The Role of Law in Food Safety

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Scientists and technologists particularly have the burden of articulating scientific truths not only to those getting scientific training, but to those who do not and never will have it. As science pushes forward into new fields and, more importantly, is further applied to the everyday services of man, lack of knowledge of the facts of science breeds fears, supports crackpots, and makes for bad laws.

"THE ROLE OF LAW IN FOOD SAFETY" is a dressed-up name for one aspect of the broader matter that we have come to know as "chemicals in foods." In this meaner light, therefore, the subject is the part laws play in protecting the public against addition of unsafe chemical substances to the diet, and contemplated revisions in such laws.

But this mean and, in fact, baleful light is really not the correct one either. "Chemicals in foods" is a misnomer that in reality should be "chemicals in chemicals," or better, "new food substances." It is a semantic misnomer. Chemical and food specialists know the degree to which the public—even in this chemical age—considers chemicals to be one of those several esoteric materials having the power of blowing up and which, when brought into contact with the human body, destroys it in mysterious and painful ways. It is no wonder that the predetermined popular answer to any so-called chemicals in foods question is that there shall be no chemicals in foods.

Existing Laws

There are two basic kinds of law affecting foods and tending to assure their safety. I use the word "tending" purposefully. Legal laws, unlike the laws of science, merely influence human conduct; and they are not immutable. We have yet to control the lawbreaker.

The first general classification is the common law of product liability, worked out over the years as a result of litigations in the courts. In essence it provides that he who harms another by an injurious product must compensate the one harmed. We need not stop to dwell on the deterrent effect of product liability law, any more than on the deterrent effect of religion and morals; it has significant effect, the degree depending on the character and background of the individual and his fear of punishment.

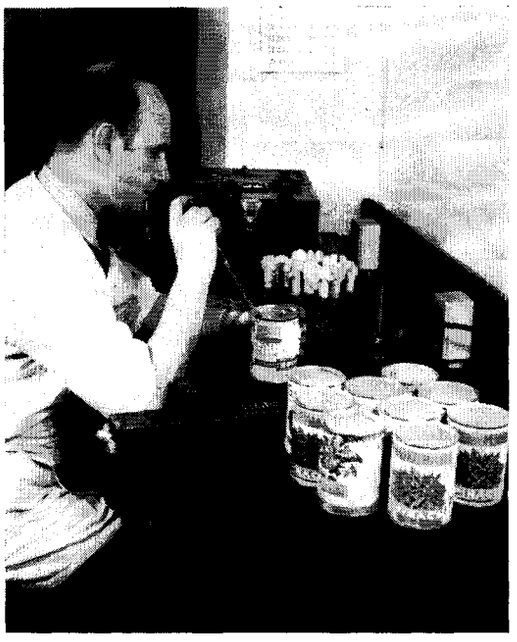
The second is statute law made by the legislatures. Statute law can be said to be the will of the people voiced through their elected representatives, at least in the democratic countries, intended to control conduct to a degree not controlled by ethical, religious, and other legal forces. In the last half century the people of the United States have enacted a number of laws affecting the purity and safety of their food supply. Most basic and important is the Federal Food, Drug and Cosmetic Act which governs the purity, quality, and labeling of all foods moving in interstate commerce. There is the Meat Inspection Act, which provides for inspection and control of meats shipped in interstate commerce, and the Federal Insecticide, Fungicide, and Rodenticide Act affecting the interstate shipment of substances that may appear in or on foods as residues. There are federal laws specifically affecting, for example, milk and tea; state laws affecting foods moving only within the states; and state and local ordinances and regulations dealing with certain foods such as water and milk.

The Food, Drug and Cosmetic Act forbids shipment in interstate commerce of any food that bears or contains a poisonous or deleterious substance. If the substance is naturally in the food, it is forbidden unless, as the Statute says, the quantity contained does not orinarily render it injurious to health. Added substances are treated more strictly. If poisonous or deleterious, they are forbidden altogether, except where required in production or where they cannot be avoided by good manufacturing practice. Then, they may be used only to the extent permitted by tolerances which the Secretary of Health, Education & Welfare is ordered to issue.

The food standards section of the Food and Drug Act often crops up in discussions of laws affecting chemicals in foods. The section actually is intended to prevent economic adulteration, rather than to assure safety of ingredients. Under it the Food and Drug Administration prescribes what and how much shall go into a particular food, such for example as white bread. Any producer of a product purporting to be white bread must conform to that standard unless he keeps his distribution within state bounds. The idea is to assure that people who buy bread get what they think they are getting. Although the purpose is thus to prevent cheating on the contents of the staple foods that are standardized, the practice of the Food and Drug Administration has been also to determine in food standards hearings issues of toxicity of proposed ingredients. The standardization technique is generall considered, however, to be an impractica one for resolving such problems and would be greatly simplified if safety matters were to be excluded from it altogether.

The Federal Insecticide, Fungicide and Rodenticide Act requires registration with the Department of Agriculture of all pesticidal substances that are to be shipped in interstate commerce. Data that must be submitted to the department includes the name of the substance, its labeling, all claims to be made for it, including use directions, and, as the department requests, the formula of the substance and a description of the tests made upon which the claims are based. While the statute can be read to require government pre-approval as to safety to man when the substance is likely to appear in foods in residue form, that fact is at least not spelled out in detail, and there are differences of opinion as to the effectiveness of the law in that regard. In practice, there is close cooperation between the Department of Agriculture and the Food and Drug Administration on the safety-to-man aspect of proposed pesticides, and registrations have been held up because of safety questions. Registrations must be issued on demand of the applicant, but he lays himself open to subsequent prosecution for violation of any of the provisions of the statute, and in practice few registrations have been so issued; none so far as I know where the issue involved was safety to man.

The Federal Food, Drug, and Cosmetic Act, as now written, forbids interstate delivery of food containing any substance not original and natural to it, whether intentional additives or incidental residues, if "poisonous or deleterious," unless, where found necessary to production, it is within tolerances announced by the Food and Drug Administration. The food and food ingredient producer stands in the position of the ordinary citizen told by law what he can and cannot do. He may violate that law, but he does so at his peril. If he goes ahead with the use of a new substance considered by the Food and Drug Administration to be violative of the law, that agency in the posture of a policeman may approach with its club and order discontinuance. If this fails, the administration may hail him into court for imposition of penalties, seizure and condemnation, or injunction against further deliveries. Where there is any dispute on the issue of safety, the court acts as the arbiter, hearing all the scientific witnesses that either side may bring forward, and deciding whether the substance is poisonous or deleterious, and required or not required in production or good manufacturing practice, within the meaning of the statute's words.



Laboratory testing by FDA of samples of retail food products to check conformity with standards and regulations

Proposed Changes in Existing Law

As a result of a background too extensive to review here, the Congress of the United States several years ago named an investigating committee—the Delaney Committee—to look into the present state of things and to recommend whether existing statutes were adequate to protect public health from harmful substances that may be getting into the diet. That committee's majority concluded after nearly two years of hearings that the present statute was inadequate and that basic changes should be made to give the government more power over the distribution and use of new food additives. Its position can be summarized this way:

Today it is necessary that the government gather evidence to prove that a particular added substance is poisonous or deleterious and then, if the food producer persists in using it after warning, seize the food and have it condemned, bring court action against him to stop him, or impose criminal penalties. The Delaney Committee felt that the law should be changed to require the ingredient supplier (or food producer) to present his evidence of safety to the government ahead of delivery or use, and to get government approval before delivering the additive or the food containing it. The argument advanced for the change is that while the great majority of food and chemical companies conduct thorough safety testing, make their products meet completely adequate safety standards, and informally get prior concurrence of the Food and Drug Administration as to these adequacies, there may some day be an instance where an individual would not be so aware of or so conscientious of his ethical, moral, and legal responsibilities. In such an instance—the argment goes—the Food and Drug Administration must discover the addition in the food and (assuming that its weapon of publicity did not work) obtain evidence of its poisonous or deleterious character before it can bring a successful action under existing law to stop the potential hazard to public health. And finally, as chronic toxicity testing takes long periods of time, the potential injury to consumers of that particular food in the meantime might be severe.

Stated another way, the proposed change in the law would add to the government's role of policeman the role of licensor. No longer would the producer stand in the position of being solely responsible for deciding whether going ahead with a new additive will break the law. He could not go ahead under any circumstances until he had obtained prior permission from the Food and Drug Administration to do so.

In order to understand the full significance of this proposal, it is necessary to consider some aspects of a comparatively new field of law that has grown up with the development of administrative agencies—specialized arms of the executive or law-enforcing branch of the government. The proposed change would transfer additional functions and therefore powers to the administrative agency known as the Food and Drug Administration.

Absolute Powers for HEW

Under the present statute—where litigation becomes necessary—the agency must prove its case for statue violation before the courts; under the new proposal the proponent of the food additive would be required to prove its case for non-violation of the statute before the administrative agency. Our democratic procedures insist on the traditional checks and balances, and the agency's decision would have to be appealable to the courts. However, as a very practical matter, the administrative agency with a licensing authority has an almost final power of disposition over the matter. The courts in considering an appeal from the agency's decision will not review the merits of that decision unless the statute expressly so provides. Therefore, were the statute to be written as proposed by Congressman Delaney, the Secretary of Health, Education, and Welfare (acting on advice of the Food and Drug Administration) would have the power to deny absolutely the use of a new substance proposed for use in foods, or for a use that might cause it to appear in foods as a residue, if—in the opinion of the Secretary—it has not been adequately tested, testing showed it to be unsafe, testing did not show it to be safe, methods of analysis to determine residues are inaccurate or incomplete, or if the Secretary feels that he (or she) does not have enough information on which to base an opinion. The courts, taking the view that the Secretary is an expert in his field, will not reverse the decision or order the matter back for reconsideration unless convinced that the Secretary acted arbitrarily or capriciously in coming to his conclusion. It is rare in these circumstances for the courts to overrule the administrative agency.

This type of prior approval control has in fact been in effect on new drugs since 1938, and as far as I know has worked satisfactorily for them. The Food and Drug Administration has certainly for the most part discharged its heavy responsibility in accordance with the scientific facts and with judgment and fairness. It does not follow necessarily, of course, that this is the type of control that should be placed over the addition of new substances to food, any more than such controls should be extended to other proscribed acts covered by the Federal Food, Drug, and Cosmetic Act, including for example all those affecting food alone. Among other things it must be kept in mind that new drugs are generally their own dramatic proponents. In the public mind, the agency must not unnecessarily hold back some new alleviant of disease. The Administrator thus has constantly in the background the most powerful impetus for action. That would rarely be true in the case of foods. Again, drugs are to be taken generally in alleviation of specific conditions and under professional supervision. Responsibility of the approving agency can to a great degree be shared with the physician. None of these are true of food additives. They can be expected to be consumed for long periods of time by a large variety of the population and with no specific professional supervision. The government agency thus assumes a sole burden of responsibility

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so great as to risk negative decisions without appropriate regard to accepted scientific opinion and judgment.

For these reasons, a great deal of thought has been given to modifications of existing law that would be directed to strengthening it but would not have the disadvantage of placing the final power of approval or disapproval in the hands of a government agency. Proposals have been made, for example, for a panel of experts in the various scientific fields involved to decide or recommend decisions on the scientific issues under consideration.

Need for Perspective and Objectivity

While laws are no cure for the wrongdoer but only influence human conduct, they are perhaps the strongest man-made means available to influence it. Any law that affects essentially a scientific field is, therefore, of great moment to science. The determination of facts on which is predicated the need for enacting or revising laws, the drafting of laws themselves, and their enforcement, all concern the scientist. He will be particularly jealous that action springs from facts objectively obtained and from experienced judgment, in order that injustice not be done and that man shall progress unhampered by falsehood, prejudice, and fears of what is not understood.

It should be expected, for example, that fact-finding to determine the need for law revision on the subject of new additives in foods would involve a careful study of the opinions of established experts in the fields, opinions obtained from them objectively, fairly, and unhurriedly; that those appointed to carry out the study would themselves be qualified in the fields involved or know or have the means of evaluating fairly the qualifications of those who give opinions; and that they would be broad-minded and free of prejudgment of the issues. With the conclusion of the Delaney Committee hearings, at least some aspects of this fact-finding have ended for the moment. But scientists can well afford to spend some time in reading the testimony and cross-examination in that hearing. Without regard to the conclusions reached by the committee, such a review will better qualify one to answer for the future whether the traditional Congressional hearing is the proper technique to determine scientific facts and opinions on which to base new legislation.

Moving from that to broader considerations, we can all accept the principle that there must be a legal control, a control supplementing the influence of the morals and ethics of food and food ingredient producers, no matter how enlightened and conscientious they may be. We have gone far enough in our sociological development to recognize that people shall no more serve as testers for salt, iodine, sodium bicarbonate, and tomato love apples. We can thank our ancestors who tried out these present foods for us, but we will see to it that we do not test in that sense for our descendents. Our present food laws are adequate evidence of this attitude.

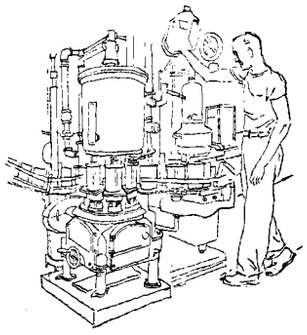
Today, in the face of an increasing discovery and development of substances that have utility in the growing, manufacture, packaging, and storing of food, there is a general feeling that legal controls and procedures should be strengthened to assure that no harm to man results, or at least that any harm that may conceivably result is balanced against the advantages.

On the other side of that coin, we can, I believe, accept the principle that scientific development in this field should not simply be shut off; that in view of the chemical nature of all foods, there is nothing basically wrong in the further development and use of synthetic substances having dietary or other utility in foods. Were remote possibilities of conceivable harm to be the accepted criterion for proscription by government in any field of scientific development, it would be a dark blow to science. Automobiles, airplanes, paint, and electric and atomic power among others would in principle have been forbidden or now subject to proscription. Our inherently progressive and optimistic natures lead us to ask that our laws, and our government that enforces them, shall allow as well as disallow, and on scientific and reasonable grounds only.

Considerations for Allowances And Disallowance

What considerations shall there be for such allowance and disallowance of new food additives?

First and foremost obviously is that any proposed new ingredient, whether intended or fortuitous, must be safe to man. The issue of safety to man is not a simple one, as the toxicologist and pharmacologist can testify. Determination of the effect of external substances on the human body is a developing scientific field in itself, and conclusions can be made only in relative and not absolute terms. Were the methods of toxicological testing, the interpretation of test results, and the standards of acceptance well established for all situations, we might even write a law incorporating those exact methods and standards. This unfortunately is not ture. At the same time, toxicology is a science that gives workable if not perfect answers on



which informed judgment can predicate action. The problem is to see that the legal mechanism accurately reflects the experienced judgment of those who understand and know how to use the science of toxicology.

It is difficult to escape the feeling that the stringency of safety standards for a particular product will and perhaps should be affected by the expected benefits to flow from its use. Will it replace other and less safe substances? Will it save foods, or increase production or supply? Will it confer health benefits? While this is so, serious question can be raised whether government should have even indirectly the power to deny the use of any particular substance on the ground that government does not consider it useful to the people. The lawyer would question whether in granting such a power to government, we are being faithful to a basic principle of our founding fathers that those governed least are governed best.

Finally, the control imposed must reflect the best in expert opinions in the scientific disciplines involved so that those who invest in research may expect fair and objective treatment in utilizing the results of such research, and that scientific advancement will thus not be unnecessarily retarded.

These questions will not be disposed of with the disposition one way or the other of the food additives issue. As the results of science are brought to bear ever more intimately in the service of man, it will be clear that there must continue to be arbitration between the public and those who produce the benefits of science, to assure that there is a proper balancing of harms and benefits. The scientist and the lawyer will have their individual responsibilities—to understand each other's problems, and to work for understanding, clarity of vision, honesty, and perspective. Only with these can the people speaking through their legislatures write good laws that will protect the public, promote and not retard progress for the short and long term, and at the same time maintain our democratic processes and traditions.

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