AgBioForum – Volume 3, Number 2&3 –2000 – Pages 137-140

THE ROLE OF SCIENCE IN REGULATION AND DECISION MAKING

Stephen Sundlof[1]

This paper discusses the problem of making decisions based on science, without taking into consideration societal values. Science is value-neutral which is problematic if it is used as a sole guide to decision-making, as is the case in the United States' regulation of genetically modified foods (GMFs). In order to resolve political conflicts that may arise from technologies that involve conflicting values, it is argued that interested stakeholders must come together, discuss the issues, and find common ground.

Key words: decision-making; values; society; complexity; scientific uncertainty.

A basic premise of all free societies is that decisions are based on a shared set of values among their members. These commonly held values bind societies together, and they form the basic rules by which societies are governed. "Liberté, egalité, et fraternité" captures the essence of French shared national values. In the US, the Constitution and the Declaration of Independence are expressions of similar shared values.

In contrast, decision making within the US public health regulatory agencies is designed to be "value-neutral." Instead, scientific agencies, such as the Center for Veterinary Medicine (CVM) in the Food and Drug Administration (FDA), are required by law to develop regulations based on sound science.

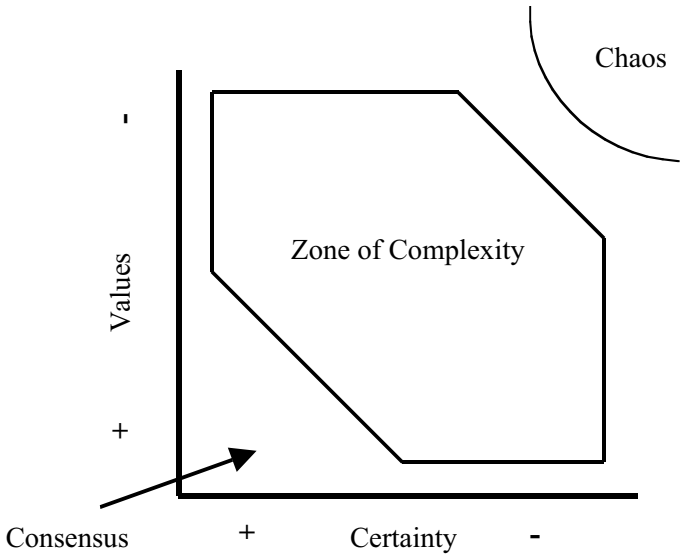
Science and values provide completely different guides to decision making. Values are emotional connections between individuals, whereas science is value-neutral. The scientific process attempts to minimize the influence of values, because they introduce biases into decisions. Scientists strive to be dispassionate observers to prevent personal values from influencing the decision making process. Many of the tenets of science -- e.g., blinding of studies and the independent peer review process -- are based on the concept of the dispassionate observer. There is a dichotomy, therefore, between science and value driven decision-making. Most societal controversies that take place are based on differing values among individuals within the society. Science, on the other hand, is a deliberate, rational process.

[1]*Stephen Sundlof is the Director of the Center for Veterinary Medicine, United States Food and Drug Administration (USFD) in Rockville, MD.* *© 2000 AgBioForum.*

Decision Complexity

Science-based decision-making strives to reach decisions based on scientific certainty. However, chaos theory, and other scientific theories predict there is no such thing as scientific certainty. Werner Heisenberg, one of the founders of quantum physics, suggests at the most fundamental level of nature, uncertainty always exists. Scientists strive to minimize this uncertainty, for example, by assuming full knowledge or certain outcomes, but these are abstractions and scientists recognize that in reality some degree of uncertainty remains. Such scientific certainty can be measured on a continuous scale from positive (+) to negative (-) (see figure 1). More certain outcomes are denoted by positive certainty whereas less certain outcomes are denoted by negative certainty.

Figure 1: Certainty Versus Values in Decision-Making Processes.



On the vertical axis of figure 1 are societal values. In the middle, is what is referred to as the "zone of complexity." When a technology raises an issue that has a certain outcome, scientific or otherwise, and when everyone can agree about that outcome (in terms of values), societal consensus is reached. As society moves farther away from the origin, the decision making process becomes more and more complex. The "zone of complexity" denotes inherently unpredictable processes -- how decisions turn out is not known and cannot be predicted with any accuracy.

Most of the time, decisions regarding new technologies are made with some degree of uncertainty and conflict. This decision-making environment in which these decisions are made can be considered a political environment (see figure 2). This is the decision environment facing biotechnology right now.

<u>The Case of GMFs</u>

Most scientists agree that with few exceptions, genetically modified foods (GMFs) are safe for humans to eat. But GMFs have raised many other issues -- ethical, religious, moral, and animal welfare -- to name a few.

Figure 2: Political Environment of Decision Making.

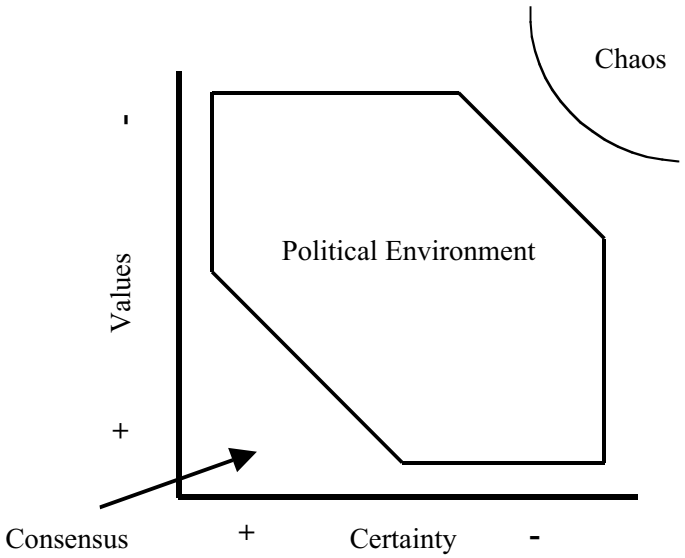
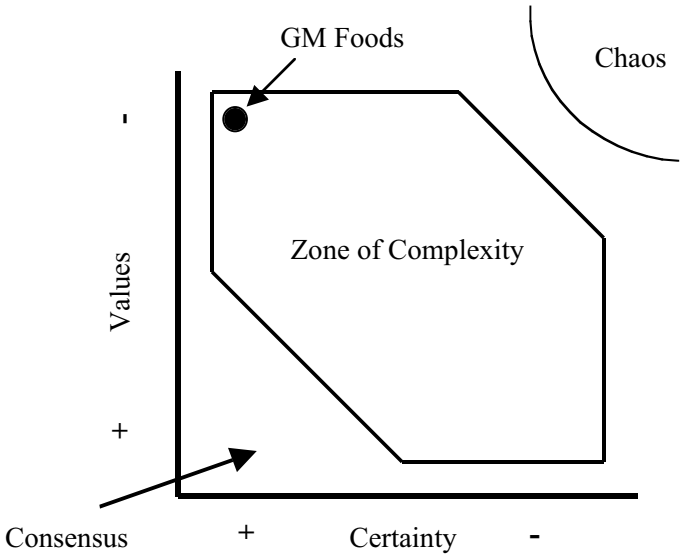


Figure 3 illustrates the position of GMFs in the certainty-values complex. In the United States, the conflict between science and such values has placed stress on the regulatory system. Because the FDA is required to act on the basis of science alone, unless there are cogent scientific reasons, the FDA cannot reject GMFs.

The issues surrounding biotechnology contain both scientific uncertainty and societal values. Within such a context, the process ultimately becomes political. When decision-making processes become politicized as in the case of biotechnology, it leaves the door open to what has popularly been termed "junk science." Here the intent is to protect and defend strongly held values, but the arguments are cast in the guise of scientific debate. So the inherent uncertainty, however small, is exploited and can significantly influence decision making within the political process.

Figure 3: The Position of GMFs in the Certainty-Values Complex.

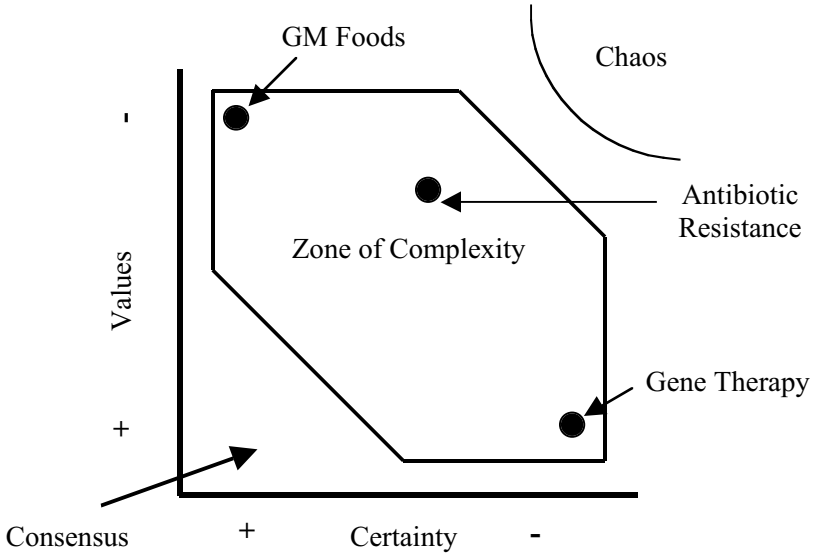


Not all biotechnologies score similarly against the value-uncertainty dimensions, consider gene therapy for instance. At this time, gene therapy techniques are inherently uncertain. Until recently, there had been no successful gene therapy treatments. However, a number of patients have suffered and died as a result of experimental gene therapy techniques. In the United States, hearings are currently being conducted on Capitol Hill on gene therapy research. Despite such uncertainty, gene therapy enjoys societal acceptance in most countries. Individuals do not want to alter the genetic content of food, but are willing to alter the genetic makeup of a person. They perceive a direct benefit in the elimination of genetically induced diseases. Gene therapy belongs in the lower right hand corner of figure 4, therefore.

The Case of Antibiotic Resistance

Another example may be derived from the regulation of antibiotic resistance. Antibiotic resistance entails a considerable amount of uncertainty. Bacterial populations are chaotic systems and small perturbations in bacterial populations can have substantial effects that cannot be predicted in advance. There are also strongly held opinions and positions about the impact of antibiotic resistance on human health.

Figure 4: Biotechnology Issues in the Certainty-Values Complex.



Making decisions about antimicrobial drugs will therefore be challenging for the FDA, as it tries to find a balance between animal and public health needs.

Concluding Comments

With decision situations that fall in the zone of complexity, linear methods of solving problems, such as strategic planning and action plans, do not always work effectively. In order to resolve conflicts, and arrive at sustainable solutions, stakeholders must come together, discuss the issues, and find common ground.