Both Kenya and the Philippines have been regarded as ‘test cases’ for biotechnology and biosafety regulatory development in their respective regions.

Biosafety and its regulation has become the lightning rod for debates about the governance of transgenic (GM) crops in developing countries. This focus has tended to narrow policy debates about agricultural biotechnology to the control and management of physical risk. Questions about which technologies are most appropriate, or how to manage their socio-economic impacts, tend to be sidelined.
The STEPS Centre conducted research between 2007 and 2010 on biosafety regulation in Argentina, China, Kenya and the Philippines. In November 2010 we convened a workshop in Nairobi to provide a forum for regulators and other stakeholders from the Philippines and Kenya to share lessons in biosafety regulation. This briefing draws on the research to outline challenges for Kenya and other countries moving to implement legislation on biotechnology.

Flexibility – but for whom?
Both Argentina and China have used the flexibilities that exist in international regulations when developing and implementing their own rules. In Argentina this flexibility was used to support the commercial farming sector. In China, it was used to support domestic GM seed industries. But in neither country has this flexibility been used to respond to the needs of smallholder farmers. Indeed, in both countries, small farmers’ circumstances and problems are not well-recognized by regulation.

Involving civil society
In Argentina and China, civil society organisations have been largely absent from debates about transgenic crops and their regulation. By contrast, in the Philippines, civil society organisations (CSOs) play an important role.

The National Biosafety Committee of the Philippines, the first in ASEAN, was established in 1990. Even today it is one of the few biotechnology regulatory bodies in the world that includes civil society representatives. Twenty years on, however, both state regulators and civil society organisations face new challenges associated with increasing levels of scientific and regulatory complexity.

CSOs engaging in biosafety debates in the Philippines today pursue a range of complementary advocacy strategies. These include: national campaigns (e.g. GMO labelling); local advocacy (lobbying for alternative regulatory pathways at the provincial level, such as an organic agriculture ordinance and a GMO ban ordinance); and the provision of technical support to state regulators in intergovernmental negotiations.

Kenya: implementing the law
In Kenya, the Biosafety Bill (the third in Africa after South Africa and Burkina Faso) became law in February 2009, following a lengthy and polarised debate. By contrast, in the Philippines, both state regulators and civil society organisations (CSOs) had lobbied for an executive order rather than a law, in order to avoid a protracted parliamentary debate and maintain flexibility in the regulatory system.

Kenya now faces the challenge of implementing the law. A key lesson from our workshop was that, once the implementation phase begins, there is a shift in emphasis from regulations (on paper) to practice (in the laboratory, greenhouse and field). The challenge for CSOs in Kenya is now to understand how regulation is done in practice.

Similarly, public engagement needs to take place at multiple levels, not just in the capital. The most important forum for public engagement in the Philippines has been public hearings up and down the country.

Challenges for Kenya:

- **Who benefits from flexibility?** The examples of Argentina and China show that flexibility at the national level doesn’t necessarily translate into better policies for farmers. There are many claims on the ‘public interest’. Unless there is a conscious focus on smallholder farmers, their needs will be sidelined.

- **Contexts matter.** What are the implications of commercialising GM crops for smallholder farmers? Answering this question means acknowledging informal practices of seed-saving and exchange. This is not just an issue of biosafety regulation; coordination is needed across all seed-related policies, including those concerning intellectual property.

- **What role for civil society organisations?** As Kenya moves to the implementation stage, civil society organisations need to engage more with the detail of regulatory assessment. This takes time, effort and resources. It means CSOs have to make choices about what role(s) best match their mandate and expertise, and they need to work together to complement each others’ strengths and strategies.

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**Biosafety regulation in Kenya – defining moments**

- **1990** Government appointed “National Committee on Biotechnology Advances and their Applications” initiates an evaluation of biotechnology.
- **1991** Virus resistant sweet potato research begins at the Kenyan Agricultural Research Institute (KARI).
- **1993** DGIS Netherlands programme founds and starts Kenyan Agricultural Biotechnology Platform.
- **1998** Guidelines for biosafety published by the National Council for Science and Technology (NCST)
- **1999** Biosafety framework established via UNEP-GEF project. Insect Resistance Maize for Africa research begins (CIMMYT, KARI, Novartis).
- **2003** National Biosafety Committee (NBC) approves research and contained trials on Bt cotton and virus resistant cassava. Draft Biosafety Bill prepared.
- **2006** National Biotechnology Policy approved by cabinet.
- **2007** Private motion against Biosafety Bill is debated in parliament.
- **2009** Biosafety Bill receives presidential ascent and becomes law. Drafting of regulations and institutionalisation of National Biosafety Authority (NBA) begins.