

Introduction

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Genetically modified organisms (GMOs) are now an established feature of the agricultural landscape, with 125 million hectares of biotech crops being grown in 2008.¹ Further, in the United States (which accounted for half of that total area), it is estimated that, as at 2009, GM varieties will comprise some 91 per cent of soya and 85 per cent of maize.² On the other hand, the picture is far from even. In 2008, only 14 countries grew 50,000 hectares or more of GM crops;³ and there are notable agricultural ‘powerhouses’ where the new technology has been less enthusiastically embraced by producers. For example, Spain is the only Member State of the European Union (EU) in which commercialization of GM crops has occurred on a significant scale (but, even there, only some 100,000 hectares were grown in 2008); and in Russia and Ukraine the biotech revolution has barely started.

Despite this somewhat uneven picture, there may be detected a sense that the advance of modern biotechnology is becoming inevitable, with countries finding it increasingly difficult to preserve the integrity of a ‘GM-free’ food chain. In particular, three major exporters of livestock feed (Argentina, Brazil, and the United States) have all now embraced the GM revolution;⁴ and importing countries are faced with very tight supply of conventional maize and soya. As stated by Commissioner Fischer Boel in October 2009, ‘[e]ven if we can get the soya from elsewhere—which is far from clear—our livestock sector would have to pay higher prices.’ In particular, she pointed to the irony of the European livestock sector collapsing and the slack then being taken up by imports of meat produced with GMOs over which the EU had no control.⁶ The advancement of modern biotechnology is also advocated as a means of achieving global food security. Thus, the United Kingdom Royal Society saw GM crops as at least part of the solution in its 2009 report, *Reaping the Benefits: Science and the Sustainable*

¹ C James, *Global Status of Commercialized Biotech/GM Crops: 2008 (ISAAA Brief No 39)* (Ithaca, NY: International Service for the Acquisition of Agri-biotech Applications (ISAAA), 2009) Executive Summary.

² National Agricultural Statistics Service (NASS), *Acreage* (Washington, DC: USDA, 2009); and see further Chapter 12.

³ C James (n 1 above) Table 1.

⁴ See Chapters 11 and 12.

⁵ Speech/09/474, ‘GMOs: Letting the Voice of Science Speak—Policy Dialogue at “European Policy Centre”’, Brussels, 15 October 2009 (speeches of the Commissioner for Agriculture and Rural Development are available at <<http://europa.eu/rapid/>>).

⁶ *Ibid.*

Intensification of Global Agriculture.⁷ That said, there are voices which consistently deny that GMOs could ever be the ‘silver bullet’ to remove so major a problem.⁸

Importantly, at the same time there is general acceptance that, once commenced, the spread of GMOs may prove irreversible. Indeed, this is expressly countenanced in the Preamble to Directive (EC) 2001/18 of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms (‘Deliberate Release Directive’).⁹ Likewise, the United Kingdom GM Science Review Panel has acknowledged that, for the present, there is no method by which GM crops grown on a commercial scale can be genetically isolated from conventional and organic crops.¹⁰ In addition, it is impossible to discount the occurrence of incidents which lead to large-scale escapes of GMOs into the food chain. For example, in the United States there has been the StarLink™ episode (when GM material not authorized for human food was found in taco shells);¹¹ and in the EU there have been ongoing difficulties with imports of Chinese rice products.¹²

Against this background, the regulatory response would also appear somewhat uneven. There is clear evidence of certain countries, or wider international bodies, adopting a cautious approach. A graphic illustration is the African Model Law on Safety in Biotechnology, which not only accommodates a strong version of the precautionary principle, but also requires that socio-economic criteria be taken into account.¹³ By contrast, other countries (such as Argentina and the United States) base their approach on the principle that GM food is substantially equivalent to traditional food, which to date has led to consistent authorization of new varieties.¹⁴ In this context, a matter of some interest is the extent to which individual countries have defined themselves by reference to their approach to modern biotechnology. To take an extreme case, during the 2002 drought which affected Southern Africa, Zambia refused food aid in the form of maize (including milled grains) from the United States, on the basis that there could be contamination from GMOs;¹⁵ and, more generally, several

⁷ Royal Society, *Reaping the Benefits: Science and the Sustainable Intensification of Global Agriculture* (London: Royal Society, 2009).

⁸ See, eg Policy Department of Oxfam (Great Britain), *Genetically Modified Crops, World Trade and Food Security: Position Paper November 1999* (Oxfam, 1999) 3; and see also Friends of the Earth Press Release, *Royal Society Food Report—Friends of the Earth Reaction*, 21 October 2009.

⁹ [2001] OJ L106/1, Preamble (4).

¹⁰ GM Science Review Panel, *GM Science Review: First Report—an Open Review of the Science Relevant to GM Crops and Food Based on Interests and Concerns of the Public* (London: 2003) 18.

¹¹ See further Chapter 12. Another such episode was that involving LibertyLink rice.

¹² See, eg European Commission, IP/08/219, *Commission Requires Certification for Chinese Rice Products to Stop Unauthorised GMO from Entering the EU*, Brussels, 12 February 2008.

¹³ Available at <<http://www.nepadst.org>>, last accessed 3 July 2009; and see further Chapter 9.

¹⁴ See Chapters 11 (Argentina) and 12 (United States).

¹⁵ See, eg R Walters, ‘Crime, bio-agriculture and the exploitation of hunger’ (2006) 46 *British Journal of Criminology* 26.

African countries would seem to associate acceptance of GMOs with a loss of sovereignty. Political considerations, and national positioning, may also be detected behind the overtly anti-GM stance adopted by Scotland, in contradistinction to the more equivocal approach of the UK Government.¹⁶ Further, by spring of 2009, the only GM variety grown commercially in the EU (maize MON810) was banned in six Member States (Austria, France, Germany, Greece, Hungary, and Luxembourg). It would be hard to deny that the GM debate resonates far beyond the confines of agriculture and the food chain and continues to act as a lightning rod for wider issues at national and global level.¹⁷

While national attitudes to GMOs show considerable variation, ambivalence may also be found in individual legislative regimes, as can be illustrated by three examples from that applicable in the EU. First, under the Deliberate Release Directive, great emphasis is laid upon the authorization process (together with its environmental risk assessment) as a means of ensuring that the deliberate release of GMOs will not have adverse effects upon either human health or the environment. Yet, under Directive (EC) 2004/35 of the European Parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage ('Environmental Liability Directive'), deliberate releases of GMOs (as defined under the Deliberate Release Directive) fall within the list of activities which may give rise to liability.¹⁸ Secondly, the Community guidelines on measures for the coexistence of GM and non-GM crops encourage the use of insurance against liability for cross-contamination by GMOs.¹⁹ Yet, by 2009 it could be noted by the European Commission that 'insurance products covering risks of GMO admixture seem not to be available on EU markets' (notwithstanding that the coexistence measures of four Member States were already requiring these products, or might do so following a case-by-case assessment).²⁰ Thirdly, the same Community guidelines recite that no form of agriculture (whether conventional, organic, or using GMOs) should be excluded in the EU, but also that the issue of coexistence addresses 'the most appropriate management measures that can be taken to *minimise* admixture'.²¹ In

¹⁶ See, eg Scottish Government News Release, *Genetic Modification (GM)*, 24 April 2009 (available at <<http://www.scotland.gov.uk/News/Releases/2009/04/24150325>>, last accessed 29 June 2009).

¹⁷ For discussion of such issues, see S Bonny, 'Factors Explaining Opposition to GMOs in France and the Rest of Europe' in RE Evenson and V Santaniello (eds), *Consumer Acceptance of Genetically Modified Foods* (Wallingford, Oxon: CABI Publishing, 2004) 169.

¹⁸ [2004] OJ L143/56, Annex III, para 11. See further Chapter 8.

¹⁹ Commission Recommendation 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming ('2003 Commission Recommendation') [2003] OJ L189/36, Annex, para 2.1.9.

²⁰ European Commission, *Report from the Commission to the Council and the European Parliament on the Coexistence of Genetically Modified Crops with Conventional and Organic Farming* COM (2009)153, 5.

²¹ 2003 Commission Recommendation, Preamble (1) and (5) (emphasis added).

consequence, there is acknowledgement that only by permitting cross-contamination up to defined thresholds can the regulatory regime be made to work; and this must raise the question whether, if GM cropping becomes well-established, organic agriculture will be viable throughout the EU. A product may still be 'organic' as decreed by the Community legislation;²² but, if it is not organic in the mind of the consumer, its commercial position may be jeopardized.

Accordingly, it would seem clear that the regulation of GMOs will increasingly affect the food supply of every person and that different countries will in all likelihood continue to adopt substantially different approaches. It would also seem clear that, even where countries have proceeded to the enactment of regulatory regimes, those regulatory regimes may present internal contradictions and be strongly contested. Significantly, such issues do not seem to dissolve with time. On the contrary, there is some evidence that the passage of years, together with greater information and education, serve only to entrench the views of the public. For example, a 2005 survey found that in France the proportion of the decided public against GMOs rose from 46 to 71 per cent over the period from 1996.²³ This may be a factor behind the possibility of change to what would appear entrenched policies; and a good example is the indication by the President of the European Commission in September 2009 that Member States may be allowed to decide whether or not they would wish to cultivate GM crops in their territory.²⁴

For all these reasons, there is always good reason to revisit the regulation of GMOs, and this book will seek to provide new insights into existing issues, while also extending to less-well-trodden ground. It is divided into four parts; and, although there is some emphasis on the position in the EU, there is also a conscious endeavour to reflect the truly international nature of the debate by exploring the legal ramifications of GMOs in representative countries throughout the globe, and also with reference to world trade. That said, it is accepted that no work could hope to be comprehensive where a subject has generated so much controversy and, for example, there is no attempt to cover matters of intellectual property law.

Part I addresses cross-cutting themes in three chapters. In Chapter 1, Luc Bodiguel and Michael Cardwell discuss the impact of the public on the governance of GMOs, considering both formal influence through rights to participation in the legislative process and less formal influence through consumer

²² Under Council Regulation (EC) 834/2007 on organic production and labelling of organic products [2007] OJ L189/1 a product remains 'organic' despite the adventitious presence of authorized GMOs up to a 0.9% threshold.

²³ G Gaskell *et al*, *Europeans and Biotechnology in 2005: Patterns and Trends—Final Report on Eurobarometer 64.3* (Brussels: European Commission, 2006) 21. For a more recent survey, see European Commission, *Attitudes of European Citizens Towards the Environment—Special Eurobarometer 295* (Brussels: European Commission, 2008) 65.

²⁴ José Manuel Barroso, *Political Guidelines for the Next Commission* (Brussels: European Commission, 2009) 39 (available at <http://ec.europa.eu/commission_barroso/president/pdf/press_20090903_EN.pdf>, last accessed 20 October 2009).

preferences and anti-GM protest. In Chapter 2, Christophe Charlier and Egizio Valceschini examine the importance and limits of cost-benefit analysis (CBA) in relation to GMOs. The chapter demonstrates, not least, the complexity of any CBA in these circumstances, consequent not only upon the novelty of GMOs, but also factors such as the absence of scientific unanimity and consumer fears. On the other hand, it is argued that CBA still renders it possible to make some assessment of the economic legitimacy of biotech products, which can then be fed into the decision-making process. Finally, in Chapter 3, Karen Morrow considers the extent to which traditional risk analysis is appropriate in the case of GMOs. She highlights a greater willingness to contest the views of experts, with the regulation of risk having an increasingly public dimension; and she explores the relationship between risk and the precautionary principle. The chapter concludes with an examination of recent decisions of the courts relating to risk, with particular reference to the United Kingdom and the European Court of Justice.

Part II is concerned with the regulation of GMOs in the EU and consists of five chapters. The first of these, by Marine Friant-Perrot, tracks the development of the Community regulatory regime, with attention directed to the legislation governing deliberate releases into the environment, GM food and feed, and traceability and labelling. It then locates the specific provisions for GMOs within the growing corpus of Community food law and analyses, *inter alia*, the extent to which an integrated approach is being achieved 'from farm to fork'. Chapter 5, by Maria Lee, provides an in-depth analysis of multi-level governance in relation to GMOs, arguably a *locus classicus* for the implementation of legislation through dispersed authority. However, in this context multi-level governance is found to be not straightforward; and there is focus on the role of the European Food Safety Authority and the operation of comitology, both largely immune to the views of 'the public'. The chapter is completed by an evaluation of multi-level governance following the authorization process, together with implications for the internal market. Chapters 6 and 7 both discuss the vexed question of coexistence between GM and non-GM crops. The former, by Peggy Grossman, addresses the question at EU level and provides a detailed treatment of European Commission initiatives, most notably the Community guidelines upon which national measures are based. Emphasis is accorded to the key importance of tolerance thresholds, the special demands of organic agriculture, and attempts to gain 'GM-free' status through bans on GMOs. The latter, by Luc Bodiguel, Michael Cardwell, Ana Carretero García, and Domenico Viti, addresses the same question at Member State level, looking more closely at the development of measures in France, Italy, Spain, and the United Kingdom. Notwithstanding that Community guidelines apply, considerable variation in terms of national implementation is revealed; and the discussion extends to the impact on the regulatory process of the individual constitutional settlements of Member States. For example, in Italy there has been a battle of

competences between the regions and the state. Likewise, national imperatives and preferences would seem to be reflected in such legislation as has been enacted, with the regime in France being far more ‘top-down’ than that in Spain. In Chapter 8, Chris Rodgers assesses the role of environmental liability regimes generally, including the extent to which it is possible to apply a Coasean analysis. He then provides a detailed treatment of the application to GMOs of both the Environmental Liability Directive and the Lugano Convention, exposing several weaknesses.

Part III is more overtly comparative, examining pertinent issues in Africa and North and South America. Chapter 9, by Fikremarkos Merso Birhanu, highlights the unique position of Africa, a continent where agriculture is of great importance to national economies, yet which has low levels of food security. The regulation of GMOs is evaluated at continental, sub-regional, and national level, with the African Model Law on Safety in Biotechnology providing a template which is more or less closely followed. While a developed agricultural sector (as in South Africa) might be an indicator of enthusiasm for GM crops, the position is found to be more complex; and a recurring theme is the need for Africa to own the new technology. In Chapter 10, Jane Matthews Glenn provides a detailed critique of two controversial Canadian cases on GM crops, *Monsanto Canada Ltd v Schmeiser*²⁵ and *Hoffman and Beauvoisin v Monsanto Canada and Bayer Cropscience Inc.*²⁶ Broader principles of liability are also examined, with particular reference to GMOs. Questions raised are whether it would be possible to recover for pure economic loss; and whether regulatory decisions to authorize GMOs are ‘policy’ (as opposed to ‘operational’) decisions, thus becoming immune to challenge before the court. In Chapter 11, Rosario Silva Gilli traces the development of regulatory frameworks for GMOs within the countries of MERCOSUR. While GM crops are cultivated in the territory of all four full members (Argentina, Brazil, Paraguay, and Uruguay), different degrees of enthusiasm for the new technology are observed. The chapter ends with an assessment of whether MERCOSUR might operate as an engine for harmonizing the disparate national regimes. The final chapter in this part is by Peggy Grossman and discusses the governance of GMOs in the United States. She contributes a full study of federal law and policy, including the role of the various regulatory agencies. In addition, there is consideration of the extent to which individual states can, and have, legislated in this field, followed by broader exposition of potential liability under state tort law, with particular reference to nuisance. Notably, this chapter contains an extensive treatment of the *StarLink* litigation.²⁷

²⁵ [2004] 1 SCR 902; affirming (2002) 218 DLR (4th) 31 (Federal CA); affirming (2001) 12 Canadian Patent Rep (4th) 204 (Federal Ct, Trial Div).

²⁶ (2007) 283 DLR (4th) 190 (Sask CA); affirming [2005] 7 Western Weekly Rep 665 (Sask QB).

²⁷ *In re StarLink Corn Products Liability Litigation* 212 F Supp 2d 828 (ND Ill 2002).

Part IV is avowedly international in focus, with a chapter on the *EC—Biotech* case,²⁸ and a further chapter locating the regulation of GMOs within the broader context of international law. Chapter 13, by Joe McMahon, investigates the contested role of science within the Agreement on the Application of Sanitary and Phytosanitary Measures ('SPS Agreement'); and, more precisely, it analyses three key aspects of the Panel's decision, namely the concept of a measure, the role of risk assessment, and the provisions on transparency. In addition, he evaluates whether the Panel missed an opportunity to reconcile the demands of science with other factors to be taken into account when making a decision on risk. Chapter 14, by Duncan French, looks both at and beyond the Cartagena Protocol and SPS Agreement, in order to inquire how international law may accommodate new regulatory challenges, such as GMOs. At the same time, it highlights two specific issues: the role of treaty interpretation as an aid to reconciling what at first sight might appear to be conflicting primary rules; and the utility of 'sustainable development' in providing a balanced framework to capture socio-economic aspects within the decision-making process. The conclusion reached is that the regulation of GMOs should only be considered when fully appraised of general international law principles.

²⁸ WT/DS291/R, WT/DS292/R, and WT/DS293/R, 29 September 2006.

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