BY THE COMPTROLLER GENERAL

Report To The Congress

OF THE UNITED STATES

Regulation Of Cancer-Causing Food Additives — Time For A Change?

The 1958 "Delaney Clause" of the Federal Food, Drug, and Cosmetic Act, which requires the Food and Drug Administration to ban the use of cancer-causing food additives, continues to be a source of controversy, an emotional issue, and a target for change.

While food safety experts agree that the Delaney Clause should be changed because of its inflexibility, they disagree on the regulatory alternatives that should replace it.

This report discusses the views of experts on this matter, the scientific tests used as a basis for decisionmaking, and the manner in which different agencies regulate cancer-causing substances. It also presents several alternative decisionmaking frameworks for the Congress to consider.

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COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON D.C. 20548

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To the President of the Senate and the
Speaker of the House of Representatives

This report discusses the Delaney Clause, which was incorporated into the Federal Food, Drug, and Cosmetic Act by the Food Additives Amendment of 1958. The Clause requires the Food and Drug Administration to ban food additives which are found to cause cancer when ingested by humans or animals or are found, after tests which evaluate the safety of food additives, to induce cancer in humans or animals. We made this review at the request of seven Members of Congress to determine if modifications were needed to the Delaney Clause and to present an overview of the social, scientific, and regulatory issues involving food additives that may cause cancer.

We are sending copies of this report to the Director, Office of Management and Budget; the Secretaries of Health and Human Services and Labor; the Administrator, Environmental Protection Agency; and the Chairman, Consumer Product Safety Commission.

Charles A. Bowsher

Comptroller General
of the United States

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

REGULATION OF CANCER-CAUSING FOOD ADDITIVES--TIME FOR A CHANGE?

D I G E S T

Recent debates over the safety and regulation of saccharin and nitrite have increased public concern about the use of food additives, particularly the possibility that some might cause cancer.

About 2,700 food additives and 33 color additives used in food are regulated by the Food and Drug Administration (FDA). These substances are used to preserve, color, flavor, and aid in processing food or maintaining its nutritional quality.

WHY THE REVIEW WAS MADE

In response to a request from seven Members of Congress, GAO determined

--the opinions of experts regarding the perceived impact of the Delaney Clause, which bans the use of cancer-causing food additives, the need to delete or modify it, and alternative ways of doing so;

--the public attitude toward allowing the use of carcinogens in food;

--the social, scientific, and regulatory issues that cause disagreement about the Delaney Clause and the use of food additives that may cause cancer; and

--the regulatory alternatives to the Delaney Clause. (See p. 2.)

WHY THE DELANEY CLAUSE IS AN ISSUE TODAY

The 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act provides that no additive shall be deemed to be safe if it is found to induce cancer when ingested by humans or animals or it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in humans or animals. This provision is known as the Delaney Clause. (See p. 1.)

The Delaney Clause is a source of controversy, an emotional issue, and a target for change.

The heart of the issue centers on Delaney's "zero-risk" concept that no substance, in any amount, may be intentionally added to food if it has been shown to cause cancer.

TOTALLY RELIABLE TESTS TO DETECT AND ASSESS THE RISK OF CANCER FROM FOOD ADDITIVES HAVE NOT YET BEEN DEVELOPED

Tests to determine whether food additives cause cancer and statistical models to assess their risk to humans are available, but they have not yet been developed to the point where many experts totally accept their reliability. The most widely used tests can be divided into four categories:

--Molecular structure analyses provide limited information about the possibility of a substance causing cancer by analyzing its chemical structure. These analyses are not regarded as strong indications of either safety or risk.

--Short-term tests are based on the presumption that cancer is related to changes in cells which can result in mutations. There are now about 100 different such tests, but none can detect every cancer-causing substance.

--Animal tests are generally regarded as the best method available for evaluating a substance's cancer-causing potential. The number, type, location of tumors, and, in some cases, the time it takes for a tumor to develop in test animals and in control animals are compared.

--Epidemiological studies (for example, a comparison of cancer incidence between asbestos workers and other groups) are the most convincing evidence of a substance's human cancer-causing potential. Epidemiological studies can rarely provide useful and timely answers to regulatory problems because of their general insensitivity for detecting relatively small changes in the rate of occurrence of a disease and their retrospective nature. (See pp. 8 to 16.)

EXPERTS GENERALLY AGREE THE DELANEY CLAUSE SHOULD BE CHANGED BUT DISAGREE ON HOW

GAO conducted 50 interviews with biomedical researchers, industry and consumer group

representatives, and former FDA commissioners and general counsels.

With the exception of some consumer group representatives, most experts believed the Delaney Clause should be changed but differed significantly on how to change it. Food safety experts agreed that the principle of the Delaney Clause--not adding cancer-causing food additives to the food supply--is desirable in theory, but most believed that the Clause is impractical and should be changed. (See pp. 20 and 21.)

Proponents of change believe that a goal of absolute safety is unrealistic primarily because scientific advances enable one to (1) detect minute amounts of substances in the parts per billion or trillion range and (2) identify carcinogens in the food supply that may not pose a significant risk to human health. (See p. 20.)

In addition, the proponents of change noted that the risks associated with other hazards in the workplace and the environment are regulated with some discretion; all cancer risk is barred only for food and color additives. Some believe that the cancer risk from certain food additives may be outweighed by the benefits derived from the additive's use. (See p. 20.)

Opponents of change argue that the Delaney Clause is the most effective way to deal with food additives that may cause cancer since not enough is known about cancer to allow their use. Some maintain that, because the risk from cancer-causing substances cannot be quantified, a zero-risk standard is a cautious and prudent societal judgment. (See pp. 20 and 21.)

PUBLIC ATTITUDE REGARDING CARCINOGENIC FOOD ADDITIVES

GAO identified 12 public opinion polls conducted over the past 10 years which addressed the question of food safety. These polls showed that the public approves of the general policy of banning cancer-causing food additives. However, the public is opposed to a ban for specific substances like saccharin which have been in use for a number of years and have perceived benefits. (See pp. 33 to 36.)

DIFFERENT REGULATORY POLICIES FOR DIFFERENT USES OF CANCER-CAUSING SUBSTANCES

Cancer-causing substances are regulated differently within FDA and among FDA and other Federal agencies because of differences in social, economic, and health considerations. Under the Federal Food. Drug, and Cosmetic Act, not all substances added to food are regulated as food additives. (See p. 37.)

Federal laws that regulate pesticides, environmental contaminants, consumer products, and hazardous substances in the workplace require that the risk from exposure to carcinogens be balanced against one or more of the following factors: health, social, economic, and environmental benefits; costs to the consumer and industry; and technological feasibility.

Under these laws, cancer-causing substances are regulated no differently from other toxic chemicals. (See ch. 4.)

CONGRESSIONAL OPTIONS FOR REGULATING CANCER-CAUSING FOOD ADDITIVES

Three obvious alternatives are possible: (1) leave the Delaney Clause unchanged, (2) repeal it, or (3) amend it in some way. (See ch. 5.)

If the Clause were deleted from the Food, Drug, and Cosmetic Act, both carcinogenic and noncarcinogenic food additives would be regulated under the general safety clause. Thus, a cancer-causing food additive could be used if there was a reasonable certainty that no harm would come from its proposed use.

Under the third alternative, amending the Clause, three options could be considered: (1) set an acceptable level of risk, (2) compare risks and benefits, and (3) compare the health risk of using a carcinogen with the health risk of not using it.

Under the first option, FDA would determine that the estimated health risk from the use of the substance would be insignificant or within an acceptable level. Many officials at FDA favored

this approach. In considering this option, the Congress needs to be aware that different mathematical models for estimating human risk can produce widely varying results which differ by many orders of magnitude.

Benefits that can be considered under the risk-benefit option include: (1) health benefits--the substance provides an essential nutrient, (2) economic benefits--reduced cost or increased supply, and (3) other benefits, such as increased appeal--improved aesthetic value and utility.

Under the last option, FDA would be required to balance risks and determine whether a ban or other restriction on the use of a carcinogenic food additive would result in a greater health risk than allowing its use.

If the Congress chooses to address these options, it should consider whether to apply them equally to cancer-causing and non-cancer-causing substances.

MATTERS FOR CONSIDERATION BY THE CONGRESS

GAO believes that the Congress should reexamine whether the Delaney Clause is still appropriate because of (1) advances in the ability of analytical detection methods to identify substances at very low levels, (2) uncertainties about the human risk from low levels of carcinogens, and (3) the inflexibility of the current law. (See p. 57.)

AGENCY COMMENTS

The Department of Health and Human Services said that it is considering alternative approaches that could be adopted for regulating carcinogens in the food supply and that GAO's report would be useful in formulating a policy.

The Environmental Protection Agency concurred with the general findings and conclusions of this report and added that the findings provide a sound basis for GAO's recommendation that the Congress reexamine the Delaney Clause. The Department of Labor and the Consumer Product Safety Commission provided comments which they believed clarified information in the report. (See p. 58.)

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