Final Submission to Environmental Politics

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Profile: GMOs and Regulatory Styles

While the release into the environment and marketing of genetically modified organisms - GMOs - and their derivative products, represent issues with global relevance and implications, no singular approach has developed to regulate them in the two decades since gene-splicing technology became commercially viable.

The aim of this profile is modest: its main objective is to sketch the histories of the regulatory "paradigms of assessment and control" (Jasanoff, 1995: 313) concerning rDNA research in the US and EU, outlining the two divergent strategies which ultimately emerged from their experiences. A key factor contributing to the eventual development of two distinct approaches toward the derivative products of genetic modification concerns the level of organisation found in the scientific and industry constituencies in the two blocs. The piece ends noting the importance of placing the regulation of this specific issue within a template of global politics - a point illustrated with some contemporary examples from Japan and New Zealand.

The US: Evolution of a 'Product-Oriented' Style

The first loosely regulatory initiative relating to research in genetic modification stems from the self-imposed guidelines drafted by those scientists in the US at the forefront of genetic manipulation experimentation in the 1970s. This code was drawn up at the

International Conference on Recombinant DNA Molecules at Asilomar, California in 1975[2] and formed the basis of the laboratory research guidelines adopted by the US National Institutes of Health (NIH). It was Asilomar which alerted some key constituencies to the potential importance of rDNA technology, although it was certainly the scientists who, necessarily, held the detailed knowledge and thus it could be argued, the whip hand. Indeed, the emphasis placed by the scientific community upon the *lack* of negative consequences of genetic engineering is widely acknowledged as the argument which dissuaded Congress from the need for legislative initiatives to replace the guidelines (Cantley, 1995). Such was the confidence in the science that an initial ban which the scientists set, covering certain deliberate release experiments, was revoked after only two years (Jasanoff, 1995: 328).

The Asilomar-NIH concordat was initially intended as a voluntary - and temporary - agreement within the scientific community. Nevertheless, the code's endorsement by the federal NIH ensured that the scientists' code was to set the tone for the future federal and binding approach to GMO regulation, as genetic modification moved out of the laboratory and into the real world.

The pace at which scientific exploration on rDNA developed in the US meant that the first applications for deliberate release experiments had no tailor-made institution to be submitted to (Jasanoff, 1995: 314). As Jasanoff reports, this gap ensured that the NIH's Recombinant Advisory Committee (NIH RAC) was logically viewed as the formal body to scrutinise such requests. In addition, this committee oversaw federally funded

rDNA experimentation, the result being a situation where "governmental control... was tied to the sponsorship of research" (1995: 314).

This approach both to manage experimentation and foster commercialisation - which evolved in the late 1970s under the NIH RAC's research conduct guidelines - can be viewed as having set the tone for the regulatory approach concerning the derivative products of genetic modification. This approach has been popularly encapsulated by the shorthand term: a 'product-oriented' system (Gibb et al 1987 cited in Kim, 1992: 1161 & Jasanoff, 1995). This describes US administrations' consistent focus upon the intended *use* of the end product rather than the recombinant technology deployed to create it in the first place. Thus, in the US, the authority of *existing* laws and agencies are deemed sufficient to cope with any novelties of genetic modification.

The NIH's dual regulatory role was ended in 1986 by a court ruling against one of its decisions. This forced the US government to divide assessment between the NIH and three other agencies - the USDA, the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) - which were co-ordinated by the "Biotechnology Science Co-ordinating Committee" (BSCC). However, this farming out of NIH competences did not shake the core assumption - that all organisms carry equivalent safety considerations - which had underpinned the federal approach post-Asilomar. This understanding of the technology had been largely secured by the pivotal role of scientists in the US's early regulatory experience (Jasanoff, 1995). This further highlights the central importance of the "well-grouped" scientific constituency which had formed around genetic engineering (Cantley, 1995), with professional bodies like the American Society of Microbiologists (ASM) at this lobby's core.

The consistency of the US's focus on product has been matched by the undeviating pro-product pressure from both the scientific lobby and that of the biotech industry. Industry organisations (the Industrial Biotechnology Association - IBA and the Association of Biotechnology Companies - ABC) were set up in the early 1980s to represent the fledging industry, primarily against various judicial attacks (Cantley, 1995: 535). This robust organisational defence in favour of the prevailing policy undoubtedly made it easier to keep any political and public challenges in check.

Europe/EU: The Evolution of a 'Process-Oriented' Style

The alternative regulatory approach to GM products is characterised by concern with the actual GM technology itself, and is known as the 'process-oriented' approach. Under process-informed regulatory regimes, emphasis rests firmly upon formal authorisation along with case-by-case health and environmental risk assessments, both before and after a GM product's release into either environment or market. The (pre-) caution which underpins this approach is reflected in the contingent nature of the legislation it yields – with many of the 'process' regulations being characterised by reviews and revision, in response to scientific developments, popular opinion and the commercial world.

One of the first European countries to make operational such a process schema was Denmark, with its 1986 Environmental and Gene Technology Act. This prohibited the deliberate release of GMOs unless special approval had been proffered by the Minister of Environment. However, although the law appeared fairly restrictive, by 1989 Denmark had authorised selected field trials of herbicide-resistant sugar beet. Of course,

since 1990, Denmark and the 14 other countries of the European Union have had their regulatory strategies directed from the supranational level by two directives, underscored by a process logic: 90/219/EEC (contained use) and 90/220/EEC (deliberate release).

However, it would be a mistake to assume that the path toward this process legislation was linear. Individual European countries and also the EU (in its various forms) adopted regulatory tones very similar to the US throughout the 1980s concerning both end products as well as rDNA research. In particular, the UK's approach to research mirrored the flexible notification guidelines established under Asilomar, with the Genetic Manipulation Advisory Group (GMAG) paralleling the work of the NIH RAC. Indeed, the UK led the scientific community in the early phase of regulation (as it did in research), being the first to introduce a moratorium on rDNA experiments in 1974 after the publication of the 'Berg letter'.

At EU level, lessons on research regulation were drawn directly from the US. This was exemplified in 1980 when the Commission withdrew an authorisation proposal for rDNA research, replacing it by a proposal for more flexible, non-binding notification. The result was Council Recommendation 82/472 which deemed existing sectoral level legislation as sufficient to oversee the technology's development. It should be noted that the Commission's endorsement of technique-based oversight of research occurred after a meeting between the Commission officials and the Director of the US's NIH.

However, Europe ultimately diverged from the course set by the US. Political pressure, principally from the European Parliament's Viehoff Report (1987) on biotechnology,

signalled a challenge to the notion that notification of research alone was adequate. The report's argument drew upon concerns that some experimental releases had already taken place without any binding legislation in place regarding safety (Cantley, 1995; 542), and cited genetic engineering as carrying with it "special risks". With this statement, Viehoff rejected the international consensus which had formed around the OECD's 1986 report. *Recombinant DNA Safety Considerations* (known as the 'blue book') had defended the technique style of regulation, and interestingly was part-authored by European Commission officials from DGXII.

The European change of approach is exemplified by Directive 90/220, covering the procedures for the approval of new GM products and releases. This legislation has proved to be particularly controversial. Under this directive, 'national competent authorities' assess the applications for GMO authorisation on a case-by-case basis. In contrast to the US, these assessment bodies are often composed of interested parties, such as environmentalists, as well as scientists. This 'insider' status of selected lay actors brings into relief a key difference between the process- and product-oriented systems, with critics of the former arguing it entails more than a straightforward appeal to 'objective knowledge', i.e. science. In addition, the European case has a supranational dimension, whereby licences for *commercial* releases may only be granted with the approval of the member states by majority vote, where an objection is raised by another country.

As a directive, '220' merely lays down the *minimum* standards which member states must ensure are met in their own laws. So while the supranational level ensures EU states are covered by a 'process' umbrella, it is these individual countries which control

the manner in which it is implemented. Thus states can give some degree of expression to their own conceptualisation of risk, leading to various strains of the process style housed under the one roof[3].

The very existence of directive 90/220 undoubtedly reflects the absence, for most of the 1980s, of any powerful biotech lobby organisation in Europe. The first operation - the Senior Advisory Group on Biotechnology (SAGB) - was not set up until 1989 - too late to have any meaningful impact upon the pending legislative proposals. As a result, throughout the 1990s, the European lobby - latterly in the shape of EuropaBio - was in a position of attacking what the industry dubbed 'catch 220' (Cantley, 16/12/98: 20) and its protracted approval procedures[4]. Their criticisms have been widely acknowledged in the EU, and the 90/220 replacement directives and regulations currently being discussed broadly aim to provide clearer procedures for biotech firms marketing GM products. The European lobby focused upon the argument that the potential for wealth creation was being stifled by the process legislation, and putting the EU at a competitive disadvantage. However the legislation being developed is set to *retain* the theme of authorisation, fitting with the public mood in Europe. Thus some dilution - but no reversal - of the process approach of product regulation is likely.

Beyond the US/EU dualism

The US and EU are, of course, part of a wider global narrative. Indeed, one of the notable features of the GMO issue concerns the degree of influence which the actions of

one country or bloc can have upon another. As noted, the US has been influential, and for many nations been the country to watch (particularly in the regulation of rDNA research). Recent developments in New Zealand's approach to GMOs flag up the centrality which exogenous forces can have in determining the type of legislative regime favoured by a country in a given context. Reporting in *The Ecologist* (August/September 1999), Jeanette Fitzsimons, Member of Parliament and co-leader of the NZ Green Party, describes the government's vacillation between process- and product-oriented approaches when deciding its stance on GM product labelling. The apparent move away from a commitment on mandatory labelling should be viewed as underscored by desire for an NZ-US free trade agreement (Fitzsimons quotes leaked cabinet minutes and communications from the US to this effect).

However it is not only formal legislative developments which can have a knock-on effect at the national level. Developments in popular opinion and environmental spheres should also be viewed as capable of effecting change. An example of environmental developments could be seen in September 1999 when Japan announced plans for a five-year project to investigate the possible *long-term* environmental implications which GM releases may entail. In particular, this related to concerns about possible negative consequences of gene transfer between crops (Saegusa, 2/9/99: 3), with the Monarch butterfly controversy in the US as the instigator[5].

Round-up

The EU played 'follow the leader' with the US (and UK initially) in the first regulatory

flurry surrounding rDNA research, with consensus built around the adoption of flexible, voluntary guidelines. However this harmonised approach was ended in the mid-1980s as political pressure in Europe mounted over how to regulate both research and the technology's eventual end-products. The European Parliament's Viehoff Report coupled with the lack of an organised industrial and scientific lobby -like those of the US - effected a total change of direction, away from the technique and product based approaches. The result has been two management systems co-existing in GMO regulation, vying for the support and conversion of other countries.

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Abbreviations

ABC	Association of Biotechnology Companies
ASM	American Society of Microbiologists
BSCC	Biotechnology Science Co-ordinating Committee
DNA	Deoxyribonucleic Acid
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
GM	Genetically Modified
GMAG	Genetic Manipulation Advisory Group
GMO	Genetically Modified Organism
IBA	Industrial Biotechnology Association
NIH	National Institutes of Health
NIH RAC	National Institutes of Health Recombinant Advisory Committee
NZ	New Zealand
OECD	Organisation for Economic Co-operation and Development
rDNA	Recombinant DNA
SAGB	Senior Advisory Group on Biotechnology
US	United States
USDA	United States Agriculture Department

Footnotes

[1] The author would like to thank Mark Cantley and David Judge for their insightful comments on earlier drafts. The usual disclaimer applies.

[2] It should be noted that the 1975 Asilomar was preceded by a similar conference at the same location in 1973. It was this earlier conference which placed genetic engineering firmly on the US scientific agenda. For further reading Mark Cantley provides an accessible account of these two key meetings at Asilomar in the 1970s, as well as a detailed regulatory history.

[3] It should be pointed out that the ability of member states to introduce specific national provisions must be based on new scientific evidence and is restricted by the terms laid out in Article 95 (ex 100a).

[4] This refers to the idea that 90/220's initial goal to attenuate consumer and environmental anxieties about this new technology may have had the unintended consequence of frustrating the development of safer products.

[5] This refers to Cornell University research published in *Nature* which reported that Monarch butterflies had been poisoned by modified corn (*Bt*-corn).