Latest M&A review gives foreign investors more certainty in US

Mark E. Plotkin and David N. Fagan

NEW regulations setting out the United States' national security review process for foreign mergers and acquisitions of US businesses became effective in the week before Christmas last year.

They are the ultimate step in a lengthy effort to revise and strengthen the reviews undertaken by the Committee on Foreign Investment in the United States (CFIUS).

CFIUS administers the so-called Exon-Florio statute, which provides the US President with the authority to review mergers, acquisitions and takeovers (M&As) that may result in foreign control over a US person or entity engaged in interstate commerce in the United States. (Greenfield investments are not subject to CFIUS review.)

For M&As that threaten to impair US national security in a manner that cannot be mitigated or that is not, in the President's judgment, otherwise addressable, the President can suspend or prohibit such foreign investments, a decision not subject to judicial review.

The Exon-Florio statute itself, and CFIUS as the statute's administering body, came under political attack in the wake of the 2006 Dubai Ports World debacle.

Some in the US Congress sought to tighten drastically the legal regime for foreign investment in the United States.

Fortunately, through the leadership of certain key members of Congress, the Administration and the business community, the debate shifted to improving the review process in a manner that protects national security while preserving the openness of the US to foreign investment.

The end result was the Foreign Investment and National Security Act of 2007, which enhanced Exon-Florio and the CFIUS process. The Treasury Department, working with the other CFIUS agencies, has now issued final regulations implementing the Act.

The amended CFIUS process, which went into effect on December 22, maintains the formal existing timeframes for reviewing M&As, providing a critical measure of certainty to foreign investors and US parties.

While the number of M&As filed with CFIUS has been rising steadily in recent years, CFIUS likely will continue to review just a fraction — generally estimated to be less than 10 percent — of foreign investments in the US.

Even with the enhanced number of filings and increased investigations, the majority of CFIUS' reviews will conclude in the initial 30-day time period.

It is important to note, however, that M&A parties should tread carefully with their discretion on when and whether to notify CFIUS of a transaction and to require CFIUS approval before closing the transaction.

CFIUS does monitor M&A activity, and it is always preferable for parties to raise a transaction with CFIUS voluntarily rather than to have CFIUS formally come calling after the transaction is announced.

Greater clarity

While relatively few covered M&As raise potential national security concerns, the President and CFIUS have the power to unwind a transaction after closing.

Conversely, a CFIUS review and approval provides a form of safe harbor for a transaction that can only be revisited in very limited, exceptional circumstances.

Given this dynamic, parties are well advised to assess the CFIUS-related ramifications of a potential transaction involving foreign investment — and to determine whether a CFIUS review is advisable — in advance of entering into a covered M&A.

In the end, the revised CFIUS regime largely preserves existing practices and timeframes, and provides somewhat greater clarity to transaction parties.

Given the difficult place where the process commenced after Dubai Ports World, this is a positive result, and benefits foreign investors and US parties alike by assuring greater transparency and stability in the CFIUS review process.

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Regulators foil science's vitamin A deficit remedy

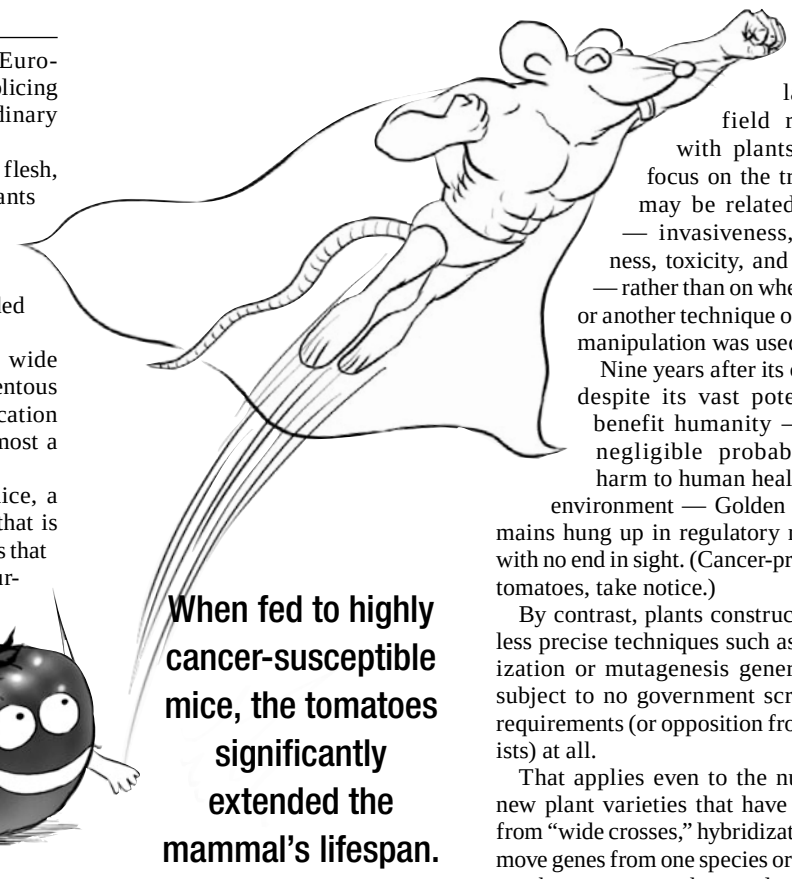
Henry Miller

A GROUP of multi-national European scientists has used gene-splicing techniques to create an extraordinary tomato.

It boasts a deep purple skin and flesh, and contains levels of antioxidants 200 percent higher than unmodified tomatoes. When fed to highly cancer-susceptible mice, the tomatoes significantly extended the mammal's lifespan.

These studies have received wide attention, but an equally momentous achievement of genetic modification has been largely ignored for almost a decade.

That innovation is Golden Rice, a collection of new rice varieties that is bio-fortified, or enriched, by genes that express beta-carotene, the precursor of vitamin A, which is converted in the body, as needed, to the active form.



When fed to highly cancer-susceptible mice, the tomatoes significantly extended the mammal's lifespan.

Most physicians in North America and Europe never see a single case of vitamin A deficiency in their professional lifetimes.

But the situation is very different in poor countries, where vitamin A deficiency is epidemic among the poor, whose diet is heavily dominated by rice (which contains neither beta-carotene nor vitamin A) or other carbohydrate-rich, vitamin-poor sources of calories.

In developing countries, 200-300 million children of pre-school age are at risk of vitamin A deficiency, which can be devastating and even fatal.

It increases susceptibility to common childhood infections such as measles and diarrheal diseases, and is the single most important cause of childhood blindness in developing countries.

Every year, about 500,000 children become blind as a result of vitamin A deficiency, and 70 percent die within a year of losing their sight.

In theory, we could simply supplement children's diets with vitamin A in capsules, or add it to some staple foodstuff, the way that we add iodine to table salt to prevent hypothyroidism and goiter. Unfortunately, neither the resources — hundreds of millions of dollars annually — nor the infrastructure for distribution are available.

Biotechnology offers a better, cheaper, and more feasible solution: Golden Rice, which incorporates beta-carotene into the genetically altered rice grains.

The concept is simple. Although rice plants do not normally synthesize beta-carotene in the endosperm (seeds), they do make it in the green portions of the plant.

By using gene-splicing techniques to introduce the two genes that express these enzymes, the pathway is restored and the rice grains accumulate therapeutic amounts of beta-carotene.

Golden Rice offers the potential to make contributions to human health as monumental as the discovery and distribution of the Salk polio vaccine.

With wide use, it could save hundreds of thousands of lives every year and enhance the quality of life for millions more.

Bureaucratic dithering

But one aspect of this shining story is tarnished. Intransigent opposition by anti-science, anti-technology activists — Greenpeace, Friends of the Earth, and a few other groups — has spurred already risk-averse regulators to adopt an overly cautious approach that has stalled approvals.

There is nothing about Golden Rice that should require endless case-by-case reviews and bureaucratic dithering.

As the British journal Nature argued in 1992, a broad scientific consensus holds that "the same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods.... (Therefore) no conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques that modify DNA and transfer genes."

Put another way, government regulation of field research with plants should focus on the traits that may be related to risk — invasiveness, weediness, toxicity, and so forth — rather than on whether one or another technique of genetic manipulation was used.

Nine years after its creation, despite its vast potential to benefit humanity — and a negligible probability of harm to human health or the environment — Golden Rice remains hung up in regulatory red tape, with no end in sight. (Cancer-preventing tomatoes, take notice.)

By contrast, plants constructed with less precise techniques such as hybridization or mutagenesis generally are subject to no government scrutiny or requirements (or opposition from activists) at all.

That applies even to the numerous new plant varieties that have resulted from "wide crosses," hybridizations that move genes from one species or genus to another — across what used to be considered natural breeding boundaries.

Judith Rodin, the president of the Rockefeller Foundation, announced last October that her organization would provide funding to the International Rice Research Institute to shepherd Golden Rice through national regulatory approval processes in Bangladesh, India, Indonesia, and the Philippines.

This is good news, but what is really needed is a multi-faceted, aggressive reform of the regulatory process so that all new genetic constructions will have a chance to succeed.

In an April editorial in the journal Science, Nina Fedoroff, a plant geneticist who serves as senior scientific advisor to US Secretary of State Condoleezza Rice, wrote: "A new green revolution demands a global commitment to creating a modern agricultural infrastructure everywhere, adequate investment in training and modern laboratory facilities, and progress toward simplified regulatory approaches that are responsive to accumulating evidence of safety."

The Golden Rice story makes it clear that we do not yet have the will and the wisdom to make that happen.

(The author is a physician and fellow at the Hoover Institution, and was an official at the US National Institutes of Health and at the Food and Drug Administration from 1977-1994. The views expressed are his own. Copyright: Project Syndicate, 2009. www.project-syndicate.org.)