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# Trends in Biotechnology

## Africa needs streamlined regulation supporting deployment of GM crops

--Manuscript Draft--

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<b>Corresponding Author:</b>	Howard Atkinson, Ph.D. University of Leeds Leeds, W. Yorkshire UNITED KINGDOM
<b>First Author:</b>	Howard Atkinson, Ph.D.
<b>Order of Authors:</b>	Howard Atkinson, Ph.D. Hugh Roderick, PhD Leena Tripathi, PhD
<b>Abstract:</b>	Future food security in Sub-Saharan Africa requires enhancement of its crop production. Transgenic crops with a poverty focus can enhance harvests and are available for staples such as cooking bananas and plantains. One constraint is optimisation of national biosafety processes to support rapid and safe uptake of such beneficial crops.

# Africa needs streamlined regulation supporting deployment of GM crops

Howard J. Atkinson<sup>1</sup>, Hugh Roderick<sup>1</sup> and Leena Tripathi<sup>2</sup>

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<sup>1</sup>Centre for Plant Sciences, University of Leeds, Leeds LS2 9JT, UK.

<sup>2</sup>International Institute of Tropical Agriculture, Nairobi, Kenya.

**Future food security in Sub-Saharan Africa requires enhancement of its crop production. Transgenic crops with a poverty focus can enhance harvests and are available for staples such as cooking bananas and plantains. One constraint is optimisation of national biosafety processes to support rapid and safe uptake of such beneficial crops.**

## 15 Keywords

Genetic Modification (GM), Regulation, Africa, Biosafety

### Africa and food security

The population of Africa is projected to double by 2050 and to comprise 25% of the world population by 2100. Feeding all on this continent is a major future challenge. Sub-Saharan Africa (SSA) is currently the largest global receiver of food aid and yet 23.8% of its current inhabitants are undernourished [1]. Future food security may be enhanced by effort in some regions of high need where cereals such as rice are key crops [2]. That approach is inadequate for the humid tropics of SSA e.g. Southern Nigeria [2] where banana and plantain (*Musa*) feed more people per unit area than other staple crops. They are cheaper to produce than rice or wheat [3] and they do not suffer the level of global price shocks that occur for staples such as rice, maize and wheat to which many SSA countries are vulnerable. A further concern is that output is mainly increasing in SSA by expansion of cultivated areas, which has long-term consequences for African biodiversity.

Broad-ranging support is required for agricultural improvements in SSA including recognition of farmer needs, widely available and affordable planting material, dissemination of knowledge for their effective use and access to markets. Policy makers concerned about food security should consider genetic modification (GM) approaches when other solutions to identified problems are unavailable [4]. This requires effective regulations to advance safe traits without undue delay. Several SSA countries already have biosafety regulations and others are developing regulatory laws for research and commercial release of GM crops. Our concern is external influences that slow rate of progress to uptake of safe GM crops. Such delays have several causes including misinformation campaigns of certain non-governmental organisations (NGOs) and the influence of the European Union (EU). Its sway stems from being a major funder of development assistance to both Africa and international biosafety programmes [5]. One perceived risk is a potential reduction in exports to the EU and elsewhere once products are transgenic. A compensatory fund financed by biotechnology companies has been suggested to offset these market losses [6]. This approach may not be readily agreed, is indirect and does not address deployment of GM public goods. It is irrelevant to key subsistence crops such as cooking banana and plantain that have large national

50 markets but limited export markets. We recommend development of a regional regulation approach that supports safe uptake without undue delay. This is needed to maximise the contribution of GM crops to future food security in Africa.

### **A case study: transgenic plantain and cooking banana**

55 Banana and plantain crops are suited for transgenic improvement for food security in SSA. Their sterility impedes improvement by traditional cross-pollination techniques but enables development of beneficial GM traits without risk of gene flow to other crops or wild relatives [3].

60 Banana Xanthomonas Wilt (BXW) has caused estimated economic losses of \$2–8 billion over the last decade in Africa in the absence of effective natural host plant resistance. Two transgenically expressed resistance genes enhance the hypersensitive response when plants are challenged with bacterial pathogens. This resulted in 100% resistance to BXW over three successive crop cycles with no  
65 adverse effect on flowering and yield characteristics (Figure 1) [9]. The two proteins do not resemble potential allergens and occur naturally in foods such as rice and peppers.

Nematodes cause losses of up to 70% to banana and plantain in SSA. The  
70 expression of two novel transgenic traits has provided up to 99% nematode resistance in a field trial (Figure 1). One transgene is a non-toxic cystatin found naturally in foods that is not an allergen [3]. The second is a non-lethal small peptide that disrupts nematode orientation to roots. It lacks the minimum of 12-30 amino acids containing two IgE-binding sites required of an allergen [10]. When expressed  
75 in potato, neither defence had an adverse impact on non-target organisms in field trials [8]. In both the above examples, co-expression of different transgenes for resistance will be employed to enhance future durability of the GM resistance to BXW or nematodes. The National Biotechnology and Biosafety Bill has been debated by the Ugandan parliament since 2012 and is expected to be passed soon  
80 enabling the future deployment of safe GM crops to farmers (<http://www.monitor.co.ug/News/National/NRM-caucus-backs-GMOs/-/688334/2707408/-/w4x9fkz/-/index.html>).

### **Developing an efficient regulatory system for Africa**

85 Only South Africa, Burkina Faso and Sudan currently grow GM crops commercially but 15 SSA countries have biosafety laws with draft bills in a further eleven countries [11]. About 13 GM traits in seven crops are currently being assessed in eight SSA countries [14]. They can be subdivided into: i) those that have passed regulatory assessment elsewhere for that crop (e.g. Bt cotton) ii) others offered in an additional  
90 crop (Bt in cowpea for pod borer resistance, [12]) and iii) novel traits. We suggest repeating food safety assessments for a transgenic protein already considered safe is unnecessary for an additional food providing the margin of safety remains above 100 fold. The main issues for already deployed crops and traits are *de novo* environmental concerns associated with cropping in Africa. Both food and  
95 environmental assessments are required for novel traits.

The Cartagena Protocol (CP) on Biosafety to the Convention on Biological Diversity (<http://bch.cbd.int/protocol/>) imposes a challenge for SSA countries seeking an inexpensive and rapid assessment of environmental biosafety. CP does not define

100 when its precautionary principle can be set aside by evidence of safe use, nor does it  
give any weighting to potential benefits, which has anti-poor consequences. CP's  
approach is also partial because it is not extended to other considerable biodiversity  
concerns such as future, intentional introductions of non-transgenic, alien organisms.  
Real concerns relate to the consequences of past introductions such as Nile Perch  
105 to Lake Victoria. It has had unintended direct and indirect negative impacts on fish  
biodiversity but benefited local human populations [13]. The CP supplementary  
protocol (Nagoya-Kuala Lumpur, <http://bch.cbd.int/protocol/supplementary/>) enables  
countries to enact legislation that imposes legal liability on GM technology providers.  
Such a law provides a disincentive for biotechnology companies and a major  
110 hindrance for not-for-profit public goods. Politicians and regulators in SSA must avoid  
the negative impacts of CP while delivering its aim of assuring environmental  
biosafety.

An agreed common approach to regulation across SSA countries would provide an  
115 economy of scale, resources and expertise and help offset delays to regulatory  
decisions by national biosafety committees that depend on part-time members [12].  
Knowledge-sharing would enhance the evidence base for decision processes by  
currently less experienced national bioregulators. South Africa has the most regulatory  
experience of commercialisation in SSA to underpin such an initiative [12].  
120 A broadly based SSA approach, however, would be a challenge to achieve in the short  
term. A regional approach may be simpler, particularly for crops like plantain and  
cooking bananas, which are restricted to humid regions of SSA. Progress would be  
enhanced by either a virtual or a physically assembling transnational regulatory  
committee. This could involve experts from those SSA countries permitting confined  
125 field trials for any crop and considering deregulation. Additional countries could join  
when they reach that position. Information gained from initial steps and confined field  
trials could be pooled and standards set that adhere to Codex Alimentarius and  
assure environmental biosafety. Costs are likely to be highest for the first crops and  
traits that are assessed, but would be split amongst members. Experience and  
130 reduced frequency of new issues should enhance subsequent rates of progress and so  
reduce costs.

### **Addressing Public concerns**

A transnational body of regulators could develop guidelines on both public  
135 consultation and countering misinformation campaigns. An example of the latter need  
is an evidenced-based dismissal of a falsely alleged increase in Indian farmer  
suicides after adoption of Bt cotton [14]. Misinformation campaigns occur in SSA  
countries (e.g. <http://www.independent.co.uk/news/world/actionaid-the-charity-spreading-groundless-fears-over-gm-10126504.html>). They have delayed but  
140 probably not prevented passing of a law allowing deployment of safe GM crops in  
Uganda.

### **Concluding Remarks**

The nematode and bacterial wilt resistant cooking banana and plantains we have  
145 developed provide one basis for assessing pro-poor novel traits. The probability of a  
safe outcome is likely and the traits have a combined estimated value of >\$1,000  
million for just Uganda over 30 years [15]. They are sterile plants which reduces the  
range of environmental biosafety issues relative to most other crops. The aim must be  
a regulatory system that minimises both costs and delays by attending only to

150 scientifically valid risks. Regulators in SSA require protection from excessive  
commercial, NGO and political influences including those emanating from the EU [5].  
Their processes must favour rapid assessment and uptake of safe GM crops.  
Streamlined regulation will not alone meet the future need. Additional barriers to be  
155 overcome include misinformation, polarized public opinion and unsatisfactory  
political management of conflicting viewpoints by allowing GM crop field trials but not  
their release to farmers [12]. Progress soon is important so SSA nations retain control  
of introductions rather than having to respond to GM traits being introduced illegally  
across porous country boundaries. SSA countries need to reduce a dependence on  
160 aid for food security rather than risk future donor fatigue.

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## LEGEND FIGURE 1

**Figure 1:** Transgenic control Banana Xanthomonas Wilt (BXW, [9]) and nematodes  
200 [3].

a) Severely BXW affected plant showing rotten fruit in a bunch b) fruit of a non-  
transgenic plant in a contained field trial showing premature ripening c) fruit bunch

of a transgenic plant from the same field trial showing no external symptoms. The nematode *Radopholus similis* (d, stained) rots plantain and banana roots resulting in reduced plant growth and loss of bunches caused by toppling of the plants during storms (e). A confined field trial has established the nematode induced stunting of first ratoon plants (f) can be prevented by transgenic expression of a peptide (g).

**Box 1: Assessing Biosafety of GM crops**

210 **Food biosafety:** The Codex Alimentarius Commission (FAO and WHO) framework defines the information required of GM food crops, including the transgene source, the insert and flanking DNA sequence, potential toxicity/allergenicity, anti-nutritional characteristics and effects on endogenous nutrients, toxins and allergens. A minimum margin of 100 fold between exposure levels for animals without adverse effects and the estimated human daily intake of the transgenic protein indicates safe food. Ensuring the novel protein has less than 35% identity to known allergens over 80 amino acids using databases avoids complex IgE tests for allergens. Such allergenicity assessment is limited by absence of prevalence data for food allergens and information on common food triggers in SSA populations [7].

220 **Environmental biosafety:** Key issues are prevention of transgene flow to other plants and lack of adverse effects on non-target organisms. Impact is assessed for a subset of indicator species with emphasis on beneficial organisms or those of a conservation concern. The range will depend upon the hazards associated with the transgenic protein and factors such as tissue specific expression that affect exposure levels. Bar-coding of non-target organisms represents one robust environmental risk assessment approach for SSA and elsewhere [8].

Figure

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