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Aynsley Kellow

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Introduction

The recent experience in the United Kingdom with "Mad Cow Disease" or Bovine Spongiform Encephalopathy (BSE) has engendered a particular sensitivity among consumers regarding what they are eating. BSE, thought to be caused by a protein molecule called a prion, produced the devastating "new variant" Creutzfeldt-Jacob disease (vCJD) in humans who consume nerve tissue.[1]

BSE was shocking, not so much because of the scope of the problem in humans since relatively few people have contracted vCJD, but because of the horror of the disease. "Spontaneous" CJD was best known previously among those treated with growth hormone extracted from the pituitary glands of dead humans, or as "Kuru" in Papua, New Guinea, where ritual cannibalism involved the consumption of human brain tissue. The BSE experience has fueled concerns about foods which have been produced using the new technology of genetic engineering. But the way in which concerns have developed into policy responses has been markedly different in Europe than in the U.S., where concerns exist, but have not had a significant impact on policy development. Why?

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* Aynsley Kellow is Professor and Head of the School of Government at the University of Tasmania, Australia. His degrees are as follows: B.A. (Hons) and Ph.D. (Otago). He is the author of *International Toxic Risk Management: Ideals, Interests and Implementation* and co-editor of *Globalisation and the Environment: Risk Assessment and the WTO*. He has also published articles in journals such as *Natural Resources Journal*, *Policy Studies Journal*, *Political Studies*, *Environmental Politics*, *Energy and Environment*, and *International Political Science Review* on aspects of public policy and environmental politics. *Email: akellow@utas.edu.au.*

1 As John Adams has noted, however, the prion theory of causation is by no means universally accepted. *See* John Adams, *Cars, Cholera and Cows: Virtual Risk and the Management of Uncertainty,* 80 Science Progress 253 (1997). The theory that BSE causes nvCJD is weakened by contrary facts, such as known cases of nvCJD among vegetarians.

To answer that question, we must delve into the process of risk assessment, whereby different political systems confronted with the same scientific evidence can reach fundamentally different positions on how to manage any particular risk. In doing so, we can also shed some light on why, what the alarmists have labelled "Frankenstein food," has evoked much more concern than the use of genetic engineering to produce pharmaceuticals. In a wonderful irony, genetic engineering has, for a decade, allowed the production of a growth hormone which has avoided the risk of CJD without giving rise to any alarm. Understanding risk assessment also allows U.S. to understand why this is so, and points towards ways in which we should assess the risk of genetically modified organisms (GMOs).

Concerns about beef in Europe are not new. Hormone-treated beef has been in dispute between the EU (EU) and the U.S. since 1985, when the then European Community imposed a regulation prohibiting the sale or importation of beef raised with the assistance of artificial hormones. At that time, problems had arisen in Italy among children who consumed European beef which had been injected intramuscularly with hormones, while the U.S. argued that their production methods did not give rise to the same risks since they used hormone patches behind the ear of cattle beasts. Since the ear was not consumed, there was no chance that high concentrations of residues could find their way into meat sold for consumption.[2]

The more recent dispute has not involved artificial hormones at all, but naturally-occurring bovine somatotrophin (BST) produced by organisms which have been genetically modified (GM).[3] Recombinant BST (i.e., bacteria whose genetic material has been modified so they will produce it) has been available for commercial use in the U.S. since February 1994, but was not approved for use in the EU, Australia, Canada, New Zealand, or Norway. The product is

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2 *See* John H. Jackson, *Dolphins and Hormones: GATT and the Legal Environment for International Trade After the Uruguay Round,* 14 UALR L.J. 429, 435-36 (1992).

3 *See Globalisation and the Environment: Risk Assessment and the WTO* (David Robertson & Aynsley J. Kellow eds., Edward Elgar 2001) (regarding the relationship between trade rules, environment, and quarantine risk).

produced using the identical BST synthesised by the cattle, and is thus indistinguishable from naturally-grown beef — itself the result of animal husbandry techniques and eons of selective breeding by humans to improve productivity. So why the concern?

Part of the answer can be gauged from the way in which other EU nations exploited Britain's BSE tragedy, in which about one million cattle had to be slaughtered.[4] The tragedy was a bonanza for continental beef producers, since it allowed bans on trade in British beef within the European single market and restaurants were able to advertise their steak as being non-British or "French Charolais." There is almost always a silver lining for someone in any such dark cloud — but more on that later.

Risk and Nature

Increasingly, we care about how our food is grown and prepared. We no longer eat restaurant dishes with classic names like "Steak Diane," but instead prefer dishes with names such as "rump of grass-fed yearling Aberdeen Angus beef, pan-fried . . . ." The sizzle has become at least as important as the sausage, and part of the sizzle has to do with our conceptions of nature, particularly with somewhat romantic notions of purity or the absence of contamination. Organic is good, despite the fact that organic chemistry has given the U.S. all those pesticides about which we are so concerned.

"Chemical" is usually synonymous with synthetic chemical, and these notions of purity extend to the bottled water we buy. It was possible to buy bottled water from the Snowy Mountains in Australia which was labelled organic — somewhat absurd when the whole point of drinking bottled water is to be sure that it is absolutely free from organic substances. Similarly, the label of water bottled at a spring in Tasmania boasted that it was free of chemicals — right beside an analysis of the calcium and other minerals it contained.

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4 The economic cost to the U.K. has been over £3 billion (approximately $5.25 million in U.S. dollars).

And while we are told that we should be concerned about traces of chemicals in the environment which can mimic hormones, we are increasingly drinking soy milk. Soy milk contains sufficiently high concentrations of phytoestrogens that are recommended as both a natural alternative to hormone replacement therapy and as a means of preventing prostate cancer.

Our perceptions of risks and benefits, as these examples show, are almost inevitably affected by factors other than just the objective science describing toxicity, carcinogenicity, and so on. Many of our perceptions of risk are affected by questions such as: whether the risks affect children or adults; whether the risks are accepted voluntarily or imposed; whether processes are secret or open; whether the risks are assessed by industry or by analysts seen as disinterested; whether they involve the catastrophic death of large numbers of people or a succession of isolated deaths; what kind of deaths occur; whether the effects are immediate or delayed; and whether the risks are natural or man-made. For example, travelling ten miles by bicycle in the U.S. and living for fifty years within five miles of a nuclear reactor have both been estimated to yield an increased probability of death of one in one million, yet we respond to these risks quite differently.[5]

One factor which affects our perceptions of risk associated with chemicals, GMOs, and drugs is the fact that these products are manufactured by large, faceless corporations, usually transnational corporations, which are seen as being beyond the control of governments. As anthropologist Mary Douglas has pointed out, many of our fears about such risks reflect our sense of powerlessness in the face of such corporate giants in an increasingly globalised world.[6] But she also argues that risks are used to blame those already disliked.

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5 *See* Paul Slovic, *Perception of Risk: Reflections on the Psychometric Paradigm*, in *Social Theories of Risk* 117 (Sheldon Krimsky & Dominic Goldings eds., Praeger 1992); Roger E. Kasperson et al., *The Social Amplification of Risk: A Conception Framework* 8 Risk Analysis 177 (1988); Joseph V. Rodricks, *Calculated Risks: Understanding the Toxicity and Human Health Risks of Chemicals in Our Environment* (Cambridge U. Press 1992); *see also* John Adams, *Risk* (UCL Press 1995) (an excellent introduction to the topic).

6 Mary Douglas, *Risk & Blame: Essays in Cultural Theory* 15 (Routledge 1992).

This phenomenon is exacerbated by the fact that the regulation by such hazardous substances poses problems which are tailor-made for those who would wish to amplify the risks. All typically involve intellectual property, and patent law provides for a period of monopoly to recover development costs and profits, balancing the public good of having lower prices which competition would bring against the public good of encouraging research, and development by industry. But this means that most of the research regarding the safety of such products is conducted either by the corporations themselves, by contract scientists, or research laboratories who must be contractually bound to honor commercial confidentiality.[7]

Regulators must use such science in making licensing decisions, but it is easy to construct a somewhat paranoid discourse around both the science and the scientists in such circumstances. Products found to represent a low hazard can still be claimed to constitute an unacceptable risk when most of the science can be dismissed as the biased product of self-interested industry or of corrupted scientists who have undertaken research consultancies.[8]

Science can be wrong. Bias is a constant problem. But science has developed means of minimizing such pitfalls. It can never eliminate them completely, but the canons of the scientific method, if followed, can improve the reliability of scientific knowledge. The courts in the hyper-litigious U.S. have had to rule on what constitutes acceptable scientific evidence in the face of a tendency for parties to hire their own expert witnesses. The courts have, not surprisingly, decided that the appropriate test was whether the information was generated by following key elements of the scientific method, such as replicability of results and publication after anonymous peer review.[9] Scientific

7 Patents for pharmaceuticals might offer no protection if a competitor could add to the molecule an additional but meaningless chemical element or two which might simply be removed in reaction with stomach juices, for example. For more information regarding this matter, see Aynsley Kellow, *International Toxic Risk Management: Ideals, Interests and Implementation* (Cambridge U. Press 1999) (a discussion of the importance of patents in regulation of chemical and pharmaceutical risk).

8 *See* Sharon Beder, *Global Spin: The Corporate Assault on Environmentalism* (Scribe 1997) (an example of this genre).

knowledge always contains some residual uncertainty, but we have learned to place more faith in knowledge that emerges from such a process than that which appears from research that has not followed established scientific protocols.

While the source of funding might alert the U.S. to the direction in which a piece of scientific research might be biased, the appropriate test must be adherence to the scientific method. Against such science, we are often asked to be alarmed about the implications of research which has not yet been replicated and, in some cases, not yet published in peer-reviewed journals. Regardless of its source — industry or an environmental group — we should be extremely wary about acting upon such "science."

This is so even for those interest groups which profess to have the public good at heart. It has been suggested that there is a "danger establishment," consisting of scientists (especially in grant-rich areas of research), journalists, politicians, bureaucrats, and environmental and other public interest groups which have an interest in exaggerating dangers.[10] Because many researchers and journalists often clamour to build support or a readership, they tend to shout to be heard. We need to be aware, in other words, that bias can enter our social risk assessments from many directions. Recall examples such as the McBride case in Australia, where research by the scientist who discovered the teratogenic effects of thalidomide was found to have been falsified to exaggerate the dangers of a drug to secure continued funding for a research institute.

We should see Greenpeace — even if we share its goals — as not just an environmental group, but also as a transnational private company which licenses its trademark to thus-controlled foreign subsidiaries and which has among its informal goals that of system maintenance. Like any organization, it has salary and operating costs to cover, and it must try to retain its annual revenue base of well over $150 million

9 *See* James T. Rosenbaum, *Lessons From Litigation Over Silicone Breast Implants: A Call For Activism by Scientists,* 276 Science 1524-25 (1997).

10 *See* Thomas M. Dietz & Robert W. Rycroft, *The Risk Professionals (Social Research Perspectives, Occasional Reports on Current Topics, No. 14)* (Russell Sage Foundation 1987).

worldwide. It would be an exceptional organization which managed to purge itself of the pursuit of system-maintenance. It can therefore be expected to focus its effort in areas and ways which will heighten concern and willingness to pay, especially since it rewards fund-raising success internally with decision-making influence.

Greenpeace specializes in politicized science, often committing the cardinal scientific sin of bringing the evidence to the theory, usually in the form of dramatic visual footage supplied to the media from some remote location. Perhaps because of the remoteness and perhaps because of Greenpeace's perceived disinterestedness, news editors screen such footage when they would not do the same for footage supplied by more obviously interested sources.[11] Footage of the retreating Bering Glacier on the eve of a climate change conference provides powerful support for action on climate change, but science is also interested in why, for example, glaciers in New Zealand are advancing.

We can illustrate this with the problems generated by Greenpeace's politicization of science associated with GMOs. In June of 1999, France was leading the push within the EU to ban the importation of genetically modified food. France is not regarded as an environmental vanguard state in Europe, but it is one of the strongest supporters and greatest beneficiaries of the Common Agricultural Policy. It was supported in this push by Greenpeace, whose members dressed as butterflies and carried a banner containing the slogan "Give butterflies a chance" to the meeting of EU Environment Ministers in Luxembourg on June 24, 1999. Citing a recent U.S. study which indicated that pollen from genetically-engineered Bt-maize could kill the larvae of Monarch butterflies, Greenpeace invoked the precautionary principle in urging a ban. The EU froze the approval process.

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11 At a political science conference in Christchurch, New Zealand in 1998, a TVNZ news executive stated that his corporation never screened footage from sources outside the company or established news services — except for Greenpeace!

This piece of scientific knowledge, combined with the precautionary principle, gave considerable power to the coalition of Greenpeace and European agriculture, but it took what appears to have been sound but limited science further than it should have and ignored contextual factors completely in providing a convenient protectionist cloak.

The Monarch butterfly research was published by John Losey at Cornell University in a refereed letter to the journal Nature.[12] Losey issued a careful press release, which was totally ignored by the media and Greenpeace, stating that the research was conducted in the laboratory and that it would therefore be inappropriate to draw any conclusions about the risk to Monarch populations based solely on these initial results. The reasons for this caution are obvious when the nature of the experiment is considered. Hatchling Monarch larvae were given a diet consisting solely of milkweed leaves (their exclusive diet) dusted with corn pollen.[13] In the wild, larvae are known to avoid leaves with pollen on them and move to a clean leaf. Further, milkweed is rarely found in cornfields because farmers seek to control all weeds, but it is commonly found in pastures and old fields. Maize pollen also does not travel far — little can be found thirty feet from a cornfield and it is practically non-existent at 100 feet. Finally, the period when maize pollinates and monarch larvae feed are both very short and might not even overlap in some seasons.

The toxin produced by the GM maize in this experiment was Bt toxin, so named because it is found in a common soil bacterium, Bacillus thuringiensis. Bt toxin is used by organic farmers as essentially their only pesticide, and they fear that its use in GM crops might cause the insects it protects against to develop immunity. This, rather than concerns over Bt toxicity, lies at the heart of opposition from organic farmers.[14]

Reductionist risk assessment — attempting to regulate solely on the basis of toxicity — ignores these crucial exposure factors and relies

12 John E. Losey et al., *Transgenic Pollen Harms Monarch Butterfly,* 399 Nature 214 (1999).

13 Older larvae might be less susceptible.

14 *See* VitalSource, *GM: What is Known and/or in Dispute?* at <http://vitalsource.org/gm/science.html> (accessed July 14, 1999).

solely upon the science of toxicity, which can be persuasive, especially to those who wish to invoke the risk-averse precautionary principle. It not only advantages economic interests threatened by the advantages of Bt-maize. It also carries an environmental opportunity cost, since non-modified maize is sprayed for insect pests eight to ten times, a practice which is likely to cause substantially more harm to Monarch butterflies and other insects.

Social risk assessment requires a careful analysis of the best available science, an understanding of the social and psychological factors which will inevitably intrude into the process, and careful policy analysis.[15] Such policy analysis requires prioritization of candidates for risk management, a task made more difficult because of the shouting of the "danger establishment," and the need to carefully weigh the costs and benefits involved. No activity can ever be risk-free. There is always a need to consider the costs of risk management — including opportunity costs — and to be careful of the social context within which the decision is made. A cholera epidemic in Peru once killed 3,000 people because of a decision to follow a U.S. Environmental Protection Agency risk assessment and not chlorinate water supplies.[16] Chlorinated water carries an elevated risk of bladder cancer of 0.8 per 100,000,[17] but we need to remember that the costs of avoiding this risk can be much higher.

Risk and Precaution

The cholera example is particularly apt because the actions of a physician amid the squalor of the industrial revolution are often taken as reinforcement of the need to apply the "precautionary principle" in cases of environmental or health risk. In 1849, before the discovery of the cause of cholera, a London doctor, Dr. John Snow, suspected that the source of one outbreak might be the water from a particular well and removed the pump handle.

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15 *See* John D. Graham & Jennifer Kassalow Hartwell, *The Risk Management Approach,* in *The Greening of Industry: A Risk Management Approach* (Harv. U. Press 1997).

16 Christopher Anderson, *Cholera Epidemic Traced to Risk Miscalculation,* 354 Nature 255 (1991) (many thousands more died after the publication date of this item).

17 Rodricks, *supra* n. 5, at 218.

Precaution is, of course, much better than cure, but such an anecdotal understanding of history glorifies post hoc those who happened to be right and ignores the multitude of cases where doctors acting on similar imperfect knowledge were sadly wrong. How we should exercize precaution is by no means self-evident, and the reasonable-sounding, commonsense precautionary principle is frequently misquoted and distorted to the point of nonsense.

The accepted version of the precautionary principle (in the Rio Declaration in 1992) reads: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[18] This is commonsense, but alone it cannot be operationalized. We need to add meanings to the terms, serious, irreversible, damage, and cost-effective, and decide what level of uncertainty we are prepared to accept as the basis for action.

Advocates of this view often use the example of cigarette smoking. It involves both business interests and uncertainty, and they like to point to the exploitation of that uncertainty by industry to forestall regulatory action. We now know the precise mechanisms by which substances initiate cancer and attempt to aid progression by damaging particular genes, but in fact we commenced regulatory action against tobacco long before we had identified precise mechanisms of causation. We did so on the basis of good peer-reviewed science which indicated a problem over thirty years ago. While the tobacco lobby has been particularly active and we have not banned tobacco, that reflects a number of factors, including the loss of regulatory control prohibition and taxation revenue to pay the costs of damage, which regimes carry with them (witness heroin).

But it is not prudent to take regulatory action on the basis of no evidence, or non-peer-reviewed science, or even a handful of scientific papers. Sometimes we choose to accept risks; a risk assessment of quartz might have resulted in a ban on children's sandpits in Sweden until reality prevailed.[19] Motor vehicles kill thousands, directly or

18 *See* Lawrence E. Susskind, *Global Diplomacy: Negotiating More Effective Global Agreements* 79 (Oxford U. Press 1994).

19 *See* Robert Nillson, *Integrating Sweden into the European Union*, in *The Politics of*

indirectly, but we accept that their benefits outweigh these risks (although there are strong lobbies which contest the existing risk-benefit trade-off and seek more regulation). But some seek to invoke the precautionary principle as a justification for not just reversing the burden of proof, but to demand a logically-impossible proof of safety, or the absence of harm. Demanding that a negative be proved is the logical equivalent of asking people to prove that they are not witches.

In addition, however, environment groups and official documents have stretched the meaning of the precautionary principle to the point where it legitimizes the risk management strategy of Chicken Little and has even found its way into international policies. For example, Recommendation 89/1 of June 22, 1989 of the Paris Convention for the Prevention of Marine Pollution from Land-based Sources stretched it to include action "even where there is *no* scientific evidence to prove a causal link between emissions and effects."[20] If this is accepted, all one needs is some indication of serious and irreversible effects, and one can demand logically-impossible proof of an absence of harm or else regulatory action will be taken.

Everything is capable of causing harm under some circumstances; as Paracelsus put it 500 years ago, everything is poisonous — the dose makes the poison. So we must insist that the precautionary principle is not misused and that risk assessment considers factors such as doses, exposure pathways, individual and species susceptibilities, costs and benefits, and the consequences of regulatory actions. Unless we do, we are to forgo the benefits that a product might bring, and produce either policy paralysis (as regulators freeze like rabbits in the glare of a multitude of precautionary spotlights), or a wasteful misplaced set of priorities (causing regulators to chase any number of hares which have been released).

Chemical Risk: Scenarios for a Regulatory Future 159, 167 (Roland Bal & Willem Halffman eds., Kluwer 1998).

20 Nigel Haig, *The Introduction of the Precautionary Principle into the UK*, in *Interpreting the Precautionary Principle* 243-46 (Timothy O'Riordan & James Cameron eds., Earthscan 1994) (emphasis added).

Risk and GMOs

How does this apply to GMOs? In order to answer that question, it is necessary first to state that the discussion which follows does not seek to make a risk assessment of GMOs, nor engage in a detailed discussion of the science of genetic modification and the hazards it might pose. The analysis accepts that genetic engineering is a hazardous activity which has been subjected to regulatory scrutiny from basic research through to its applications since its inception in 1970. It accepts also that the products of this technology provide benefits. It accepts that the risk management process will be difficult and complex, but unless it is performed, we run the risk of either forgoing benefits or experiencing hazards.

But it also holds that risk assessment must be sensitive to particular products and practices and specific exposures. A bacterium modified to produce BST poses different risks than genetically modified cotton, and cottonseed oil so produced poses different risks from the consumption of a GM tomato where live DNA might be ingested. The dangers posed by the possible escape of genes to wild species depend crucially upon the GM species and the environment into which it might be placed. For example, for the U.K., there are no compatible wild relatives for maize or potatoes, so no gene transfer can occur. Rice and soya are inbreeding species, so transfer is possible, but unlikely. With oil rapeseed, on the other hand, this is an outbreeding species with many wild relatives, so greater caution is necessary. The same holds for the danger of consumption. Sugar from GM sugar beet contains no genetic material whatsoever. Flour from GM soya may contain the new gene or its product, but many of the purification processes used in food production will destroy any DNA present in the raw material.[21]

It is entirely possible that we might, as a society, decide that the risks of one GM product are worthwhile while rejecting others. We might reject a GM blue rose as being a trivial use of the technology which poses an unacceptable risk, while accepting the gains of GM

21 *See* The Royal Society, *Genetically Modified Plants for Food Use* (The Royal Society 1998) (discussion of these issues).

foods which taste better, keep better, and thus result in less wastage. Lumping all genetic engineering together, and certainly condemning all GM foods as Frankenstein food, is neither accurate nor helpful.

Making such decisions requires the participation of a wide range of people other than just the relevant scientists, industry, and environmental groups. Risk management is a process which requires the application of relevant science, as well as statistics, ethics, economics, sociology, and even political science, and certainly must have regard to the views of the public. Attempts by scientists to prevent what they might see as the intrusion of non-experts into the process are not only unhelpful, but are likely to heighten public suspicion and apprehension. Transparency and trust are vital.

There is a legitimate role for both industry and environmental groups in this process, but neither should be allowed to dominate the process. Unfortunately, the alarms seem to have run ahead of a reasoned consideration of the issues. Despite the fact that there are few GM plants yet licensed for use, we have considerable apprehension as the result of tabloid reporting of the perils of Frankenstein food, with local government authorities even banning GM food in kindergartens and day-care centers.

The fear of Frankenstein food has been markedly more in evidence in Europe than in the U.S., and it has had more impact on government policies and on the policies of corporations. Some supermarkets have refused to stock GM foods as the result of the effectiveness of boycotts by Greenpeace's "Genetic Hazard Patrols." The responses of European governments have varied. The U.K., France, and Spain appeared initially to be more permissive than the northern European nations where support for Greenpeace and green political parties is strongest, but the question arises as to why the alarms have had greater impact in the EU than in the U.S.

A similar question arises as to why concern has been almost non-existent over the use of genetic engineering to produce pharmaceuticals. The answer to the first question lies partly in the accepted fact that cultural dispositions to risk vary,[22] even within Europe, with much stronger support for such causes evident in Northern Europe than in Southern Europe. But consumers in the U.S., especially in the western states, are well known for their propensity to be concerned about such risks. The best explanations for these regional differences lie in a happy coincidence between such values and economic interests which has led to the institutional innovations that privilege risk-averse responses.

The precautionary principle had its origins in Germany as the *vorsorge prinzip* (roughly "preventative action principle") and was used to justify the "Green Keynesianism" developed by Helmut Kohl, also known as "ecological modernization."[23] The export of the precautionary principle has not only bolstered the approach domestically, but has helped create markets for the export of technology and services developed domestically. This is known as a "first mover" strategy and runs counter to the widespread belief that environmental regulation hinders the competitiveness of nations — though it does depend on the successful export of policies and standards which will create a market for the technologies and services in which the nation has a new-found advantage.[24]

As we saw previously, when misapplied, the precautionary principle has considerable potential to undermine the risk management process from the outset by giving credence to poor science. This has happened with GM food. In a notable case, research on rats at the Rowett Research Institute in Aberdeen, Scotland, was reported on television in 1998 to suggest that potatoes modified by the addition of a snowdrop gene to produce a natural insecticidal chemical (i.e., lectin) interfered

22 Aaron Wildavsky & Mary Douglas, *Risk and Culture* (U. Cal. Press 1981).

23 Sonja Boehmer-Christiansen, *The Precautionary Principle in Germany — Enabling Government*, in *Interpreting the Precautionary Principle* (Timothy O'Riordan & James Cameron eds., Earthscan 1994).

24 David Vogel, *Trading Up: Consumer and Environmental Regulation in a Global Economy* (Harv. U. Press 1995).

with the development of both the rats' internal organs and their immune systems. The research was not on transgenic potatoes about to be marketed, but an early part of research aimed at finding whether a form of lectin which was (on the basis of previous testing) likely to be least toxic to humans could protect potatoes from nematodes.

The researcher, Dr. Arpad Pusztai, has since been dismissed from his job for a serious breach of scientific protocol — going public with his claims before his research had been peer-reviewed and published in a recognised scientific journal.[25] No paper had then been submitted for publication, and a panel of six toxicologists appointed by the Royal Society dismissed the research as being irrelevant, inconclusive, and flawed in many aspects of design, execution, and analysis.[26]

By the time this rebuttal appeared, the claims had already been a key catalyst in the GMO debate in Britain, and a group of twenty scientists had held a press conference to declare their support for Dr. Pusztai. Despite the conclusion by the Royal Society panel that any observed differences between GM-fed rats were uninterpretable because of the technical limitations of the experiment and the incorrect use of statistical tests, Friends of the Earth (FOE) was unswerving in its views of the dangers of GM foods. FOE spokesman Tony Juniper resorted to the "witchcraft" position: "There's no concrete proof that they are safe."[27]

According to Debora MacKenzie in the New Scientist, the technical limitations of the experiment included the fact that Pusztai could not make the rats eat enough potato.[28] Another limitation was the presence of known toxins in potatoes. The only obvious conclusion supported by his research, Mackenzie stated, was that rats hate

25 Technically, Dr. Pusztai's contract expired and he was not reappointed.

26 *See* BBC News, *GM Food Study was Flawed* <http://news.bbc.co.uk/hi/english/special_report/1999/02/food_under_the_microscope/newsid_289000/289002.htm> (May 18, 1999). Pusztai's research was later published in *The Lancet*, under highly controversial circumstances since rejection was recommended by several reviewers and the editor was criticized for relaxing standards of peer-review to publish research of public interest.

27 *Id.*

28 The rats were malnourished no matter what kind they were eating and had to be given protein supplements to meet Home Office guidelines for animal experiments.

potatoes.[29] In fact, it was worse than that, as the methodology did not involve blind testing under which researchers are unaware of which rats were in the control group and which were being fed GM potato. This created the possibility for the introduction of researcher bias, something of concern when Dr. Pusztai was prepared to go public before publication.

There are a number of technical issues which make the testing of GM foods difficult, but as the reference to toxins in potatoes suggests, this holds for unmodified food also, since people die each year from the cyanide in peach seeds and undercooked kidney beans, which are poisonous (they contain the very lectins involved in Pusztai's research). Many foods also naturally contain chemicals which have exhibited carcinogenic properties in laboratory tests,[30] but in such small amounts that test procedures are likely to require such large quantities to be fed to rats that the acute toxicity of other substances is likely to kill them first.

An attempt to test GM tomatoes in the Netherlands involved feeding rats the freeze-dried equivalent of thirteen tomatoes a day each. This dose was still not enough. Monsanto's GM maize does not contain enough of the Bt toxin produced by the novel gene for it to be isolated for testing. They have to produce it from bacteria and then test it, but this raises questions about whether the two toxins are identical. Some transgenic foodstuffs (e.g., Flavr Savr tomatoes, Round-up Ready soybeans, and virus-resistant squash) have undergone extensive testing without any suggestion of serious health effects,[31] which should have urged caution about the potato research.

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29 Debora MacKenzie, *Unpalatable Truths,* New Scientist at <http://gmworld.newscientist.com/> (June 10, 1999).

30 *See* Bruce N. Ames et al., *Ranking Possible Carcinogenic Hazards,* 236 Science 271 (1987).

31 *See* Organisation for Economic Co-operation and Development (OECD), *Food Safety Evaluation* (OECD 1996).

This suggests there is a need for caution as to how we evaluate the hazards of GMOs, but it also stresses the need for the best possible science underpinning our risk assessment processes. Much of the difference between the approaches of the EU and the U.S. reflects the different philosophies of risk which operate in each jurisdiction. The institutionalization of the precautionary principle in Europe encourages calls for action and government action itself on the basis of such "scientific" evidence as the potato research of Dr. Pusztai, while the U.S. approach to risk has been to examine the economic costs and benefits of any risk management action.

Ironically, the lack of consideration of economic factors with the EU approach facilitates the use of fears of GMOs by economic interests. The fight against U.S. beef produced using recombinant BST has been led by British beef producers, themselves harmed by BSE, and the whole issue has allowed Europe to revisit the 1985 issues. The U.S. has advantages in the use of biotechnology, and its economic efficiency poses a considerable threat to the enormously costly and inefficient Common Agricultural Policy, already under pressure after the Uruguay Round liberalisations in agricultural trade. The GMO debate has provided less efficient European producers of beef, soybeans, and so on, with an opportunity to try to hobble their more efficient U.S. competitors.

This partly explains why there has not been a similar outcry over genetic engineering in the pharmaceuticals sector. Europe has an efficient, competitive pharmaceuticals sector which would oppose and contest campaigns on the issues, rather than support them (as with agriculture). But even though the consumption-related risks from pharmaceuticals — often directly injected into the body or packaged in such a way as to facilitate absorption even after attack by digestive juices — would appear to be equivalent to those associated with foods, there has not really been a campaign mounted against them. There are at least two other factors at work here: one relating to pharmaceuticals and the other to agriculture.

The first is that the benefits side of the equation is much clearer with pharmaceuticals and would be much more difficult to counteract. A soybean which can be produced more cheaply does not quite offer

the same kind or size of benefits as a drug produced by a GM bacterium. Focusing political campaigns on food promises better political returns than attacking possible cancer cures, especially when it coincides with agricultural interests in Europe.

The second is that the anti-GM food campaign resonates strongly with a campaign in the early 1980s over the introduction of Plant Variety Rights (intellectual property rights for plants). Many concerns then, such as the fear that agricultural genetic material being controlled by large transnational corporations, not only have been repeated with the GMO campaign, but the same fear of transnational dominance is a key factor in amplifying risk perceptions of GMOs.

These fears were heightened by plans for the insertion of so-called terminator genes into seeds, which would render the seeds of transgenic crops infertile requiring growers to buy again from the multinationals rather than engaging in the traditional practice of saving seed for next year's crop. While this technology was owned by Delta and Pine Land and the U.S. Department of Agriculture, Monsanto planned a takeover of Delta and Pine Land, and it was attacked by activists over terminator technology subsequently renouncing any future use of it. Regardless, this would appear to have been something of a non-problem. Third World farmers would be perfectly able to continue traditional farming practices with traditional seed; transgenic crops will only be grown where the benefits outweigh the costs of doing so. The terminator situation was no different from that obtained with the seeds of infertile hybrids, except that terminator genes could be seen to serve a useful risk management function by preventing the escape of GM stock into the wild. The feature was thus used to amplify risk perception, while actually increasing the risks of GM technology.

Conclusion

The assessment of the risks of GMOs reflect numerous social and institutional factors, and these help explain the differences between the approaches in the U.S. and the EU, and between transgenic food and transgenic medicine. These factors give rise to particular problems for the trade regime as they offer plenty of scope for non-tariff barriers to be erected in the name of the protection of health and the environment.

They also throw some light on the elements we need to bring together in order to properly assess the risks associated with GMOs.

First, there is a fundamental need for good science, and insistence on sound, peer-reviewed science, and rejection of evidence gathered to support theoretical predispositions — either that GMOs are dangerous or that they are harmless. Second, there is a need to consider the benefits, the dangers, and the costs, including opportunity costs, of any decision we make. We should expect that any GMO might not be all that the owners of the technology might make it out to be, but neither is it without the promise of considerable benefits. Therefore, it cannot be rejected lightly. There is also a need to undertake specific risk assessments for different kinds of GMOs, taking care to distinguish production-related risks (e.g., GM canola cross-pollinating or out-breeding with other species) from consumption-related risks (e.g., if Dr. Pusztai turned to be right, GM potatoes affecting our immune systems).

In addition, there is a need to accept that the social evaluation of risks is likely to be more accepting of GMOs in medicine than in health, and that such evaluations must be a central part of any risk management process. There are identifiable reasons why, what society will accept in saving lives, society might not tolerate in producing food. That intolerance might hinder the adoption of GM technology in agriculture, but attempting to impose outcomes on a reluctant public is likely only to heighten fears. Openness and transparency — together with good science and a consideration of costs — are the keys, but this does not mean that the proponents of GM technology should abandon the field to their critics. Society requires a full and open debate which will expose the exaggerated claims which might come from any side and allow it to make better decisions about which risks to accept and which to reject.

Issues, such as genetic engineering, are tailor-made for the development of what Frank Furedi has called a "culture of fear."[32] Such a culture thrives on secrecy and attempts to manipulate public opinion to secure consent, which inevitably arouses suspicion and

32 Frank Furedi, *Culture of Fear: Risk-taking and the Morality of Low Expectation* (Cassell 1997).

hostility. If genetic engineering is to be regarded as involving socially-acceptable risks, the process by which the risks are assessed and managed will have to be one the public trusts.

Our risk assessment of GM foods must therefore be careful to take many factors into account. Genes (i.e., DNA) are a normal constituent of our diet. It has been 200 years since the first report of hybrid cereals were made, and we have been consuming the fruits of the deliberate human transfer of genetic material between species since 1876 (Triticale wheat x Rye cross). GM techniques expand these possibilities enormously and rightly should be subjected to careful regulation. But we would be wrong in supposing that all the risks we face are caused by human agency, or that we are completely incapable of regulating them.

Ironically, both these lessons can be drawn from the mad cow disease experience. The former is suggested by the fact that the best hypothesis about the origins of BSE and vCJD seems to be a chance occurrence of a rare spongiform encephaly, probably from scrapie in sheep, which found its way into cattle food and then into the human diet.[33] The route might just have readily gone straight from sheep to humans, but for a roll of the genetic dice. The outbreak might have resulted from feeding rendered sheep carcasses to cattle, but the genetic chance occurrence appears to have been a completely natural occurrence.

The BSE/vCJD outbreak, despite the alarms, also demonstrates that we are capable of regulating risks. BSE in cattle was first positively diagnosed in cattle in 1986, and regulatory action was taken in 1988 and 1989 to remove infectious material from the animal and human food chains. The risks of human exposure were highest at this time, when public concern was almost non-existent, and with a possible ten-year incubation period. By 1997 there were only nineteen established cases of vCJD in Britain and one in France, while there were over 80 by 2001. The horrific manner of death, rather than the frequency, has heightened public concern. About one million cattle were slaughtered and Britain's beef trade was harmed, but despite the high economic stakes, scientists and regulators minimized the impact of the tragedy. It is most certainly a tragedy, but it has not quite been an apocalypse. The

33 The Royal Society, *Second Update on BSE* (July 21, 1997).

role of good science and risk management in limiting the scope of the tragedy has been submerged in a climate of dread, and the risk management success overlooked.

The BSE/vCJD tragedy had nothing to do with the GMO debate, except its impact on public perceptions. Indeed, GM growth hormones have removed the major source of risk of transmission of spontaneous CJD barring outbreaks of ritual cannibalism. But the suspected origins of the BSE outbreak also contain an important lesson about how we should evaluate the risks of GMOs.

Until the early 1980s, the process by which carcasses were rendered for stock food destroyed the infectious prion from the scrapie as they were subjected to high temperatures and organic solvents to remove the tallow. The price of energy rose, the price of tallow fell, and concerns emerged over the exposure of workers to organic solvents leading to the adoption of a new process created to avoid solvents and high temperatures. The scrapie prion survived the new process and subsequently it is believed to have infected cattle.[34]

This serves to remind us that our actions have consequences that are difficult to imagine. This holds not just for the introduction of new technologies, but also for changes to old ones. GMOs present risks, but they also present considerable opportunities. The challenge is to manage the risks in order to maximize the benefits. How we do this requires the best possible science, the right amount of precaution, and open and democratic processes, an admixture which will be difficult but not impossible to achieve.

34 The Royal Society, *BSE – A Statement by the Royal Society* (April 2, 1996).