Perspectives

FOOD ECONOMICS RESEARCH IN ESCS

By William T. Boehm

Increasingly, the Department of Agriculture is being asked to provide assessments of the impacts of its policies and programs on all participants in the food system—including consumers. Recent reports by the Office of Science and Technology Policy (STP), the National Academy of Sciences (NAS) and the General Accounting Office (GAO) all highlight the importance of these requests.

The need for such research is clear:

- Lifestyles have changed so dramatically in the past 15 years that educators and nutritionists alike are now concerned that consumers are less capable than ever of making food choice decisions that will provide nutritionally sound diets. As a result, there have been many proposals to greatly expand the public's role in the food system.
- Changes in the food system have been occurring so rapidly that increasing concern is expressed about their effect on the safety, quality, and integrity of the system. In many cases, we simply don't know the consequences of increasing our consumption of highly processed and fabricated foods. Proposals now being considered will be resolved more nearly in the public interest when the consequences of the relevant alternatives are clearly understood by all parties.

Chemicals have been used so successfully to increase food production, retard spoilage and preserve foods that concerns are not expressed about the diet and health related side effects of the chemicals themselves. As a result, there are proposals, almost daily, to ban or otherwise regulate the use of food and feed additives that, in some cases, have been used for hundreds of years. Impact analysis of these proposals are essential to the process of informed policymaking.

- USDA's food assistance programs have been reasonably successful in meeting the needs for basic survival, but often they have not placed enough emphasis on nutritional balance. Part of the reason for this is the lack of basic knowledge on nutritional needs. But, even beyond that, the interrelationships among income, nutrition, health and productivity for specific nutritionally vulnerable groups are not clearly understood. Programs, which rely on individual food choices, cannot be cost-effective without incorporating the influence of these interrelationships.
- Finally, while the agricultural price support programs have been reasonably successful in enhancing farm incomes, there remains a less than clear understanding of what influence these programs have on consumer prices

and the nutritional value of diets. Implementation of a national food policy presumes that proposals to improve the economic position of some food system participants will be considered only with a clear understanding of their effect on all others in the food chain.

ESCS must be in a position to provide basic research evidence as well as policy analysis to help answer many of the questions being asked. The research program emerging in Food Economics is a start.

Food Economics Research Thrusts

The basic purpose of the research is to provide analytical support and policy analysis of the economic aspects of food consumption and human nutrition. The research emphasis is on analyzing and explaining why things are as they are including the forces operating to create changes. Analysts are responsible for the longer-term development of research tools and techniques useful for improving the agency's ability to monitor and explain what and how economic and institutional forces impact on the food consumption sector.

The program has four major components. Each is discussed briefly below.

I. Food Sector Situation

A high priority responsibility of the program was to be the analysis and communication of the food sector situation. Research in this area will focus on the development of systems useful for monitoring the availability, consumption and price of food. We hope to improve the general understanding of eating habits, not merely reporting that they are changing but why and ultimately what the consequences of such changes are. In addition, the sector situation activity will increasingly focus on the distributional aspects of food expenditures by income group.

II. Basic Research on Factors Affecting Food Choices

This research is aimed at improving the general level of understanding regarding the role of prices, incomes, family size and composition, advertising and labeling, health status, attitudes, and lifestyles on consumer behavior in the food market. The research provides the foundation for policy analysis and evaluations of Federal programs in nutrition education, food distribution and public assistance, and food safety and quality regulations. In addition, this research helps to improve our understanding of the nutrition related consequences of Federal agricultural production, marketing, and income stabilization programs.

A sub-unit of this research relates to identifying the relationship between the demand for nutritional intake and the demand for marketing services.

Both the BLS Consumer Expenditure Survey and data from the USDA Nationwide Food Consumption Survey provide sources of data for this activity.

III. Food Policy Analysis

In order to assist the policymaking process, ESCS needs to be in a position to respond forcefully with the results of sound economic analyses on food policy issues.

Numerous research questions are being addressed under the very general heading of 'nutrition policy.' Such studies include evaluations of:

- Agricultural production implications of changing dietary patterns,
- Proposed changes in food quality regulations,
- Commodity purchase programs including their effectiveness in improving farm income as well as national dietary intake,
- Proposals to restrict the use of food and feed additives (food safety), and the
- Role of market information in making food purchases.

In short, the research aims to develop the capability to simulate the economic consequences of policy interventions at the *food consumption end.*

IV. Evaluations of the Effectiveness of USDA's Food Distribution Programs

In Food Economics, we have a small program of research underway in this area. Funding is from FNS as well as from ESCS appropriations. Most of the studies now being conducted are at the request of FNS. The work is being continued but other studies which are less program specific are also being undertaken. One of our priorities is to begin documenting what effect, if any, the present programs have had on supporting farm income and/or improving the nutritional well-being of recipient households.

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THE REGULATION OF FOOD SAFETY

By Robert J. Lenahan

In recent years questions about food safety have become a more visible item on the food policy agenda. Most often the discussions about these issues become quite technical. Some have suggested that the wide variation in the regulations themselves makes it difficult to focus on the important points in the discussion. This article puts the existing food safety regulations in perspective. The major legislative statements are reviewed and discussed in an attempt to improve understanding about the regulatory process.

The Regulatory Authority

The Food and Drug Administration (FDA) of the Department of Health, Education and Welfare, under authority granted by the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et. seq.*), is charged with assuring the safety of the Nation's food supply. The Department of Agriculture (USDA), through the Federal Meat Inspection Act (21 U.S.C. 601 *et. seq.*) and Poultry Products Inspection Act (21 U.S.C. 451 *et. seq.*), shares concurrent jurisdiction with FDA over meat, poultry, and derivative products which have entered the Federal meat and poultry inspection systems. Other Federal agencies, including the Environmental Protection Agency, the Public Health Service, and the Department of Transportation, are also involved, though to a lesser extent, in this process.

The Food, Drug and Cosmetic Act

The Federal Food, Drug and Cosmetic Act (FFDCA) was originally enacted in 1938 and included prohibitions against 'any poisonous or deleterious substances in food which may render it injurious to health.' At that time, it included no provisions for premarket testing of substances such as food additives, color additives, or new animal drugs. Subsequent amendments prohibit the addition of substances to food that have not been shown to be safe by appropriate tests.

Food Additives

The first such amendment, the Food Additives Amendment (Public Law No. 95-929) was enacted in 1958. It was designed to protect consumers by requiring premarket testing of all substances which met the following definition of the term 'food additive':

> Any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for such use) if such substance is not generally recognized among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use;—(21 U.S.C. 321(s)).

Included in this amendment is the first enactment of the so-called 'Delaney Clause,' which was added to the bill as a committee amendment and became part of section 409(c)(3)(A) of the FFDCA.

> *Provided*, that no additive shall be deemed to be safe if found to induce cancer when ingested by man or animal, or if it is found, after tests that are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal.

Also specified in this section are the procedures for obtaining approval of food additives. Before such an ingredient may lawfully be used, it must be the subject of an approved food additive regulation which establishes a tolerance for the use of such a substance. The substance must be shown to be safe under the conditions of its intended use, and it also must be shown to effectively perform its intended function when used at the intended levels. The Delaney Clause dictates that approval cannot be granted for the use of any food additive that has been shown, through appropriate testing, to induce cancer in man or animal.

Color Additives

In 1960, the color additive amendments (Public Law No. 86-618) were added to the FFDCA. These amendments require that the safety of such substances be demonstrated before FDA approval for their use is granted. These amendments also added another Delaney Clause to the FFDCA, virtually identical to the first. It is included in section 706(b)(5)(B) (21 U.S.C. 376(b)(5)(B)).

Under the FFDCA, the term 'color additive' means a material which—

> (A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change or identity, from a vegetable, animal, mineral or other source, and
>
> (B) when added or applied to a food, drug or cosmetic, or to the human body or any part thereof, is capable (above or through reaction with other substance) of imparting color thereto;...(21 U.S.C. 321 (t)(1)).

The safety and testing procedures regarding color additives parallel those required for food additives. The sponsor of such a substance must demonstrate that it is safe. FDA is expressly precluded from permitting the use of any color additive that has been found to induce cancer in man or animal.

Animal Drugs

The various provisions of the FFDCA governing the premarket approval of drugs intended for use in animals were consolidated under the Animal Drug Amendments of 1968 (Public Law No. 90-399). The term 'new animal drug' means:

> Any drug intended for use by animals other than man, including any drug intended for use in animal feed....(21 U.S.C. 321 (w)).

Procedures for obtaining approval for use of such substances are similar to those required for obtaining approval for food and color additives. Under these amendments, approvals for the use of such substances, which are used in the livestock industry for the treatment and prevention of disease and as growth promoters, are granted after a two-part evaluation by FDA. First, there must be a determination that the drug is safe and effective for use in animals. Second, the safety data must be reviewed to assess the safety of potential residues which might occur in food derived from such animals (21 U.S.C. 360b (d)(1)).

These amendments included another reiteration of the Delaney Clause directing FDA to disapprove new animal drug applications if:

> Such drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the foregoing provisions of this subparagraph shall not apply with respect to such drug if the Secretary finds that under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found...in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals.

As the statutory language indicates, this third enactment of the Delaney Clause differs from its predecessors in that its application in the new animal drug area is not absolute, assuming that the drug will not adversely affect the animals involved, and that no residues will be found in the edible portions of such animals.

Pesticide Chemicals

In 1954, the Pesticide Chemical Amendment (Public Law No. 85-791) was enacted. This amendment created a category of added poisonous substances known as 'pesticide chemicals' and authorized their use in or on 'raw agricultural commodities' unless they were 'unsafe' within the meaning of the newly enacted section 408 of the FFDCA (21 U.S.C. 346a).

The Environmental Protection Agency (EPA), established in 1970, assumed the authority formerly vested in FDA for establishing tolerances for perticide chemicals under the FFDCA, together with authority to monitor compliance and enforcement of such tolerances.

These statutes establish a regulatory system regarding pesticide chemicals which is essentially the same as that for food additives, color additives, and new animal drugs. However, three important distinctions should be made. First, the FDA jurisdiction in this area does not extend to all foods, but only to raw agricultural commodities. Second, another Federal agency, EPA, has been given the authority to prescribe tolerances. Finally, there is no application of the Delaney Clause to this area of food regulation.

The USDA Role

As stated earlier, FDA has overall responsibility for assuring the safety of the Nation's food supply. Concurrent jurisdiction is, however, shared with the Department of Agriculture over meat, poultry, and products thereof which have entered the Federal meat and poultry inspection systems. In this area, the USDA operates under the authority of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA).

These Acts are designed to protect the public from unwholesome, adulterated or misbranded meat, poultry or products thereof. While many of the provisions of these Acts are complementary to provisions in the FFDCA, the FMIA and PPIA also require mandatory ante mortem, post mortem, and processing inspection of all meat, poultry and products thereof prepared for commerce. Federal inspection is also required in States which do not maintain inspection systems at least equal to the Federal programs. They further prohibit the sale, transportation, and offer for sale or transportation, of meat, poultry and products thereof which are adulterated within the meaning of these statutes.

The Methods of Regulation

While the USDA and the FDA each have a responsibility to ensure the safety of food products of various origin, the manner in which they do this is quite different. The USDA, which conducts inspection of meat, poultry and products thereof, requires each processing plant to be registered and to have official USDA inspection personnel on the premises to conduct a continuous inspection of animals. The FDA, which regulates all other foods, takes a different approach. The FDA system, in accordance with that Agency's legislative charges, checks food establishments at infrequent intervals, depending upon the risk associated with the specific commodity present. An FDA inspector may inspect a 'very high risk' establishment, such as a manufacturer of milk products, twice a year, while visiting a 'low risk' establishment, such as soft drink bottler, only once every few years. Thus, the FDA depends quite heavily on the industry and individual processor to police themselves.