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NGO war on biotechnology

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Abstract

Discussions of the risks and benefits of recombinant DNA technology, or 'genetic modification' (GM), should occur within the context of experience with older, 'conventional' techniques for genetic improvement. But critics' alarmist reports and commentaries invariably emphasise the things that might go wrong *only* with recombinant DNA-modified organisms, while studiously avoiding the essential broader context. They ignore vast amounts of data, including literally millennia of experience with less precise methods used for genetic modification, and they continue to deny the well-established scientific consensus that no unique risks attend the use of recombinant DNA techniques. They promulgate the perception that recombinant DNA technology is unproven, untested and unregulated – and promote an approach to regulation in which there is an *inverse* relationship between degree of scrutiny and risk. The disproportionate regulation of the products of recombinant DNA technology needlessly raises the cost of research and development, while it fails to advance consumer or environmental safety. The question we must ask is not whether regulation generally is or is not justified, but rather what should be regulated and how? The use of certain techniques – in particular, those that are the most precise and predictable – as a trigger for regulation cannot be justified scientifically. Regulatory efforts should be redirected to focus oversight on new organisms that express characteristics likely to pose significant risk, regardless of the methods used in their development, while leaving relatively low-risk traits of both classical and molecular genetic modification unburdened by costly regulation.

Keywords: *genetic modification, GM, recombinant DNA technology, biotechnology, risk analysis, NGOs, biosafety, government regulation*

Few scientific and technological endeavours have been as controversial over the past decade as food and agricultural applications of the 'new biotechnology' – also known as recombinant DNA technology, gene splicing and genetic modification (GM). The public debate has been driven more by passion and politics than by data and acumen. A vast amount of experimental research and extensive experience with commercial applications of organisms modified by both old and new techniques suggest that recombinant DNA-modified organisms pose no unique risks compared with classically modified organisms with similar phenotypes. The risk of any organism, whether it is unmodified or modified with recombinant DNA techniques or classical methods, is a function of its genotype and phenotype, regardless of its provenance. But, for a variety of reasons, this essential context has been missing from much of the public debate. Every new scare story about GM organisms' (GMOs) propensity to run amok and pseudo-crisis is spurred by these out-of-context misrepresentations.

The new biotechnology's most doctrinaire antagonists do not disguise their hostility. Jeremy Rifkin, for example, claims that recombinant DNA technology threatens 'a form of annihilation every bit as deadly as nuclear holocaust'.[1] Greenpeace demands biotech products' 'complete elimination [from] the food supply and the environment'.[2] And former UK environment minister Michael Meacher, speaking on behalf of Greenpeace, has admitted that there could *never* be sufficient testing to convince him of the safety of biotech foods: 'The real problem is whether 10, 20, 30 years down the track, serious and worrying things [will] happen that none of us ever predicted.'[3]

The USA has been perhaps the most hospitable environment for rDNA-engineered crops, yet even there the technology is under assault from a range

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of non-governmental organisations (NGOs). Some of these groups pose as open-minded sceptics, rather than antagonists, but beneath the rhetoric, their arguments and actions lead us to much the same place: attempts to create a groundswell of anxiety toward biotechnology, and to elicit unnecessary, hugely burdensome government regulation that will make product testing and commercialisation increasingly untenable. Nevertheless, their publications and announcements receive extensive media and government attention, largely because the organisations – including the Center for Science in the Public Interest (CSPI) and the Pew Initiative on Food and Biotechnology – present themselves as occupying the disinterested middle ground in the biotechnology debates.[4–6] But their claim to be genuine moderates and honest brokers does not make it so.

These and other similar organisations feign 'moderation' by vaguely acknowledging biotechnology's potential, and by raising scientific-sounding concerns. But genuine moderation means more than the absence of absolutist rhetoric. Just as the value of real estate depends on 'location, location and location', the value of dialogue on biotechnology's risks and rewards requires 'context, context and context'.

Genuine balance requires that discussions of biotechnology's risks and benefits be placed within the context of the risks and benefits of older, 'conventional' genetic modification

Genuine balance requires that discussions of biotechnology's risks and benefits be placed within the context of the risks and benefits of older, 'conventional' techniques of genetic modification. But both the radical and moderate critics' subtly alarmist reports and forums invariably emphasise the things that *might* go wrong only with recombinant DNA-modified organisms, while studiously avoiding the essential broader context. They ignore vast amounts of data, including literally millennia of experience with pre-gene-splicing GM, and they continue to deny the well-established scientific consensus that no unique risks attend the use of gene-splicing techniques. They carefully nourish the myth that 'genetic modification' – by which they mean only gene splicing – is a distinct category that is somehow fundamentally different from (and more worrisome than) other, earlier methods of genetic improvement.

In fact, not only does every hypothetical risk of gene-spliced organisms also exist with conventional breeding methods, but the risks are often *greater* with the older, less precise techniques.[7–9] Although standard assessment methods for new plant varieties typically are able to identify potentially harmful outcomes, occasionally the imprecise, trial-and-error techniques of conventional breeding methods lead to problems. Two conventionally bred varieties each of squash and potato and one of celery were found to contain dangerous levels of endogenous toxins and were, therefore, barred from the marketplace.[10–14]

These kinds of mishap are far less likely when genetic changes are wrought with the more precise and predictable gene-splicing techniques, which allow only one or a few fully characterised genes to be transferred to the daughter plant. Furthermore, although molecular characterisation and chemical analysis can be performed on any plant, modified or not, they are not routinely performed on classically bred (ie non-gene-spliced) organisms; they are, however, standard practice for gene-spliced varieties.[15] And while basic phenotype testing (such as for agronomic properties) is commonplace with all new plant varieties, the addition of only a few new genes with recombinant DNA techniques makes detection of both intended and unintended changes much easier.[15] Nevertheless, critics such as CSPI, Pew, the Union of Concerned Scientists (UCS), Environmental Defense, and Resources for the Future (RFF) fret continually over the 'uncertainty' about the new biotechnology's safety. Never is there any hint that similar – and often greater – uncertainties characterise the products of more conventional breeding

techniques. Nor is there any discussion of the safety testing that plant breeders, farmers and others conduct as a matter of course, or of the quality assurance that is imposed by the procedures involved in the certification of seeds.

For example, one CSPI report laments that, when it comes to gene-spliced organisms, 'Toxicants and anti-nutrients that may affect food safety and nutrition are not always evaluated', and it calls for wholesale changes in the way biotech foods are regulated.[16] The report studiously omits the fact that this risk exists no matter the breeding technique involved – as the toxic potatoes and squash mentioned above aptly demonstrate – or that extraordinarily few classically bred organisms are subject to testing of any kind to detect possible toxicants or anti-nutrients. But standard phenotype testing conducted outside the framework of government regulation has typically proven adequate for ensuring the safety of our food supply.

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The CSPI and the others fret about the 'transfer of the engineered gene to other species, the emergence of pesticide-resistant pests, and the adverse effects on small farmers or developing nations.'[17] The UCS commissioned testing that found gene-spliced material in 'conventional' seed preparations, and – in the press but not in any scientific journal –were quick to condemn this 'contamination'.[18] Even if it turns out to be true, the appropriate response to this finding is a collective yawn: gene flow is ubiquitous. All crop plants have relatives somewhere on the planet, and some gene flow commonly occurs if the two populations are grown close together. Although genes are known to cross from cultivated plants to other crops or wild relatives, this is true no matter how the plants in question were developed,[19] and pesticide-resistant pests were problematic for farmers long before the advent of recombinant DNA techniques. Growing hundreds of crops, virtually all of which (save only wild berries and wild mushrooms) have been genetically improved, the practitioners of 'conventional' agriculture have meticulously developed strategies for preventing pollen cross-contamination in the field – when and if it is necessary for commercial reasons.

Pesticide-resistant pests were problematic for farmers long before the advent of recombinant DNA techniques

The history of canola – the general term for the genetically improved rapeseed developed by Canadian plant breeders a half-century ago – offers a good example. The original rapeseed oil, used as both a lubricant and as an edible oil, was potentially harmful when ingested because of high levels of a chemical called erucic acid and glucosinolates (compounds that release goiterogenic agents after enzymatic hydrolysis). Conventional plant breeding led to the development of genetic varieties of rapeseed with low concentrations of erucic acid and glucosinolates, and oil from this 'double low' plant, dubbed 'canola', is now widely consumed throughout North America and Europe. High-erucic acid rapeseed oil is still used as a lubricant and plasticiser, however, so the high- and low-erucic acid varieties of rapeseed plants must be carefully segregated in the field and thereafter during processing.[20] North American farmers and processors accomplish this routinely and without difficulty. But the activists choose to ignore such relevant history and context. Contrary to their remonstrations that they are non-partisan and agnostic about biotechnology, their workshops, conferences and publications show a pervasive anti-biotechnology and pro-regulation bias.

A 2002 report from the Pew Initiative agonises about the potential of foods from future generations of gene-spliced organisms to cause allergic reactions, because scientists understand 'little about the fundamental mechanism by which people develop allergies,' and '[t]he ability of [gene-splicing] to move genes from one organism into another creates the possibility of introducing allergenic proteins into foods that would not ordinarily contain them.'[21]

When considered in the abstract, this

All types of plant breeding – whether accomplished by classical techniques or the newer molecular methods – routinely introduce new DNA, proteins and other substances into the food supply

may appear to be a legitimate concern. Science really does know little about what makes certain proteins allergenic, and our ability to predict whether novel proteins added to the food supply will prove to be allergenic in any sub-population is far from perfect.[22] However, all types of plant breeding – whether accomplished by classical techniques or the newer molecular methods – routinely introduce new DNA, proteins and other substances into the food supply, and farmers and plant breeders alike have for centuries sought and wrought gross genetic improvement of food crops. Since the 1930s plant breeders have performed 'wide-cross' hybridisations in which large numbers of 'alien' genes (often from wild species that were not before part of the food supply) are moved from one species or one genus to another to create plant varieties that cannot and do not exist in nature; these wide crosses transcend what used to be thought of as 'natural breeding boundaries'. Mutation breeding, in which plant seeds are exposed to radiation or chemicals to induce random genetic mutations, has been in common use since the 1950s. And tissue culture techniques are known to give rise to spontaneous mutations, which may be useful, benign or detrimental. Common commercial varieties derived from wide crosses or mutation breeding include rice, wheat, maize, potato, tomato, squash and countless others.

When they use pre-recombinant DNA technology such as wide-cross hybridisation and mutation breeding, breeders and food producers lack knowledge of the exact genetic changes that produced the useful traits. More important, they have no idea what other changes have occurred concomitantly in the plant – including those that could alter the ability to cause allergic reactions, over-express a natural toxicant or anti-nutrient, or generate other undesirable changes. Only the use of recombinant DNA techniques allows breeders to identify and more completely characterise the changes that have been made in the progeny. This increased precision and predictability enhance the safety of recombinant organisms in the field and of the foods derived from them – but paradoxically the newest and best technology acts as a trigger to far more intensive regulation.

Many critics fall back on the cliché that gene splicing is 'unnatural' and inherently different from classical breeding because unrelated organisms cannot swap genes in nature (see for example Anon[23]) or that the insertion of DNA at essentially random positions in the genome can disrupt the normal functioning of endogenous genes.[24]

Once again, the essential context is missing. Innumerable recombination events among unrelated organisms occur constantly in nature by several mechanisms.[25] In the gut, in infected wounds, in decomposing bodies and in decaying plant material, bacteria take up naked mammalian DNA (albeit inefficiently) from disintegrating cells. Over the past thousands of millennia, mammalian–bacterial, plant–bacterial and other genetic hybrids have appeared, been tested by competition within bacterial populations and by environmental stresses, and ultimately conserved or discarded by natural selection.[25] This sort of genetic recombination also has been rampant among fungi and viruses. One need look no further than the promiscuous genetic recombination that occurs continuously among the organisms, living and dead, on the underside of a dead log in the forest, or in a compost heap.

Certain kinds of gene transfer once thought to be impossible in nature because of phylogenetic distances (so-called 'natural breeding barriers') are also now known to occur. Researchers have demonstrated, for example, that genes can be transferred through natural interaction between Gram-positive and Gram-negative bacteria.[26] Others have shown that gene transfer can occur between bacteria and yeast.[27] And viral sequences

have been found integrated into various plant genomes.[28]

Perhaps most relevant to any discussion of the 'naturalness' of gene-spliced crops is the discovery that crown gall disease in plants results from a natural transfer of DNA from *Agrobacterium tumefaciens* to plant cells.[29] By observing *Agrobacterium*'s natural gene-splicing properties, researchers first discovered how to transfer target genes into dicotyledonous plants. They used naturally occurring enzymes that cut DNA sequences at specific places to remove the 'infective' genes from *Agrobacterium* and replaced the segment with a useful target gene sequence, thereby hijacking this natural process for productive ends.[30–32] This use of a natural process for plant modification surely blurs the line between 'natural' and 'unnatural,' but in any case, it is no less natural than mutation or tissue culture techniques that are now commonplace in so-called classical breeding.

The use of natural processes in gene-splicing surely blurs the line between 'natural' and 'unnatural', but in any case is no less natural than mutation or tissue culture techniques

Some critics cry foul even when plant breeders use recombinant DNA technology to transfer genes between sexually compatible plants. For example, breeders at the International Rice Research Institute in the Philippines used gene-splicing techniques to transfer into a cultivated variety from wild rice the *Xa21* gene, which confers resistance to a common bacterial blight; previous repeated attempts to breed the gene into elite cultivars without eroding other important traits had proved unsuccessful.[33] Until recently, it was possible to move *Xa21* into elite cultivars only with recombinant DNA techniques. Yet, even though this breakthrough product would have received no government oversight and no special attention from anti-biotechnology campaigners if it had been produced with conventional methods, NGO-based protesters delayed field trial approvals for many years, arguing that because there were blight strains against which *Xa21* was not effective, the new variety posed a biosafety threat to Filipino rice growers.[34]

With such broad sharing of genes in nature, debates about the proprietary nature of 'plant', 'bacterial' and even mammalian genes seem irrelevant

But the source of transferred genes is a diversion. Nearly identical DNA sequences and biochemical pathways are found spread across the phylogenetic map. Scanning the DNA sequence of the *Escherichia coli* genome, for example, reveals gene sequences that are virtually identical to those in a variety of organisms, including other bacteria, plants, insects, amphibians, birds and humans.[35] Up to 90 per cent of rat genes have matches in both humans and mice,[36] and as many as 48 per cent of human genes associated with diseases can be found in the simple plant *Arabidopsis thaliana*.[37] With such broad conservation and 'sharing' of genes in nature, debates about the proprietary nature of 'plant,' 'bacterial' and even mammalian genes – and about the significance of one or a few new 'transgenes' inserted into a new crop variety – seem irrelevant. The real concern should be not the source of a newly introduced gene or the method of transfer, but its function, and whether it is harmful, beneficial or without effect.

A somewhat more sophisticated – but no less specious – criticism of recombinant DNA techniques is that the essentially random insertion of transferred genes could interfere with the normal functioning of other genes or activate previously dormant sequences.[38] This could theoretically produce such unintentional effects as a reduction in important dietary nutrients that normally occur in a crop plant or an increase in the level of endogenous plant toxins or anti-nutrients. But again, expressing concern about such 'insertional mutation' effects only when gene splicing is involved shows the critics' bias. Similar effects are vastly more likely to occur with radiation and chemical mutation because those procedures generate gross and unpredictable impacts on the plant genome that are difficult to test for after the fact. Perhaps more important, transposable elements that 'jump' into and out of various sites in a plant's genome – inserting themselves into and between genes[39] – are known to 'alter gene expression or serve as sites of

chromosome breakage or rearrangement',[40] but there is no solid evidence that this common interference with gene expression produces health or nutritionally relevant impacts on plant-derived foods.

Why do biotechnology's critics omit these relevant comparisons so systematically and assiduously? There appears to be no credible reason other than the intention to frighten the public and intimidate regulators into tightening the already extraordinarily burdensome regulation that is unique to recombinant DNA technology. Neither government regulators nor the NGOs have shown any concern about the real risks of plant breeding. Instead, they are preoccupied solely with the hypothetical risks of recombinant DNA technology. The NGOs' narrow focus ignores the lessons of both biology and the history of agriculture.

The NGOs seem to ignore the lessons of both biology and the history of agriculture

Another tactic favoured by activists is to establish a kind of moral equivalence between those who hold ideological, anti-biotechnology views and those who are committed to sound science as the basis for public policy. For example, the Pew Initiative created a clever device intended to bolster and endorse its pro-regulation views: a 'stakeholder forum' comprising representatives of the food and biotechnology industry, farmer organisations, food retailers and anti-biotechnology activists. The forum was portrayed as a 'balanced' dialogue between biotechnology's supporters and opponents that supposedly included views across a broad spectrum. However, the reality was quite different. The views represented ranged from the centre to the far left, with the latter heavily represented. And, in order to mollify their critics, the representatives from the middle-dwelling big agribusiness and biotechnology companies capitulated to the reality of greater, discriminatory regulation of gene-spliced organisms and products derived from them. The anti-biotech faction included such tenacious critics of agricultural biotechnology as Environmental Defense's Rebecca Goldburg, the Union of Concerned Scientists' Margaret Mellon, and US Public Interest Research Group's Richard Caplan. The 19-person committee contained just three academic scientists.[41]

Pew's notion of 'balance' was to mix anti-technology radicals with academics and industry representatives who have largely moderate, mainstream views. It was transparently obvious in which direction the 'consensus' was intended to go. It is also revealing that every member of Pew's stakeholder forum had to agree at the outset that the current regulatory apparatus was of questionable 'credibility and effectiveness'.[42] In spite of this, the stakeholder negotiations broke down when the most extreme anti-biotechnology activists overplayed their hand. They made demands that went beyond even the excessive restrictions that the food and biotechnology industry representatives were willing to concede. Although the industry representatives were prepared to endorse a wholly unwarranted new requirement for a formal pre-market notification process for all new gene-spliced food crop varieties, the more radical faction insisted that regulators must require a formal pre-market authorisation of all gene-spliced food crops, regardless of the level of risk posed by individual crops.[43]

The radical agenda was pushed especially hard by one member of the stakeholder forum, Greg Jaffe of the Center for Science in the Public Interest. Jaffe is credited with drafting legislation introduced in the US Congress by Illinois Senator Richard Durbin to establish a mandatory approval process for foods derived from gene-spliced plants. The CSPI then orchestrated a campaign to garner support for the Durbin bill while portraying itself as a disinterested bystander that favoured the legislation on its merits.[44] It should come as no surprise that many of the same people who signed the CSPI petition supporting Senator Durbin's bill were also to be found on the Pew Initiative's stakeholder forum, or

participated in Pew conferences, workshops and reports.

In ultimate effect, the Pew and CSPI efforts are not unlike the UK government's attempt to foster public debate by establishing its 'GM Nation?' programme. A science reporter for London's *The Times* described GM Nation? as 'farce from start to finish. . . . The lack of advertising and helpful scheduling mean that every [meeting] has been stuffed with green campaigners and New Age zealots who think GM crops are the root of all evil.'[45] If one genuinely hopes to promote broader understanding of food production or recombinant DNA techniques, hosting 'consensus group' meetings and probing the public's opinions is not enough. One must also ensure that activists motivated by a desire to handicap the technology do not outnumber those with relevant expertise and who hold views that fall within the mainstream of scientific thinking.

Any pollster (as well as common sense) will tell you that it is not hard to design survey questions to elicit a desired response

The sceptics' agenda, however, is not to be honest brokers, but rather to keep the controversy rolling and to elicit even more strict and burdensome regulations – which would not make biotech products more safe, but only more expensive to develop, less competitive and, therefore, less likely to appear and survive in the marketplace. In the absence of any evidence of unique or incremental risks of the new biotech – and consistently ignoring the essential context of the new and old biotech – the NGOs cite the public demands for more regulation as a rationale for discriminatory oversight. It is they, however, who have created and perpetuated the controversy over the safety and usefulness of gene-splicing techniques.

NGOs cite public demands for more regulation, but they seem to have created and perpetuated the controversy over the safety of gene-splicing techniques

The survey described in the Pew Initiative's 2003 report, 'Public Sentiment About Genetically Modified Food', is a case in point. It finds that 'Americans' knowledge about [biotech] foods remains low', with 54 per cent saying they have heard nothing or not much about them. Then, without enlightening the subjects or offering them any sort of proper context, the survey goes on to pose leading questions about safety and regulation. Not surprisingly, 89 per cent agreed with the statement, 'Companies should be required to submit safety data to the FDA [Food and Drug Administration] for review, and no genetically modified food product should be allowed on the market until the FDA determines that it is safe.'[46]

This polling technique is rather like the example of Idaho Junior High School student Nathan Zohner, who found that 86 per cent of survey respondents thought the substance dihydrogen monoxide should be banned after they were informed that prolonged exposure to its solid form causes severe tissue damage, exposure to its gaseous form causes severe burns, and it has been found in excised tumours of terminal cancer patients. Only 1 in 50 of young Nathan's survey respondents correctly identified dihydrogen monoxide as *water*, or H_2O.[47] Any pollster (as well as common sense) will tell you that it is not hard to design survey questions to elicit a desired response.

What the almost nine-in-ten respondents in Pew's survey seemed not to recognise is that:

- with the exception of wild berries, mushrooms and game, and wild-caught fish and shellfish, virtually *all* the organisms – plants, animals, microorganisms – in our food supply have been modified by one genetic technique or another;
- because recombinant DNA techniques are more precise and predictable than their predecessors, biotech foods are likely to be even *more* safe than other foods;
- food producers in the USA already are legally responsible for assuring the safety of their products, and regulators do not normally perform safety determinations but primarily conduct surveillance of marketed foods and

take action if any are found to be adulterated or mislabelled; and

- unwarranted, excessive regulation, including unnecessary labelling requirements, discourages innovation, imposes costs that are passed along to the consumer and are a disproportionate burden on the poor.

With critics raising at every opportunity the possibility of hypothetical risks of gene-splicing, it is no wonder that many of those who *have* heard about the new biotechnology find it confusing and somewhat intimidating. But more generally, confusing the public on scientific and technological subjects is not difficult. A study by the US National Science Foundation found that fewer than one in four Americans know what a 'molecule' is, and only about half understand that the earth circles the sun once a year.[48]

Confusing the public on scientific and technological subjects is not difficult

Similarly, in the 2002 Eurobarometer survey of EU residents, 35 per cent of Europeans believed the statement 'ordinary tomatoes do not contain genes while genetically modified tomatoes do' was true, while 29 per cent did not know.[49] Only 49 per cent knew that eating a GM fruit would not modify a person's genes. In a 2003 survey, the Food Policy Institute at Rutgers University asked those same questions to American respondents and found that only 57 per cent recognised that all tomatoes contain genes.[50] Only two-thirds knew that eating GM fruit would not alter their own genes!

These kinds of results are not surprising. A reckoning of the costs and benefits to an individual confronted by such complex issues explains why few citizens bother to master the subtleties of many government policies, let alone those that involve scientific phenomena. There is vastly more to public policy issues – taxes, foreign affairs, farm subsidies, healthcare delivery and so on – than any one person can grasp. For most citizens the benefit of learning about issues and policies that do not directly affect them is small and the cost is large, so they establish priorities and pursue knowledge that is of the greatest immediate advantage. As a consequence, most often they end up not knowing much about science, technology or public policy. Economists have characterised these poorly informed citizens as 'rationally ignorant'.[51] Most non-experts *choose* to remain uninformed about the nuances of complex policy issues and instead focus their limited time and resources on other pursuits. Nevertheless, the rationally ignorant do participate in democratic processes, and their uninformed opinions do affect political outcomes. Their opinions tend to be derived from lowest common denominator information sources such as popular culture, television news (and even entertainment programming) and activist political campaigns, which lack essential detail and context.

Some NGOs cynically exploit the public's rational ignorance. They pitch fears, not facts, incessantly to an unsuspecting public, and convince regulators to impose (or maintain) unnecessary regulation on the new biotechnology. They have enjoyed modest success. Over-regulation has inflated the costs of research and development, made commercialisation – and even the ability to perform field testing – uncertain, and put crop biotechnology off-limits to some philanthropists.

It is tempting to discount the negative impacts of excessive regulation. But regulatory oversight – whether merited or not – comes at great cost to producers and consumers. In the USA, for example, case-by-case review, cumbersome field-test design and other requirements implemented by the Department of Agriculture and the Environmental Protection Agency have made recombinant DNA-modified plants disproportionately expensive to develop and test. These rules alone can add as much as tens of millions of dollars to

development costs, a prohibitive barrier for all but the most profitable applications – and US rules are among the least burdensome found anywhere in the industrialised world.[52–54] In addition, government decision-making processes must take into consideration public attitudes and other political obstacles, which can add uncertainty and lengthy (as well as costly) delays to the developmental process.[55] Ultimately, these burdens make most public goods research and development of low-profitability crop varieties prohibitively expensive when it involves recombinant DNA technology.

Consider the example of Harvest Plus, an alliance of organisations devoted to producing and disseminating staple foods rich in micronutrients such as iron, zinc and vitamin A. According to its director, the group has decided that, although it will 'investigate . . . the potential for biotechnology to raise the level of nutrients in target crops above what can be accomplished with conventional breeding . . . there is no plan for Harvest Plus to disseminate [gene-spliced] crops, because of the high and difficult-to-predict costs of meeting regulatory requirements in countries where laws are already in place, and because many countries as yet do not have regulatory structures.'[56]

The imposition of unwarranted regulation in order to quell public apprehension is not wise

Regulation is often warranted, but the level of scrutiny should be commensurate with risk. The imposition of unwarranted regulation in order to quell public apprehension is not a wise use of government power, nor is it likely to succeed. As the president of Consumer Alert, an American national consumer organisation, testified to a panel convened by the National Institutes of Health (NIH), 'For obvious reasons, the consumer views the technologies that are *most* regulated to be the *least* safe ones. Heavy involvement by government, no matter how well intended, inevitably sends the wrong signals. Rather than ensuring confidence, it raises suspicion and doubt.'[57]

"We did what they wanted, but after we did it they turned out to want something else", is among the oldest of political complaints

Adding insult to injury, in February 2005 the CSPI issued a report finding that, due to the uncoordinated nature of the US regulatory process and its 'patchwork of legal authorities', the time US regulatory agencies take to review new gene-spliced crop varieties has doubled since the late 1990s and 'the number of biotech crops going through the regulatory review process decreased sharply between the last five years of the 1990s and the first five years of the 21st century.[58] The 'study' then sheds crocodile tears because the biotechnology industry is 'stagnating, not thriving', and laments that biotech's full potential might never be realized. 'One would expect that the regulatory pathway for biotech crops in the 21st century would be quicker and easier than in the 1990s', notes the author. One would indeed, unless one knew that NGOs such as the CSPI have lobbied for years to make the regulatory process more burdensome, not less so.

It is apparent that biotechnology's opponents will not be satisfied with appropriate, scientifically defensible, risk-based regulation. At every opportunity, they raise spurious questions and claims, attempting both to prolong 'controversy' and to maintain existing regulatory regimes. Biologist Donald Kennedy, editor of *Science* and former US Food and Drug Administration Commissioner and Stanford University president, has analysed various aspects of governmental oversight of America's scientific enterprise. Bringing to it the experience of a scientist and regulator, Kennedy observes that bad public policy usually results when we respond politically to some popular movement, such as radical environmentalism, only to discover that we have mistaken its real motivation. ' "We did what they wanted, but after we did it they turned out to want something else" is among the oldest of political complaints. It has all kinds of bad consequences. Not only is the wrong policy put in place, but those who have tried to be responsive experience alienation and disillusionment when they

discover that they have not provided any satisfaction.'[59]

Kennedy chides policy makers: 'Frequently decision-makers give up the difficult task of finding out where the weight of scientific opinion lies, and instead attach equal value to each side in an effort to approximate fairness. In this way extraordinary opinions . . . are promoted to a form of respectability that approaches equal status.'[59] Kennedy is too kind. Often the policy makers do know where the weight of scientific opinion lies but are insufficiently courageous to implement sound policies, or they may wish to use the demands of activists as cover for their own bureaucratic empire-building.

To the NGOs, sensible regulatory policy is not a goal in itself, but is merely a bargaining chip to be held or given up in negotiations

Biotechnology's antagonists are reluctant to let the world know their real agendas, but once in a while we get a revealing glimpse. The Pew Charitable Trusts, the parent of the Pew Initiative on Food and Biotechnology, has announced that it is changing its legal and tax status from the more restrictive 'foundation' to a 'public charity', in order to be able to undertake more overt lobbying and advocacy – that is to say, to continue to do what it was doing previously, but without the pretence of 'balance'.[60]

There are more substantive, less legalistic examples, such as activists' bizarre response to 'golden rice'. In 2000, a university research team based in Switzerland and Germany announced an extraordinary scientific tour de force that resulted in a marked enhancement of beta-carotene, or provitamin A, in rice grains.[61] The creation of this 'golden rice' (so-called because of its yellow colour) was widely hailed as an example of how gene splicing can benefit society, especially the inhabitants of less developed countries.

Critics first claimed that golden rice would be unhealthy, because too much vitamin A can be toxic, and then they declared that golden rice had too *little* beta carotene

Astonishingly, activists lost no time in attacking even this beneficent innovation. The developers of golden rice were criticised for working with companies to distribute seed to the indigent. Critics first claimed that the rice itself would be unhealthy, because too much vitamin A can be toxic.[62] Nutritionists rapidly discredited that claim, explaining that golden rice contains beta-carotene, the chemical precursor of vitamin A, which is not known to be toxic at any dose. Then, torturing the data, Greenpeace declared that golden rice had too *little* beta-carotene and that an adult 'would have to eat around 9 kg of cooked rice daily to satisfy his/her daily need of vitamin A.'[63] German Greenpeace campaigner, Benedikt Haerlin, threatened direct action against test plants in the field.[64] And the activists' media allies, including *The New York Times Magazine*, whose Michael Pollan dubbed golden rice 'the great yellow hype',[65] rushed to support them. This is a grotesque misrepresentation. Even small amounts of vitamin supplementation can have huge effects.[66] Golden rice and other products like it can be a life-enhancing, life-saving adjunct to those with vitamin A deficiency – but only if its producers can overcome NGO opposition and regulatory hurdles, and get it to the farmers who need it.

Such misguided activism might make those who 'merely' demand stifling regulations appear temperate by comparison. But correspondence published in the journal *Science* in 2003 opened a window into the motivations of the 'moderate' wing of the anti-biotechnology lobby. Steven H. Strauss, a Professor of Forest Science at Oregon State University, had proposed in an article in that journal a very modest streamlining of the regulation of negligible-risk genetic constructions of gene-spliced plants.[67] The reform that he suggested would remedy, in a small way, the irreconcilable paradox in the current oversight of plant biotechnology: that the use of the most precise and predictable techniques is far more stringently regulated than techniques that are less precise and predictable. In other words, Strauss was lobbying for regulatory proportionality, recognition of the basic principle that the degree of oversight should be commensurate with the degree of risk.

Jerry Cayford, of Resources for the

Future, responded to Strauss in a letter published in *Science*:[68]

> Steven H. Strauss makes a plea for less onerous field trial regulations for less radical genetic modifications . . . thereby helping smaller companies and public-sector investigators to be able to afford to try out crop variants. Unfortunately, his pleas ignore the politics of the genetically modified (GM) food debate . . . Strauss' proposal, reasonable as it may be, asks critics to surrender a major bargaining chip – strict regulation of field trials – but offers them nothing in return.

The question we must ask is not whether regulation is or is not justified, but rather what should be regulated and how?

In other words, although it would favour consumers, researchers and the public interest, sensible regulatory policy is not a goal in itself but is merely a bargaining chip to be held or given up in a negotiation among radical groups, business interests, academic researchers and government regulators. Strauss responded, in turn, 'the costs to people and environment of effectively losing genetic engineering from most agricultural sectors as a result of excess regulation are too great for so simple-minded a political approach.' He added that there are few practices more '"democratizing" than protecting and promoting the ideas and work of society's innovators when applied to improve food quality, dependability, and affordability.'[69]

'Regulatory triage' would focus limited public resources on those products that are most likely to pose a genuine risk, thus using public funds more wisely

This *coup de grace* in Strauss' response serves as a worthy epilogue to the efforts and motivation of biotech's antagonists: '[W]ith the high level of regulation and stigma successfully implanted in places such as Europe, policies and attitudes may take a generation or more to change course. The opportunity costs in dollars, and costs to human health and environment, will be incalculable.'[69]

No one should mistake the anti-biotech NGOs' misdemeanours for naive exuberance or excessive zeal in a good cause. The activists might be forgiven if, in the pursuit of consumer and environmental safety, they advocated more stringent regulation of all plant breeding or more careful industry practices generally. But their agitation for disproportionately stringent regulation of a superior technology cannot be rationalised as the pursuit of improved product safety. All forms of plant breeding pose similar types of risks, and the risk of any organism is solely a function of its genotype and phenotype. Activists are promoting an approach to regulation in which there is an *inverse* relationship between degree of scrutiny and risk.

The disproportionate regulation of the products of recombinant DNA technology needlessly raises the cost of research and development while it fails to advance consumer or environmental safety. The question we must ask is not whether regulation generally is or is not justified, but rather what should be regulated and how? The use of certain techniques – in particular, those that are the most precise and predictable – as a trigger for regulation cannot be justified scientifically.

Instead, regulatory efforts should be redirected to focus oversight on new organisms that express characteristics likely to pose significant risk, regardless of the methods used in their development, while leaving relatively low-risk traits of both classical and molecular genetic modification unburdened by costly regulation. This 'regulatory triage' would focus limited public resources on those products that are most likely to pose a genuine risk, thus using public funds more wisely. Such a regulatory approach would also free many negligible risk products from unnecessarily strict oversight and allow them to be placed on the market sooner, where they can begin to benefit consumers and the environment. Focusing only on recombinant DNA techniques, and treating all gene-spliced products as though they are uniquely risky, is counterproductive and does more harm than good.

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Plant biotechnology, the regulator and the consumer

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Abstract

The use of genetic modification (GM) technologies to modify food crops provides one of the most hotly debated and often discussed applications of science. As the science develops, new generations of GM crops will be produced and current consumer views might change. This brief paper discusses mechanisms by which the complexity of decision-making at the regulatory level might be better understood by the public and hence provide tools for individuals to inform their own views and purchasing choices.

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Keywords: *GM plants, regulatory systems, consumer views, complexity of decision-making*

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Some ten thousand years ago the industry that we now know as modern agriculture, primary food production and the base of our food chain was already selecting plants to develop for new crops, disease resistance, vigour and high yields, and to optimise the yield for the local conditions. Gradually over the centuries we developed the strains continuously, without having much knowledge of the actual internal mechanisms of plant genetics and biochemistry but then suddenly, in the 1970s, we were able to understand more about plant genes and the structural and metabolic activities that the 30,000 or so genes in a typical plant cell encode. With this knowledge we have been able to modify the genetic information in living organisms in a new controlled way, by transferring one or more pieces of DNA directly between them. This genetic modification has led