By Eric F. Greenberg, Attorney-at-law

'Meat' the regulators who tackle the tough questions

Today I want to talk about how federal regulators do their jobs. Let me stop you right there before you point out that the federal government is shut down right now and assure you that I know that but that I have faith it will reopen at some point—I hope it happened by the time you read this!—and all the regulators will get back to doing what they do.

Longtime readers probably already know that, even as a lawyer representing and defending the regulated industries, I have never shared the oft-heard view that 'government' is always a problem and 'regulations' are always a scourge.

More specifically, I don't think more regulatory controls are always the solution to problems, I support any effort to seek more efficient regulatory means to an end, and fight hard against wrong or unfair regulations. But I am not a cynic about regulatory agencies and personnel as such. Without regulations, our nation would be a less predictable, less fair, less convenient, and less safe place to live.

In fact, in my experience, people who work for the U.S. Food and Drug Administration and other federal and even state agencies tend to be dedicated, careful, smart people who make every reasonable effort to do their jobs in a way that complies with legal requirements, often in the face of budgetary restraints or uncertainties that do nothing for them but make their jobs harder.

Not to overstate the obvious, regulators generally have great familiarity with the laws and regulations that they are supposed to implement. Regulations of all kinds contain requirements, specifications, definitions, limitations, procedures, and exceptions, and the regulators are pretty well familiar with all of those and can handle routine matters without hesitation.

Ah, but problems can arise for regulators, and the regulated industries, when they are confronted with out-of-the-ordinary, new products or procedures that challenge the traditional categories and definitions, so it isn't obvious how they should be regulated. (In the worst position of all are the beleaguered lawyers who try to advise these companies. Sniffle.)

Thus, FDA knows how to regulate food contact substances in packaging, as food additives in most cases, but innovative active and intelligent packaging doesn't always obviously meet the traditional definition of 'food additive' or 'food contact material,' and requires some extra thought to determine what regulatory requirements apply to them. Another example: FDA knows how to regulate drugs and how to regulate medical devices, but some years ago when the pioneers of medical science figured out how to combine drugs with devices, FDA had to work through what to do when confronted with so-called combination products such as stents that let out drugs in the body.

And a number of agencies, including FDA, the U.S. Department of Agriculture, and the Environmental Protection Agency, have attacked the problem of updating how products of biotechnology are to be regulated, whether from plant or animal origin, in an effort to keep up with innovation. The agencies have also developed specific policies to address the unique issues presented when traditional substances are intentionally engineered to contain nano-scale particles.

A fair argument could be had about whether FDA in particular is too slow to accept innovative technologies, or even to figure out what it thinks of them. My sense is that they pedal as fast as they can on such questions, given the limitations on resources that force them to constantly make and revisit priorities. Thus it is that the emergence of cell-cultured food products from cell lines of livestock and poultry, that is, lab-grown meat, one of the most far-out and innovative ideas of recent decades, has challenged the relevant regulators. After all, the FDA regulates most of the foods in the U.S. food supply, and the U.S. Department of Agriculture regulates meat and poultry products, so it wasn't obvious which one should take responsibility.

These cell-cultured food products allow growth in a laboratory of what otherwise would be grown in, you know, an animal. Several companies are already developing commercial products of this type. In addition to figuring out how and whether the creation of these foods should be overseen or controlled, regulators recognize that the retail labeling of these products needs special attention, so as to inform consumers accurately, especially given that right now you can see this technology variously described as lab-grown meat, fake meat, imitation meat, in vitro meat, among other names.

FDA has experience, to quote its recent statement, with "regulating cell-culture technology and living biosystems," and USDA has "expertise in regulating livestock and poultry products for human consumption." The agencies, after hearing from public stakeholders via a public meeting last year and written public comments, developed a division of labor for these new cell-cultured foods.

The agencies announced in November of last year that they will create "a joint regulatory framework wherein FDA oversees cell collection, cell banks, and cell growth and differentiation. A transition from FDA to USDA oversight will occur during the cell harvest stage. USDA will then oversee the production and labeling of food products derived from the cells of livestock and poultry."

The brave new world of cell-cultured meat promises to bring genuinely mind-blowing, innovative new products to our lives, just as has happened with many other innovative technologies. As you watch it happen, pause to acknowledge the important role of the regulators who, rather than being cowed by the challenges, do their best to help steer these innovations to market to assure they are safe and fair, and risks stay low. (Apologies for the puns, which are indeed intended.) **PW**

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