climate change. And provide environmental benefits by reducing the use of agricultural chemicals and reducing the need to clear forests to expand crop acreage. At the same time, GMO crops may pose ecological risks that developing countries are often ill-equipped to manage. GMO crops may also encounter consumer resistance and regulatory restrictions in many developed countries. To date, however, most developing countries have been trapped in the crossfire of conflict between the EU and the US, which has also prevented international trade regulatory bodies, including the WTO, Codex Alimentarius, and Biosafety Protocol regime, from providing meaningful guidance on GM trade regulatory issues. South Africa and other like-minded developing countries interested in the responsible use of GMO crops need to develop an international forum to promote their interests. The growing power of developing countries in international trade policy, reflected in the Doha round collapse and the resulting weakening of the WTO, makes such an initiative more realistic and likely [6].

Objective

To review regulation of GMO trade and utilization in developing countries

Regulation of Genetically Modified Organisms Trade and Utilization in Developing Countries

Latin America

Policy Implications for Trade and Development: The first genetically modified (GM) crops (including potato, soybean, cotton, and canola), commercialized in the United States between 1995 and 1996, soon caught on in Canada and Argentina as well. The benefits of these crops included reduced herbicide and pesticide use, drought and insect resistance, and higher yields across the board, yet they nevertheless failed to take hold outside of these highly developed agricultural economies. European Union (EU) countries that had initially embraced these innovative GM crops soon turned against them [7].

Today, the GM crop revolution has enveloped many developing countries as well, but the challenges surrounding genetic products have not resolved themselves. In contrast to the previous Green Revolution, which was carried out largely by public research institutions, the GM revolution is largely private.

The difference lies in the technical requirements of the technology. While the strong network of National Agricultural Research Institutes (NARIs) in developing countries around the world could innovate in the 1970-the 80s using conventional plant breeding techniques, GM innovation today requires advanced laboratories, highly skilled staff, and well-constructed regulatory systems. Thus, only a handful of this once innovative NARIs can now compete with multinational corporations in the creation of new GM crop products. Most remain focused on adapting already patented foreign GMOs to local conditions through conventional breeding techniques. Growth in developing country agricultural research spending continues to rise, but at a much slower rate than during the Green Revolution, and not quickly enough to establish substantive domestic GM innovations. The result of this shift from public to private agricultural innovation is a rising system of Intellectual Property Rights (IPRs) in agriculture, where multinational corporations own the rights to nearly all GM crops grown in developing countries. Increasingly strong international IPR norms have arisen since the onset of the GM revolution in the mid-nineties, including the Trade-Related Intellectual Property Rights Agreement (TRIPS) of the World Trade Organization, which imposes the United States' IPR norms on all WTO signatories, allowing only brief waivers for less developed nations. Concerning GM crops, the International Union for the Protection of New Varieties of Plants agreement (UPOV), establishes norms of licensing and Plant Breeders Rights (PBRs) intended to protect producers' IPRs and ensure the collection of royalties on all licensed products. These two agreements give multinational corporations unparalleled access to local markets within developing countries, as well as the legal clout to extract royalties [8].

While private innovation is highly efficient and effective in developing new GM technologies, the problem for developing countries lies in where multinationals emphasize this innovation. Green Revolution technologies were directed primarily at poor small-hold farmers, while new GM technologies focus on large-scale, advanced monoculture agriculture. This explains why Argentina was quick to embrace GMOs, and also why many other developed countries have hesitated in their adoption.

Within this context of reorientation, privatization, and expansion, Latin America emerges as a striking case, in both the scale of its adoption and in the diversity of its approaches. Of the 29 countries which had approved GM crops in 2011, 10 were in Latin America, and half of all developing countries GMO-adopters are Latin American. 37% of global GM crop hectarage lay in the region a total of 59.3 million hectares in 2011. Furthermore, of the 12 million hectares of GM crops added globally in 2011, 7.05 million, or 59%, were added in Latin America. Most of this growth comes from Brazil and Argentina, the second and third largest GMO producers in the world, respectively. Brazil alone accounts for 19% of global GM crop hectarage calculated [9].

Latin America's history as an exporter of primary agricultural products explains part of this: many countries in this region host agricultural ecosystems similar to the North American ecosystems for which GMOs were originally invented. They also grow many of the same types of crops–soy, maize, and canola. Another piece of the explanation may lie with Argentina's early and fervent adoption of GMOs. Strong evidence exists that illegal and unregulated GM seeds crossed Argentine borders with Uruguay, Paraguay, and Brazil, spreading throughout these nations' macroeconomics and effectively forcing their governments to acknowledge a GM reality through appropriate policy changes. Given its vast agricultural potential, Brazil would undoubtedly have adopted GMOs eventually, but the decision was preempted by the illegal smuggling of GM seeds from Argentina. This situation illustrates again a fundamental difficulty faced by developing countries in general, and Latin American countries specifically: the regulation and tracking of GM products require a very high level of technical competency and organization, something lacking in nations such as Paraguay, Bolivia, Colombia, Uruguay, and elsewhere.

In short, the treatment of GMOs in Latin America will be predictive for the rest of the world. As more and more developing countries begin to contemplate these newly dawning technologies, the templates for adoption that they will follow are already forming in South and Central America. With its high rate of adoption and diverse policy approaches, the Latin American region can provide analysts, governments, and multinational businesses with a window into the future of the GM Revolution [10].

Briefs on Trade and Regulation of Latin American countries

Chile: Chile offers a rather mixed bag in terms of GMO trade policy. With 22.8% of non-meat agricultural exports going to the US and only 3.4% to the European Union and Japan (UN Comtrade), one would expect an orientation toward a more permissive policy. What has occurred in actuality is a division between the internal market dynamic, which remains closed from most GMOs, and its export market, which exports over US$360 million in non-meat agricultural products, largely to the United States and China. Thus, the apparent contradiction between a closed internal market and a US (pro-GMO) export orientation resolves itself: the US$360-million-dollar seed production market in Chile, controlled for the most part by foreign multinationals, is channeled through Chile as a "world laboratory" for GM seeds without ever reaching Chilean consumers. In short, to quote N. Ramiraz, an agricultural specialist for the USDA in Chile, "Chile does not produce any crops for sale domestically. However, Chile has propagated transgenic seeds under strict field controls for re-export for more than a decade." Preventative or precautionary domestic measures do not preclude promotional trade regulations.

Chile 2009 imported approximately 890,000 kg of GM seed, 97% of which came from the United States, cultivated this seed, and re-exported 45,291,624 kg of seed back to the USA (UN Comtrade). Resolution 1523 of 2001 (Ministry of Agriculture and SAG) regulates this process, whereby the seed is cultivated throughout the Northern Hemisphere's winter and then re-exported without ever contacting Chilean consumers (USDA GAIN 2011). Thus, no significant barriers stand in the way of GM production in Chile: GM seed imports are treated equally with non-GM imports as long as they remain within the closed production channel detailed above [11].

Brazil: Brazil, Latin America's largest soybean producer (soybean exports were US$16.33 billion in 2011) (UN Comtrade), displays exceptionally high Revealed Comparative Advantages for several important agricultural products, including soya beans, soya oil, and various maize products.

Brazil trades heavily with the United States, Argentina, and China, with 33% of exports and 39% of imports involving these three countries (UN Comtrade). However, when one focuses on the agricultural sector alone, as explained earlier, export orientation shifts to Europe. Brazilian imports from the USA in major agricultural products only totaled an approximate US$5 million in 2011, and its exports to the US in these products totaled 3,574,942 kg. in total. This was only .06% of exports to Europe and Japan of these same crops, giving Europe+Japan a 29.5% share of Brazil's non-meat agricultural exports, contrasted with a 0.1% share for the United States [12].

Brazilian GMO adoption and trade with Europe

Brazilian agricultural exports to Europe and Japan show a trending increase from 1990 to 2007, as the growing nation built stronger ties with the European Union. This trend reversed itself sharply after 2007, showing a very notable decline in export volumes after this date. While agricultural exports to Europe are still significantly higher than those to the United States, the drastic decline may indicate the lagging but very real effects of Brazil's massive reorientation toward GMOs (UN Comtrade). Passed in 2005, Brazil's far-reaching Biosafety Law was the first in Latin America to incorporate a specifically GMO-focused regulatory body into national law. The Biosafety Law effectively legalized what had been increasing cultivation of GM crops, smuggled across the border from Argentina as early as 1998. After the legalization, and now under the governmental aegis, GMO cultivation took off in Brazil. Plateauing hectarage numbers before 2005 became skyrocketing growth after the passage of the Biosafety Law. In 2011 alone, Brazil saw a 19% increase in its GM crop cultivation.

During this same period, Brazil's trade with Europe and Japan has been in constant adaptation and evolution. Agricultural trade dipped in 2005, spiked by 2007, and after that fell by more than half up to 2011. (UN Comtrade). An important point is that this analysis is not tracking total trade volumes, which have increased nearly 400% over this same time frame [13].

Thus, while total trade between Brazil and Europe, and Japan has been increasing steadily since 1995, trade in the very agricultural products that Brazil has approved for GM (Brazil has approved HT soybean, Bt cotton, Bt maize, and crops analyzed in export data were maize, soya, and cotton) has declined since slightly after the passage of the Brazilian Biosafety Law in 2005.

The European Union and Japan, more so than nearly any other country or regional group, are highly precautionary toward GM products. They demand strict regulations on GM imports, as well as any domestic cultivation. Thus, the declining import of Brazilian agricultural products, which are increasingly GM, is entirely intuitive, but very illustrative of the kind of tradeoffs faced by developing countries in their decision-making calculus regarding GMOs. Luckily for Brazil, rising Chinese demand for Brazilian exports, including all of these agricultural products, has picked up the slack. Over the 2005-2011-time frame in which Brazilian agricultural exports to Europe and Japan have declined by well over half, China's receipt of these same products has increased from 7,593,095,615 kg. 22,789,222,077 kg., a ~300% increase (UN Comtrade).

Brazil ratified the Cartagena protocol in 2006, establishing "detailed documentation requirements for genetically modified organisms in

the international trade of agricultural commodities," according to a European Commission press release from Curitiba, Brazil. Given the nation's detailed labeling requirements, Brazil does not appear to discriminate between GM and non-GM foods for import or export, and it equally makes little substantial effort at the segregation of production and supply lines, which would be necessary for export segregation.

Argentina: Argentina has many fewer small-hold farmers and shows significantly more reliance on modern monoculture agriculture than comparative Latin American countries such as Brazil. Examining the Balassa index, Argentina has a strong incentive to invest in agricultural improvement and expansion, given the fact that it has a Revealed Comparative Advantage in almost all crop sectors with GM potential.

38% of Argentina's total exports stay within Latin America, while 5.4% of non-meat agricultural products reach the European Union or Japan. While this number appears rather small, it can be misleading in that Europe and Japan do receive much of Argentina's exports, but these are in the form of beef. Since this product is fed on GM feedstuffs but does not retain intact GM content, EU regulations do not monitor or limit beef as strictly as they do feedstuffs endogenous to Europe or GM feedstuffs/foods imported directly into Europe (REGULATION (EC) No 1760/2000 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labeling of beef and beef products and repealing Council Regulation (EC) No 820/97, and REGULATION (EC) No 1830/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC) (Official Journal of the European Communities, 2003). This same principle–a of relative buffering of the negative effects of GM production on trade with the EU thanks to a diversion of GM crops into feedstuffs for EU-destined beef–applies equally to other MERCOSUR countries (Uruguay, Brazil, and Paraguay) [14].

Argentina has approved full imports and exports of Bt Cotton, Bt maize, and HT soybean. Given its 100% GM soy production, it exports ~US$10.5 billion in GM soy products each year (UN Comtrade). It does not discriminate between GM and non-GM imports or exports besides the aforementioned approval process for new releases. However, the Argentine National Seed Institute has forbidden imports of GM rapeseed with Resolution 305/2007. It requires a certified absence of GM seeds in rapeseed shipments for all imports (USDA GAIN, 2011). This appears to be the only strict regulation on GM border crossings in Argentina.

Uruguay: Uruguay exports few potentially-GM crops. Since it has approved GM event releases in HT soybean and Bt maize, these crops thus include all maize and soy products (given that 100% of soybean and 83% of maize are GM (James, 2012). With a value of about US$455.7 million, Uruguay's soya bean exports constitute a significant portion of its foreign trade, which seems reasonable given that soya is Uruguay's only GM crop showing a revealed comparative advantage on either the world market or within Latin America (UN Comtrade). Approximately 36.7% of Uruguayan exports remain within the region, and the majority of soya products go to the United States. Beef is by far Uruguay's biggest export: it accounted for US$3.4425 billion in exports in 2009, which is 63.9% of total exports. 32.6% of this beef went to Europe or Japan (UN Comtrade). The argument extended in section 3.2c in regards to other MERCOSUR countries' beef exports as a diluting effect on the GM crops/exports to Europe controversy applies perhaps most powerfully in Uruguay, given its sheer lack of raw GM exports and simultaneous dependence on GM-derived beef destined for Europe. As mentioned earlier, future regulations may alter MERCOSUR nations' abilities to escape this current contradiction.

The United Nations' Comtrade database does not show any trade-in GM crops between Uruguay and the EU or Japan (country groups that are traditionally oriented away from GM products and regulate their import much more closely. Uruguay's total crop hectarage declined considerably between 2006 and 2008, which was precisely the duration of the moratorium on GM crop commercialization (UN Comtrade). Since then, the total hectarage has leaped back up. GM crops as a percentage of this quantity have remained relatively stable, and the 33% increase in GM crop hectarage in 2010 mirrored a similar increase in total hectarage. The strong decline in hectarage during the GM moratorium, and strong rebound after it was lifted, suggest a link between the two. GM crops may have gained such a decisive foothold in the country before 2006 that the moratorium simply could not overcome their momentum. In this light, the harmful effects of the moratorium across the agro-economy may have forced the government to reverse course. Here again, then, we can see the interplay of trade and policy, and the influence GMO trade can have in molding national laws.

A USDA GAIN report from 2011 claims that Uruguayan rice farmers (rice made up a substantial US$1.3 billion in exports, or 24.2% of total exports in 2009) would push for GM rice products but do not want to damage export markets. The weight of this claim seems dubious, given that only ~8% of Uruguayan rice exports go toward Europe or Japan, but this situation would be illustrative of the concerns and quandaries facing any producer, large or small, when considering the use of GMOs.

Paraguay: As a landlocked nation, Paraguay's exports must pass through these surrounding nations, which can sometimes skew trade statistics, especially if raw goods like soya beans (a large Paraguayan export) have value-added in Argentine or Brazilian processing facilities and thus appear in the Argentine or Brazilian export numbers. Paraguay's landlocked status may explain why its exports alone make up 40% of endogenous Latin American non-meat agricultural trade. In fact, despite a relatively negligible role in world international trade, Paraguay dominates within Latin America, detailing exports from Latin American countries to other Latin American countries [15].

The majority of Paraguay's agricultural exports go to Brazil and Argentina (UN Comtrade). Since both of these nations have embraced GMOs, Paraguay should see little discrimination in its GM soy exports. As touched on earlier, Paraguay dominates internal Latin American trade in agricultural products. ~86% of soya beans traded within the region come from Paraguay, as do ~78% of rape/colza seeds (UN Comtrade)

Paraguay's dominance is further illustrated in its Balassa Index, which is strong>1 for all major non-meat agricultural products that are prevalent within the country. This indicates a strong comparative advantage in agricultural production in comparison with the world. When compared to other MERCOSUR countries in the area of Latin American trade, Paraguay is one of the few countries with a strong comparative advantage, especially in soy products (UN Comtrade). While agricultural trade is strong, bans on GM corn cultivation represent a slight limitation on GM expansion. Furthermore, the fact that GMO introduction to Paraguay was illegal, that the government banned

GMOs until it realized their inevitability, and that it continues with anti-GMO regulations (albeit grievously unenforced/unenforceable), trade conditions should be seen as relatively preventative.

Mexico: Soon after NAFTA came into force, the Mexican government either waived or failed to apply a majority of the import restrictions which had been built into the agreement, including on maize products. Thus, as the United States proceeded to increase its domestic agricultural subsidies, particularly to maize producers, Mexican farmer support fell: by 2004, US subsidies had risen 48% while Mexican subsidies had fallen 39% until they matched only 10.4% of the US subsidy support. Corn flows from the United States increased dramatically, bringing GM maize products to Mexican markets. Mexican regulators, conscious of the potential vulnerability of the smallholder-controlled landraces, decreed that GM maize imports could be used only for consumption, not production.

Under NAFTA, Mexico's trade is intimately tied with that of the United States: 80.5% of Mexican agricultural exports go to the United States (UN Comtrade). In turn, the US promotes its agricultural exports to Mexico, which, of course, contain GM components. As explained earlier, US farm subsidies underprice small Mexican producers, especially in maize, forcing these smallholders off their farms and into situations of forced urbanization or immigration (Aoki, 2012). At the same time, the flooding of the Mexican consumption market with GM maize makes this seed visible to large Mexican maize producers, who see the undeniable up-front technological benefits offered by the herbicide and pest tolerant, sometimes drought-tolerant seeds. Thus, GM products are effectively promoted to lower production costs through US subsidies, to boost US exports. This creates a strongly promotional environment for these transgene products within Mexico, perhaps against the interests of many, but within the interests of those making large-scale crop production decisions, both in the United States and in Mexico

Africa: Opposition to GMOs in Africa has manifested itself in several ways. African governments adopted tight restrictions on the international movement of living GMO crops and seeds under the Cartagena Protocol, a UN Convention on biological diversity launched in 1996. The position against GMOs has acted as a brake on scientific research. Currently, only three African nations produce biotech crops South Africa, Egypt, and Burkina Faso. Only the first two grow GM food crops, and only South Africa grows them in significant quantities [16].

GMOs Regulation in Zimbabwe

This discussion explores the contexts for the regulation of new agricultural biotechnologies in Zimbabwe. It argues that many of the key uncertainties about GMOs are context-dependent and that there is a need for a locally developed, flexible regulatory system that recognizes inevitable uncertainties and encourages broad forms of engagement with regulatory decision-making. This argument runs counter to those who claim that a universalistic; solely science-based approach is required, allowing a harmonization of regulation in this area.

The paper examines the emerging experience of the Zimbabwean biosafety regulatory system, focusing on two issues: the release of Bt (Bacillus thuringiensis) maize and cotton crops and the importation of GM maize as food aid. Both questions have tested the regulatory system in different ways. Both cotton and maize are important in Zimbabwe and are grown in both the small-scale and large-scale farming sectors.

The implications for the future of regulation in the Zimbabwe context – and by extension other similar countries are then briefly reviewed.

Importing GM food aid

In the latter part of 2001, it became clear that Zimbabwe would have to import food at some point over 2002. By 2002 this had evolved into a serious food crisis, with a forecasted maize deficit of 237,320MT in national requirements of 1.64 million MT of maize estimated for the consumption year ending March 2003, even after allowing for significant imports. This comes on the back of low harvest production in the 2001–2002 season (estimated at under 500,000MT of maize) and low stock levels. By the end of 2002, 788,389MT of maize had been imported, 14 percent of this from humanitarian assistance and the rest commercially. By the end of March 2003, a further 592,127MT is expected to be imported. Given the slow pace of imports, uncertainties about the government's ability to pay, and donors' willingness to support Zimbabwe, how the remaining deficits will be covered until the 2003 harvest is unclear. With maize as the main staple, eaten regularly by Zimbabweans three times a day, getting hold of maize was a major priority. The government sought food imports from a variety of sources both within the region and beyond. But the scale of the deficit was such that the UN World Food Programme (WFP) became increasingly involved. As the major donor to the WFP, the US (through its aid program, USAID) provides support in terms of food grain (rather than financial contributions offered by most other donors). US maize is predominantly GM, and this raised questions about biosafety. The chair of the Board took a proactive stance in 2001 and organized several consultations on the issue. By the time the crisis was heating up, an emerging position existed within the Board.

But this was not just a technical decision, this was also hot politics. Initially, it appears that the WFP did not have thought through policy on GM food imports into the southern African region, and confusion reigned. One Board member complained: 'WFP behaved very arrogantly. They took no notice of the existing regulations'. The Board insisted that the whole importation question must come under the regulations, and any imports should be approved by the Board. This was expressed in strong terms to the WFP and USAID. As the controversy developed across the region, especially following the rejection of any GM imports of any sort by Zambia (Environment News Service, 2002) the pressure intensified [17].

This heated international and regional debate was preceded by several discussions within Zimbabwe. In November 2001, the Board met, together with a range of invited stakeholders, considered a range of different options, and finally decided on what was the most appropriate strategy for GM imports, assuming they would be needed. They concluded that based on available evidence from studies in the US and a 'basic understanding of gut physiology and biochemistry' the risks of consuming Bt maize were not significant. However, the dangers of introducing GM maize through planting were apparent, and so all maize coming into the country should be milled before distribution. To their credit, Board members took part in several public discussions around the food safety, environmental, and trade impacts of GM maize imports convened by NGOs and others during 2002 as the public and media debate heightened. There was also intense press interest in the issue in mid-2002, and Board members were expected to comment on the pros and cons. The context for the regulatory decision should be borne in mind. Even in late 2001, there was a sense of urgency and a need for a firm decision. From 2002, the pressure was high from the WFP, USAID, and the US State Department who issued 2002 a series of statements arguing that southern African states should accept GM food

or, in the words of Tony Hall, the US Ambassador to the UN Food and Agriculture Organization be accused of "crimes against humanity".

The decision to import, but to require milling, essentially said that the regulatory judgment was that eating GM maize was OK, but planting not, for a range of biodiversity, trade, and other reasons. That this decision required some short-cuts and leaps of faith is recognized by many. But as one Board member put it: As with the field trials, the capacity to test for the food safety of imported GM maize was severely limited, either in terms of assessing which, if any, antibiotic markers were being used in which shipment or, for longer-term effects, what were the consequences of eating GM maize in the volumes and at the frequency that Zimbabweans eat it. In other words, the FDA assessments on food safety with all its limitations.

The existence of the regulations, combined with prior discussions of the Board together with different stakeholders (admittedly limited, but including key NGO and government personnel), was important in providing authority for the decision nationally in the face of intense external pressure. But, in contrast to the image of science-based technocratic decision-making outlined by the Board registrar, the decision on GM food imports was projected into a wider political and diplomatic realm. With intensive lobbying behind the scenes, and high-profile visits to senior government officials and the President by the UN Special Envoy Morris, the niceties of technical biosafety regulations took a back seat. When President Mugabe traveled to the World Summit on Sustainable Development in Johannesburg in August 2002, events took another turn. He returned to Harare to be welcomed by the party faithful waving placards proclaiming that Zimbabwe should be GM-free.

There are several aspects of this debate that are of interest. Firstly, in the context of a heated public debate on GM imports, the government decided to act in a precautionary fashion, and adopt a position that assured the GM-free status of Zimbabwean maize seed. Similarly, the status of Zimbabwean livestock exports as non-GM fed would also be protected. As already mentioned, it is highly likely, according to many commentators, that GM maize has already found its way into Zimbabwe, as one board member put it: 'We are a landlocked country, our borders are porous. The whole country is a field experiment'. Given this, there is a symbolic element to the decision to block the import of maize seed, but one that sent an important signal to US GM companies and others wanting to by-pass regulations, as well as a parallel signal to export markets requiring GM-free status that Zimbabwe was keen to maintain this, for the time being at least.

The decision to mill reflected a choice that GM maize was safe to eat. This was based on particular and very limited models of food safety, alongside some, informed, but necessarily speculative, arguments about gut function and digestive chemistry. The establishment of new allergenicity or toxicity experiments, with designs taking into account the particularities of Zimbabwean consumption patterns, was deemed impossible and too expensive. Nor was it deemed necessary to go back and evaluate the circumstances of the production of the knowledge in the original FDA research documents, and what they left in and out. The decision to say that GM maize was safe to eat can therefore be seen as contingent in the extreme, with a precautionary stance on food safety abandoned in favors of quick action in the face of a growing food crisis [18].

Regulation of GMO crops and foods: Kenya case study

Three introductory points: first, Kenya's economy is heavily dependent on agriculture with nearly three quarters of Kenyans making their living from farming, producing both for local consumption and for export. Secondly, Kenya's population is high in proportion to its arable area and it is continuing to grow challenging the internal self-sufficiency paradigm that is at the core of Kenya's agricultural policy. Thirdly, most investments in biotechnology in Kenya have been in the field of agriculture.

The emerging GMO environmental, health and safety regulatory system in Kenya includes a combination of policy, legal, administrative and technical instruments set in place to address safety for the environment and human health in the context of genetic modification. It includes a proposed policy on biotechnology and biosafety, a draft GMO bill and regulations and guidelines for hands on work on genetic modification. These instruments include risk assessment and management procedures, mechanisms for monitoring and inspection and a system to provide information to stakeholders about the national biosafety framework and for public participation.

It is the regulatory framework that illustrates the normative principles guiding the investment in genetic modification in Kenya. These include the precautionary principle, environmental sustainability, poverty alleviation, assurance of food security and economic development. It is worth noting at the outset that the application of genetic modification in Kenya is in the infancy stage. There has not been any commercialization of GM products and current activities are in the laboratory and field trial stages. The approach to the technology is consequently based on conjectures and opinions from other countries rather than actual local experiences.

Government GMO regulatory and management authorities

A. National Environment Management Authority (NEMA)

Established under the Environment Management and Coordination Act, 2000, the National Environment Management Authority (NEMA) is the principal Government institution responsible for the implementation of all policies relating to the environment. It coordinates all environmental activities undertaken by various government departments and bodies.

B. The Kenya Plant Health Inspectorate Service (KEPHIS)

KEPHIS is a Parastatal agency under the Ministry of Agriculture that is mandated to regulate and facilitate all plant materials coming into the country or produced locally. They are also mandated to implement the national policy on the introduction, regulating imports of GM seeds and use of GM plant species.

C. Department of Veterinary Services (DVS)

The Department of Veterinary Services performs regulatory services with respect to livestock. It has no capacity to monitor GMOs coming into the country.

D. The Kenya Bureau of Standards (KEBS)

KEBS is the institution charged with the responsibility for developing standards, including food safety standards. The institution has developed standards pertaining to various products. KEBS is responsible for regulating GMO foods. However, KEBS has not developed any code of practice with regards to the manufacturing of GMO/products of modern biotechnology. Consequently, no standards have been made available to institutions for quality or for guidance on how to deal with emergency preparedness or risk issues.

E. National Council for Science and Technology (NCST) and

National Biosafety Committee (NBC)

The National Council for Science and Technology (NCST) of Kenya which is established under the Science and Technology Act chapter 250 of the Laws of Kenya and is within the Ministry of Education, Science and Technology was designated by the Government to lead the implementation of biosafety measures in the country. It hosts the National Biosafety Committee (NBC) which is a body constituted under the Science and Technology Act. It comprises of representatives of twenty-one (21) bodies ranging from Government Ministries such as the Ministry of Environment, Regulatory Agencies, Research Institutes, Government Departments, Universities and NGO's. The role of the NBC is to draw up policies and procedures for safe handling of biotechnology as well as scrutinizing applications for the introduction of GMOs in the country.

Officials of the NBC have insisted that their role is to facilitate all the concerned while still ensuring safety and sustainability of the biotechnology / GMO systems. Their main concern is the lack of capacity of the country at the moment to implement GM technologies.

Laws and regulations

Currently, the draft Regulations and Guidelines for Biosafety in Biotechnology for Kenya, issued in 1998 by the National Council on Science and Biotechnology, comprise the main instrument for regulating GMOs in Kenya. These regulations are based on the precautionary principle, prior informed consent or advance informed agreement, public participation and consultation, access to information (without prejudice to the protection of confidential information), access to justice (through compliance, liability, and compensation systems), and enforcement procedures and sanctions. They require that the release of GMOs be preceded by the approval of the National Biosafety Committee (NBC). Membership to the NBC includes representatives of relevant institutions and line ministries such as KEPHIS, NEMA, DVS, Attorney-General's chambers. The guidelines provide that it is an offence to import GMOs without prior approval of the NBC. Penalties for offences under the biosafety regulations were left to be made by the Minister. To do this the Minister requires the powers to be conferred upon him by an Act of Parliament. To date, this has not been done although there are some prescribed penalties in draft form under the proposed National Biosafety Bill [19].

The regulations require that the release of GMOs be preceded by the approval of the National Biosafety Committee (NBC). The main aim of the regulations is to enhance the effectiveness in the use of new products and ensure safety to human health and the environment. The function of the NBC is to review and ascertain the suitability of both physical and biological containment and control procedures appropriate to the level of assessed risk involved in relevant research, development and application activities.

The regulations require institutions carrying out work on genetic modification to establish Institutional Biosafety committees. These institutional committees are required to advise their respective institutions in drawing up proposals that take cognizance of applicable biosafety measures and advise their institutions on activities that should be brought to the attention of the NBC.

So far all applications received have research institutions and private companies from developed countries collaborating with Kenyan institutions (especially KARI). Upon review of an application, the NBC sometimes recommends conditions under which proposed work should be conducted. The construction of the Level-2 laboratory and a greenhouse complex at KARI was, for instance, a requirement for work on Bt. Maize in the IRMA project. Significantly, applicants must make separate applications to the NBC to work on GM in containment conditions, release into the environment and commercialization. In practice the NBC in Kenya applies relatively high standards in screening GMOs and is slow in approving imports of GMOs and related products. This may explain why so far there is no commercialization of GMOs in Kenya. The process is not open to public scrutiny and the author was not able to get the written accounts of the decision-making processes. The way in which the regulations have been applied has given rise to a lot of suspicion and the perception that GMOs are being brought in through the back door. The fact that the guidelines have not been made available in the government's Official Gazette and that their legal status is unclear has not helped to popularize the regulations and the institution implementing them.

Proposed GMO Bill

As discussed above, Kenya is in the implementation phase of the UNEP-GEF Project and is expected to develop a national biosafety framework which comprises a combination of policy, legal, administrative and technical instruments set in place to address safety for the environment and human health in the context of modern biotechnology. The broad elements of the framework include:

- Policy on biosafety;
- Legal/regulatory system;
- Administrative system to handle requests for permits which includes risk assessment procedures to help in decision-making;
- Mechanism for monitoring and inspection;
- System to provide information to stakeholders about National Biosafety Frameworks and for Public participation.

Within the implementation phase of the UNEP-GEF project another attempt at coming up with a binding law has been made. Thus in 2003, a draft GMO bill was generated as part of the national biosafety framework alongside the policy discussed above. This draft is yet to go through Parliament. Legislators discussing it in February 2005 requested that a legal team be tasked to look through it and refine it further. The legal team comprising lawyers from NEMA, the Attorney-General's chambers, private practice and the academy discussed the draft and made changes. The author has authoritative information that the revised draft will be taken to Cabinet in the month of June 2005.

The draft bill seeks to bring Kenya's law in line with the Cartagena Protocol on Biosafety which it has both signed and ratified. Its objectives are 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 to establish a transparent and predictable process to review and make decisions on such genetically modified organisms and related activities. It deals with applications for contained use, field trials, exportation and importation and placement on the market. It is not clear where food aid which Kenya gets from Europe, America and Canada would fall in these categories especially in light of the fact that GMOs intended for use as food, feed and for processing are exempt from the advance informed agreement procedures in the Cartagena Protocol.

The draft bill also establishes a National Biosafety Authority to administer the Act. The membership of the Authority comprises of

representatives of the National Environment Management Authority, Kenya Bureau of Standards, and National Council for Science and Technology, the Department of Veterinary Services, Kenya Plant Health Inspectorate Service, Ministries of Finance and Science and Technology among others.

The draft bill contains no provisions on labeling and/or traceability. This may be because there is no commercialization of GMOs yet.

Environmental Impact Assessment

In 2000, Kenya adopted the Environmental Management and Coordination Act (EMCA) which requires environmental import assessments for specified projects (Government of Kenya, Environmental Management and Coordination Act, 1999). The EMCA is administered by NEMA. Under the EMCA, environment impact assessments (EIAs) are required to be undertaken for biotechnology projects, including the introduction and testing of genetically modified organisms.

Liability

The country's position on liability for damages caused by GMOs has not been consistent. The position taken depends largely on the key actors in the framing of the provisions. For instance, the proposed Kenya Legal Framework for safety in Biotechnology in 1999 adopted the African Model Law on Biosafety provisions on liability and redress, including strict liability, provisions for costs of reinstatement, rehabilitation or clean-up and preventive measures incurred. This was influenced by the environmental lawyers in the group. The more recent initiative, the draft GMO bill which was generated by a group comprising more scientists than lawyers, provides that "liability and redress for any damage that occurs, as a result of activities subject to this Act, shall be addressed by applicable laws".

The three torts that are relevant to liability and redress for biotechnology are negligence, nuisance and the rule in Rylands Vs Fletcher. Given that these laws predate biotechnology activities and may not cover all kinds of damage likely to arise from biotechnology activities, the issue of their efficacy has been raised and the need to work out a suitable liability and redress system for GMO intimated [20].

Public Participation

Public participation in environmental decision-making has been accepted as a guiding tenet in environmental law in Kenya and the concern for procedural rights including participation of the public is now part of Kenya's environmental law. This has followed from Principle 10 of the Rio Declaration on Environment and Development, Rio de Janeiro, Brazil (1992). The states parties to the declaration also commit themselves to grant the right of access to information held by public authorities to each individual citizen, the opportunity to participate in decision-making processes, and effective access to judicial and administrative proceedings, including redress and remedy. Increasingly, these rights have been adopted in emerging international treaties on the environment such as the Convention on Biological Diversity (1992) and its Cartagena Protocol (2000), and also in domestic legislation.

Regulatory Capacity

The regulatory capacity of most of the institutions including the NCST is very low. Some of the members of the NBC are drawn from bodies that carry out GMO work such as KARI. This raises issues of a potential conflict of interest where an application is made by an institution represented on the NBC. Since the deliberations of the NBC are not made public, it is difficult to determine how the likelihood of a conflict of interest is handled in the decision-making process. Further, though Kenya has trained a big number of regulators, few of them remain in government owing to the low remuneration. Related to this is the fact that the infrastructure for regulation has not been modified to accommodate GMOs. It is apt to say that there is no regulatory capacity in KEPHIS to regulate GMO even though capacity building is taking place. Moreover, the regulatory authorities are not well synchronized. There is for instance no reason why Kenya should not work towards establishing one regulatory authority for agriculture to include both plants and livestock.

Zambia: "We need to unravel the mystery and mystique around GMOs, and that has to start with scientific understanding."

Dr. Stephen Muliokela, director, Golden Valley Agricultural Research Trust

Zambia was the locus of heated domestic and international debates around genetically modified grains in the early 2000s, when, in the face of a mounting regional food crisis, then-president Levy Mwanawasa announced that the country would no longer accept emergency food aid that contained GMOs. Mwanawasa's stance became Zambian national policy, and the controversy sur-rounding GMOs, though less forcefully debated today, continues to a large extent to shape current attitudes.

In August 2002, the minister of information announced the government's decision not to accept genetically modified foods, despite the ongoing food crisis:

The minister cited the absence of a biotechnology policy framework; the absence of evidence on the possible risks to human safety and the environment; and the possible threat of contamination of local indigenous and hybrid seed stocks.

From there, rhetoric surrounding the issue took on political and emotive overtones that remain very fresh in the minds of Zambians today. "Beggars can't be choosers," said an unnamed State Department official, quoted widely in Zambian and African media reports of the time. "People that deny food to their people, that are in fact starving people to death should be held responsible for the highest crimes against humanity in the highest courts in the world," said Tony Hall, then U.S. ambassador to the United Nations Food and Agriculture Organization (US Calls Food Aid Refusal by Zambia a Crime against Humanity, 2002).

President Mwanawasa responded to critics: "Simply because my people are hungry, that is no justification to give them poison, to give them food that is intrinsically dangerous to their health," he told the Summit on Sustainable Development in Johannesburg in December 2002. "I will not allow Zambians to be turned into guinea pigs, no matter the levels of hunger in the country".

In this polarized atmosphere, in the midst of a food emergency, there was little room for dis-passionate debate. Zambia became a cause célèbre for biotechnology opponents, and fact, rumor, and ethical, nationalist, and pragmatic trade rationales very quickly created a jumble of negative publicity and fueled public suspicions even further. In the absence of any existing biosafety law or regulatory framework, President Mwanawasa's stance became national policy and permeated all levels of government as well as the public discourse.

Today, much of the heat has gone out of the debates around GMOs.

Although the "precautionary principle" still stands, few Zambian researchers or officials will outright dismiss the possibility of eventually adopting GM technologies.

Policy and Regulatory Framework

The Zambian parliament passed the Biosafety Act in April 2007, calling for the establishment of a National Biosafety Authority to receive and vet applications for research, development, import, transit, contained use, release, and commercialization for genetically modified organ-isms. The legislation further lays out mechanisms for liability and redress for any harm or damage caused to human and animal health, non-GMO crops, socioeconomic conditions, and biological diversity.

While the bill does not outright ban GMOs, most stakeholders see the legislation as more prohibitive than facilitative of biotechnology research. In fact, in introducing the bill to the parliament, the chair of the drafting committee emphasized that it was "aimed at ensuring that Zambia remains a GMO free country."

South Africa: "I really don't like the idea of having genes in my food." South African MP

"You ask people if they want labeling of GM foods and they say 'yes.' Then you ask them if they know what GM foods are and they say 'no". Senior official in the South African Department of Health South Africa stands apart from the rest of Africa in having a long-established and relatively well-resourced scientific community. This distinguishing feature to a large extent explains the country's early embrace of GM crop production, which was given strong encouragement by scientists. South Africa has grown GM crops since 1997, when Bt cotton was first approved for commercial release. It is now the eighth-largest producer of biotech crops in the world, growing 2.1 million hectares of genetically modified maize, cotton, and soya in 2009. More than 90 percent of the cotton grown in South Africa is genetically modified; the figures for soya and maize are 80 percent and 62 per-cent respectively. South Africa has therefore grown far more GM crops, and for far longer, than any country in Africa. South Africa is also unusual in that it produces and exports both GM and non-GM food products, maintaining parallel production lines for them both.

Laws and Policies

South Africa has developed a detailed policy and legal framework covering biotechnology generally and genetically modified organisms specifically. Lawmakers have tended to struggle to keep pace with the scientists, who have advanced the technology at a rapid rate, then led demands for regulations to go with it. The main piece of legislation governing the production and use of GMOs in South Africa is the Genetically Modified Organisms Act, passed in 1997 and amended in 2006. Under the act, which is administered by the Department of Agriculture, all applications to develop GMOs or release them into the environment must be approved by the Executive Council. The council consists of officials from six (soon to be eight) government departments, including agriculture, health, environmental affairs, and science and technology. The council reaches its decisions by consensus, based on the recommendations of an advisory council of scientists. If an application is approved, a permit is issued by the registrar of the GMO act.

The task of limiting the environmental impact of GMOs lies with the Department of Environmental Affairs. It operates the National Environmental Management: Biodiversity Act of 2004, which aims to guard against habitat destruction and prevent GMOs from upsetting the ecosystem and threatening plants and wildlife.

The Department of Health looks after issues pertaining to food safety, through the Foodstuffs, Cosmetics and Disinfectants Act of 1972. Under a 2004 act, products containing GMOs need only be labeled as such if they substantially differ from their non-GMO equivalents in terms of com-position, nutritional value, and mode of storage, preparation, or cooking. This does not apply to any products currently on the market in South Africa. Some companies choose to label their produce as "GM-free," though a 2006 study found that many of them did in fact contain GM ingredients.

Asia

GM food policy framework in India

Overview and history: Cracks in the approval process for GM processed foods Since 1989, the Genetic Engineering Appraisal Committee (GEAC) under the Ministry of Environment, Forest and Climate Change (MoEF&CC) has been responsible for approving commercial cultivation of GM crops as well as the manufacture, import and selling of processed foods made from GM ingredients. So far, Bt cotton has been approved for cultivation. After the enactment of the Food Safety and Standards Act in 2006, the GEAC wanted to restrict itself to approval of living modified organisms (LMOs) and shift the task of approval of processed foods to the FSSAI for which a notification was also issued in 2007.

In February 2018, the Union minister, MoHFW, on being asked about the vacuum in regulation of GM foods, made the following noteworthy statements in the Lok Sabha:

- Genetically Engineered Organisms (GEOs) or LMOs, intended for direct use as food or for processing as food, would continue to first require approval from the GEAC for environmental safety and then require approval of the FSSAI for food safety.
- Food or processed food containing GM ingredients produced from but not containing LMOs or GEOs would require approval of FSSAI.
- No standards for GM foods have been laid down/notified by the FSSAI. However, even in the absence of specific standards for GM foods, and Standards Act, 2006, GM foods are not allowed to be manufactured, imported or sold in the country.

Conclusion

Crops improved through biotechnology have been widely adopted by farmers around the world wherever farmers have been able to secure access to the seeds and where they do not fear the loss of export markets. However, governments in some regions have created significant impediments to farmers' use of GMO-improved seeds, most conspicuously in Europe, which has exported restrictive regimes wherever they can, with particular success in sub-Saharan Africa. African farmers' access to biotech-improved seeds has been severely and directly limited by threats from Europe to close their access to export markets; and by regulatory barriers to innovation erected through a global effort by EU and member states to create regulations in other countries that block farmers' access to biotech-improved seeds. And on top of that, a wide array of NGOs, more interested in pursuing an anti-corporate agenda than a pro-development agenda, have worked to convince nations to ban or otherwise limit productivity-enhancing GMOs. Consequently, in most cases, seeds for GM versions of African

crops simply don't exist. Even in the few cases where biotech-improved seeds do exist, it is difficult or impossible for farmers to gain access.

Despite the strongly positive track record of biotech-derived crops for farmers, consumers, and the environment, unexploited opportunities for additional, widely shared benefits are considerable. We estimate the economic value forgone in Africa from restrictive regulation at $1 billion in 2013. If such regulations continue to restrict and suppress innovation in agriculture, the cumulative costs to low- and lower-middle-income countries worldwide will be approximately $1.5 trillion by 2050. Because of the unprecedented demands to increase agricultural production and productivity over the next 30 years, such restrictive regimes must be rolled back everywhere as rapidly as possible.

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