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Daegu Protocols

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Contents of the protocols.

00. Introduction.
Regulatory procedures involving transgenic organisms in their present form are heavily biased towards containment because there is a tacit presumption that something new is dangerous until proven safe. This is sometimes referred to as the "precautionary principle" and has resulted in the rejection of biotechnology due to fear of unknown consequences which cannot be tested for or are too costly and time consuming to test for. Field trials are delayed until laboratory tests results offer a given level of predictable safety with flexible standards that depend on a "consensus" based mostly on experience. Two different positions exist to examine risks; one to define a set of risk assessment standards to apply broadly to genetic biotechnology; the other favors "case-by-case risk assessment because each genetic construct and expression differ greatly from each other in potential risks.

New technology often has no precedent or experience to guide regulatory officials resulting in inclinations to delay regulatory approvals due to inability to scientifically assess risks. Another reaction is to request excessive data that is so costly and time consuming to produce that the biotechnology is inevitably withdrawn or thwarted.

As shown by the recent recall of the drug Vioxx, and by the disastrous effects of the older drug, thalidomide, it is not always possible to predict safety based on laboratory tests.

Genetic engineering is still a new concept and transgenic organisms are being introduced at a time when we are reporting the first nucleotide sequences of genomes. Some people are uncomfortable with this new technology for religious reasons or due to fear of the unknown. However, attaching mystical properties to gene manipulation is misguided because genomic analysis shows that all organisms including viruses are made up of genetic recombination events. Indeed, multicelluar organisms owe their existence to an amalgamation of single cell precursors (Dawkins, 2005) an event that appears to have happened several times.

We used genetic mutation long before we knew what a gene was. The natural movement of small and large nucleotide sequences is a relatively new finding. Thus natural "genetic engineering" has been going on for a long time. Indeed, some of the most genetically modified organisms comprise the food we eat.

Knowing this, it is difficult to understand why an element of danger is associated with a transgene. Yet this has crept into the regulatory process stifling progress. This perception of unknown danger is exacerbated by the press media seeking sensationalism and eco-environmental public interest groups seeking a cause to attract funding.

The regulatory process should return to the thalidomide model and focus on real safety issues rather than applying arbitrary standards to transgenes. Ecologists have asked recently if the loss of habitat and therefore loss of biodiversity could lead to an increase in human diseases. This and the prospects of human-induced global warming enormously overshadow transgenes as serious societal risk issues.

The Pew Foundation report, “Bugs in the System,” (Anonymous, 2004) concluded that it is unclear which laws in the United States apply to new biotechnology and which agency should act in oversight. Rather than something being done about this, a “muddle through” approach is being taken by multiple agencies without a well coordinated singular approach. The lessons learned act as a valuable guide. Rather than repeat the same process, other countries may adopt the protocols outlined below.

0. The role of regulatory agencies.

The main role of regulatory agencies is to encourage the development of new technology by ensuring safe application and educating the public. In this the agencies are acting on behalf of the government.

Establishment of timelines and cost limits for the risk assessment data development process.

Biotechnology can address certain problems in agriculture and medicine that have defined solution.

I. Application procedures.

a. Determination of the scale of the application.

There is a difference between a new biotechnology that applies broadly around the world with a large potential market and one that is very specific and can only be applied to a local situation and probably cannot be exported to other countries because of this specificity. An example is AF-36 that was selected for compatibility with Arizona soils as a symbiotic fungus used to displace the strain of *Aspergillus flavus* that produces aflatoxin and eventually can contaminate cotton seed used for cattle feed.

b. Triage at a central receiving point.
c. Public disclosure during review.
d. International agreement and coordination of regulatory review.

II. Assignment of a biotechnology to an agency.

a. Identification of an agency.
b. Responsibility of the assigned agency.
c. Reporting procedures.

III. Dialog between the regulatory agency and the applicant.

a. Initial reply.
b. Time for reply.
c.

IV. Complaints.

a. The need for redress.
b.

V. Insufficient capacity to regulate.

When a country that is signatory to these protocols is confronted with an application for a technology that is beyond the capacity of the country to regulate, it may opt to substitute the regulatory procedures of another signatory country.

a. Substitution of a foreign registration for local registration.
b. Substitution of a foreign monitoring process for local process.
c. Financial support for biotechnology risk assessment.

National and International agency financial support of the biotechnology risk assessment process.

Development of the case-by-case method of risk assessment for a non-limited number of categories that can be applied by countries inexperienced in the biotechnology risk assessment process; starting with 5-10 categories and adding categories as the technology expands.

VI. Definition of terms.

Agency
Triage
Applicant
Biotechnology
Signatory country

References

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[Social constraints may prevent recognition of alternative interpretations.]
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'halfway technologies,' designed to shore things up and keep flawed organs functioning beyond their appointed time.

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