Legislation, leaders, and laggards

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As soon as the early breakthroughs in recombinant DNA techniques were made in the mid-1970s, it was clear that exploration of the far-reaching opportunities of modern biotechnologies would have to be accompanied by effective legislation. The moratorium on certain experiments in genetic engineering that preceded the Asilomar Conference of 1975 was imposed by scientists involved in the field in the interest of sound and sober debate about the risks that might be entailed. The reduction of risk has been the focus of interest for biotechnology legislation ever since.

If it is legislation that prevents hazards from occurring (rather than the absence of hazards), then legislation across the globe has been formidably effective over the past quarter century. The application of stringent safety standards and rigid operational procedures over both research level and larger-scale developments has prevented any dangerous or otherwise unacceptable events.

By their very nature, the risks and hazards of the early stages of modern biotechnology were of a strongly conjectural nature. In learning to deal with recombinant DNA organisms, the world was facing something it had not seen before. It was suggested at the time that there might be hazards to human and animal health or to the environment. Therefore, the legislative systems that were put in place were precautionary. The precautionary approach meant (and still means) that experiments are allowed to proceed on the basis that mechanisms are in place to deal with any anticipated hazards. It does not mean (and never has) that all work should stop unless we are sure there are no hazards.

After hundreds of thousands of experiments involving recombinant DNA, and the development of dozens of medically useful products used in millions of patients a year, the safety of humans, animals, and the environment has been maintained. This 100% track record can offer the world confidence that high levels of safety and control are possible in biotechnology.

Contained use

Legislation ensuring that genetically modified

organisms are constrained within the boundaries of laboratories, greenhouses, or manufacturing plants has been in place in many countries since the late 1970s or early 1980s. Different safety precautions are required for familiar and nonpathogenic organisms than for those that are exotic or pathogenic.

As knowledge and experience of handling recombinant organisms increases, and as researchers gain more data about risks and hazards, the legislative emphasis should shift from a precautionary approach (when we are dealing with the unknown) to the imposition of safety measures based on knowledge of the real problems. For companies in the field who compete internationally, it is important that the development of legislation (and its subsequent revision) is harmonized at least across the major global trade blocks. At the moment, much of the legislation in Europe is lagging behind: The laws are still stuck in a precautionary rut while experience justifies moving forward. European bioindustries are disadvantaged.

Release

The legislation to control release of genetically manipulated organisms, applied to all organisms but which has been of particular importance in the development of recombinant crops, was put in place in the late 1980s. Across the world, many thousands of field trials have been and are being carried out. Again, there have been no reports of hazardous, unexpected developments warranting the imposition of new, more stringent control measures.

Around 80–90% of all development of recombinant crops is taking place in North America. Although Europe's science and technology base is competitive with the USA and Canada, the development and commercial growing of genetically engineered novel crops has been mainly a North American operation (with other substantial activities in Argentina and China). In Europe, where field trials started at the same time as in North America, no commercial growing has taken place. The number of large-scale field trials in Europe has been much smaller than in the United States and Canada. This is only partly because some of the most advanced crops, such as soya and cotton, are not widely cultivated in Europe. Most of the differential across the Atlantic has been due to lack of approvals by regulatory authorities in Europe. Some authorities have been

highly indecisive and sometimes obstructive. In some cases, decisions made to approve a product at a national level have been confirmed at a European level only to be refused by another body at a national level. Few field trials and other release approvals have been granted in Europe based on objective, nonpolitical criteria.

Novel foods

In the United States, novel food products that are substantially different from current products can be marketed subject to approval from the US Food and Drug Administration (Rockville, MD). In the European Union, such products fall under the Novel Foods Regulation that applies across the EU. At present, a series of food products has been approved in the US, while in Europe, despite an early central approval for modified soybeans and maize (imported from the US), not all EU member countries have even approved these foods. The approval process for novel foods in Europe has now become almost completely politicized, much to the detriment of European companies in this sector.

The UK House of Lords (London) in a recent report said of genetically modified food, "We consider the regulatory process for assessing safety and novel foods to be thorough and proper and we see no reason to doubt the safety of foods which have been approved by the regulatory process." Despite such high-level reassurance, the future outlook of the European novel food situation still appears very cloudy. This kind of uncertainty is not what industry is looking for.

Orphan medical products

The Orphan Drugs Act in the US has been a major incentive for the development of new medicines for the treatment of rare diseases. It also stimulates the launch of new, research-based companies who view orphan drugs markets as attainable platforms for their businesses. Since the introduction of this US legislation, about 150 orphan drugs have been designated, many of which have reached the market. Hundreds of start-up biotechnology companies have been established on the basis of these opportunities.

Only now in Europe has a proposal for similar legislation been put to the Council of Ministers and the European Parliament. It is urgent that the same stimulus for biobusiness that exists in the US be made available in Europe. ///

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