Modern Biotechnology in the European Union: *Perceptions versus Reality*

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Introduction:

Much of the debate about modern biotechnology, specifically genetically modified organisms (GMOs) in Africa has relied more on the perceptions created out of the divergent views and ideologies on the technology between Europe and the USA, rather than facts (Anderson & Jackson, 2003).

Importantly, and for obvious historical trade ties between Africa and Europe, internal risk policies of a few private European food importing companies demanding "organic produce", and pronouncements by some opinion shapers have been taken as official European Union (EU) position on GM technology. To a large extent, this has created confusion and complicated policy choices for African countries as the same ideologies find their way into government offices and influence decision makers.

The popular belief in the African public opinion is that "Europe is categorically against GM-technology". But, is EU a no-go zone for GMOs? What is the official current status of research, regulatory, planting and trade with genetically modified crops in the EU? What informs research and development of the technology in the EU?

This policy brief is an attempt to share the most current status of GM technology in the EU with a view to enhancing understanding of the trends and factors that inform policy choices by its member states.

GMOs research and development in the EU

The most comprehensive update of research on GMOs in the EU is contained in the report "A decade of EU-funded GMO research (2001 - 2010)" by the Directorate-General for Research and Innovation. Biotechnologies: 2010. For 25 years, the EU has provided research grants to more than 130 research projects, involving more than 500 independent research groups. Many of these research projects were launched to address not only the scientific unknowns but, more importantly, public concerns about the potential environmental impact of GMOs, food safety, the co-existence of GM and non-GM crops, and risk assessment strategies.

The report concludes that biotechnology, and in particular GMOs, are not *per se* more risky than conventional plant breeding technologies. Projects dealing with the development of new products and processes based on GM technology fully integrate safety assessments in their conception, experimentation and development. Further, EU boasts of a very strong R&D base in life sciences including agricultural biotechnology. Between 1992 and 2008 for example, about 2,404 field trials had been conducted in EU countries. This is against 14,300 trials in the US from 1987 to 2008.

Indeed, one of the flagship initiatives in the 'Europe 2020' strategy, adopted by the European Council in 2010 is the creation of an 'Innovation Union' with a focus on building a Bio-Economy by 2020. The Bio-Economy, as defined by the OECD, refers to economic activities relating to the invention, development, production and use of biological products and processes, allied with significant advances in the life sciences and biotechnologies.

The current regulatory framework for GMOs in EU

Generally, the regulatory framework in industrialized countries including the EU member states has evolved over time from the early 1980s culminating into the publication of the OECD Recombinant DNA safety recommendations or the so called "Blue Book". The first outline of the European Commission Directives on GMOs was published in 1987. Ever since, various Directives and Regulations have been developed, reviewed and revised. They include:

Environmental safety

- Directive 2009/41 on contained use of genetically modified microorganisms (replacing Directives 90/219/EC and 98/81/EC)
- Directive 2001/18/EC on the environmental release of genetically modified organisms (replacing Directive 90/220/EC)
- Regulation 1946/2003 on trans-• boundary movements of genetically modified organisms for implementing the Cartagena Protocol on Biosafety, an international legally binding instrument on Biosafety by its signatories.

Food Safety

- Regulation 1829/2003 on genetically modified food and feed
- Regulation 1830/2003 concerning traceability and labelling of GMOs. (Ref: PRRI, 2010)

In addition to these directives and regulations, there are various guidance documents, for example, on information requirements, environmental risk assessment, food and feed safety assessment, monitoring and sampling, and related areas such as co-existence. The European Food Safety Authority (EFSA) is responsible for carrying out risk assessment of GMOs in the EU. Member States participate throughout the risk assessment process. An EFSA GMO Panel is responsible for preparing and adopting the GMO risk assessment dossier, upon which decisions on GMO authorisation applications are made.

Current procedure for authorising the cultivation of GMOs in the EU

GMOs are authorised on a case-by-case basis and on the basis of the particular uses defined by the applicant. The GMOs are subjected to rigorous health and environmental risk assessments. Applications for cultivation can be submitted under EC Regulation No.1829/2003 for GM food and feed. Directive 2001/18/EC is also used to authorise for deliberate release of GMOs into the environment for uses other than food/feed. In both cases, Member States play a significant role, carrying out the initial risk assessment of the GM crop intended for cultivation.

Cultivation of GM crops in the EU

By 2010, two GM events had been approved for cultivation in the EU (Figs. 1&2). One GM maize event– MON 810 authorised in 1998 occupies the largest area and aims to protect maize against a harmful pest – the European corn borer. It is cultivated in Czech Republic, Poland, Portugal, Romania, Slovakia and Spain. A GM starch potato, known as "Amflora" potato, was authorised for cultivation and industrial processing in March 2010. The potato has increased amylopectin starch content and is intended for industrial uses. Amphlora potato is cultivated in Czech Republic, Germany and Sweden.

Figure 1: Cultivation of GM Crops in the EU



Figure 2: Biotech Crops Cultivation in the EU



GMOs authorised in the EU for feed and/or food uses

Besides cultivation, placing on the EU market of GMOs and the use of their derived products in the food and feed chain is subject to an EU authorisation. As of 2010, authorised GMOs included one sugar beet, three soybean, three oilseed-rape, 7 cotton and 23 maize products. "Amflora" starch potato is the most recently authorised GM crop and its by-product (pulp) is authorised as feed. A list of authorised GM plants and the precise scope of their authorisation is available in the EU register of GM food and feed, which can be found at:

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

Besides, 70 GMO products are currently in the EU approval process. They include 21 for cultivation (maize, potato,

Figure 3: Net imports of soybean into the EU-27 from the rest of the world, 1998-2008, by country in million tonnes (excl. soybean for sowing)



soybean, sugarbeet) and 49 for food, feed, import and processing. Volumes of GM produce, particularly GM-soya beans, are imported from the Americas for the feed industry (Fig. 3). Labelling, unlike GM food, is not a requirement in EU for livestock products based on GM feed.

Opposition to GMOs in the EU: A mix of ideologies and self-interests

A strong movement of opposition to genetic engineering in agriculture has developed throughout the world, particularly so in some EU countries. The movement has led to hostility towards GMOs, as well as to acts of vandalism of research trials. Some member states (Austria, France. Germany, Greece, Hungary and Luxembourg) have prohibited the cultivation of the GM maize MON810 on their territories. However, in a historical ruling in September 2011, the European Court of Justice ruled as illegal, the French cultivation ban of GM maize. Countries like Austria, Hungary and Luxembourg have notified the Commission of their intent to prohibit the cultivation of the "Amflora" potato. Germany however approved its cultivation in 2010. Poland has legislation in place forbidding the marketing of all GM seeds, even though some of the country's farmers are still cultivating GM maize.

Opposition to GMOs in some of these countries is associated more with political and ideological

predispositions than scientific evidence. A group of Swedish scientists have criticised EU's legislations on GM crops terming them "overregulated and expensive", consequently making product development by the public sector extremely difficult

(http://blogg.slu.se/forskarbloggen/? p=433).

On the other hand, more than 87 recombinant (GM) drugs have been approved by European Pharmaceuticals and Medicines Agencies since 1982 (Paarlberg 2008). The divergence in acceptance of medical versus resistance to GM foods or crop biotechnology in the EU therefore reinforces the fact that it is not the practice of genetic engineering as such that some member countries find unacceptable or unsafe, but rather, the purpose for which the technology is applied. Opinion is divided among the member states but one thing that is very clear is that priorities are different in the decision-making on when and how to apply the technology.

The EU is heavily dependent on imported proteins for food and feed purposes. Ninety percent of imported soybean, for example, is sourced from lead GM soybean growing countries of Argentina, Brazil and Canada. Europe does not have the optimum environment to produce and non-GM soybean is becoming more difficult to source and increasingly costly. This means economic considerations exert more weight when it comes to sourcing of livestock feed.

For the majority in the EU where food is abundant, there may be no incentives to apply modern biotechnology to produce more. However, increasing longevity is high priority for them, thus

Conclusion:

This overview indicates that contrary to common perceptions, EU continues to make investments in biotech research and acknowledges the importance of the technology in its 2020 strategic plan. EU countries also import and consume millions of tonnes of GM produce where social and economic benefits are demonstrated. African policy decision makers. without compromising *biosafety* considerations and social responsibilities - and equally without re-inventing the wheel – need to consider GM technology on a case-by-case basis and with due considerations to socio-economic realities. From the regulatory viewpoint, the on-going regional harmonisation processes, such as those by COMESA and ECOWAS, could learn from EU's experience, but should not necessarily emulate it.

there is wide acceptance and investment in modern biotechnology applications and products in medicines and pharmaceuticals. The contrary is true in sub-Saharan Africa (SSA) where food insecurity is a daunting challenge. The majority of countries account for almost 85% of emergency food aid deliveries globally. Cyclical droughts whose recurrence has increased over the years, pest infestation and low productivity predispose SSA countries to perpetual food insecurity and degradation. This environmental makes technological interventions including genetic improvement of staple crops aimed at increasing production in African agriculture a moral imperative.

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ACTESA was established by the Heads of State of COMESA in 2009 as a Specialized Agency to integrate small farmers into national, regional and international markets. The main goal of ACTESA is to increase farmer productivity and incomes in the Eastern and Southern Africa region through trade in strategic agricultural commodities. www.actesacomesa.org

The Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA) is a non-political organization of the National Agricultural Research Institutes (NARIs) of Burundi, D. R. Congo, Eritrea, Ethiopia, Kenya, Madagascar, Rwanda, Sudan, Tanzania and Uganda. It aims at increasing the efficiency of agricultural research in the region so as to facilitate economic growth, food security and export competitiveness through productive and sustainable agriculture. www.asareca.org

The International Service for the Acquisition of Agri-biotech Applications (ISAAA) is a non-profit making international network founded in 1990 to facilitate the acquisition and transfer of agricultural biotechnology applications and knowledge-sharing for the benefit of resource-poor farmers in the developing world. www.isaaa.org

The Program for Biosafety Systems (PBS) is managed by the International Food Policy Research Institute and supports partner countries in Africa and Asia in the responsible development and safe use of agricultural biotechnology. PBS is funded by the U.S. Agency for International Development. http://pbs.ifpri.info/

