



Science-based Regulation: Whose Science?

As we saw last month, because there is so much regulatory discretion vested in regulators, the food industry must live continuously under a cloud of regulatory uncertainty. Soft laws (administrative guidelines, directives, standards, etc.) are routinely made, revised, interpreted and enforced by regulators in ways that often defy our traditional understanding of the rule of law.

Take, for example, the Oct. 9 Notice to Stakeholders issued by Health Canada providing a whole new regulatory regime for food-like Natural Health Products (NHPs). With no consultation with any company or industry association, and without going through any legal or public political process, Health Canada announced major changes regarding the process for the approval of food-like NHPs. Effective immediately, any application for regulatory approval of a food-like NHP requires evaluation by the Food Directorate as well as the Natural Health Products Directorate. Why is the standard of evidence for a claim as an NHP different from the standard of evidence for the same ingredient in a food? The stated reason is that these products may be consumed *ad libitum* (at will) and therefore they may require additional labelling “to ensure safe consumption.” As though a consumer is more likely to overdose on yogurt or a beverage than the same ingredient in powder or capsule form!

The decision was even applied retroactively. One product had been thoroughly reviewed and approved by Health Canada scientists last spring, including the efficacy of its three claims. The decision was posted on the website and registration was imminent. However, after the Oct. 9 announcement scientists at another part of Health Canada had no issue as to product safety (the stated rationale for the new policy), but interpreted the data differently, denied the claim and unilaterally removed the decision from the website. Registration was denied. I am not making this up.

The regulators justify their action as being science-based – but whose science? Although there may be lots of internationally accepted science to support the claim, regulators may pick the science that supports their bias. Hiding behind science is an old regulatory trick to justify policy decisions.

Part of the problem at the heart of this regulatory mess is confusion over what we mean by “science.” In research

science, scientists never purport to prove or disprove anything; they simply support or reject a hypothesis. Science is a search for truth and always uncertain. In regulatory science, “science” is certain and provides the basis for decisions that have definite consequences. In regulatory science, policy is often dressed up as science and used to justify hard regulatory decisions that have profound consequences for the regulated. Regulators also regularly revise “science-based” standards, sometimes causing economically disastrous retroactive consequences for food companies.

A further complication arises from the fact that the classical risk model is simply not robust enough to adequately describe the deep complexity of risk analysis. In the classical model, risk assessments are carried out by scientists to determine the likelihood of an event happening and the consequences if that event should occur. Risk management is carried out by others who take the risk assessment and weigh it against the political, economic, ethical and social considerations, make a policy decision and then explain the decision to the public by way of a risk communication strategy.

Unfortunately, the world is much more complicated than that. In the real world one cannot separate science from policy. As Vincent Covello and Lee Merkhofer emphasize in their analysis of risk assessment methods: “In practice, assumptions that have potential policy implications enter into risk assessment at virtually every stage of the process. The idea of a risk assessment that is free, or nearly free, of policy considerations is beyond the realm of possibility.” Moreover, because of the disdain that the public has for “political” factors, no minister wants to admit that the regulatory decision was based on political considerations. So, again, we have decisions justified as necessary because of the “science,” even if other factors played a role as they are supposed to.

Wide regulatory discretion, combined with uncertain science selectively applied, means that food companies are always swimming in a sea of regulatory uncertainty – not a good environment for investment and innovation.

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