A: ISSUES FACING THE REGULATORY COMMUNITY AS REGARDS BIOTECHNOLOGY, GENETICALLY MODIFIED ORGANISMS AND TRANSGENIC CROPS

Biological and Environmental Risks Involved in the Use of Transgenic Crops
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The release of transgenic organisms has evoked an unusual legal process in that laws governing it are prospective on perceived risks rather than retrospective on experienced risks as is the usual case with legislating against problems. Most countries undertaking transgenic releases have adopted a regulatory structure usually comprising controlled releases to address questions of perceived risks followed by uncontrolled commercial releases. There has been an increasing number of commercial releases from approximately 11 million hectares of transgenic crops in 1997 to more than 27 million hectares in 1998. Most of these commercial releases have been in industrialized countries with only a small proportion in developing countries. The controlled releases, together with laboratory experiments, have addressed a range of perceived risks which can be put into three groups: risks to humans and domesticated animals, risks to the environment, and commercial risks. These perceived risks have to be assessed against the baseline of current and projected farming practices with non-transgenic crops. Few, if any, of these perceived risks have been shown to be real risks which are significantly more important than the non-transgenic situation. The situation with plants transgenically protected against virus infection was discussed. In some countries, the discussions on transgenic crop releases have entered the public domain. The debate has raised various ethical issues and reflects the wish of society to be involved in the adoption of new technologies. [L]

Risks of the Release of Transgenic Herbicide-Resistant Plants with Respect to Both Humans and Animals, and the Environment
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Cultivation of transgenic crops, produced by recDNA technology, has increased markedly during the last 3 years. Introduction of herbicide-resistant crops bears potential agronomic and environmental advantages, such as replacement of persistent herbicides by environmentally more benign compounds, reduction of herbicide use, and prevention of soil erosion. Potential disadvantages of the cultivation of such crops may be an increase in dependency on chemical weed control methods, increase in the development of resistance in weeds or the formation of multiple-herbicide-tolerant weeds through cross pollination, and a negative impact on biodiversity. Development and release of transgenic herbicide-resistant crops in the environment and market introduction of derived foods and animal feed have been the subject of thorough risk assessment of issues related to human/animal and environmental safety. Various national and international regulatory bodies have issued guidelines and regulatory directives which cover the legal requirements for release of these crops. Assessment of risks for humans and animals involves: (i) characterization of the donor and host organisms; (ii) characterization of the molecular/genetic aspects of the genetic modification; (iii) potential for gene transfer, in particular the relevance of genes coding for antibiotic resistance; (iv) safety of gene products and metabolites; (v) establishment of substantial equivalence, i.e., a systematic analytical comparison of the composition of genetically modified plants and derived food or feed products with that of non-modified control varieties grown under identical conditions; and (vi) determination of the metabolism of applied herbicides on transgenic plants and levels of residues on these plants and in the foods of animals fed transgenic plant material. Evaluation of environmental issues related to cultivation of transgenic herbicide-resistant plants is focused on (i) potential for gene transfer/gene escape between modified crops and other plants; (ii) treatment of volunteers infesting follow-on crops; (iii) safety assessment for non-target organisms, i.e., birds, insects and other invertebrates and soil organisms; and (iv) resistance/tolerance issues like selection pressure for resistant weeds, shifts in weed composition, and the formation of new resistant weeds. Experience with large-scale breeding of transgenic herbicide-tolerant crops has been gained mainly in the USA, whereas in Europe cultivation of such crops is limited to relatively small field-plot experimentation. Long-term effects of large-scale breeding depend on specific agricultural infrastructure and ecological conditions, and can therefore not easily be extrapolated between countries. Further studies are therefore needed on transgenic crop cultivation with respect to overall use of herbicides, development of resistance in weeds, changes in weed composition, and influences on biodiversity. Based on this information, codes of practices and specific monitoring programs may be designed.

Transgenic Arthropods for Pest Management Programs: Risks and Realities

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It is now possible to manipulate genetically both pest and beneficial arthropods using recombinant DNA methods. A variety of transposable element and viral vectors can be used to insert DNA into the chromosomes of arthropods and a variety of potentially useful genes have been cloned. The genetic manipulation of both pest and beneficial arthropods opens new opportunities for improving pest management programs but also creates new responsibilities because we will have to evaluate the potential risks of releasing such transgenic organisms into the environment. The deployment of genetically engineered arthropods in pest management programs will require the resolution of several scientific and environmental issues, including quality control. Another fundamental issue is whether we understand how to deploy the genetically manipulated arthropod. Potential risks associated with permanent release into the environment include the possibility of altering the transgenic strain’s behavior, ecological range, or host specificity. Risks will vary with the arthropod species, its effect on human health or its role in the environment; risks also will vary depending upon the genes inserted and the method of insertion used. Measuring the potential