Is there really a light at the end of the tunnel?

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I appreciate the opportunity to be with you today to talk about food safety policy. It has become one of my favorite subjects. Indeed, it may be one of the all time favorites on the public policy hit parade. It has provided countless opportunities for speech making and fostered innumerable articles in legal and scientific journals. What would we all have to do and talk about if our safety policies were revised to everyone's satisfaction? Since that doesn't appear to be an imminent prospect, we can all relax. That aspect of our jobs appears to be secure for a while, at least.

Events of the past few years seem to have brought about a broad recognition that some change needs to be made in our food safety policy to make it practical and in tune with contemporary values and knowledge. It is the anticipation of change coupled with a perception of a willingness to change that leads me to raise the question: Is there really a light at the end of the food safety tunnel?

One response to this rhetorical question is: Perhaps, it all depends. Certainly, much has happened in the last 4 years since FDA announced its intention to ban saccharin because it had been found to cause cancer in test animals. In the intervening period since the announcement, several other important events have taken place and have served to strengthen the argument that some change in food safety policy is necessary. The almost proposed phase out of nitrite, coming hard on the heels of the saccharin debate created an outcry that dwarfed that of saccharin, and certainly would have eclipsed it if it had proceeded. Certainly, saccharin and nitrite caused the public and the Congress to focus on food safety policy as never before. Questions were raised about the reliability of animal tests as a regulatory tool and the relative degree of risk that our policy seemed to dictate. Or, to be more precise, the no risk policy that our food safety standards appeared to be seeking to achieve.

Three other events of significance took place in the past few years that are moving us in the direction of an acceptable risk food policy. The Supreme Court decision in the OSHA benzene case concluded that it was not sufficient to find that a substance caused cancer, but that it was necessary to show that the risk attendant to the use of that substance was appropriate to the degree of regulatory control being exercised.[1] The court held that the Secretary of Labor must find that significant risks are present and can be eliminated or lessened by changes in practice.

The well known acrylonitrile case, certain to go down in the annals of food and drug law history, provided another milestone decision. The U.S. Circuit Court of Appeals for the District of Columbia held that the Commissioner of Food and Drugs had the discretionary authority to determine the existence of a de *minimis risk* and to permit the use of packaging materials classified as food additives having such a de minimis risk.[2] Again, the standard of insignificant risk was the governing principle. This principle, of course, has broader application to other indirect additives, as well as to direct and color additives. Finally, FDA's decision in the matter of lead acetate containing hair dyes was an application of de minimis risk recognition in a very direct way.[3]

There are still other indicators pointing to a change in food safety policy. FDA, of course, has pioneered as a proponent of risk assessment as a regulatory tool. In 1972, it proposed the use of risk assessment as an essential element of its "sensitivity of the method" policy for regulating new animal drugs. In addition to the sensitivity of the method use of risk assessment, work is underway in FDA to extend the approach to

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indirect additives resulting from packaging and other high technology processes such as those involved in the manufacture of colors and synthesized foods. No formal proposals have been made but agency officials have publicly stated their intentions to use risk assessment and the de minimis technique established in the acrylonitrile decision.[4]

If we appear to be making progress, why is there a question about putting a more workable food safety policy into place through legislation? Simply because, as you all know, the only things that are certain in life are death and taxes. Although there is considerable consensus that something needs to be done to establish a more workable food safety policy, we still have a considerable way to go. For one thing, the congressional workload this session is extremely heavy with legislation to reauthorize expiring programs. Another reason for raising doubts is that defining socially acceptable risk in the abstract is not an easy task. It will require considerable thought and negotiation.

By the time hearings dealing with any significant and substantial change in the food laws are accomplished, another election year will be upon us—and you know that election years tend to produce extreme conservatism in the Congress. Despite the strong rhetoric from a significant number of influential congressmen, it still requires a majority of the 535 potential votes in the House and the Senate to enact new legislation. I believe there is still serious concern by many in Congress about the wisdom of being associated with a vote seen as relaxing the standards of consumer protection and health in this country. I am hopeful, however, that common sense eventually will prevail and a change in food safety policy is not a matter of whether, but when.

Proceeding on that optimistic thesis, I thought it would be useful to examine some of the principles on which a new food safety policy might be based. In doing some research for this talk, I ran across the text of a talk I delivered shortly after FDA announced that it intended to ban saccharin back in March, 1977.[5] There were basically three options that seemed available at that time:

- the first option was simply to repeal the Delaney Clause. I rejected that option as unworkable then and it remains unworkable today. The fact is that the Delaney Clause per se is superfluous. Its absence would not result in different FDA decisions unless other changes are made in the Food, Drug and Cosmetic Act. Agency and Department officials have stated that in the absence of the Delaney Clause, the general safety provisions of the Act would serve to prohibit the use of carcinogens. In practice, of course, this has been the case. The presence of the Delaney Clause serves to inhibit a practical risk acceptance application of the general safety provisions of the Act. It is more symbolic than substantive.

- Risk assessment and acceptance presented the second major option available then as it is now. The mechanism suggested for its use was that of a rebuttable presumption. That is, if a substance was shown to be a carcinogen it would be prohibited from use unless a showing of acceptable risk could be made using risk assessment techniques. The prohibition also could be over-ridden by showing, with appropriate scientific evidence, that the effects produced in test animals might be different than those in man; or that a threshold for effects could be shown; or that other valid scientific reasons existed for rejecting a carcinogenic finding in laboratory tests. Further, approval of a food substance could be permitted if direct health benefits could be shown that might outweigh its health risks, e.g. for essential nutrients or disease preventatives.

- The third option was an expansion of risk assessment to include consideration of benefits that would be available from the use of a substance shown to be carcinogenic. The benefit determination would be broadly based and include not only health benefits but economic benefits, such as the cost and availability of foods and other social value judgments.

Things haven't changed much since then in terms of the basic approaches to food safety policy. Each had its proponents then and each has its proponents now. Unfortunately, we appear no closer to a consensus now than we did at that time on which approach to take.

One thing does seem clear: if you examine the principles and mechanics behind each approach, you will find that risk assessment and risk acceptance should be an essential element of a new food safety policy. Risk assessment and risk acceptance go hand in hand. There is no point to examining the degree of risk unless you are prepared to make a judgment about accepting a certain level of that risk. Defining a socially acceptable risk, as I've noted, is not easy. There are, however, some approaches to this that may be worthy of exploration:

- Statutory dividing lines could be used for different food substances, each accorded a different standard. As a result of a congressional risk-benefit evaluation, this is the case now, with eight categories of substances added to foods. A simpler classification scheme, consisting of three categories, might be preferable: basic and traditional foods, food contaminants, and food additives. Besides administrative neatness, this scheme would assure continuity of use of commonly used food substances. The traditional food category would comprise those foods of plant or animal origin, in use for a material time and to a material extent. Food additives would comprise those substances not

classified as a traditional food or a contaminant.

- Criteria could be defined for evaluating risk acceptability. It is improbable, politically and practically, that Congress would establish any quantitative risk standard. The extent of any legislative action would likely take the shape of generalized criteria embodying terms such as "insignificant risk," or "not ordinarily injurious to health," or "necessary and unavoidable." Application of the criteria would fall to FDA and others, but this would be workable given the case precedents I cited earlier along with policy guidance given by legislative history and rulemaking activities.

I will leave the task of drafting such concepts to others more qualified. These concepts are not mutually exclusive. Should existing food categories be retained, they could be administered using acceptable risk criteria. Risk assessment is a shorthand term for a reasoned, orderly approach to decision making. It is not simply a mechanism for abandoning consumer health and safety protection.

Risk assessment has both quantitative and qualitative elements. The quantitative aspects of risk assessment are perhaps the most widely discussed and widely misinterpreted. Quantitative risk assessment is not a single numerical answer obtained from plugging test data into a formula. Rather, risk assessment is an attempt to quantify the range of probable results. It uses a variety of statistical estimating techniques to evaluate test data and project an outcome in probabilistic terms somewhat like life insurance actuaries forecasting life expectancy based on age, physical characteristics and life style.

Much of the debate over risk assessment has taken place over the different statistical estimating techniques. In my view, this is a gigantic red herring. It has caused the debate to be focused on relative minutia rather than substantive principles. Any change in food policy should not attempt to set the kind of estimating techniques that should be used. These should be open ended and determined by the data and the biological system being evaluated. Since we are not seeking a point estimator, we may wish to use more than one estimating technique to gain a better understanding of the impact of any decision to accept a risk. The straight line technique, the most conservative estimator, could be used as a reference point for the upper level of risk that could be involved.

In any event, quantitative risk projection will not be the sole determinant of any decision to prohibit or to accept the use of a food substance. The qualitative aspects of risk evaluation also are highly important in reaching a decision. One needs to look carefully, for example, at the relationship between the test animal system and the human system in making any sort of projection of the applicability of animal test data. Further, we must begin to consider more seriously the nature of the effect produced by the test substance. We need to be able to distinguish those substances which are direct carcinogens from those which are indirect carcinogens. The terms promoter, initiator and co-carcinogen have been used to describe those substances considered to be indirect or secondary carcinogens as opposed to primary carcinogens. We must build into the decision process a differentiation between the direct or primary and indirect or secondary types of carcinogens. That we may not have the scientific knowledge now to distinguish in every case between these two types of carcinogens should not prevent us from establishing a legal framework that will permit the distinction to be made once our scientific knowledge permits us to do so.

As an example, selenium has been characterized as a carcinogen by some.[6] High doses of selenium administered to test animals will produce cancer. An examination of the mechanism producing this result, however, indicates that a clear step function is involved. Administration of selenium at levels sufficient to cause liver damage is a precondition in the test animal for a carcinogenic response. It is damage to the liver that must occur before carcinogenesis takes place. Levels of selenium below the liver damage producing level did not yield a carcinogenic response. FDA recognized this in 1974 when it approved the use of selenium as a non-carcinogenic additive to animal feeds.

Our food safety policy must begin to recognize the scientific distinctions between different types of substances that may produce cancer as an end result. Levels of consumption and probable outcomes associated with those levels need to be taken into account in making safety decisions. The concept of a threshold for carcinogens has been vigorously objected to by proponents of a no risk policy. However, a practical threshold exists for some substances, such as selenium, that could be called carcinogens.

There is far less consensus on the concept of risk benefit tradeoffs than there is on the use of risk assessment. The proponents of a risk benefit policy believe that it will be possible to show for many desirable food substances that may produce cancer that there is indeed a favorable balance to be obtained when comparing the risks from cancer against the benefits to be obtained. I think this is misplaced confidence and optimism. Those who are familiar with the large scale scientific data production requirements for evaluating safety of food substances would do well to be skeptical about the merits of a benefit evaluation approach. When the 1958 food safety amendments to the Act were being considered, the food industry was united in its opposition to any form of benefit evaluation for food additives. Much of the food industry today continues to hold to that view. There are two reasons for this: one is philosophical, the other practical. On a philosophical level, it is inappropriate that the government should assert its value judgments about the benefits of different foods. This is a highly subjective area for government to

muck around in. Inevitably it would lead to greater dissatisfaction with food safety policies when unpopular decisions are made, as they surely will be. Benefit determination in this area is an art rather than a science and no amount of consumer research opinion, ethical evaluation, or other form of social science research can offer an objective basis for making decisions that will be popularly accepted.

On a practical level, including benefit determinations in an already complicated and lengthy decision process for evaluating food substances is certain to increase the difficulty exponentially. It is not too hard to visualize reams of data being supplied to the evaluators by people on both sides of an approval issue. Economic studies, consumer research studies, sociology textbooks and other various and sundry materials will be thrown up for consideration whenever there is an important issue to be decided. The government would have to employ an entire new team of people with capability to make the sorts of benefit analyses that are contemplated. This responsibility cannot be delegated to committees. Execution and defense of such decisions ultimately rest with the agency responsible for the decision. In short, I believe benefit decision making is the wrong way to go.

It has been suggested that the benefit determination be used as a last resort; a sort of life saver approach. After running head up against an unacceptable risk determination, the substance at issue would then be reviewed in terms of the broad benefits it would provide. Such an approach would have to be very carefully delimited or it would begin to follow Murphy's and Parkinson's laws in very short order. Murphy's law says that if things can go wrong, they will, and Parkinson's law says that work expands to fill the time available, with increasing attention being paid to smaller and smaller things. So, in my judgment, would it be with benefit evaluation. Benefit data would be requested routinely on the expectation that it might possibly be needed in the event of an unsatisfactory risk assessment.

Turning to other matters, there are three aspects of food policy on which there appears to be consensus. First, it is necessary to recognize the status of basic and traditional foods, i.e., those having a long history of use. Regardless of the classification system used to describe different food substances, it will be necessary to assure that we don't engage in unproductive use of resources retesting the entire food supply for suspected risks. The concept "if it ain't broke, don't fix it" applies very well here. There must be more than a mere suspicion before undertaking an extensive examination of foods which are not ordinarily injurious to health. Any approach to food safety policy must carefully coordinate the standards for acceptable risk with those needed to ensure the continued use of basic and traditional food ingredients or we will have an unworkable policy.

Secondly, a flexible enforcement policy needs to be established. When and if a ban of a food substance is necessary, it should be tailored to the circumstances. Absent a compelling reason for immediate withdrawal, elimination of foods should take place using a reasonable phase out period. Precipitous action based on theoretical risk is wasteful and brings into question the credibility of legitimate consumer protection actions.

Finally, the decision process itself is in need of attention. Perhaps the most important process change that should be made is the use of peer review for evaluating the scientific evidence supporting any food safety decision. I am not sanguine about the use of advisory committees. It is not difficult to point to some horrible examples of advisory committee activities. On balance, however, the peer scientific review provided by an advisory committee serves a highly useful purpose. Peer review helps to assure that the substance of an issue is thoroughly explored; that the important questions are raised and responded to; and that the process of evaluation is done openly so that interested people can observe the progress of events and better understand the conclusion drawn by the review.

I've a strong feeling about the evaluation process. For one thing, the process should clearly separate the components of an issue. There is a scientific component, a legal component and a policy component. These are not always separable into nice, tidy packages. Nevertheless, the results of an evaluation should be explained in terms of these components. The peer review process should be designed to deal with the scientific component. Advisory committees can't and shouldn't be given the charge to render decisions for an administrative agency. It is the agency that has the authority and the accountability to the public for its actions. Therefore, it is the agency that should, in the possession of all the facts, render the decision. Science doesn't offer us certainty, much as we would hope and like it to. The results of a scientific review may leave us with some uncertainty. Dealing with that uncertainty is a part of the public policy process. Peer review can help identify the uncertainties; it is up to the administrative agency to resolve those uncertainties within the bounds provided by law and policy.

Returning to my original question: Is there a light at the end of the tunnel? I think there is. Some work has already been done, much more can be done within the framework of existing food law. We now need to sift through the many ideas that have been advanced and begin the steps that will make that law responsive to contemporary needs and values.

1. Marshall v. API, No. 78-1036 and AFL/CIO v. API, No. 78-911—Supreme Court, July 2, 1980
2. Monsanto v. Kennedy, No. 77-2023 (D.C. Cir. Nov. 6, 1979)
3. 45 FR 72112 (Oct. 31, 1980)
4. *Food Chemical News,* Vol. 22, No. 52, March 9, 1981, p. 3.
5. Delivered before the National Flexible Packaging Association, March 24, 1977, Published in *Vital Speeches of the Day,* Vol. XXXXIII, No. 15; May 15, 1977.
6. 38 FR 10458 (April 27, 1973); 39 FR 1335 (Jan. 8, 1974)