Statement of Rod Leonard
Community Nutrition Institute
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An Idea Whose Time Has Come: The Precautionary Principle

Thank you for the opportunity to present these views and recommendations on the food safety policies of the Food and Drug Administration.

The question is whether labels should be required for foods which contain genetically modified ingredients. The issue is the instability in the U.S. and global food system caused in no small part by failed FDA policies adopted over the past decade. Only by examining the failure of FDA policy can we understand why we are here to discuss the need for food labels.

First, these hearings are evidence of FDA's failure to practice democratic governance, i.e., to disclose proposed policies, insure public participation in decisions on proposals, ensure accountability and to act in a lawful manner. These hearings should have been held in 1992. Instead, FDA followed industry's advice to tell the American citizens the level of risk the agency would impose rather than ask those at risk what is acceptable.

Second, the hearings demonstrate FDA's use of science in regulating food safety policies is unsound. FDA policies fail to utilize scientific data on harm to health because the agency's risk analysis method does not generate and cannot examine relevant scientific data.

Third, FDA compounds the failure by its pathological fear of admitting error. Or, put another way, FDA doesn't know how to change until the cost to the public of failure becomes so high the agency is forced to change or suffer political consequences.

This is no way to run a railroad, or public health programs.

Standards, or rules, are always a political decision informed by science, a view stated regularly by the European Union in numerous multilateral fora. Standards provide stability. Communities want to maximize health and provide minimum risk to citizens. Government don't want to be surprised by an outraged people angry because the risks are unacceptable. Companies and corporations, i.e., the commercial sector, want a marketplace that is predictable, i.e., commerce hates surprises because they endanger profits and enrage stockholders.

The singular reason FDA is holding these hearings is the public in the U.S., Europe, Japan and elsewhere is becoming angry over the agency's decision in 1992 to introduce "substantial equivalence" as a regulatory device to permit genetically modified

ingredients to be substituted in foods for conventional ingredients. Substantial equivalence has no basis in science. The concept is a political device to avoid a public discussion of the novel nature of GM ingredients. The decision avoids informing the public of a significant change in regulatory policy, denies the public an opportunity to participate in deciding whether the change involves risks that are acceptable, hides the agency from accountability and performs the public's business in a manner that is probably unlawful.

FDA's error on substantial equivalence of GM foods has created the worst possible surprise for U.S. exporters of grain and other commodities and of food products. European and Japanese consumers do not buy into the concept of substantial equivalence, and will not accept foods with GM ingredients. As a result, European governments are requiring labels on all foods with GM ingredients. GM corn and soybean essentially banned in Europe for three years.

The consequence of GM rejection are massive. American farmers planted GM seeds and U.S. food processors accepted GM grain as food ingredients in the belief fostered by FDA that Europe, Japan and other export markets would follow the U.S. lead, i.e., that global markets would be stable. FDA has devoted considerable staff resources to ensure that international standards would follow U.S. practices, i.e., that substantial equivalence would be adopted as a global standard for trade in commodities and food. Had FDA been less concerned about trade and listened more carefully to citizen concerns, the food industry would not have been so badly misled.

Thus, the FDA error in ignoring citizen concerns globally has caused the public to question whether the agency is putting health at risk, and the uproar has caused substantial losses of export markets for U.S. foods and food commodities. In other words, industry received the worst possible surprise.

This situation will happen again in a global economy because FDA is programmed to fail. The question is, how does FDA admit error, change its policies? The agency already has decided, I would surmise, that it must now permit labeling of foods containing GM ingredients, if not to do the right thing for U.S. consumers, then to recognize the U.S. must get in step with the developments in Europe, Japan and elsewhere. Otherwise, the commercial losses for U.S. farmers and food companies will continue. Mandatory labeling is a necessary commercial adjustment.

However, labeling does not address the basic problem, i.e., how will FDA prevent a similar debacle in the future? The answer? FDA should acknowledge that substantial equivalence is based on a flawed scientific method, i.e., the precautionary approach, and adopt in its place the Precautionary Principle as a guide to safeguard public health in decisions to licence additives, chemicals and contaminants.

The current practice in risk assessment, which FDA defines as the precautionary approach, evaluates harm on a case-by-case basis. The approach is based on the reductionist method, i.e., a process of linear analysis that describes only what is known. While not intentional, the process may cause harm because of the scientific method involved. If the examination of all known data finds no significant risk, the agency

concludes that no risk exists. In the absence of finding risk, the agency concludes it must licence a substance or product.

In contrast, the Precautionary Principle is a scientific method based on non-linear analysis. Health and the environment are complex, not static systems. Risk, or probable harm, occurs in complex systems from feedback, looping and other non-linear conditions which exist and can be examined only in dynamic situation. Harm in complex systems is non-linear, inherently uncertain and unpredictable, and can be examined only through non-linear analysis.

FDA needs to make a decisive break with the past. The agency should move beyond reductionism decisively. Incorporating non-linear analysis through the Precautionary Principle offers FDA the opportunity to introduce a far more disciplined, more broadly comprehensive use of science in its practices.

Regulatory policy in complex systems not only must look back but also look ahead. Anticipating the future is a process of theoretical analysis, i.e., examining the probability of harm utilizing data from a reductionist, or a case-by-case assessment, but evaluated within a systems perspective. The reliability of a systems analysis will be confirmed, however, by information developed through non-linear analysis, or the data the system generates as it functions in society.

The Precautionary Principle in FDA policy would encompass new concepts, including these two features, i.e., (1.) safeguard health and the environment by licencing products which demonstrably provide a safer food supply; and, (2.) adopt regulatory procedures that assess harm as a condition found in complex system, i.e., rely on non-linear analysis as the primary scientific method.

I urge FDA to recognize the close of the 20th century as an opportunity to thrown off the procedures and methods, including such flawed artifacts as substantial equivalence, which clearly handcuff the ability of the agency to ensure a safe, reliable food supply.

This hearing is as admission of past error. The public will forgive error, but only if a new policy is adopted which clearly recognizes the need and reasons for change. I invite FDA to ensure participation of the public in how such future errors can be avoided, and to carry out a series of hearings across the country on recommendations for adopting the Precautionary Principle as the regulatory framework for a new FDA.

Rod Leonard
CNI/Minnesota
41156--45th Ave
Wahkon, MN 56386
320-676-8753 phone
320-676-3066 fax
e-mail: relcni@ecenet.com