15

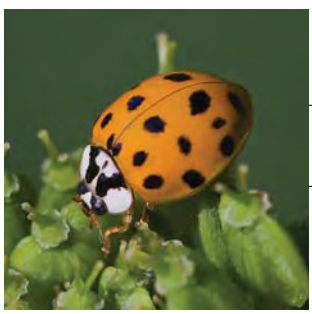
WINNING THE OBSTACLE RACE

Regulatory systems for agricultural biotechnology

KEY THEMES

- The genomic misconception.
- Regulatory obstacles.
- Major reforms needed in the developing world.
- Improving regulation.

The cultivation of *Bt* cotton in six northern provinces of China during 1990–2010 halved the use of pesticides and doubled the numbers of ladybirds, lacewings and spiders.



Andreas Trepte/www.photo-natur.de

The revolution that faltered

What happened to slow progress in the adoption of the new biotechnologies? After decades of research, debate and self-examination, scientists arrived at a consensus: genetic modification (GM) could be used safely and effectively to engineer microorganisms, plants and animals with genes in their cells designed to solve practical problems in medicine, agriculture, food processing, environmental remediation and industrial production. It seemed as if a biological revolution was gathering pace.

But the optimism was short-lived. It fell foul of the forces of scepticism, misunderstanding, technophobia, antagonism, domestic and international politics, overzealous regulators, commercial interests and a determined protest lobby of non-governmental organisations with other agendas.

The genomic misconception

At the heart of opposition to GM, in the words of the Swiss botanist Klaus Ammann, lies the "genomic misconception". Many people believe that GM technologies create new, unique and unprecedented risks to human and animal health, the environment, farming practices and agricultural development. And this view manifests itself in the regulatory structures that governments around the world have adopted.

The genomic misconception stems from an emphasis not on the *product* of GM technology but on the *process* by which it was produced.

When the USA set up the machinery to regulate agricultural biotechnology, it adopted a policy of using existing legal and administrative agencies and an approach focusing on the end product rather than the means of production. In practice, however, things worked out differently.

The US Department of Agriculture, Animal and Plant Health Inspection Service created a new category of "regulated article" for field trials and the commercial release of GM crops. The Environmental Protection Agency also created a new

category for genetically engineered insect-resistant crops called plant-incorporated protectants. And the Food and Drug Administration also modified its demands for foods containing ingredients from GM crops. Thus, the USA's regulatory agencies all subject them to extra, intensive oversight.

The European Union (EU) from the outset has had totally new laws and regulatory procedures for predominantly agricultural GM products. These new laws and procedures are focused solely on the process by which such products are produced and emphasise both risks and speculative hazards. They demand close to zero risk before granting approval, and tend to downplay, if not ignore, the benefits of agricultural technology.

At a broader level, the genomic misconception is represented in international law through the Convention on Biological Diversity's clause calling for a binding agreement on trade that deals solely with GM products. Likewise, the Cartagena Protocol on Biosafety singled out agricultural GM products as special cases of risk and liability. Indeed, the Protocol uses the term "benefit" only three times and "risk" 67 times.

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Plants engineered to absorb contaminants from the soil might help to convert polluted sites into safe agricultural land, playing a crucial role in environmental remediation.

Predictable and unfavourable consequences

Not surprisingly, these regulatory structures have had adverse effects on agricultural GM. In 2011, the US regulatory agencies approved a nutritionally enhanced soybean and a drought-tolerant maize for commercial release. By 2013, the country had approved 165 applications for commercial release of GM traits in eight different major crops – maize, soybeans, cotton, rapeseed, sugar beet, alfalfa, papaya and squash – and 70.1 million hectares were planted with GM seeds that same year. So on the face of it, the US regulatory structure seems very accepting of GM innovation.

In practice, however, the approval process has become increasingly time-consuming, costly and effort-intensive. The approval of GM products costs ten times as much as for conventionally bred products – multi-millions of dollars – and takes a far longer time, usually five to seven years. The necessary documentation also far exceeds that needed for conventionally bred non-GM products.

Even more discouraging is the fact that some GM products languish in a regulatory limbo for a very long time without getting a decision: GM salmon has been more than 10 years in the regulatory waiting room. Another promising

product – rice with proven benefits for children with diarrhoea – was eventually abandoned because of costs, delays and over-heavy regulatory demands.

One final hurdle in the USA is that the GM regulatory structure creates a litigation risk. Many lawsuits have been brought by opposition groups based on a number of statutes governing approval. Whatever the outcome, these lawsuits impose delays, expense and huge uncertainty on GM products. So it seems as if a GM product must not only steer its way through the US regulatory structure; it must also find a path through the judicial system.

In Europe, the complex and intricate regulatory structure has mostly resulted in decision-making paralysis. After years of risk analysis and lengthy debate among EU members, the result is stalemate. While the European Commission has approved approximately 40 agricultural GM products for import as human food or animal feed, it has only approved two novel crops – potato and maize – for commercial cultivation on European farmlands. The system is often described as dysfunctional.

In the absence of sufficient political support in the EU, groups opposed to GM crops have dominated the debate in the media and the public at large. Retailers have shunned them, universities have shied away from research on them, and protesters routinely vandalise field trials and GM crops. With seed and chemical companies abandoning Europe for the USA, the EU has become the only region in the world where the development and use of GM technology is declining.

Salmon modified to reach adult size much faster than wild or conventionally bred fish have been around since 1996, but further research into their impacts is deemed necessary before they can become commercially available.

The scene in developing countries is more promising. For all the risk aversion permeating the Cartagena Protocol on Biosafety, developing nations grew 82.7 million hectares of GM crops in 2013, the second year in which the developing world planted more hectares of biotech crops than industrialised countries. Of the 27 countries that cultivated GM crops that year, 19 were developing and 8 industrialised. More than 16.5 million small, resource-poor farmers, representing over 90 per cent of all GM farmers, used the new technologies to improve their yields, the productivity of their labour force, their safety, income and food security. Brazil is currently approving agricultural GM traits for commercial release more quickly and more cheaply than probably any other country in the world.

Developing countries thus seem to offer a more favourable environment for adopting GM innovation than the developed world. But, even here, there are serious impediments. Many nations are uncertain and confused about GM crops, particularly

when the EU's regulatory system threatens their exports to Europe. Zambia, Kenya and Zimbabwe have even gone so far as to ban imports of GM grain that would feed populations facing famine, denying hungry people access to agricultural commodities that hundreds of millions elsewhere are eating routinely as part of their diet.

As explored in Chapter 10, India's experience of *Bt* brinjal – eggplant – is another example of poor people being denied the benefits of GM foods. Although the new brinjal was seven years in testing and approval, the Indian government overturned the decision of the approving agency.

Changes needed

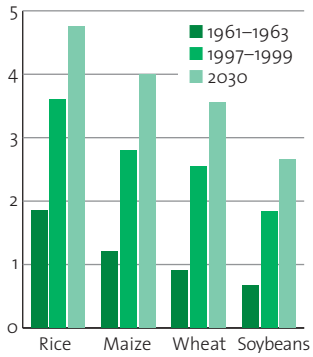
Effective and proportionate regulations are necessary, but several reforms would help to overcome barriers erected by burdensome and inappropriate regulatory procedures. As discussed in Section 2, developing countries would benefit from improved funding for public-sector research. Despite impressive results in laboratories and greenhouses, too few publicly funded GM crops have reached farmers' fields. Public research institutions need funding to cover heavy regulatory compliance costs that can run into millions of dollars for one GM product, which they cannot otherwise afford and which therefore deters them from undertaking such research.

Developing nations need to build capacity in the latest plant-breeding techniques offered by modern biotechnology, but young scientists, perhaps daunted by the complexity both of regulations and of intellectual property law for patenting, appear reluctant to enter GM research, often leaving the field entirely or just using conventional or modern non-GM breeding techniques. In addition, scientists need to have access to lawyers and regulators to help negotiate the legal and regulatory requirements. Plant biologists might show more interest in GM research if there were more skilled personnel able to steer GM products through these complex procedures.

The new GM technologies are critical for food security, safety and nutrition in developing countries. Excessive and unnecessary regulation does not simply have negative impacts on their economies; it costs lives through hunger and malnutrition. The lesson of biofortified Golden Rice, trapped in red tape for more than a decade, needs to be learned: many valuable crop traits have to be engineered through genetic modification. There is no other way.

Figure 15.1 Global yields of major crops, 1961–2030

Tonnes per hectare



Source: FAO

While it is unlikely that yields will grow as much in the first few decades of the 21st century as they did during the last few decades of the 20th, a similar momentum could be maintained if modern biotechnology is widely applied.

Regulatory structures also need to change

The most direct reforms to the world's regulatory systems would come from a change of attitude on the part of governments. If they were to remove the "genomic misconception" from their thinking and treat plant breeding using GM technologies just like any other breeding methods, focusing on product not process, then safe, efficient, socially beneficial and environmentally benign novel crops would populate farmlands more freely.

Even if this does not happen, countries can still improve their regulatory structures by adopting a risk analysis attitude to GM technology rather than an excessively precautionary attitude, which among opponents of the technology is effectively a zero-risk attitude. But zero risk is unattainable. There is risk in every human activity and it has to be balanced against benefit.

Governments should recognise that the experience of agricultural GM technology has been favourable for nearly two decades. A huge amount of research already demonstrates that there is substantial consensus about the biosafety of GM. Governments can, therefore, lessen their heavy data requirements and streamline the decision-making process for new crops and varieties that use genetic traits already approved in other crops and varieties. They can harmonise their regulations with those of other governments and accept the decisions made by competent regulatory agencies in fellow states.

Above all, perhaps, governments could follow the example of Sweden, the UK and the USA, where scientists have recently called on the regulatory system to reflect science-based decisions and to lessen its burden on agricultural GM crops.

In the words of one expert observer: "We need science to come back to farming." The scientific consensus is that the new GM technology is safe, efficacious, beneficial and socially wise. Developing nations and their regulatory systems should adopt this attitude if they are not to be trapped in underdevelopment.

This 14th century portrayal of cotton by John Mandeville – depicting sheep in the place of cotton bolls – charmingly foreshadows the sometimes fanciful fears of modern-day opponents of genetic modification.

John Mandeville/PD

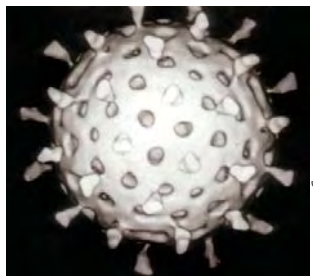
Sustainable and intensive

In making this shift in attitude, developing countries also have to bear in mind the undeniable constraints on agriculture of limited available land and a need to meet environmental obligations. In other words, the future of farming lies not in extensification – opening up new areas for production – but sustainable intensification, getting more from the same, or even less land.

In 2008, the World Bank estimated that as much as 50 per cent of the world's increased crop yields during the 1980s and 1990s came from the genetic improvements made to new varieties. Agricultural GM technology and other advanced methods such as farmed animal cloning, synthetic biology and nanotechnology could bring about the levels of intensive sustainable farming required to maintain this momentum.

In summary, then, in the face of the challenges of the 21st century, present regulatory systems that are hostile to agricultural GM technology must change. Developing nations must set their own independent course for intensive, sustainable agricultural development irrespective of the attitudes and actions of any developed nations regarding science and innovation.

As the Chinese proverb states: "A person who has food has many problems. A person who has no food has only one problem."



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Rotavirus (which causes severe diarrhoea) kills more than half a million people every year. Rice modified to deliver an antibody might have been a solution to the problem...