Proceedings

OUTLOOK '90

66th Agricultural Outlook Conference
U.S. Department of Agriculture
Washington, D.C.
November 28 - November 30, 1989

ANNUAL AGRICULTURAL OUTLOOK CONFERENCE
United States Department of Agriculture
Washington, D.C. 20250-3900

Outlook '90, Session #24 For Release: Thursday, November 30, 1989

CRITICAL ENVIRONMENTAL ISSUES FOR FOOD SAFETY AND QUALITY*

Frank E. Young, M.D., PH.D
Commissioner of Food and Drugs
Rockville, MD

Thank you Assistant Secretary Smith for that very kind introduction. Indeed, I am glad to be a part of this morning's program for three very important reasons:

- First, it provides me with an opportunity to address an audience which includes persons responsible for growing and buying agriculture commodities.
- Second, it provides a forum where they can express their concerns regarding the use and availability of pesticide chemicals for crop growth--and I can share the Food and Drug Administration's views on food safety for the 1990's.
- And third, it allows me a chance to emphasize the essential role that each of the regulatory agencies participating in this exchange plays in assuring that the pesticide chemicals which are applied to the nation's food supply are safe for their intended uses.

Challenges for 1990--The Need for an Inter-Agency Approach

As we focus on the critical issues in food safety and quality for the 1990's, the magnitude of government responsibility to the American public in this area is not lost upon the sister agencies before you. Each agency has an important slice of the regulatory pie which is essential to providing a safe whole. For we are jointly charged with providing a food supply free of harmful chemical residues. Just as important, we have the responsibility of sustaining public confidence that our food supply remains a safe source of nutrition.

This charge presents a host of challenges: Challenges which, I believe, we are meeting responsibly and judiciously. Challenges which, because of our technological age, require us to periodically assess the way we are doing our jobs. Challenges requiring us to initiate changes in some areas of protective regulation, and to simply fortify and strengthen others.

*NOTE: This text is the basis of Commissioner Young's oral remarks. It should be used with the understanding that some material may be added or omitted during presentation.

FDA's Role in Assuring a Safe Food Supply

I do not need to tell those of you present that the American food supply is one of the safest in the world. It offers a quality, abundance, and variety that is unparalleled internationally. This result has not been accomplished by chance.

Rather, it results in part from FDA's diligence and expertise in enforcing the Federal Food, Drug, and Cosmetic Act--known by short hand as simply "the Act."

Under the Act, the FDA's Center for Food Safety and Applied Nutrition (CFSAN) functions to ensure that our foods are pure and wholesome, safe to eat, and produced under sanitary conditions. This responsibility for foods covers essentially all food in interstate commerce except meat and poultry products, which are regulated by USDA.

In meeting this enormous responsibility, FDA has the task of regulating and approving food and color additives that are added to foods to increase their shelf life, along with assuring that other ingredients that may be added to food are generally recognized as safe (GRAS).

In assuring that Americans continue to have access to a safe and wholesome food supply, the FDA carries out the following additional and crucial tasks:

- We keep food products containing unsafe levels of industrial chemicals, metals, pesticides, mycotoxins and bacteria off of the market and away from the consumer.

- We prevent the marketing of food adulterated--through improper processing and handling--by filth, decomposition, and foreign objects.

- We maintain the quality of food products produced in our factories through the inspection of food establishments.

- We protect consumers from fraud by acting against deceptive packaging and false, inadequate or misleading labeling.

- We help individual States improve their activities to assure the safety of food service operations, shellfish, and milk.

I might add that while the average consumer may not immediately associate it with food safety, our responsibility for providing nutrient information on foods, guidelines and food labeling standards both for regular and dietary foods are extremely important to people who need this information to make specific food choices.

Indeed, it enables consumers to make nutritional choices when they buy food, particularly for the prevention and dietary management of disease.

I can personally attest to the importance of food labeling to American consumers. This fall, I have chaired food labeling hearings in Chicago and San Antonio, and two additional hearings are scheduled within the next 2 weeks. I have heard from many individuals and groups with a stake in this issue that the time has come for significant changes in the way our food is labeled.

I think you will agree that the FDA has a full agenda in its role as guardian of the Nation's food supply. Our role includes monitoring foods for various food contaminants, including pesticides, which brings us to one of the immediate concerns of today's forum.

This morning, I would like to share with you new concepts and regulatory proposals that FDA believes are critical to addressing the current food safety challenges and assuring the safe use of pesticide chemicals in the next decade--and indeed into the 21st Century. They focus on innovations that will require an even closer working relationship among FDA, the United States Department of Agriculture (USDA), and the Environmental Protection Agency (EPA). We at the FDA are strongly committed to this close working relationship; we welcome it.

Safety of the Food Supply: The Case for Effective Monitoring

Our record of food safety has been achieved through regular monitoring of imported and domestic food commodities, as required by law. Monitoring foods for the presence of unacceptable residues is an important part of our mandate. It is a responsibility that requires our time and attention on a daily basis. And it is undertaken with the health of the American public foremost in our minds.

Although the individual American consumer may be heartened to know that three Federal agencies are cooperating to assure a safe and abundant food supply, the public is basically unconcerned with who has what responsibility. Rather, consumers seek a simple, earnest answer to the fundamental question, "Is this food safe to eat?"

To make certain that we can answer that question in the affirmative, FDA regularly collects samples from individual lots of domestically produced and imported foods to analyze them for pesticide residues. The methods used to detect the presence of residues in foods are usually capable of determining levels well below the established tolerance. Additionally, new methods are being introduced to give on-line quality control, such as probes for microbial contaminants in factories and rapid screening tests for detection of pesticides in the field. Residue tolerances are always set conservatively, resulting in a built-in margin of safety to the consumer.

Thus, when violative residues are found in domestic food samples, the Agency takes appropriate regulatory action. When they are found in import samples, the product is usually detained at the port of entry.

FDA uses this monitoring information, coupled with the data obtained from the various states and international agrochemical data banks, to determine where potential problems might occur and to assist in planning future monitoring of domestic and imported commodities.

Monitoring of Foods in the "Post-Alar" Era

The encouraging news is that our monitoring of the food supply for over 25 years has shown that above-tolerance residues are rarely found. Rather, violations more commonly involve commodities that contain small amounts of pesticides for which no tolerance has been set. The record indicates that over all we have been doing a good job.

This is not the impression one would get from reading about the Alar controversy earlier this year. In the "post-Alar" world, there is room for improvement on the part of all agencies responsible for food safety.

Concerns generated by Alar emphasize that we have to become more effective in evaluating potential pesticide risks, reducing those risks, and informing the American public of our actions---to allay perceptions of unacceptable food quality and increased health risks.

We also must clearly distinguish between the sensitivity of the method used and the presence of a residue. The regulatory limit for action merely is designed to establish when the sample is violative and does not establish that no pesticide is present.

The President's Food Safety Plan

In addressing critical issues of food safety for the 90's, I believe that in addition to our present activities, risk management and risk communications will be at the top of our list. But before we can communicate more effectively, we need to be certain that our own house is in order. That's why the efforts of the Domestic Policy Council are so important. They resulted in the Food Safety Plan which President Bush announced last month.

The plan, which will lead us into the 1990's, focuses on four goals:

- Protecting the public health by preventing harmful exposure to pesticides in the food supply.
- Providing simpler and more workable regulations for pesticides used in agriculture, thus helping the farmer know about and follow food safety laws.
- Strengthening the oversight of pesticides and their use by assuring that unsafe pesticides are not used and by speeding the development of safe alternatives.
- Building public confidence in the safety of the current and future food supply.

Although the regulatory statutes under which the EPA, USDA, and FDA operate continue to serve as effective barriers for protecting the public from harmful pesticide residues in their foods, the Alar controversy focused on the limitations of those laws. Specifically, it has been pointed out that:

- Our current pesticide regulatory system takes too long to identify potentially harmful chemicals. And, once problems are identified, it takes too long to remedy them.

- The cancellation procedure for pesticides is cumbersome and time consuming.

- There are inconsistencies in the Food, Drug, and Cosmetic Act regarding the setting of tolerances for raw agriculture commodities versus processed foods.

- We should reassess whether the Delaney Clause provides the most effective means of regulating pesticide-treated foods.

Revisions in FIFRA and the Food, Drug, and Cosmetic Act

The President's initiative seeks to confront these issues and strengthen the existing laws by calling for major revisions to EPA's Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Food, Drug, and Cosmetic Act. In FIFRA, these revisions will streamline EPA's ability to remove potentially hazardous pesticides from the market, and enhance the agency's enforcement program to ensure the safe use of pesticide chemicals.

In the Food, Drug and Cosmetic Act, the initiative would eliminate a long-standing inconsistency in the law governing pesticide residues in foods, and establish a "negligible risk" standard for such residues.

It should be noted that this initiative was developed with the participation of all relevant government agencies as well as the private sector. And, while the President's plan provides seven initiatives involving food safety, there are two particularly important aspects---relating to the broad consumer protection mandate of the FDA---that I want to discuss in more detail with you this morning.

Negligible Risk

Let me begin with the concept of "negligible risk." The President's plan proposes that, for pesticide residues in food posing carcinogenic risks, the Food, Drug and Cosmetic Act should be amended to eliminate the Delaney clause and to add a tolerance threshold at--or below--the level at which the public health is not threatened. The term which sets the standard for this new threshold is "negligible risk."

Fundamentally, the President's plan allows for the establishment of a tolerance level for pesticide residues in food, below which it is deemed that the public health is not threatened--thus permitting a pesticide which satisfies this requirement to remain in use. The tolerance level for various carcinogenic chemical substances would be established based on predicted risk level criteria. Basically, this "negligible risk" level, (or "biological zero risk" as I like to refer to it) replaces the concept of absolute zero risk for cancer contained in the Delaney Clause.

Under the President's proposal, "negligible risk" or biological zero risk would not be defined by law. Rather, the law would set a standard that--under appropriate regulatory risk-assessment procedures--translates into a statistical increased risk of at or below a range of one hundred thousand to one in a million, based on lifetime exposure. These risk estimates represent the "upper bound," or worst case, levels of risk.

As you know, pesticides which concentrate in processed foods are subject to the Delaney clause in the law, while pesticides in raw agricultural commodities are not. This results in inconsistencies in the Food, Drug, and Cosmetic Act. Under one section of the Act, EPA may consider risks and benefits in setting tolerances for pesticides on a raw agriculture commodity, such as tomatoes--and EPA may legally set a tolerance for a known carcinogen.

However, the Delaney clause bars EPA from setting a tolerance on a processed food (like tomato paste), if there is any evidence of cancer risk, no matter how small the risk.

The Case for Elimination of the Delaney Clause

The Delaney clause has been interpreted as requiring absolute safety--or zero risk--because it prohibits the presence of even negligible quantities of a carcinogen. Thirty years ago when the clause was first enacted, such an interpretation was consistent with the science and knowledge of the day. Today it is not.

Current scientific advancements along with increasingly sensitive analytical methodologies have resulted in many more--and increasingly sophisticated--risk assessment techniques. We are now able to detect chemical residues in our foods at parts per trillion or less. These advances have led scientists to conclude that, in some circumstances, some substances shown to be carcinogenic in high-dose animal studies represent no risk to human health when present in much smaller amounts in the food supply under specified conditions of use.

Consequently, in 1987, the National Academy of Sciences (NAS) recommended in its report, "Regulating Pesticides in Foods: The Delaney Paradox," that the "zero-risk" Delaney clause be eliminated because it is scientifically unjustified.

The Academy also noted that the Delaney clause may have the unintended effect of keeping safer pesticides off the market which could replace older, riskier pesticides if use of the newer substances were allowed. The Academy therefore recommended that "negligible risk" be adopted as the uniform standard for tolerances on both raw and processed foods.

Negligible Risk Standard for All Foods

I should note that although the concept of "negligible risk" would be introduced in the context of carcinogenic pesticide residues, the Administration's proposal also noted that the same principles would naturally apply to other areas of food safety where additives are introduced into food.

This is an important point. Not only would it remove an inconsistency in current law, it would bring the regulation of potentially carcinogenic residues in the food supply into line with current scientific thinking and analytical methods.

National Uniformity of Pesticide Tolerances

Let me begin with a discussion of national uniformity of pesticide tolerances. Under the current law, individual states may set tolerances for pesticide residues in food that are lower than those established by EPA. When this has occurred, it has been confusing to consumers and a source of concern to the food industry. Just as important, inconsistent tolerances have raised concern about possible repercussions in the international trade community for raw and processed food products.

The President's proposal--and all of the Agencies here today support it--provides for national uniformity, prospectively, for chemical tolerances. Under the proposal, once a pesticide has been re-registered pursuant to the 1988 revisions of FIFRA--and an appropriate tolerance has been set as part of that process--the national uniformity provision takes effect. In this way, new tolerances set under modern state-of-the art science, would have nationwide applicability.

Any state or local standards applicable to the same chemical substances must then be identical to federal standards. A state may, however, enforce a more stringent standard if it has met established EPA criteria and obtained a waiver from EPA. The criteria will allow waivers only when special local circumstances warrant.

Uniform national pesticide tolerances is clearly an issue whose time has come. When one considers that the world is becoming smaller, that the nation's food supply is an international food supply, and that the European Community intends to be fully integrated by the year 1992, we need to be of one accord with tolerances for residues in foods.

Communicating "Zero-Risk" versus "Negligible Risk" or Biological Zero

The next crucial step is to effectively communicate to American consumers the merits of what we are doing. If we are to succeed, and we must, it will take the collective efforts of all here today. Our primary goal will be to clearly explain that going from a "zero risk" to a "negligible risk" does not entail an increased health risk on the part of the public.

Conceptually, "zero risk" versus "negligible risk" is a change. But in practice, in real life terms, it is not. What has changed more than anything else is our ability to measure trace amounts of any substance, including carcinogens. The concept of "zero risk" does not mean today what it did in 1958, when the first Delaney Clause became law. For any given food product, there was a level of risk back then, and it was, like the comparable risk today, a "negligible risk."

It only appeared to be a zero risk, because science lacked the precise and sophisticated analytical tools to detect and measure the risk.

This evolutionary change in the concept of risk embodied in the Federal Food, Drug, and Cosmetic Act is essential. If the Act is not changed, we will be at a terrible impasse as analytical methods improve even further.

A third point is a corollary to the second. It requires that a single, scientifically-based method of risk assessment be developed through consensus--and that this method is applied by the EPA, the USDA, the FDA, state officials, and private sector groups. The trust of the public cannot be maintained or strengthened if we do not use the most up-to-date methods to define and quantify risks.

Honoring the Public Trust and Communicating the Facts

The current dilemma is that just as the government is endorsing a standard of "negligible risk," many consumers are calling for a "risk free" society. And while a "risk-free" society does not exist--it cannot exist--the standard of "negligible risk" provides the best possible level of consumer protection. I think the majority of the American public will also agree, if we take the time to communicate and to sensitively listen to concerns. I believe that the Good Lord gave us two ears and one mouth so we can listen twice as much as we talk--and not only to listen but to hear. This dialogue and trust between the public and public servants must be strengthened.

There is no question that we will continue to improve and increase our monitoring of pesticide residues in the food we consume. Strategies such as integrated pest management and decreased reliance on pesticides are promising, and we wholeheartedly support them.

Concluding Observations

I have four concluding observations.

The first is based on our assessment of risk in the food supply. Although we can with great confidence assure the safety of the food supply, we cannot guarantee zero risk. This means that we--and here I mean the collective "we" that includes growers, producers, processors, scientists, regulators, and consumers--will have to strive continually to improve our ability to communicate the nature of risk more effectively.

Second, we must develop formal courses about risk assessment, risk avoidance, and public health in our educational system. Despite the relatively higher risk of drug abuse in our society, I have participated in far more hearings on food safety than substance abuse. We must be able to distinguish between real and imagined risks and determine what risks are worthy of our increased efforts to reduce them.

Third, we must do all we can to avoid circumstances that would force regulatory decisions to be made on the basis of emotion rather than science, particularly at a time of crisis.

Finally, we should always tell the truth. This means reporting the bad along with the good. It means treating all groups with a stake in food safety issues like the intelligent adults that they are.

For regulatory agencies like the FDA, it means earning the trust that society places in us: consumers rely on us to inform them about the safety of the food that sustains and nourishes them every day. This is one of the tasks that government can do best, and it is a task that only government is authorized to carry out. But to do so, we must have both integrity and public trust.

Thank you for your attention. If there are questions, I would be pleased to answer them.