GUIDANCE FOR A FIT-FOR-PURPOSE REGULATORY FRAMEWORK FOR GMOS
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Consensus Document

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This document is a guideline to assist the development and enhancement of a fit-for-purpose and proportionate regulatory framework for GMOs in agriculture in sub-Saharan Africa (SSA) that includes a reasonable set of regulatory principles and considerations to ensure the safety of human health and the environment, whilst providing the opportunity to access the benefits of biotechnology. These principles and considerations can be adapted to country-specific legislative and regulatory frameworks as required to align with their specific social and environmental goals.

The development of a country-specific framework needs to incorporate consideration of existing biosafety frameworks and their functionality. Further, development needs to be cognisant of the implications and obligations of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.
1. POLICY FRAMEWORK

A policy framework would include a set of principles and long-term goals that form the basis of making rules and guidelines. Such a framework should include:

1.1. Policy recognising the nation’s approach towards R&D, release and use of GMOs.

1.2. Policy defining decision-making responsibilities within, and on behalf of, the government, and defining the decision-makers’ mandate.

1.3. Policy defining the approach and level of participation by other departments / ministries, (and where necessary input from industry, public sector scientists, NGOs and other public representatives etc.).

1.4. Policy defining goals to which decision-making should address:
   a) Protection goals (possibly including environmental / biodiversity protection; human / animal health; protection of endangered and iconic species; socio-cultural issues; agricultural practices).
   b) Benefit goals (possibly including food security; replacement of harmful agricultural practices; sustainable development; responsiveness to climate change; safety).

1.5. Policy recognising that certain data sets can be shared and used by other countries / regions (potentially all issues not specifically related to the environment).

1.6. Policy recognising that certain human capacity and expertise can also be shared and used by countries and regions, and hence specific capacity limitations in a particular country can be resolved by using expertise found within the region.

1.7. Policy recognising that there is a need to build capacity in risk analysis that meets regulatory needs.
2. DECISION-MAKING

Establishing the context for decision-making involves consideration of a number of components. These may include objectives, legal and administrative requirements, the type of release, the type of approval, treatment of confidential business information (CBI), and the approach to risk analysis (risk analysis includes risk assessment, risk management and risk communication).

Communication between regulators and applicants can clarify administrative processes and requirements for case-specific data. Timeframes for decisions need to be reasonable, taking into account the growing seasons, as applicable, while recognising the guidance provided by relevant international treaties (e.g. the Cartagena Protocol on Biosafety). Capacity to meet the need for proportionate regulation should be addressed so as to ensure a cost-effective and efficient process.

2.1. Risk Assessment

Data that is relevant, appropriate and clearly defined for the type of application (contained, confined and open release) will be required. This information is used to identify credible / plausible pathways to harm. These are used to identify risks which will form the basis of the assessment. The risk assessment (involving a case by case assessment) makes use of existing data, and builds on familiarity with modified and unmodified organisms. While confined and contained field trials are the means to gathering appropriate data (and hence, in the absence of evidence against harm, the risk management measures need to deal appropriately with exposure) ultimately a general release assessment should consider relevant sections of the following:

a) Human / Animal Health
   - Toxicity
   - Allergenicity
   - Compositional / Nutritional analysis

b) Environment / Biodiversity Protection
   - Impact of gene flow (a) within species and (b) to wild relatives
   - Weediness / invasiveness
   - Non targets (‘pesticidal’ plants)
   - Biodiversity, including agricultural biodiversity
   - Soil and water resources
   - Plant pest (vector for plant disease)

2.2. Other considerations

Socio-economic considerations, which may include, *inter alia*:
   - Trade implications
   - Food cost implications
   - Replacement of beneficial / more harmful agricultural practices
   - Job creation / loss
• Food security
• Improved health / nutrition
• Source(s) of the transgene(s)
• Implications for agricultural practices, including gender issues

2.3. Risk Management
The Risk management process must recognise that the emphasis for confined field trials is on the control of the spread and persistence of the GMO, whereas for commercial release the end use must be considered.

a) Regulator / Government responsibilities:
• To identify and select from a range of risk management measures and to require, if necessary, the most cost-effective and feasible measures to address the risks identified in the risk assessment.
• To ensure compliance conditions are based on scientific evidence.
• To undertake inspections to ensure compliance.

b) Applicant responsibilities:
• To comply with specified conditions that minimise human / agricultural / environmental exposure up to the point where commercialisation / general release is permitted.
• To use accredited standard safety facilities for contained experiments (laboratories / greenhouses).
• Confined Field Trials: to incorporate controls to limit or restrict the spread and / or persistence of GMOs, based on scientific data and a case by case assessment of the potential risk of intended / unintended accidental dissemination.
• Experimental design of the field trials, provided it is compliant with specified minimal conditions (as per 2.3.b. Point 1 above), and ultimately delivers the required data for the risk assessment.
• Description of contingency plans to address any threats of serious or irreversible damage should be submitted as part of the authorisation process.
• Adherence to all reporting requirements.
• In the case of unconfined or other large-scale commercial release, preparation of a pro-active risk management plan, where appropriate, to ensure the safe and sustainable use of the technology (e.g. an insect resistance management (IRM) plan for pesticidal GM plants).

2.4. Risk Communication
Countries should consider their approach to risk communication, and this may include:

a) The manner in which consultation and stakeholder engagement is assured, taking into account their responsibilities to protect CBI. Regulatory decisions need to be defensible, consistent and accessible.

b) Public confidence in the regulatory system should be promoted through
transparent and pertinent communication strategies, by both the Government and applicant, where appropriate.

c) If labelling is required, the communication of risk should be informative and useful.

2.5. Liability and Redress
Countries need to consider the implications of their legal approach to liability and redress, to include:

a) If the GMO causes harm as a result of the genetic modification, liability should be attributed to either the originator / manufacturer (if it is inherent to that organism), and / or the operator (where there is misuse of the GMO).

photographers
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• **Regulatory framework.** The development of a country-specific regulatory framework needs to incorporate consideration of existing biosafety frameworks and their functionality as well as the implications and obligations of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety (CPB). The regulatory framework, to which these notes are annexed, consists of those elements that are deemed necessary to ensure the delivery of regulatory obligations.

• **Administrative system.** Laws must be supported by an enabling institutional arrangement for effective implementation and enforcement.

• **Use of terminology.** It is necessary that a common ground is found for the use of terms and that appropriate terminology is adopted while respecting relevant international agreements.

• **Data requirements.** Data requirements should not be excessive and regulatory authorities should seek only information that is relevant for decision-making. It may be necessary to look at experiences from other jurisdictions in order to rationalise data requirements.

• **Approval process.** The approval process should be cost-effective and the regulatory mechanism(s) should not be overwhelming. This requires clear communication channels between the relevant government agencies, regulators and applicants. It may be necessary to look at experiences from other jurisdictions in order to streamline the approval process.

• **Environmental Risk Assessment (ERA).** Conducting an ERA for GMOs is a requirement for general release of GMOs in many countries, but its scope or relevance when conducting a CFT is less clear. It is necessary that decision-making takes cognisance of the fact that ERA should not necessarily be a pre-requisite for approval of CFTs. For CFTs, more importance is given to Risk Management, especially as not all of the data for an ERA is necessarily available (its generation is usually the reason that authorisation for the CFT is being sought).

• **Compliance.** Authorisations should come with conditions to ensure compliance. Even though non-compliance can arise from legislative obligations, it is necessary to ensure compliance to the requirements of the relevant international agreements.

• **Socio-economic considerations.** Efforts should be made to understand socio-economic issues so that key aspects can be quantified and addressed. Addressing socio-economic issues is not a mandatory requirement by international agreements, such as the CPB, and therefore no boundaries should be specified with regard to socio-economic issues.

• **Labelling.** Labelling (if required) should be linked directly to a recognised risk to a section of the population.

• **Liability and redress.** Although liability and redress provisions are necessary to enable developers of GMOs to adopt appropriate scientific safeguards and effective technology stewardship procedures, strict liability provisions have the potential to discourage agro-biotech research. Liability should be protective rather than restrictive.

• **Post-harvest monitoring.** Post-harvest monitoring conditions of field trials need to be aligned with the biology and cultivation practices of the crop. In cases where a trial is conducted at the same site over several years, post-harvest monitoring should be conducted at the completion of the trial, and additional to regular monitoring undertaken during the trial.