

## BOOK REVIEW

### INNOVATION AND LIABILITY IN BIOTECHNOLOGY: TRANSNATIONAL AND COMPARATIVE PERSPECTIVES

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Food scarcity is an ever-increasing problem. One solution lies with the use of biotech crops that can withstand drought and disease. However, many people remain wary of the tag 'genetically modified', concerned about the potential harm biotech crops might cause to biodiversity and human health. It is necessary for legal systems (both national and international) to develop a framework of rules which permit the development and use of biotech crops whilst minimising the opportunity for harm to be caused by them and ensuring that effective means of redress are available in cases where their use does cause harm.

The authors of this book propose a framework, the 'Liability Analysis Framework' or 'LAF', to deal with situations where the use of biotech crops has caused (or is likely to cause) harm, whether to health, wealth, biodiversity or otherwise. The authors present their framework as a work in progress. As they state right at the beginning of their book they hope it will be "the means to stimulate new and exciting discussions". Certainly there are plenty of points in the book which form a perfect base for further research, thought and debate.

The LAF comprises three overlapping aspects: contractual legal issues; legislative regulatory issues; and common law / statutory issues. The potential for legal disputes concerning biotech crops is large and a broad range of possible liability situations fall within the LAF's purview. Disputes may arise between players in the biotech industry (e.g. between a manufacturer and a transporter of biotech seed over responsibility for a spillage); between biotech firms and consumers (e.g. quality of product); between biotech firms and government (e.g. compliance issues or harm caused to biodiversity); between farmers of biotech crops and farmers of organic crops (e.g. intermixing of crops or seed).

Five case studies are used to examine the legal regimes applicable to biotech crops in North America (the US and Canada) and Europe (Denmark and Germany). The regimes in North America are more favourable to the biotech industry than those in Denmark and Germany. All four jurisdictions impose liability in cases of physical damage caused by commingling of biotech crops or seeds with non-biotech products, but Germany goes further and imposes liability for pure economic loss. Whilst Denmark does not impose liability for pure economic loss, it effectively taxes biotech farmers by requiring them to pay a fee, calculated on a per hectare basis, into a statutory compensation fund. The authors conclude that the stricter regimes in Denmark and Germany act as a disincentive to farmers growing biotech crops.

Liability for genetically modified organisms is a topic for international as well as national law and the authors analyse the discussions that took place between the parties to the Cartagena Protocol on Biosafety concerning liability for damage to biodiversity caused by genetically modified organisms. Those discussions resulted in the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress which was finalised after the book went to press.

The scope of the LAF is wide and, having looked at specific examples of liability, the authors turn to consider broader issues: the interface of patent policy with regulation and liability; the development and use of coexistence strategies; and non-adopter liabilities. These discussions raise interesting questions: Should a patentee be liable for harm caused by the patented product? If so should the duration of such liability be co-extensive with the term of the patent or should it last longer? Should co-existence strategies be left to develop on an ad hoc basis or should governments regulate for them? Should there be regulations concerning seed purity? Should non-adopters (i.e. farmers who do not use biotech crops) be liable for damage caused by their decision such as the spread of weeds, diseases and toxins that might otherwise have been avoided?

Another aspect of the LAF is liability communication. The authors address the importance of educating the public about the benefits and drawbacks of innovative technologies. Whereas North Americans are confident about food biotechnology, Europeans are much more wary, a fact reflected in the tougher regulatory and liability regimes that were observed in the European jurisdictions studied. The authors consider ways in which consumer confidence can be improved and conclude that three factors will lead to greater biotech crop acceptance: continued safe use; the expiry of patents over current biotech crops (which will ease the 'ownership of life' controversy) and, pragmatically, the economic pressures caused by rising food prices. An over-precautionary approach to regulation can be disadvantageous to consumers where it prevents them obtaining the benefit of an innovative product. The authors illustrate this point by looking at the situation in Canada, where significant delays in regulating 'plant molecular farming' techniques (by which antibodies or enzymes for use in humans are produced in plants) resulted in some firms in the industry transferring their activities to the US.

In their concluding remarks the authors reiterate the main theme of the book, that of obtaining the right balance between innovations on the one hand and risk management on the other:

“Ultimately, one overriding issue is beginning to emerge: to what degree will industries and societies be affected by the rigorous application of liability to future innovations? Will liability laws enable an industry to manage risk better, or will they place insurmountable hurdles to innovation, leaving biotech crops in a niche role?”

The message that comes across from the book is that the initial distrust that can greet innovative technologies should not cloud the thinking of those responsible for devising and imposing liability regimes. Innovative products have the capacity to do much good and it would be wrong to stifle their development with over-rigorous liability regimes. Indeed, the authors' technique of asking what damage could be caused by not using biotech crops certainly challenges the precautionary approach that might otherwise be adopted by readers. However, as the authors recognise, there is potential for biotech crops to do harm and that cannot be overlooked. It is important

to ensure adequate regulation to manage the risk of harm and also, once products are authorised for use on the market, ensure robust liability regimes are in place to give people, firms and governments adequate redress when things go wrong. The LAF that the authors propose attempts to take all aspects of the debate into account and serves as a strong basis upon which further debate can be founded.

This concise and thought-provoking book is an excellent introduction to the area of liability for biotechnology products for students, legislators and those working in the biotech industries. Whilst its focus is on biotech crops the framework it proposes will have wider application to other biotech products. It is highly recommended reading.

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