

Africa needs streamlined regulation to support the deployment of GM crops

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Future food security in sub-Saharan Africa (SSA) 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 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. Although SSA is currently the largest global receiver of food aid, 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]. This approach is inadequate for the humid tropics of SSA, for example, in 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, and dissemination of knowledge for their effective use and access to markets. Policymakers 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 the rate of progress towards uptake of safe GM crops. Such delays have several causes including misinformation campaigns of some non-governmental organisations (NGOs) and the influence of the 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 the deployment of GM public goods. It is irrelevant to key subsistence crops such as cooking banana and plantain that have large national markets but limited export markets. We recommend development of a regional regulatory 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

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

Banana Xanthomonas wilt (BXW) has caused estimated economic losses of \$2–8 billion over the past 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 adverse effect on flowering or yield characteristics (Figure 1) [9]. The two proteins do not resemble potential allergens and occur naturally in foods such as rice and peppers.

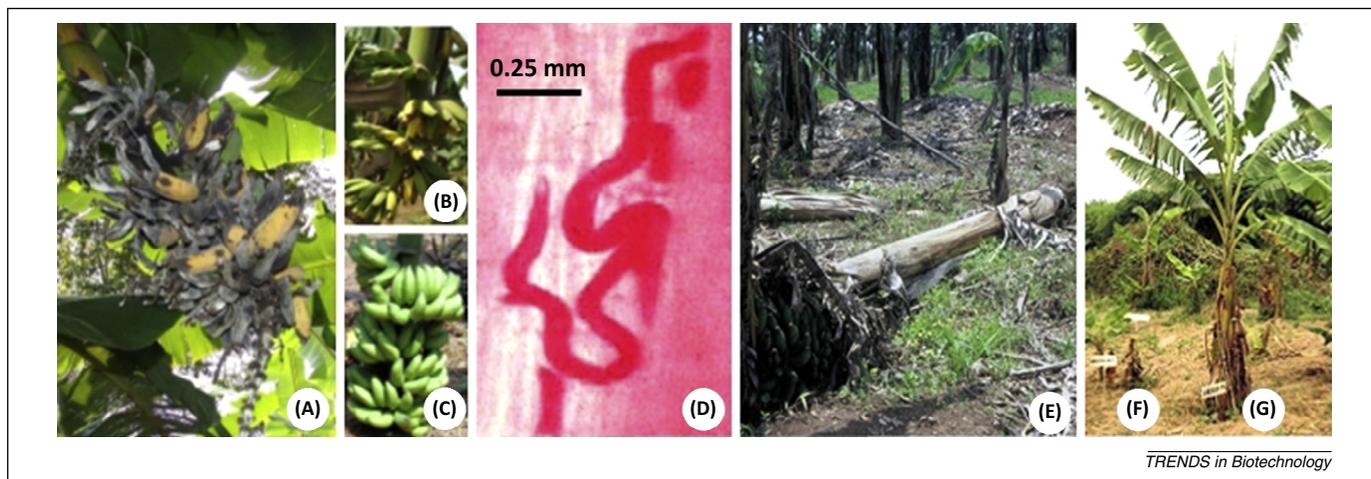
Nematodes cause losses of up to 70% to banana and plantain in SSA. The expression of two novel transgenic traits has provided up to 99% nematode resistance in a field trial (Figure 1). One transgene encodes a non-toxic cystatin found naturally in foods that is not an allergen [3]. The second encodes a non-lethal small peptide that disrupts nematode orientation to roots. It lacks the minimum 12–30 amino acids containing two IgE-binding sites that are required of an allergen [10]. When expressed 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, enabling the future deployment of safe GM

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Figure 1. Transgenic control of banana *Xanthomonas* wilt (BXW) [9] and nematodes [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* (stained) (D) 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 that nematode-induced stunting of first ratoon plants (F) can be prevented by transgenic expression of a peptide (G).

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

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 11 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 crop (Bt in cowpea for pod borer resistance [12]); and (iii) novel traits. We suggest that repeating food safety assessments for a transgenic protein already considered as safe is unnecessary for an additional food, provided that the safety margin remains above a factor of 100. The main issues for already deployed crops and traits are *de novo* environmental concerns associated with cropping in Africa. Both food and 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. The CP does not define 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. The approach of the CP is also partial because it does not extend 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 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 is a major 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 economy of scale, resources, and expertise, and would help to 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]. 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 assembled transnational regulatory authority. This could involve experts from those SSA countries permitting confined 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 the *Codex Alimentarius* (Box 1) 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 reduced frequency of new issues should enhance subsequent rates of progress and thus reduce costs.

Addressing public concerns

A transnational body of regulators could develop guidelines for both public 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 probably not prevented,

Box 1. Assessing the biosafety of GM crops

Food biosafety: the *Codex Alimentarius* (FAO and WHO; <http://www.codexalimentarius.org/>) 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 100-fold margin 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 the absence of prevalence data for food allergens and information on common food triggers in SSA populations [7].

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 on factors such as tissue-specific expression that affect exposure levels. Barcoding of non-target organisms represents one robust environmental risk-assessment approach for SSA and elsewhere [8].

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 developed provide one basis for assessing pro-poor novel traits. The probability of a safe outcome is high, and the traits have a combined estimated value of >\$1000 million for only 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 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 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]. Prompt progress is important to ensure that SSA nations retain control of introductions rather than having to respond to GM traits introduced illegally across porous country boundaries. SSA countries need to reduce their dependence on aid for food security rather than risk future donor fatigue.

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