
Editorial: In defence of science-based regulation

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Barely a week after my Hoover Institution colleague economist Milton Friedman passed away in November, I had a stark, first-hand reminder of the wisdom of his limited-government, libertarian views. These epiphanies came in Chiba, Japan, during the deliberations of the UN task force on regulation of foods obtained with recombinant DNA (or gene-splicing) technology. As the proceedings became progressively more bizarre and unconstructive, I kept thinking of the old aphorism, the government that governs best governs least. The regulator-wannabes of the UN and the individual nations in attendance obviously believe otherwise.

The scope of this exercise, under the auspices of the Codex Alimentarius Commission, which sets food standards on behalf of the UN's Food and Agriculture Organization (FAO) and World Health Organization (WHO), makes absolutely no sense. Now in its seventh year, the mission of the task force is to create new regulatory requirements exclusively for foods made with the newest, most precise and predictable techniques of biotechnology – gene-splicing, or genetic modification (GM) – while exempting others made with far less precise and predictable conventional technologies. Having already stifled innovative research on food plants and microorganisms, it is now metastasizing to other areas, such as animals and even animals immunised with high-tech vaccines.

It is one thing to regulate novel foods with *traits* that are of potential concern, but quite another to regulate merely because a certain technique has been used, especially when that technique is state-of-the-art. It is rather like circumscribing for extra regulation only cars outfitted with disk brakes, radial tires and air bags – and then limiting only those vehicles to a lower speed.

The members of this task force – including the representatives of the US government – systematically ignore scientific principles and the basic axiom that the degree of regulatory scrutiny should be proportionate to risk. They disregard the scientific consensus that gene-splicing is an extension, or refinement, of older, traditional techniques of genetic modification, and that it does not warrant discriminatory, excessive regulation. They overlook the fact that during two decades of widespread use, the performance of gene-spliced crops has been spectacular, with farmers enjoying increased yields, decreased use of agricultural chemicals, and lower occupational exposures to pesticides.

This regulatory charade is The Big Lie, writ large. This Codex task force (which operates on behalf of the UN's FAO and WHO, remember) makes a mockery of the UN's own Millennium Development Goals – especially the first and most ambitious: 'to eradicate extreme poverty and hunger' by 2015. That cannot be accomplished without innovative technology, and innovative technology will not be available if it is regulated excessively and stupidly.

The task force's approach is incompatible with the published policies of the US Food and Drug Administration (FDA), which boasts the most scientifically defensible, risk-based approach to biotech regulation anywhere in the world. However, the head of the US delegation, Dr Eric Flamm, a senior FDA bureaucrat, is unfazed by the inconsistency; he maintains that at Codex the members of the delegation represent not their own agencies or departments, but the United States Government. One wonders whether FDA's leaders – who proclaim during every speech that the agency is committed to science as the basis for policy – share this view. After all, Federal courts take a dim view of bureaucratic actions that conflict with duly established regulatory policy.

Why does the United States collude on this travesty? The representatives of US regulatory agencies offer several rationales: Because virtually every other country has in place irrational,

unscientific regulation, we must follow suit; the task force is really addressing issues of trade, not science; and most important, American industry demands that we play along.

UNPERSUASIVE ON ALL COUNTS

The Codex deliberations are disastrous not only scientifically and economically but also put the United States at a disadvantage with respect to trade issues. Unduly burdensome Codex standards for biotech foods compromise the ability of the World Trade Organization to provide relief from arbitrary or protectionist policies. Codex standards provide cover for unfair trade practices because with them in place, a country that wishes to block trade in gene-spliced foods for any reason can defend against charges of unfair trade practices simply by remonstrating that it's deferring to Codex.

It is true that a narrow segment of US industry – big agribusiness, whose lobbyists flock to the Codex task force meetings – endorses the Codex process, but food companies regard it as a lose-lose situation created by government at the urging of the big agribusiness companies during the 1980s. The latter fail to realise that encouraging excessive, unscientific regulation is like eating your seed corn: a short-term expedient but a long-term catastrophe, especially for smaller farmers, plant breeders and academic researchers (who are not represented at Codex).

Interestingly, corn could have offered a kernel of stimulus to improving the regulatory status quo: There is increasing pressure to use biotechnology for the production of ethanol, commonly made from the fermentation of corn. Thanks to the Republican rout in the midterm election, two Midwestern Democrats from the Corn Belt, Rep. Collin Peterson of Minnesota and Sen. Tom Harkin of Iowa, will oversee the crafting of legislation as the new chairmen of the respective House and Senate agriculture committees. This guarantees a boost to an ethanol industry that already benefits from a panoply of government supports, including a tariff on imported ethanol, subsidies for growing corn and blending the fuel, crop insurance and a guaranteed market. The Energy Act of 2005 requires refiners to triple ethanol use from 2.5bn gallons last year to 7.5bn gallons by 2012.

This pressure on corn inventories – a concern for anyone who raises grain-fed livestock anywhere in the world – could provide a strong incentive to rationalise regulation: gene-spliced corn varieties boast higher yields. But at the urging of the big agribusiness companies, the Codex task force instead has chosen to rearrange the chairs on the Titanic – or perhaps more aptly, to carry out extensive interior redecorating of the entire ship.

The dynamics of the discussions in Chiba were instructive ... and irritating. American regulators assumed their usual role as shills for big agribusiness, which created its own Frankenstein's monster during the 1980s by demanding *sui generis*, excessive regulation of agricultural and food biotechnology. The industry's plan was to roll back regulation after competition from agbiotech start-ups and seed companies had been eliminated by high barriers to entering the marketplace, but that 'regulatory rescue' strategy has failed. As at other venues sponsored by UN agencies, the Organization for Economic Cooperation and Development (OECD) and the like, attempts to rationalise or liberalise regulation have been handily neutralised by the EU, its members and surrogates. This was very evident in Chiba.

Even as the EU vitiated any possible value of the various agenda items during its interventions, its delegate continually reminded the group that nothing emanating from Codex would in the least affect EU policies, procedures or (non-)approvals. As the interventions from the EU and United States ping-ponged back and forth, agribusiness lobbyists literally were whispering in the ear of the US government representatives, trying to eke out small concessions for their own narrow interests (and their end-of-the-year bonuses). At the end of the conference, Michael Phillips, vice-president of the Washington DC-based Biotechnology Industry Association (BIO), admitted to me that the outcome in Chiba 'is as stupid as you think it is, but we got what we needed.' Perhaps that is the sort of thing Eighteenth Century economist Adam Smith

had in mind when he observed, 'People of the same trade seldom meet together, even for merriment and diversion, but the conversation ends in a conspiracy against the public, or in some contrivance to raise prices.'

This bad-faith and inept performance by American regulators flies in the face of science-based public policy and detracts from the robustness of academic research and the well being of other sectors of the US economy. American officials now regularly collude in these anti-scientific debacles, the outcomes of which consistently sacrifice US interests to those of the European Union and anti-technology NGOs (which, inexplicably, are permitted full participation in Codex task forces). What makes this particularly absurd is that the United States provides about a quarter of the base budget of the UN.

Thanks in large part to excessive and ill-conceived regulation, agbiotech R&D already is moribund worldwide in the public sector, little better in industry, and dead and buried in the developing world. Given the flawed scope of the work of the Codex task forces (plural) involved in biotechnology regulation, every individual biotech-regulation project is another nail in the coffin of wider diffusion of the technology. The representatives of agribusiness at Codex are unapologetic about the burden that these regulations place on academia, and they freely admit that it will be virtually impossible ever to revisit the inaccurate assumptions that drive the work of the Codex task force.

How can we begin to fix this? I'm reminded of a classic fable, 'The Peterkin Papers,' by Lucretia Hale, which tells the tale of a well-meaning but rather dimwitted family. One day, Mrs Peterkin discovered that she had mistakenly put salt instead of sugar in her cup of morning coffee, making it taste awful. She called her family around to help her decide what to do. First, they took the coffee to the local pharmacist who tried adding ammonia and various other chemicals, including a dash of arsenic, but that only made the coffee taste worse. They proceeded then to the neighbourhood herbalist, who added more ingredients to the coffee, but that made it even more distasteful. In desperation, the Peterkins turned to the famed Lady from Philadelphia, who was reputed to be very wise. 'Why don't you dump it out and make a fresh cup of coffee?' the lady suggested.

Instead of that drastic but necessary remedy, under the auspices of the UN, bureaucrats from scores of countries continue to add more and more noxious nostrums and force the brew down the throats of researchers and consumers everywhere.

As the economic engine behind all the work of the United Nations, it falls to the United States to take the lead. The United States should cut off funding and all other assistance to foreign governments, United Nations agencies and other international bodies that implement, collude, or cooperate in any way with unscientific regulatory policies. Flagrantly unscientific regulation should become the 'third rail' of American foreign policy. In addition, the United States must direct its representatives at international conferences to hew to scientific principles and to the old axiom that no agreement is better than one that moves us backwards.

Uncompromising? Aggressive? Yes – but justified in the face of the virtual annihilation of entire areas of legitimate research and development, under-use of a critical technology, further disenfranchisement of poor countries, and disruption of free trade. Extreme measures in the defence of liberty are no vice, and moderation in the pursuit of justice is no virtue.

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