25 Conclusions and Recommendations

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The World Needs Agricultural Biotechnology

Global economic growth and agricultural production over the last two decades have lifted millions out of poverty and malnutrition, yet a ninth of the world's population continues to suffer from chronic undernourishment, and most of these people, about 780 million, live in developing countries (World Hunger Education Service, 2015). Looking to the future, the world is facing a 'perfect storm' through a combination of factors, some of which are listed below.

- The most recent estimates of population growth show world population increasing from 7.3 billion to 9.7 billion by 2050, with more than half this growth coming from Africa, where the population is expected to double to 2.5 billion, 100 million more than was estimated 2 years ago (United Nations, 2015)
- The steady increase in yield for some staple crops (especially cereals) since the early twentieth century has now plateaued as they start to reach their yield potential ceiling (Grassini *et al*., 2013). Although total world food production may perhaps be sufficient to meet projected demand in the years up to 2050, several developing countries and regions have a long history of near-stagnant yields and policy environments that are not very promising (Alexandros and Bruinsma, 2012). Unless this trend can be reversed, those countries will be in a situation of increasing food deficit.
- Land and water resources are increasingly in demand, especially in developing countries, and are subject to overuse, leading to higher levels of environmental and biological stress. This is resulting in soil degradation, salinisation of irrigated areas and competition from uses other than for crops, which is impacting on the capacity for food production.
- Climate change is exacerbating the challenges faced by the agricultural sector, while at the same time agriculture is contributing significantly to the greenhouse-gas (GHG) emissions responsible for climate change. The changing climate is directly affecting crop yields in some regions due to increasing drought, heat waves or severe weather episodes such as flooding. Climatic shifts are also leading to increasing incidence of new pests and diseases that can badly affect crop performance.

In view of these challenges, much has been written about the need for the 'sustainable intensification' of agriculture. This is defined as 'the goal of producing more food with

less impact on the environment, intensifying food production while ensuring the natural resource base on which agriculture depends is sustained, and indeed improved, for future generations' (The Montpellier Panel, 2013). These important aspirations are in line with the need for agriculture to address the Sustainable Development Goals as mentioned in Chapter 1. However, it is clear that none of these challenges can be addressed without continued agricultural innovation, of which opportunities through agricultural biotechnology represent a substantial part. The Montpellier Panel report specifically addresses the need for genetic intensification, using both conventional breeding and modern biotechnology to concentrate desirable genes in plants and animals.

Throughout the preceding chapters in this book the authors have addressed the various factors that are impeding, both in developed countries and in developing countries, the adoption of solutions that are available through modern biotechnology, with particular focus on genetically modified organisms (GMOs), but also looking to the future as certain types of new breeding techniques (NBTs) are looking extremely promising. The primary focus of the book is on developing countries since, as mentioned above, these are the countries which are most challenged by malnutrition, low agricultural productivity and food deficits. Now in this final chapter we summarise some of the key messages and make some recommendations as to the way forward.

The Key Messages

It is apparent to all that the debate regarding GMOs has become extremely polarised. Yet, as described in this book, GMOs have enormous potential to contribute to sustainable intensification. Even with the limited, genetically simple traits that are currently available in commercialised GM crops, the benefits have been substantial, not only in economic but also in environmental terms, through reductions in pesticide use and GHG emissions (see Chapter 15 and, for more detail, Brookes and Barfoot (2016)). As the new biotechnologies, such as gene editing, are increasingly applied to crop and livestock improvement (see Chapter 2), the list of traits will expand dramatically and will include more complex traits that will improve yield and quality as well as the ability to adapt to the biotic and abiotic threats of a changing climate.

Over the past two decades, many of the polemical arguments against GMOs have focused not only on perceived risks of the technology but also on the undue influence of the multinational companies (MNCs) as purveyors of the technology, as mentioned in Chapters 4 and 14. In Chapter 14 we heard the view expressed that the anti-GMO movement was merely a proxy for the anti-MNC movement. Yet the extremely stringent regulations imposed by many countries have resulted in escalating regulatory costs, which have imposed such high barriers to entry as to ensure that only the MNCs can afford to bring the technology to market. These stringent regulations prevent the commercialisation of crops (developed usually with public funding) that are locally important in developing countries. Interestingly enough, a recent publication (Schiek *et al.*, 2016) suggests that the costs of developing a GM crop as a public good for deregulation and release in a developing country may be much lower than earlier estimates

would suggest. This paper does not state exactly which tests are included in the estimate (e.g., whether provision has been made for any feeding trials, and what compositional analyses are included), and it does make clear that any additional hurdles imposed by regulators could significantly increase the costs. Despite this rather optimistic assessment, the track record of publicly funded projects suggests a more pessimistic picture. A good example is given for Brazil in Chapter 22, which, despite being the country with the world's second-largest production of GM crops, has not been successful in commercialising GM crops developed by its own scientists. A similar situation exists in South Africa (Thomson, 2016) and for many other publicly funded programmes (Huesing *et al.*, 2016).

The high regulatory costs, which are often effectively imposed on producers by importing nations in the developed world, are also cited in Chapters 9 and 20 as barriers to crop improvement. Indeed, it is questionable whether some of the improved GM crops currently undergoing field trials in West Africa (Chapter 23) and Uganda (Chapter 24), as well as the biofortified rice discussed in Chapter 12, will ever make it to market. The message in Chapter 24 that biosafety systems should be regarded as an integral part of a biotechnology innovation system is a key challenge in this regard; the two should not be working against each other.

Many developing countries that are party to the Cartagena Protocol on Biosafety (CPB) have adopted strict risk-averse regulation founded on the precautionary principle (PP); this is also embedded in European legislation. However as described in Chapter 13, the problem with the articulation of the PP in the CPB is that it does not involve any limits, and its unchecked application has led to rejection of safe products as a result of unfounded fears. The inappropriate application of the PP is also cited as a major problem in a number of other chapters, including Chapters 14, 15 and 23, and we believe it to be largely responsible for the current impasse in the introduction of GMOs. Jansen van Rijssen *et al*. (2015) provide a detailed critique of the PP, and amongst others cite Peterson (2007), who stated that the PP 'replaces the balancing of risks and benefits with what might be described as pure pessimism'. We believe that the problems with the CPB (as well as with European legislation) include (1) the fact that consideration of benefits is ignored and (2) the focus on process-based assessment rather than the product-based approach as used in the Canadian regulatory system described in Chapter 5. We discuss these issues further below.

Internationally, the term risk analysis is widely accepted, but the concept of benefit analysis is rarely mentioned. As described in Chapter 3, the risk analysis methodology, which is based on problem formulation, focuses on the harm which might arise from the introduction of a GMO; benefit is considered only at a secondary stage (if it is considered at all). It is difficult to see how (for example) nutritionally enhanced crops would fare in such an analysis. Socio-economic impact analysis as described in Chapters 8 and 10 certainly takes into account benefits, but this is only one dimension of benefit; in any case, socio-economic considerations are not taken into account in all jurisdictions. Chapter 4 focuses on the need for a balanced risk–benefit analysis; it is apparent from analysis of the legislation of many developing countries, as summarised in that chapter, that, in line with the requirements of the CPB, the focus is almost exclusively on risk.

Considering that no risks have materialised during the 20 years since the introduction of GMOs, we consider this excessive focus on risk, as opposed to risk–benefit analysis, to be inappropriate.

The focus on process-based legislation as embedded in the CPB and in many instances of national legislation sets GMOs apart from other breeding techniques. This may have been appropriate when GMOs were first introduced and there was a high level of uncertainty about the technology. However, in the intervening years it has become clear that there is in fact much less uncertainty in genetic modification than in many other breeding techniques. Imprecise techniques such as mutation breeding and embryo rescue are not subject to any regulatory oversight. Meanwhile, the NBTs, including genome editing as described in Chapter 2, have introduced a continuum from conventional breeding to genetic modification, and therefore it is no longer appropriate to separately impose stringent controls on what have traditionally been labelled 'GMOs'. Instead, the assessment needs to be of the product, not of the process by which it was obtained. There are indications that in the future the new gene-editing technologies, where the genetic change may be indistinguishable from naturally occurring variations (termed polymorphisms), might not be subject to the same level of regulation as the earlier, twentieth-century GM technologies (Carroll *et al*., 2016; Strauss and Sax, 2016). This was reinforced by the conclusion of a report by an impressive list of academic experts that was published in mid 2016 by the US National Academies of Sciences, Engineering and Medicine (US National Academies, 2016).

Despite the product-based approach of the USA, and the US National Academies report, the US Senate has passed a bill that would introduce a national standard for mandatory labelling of GM foods (termed 'bioengineered foods' in the bill) (US Senate, 2016). This is clearly process labelling rather than product labelling. Chapter 6 covers labelling issues in some detail, and makes specific recommendations for labelling regimes in developing countries, in particular recommending voluntary rather than mandatory labelling. It remains to be seen what impact the new approach in the USA will have on developing countries, but the cost implications of labelling should not be ignored.

Issues surrounding socio-economic analysis come under the spotlight in Chapters 8 and 10, but are also relevant in Chapter 12, where the social acceptability of biofortified rice is examined. The authors point out that socio-economic considerations (SEC) have been included in the CPB, as well as in many instances of national legislation, without any definition of the term. Both Chapters 8 and 10 make a strong case for SEC to be evaluated in a scientifically sound manner and with a clear definition of the elements that are being evaluated; considerations should be based on real data rather than suppositions, with the recognition that there are many limitations to what can be determined in an *ex-ante* evaluation. In contrast, as described in Chapter 13, a broad interpretation of SEC has given decision-makers the ability to respond to perceived consumer 'outrage' by blocking regulatory approvals, sometimes just because of assumptions about consumer attitudes. Chapters 18 and 20 provide examples of regulatory decisions that have been overthrown due to consumer pressure in China and India. The EU 'opt-out' clause in Directive 2015/412 broadens the basis for EU member countries to prohibit

cultivation of GM crops not only due to ill-defined socio-economic impacts, but also due to a range of other factors, including 'public policy'. We are extremely concerned about these developments, and wish to stress that it is not appropriate for politicians to ignore sound science and block the technology on an arbitrary basis.

If public opinion is to be turned around, there needs to be much better communication at all levels between scientists, the public, policymakers and the media. Chapter 16 stresses the need for more public participation in decision-making, and provides clear indicators as to how biosafety communication should take place, while acknowledging that public participation and communication are currently being neglected in many developing countries. Chapter 17 specifically examines the role of the media. With the rise of social media as an uncensored means of communication, 'good news' messages need to be shared much more strongly, rather than the (often false) scaremongering and anti-MNC messages that have a tendency to go viral. Currently the initiative is in the hands of the anti-GMO activists; a change in approach will require scientists to play a much stronger leadership role in communication and popularisation of the topic.

Several chapters in the book discuss the opportunities for developing countries to address some of their capacity limitations by sharing knowledge and expertise. Harmonisation of regulatory requirements is one important step towards a shared approach by which risk assessments could be undertaken at regional or continental level rather than by individual countries. Chapters 9, 13 and 23 advocate regional or continental harmonisation of risk assessment, while Chapter 11 provides information on OECD consensus documents that are freely available as a resource for regulators to use. Harmonisation needs to go hand in hand with the development of increased capacity, and, as stated in Chapter 7, regional capacity-development programmes could become a conduit to promote collaboration and sharing of resources between countries. Chapter 7 also proposes an innovative, targeted approach to capacity development designed to address the fact that, after 15 years of technical assistance and donor support, many countries have not yet developed a functional biosafety system. We support a harmonised approach, and would encourage countries that lack expertise to be willing to accept the results of risk assessments carried out regionally or internationally.

Particularly in the case of food/feed safety assessments, if agreement on the requirements could be reached at international level, this could pave the way for a single accredited body to undertake the assessment, negating the need for country-specific assessments. This could also help to alleviate the problem of asynchronous approvals of events for commodities, leading to disruptions in international trade, as described in Chapter 21.

Finally, we recognise that modern agricultural biotechnology does not exist in a vacuum but needs to be regarded as an integral part of a holistic agricultural system. The benefits will not be realised unless attention is paid to sustainable agricultural development in a broader context. The governments of developing countries, as well as donor programmes, need to focus on upgrading all aspects of the agricultural system, including seed systems, fertilisers and other agro inputs, as well as markets, so that new technologies are not introduced in a vacuum but are part of a holistic system that contributes to sustainable intensification of agriculture.

The current international regulatory framework for GMOs is unlikely to facilitate the development and adoption of GM products, especially those targeting the nutrition deficit and low agricultural productivity in developing countries. Responding to this challenge, the recommendations in the next section are proposed to address this problem.

Recommendations

Following on from the discussion in the previous section, we conclude the book with some final recommendations.

1. The Cartagena Protocol on Biosafety, largely dating from 2000, is now outmoded and inappropriate, so it needs to be revamped or abandoned.
2. Product-based safety assessment should be the new international norm; process-based assessment is not flexible enough to accommodate rapidly developing technology trends.
3. Regulatory requirements should be in line with actual identified risks, and should be of such a nature as to facilitate the introduction of the improved crops much needed by farmers in the developing world.
4. Risk analysis and benefit analysis should go hand in hand. Benefits should be not only assessed but also communicated at all levels. As with most other technologies, regulation and management of GMOs should reflect the balance of scientifically based risk–benefit assessments.
5. Capacity-building activities should be designed to maximise the opportunities to equip decision-makers with the confidence to move forward with the technology.
6. The requirements for socio-economic considerations, where they are to be included, should be clearly spelled out upfront. They should address only issues that can be adequately considered in an *ex-ante* evaluation.
7. Regional and international efforts at harmonisation should be strongly promoted and encouraged.
8. Broader public participation should be encouraged, and information should be widely shared, while respecting that decision-making needs to be based on sound science.
9. Government officials and policymakers should be actively discouraged from making arbitrary decisions that ignore the input of experts.
10. Developing countries need to invest in agriculture, and, in the particular case of Africa, need to live up to their commitment in the Malabo declaration to allocate at least 10% of public expenditure to agriculture (African Union, 2014).

We urge all concerned parties, namely scientists, government officials, donors, the media and international bodies, to take note of these recommendations and act on them expeditiously. We believe these recommendations could effectively contribute to the successful development of GMOs and increase the adoption of the technology in developing countries.

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