IPA BIOTECHNOLOGY BACKGROUNDER

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Regulating Biotechnology

Some Questions and Some Answers

John Hyde

Summary

Forty years ago James Watson and Francis Crick discovered the molecular structure of DNA and, from the early seventies, biotechnologists progressively learned more precise ways of introducing genes into plants and animals. Although by cross-breeding and selection most domesticated and cultivated species have been changed radically from their *wild* forebears, technology which became referred to as 'genetic engineering' or 'recombinant DNA (r-DNA) technology' allowed the incorporation of novel characteristics which traditional breeding cannot achieve. The term 'genetically modified' came to refer to matter that carries genes introduced by 'gene splicing'.

Australian governments currently face considerable pressure to regulate further the use of r-DNA technology and its products. If the Federal Government should err in one direction, Australians could consume dangerous substances and the environment could be degraded—including being invaded by varieties of weeds that are particularly pestiferous.

If it were to get it wrong in the other direction, it would cause a decline in our industries' competitiveness thereby reducing Australian living standards, prevent the production of cheaper food and fibre, deny effective treatment to ill people, and encourage our scientists to take their skills elsewhere.

Therefore, before assuming the best or the worst, Australians should learn what genetic modification is and put its rewards and dangers in context.

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Twenty-eight questions often raised in debate about the use of recombinant DNA follow. I am indebted to *Altered Genes* edited by Richard Hindmarsh, Geoffrey Lawrence and Janet Norton for the questions. The responses are my own. Such is the stuff of debate in a liberal society!

QUESTION: Is the new biotechnology significantly different from long-established methods of genetic modification by cross-breeding, selection and the practice of employing irradiation to induce mutation?

RESPONSE: It is different in these respects:

(a) it allows us to introduce or remove single genes instead of large blocks of DNA, thereby enhancing precision in the genetic improvement of plants and animals, and mitigating much of the hit-and-miss and associated risk common to the more traditional methods;
(b) because the need to back-cross to eliminate unwanted traits is avoided and outcomes have become more predictable, much more change is made possible; and
(c) it allows us to introduce genes from species other than that of the host.[1]

QUESTION: Might not genetically modified (GM) foods contain harmful carcinogens, allergens or other poisons?

RESPONSE: Yes, but not because they are genetically modified. Most plants contain substances which if ingested in sufficient quantity would kill us. But long before we eat too much we lose our appetite for the particular substances. All GM foods are assessed to see if they are unsafe.

QUESTION: Even if GM foods are perfectly safe, shouldn't genetically modified products be labelled as such, giving consumers the choice of whether to eat them or not?

RESPONSE: In Australia, New Zealand, the US, Canada, the European Union and Japan, foods that contain GM products that are not 'substantially equivalent' to existing food products must be labelled as such. (The term 'substantially equivalent' was developed by the Organisation for Economic Co-operation and Development and the World Health Organisation to identify foods that are 'compositionally and nutritionally similar within the limits of normal biological variation in edible varieties of plant'.[2])

The Australian New Zealand Food Standards Council—made up of health ministers from all States and Territories, the Commonwealth and New Zealand—nevertheless intends to expand the mandatory labelling of foods that contain genetically modified material so that it includes those that are substantially equivalent to existing foods. Its rationale is not official concern about health risks but an attempt to satisfy demands made by members of the public that foods containing GM material be identified.

It is not clear, however, that the intended broadening of the labelling requirement to include substantially equivalent foods will benefit most people. Those people who want to know whether their purchases contain or may contain GM material, and are prepared to pay what it costs to provide that information, will provide the demand for a profitable niche market similar to that which exists now for 'organic', halal and kosher foods. The proposed mandatory labelling policy will:

- Imply that there is a health risk with GM food, where none can be detected by experts;
- Eliminate the differentiation between GM products which are 'substantially equivalent' and those that are 'substantially different' (GM modified products are so widespread and food chains so complex that most foods would need to carry a warning stating that they might be affected by the new biotechnology);
- Be costly (tracing back and describing the degree and nature of possible 'GM contamination' could add appreciably to the price of, in particular, those foods most needed for a healthy diet[3]); and
- Discriminate against packaged food, as the labelling requirement will not apply, for instance, to food served in restaurants.[4]

As long as consumers are willing to pay for their knowledge, they have a right to know. However, the case for compelling those who do not wish to bear the cost of labelling GM foods to subsidise those who do is no greater than it would be for compelling uninterested parties to pay for identification of grains treated with fungicides, fish caught with nets, meat killed in abattoirs that do not adhere to certain religious rites and so on—through a very long catalogue.

QUESTION: Might it not then be appropriate to label foods that have not come in contact with the new technology, in the same way that organic, kosher and halal foods are currently identified?

RESPONSE: Yes it might, and it is worth noting that such labels are voluntary—nobody is forced to label their food 'halal'. Before labelling provisions along such voluntary lines are introduced, producers of non-GM foods would need to agree on definitions and arrange for certification—as the organic farmers have done. There is no reason to restrict product differentiation whatever the differentiator may be—as long as it is the truth. It is another matter to *require* such differentiation—thereby legitimising claims that such differentiation is appropriate—when there are no specific health or other dangers to justify doing so.

QUESTION: Is the information we get from scientists reliable?

RESPONSE: Not necessarily. There is such a thing as bad science and scientists are as prone to the temptation to self-promote as are other people but, to the extent that they remain within their areas of expertise, information derived from them is considerably more reliable than the opinions of laymen, salesmen and promoters. Of course, when hard scientists venture into the social sciences they should be treated as laymen. And, of course, science can be misused.

QUESTION: Can scientists predict every consequence of genetic engineering?

RESPONSE: Absolutely not, but neither can every consequence of any human activity be predicted. A significant feature of experimentation with r-DNA is that the experiments are more thoroughly monitored than with most experimentation, including genetic development by longer-established means.

QUESTION: Is media coverage of biotechnology biased in favour of the scientists' perspective?

RESPONSE: From current information it is impossible to say. Tiffany White's apparently well-conducted 1995 survey of the *Sydney Morning Herald*'s coverage indicated that it was, but a similar survey of the Internet would surely reach the opposite conclusion and so would a survey of the ABC or the Melbourne *Herald Sun*. The important fact is that both pro and con arguments are readily available to any serious student of the topic. The important question that remains is whether either or both sides are resorting to misinformation, exaggeration or irresponsible hyperbole.

QUESTION: What hope, if any, does genetic engineering hold for the elimination of chronic shortages of food for the world's poorest people?

RESPONSE: It will not affect those causes of malnutrition such as the absence of stable property rights, price control and warfare that are to be found within the several communities' social systems. It will, however, increase yields in many instances and reduce the necessity for expensive inputs, particularly herbicides and insecticides but also arable land itself. Therefore, food and fibre will cost less.

QUESTION: Can we trust the Australian regulatory procedures to protect us?

RESPONSE: No regulatory system can guarantee absolute safety.

Australians have, nevertheless, experienced very few episodes like the recent South Australian one of unsafe smallgoods where there was a death. Our food standards are based on international best practice, underpinned by an appropriate mixture of sound science and precaution. Issues relating to human health and safety are subject to a fully transparent, risk-based assessment process. Australian regulatory agencies actively participate in work to develop principles, guidelines and standards carried out by international organisations such as OECD, Codex, WHO and FAO.

Whether the good record is attributable more to regulatory rigour than to the commercial incentive not to offend customers is beside the point. The fact is that, in Australia, commercially available foods are exceptionally safe and GM foods are assessed even more rigorously than are non-GM foods. Nevertheless, anti-r-DNA activists are calling for further restriction of commodities that have been genetically engineered (process regulation) rather than assessment of all commodities against established standards (product regulation). And there seems to be widespread, if lukewarm, support for process regulation—at least in the

case of foods. Governments often feel obliged to regulate to placate such sentiments. Even so, it is hard to see how such a change would in fact improve food safety when it would divert resources and attention from the dangers themselves to the processes.

Safety also relates to protection of the environment and public health.

The case for regulating research and the release of new products is generally accepted, that is, for restraining the cowboys.

Several biopharmaceuticals are produced from recombinant organisms and the regulatory system, including clinical trials, is well understood, transparent and widely accepted. It does, of course, increase drug costs materially.

Commercially available products are regulated by a system that will comprise the existing regulators with a legal remit to cover some aspects of genetically modified organisms (GMOs) and the products derived from them. The relevant authorities are:

- The Australia New Zealand Food Authority (ANZFA);
- The Therapeutic Goods Administration (TGA);
- The National Registration Authority for Agricultural and Veterinary Chemicals (NRA);
- The National Industrial Chemicals Notification and Assessment Scheme (NICNAS); and
- The Australian Quarantine and Inspection Service (AQIS).

There will also be a new Office of the Gene Technology Regulator (OGTR). OGTR will supersede the existing arrangements under the Genetic Manipulation Advisory Committee (GMAC) which advises on research and environmental release of GMOs. It will also cover any gaps where no other regulator has responsibility.

The system works, although many people claim that it works less well than it should. It has well-established procedures, precedents and qualified staff. It is, however, complex and arcane.

QUESTION: Plant variety rights legislation and the Trade Related Aspects of Intellectual Property Rights (TRIPS) treaty among World Trade Organisation (WTO) members are objected to on the grounds that there should be 'No Patents on Life'. Are property rights in living things fair?

RESPONSE: Most people accept private ownership of plants and animals and the slogan plainly is not intended to be taken literally. The issue must be whether private property rights in *varieties* of flora and fauna, preventing free access to the genetic material, are appropriate. But even here, private ownership is of long standing—stud breeders own sires and charge for services for instance. These breeders' property rights are not protected by patent but by ownership of the animals with the superior genes. That a different process should enforce the relevant property rights would seem not to involve a major difference of principle.

QUESTION: Is the biotechnology industry engaging in bio-discovery or bio-piracy?

RESPONSE: It is sometimes erroneously asserted that, in the search for drugs to treat human ailments such as HIV, pharmaceutical companies such as AMRAD are patenting the medicines of indigenous peoples. It is similarly claimed that, in the search for better foods, food manufacturers such as Nestlé are patenting the foods of indigenous peoples. All that a commercial supplier can do, however, is to patent processes by which the traditional medicines and foods are rendered more useful for human employment. There remains the question of whether indigenous or other commercially unsophisticated people are always adequately rewarded for assistance that in due course leads to the creation of intellectual property.

QUESTION: Is private property in living things in Australians' economic interests?

RESPONSE: Yes it is. It is true, as opponents of plant variety rights claim, that most of the world's species tend to be concentrated in the tropics and in Australia and that, provided the law does not prevent it, this biodiversity is a source of potentially valuable genetic material. Governments do have a role in protecting especially rare biota. Like Australia's mineral resources, however, it is of only potential value until it is discovered and developed. Even if such a strategy were morally justifiable, Australians do not have the capacity to conduct a hold-out strategy, that is, to deny others access to genetic material by demanding the high prices for it that can be achieved only by maintaining a monopoly. We should be instructed by our costly failure to do so with wool, where the opportunity appeared more readily available.

QUESTION: What, if any, are the economic advantages/disadvantages that Australian *producers* might gain/suffer from the Australian regulatory environment?

RESPONSE: Australians have a natural advantage, based upon the availability of relatively cheap farmland and a considerable bank of know-how, in the production of several agricultural products. Although declining in relative terms, agriculture remains a significant part of our economy and a major contributor to exports. Were Australian farmers to be denied productive advantages available to foreign competitors, Australian agriculture would not, as some have implied, become unprofitable. It would, however, become smaller (retreat to the more profitable paddocks) contributing less to gross domestic product. Average Australian living standards would then be lower than they might have been. Conversely, if Australian farmers were to enjoy a more favourable regulatory environment than that of international competitors, then Australian living standards, as they are conventionally measured, would be enhanced. Similar arguments apply to other Australian industries, not least the bio-medical industry, where we have also developed some competitive advantages at least at the discovery end of production. Therefore, the case for restrictive regulation needs to be based on factors that do not readily enter the commercial equation—in economists' terms, upon externalities. Australian producers probably also gain access to some markets from a 'clean and green' image.

QUESTION: Will farmers benefit from biotechnology or will the large companies that own the intellectual property appropriate all the benefits?

RESPONSE: Farmers will benefit. Farmers are not compelled to use the new technologies and patented seeds and, if they do not voluntarily employ them, then the companies will have nothing of value. Whether farmers benefit to the economically optimum extent will depend on whether there is adequate competition between seed merchants and between chemical producers. These organisations will, however, be subject to the normal provisions of the *Trade Practices Act*.

QUESTION: Since there is considerable resistance to GM food in many countries, might Australia do better by banning GM production and catering for a large niche market?

RESPONSE: As in domestic markets, it is unnecessary to ban GM production to cater for a GM-free preference in overseas markets. To tap these markets, respected certification of GM-free product would be needed, just as there is certification for organically grown product and for much of Australia's meat export now.

QUESTION: What, if any, are the advantages/disadvantages that Australian *consumers* might gain/suffer from the Australian regulatory environment?

RESPONSE: Regulations impose costs, restrict choice and raise prices. They can, however, if wisely drawn, greatly reduce the cost of gathering the information needed to choose wisely. For instance, it suits the average shopper to know without inquiring about the manufacturer that her purchases will not contain harmful levels of *E. coli* or salmonella.

QUESTION: What, if any, are the advantages/disadvantages that Australian *researchers* might gain/suffer from the Australian regulatory environment?

RESPONSE: Scientists need to know that they will be able to carry through inquiries that may take many years to complete. They, therefore, have a considerable interest in a stable regulatory environment—in economists' terms, they have an interest in the absence of 'sovereign risk'. Further, as much as the rest of us, they like to profit from their efforts. Most researchers, however, have a considerable advantage that people who have invested in physical capital do not have: they can migrate, taking their intellectual capital with them. Such is the nature of a national 'brain drain'.

Product developers will also be required to carry the direct financial costs of regulation.

QUESTION: What is the risk that plants that have been genetically modified to resist certain predators will become super-weeds reducing the yields of other crops or reducing biodiversity?

RESPONSE: There is already a tendency for plants introduced for pasturage or accidentally in animal food to invade bushland to the detriment of natural species. Stronger plants may do so more readily. The GMAC now and the OGTR in the future will assess these risks to prevent such adverse effects. Further,

if GM plants should spread to the detriment of people or the environment, then litigation seeking compensation for loss is possible. Fear of judgments which award damages would restrain the careless propagation of potential 'super-weeds' but it would also inevitably curtail the beneficial employment of biotechnology. The damages awarded to successful litigants are likely to be no more even and predictable than in other product-liability cases.

QUESTION: Will 'clean', that is, weed-free, crops deny wildlife its foods and nesting places?

RESPONSE: Whatever the effect in Europe where wildlife has become adapted to agriculture, in Australia where wildlife is well-adapted to the bush and is in no way dependent on grazing on and nesting in farmers' crops, this concern should not be a major issue. What is more, non-GM maize crops, for instance, are typically sprayed with insecticide eight to ten times and this is likely to have a more significant impact on non-pest insects than GM technology targeted at species that attack the crop.[5] Further, to the extent that yields are increased, the area needed to be cleared and cropped will be less than it otherwise would have been. Because most agricultural products sell into global markets, it cannot, however, reliably be predicted which countries will benefit.

QUESTION: Cotton has been genetically modified to 'kill its own pests' (Bt cotton) and soybeans to withstand applications of glyphosate (Roundup), a broad-spectrum herbicide. These technologies have enabled cotton and soy growers to reduce the number of pesticide/herbicide applications dramatically. Similar modifications of other crops and for other herbicides are expected. Will the pests and weeds of these crops in time develop resistance to the plants' newly inbuilt resistances and to glyphosate and other herbicides?

RESPONSE: Yes they will, but there is no reason to believe that they will do so more rapidly than at present and maybe less rapidly because a resistance management strategy for Bt cotton, for instance, has been encouraged by GMAC and NRA.

Species' abilities to adapt depend on many factors but are maximised at high but incomplete levels of kill. Herbicide-resistant rye grass is a current problem for wheat growers. There is thus no end in sight for farmers' struggles to stay ahead of the many bacteria, viruses, fungi and weeds that prey on their crops. Each new breakthrough, however, provides a window of opportunity by which yields are increased and unit costs reduced. Since farmers must compete, the ultimate benefit accrues to consumers and, in order to prosper, individual farmers must stay abreast of their competitors. In spite of the adaptability of weeds, pests and diseases, the real prices of foods and fibres have fallen dramatically this century. Plant breeders and farmers using the windows of opportunity as they have opened have raised worldwide living standards.

QUESTION: Is reducing the number of pesticide and herbicide applications environmentally beneficial or harmful?

RESPONSE: Reduced usage at least reduces the potential for damaging spray drift, run off and seepage to groundwater—and even if the herbicide or insecticide is non-toxic, the detergents in the formulation can be toxic, for example, to frogs.

QUESTION: Does biotechnology have the potential to assist sound environmental management directly?

RESPONSE: Yes, very great potential. A GMO has already been employed to clean up oil spills. The use of biotechnology techniques is hoped to induce sterility in selected introduced species, such as the rabbit, and to develop more salt-tolerant plants to revitalise land lost to salt encroachment that is such a serious problem in Western Australia.

QUESTION: Does genetic engineering lead inevitably, probably or even possibly to eugenics, that is, to the management of human offspring?

RESPONSE: None of these three. Eugenics is possible now and has been attempted by people with more arrogance than sense. Genetic engineering is merely one technique that might be employed by some future eugenicist. One day, genetic engineering may well be used to avoid conditions such as Down's syndrome and muscular dystrophy but that is not what people mean by eugenics. Further, should that day come, genetic manipulation might be seen as a better alternative to the currently widespread

practice of abortion or a lifelong institutional existence. For the foreseeable future, manipulation of the human genome in ways that can be passed to future generations is forbidden in Australia and there is no clamour that the ban should be lifted. The only type of genetic manipulation of the human genome currently permitted is gene therapy to treat diseases such as cystic fibrosis and cancer.

QUESTION: Will genetic research and the identification of genetic defects, abnormalities or tendencies lead to an invasion of privacy, refusal of life insurance, or denial of employment opportunities?

RESPONSE: So long as our society remains subject to the rule of law, these possibilities will depend on the rules and societal norms our society adopts concerning the uses to which personal genetic information may be put. The issue is one that our lawmakers must address. The probability that they will do so in ways that are not to everybody's liking is, however, not a good reason to inhibit research that has the potential to yield further considerable benefits. These benefits will probably include not just the treatment of genetic disease but also of disorders such as cancer and the development of more effective vaccines—both of which are already well advanced. The greater danger is, perhaps, that in the event of our society not remaining liberal and civilised, the records will assist ethnic cleansing or some other variant of eugenics. All comprehensive records, including those of Medicare, the tax office and passports, face this objection. Nevertheless, the sad truth is that ethnic cleansers have never been much inhibited by the quality of their databases.

QUESTION: It is argued that developments in biotechnology are immoral. Might it also be immoral to inhibit these developments?

RESPONSE: Yes it might. Biotechnology's manipulation of r-DNA has already produced benefits for the ill and the production of human necessities. There is every reason to believe that it will continue to make possible the production of less costly and more nutritious foods, the treatment of debilitating human ailments and environmental redemption. There is also the broader consideration that, while there can be no guarantee that the accumulation of knowledge and access to new products will continue to benefit mankind, great benefit has been the tendency so far and it appears to be accelerating. One consequence has been that worldwide life expectancy, although very unevenly spread, has increased enormously in the past 100 years.[6] The moral implications of every case must be assessed on merit but it is surely not moral knowingly to deny such obvious benefits to needy people without adequate reason. What is more, there are very many examples of scientific effort in one area, such as space travel, having unexpected benefits in others.

QUESTION: Is biotechnology interfering with God's design? If so, is this moral?

RESPONSE: We do not feel competent to answer this question and only in passing note that the Jewish Torah and Christian Bible at Gen. I: 28 admonishes man to subdue nature and have dominion over every living thing that moveth upon the earth. There appears to be no concern among mainstream Christians. Indeed Bishop Sgreccia, Vice President of the Vatican's Pontifical Academy for Life, following a two-year study by his members, has said

> We are increasingly encouraged that the advantages of genetic engineering of plants and animals are greater than the risks. The risks should be carefully followed through openness, analysis and controls, but without a sense of alarm.[7]

QUESTION: Is it more or is it less safe for research and development to be in private, for-profit hands than in the hands of governments?

RESPONSE: There is a place for both public and private research. The more basic the research and the wider its application, the more it takes on the characteristics of a public good for which no market can form and which must therefore be funded from taxes. At the other end of the scale, where research is likely to result in marketable products, there is an economic advantage in having R & D conducted by people who must be mindful of consumers' interests. Safety is not affected by the source of funds but by separating those who are regulated from their regulators and by the climate of self-discipline of the researchers. Equally, the quest for profit or for research grants could weaken that discipline and on occasion each has.

QUESTION: Since we cannot be totally sure of anything, shouldn't we take precautions?

RESPONSE: Yes, but risk is a fact of human existence that cannot be avoided. All precautions entail costs and there is a high correlation between living standards and life expectancy.[8] Since we can't do everything, precautions should be ranked with every other expenditure of human effort and undertaken when the risks warrant. People who start at every hare, squandering nervous energy and attention upon low-probability risks, can easily become victims of their own neurosis. Crying 'Wolf' entails the near-certainty that real hazards are ignored—for instance, to worry about what you ate for breakfast while driving your car (badly) does not usually aid survival.

Endnotes

1 FAO (1989), *Biotechnology for Livestock Production*, United Nations Plenum Press.

2 Jones, David (1996), 'Safety, Regulation and Innovation in the Food Sector', *Current Opinion in Biotechnology*, 7, pages 262–264.

3 A KPMG study commissioned by ANZFA estimated the cost of mandatory labelling to be in the vicinity of $3 billion in the first year and $1 billion in each subsequent year.

4 See Australian Food and Grocery Council (1999), 'Backgrounder: Biotechnology Overview'.

5 Kellow, Aynsley, *IPA Review*, September 1999.

6 Global average life expectancy at birth for men was 65 for men and 69 for women in 1997, for Australia they were 76 and 81 respectively (*World Development Indicators 1999/2000*, World Bank). In 1900, life expectancy at birth for Australians was 51 for males and 55 for females (Vamplew, W. (ed.), (1987), *Australians: Historical Statistics*, Fairfax, Syme & Weldon Associates).

7 *St Louis Review*, 12 October 1999.

8 Examination of GDP per capita and life expectancy for 132 countries from *World Development Indicators 1998* (World Bank), shows a positive correlation of 0.62.

About the Author

John Hyde is a commentator on political and economic affairs who writes periodic newspaper columns. Before entering the Federal Parliament he developed a high-fertility merino sheep flock using what were then the slow conventional means. While an MP, he was instrumental, with three other MPs, in forming the backbench ginger group which became known as 'the Dries'. He is today a Senior Fellow of the Institute of Public Affairs.

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