

Life Sciences and GMOs: Still an Uninsurable Risk?

by Mark Cantley*

1. Introduction: what does the insurer need to know?

The title of this paper is a leading question, but the assumptions which it reflects are important, as it summarizes some of the problems faced in Europe today by research, development and commercialization activities based on modern biotechnology. The question implies that “life sciences and GMOs” have been and remain uninsurable activities, neither of which is generally true; but the fact that such assumptions are made, albeit accompanied by a question-mark, is symptomatic of some of the current problems faced by research institutes or companies seeking to develop or commercialize activities based on modern biotechnology in Europe. In addressing the question, we shall suggest that a less leading formulation of the question might be, “Is the progress and application of new knowledge in the life sciences and biotechnology an uninsurable risk?”, and the answer to this might reasonably be “yes and no”.

To take another example, we do not know whether the brothers Orville and Wilbur Wright had life insurance, as their heavier-than-air flying machine lifted hesitantly into the air at Kitty Hawk, just over 100 years ago.¹ It would have been surprising if the policy had been so farsighted as to exclude from coverage such high-risk activity, yet one can imagine that their life insurer would have been annoyed if they had lost their lives in such an obviously dangerous, pointless and unnatural activity. Yet today, vast numbers of unadventurous individuals fly almost free of care around the world, confident in the knowledge that in the rare event of a fatal accident, there is a well-developed aviation insurance sector to deal with compensation. So, as with most successful technological innovations, they become routine, and insurance develops gradually, as necessary, in response to need and experience.

The *déformation professionnelle* of a risk officer is to be permanently suspicious, alert to the possibility that an unforeseen and potentially catastrophic risk has slipped into the cover, unnoticed, uncosted, unpriced, and unbilled. So for modern biotechnology, the suspicious risk officer might wish to pose two questions:

- Does this new technology present new risks?
- Can we define, measure and (therefore) insure such new risks as may arise, for example, of damage to biodiversity and/or the environment?

To both questions, the short answer is “probably not, but they merit further discussion”. We offer below some contributions to this discussion, as basis for our “yes and no” answer regarding the insurability of innovation.

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¹ The first flight, of some 120 feet, took place at Kitty Hawk, North Carolina, on 17 December 1903.

2. The new knowledge has arrived and will keep a-coming: golden opportunities

“GMO” is a popular abbreviation of little scientific value, but it has crept into some legislation, many newspaper headlines (where brevity is appreciated), and much propaganda. It actually stands for “Greenpeace Membership Opportunity”. What we have been witnessing for several decades, especially the past three, is a surge of new knowledge about the structures and functioning of living entities. Indeed, the 20th century could be summed up by the progress made in each quarter-century, in the life sciences: both basic knowledge, and increasingly sophisticated applications of that knowledge.

1. In the first quarter-century, work by Morgan and others with fruit-flies was definitive in showing that genetic information was carried by chromosomes.
2. During the second quarter, Oswald Avery and colleagues at Rockefeller laboured for decades to arrive at last at the conclusion, presented in their 1944 paper, that the carrier molecule for genetic information is deoxyribonucleic acid, DNA. The double-helix structure, and hence the outline of the replication mechanism, was elucidated by Watson and Crick (1953) a few years later.
3. Twenty years later, the full genetic code common to all living organisms had been deciphered, and Cohen and Boyer (1973, 1974) were conducting the first experiments using nature’s own enzymes to “cut and paste” pieces of DNA in bacteria, “genetic engineering”, and hence starting to exert precise control over what the resulting engineered bacteria produced.
4. By the end of the 20th century, genetic engineering had massively expanded, and the reading of genetic sequence had accelerated, its cost brought down by several orders of magnitude, to the point where decoding whole genomes of species, including, notably, that of man, had become feasible.

The cornucopia of technical developments and new knowledge is certainly not exhausted; the surge of discoveries and of technical innovations has not ceased, but is continuing to accelerate; and the resulting techniques and data become almost instantaneously available around the world, irreversibly available, for ever, to any individuals or organizations with the (relatively modest) infrastructure and skills required to make use of them. In the year 2003, we may note the following:

- The Whitehead Institute is testing the new BioMEMS 768 Sequencer, which can sequence the entire human genome in only one year, processing up to 7 million DNA letters a day, about seven times faster than its nearest rival; other technologies are in close competition (Kling, 2003); the U.S. National Institutes of Health in February 2004 invited project applications to reduce the cost of sequencing a mammalian genome to \$1,000 within ten years.
- Several companies are now offering on a single microarray chip probes for all the 30,000 (or thereabout) genes of the human genome (MacNeil, 2003).
- Over 100 entire genomes have been sequenced, the data available to all in public databanks.
- The Worldwide Protein Databank has just been established, as an intercontinental collaboration between centres in the U.S., Europe and Japan; (the DNA sequence databanks have been organized into global collaboration for over 20 years already).

In short, we face a golden age of new possibilities. “Golden”, because the new knowledge and techniques offer, and indeed are already delivering, products, processes and

techniques of greater accuracy and predictability, for applications in health care, in the agro-food system, and in our interactions with the environment. These are helping in the essential shift towards more knowledge-based economies, with greater sustainability and productivity, while improving the quality of life, and reversing the degradation of the environment. They are exactly the sort of developments needed by Europe if it is to achieve the objective, stated by the E.U. heads of government at the Council meeting in Lisbon in March 2000, of becoming by 2010 “the most competitive knowledge-based economy in the world”.

3. A 30-year-long argument and an application of the “precautionary principle”

Although future opportunities may be golden, the perception and regulation of biotechnology, particularly in Europe, continue to be problematic. There has been a loss of perspective, and a forgetting of the long and public debates in the early years of modern biotechnology; yet that experience, those debates, are worth recalling, and their consequences remain of importance. In 1973, the first concerns were being expressed about conjectural risks of recombining DNA. The conjectures continue in Europe; but knowledge and applications have moved on elsewhere.

There is a strong “continuity” argument, that what is being attempted and achieved today in modern biotechnology represents essentially the continuation, with new and sharper tools, of the longstanding pursuit of better standards of food production, health care, and care for our environment, objectives which have been pursued over decades, centuries, even millennia. Moreover, we have been eating genetically modified plants and their products for all our lives, since many of our major current food crops result from chemical or radiation mutagenesis applied to seeds, followed by selection of those which, following this crude genetic surgery, produced desirable results. Such mutagenesis and selection has been conducted for over 50 years, with productive results, negligible regulatory oversight, and a remarkable safety record.

The continuity argument is thus a strong one, based on the practically problem-free experience of mutagenesis over the past 50 years, the deliberations of expert groups such as those which worked in various countries in the first decade of the debate on recombinant DNA, and the results of many years of biosafety research. So why has concern suddenly arisen over the use of more precise and predictable tools?

Following the 1973 expressions of concern about DNA recombination, a remarkable international debate took place, extending from scientific circles to the press, the political class, the media and the general public. We may summarize a complex tale by indicating a few of the events of significance, particularly for the debate on risk assessment and regulation:

- July 1974: a scientific committee convened by the U.S. National Academy of Sciences reported, via a letter published simultaneously in *Nature* and *Science* (Berg, 1974), acknowledging concerns about certain types of experiment, calling for a worldwide voluntary moratorium (which was observed, and lasted some 18 months) and proposing an international debate.
- February 1975: an international conference of molecular biologists, at Asilomar in California, debated the conjectural risks, and what might be done to contain them: for a full account, see Rogers (1975).
- 1976: the Recombinant DNA Advisory Committee established by the U.S. National Institutes of Health publishes a first set of guidelines on rDNA work. These guidelines

have since been repeatedly modified, generally in the direction of liberalization, in view of the excellent safety record.

- 1978: European Commission proposes a tough Directive on rDNA work.
- 1980: European Commission withdraws its proposal for a rethink, in the light of scientific developments and the ongoing debate, replacing it by the proposal which becomes:

1980: European Council Recommendation 1982/472 on rDNA work: given the conjectural risks and concerns, national registration of such work is advocated, just in case . . .

- 1984: the U.S. government decides that rDNA work can be handled under existing statutes and agencies, given a “co-ordinated framework” to clarify the “who does what?” questions, and confirms this two years later as the basis of their regulatory policy, a decision which some 20 years later they have had no reason to regret.
- 1986: OECD Council Recommendation (OECD, 1986), following several years’ work by the Group of National Experts on Safety in Biotechnology, in which the member governments recognize that “there is no scientific basis for specific legislation to regulate the use of recombinant DNA organisms”.
- 1986: Danish Parliament adopts the “Gene Technology Act”, the first technology-specific national legislation on biotechnology.
- 1986: European Commission announces in a communication that they will create “A Regulatory Framework for Biotechnology”.

The international debate from 1973 to 1986 was a classic application of what we now call the “precautionary approach”, or “precautionary principle”. This was summarized in a recent communication of the European Commission (2000):

Where action is deemed necessary, measures based on the precautionary principle should be, *inter alia*:

- *proportional* to the chosen level of protection,
- *non-discriminatory* in their application,
- *consistent* with similar measures already taken,
- *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
- *subject to review*, in the light of new scientific data, and
- capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

These points summarize a dynamic and science-based approach to the management of risk under conditions of uncertainty, fully compatible with international obligations such as the World Trade Organization agreements, in particular the Sanitary and Phytosanitary Agreement,² the Convention on Biological Diversity, and the Cartagena Protocol on

² See, for example, Article 5, paragraph 7 of this Agreement: “In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.”

Biosafety which derived from it. In recent years, however, there has been a loss of institutional memory and historical awareness; and as has been pointed out (Hegel, 1837), “What experience and history teach is this – that people and governments never have learned anything from history, or acted on principles deduced from it.” We may note in passing that Hegel was not a scientist.

4. From 1986: paths diverge and in Europe concerns have mounted

The debates and the regulatory approaches adopted over the period 1973–1986 corresponded to a precautionary approach, and made important progress both in allowing research and innovation to move ahead, and in reassuring the public and the political class that they were doing so with adequate and proportionate oversight. But since 1986, approaches to the management of the conjectural risks associated with modern biotechnology diverged between the U.S. and Europe, in spite of the expert consensus which still prevails on risk assessment.

In practice, the dynamic and pragmatic character of the precautionary approach seemed to be abandoned. The regulatory response became disproportionate, driven forward by special circumstances and special interests, unconstrained by the other factors which should have played a larger role in the policy debates. One can list at least six groups who were involved, rarely arguing for lighter regulation:

- the Environment Ministries, who became *chef-de-file* for the regulation of biotechnology, thus almost accidentally gaining control over matters far beyond their competence, affecting agricultural, industrial, trade, health, education, and developing country interests;
- so-called “environmental” non-governmental organizations, who were reluctant to believe that anything developed and promoted by large multinational firms could be in the interests of the environment, and who rather perceived a short-term campaigning opportunity;
- organic farmers, whose associations, in spite of the obviously “organic” character of the DNA molecule, felt that their image would suffer by contamination if they were seen to be favouring scientific techniques and innovations promoted by large companies;
- pesticide manufacturers, suffering directly from the loss of sales, hundreds of millions of dollars, because of the rapid take-up of transgenic plants having built-in pest resistance;
- the media, print and television, who frequently adopted a simplistic campaigning mode, unmitigated by deeper consideration of the quality and potential benefits of the innovations they were attacking;
- allegedly “public opinion”, although this is a slippery fish to catch, and the responses to public opinion surveys are poor predictors of consumer purchasing behaviour.

Over the period 1990–2003, public concern in Europe has mounted, and confidence in governments and science advisers has fallen, against a background of scandals and disasters: contaminated blood, contaminated cooking oil, mad cow disease, experts who had to admit, “we got it wrong”. The court of public opinion had found the scientists guilty of hubris; nemesis must follow, and the politicians were willing executioners, egged on by the NGOs.

The resulting regulatory response has been excessive, destructive, and dangerous, insofar as it diverts always limited resources and energies, political, administrative and scientific, from real problems to pseudo-problems. We are slowly returning to normal, as the

new techniques are routinely assimilated in the relevant sectors, starting with pharma, but the needs in developing countries are primarily in agro-food. It will take time, and the delays will be paid for in terms of competitiveness in the north, and lives in the south.

The European Commission over the past several years of noisy debate has completed the installation in the E.U. of a rigorous regulatory framework, which may help to rebuild public confidence. But the debate between science and public opinion is uneasy. Who could oppose a directive on environmental liability? Yet when legislators ask scientists whether they can define or measure “damage to biodiversity”, the answer is either short and negative or a long story. As was recently reported (Squire, 2003) in the U.K. Farm Scale Evaluations of GM crops:

“... the choice of a comparable system as a benchmark may be enough to change a given ecological impact from being considered a hazard to being considered a benefit. The analysis here identified that there was no logical benchmark or ideal system for the arable habitat.”

The insurance industry has for similar reasons been similarly ambivalent about the E.C.’s draft directive.

5. The safety record, and the research

The risks remain “conjectural”, because, as was announced at the European Commission on launching a couple of years ago a review of the results of the biosafety research which the E.C. had co-sponsored over the preceding 15–20 years:

Research on the GM plants and derived products so far developed and marketed, following usual risk assessment procedures, has not shown any new risks to human health or the environment, beyond the usual uncertainties of conventional plant breeding. Indeed, the use of more precise technology and the greater regulatory scrutiny probably make them even safer than conventional plants and foods; and if there are unforeseen environmental effects – none have appeared as yet – these should be rapidly detected by our monitoring requirements. On the other hand, the benefits of these plants and products for human health and the environment become increasingly clear.

That was based on some 80 projects, involving over 400 laboratories, and € 70 million. International research confirms that judgment, for example as presented at successive international conferences since 1990.³

Commercial and practical experience in the field conveys the same message, of technical success, increased yields, reduced use of chemicals, particularly pesticides, reduced spraying, reduced use of energy, consequent health and environmental benefits. The latest report from ISAAA, the International Service for the Acquisition of Agri-biotech Applications, summarizes the current scale of cultivation:

“In 2002, the global area of GM crops was 58.7 million hectares or 145 million acres,

³ These conferences, which in most cases received some financial support from the European Commission, were as follows: 1990, Kiawah Island, S. Carolina, U.S.; 1992, Goslar, Germany; 1994, Monterey, California, U.S.; 1996, Tsukuba, Japan; 1998, Braunschweig, Germany; 2000, Saskatoon, Canada; 2002, Beijing, China; 2004, Montpellier, France. Proceedings are available.

grown in sixteen countries by 6 million farmers, of whom 5 million were small resource-poor farmers in developing countries. The GM crop area has grown 35 fold between 1996 and 2002 – one of the highest rates of adoption of any technology in agriculture. The U.S. was the largest grower of GM crops (68 per cent), followed by Argentina (23 per cent) Canada (6 per cent) and China (4 per cent) with the balance grown by the other 12 countries. Three countries India, Colombia, and Honduras grew GM crops for the first time in 2002.”

6. The current stasis in Europe

The current situation in the European Union is tense. A number of Member States have imposed a *de facto* moratorium, preventing the authorization of any GM crops since 1998. The Commission has sought by the adoption of new regulatory instruments, on traceability and labelling, on GM food and feed, and on transboundary movement of GMOs (giving effect to obligations flowing from adherence to the Cartagena Protocol on Biosafety), to provide a framework which offers the most stringent regulatory scrutiny in the world, a high degree of transparency, and consequent freedom of consumer choice; and it is hoped that this heavy framework will restore public confidence in both the regulatory oversight, and the products themselves. The Commission therefore expects to see a resumption of product authorizations in the near future.

Battles continue, for example on the rules for the co-existence of GM, conventional and organic crops, and on acceptability thresholds for the degree of co-mingling acceptable in crops before they are required to be labelled as containing GMOs. Those with an interest in claims of “purity” as they define it, e.g. organic farmers, continue to clamour for more stringent standards. Others, more pragmatic, see no practical problem, for example, the French seed industry (CFS, 2003).

The U.S. is pursuing a complaint at the World Trade Organization against the European Commission for alleged failure to implement its own regulatory procedures; it is also uneasy about the practical feasibility of the tight standards imposed by the new regulation on traceability and labelling. The Commission is seeking to demonstrate that there is a working procedure now in place. The U.S. case is thus putting pressure on a door which is already starting (slowly) to swing open.

The political debate in Europe over the past 15 years has become overheated, and often the arguments about biotechnology have been instruments for the pursuit of other agendas, of opposition to Americans, to multinational corporations, to the industrialization of agriculture. There has been a tendency to make simplistic (but seductive) statements and to exaggerate. The political investment in regulatory frameworks for supposed risks becomes so large, that it becomes inadmissible to question the validity of its basis, or to recall that a precautionary approach was supposed to include attention to scientific developments. What happened afterwards to the little boy who had the temerity to point out that the Emperor was naked?

A common rhetorical trick is to take some familiar problem, the development of resistance to weedkillers or pesticides, or the problem of pollen drift, and restate it in the context of GM crops as though it was a new problem, or one which will be incomparably greater and more difficult, or impossible, to control in the context of the new genetics. There is little or no basis for these alarmist fears: they are rhetorical tricks, for the practical answers are already available in the long-established daily practices and pragmatic wisdom

of agriculture. But rhetorical tricks can shift perceptions, and perceptions are realities – they have consequences.

7. National sensitivity or paranoia? The U.K. leads

Concerns and legislation have mounted in Europe, encouraging paranoia: the heavy regulatory burden, intended to provide public reassurance, may equally stimulate the natural question, surely anything which requires so much regulation must be exceedingly dangerous?

Similar debates are running at national level, with variations relating to national experience, culture, and local political factors. Experience in the U.K. is interesting and currently prominent, because it is a country with a strong science base, and a competitive pharmaceutical industry, but also with vocal interests in defence of the environment. Confidence in the competence of government, and of its scientific advisers, was greatly damaged by the outbreak of mad cow disease, followed (in 1996) by the disaster of its jumping to humans with the appearance of new variant Creutzfeld-Jakob disease. Seeking to reconcile the conflicting pressures, the U.K. government has for some years been conducting an extended public debate about GM crops, and in 2003 published the following reports:

- (i) 21 July 2003: GM Science Review Panel: First Report (296 pages). This “first” report invited comments, to be submitted by 15 October 2003, following which it was to reconvene to consider the comments, together with the report of the GM public debate, “GM Nation?”; to consider whether there were further issues they wished to address; to see if there had been significant developments in GM science over the summer that they should report on; and to consider the results of the farm scale evaluations of GM crops. Available at <<http://dwww.gmsciencedebate.org.uk/report/default.htm>>.
- (ii) July 2003: Prime Minister’s Strategy Unit: “Field Work: Weighing up the Costs and Benefits of GM Crops”. Available at <<http://dwww.strategy.gov.uk/>>. Comments were invited by 17 October 2003. A rather tepid endorsement of the long-term importance of the field, but indicating that in the short term, the economic benefits would not be large.
- (iii) 24 September 2003: “GM Nation? The findings of the public debate”. Available at <<http://dwww.gmnation.org.uk/>>. Reporting on a series of public meetings, this transmitted a strongly negative message about public perceptions, but admitted that the public meetings had indeed been vulnerable to “capture” by organized hostile groups.
- (iv) February 2001–August 2002: Biotechnology Safety Unit, Department for Environment, Food and Rural Affairs (DEFRA): “GM Crop Farm-Scale Evaluations: Background Papers: The Farm-Scale Evaluations of Genetically Modified Herbicide Tolerant Crops: Rationale and Chronology” (8pp.). Available at <<http://dwww.defra.gov.uk/environment/gm/fse/background/rationale.htm>>.
- (v) 16 October 2003: *Phil. Trans. R. Soc. Lond. B* (2003) 358, Issue 1439, 29 November 2003, pp. 1775–1913 “The Farm Scale Evaluations of spring-sown genetically modified crops”. Preface, Introduction, and eight scientific papers presenting the results of the three years of trials of GM herbicide tolerant crops, in 138 pages, mostly of scientific data and language, in small print. Available at <http://dwww.pubs.royalsoc.ac.uk/phil_bio/news/fse_toc.html>.

- (vi) 25 November 2003: The Agriculture and Environment Advisory Commission published “GM Crops? Coexistence and Liability”, report to the government, with nine agreed recommendations and much disagreement (158pp.). Available at http://dwww.aebc.gov.uk/aebc/coexistence_liability.shtml.

The government has thus provided a highly publicized debate with three strands: scientific (the Science Panel report, item (i) above), economic (the Strategy Unit report – item (ii) above), and public debate (the “GM Nation?” report, item (iii) above), now further informed by the results of the FSE (items (iv) and (v) above). The government has stated that “We will decide our policy on the commercial cultivation of GM crops in the U.K. . . . based on an objective assessment of all the available information.” “All the available information” is a broad phrase, and the other items listed above by no means complete the extensive commentary which has preceded, accompanied and followed the reports listed.

The “hidden agenda” of such a massive communication effort, whatever the details, is inevitably to convey and reinforce the message of an unprecedented and enormous threat to our whole way of life, our countryside, the safety of our food supply, our relationship with nature.

The U.K. Farm Scale Evaluations were published on 16 October 2003. They represent meticulous science, conducted on some 300 farm-scale trials of GM HT crops, over three years. But they have been narrowly focused on the impacts on certain species of the weed management regimes of farmers growing GM and non-GM variants of three crops. They have produced remarkably divergent reporting in the U.K. press. On the one hand, some of the tabloid press, and some of the journals once thought to be serious, have given simplistic analyses as though the trials constituted a massive and negative judgment on the whole desirability or acceptability of growing GM crops in the U.K. Others, more thoughtful, or perhaps having read the papers more closely, realized the limited nature of the trials, and the extent of all the broader questions about land use and technology that were neither addressed nor answered by the trials.

8. So what are the risks today?

The risks associated with modern biotechnology might be listed under three headings: health, environment, and economics, but such a simple categorization proves inadequate to capture both the changing nature of the risks and the impact of changing definitions and perceptions.

For health-related risks, there is little problem. There is the long experience of the pharmaceutical industry, including occasional catastrophes and the recurrent problems of unforeseen adverse effects. The new tools of modern biotechnology have been welcomed into research and production in the health care sector for their precision and for their new insights, and do not in general pose risks of a new character, although they may intensify some old ones, e.g. regarding the treatment of sensitive medical data. But the insurance aspects fit within the familiar paradigm.

For environment, the track record of GM crops has so far been satisfactory, the performance generally predictable, and no significant adverse effects have been reported. Pest-resistant plants will no doubt generate a selective pressure favouring the emergence of resistant pests, again a familiar problem with which science and agri-industry have long had to cope. However, the U.K. trials, as discussed above, raise new questions, as they open up the possibility of more refined definitions of “environmental damage”. Weed control,

historically seen as an obviously desirable objective by most farmers, is now seen as double-edged: while desirable for crop performance, it is now seen as reducing the biomass and seeds on which various insect species, and indirectly, their predators, depend. The GM crops were, in effect, too successful. Thus a more refined definition of environmental protection, to include the maintenance of farmland biodiversity, as measured by weed biomass and dependent species, offers a subtle shifting of the goalposts. This could clearly interact with regulatory requirements.

Those who have commented on the U.K. trials have of course pointed out that similar questions could equally be addressed to conventional practices, and other, non-GM, innovations, but the reality of current regulations is that they do not in general include a comparative aspect. Thus unsustainable and damaging practices based on traditional practices continue unchecked, while innovations which might offer more refined methods of control, with less adverse side effects, would be blocked. This redefinition brings into focus the apparently surprising assertion of Bruno Porro,⁴ Chief Risk Officer of Swiss Re: "The decisive element is not whether modern biotechnology is dangerous, but how dangerous it is perceived to be". In effect, a perception-based redefinition of "danger" changes the parameters of risk and leads from the question of "environmental damage" into that of "economic damage".

In considering economic risk, a good starting point is the Starlink case. Starlink GM corn was an Aventis product, approved in 1998 in the U.S. for animal feed not human use; traces of it were detected in various processed foods in September 2000. The subsequent withdrawal provoked high profile debate and concern, but was seen as politically and commercially essential, again driven by perceptions. Although no harm resulted to humans (the U.S. CDC, Centers for Disease Control and Prevention, invited blood samples to test for allergic reactions, but detected no antibodies to the novel gene product), nor to the environment, the total cost to Aventis is said to have been around U.S.\$ 1 billion.

Secondly, there was Prodigene; this company, with USDA authorization, planted in 2001 a field of corn engineered to produce trypsin (for insulin production) and cleared the field after harvest. The following year, the field was used for soya, but some "volunteer" GM corn plants sprouted amidst the soya, and grains of the illicit corn were detected at the silo, almost a cupful. ProdiGene neither admitted nor denied any violations of the Plant Protection Act, but paid a civil penalty of U.S.\$ 250,000. In addition, they had to reimburse USDA for all costs to acquire some 500,000 bushels of soybeans in storage, destroy them, and clean the facility and all equipment.

Thus, two landmark events, Starlink and Prodigene, with nobody hurt and no environmental damage, offer two reassuringly substantial losses. Starlink and Prodigene have become first points on the graph of biotech "disasters", providing initial bases for the calculation of liabilities, risks, insurance premiums. As the E.U. prepares to restart authorizing commercialization of "GMOs", and to adopt a directive on "environmental liability", as yet ill-defined,⁵ this is not necessarily good news for the future of biotechnology in Europe.

A similar issue could arise if organic farmers are allowed to be judge and jury in

⁴ Put forward at the Vouliagmeni seminar of The Geneva Association, 6-7 November 2003, on the subject of uninsured risks.

⁵ Directive 2004/35 on environmental liability with regard to the prevention and remedying of environmental damage was adopted on 21 April 2004.

defining “contamination”, imposing zero tolerance standards for presence of GM materials: redefinition changes the rules and the risks, if perceptions, be they those of consumers in the shops, political protesters taking direct action, regulators making judgments, or judges and juries expressing their opinions, are shared widely enough to influence laws, regulations, and implementing practices.

Thus the nature and definition of environmental and economic risks is shifting; it depends upon public and political perceptions and consequent legislation and subjective judgments, including regulatory overkill, and the risks become correspondingly harder to predict. We reach the limits of insurability for the moment and until experience accumulates; but if the activity is uninsurable, the accumulation of experience will be delayed.

The legislation may be ill-founded and of doubtful validity (being weak in the scientific basis), but in a climate of intimidation and media campaigning, few companies wish to be the first to take up this challenge. The legislation creates self-justifying fears and beliefs and spreads, and, when adopted by the world’s major trading bloc, has a huge influence on both legislative and private sector investment and marketing decisions around the world.

9. And who are the losers? Europe, the environment, and the developing countries

New knowledge and techniques are available and are continuing to advance in quantity, sophistication and availability. We have described some of the factors which inhibit their development and application within Europe, certainly to the detriment of agricultural competitiveness, and of more environmentally-friendly products, processes and practices. The need for the new methods is even greater in poorer countries around the world, but two significant limitations delay this diffusion.

Firstly, the techniques, and the crops and markets for which they have been developed, are inevitably those of the rich, developed world. Investment and incentives are necessary to adapt them to the needs of the developing world. Leading countries with scientific capability, such as Brazil, China, India, and perhaps South Africa, may have the indigenous capability to manage all stages of using, applying and diffusing the new methods; poorer countries do not, although their needs are among the greatest.

Secondly, the reticence expressed in Europe, not least through its heavy regulatory requirements, makes itself felt around the world – Europe is the greatest importer of agricultural produce. The European constraints are exported by several channels: by the demands imposed on imports, and on those who might wish to invest and innovate within Europe; by the terms of the Cartagena Protocol,⁶ with the implementation of which over 100 countries are now struggling (although several of the major agricultural exporters of the Cairns Group, notably the U.S., have not signed it); and by other international channels such as the Codex Alimentarius Commission, which in July 2003⁷ adopted principles and guidelines for foods derived from biotechnology.

Developing countries have the greatest needs for improving the quantity, quality and

⁶ The Cartagena Protocol came into effect on 11 September 2003, 90 days after deposit of the instrument of ratification by the 50th country to do so.

⁷ See FAO press release, 9 July 2003, at <<http://www.fao.org/english/newsroom/news/2003/20363-en.html>>: “The Codex Alimentarius Commission has adopted a landmark agreement on how to assess the risks to consumers from foods derived from biotechnology, including genetically modified foods, FAO and the World Health Organization (WHO) said today.”

security of their food production, and reducing the environmental degradation which accompanies current unsustainable practices. They are for the moment the great losers from the delay. We should not forget the key statement in the report, May 1999, of the Nuffield Council on Bioethics: “The moral imperative for making GM crops readily and economically available to developing countries who want them is compelling”; the message of that report (including that Executive Summary) was reiterated in their new draft report in 2003.

The results are doubly unfortunate, because they mean that Environment Ministries and so-called “environmental” NGOs are now opposing the development and diffusion of more environment-friendly and sustainable products, processes and practices; the products and practices desperately needed in the developing countries – already, in the present; and increasingly, as we seek to double food production to cope with population expansion of 50 per cent over the next three decades, using the current cultivated area, or less; with no more water, or less; and while seeking to reverse current unsustainable practices and the degradation of the environment.

10. An interim conclusion

Our suggested reformulation of the question about insurability, “Is the progress and application of new knowledge in the life sciences and biotechnology an uninsurable risk?”, is like asking, “Is electricity an insurable risk?”, and the insurance industry will naturally reply, “yes and no, depending upon the specific application, the experience, the use of appropriate safety procedures, etc.”

As we assimilate the new knowledge and techniques of modern biotechnology, as they move inexorably into routine application around the world, so they will progressively become routinely insurable; indeed, in many places, they already are. The progress will be gradual. It will be all the slower if negative perceptions persist, shifting the regulatory goalposts for the innovator, and redefining environmental damage in more stringent terms.

For the long and avoidable delays, a high price will be paid: by the Europeans, in competitiveness; by the environment, in delays to the development and diffusion of more sustainable products, processes and practices; and by the developing world, in unnecessary hunger, avoidable disease, and early death.

REFERENCES

- AVERY, O.T., MACLEOD, C.M. and McCARTY, M., 1944, “Studies on the chemical nature of the substance inducing transformation of pneumococcal types: Induction of transformation by a desoxyribonucleic acid fraction isolated from *Pneumococcus* Type III”, *The Journal of Experimental Medicine*, 1 February 1944, Vol. 79, No. 2, pp. 137-158.
- BERG, P. *et al.*, 1974, “Potential biohazards of recombinant DNA molecules”, *Science* 185, p.303.
- BERMAN, H., HENRICK, K. and NAKAMURA, H., 2003, “Announcing the worldwide Protein Data Bank”, *Nature Structural Biology*, 10, 12, December, p. 980.
- CFS (Confédération Française des Semenciers), GNIS (Groupement National Interprofessionnel des Semences) and UIPP (Union des Industries de la Protection des Plantes), 2003, *Filières OGM, conventionnelles, biologiques : la coexistence est possible*. Paris : Altedia M&M Conseil.
- CHANG, A.C.Y. and COHEN, S.N., 1974, “Genome Construction between bacterial species in vitro: Replication and expression of *Staphylococcus* plasmid genes in *Escherichia coli*”, *Proc. Nat. Acad. Sci.* 70, 4, pp. 1030-1034, April.
- COHEN, S.N., CHANG, A.C.Y., BOYER, H.W. and HELLING R.B., 1973, “Construction of Biologically Functional bacterial plasmids *in vitro*”, *Proc. Nat. Acad. Sci.*, 70, 11, pp. 3240-3244, November.
- EUROPEAN COMMISSION, 2000, *Communication on the precautionary principle*, COM(2000)1, February.

- HEGEL, G.W., 1837, *Philosophy of History* (ed. E. Gans).
- JAMES, C., 2003, "Global Review of Commercialized Transgenic Crops: 2002 Feature: Bt Maize", ISAAA Brief, 29.
- KESSLER, C. and ECONOMIDIS, I., 2001, A Review of Results: EC-sponsored Research on Safety of Genetically Modified Organisms, Research Directorate-General, European Commission, EUR 19884. Also online at <<http://europa.eu.int/comm/research/quality-of-life/gmo/>>.
- KLING, J., 2003, "Ultrafast DNA Sequencing", *Nature Biotechnology*, 21, 12, pp.1425-1427.
- MacNEIL, J.S., 2003, "You could have the whole genome in your hand – do you want it?", *Genome Technology*, 38, October, pp. 24-30.
- MORROW, J.F., COHEN, S.N., CHANG, A.C.Y. and BOYER, H.W., 1974, "Replication and transcription of eukaryotic DNA in *Escherichia coli*", *Proc. Nat. Acad. Sci.* 71, 5, pp. 1743-1747, May.
- NUFFIELD COUNCIL ON BIOETHICS, 1999, Genetically modified crops: the ethical and social issues. London.
- NUFFIELD COUNCIL ON BIOETHICS, 2003, "The use of genetically modified crops in developing countries: A follow-up Discussion Paper to the 1999 Report", Genetically modified crops: the ethical and social issues. London.
- OECD, 1986, *Recombinant DNA Safety Considerations: Safety considerations for industrial, agricultural and environmental applications of organisms derived by recombinant DNA techniques*. Paris: OECD.
- ROGERS, M., 1975, "The Pandora's Box Congress: 140 Scientists Ask: Now that We Can Rewrite the Genetic Code, What Are We Going To Say?", *Rolling Stone*, 189, 36; reproduced in Watson and Tooze, 1981, *The DNA Story: A documentary history of gene cloning*. Freeman.
- SQUIRE, G.R., BROOKS, D.R., BOHAN, D.A., CHAMPION, G.T., DANIELS, R.E., HAUGHTON, A.J., HAWES, C., HEARD, M.S., HILL, M.O., MAY, M.J., OSBORNE, J.L., PERRY, J.N., ROY, D.B., WOIWOD, I.P. and FIRBANK, L.G., 2003, "On the rationale and interpretation of the Farm Scale Evaluations of genetically modified herbicide-tolerant crops", *Phil. Trans. R. Soc. Lond. B* (2003) 358, pp.1779-1799.
- WATSON, J.D. and CRICK, F.H., 1953, "Molecular structure of nucleic acids: A structure for deoxyribonucleic acid", *Nature*, 171, pp. 737-738, 2 April.
- WATSON, J.D. and TOOZE, J., 1981, *The DNA Story: A documentary history of gene cloning*. Freeman.

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