It was just four years ago this month that I had the privilege of addressing the 56th Annual Meeting of the American Dairy Science Association at the University of Wisconsin on pesticide residues. Although the subject was not new in 1961, it had recently loomed as a critical problem. During 1960, and even though the pesticide amendment to the Food, Drug and Cosmetic Act had been in existence since 1954, the dairy industry experienced the first seizures by the Food and Drug Administration of dairy products moving in interstate commerce, because of contamination with pesticide residues. It was then that the full impact of the pesticide problem began to be realized, i.e., that dairy products containing very low levels of residues were in technical violation of the law, even though the amounts of residue involved were in the range of only .1 to .2 parts per million—actually, one hundred-fold less than published legal tolerances for residues on many other basic agricultural products. Actually, I think, it was this wide discrepancy between the actionable levels of residues in milk, as compared with other foods, that shocked the dairy industry into a realization of the seriousness and complexity of the problems it faced.

At that time, the dairy farm was blamed as the source of contamination. It was the prevailing opinion of regulatory people that if we could clean up farms, eliminate DDT and other chlorinated pesticides from uses on dairy animals and around milking premises, that the problem would be solved. This proved to be untrue.

The dairy industry was apprehensive, not knowing quite how to come to control the pesticide problem.

At the 56th Annual meeting, we were able to give a few clues resulting from the first year's work on the Technical Advisory Committee on Pesticides of the dairy industry. The information obtained by the Committee, although not comforting, nevertheless cast some light on the types of residues being found in milk, how they were distributed seasonally and geographically, the ranges of incidence and levels of contamination, the pathways by which these pesticides were getting into milk and milk products and, importantly, what might be accomplished through an educational program directed to our dairy farmers. Results also revealed clearly that a substantial amount of the contamination of milk was from sources beyond the control of the dairy farmer or of the dairy foods processor, e.g., that much of it was coming from feeds, both dry and green, and mostly from the agricultural environment, i.e., the application of pesticide chemicals to field crops by spraying, dusting, etc., with resulting drift.

The situation today. Has it changed? Basically, no. The need for agricultural chemicals in our animal and plant enterprises persists. The amount used is increasing each year. The same residues are found in milk and through the same pathways. Public Health considerations continue as the guiding restraints in shaping policies and controls of usage and law enforcement.

We have seen broad awareness develop throughout all agriculture that pesticides are truly great weapons to combat crop disease and destructive pests and this enable high levels of food production we enjoy today, but at the same time they can cause serious harm to human health if misused. Our public agencies, both federal and state, also recognize both sides of the problem, i.e., that production programs and, importantly, enforcement policies must consider the fact that we must have adequate supplies as well as safe milk and milk products and that these twin goals can be accomplished only if we use chemicals properly and selectively, so as to control residues within safe limits.

It is essential that enforcement policies, with respect to residues in milk, be based not on sentimental or traditional concepts of purity, but necessarily on scientific facts and principles, taking into account that there will be irreducible minimums of pesticide residues in milk and milk products, in spite of the best agricultural and industry practices, but which also are compatible with public health.

It is likewise of critical importance that outbursts of demagoguery, such as the book Silent Spring, not be allowed to cloud the scientific issues involved nor to alter the course of sound regulatory and enforcement policies by our government agencies.
A troublesome aspect of the whole situation remains—this is the zero tolerance problem, which has created confusion. The impression is widespread that zero tolerances have already been established by the Food and Drug Administration (FDA) for pesticide residues in milk, but this is not the case. For those pesticides widely used in agriculture and which we find in milk in small amounts, tolerances have not been set for dairy products at zero or any other level. And this is critical in the current situation because, in the absence of tolerances, any residue occurring in milk, regardless of how little, violates the law.

Some developments in federal programs. A recent publication (4) from the United States Department of Agriculture (USDA) is well worth careful reading by anyone interested in the pesticide problem. It is entitled The War That Never Ends. It emphasizes the damage which pests inflict on food and fiber and the tremendous economic losses that occur annually from insects, plant diseases, nematodes and weeds, etc. It points out the role of modern pesticides, together with other technical developments which have made possible the spectacular advance in American agricultural efficiency, increasing farm output per acre by at least a third, to help keep pace with the needs of an exploding population at home and growing markets abroad. Pertinent facts are given with respect to USDA’s own research and control programs involving methods for new low-volume spraying techniques whereby, for example, one plane load can do the work which previously required 27. It highlights the effectiveness of modern pesticides in helping to keep food costs down and quality high. It describes research programs of USDA for pest control without agricultural chemicals, for instance, the biological approach; also, sterilization and the use of sex attractants. A Pesticide Information Center was established in 1965, from which scientific and technical information on pests and their control is made available to scientists, administrators, and others working in the field.

The U.S. Department of Health, Education and Welfare has taken strong steps and is concerned about the dangers of pesticide residues in foods. All of you are familiar with the FDA’s continuing total diet studies showing that pesticide residues in American foods are insignificant from the health standpoint. They have recently published a bulletin (5), reporting the latest studies on all kinds of food and drink consumed daily. The products tested are those that might be consumed by a typical 16- to 19-year-old boy, the biggest eater in the U.S. population. Residues detected by the newer, highly sensitive methods showed amounts even lower than those in earlier studies. In several cities, inspectors purchased typical market basket samples of fruits, vegetables, dairy products, meats, and other commodities. These were prepared for the table by trained dietitians, to eliminate variations in preparation practices. Composite samples were then tested in FDA laboratories. All levels of the seven chlorinated pesticide residues found were low. In the organophosphate pesticides the studies detected no residues at the established detection levels.

Moreover, in fiscal 1964, FDA laboratories analyzed 32,678 samples of raw agricultural products. Thirty-four lots of foods and feeds containing residues at illegal levels were found in the channels of commerce. These were seized in federal court actions. Thus, FDA’s program continues actively responsive in the area of pesticide control to the public interest.

The President’s Science Advisory Committee, about three years ago, appointed a subcommittee to study the pesticide problem and to make recommendations. The report (3) of this committee, published in May of 1963, recommended coordination of efforts by USDA, Health, Education, and Welfare (HEW), and USD1. In carrying out this mandate, an interdepartmental committee was created to act as a clearing house among these governmental agencies, on critical matters relating to the handling of pesticide problems. The President’s Committee also recommended a study of the zero tolerance concept, which has long been subject to criticism by scientific authorities. It is noteworthy that at the recent hearings in Congress before the Ribicoff Committee the Commissioner of Food and Drugs, when questioned concerning zero tolerances, admitted readily that such tolerances are unworkable, even with respect to milk.

However, as a result of the President’s Science Advisory Committee recommendation, a special advisory committee was appointed, nominated by the National Academy of Sciences, to study the zero-tolerance question. This advisory committee, chairpersoned by Dr. James Jenson of Oregon State University, has been hard at work on this problem for almost a year. Its report is expected momentarily, and our earnest hope and expectation is that the committee will fulfill its assignment and bring forth recommendations which will help clarify and stabilize enforcement policies on the zero-tolerance question.

This report was released July, 1965.
A third recommendation of the President's Science Advisory Committee was for the re-appraisal of certain persistent pesticides with respect to their toxicity, safe tolerances, etc. The particular compounds designated for study were aldrin, dieldrin, endrin, heptachlor, and methoxychlor. Methoxychlor is a strange bedfellow in this group, but its status has been in controversy ever since the report of a special advisory committee about eight years ago. In partial fulfillment of this reappraisal, we have the recent recommendation of a National Academy of Science (NAS) Advisory Committee on aldrin and dieldrin, which has now been implemented by an FDA proposal to lower and, in some cases, to revoke tolerances for these two compounds on a variety of fruits and vegetables, and withdrawal of any tolerance on certain agricultural by-products which are used as feeds for dairy animals. This is a prudent course of action.

Food and Drug Administration continues its excellent studies on methodology. Electron-capture gas-liquid chromatography (GLC) is emerging as the method of choice, closely followed by the more recent thin layer chromatography, which is being used as a confirmatory assay, particularly where legal judgments are involved. Also, FDA has now published an improved clean-up procedure for pesticide analyses with broad application and essentiality to these methods. Their wide sampling and testing of dairy foods continues unabated, thus complementing their already comprehensive purview of the pesticide situation in our industry.

Comments on federal programs would not be complete without reference to the special study of pesticide problems by the Committee on Appropriations of the House of Representatives. This was carried out by a Surveys and Investigations Staff of the Subcommittee on the Department of Agriculture of the Committee on Appropriations, under the chairmanship of Congressman Jamie L. Whitten of Mississippi. The inquiry by the committee covered: 1) The extent to which the Departments of USDA, Interior and HEW cooperate, collaborate, and coordinate their activities so as to protect the public health, while minimizing any adverse effect on agricultural producers and processors and protecting the food supply for all Americans; 2) regulations, if any, to control irresponsible actions, statements, and criticisms of agricultural pesticides, and the instances of the effect on producers, processors, and consumers of such actions, etc.; 3) information on current and long-range implications of programs and activities of USDA, to minimize effects of the use of pesticides and to find alternative methods and practices of disease control; and 4) the degree of coordination between federal and state agencies in connection with entomology and pest control research.

The investigating staff interviewed over 185 scientists in universities and industries and also 23 physicians, including officials of the American Medical Association and university medical schools. Also, the staff interviewed officials in government and state agencies having responsibilities in the regulation and control programs for pesticides. Probably there are many of us in this room who were interviewed by these competent investigators who, in my judgment, conducted a searching and comprehensive study of the total situation. The report (1) is entitled, Effects, Uses, Control and Research of Agricultural Pesticides. I commend it for your reading.

Analytical data and the impact of changing methodology. Now, with your indulgence, I should like to show you a few slides giving data from our laboratory, illustrating the incidence and levels of pesticide residues we are finding in milk and milk products today, also illustrating the effects newer analytical methods are having upon these results.

It should be remembered that five or six years ago the only official method for DDT and its analogues in milk was the Scheeter-Haller method, sensitive to only about 2.5 ppm of residue in fat. However, at that time, a new method had just come into use. This was the Mills paper chromatography method, which was a significant improvement. It enabled identification of a wider variety of the chlorinated hydrocarbons and, although only semiquantitative, nevertheless enabled good estimations of the amounts of residues present, down to about 0.3 ppm fat basis. This method was used exclusively in our laboratory until about one year ago, when we changed over to GLC with electron capture. To refresh your memory, here is what the picture looked like five years ago (Figure 1). Here we see the incidence of aggregate chlorinated pesticide residues during a year's cycle, ranging up to 57%. Levels of these residues were from about 1.0 to 1.5 ppm in fat. It was during this period that the results of a strong educational program for dairymen began to appear, and in the latter part of that year residues decreased to about .5 ppm in fat.

Figure 2 is a histogram from the same year's analytical data. This shows which compounds were being found and the relative frequencies in manufacturing grade milk.

Figure 3 highlights the chief problem resi-
due—DDT and analogues. Eighty to ninety per cent of the positive samples contained these compounds.

Figures 1, 2, 3 represent about 4,000 samples analyzed during April, 1960, through March, 1961. In the ensuing four years and up until August of 1964, our laboratory continued to use the Mills method. Some 10,000 samples were analyzed during this time. Changes were gradual, but not dramatic. Some improvement was shown. It should be emphasized that during all of this time a continuous educational program was conducted with dairy farmers throughout our producing areas. Our program, follow-

ing the precepts of the Dairy Industry Committee, is similar in most respects, to the programs of all the major dairy processors. Therefore, these data might be considered representative of what is happening in the industry.

The incidence of DDT has dropped somewhat; however, the levels following a rather dramatic drop during the first year of the program leveled off at about 0.3 to 0.5 ppm fat basis, and there has been little change, indicating that some sources of contamination are beyond control of dairymen, and this is probably true with most or all of the other pesticide residues. These levels, as you will note, are well below the present FDA action or violative level.

Now, I think you will be interested to see what the data look like five years later, resulting from use of GLC with electron-capture. These later data bring out several interesting points. First, as you know, gas chromatography is alleged to be much more sensitive than paper chromatography. I shall agree that in some instances this is true. It has enabled us to readily detect and quantify aldrin, dieldrin, and heptachlor epoxide, which was difficult with paper chromatography. Also, GLC has revealed an interesting discrepancy with respect to our older data on methoxychlor and lindane. These two compounds have identical RF values by the Mills method. We find to our dismay that the rather high incidence of methoxychlor reported earlier was probably mostly lindane. The two compounds are readily distinguishable with respect to our older data on methoxychlor and lindane. These two compounds have identical RF values by the Mills method. We find to our dismay that the rather high incidence of methoxychlor reported earlier was probably mostly lindane. The two compounds are readily distinguishable with respect to our older data on methoxychlor and lindane.

The case with DDT, however, is in strange contrast. We find with the faster clean-up procedure, using a one-step elution from florisil columns, that even though we can identify less than 1-billionth of a gram, the small sample, together with a much lower electron affinity, actually results in about fourfold less sensitivity with gas as compared to paper. Thus, we see there are some tricky aspects to this newer methodology. There is one great advantage to gas. It is much faster and the saving in time is considerable.

Another interesting point in this next series of slides is the comparison between fluid milk from Grade A areas and evaporated milk as representing manufacturing quality.
Also, we now show the DDT group separately, whereas, in the five-year-old slides we showed the aggregate of chlorinated pesticides found. We have learned that we cannot consider all of these compounds together. The range of toxicity is too great. There is, however, common agreement between FDA and the industry that it is technically reasonable to group DDT and its analogues, since the DDE and TDE, occurring chiefly from weathering or metabolism of DDT, or both, merely diversify the residue without affecting toxicity.

Figure 4 shows monthly analyses of fluid milk for DDT and analogues during the ten-month period August, 1964, through May, 1965. Figure 5 shows similar data for evaporated milk. These data give an interesting comparison with five years ago. Even though there is some question as to sensitivity of gas chromatography for DDT, the data indicate that the incidence of DDT contamination is substantially lower. More significant, the levels are quite low, amounting only to about one-fifth of the current action level of FDA. However, we need to remember that these are averages. We still find occasional high values which are violative. It is quite clear, and I have no explanation for this, that the level of contamination with DDT and analogues in fluid milk from Grade A areas is significantly higher than in the manufactured milk products. This may be a geographical phenomenon.

Figure 6 shows, for the same period of time, the average incidence and average level of the DDT group in fluid milk and also the ranges of levels into which this group of samples fell. There is a significant lowering of incidence and of levels as compared with earlier years and a typical distribution of residue levels in comparison with the action level of enforcement. Figure 7 shows similar summary data for evaporated milk. Again, we see the higher ranges of residue levels in the fluid milk group. Figure 8 shows a ten-month summary of lindane residues in this same group of samples of fluid milk. Figure 9 shows similar data for evaporated milk. Figure 10 is a histogram showing the average incidence over the ten-month period with these same samples of whole milk for the different pesticides we are currently finding. Figure 11 shows similar data for evaporated milk.

Again, we note the differences between fluid milk from Grade A areas and evaporated milk representing a wider geographical distribution. Some interesting and perhaps significant implications are revealed in the last four slides. If you will recall the similar chart of four years...
ago, we saw a rather substantial incidence of methoxychlor and little or no lindane. Here we see one of the effects of the newer methodology. It is most unlikely that the pattern of residue contamination has changed during the past four years. What is much more likely is that what we formerly thought was methoxychlor, as revealed by paper chromatography, now is chiefly lindane, clearly delineated by electron-capture gas chromatography; whereas, the incidence of methoxychlor is now shown to be quite low. More data are needed to confirm this hypothesis, but should it be borne out, we shall need to reappraise our approach to the control of these two pesticides.

These newer data also show the presence in milk and milk products of some of the more toxic chlorinated compounds, such as aldrin, dieldrin, endrin, and heptachlor epoxide. Fortunately, the data, to this point, indicate that the occurrence of these compounds in milk is not great and that the levels are extremely low. Food and Drug Administration is reporting dieldrin and others of this group in their monitoring of the country’s milk supplies, and they are keenly alert to the possibility that these may be a more serious problem than originally suspected. This situation bears close watching.

From these preliminary data, we can postulate, though cautiously, that progress has been made during the past four or five years. The combined educational programs by industry and federal and state regulatory groups have had salutary effects, even though much more needs to be done. There is a lower incidence of the chief contaminants of milk, i.e., the DDT group, and the levels are seemingly lower and apparently without hazard to health, according to the FDA total diet studies. There is some slight indication that perhaps less progress has been made in the Grade A areas.

Apparently, safer chemicals are being used in dairy barns and on animals. The approval by FDA of such compounds as DDVP and ciodrin, along with others, such as pyrethrins and piperonyl butoxide, are providing the dairy farmer more nearly with the pesticides he needs to control flies and other infestations. I think we can expect that better methods of applying pesticides to field crops will help further to minimize exposure to contamination from sources outside the control of dairy farmers.

*A plea for finite tolerances.* A fundamental and disturbing factor remains unchanged in the FDA policy of enforcing the pesticide amendment of the Food, Drug and Cosmetic Act with respect to dairy products. More important than compiling further data on inci-
dence and levels of pesticide contamination is the interpretation placed by the dairy industry on the facts we already have, and I have tried to present them here, with respect to enforcement of the law.

As previously mentioned, there is at present no FDA tolerance, published or finite, for pesticide residues in milk. The general premise of the Food, Drug and Cosmetic Act is that there shall be no poisonous or deleterious substances in milk or other food products. Therefore, in the absence of a published finite tolerance, the law technically must be enforced with respect to pesticide residues on the basis of zero.

Food and Drug Administration, under the law, has the authority to establish a finite tolerance for any one or all of the problem residues. This they have not done. Instead, they have followed a course of enforcement action based on a discretionary or administrative action level. This level is a variable thing and up to now has been set in accordance with the sensitivity of officially adopted analytical methods. This administrative action level therefore becomes, in a sense, a man-made zero, and levels of residues falling below this action level are regarded for enforcement purposes as being zero.

In contrast to this, an absolute zero tolerance is, although a pious goal, unrealistic and unworkable. Food and Drug Administration is fully aware of this, just as we are. Actually, the majority, if not all, of the milk supplies in this country contain some trace of residue. Thus, an administrative tolerance or action level, while proclaiming zero, actually conceals the presence of residues, under the sensitivity of an analytical method.

Use of the administrative action level circumvents publication of a tolerance and, thus, avoids outcry from fringe groups or criticism of FDA from the public relations point of view. However, in spite of this advantage, the administrative system has serious drawbacks. Methodology is improving rapidly. Already gas chromatography can now identify and quantify certain residues in milk in parts per billion. Therefore, under such a system enforcement must inevitably become stricter.

You will remember that in the fall of 1963 the action level for enforcement was cut in half, from 2.5 parts per million for DDT and analogues down to 1.25 ppm. Simultaneously, action levels were set for the first time for several of the more toxic pesticides at levels, respectively, of 0.01 ppm in the milk or .25 ppm fat basis. This change in action levels was accomplished by the simple expedient of a letter from FDA to the Legal Council for the Dairy Industry Committee who, in turn, communicated this information to the industry. Interestingly, the reason given in this letter for this reduction in level was that methodology was now available which would give reliable results at these lower levels.

In the absence of any finite tolerances whereby any detectable residues are violations of the law, and with methods continuously increasing in sensitivity, the question may well be raised, How can FDA refrain from lowering the action level further? It must be clear to all of us that this is a tenuous position for the industry.

We poignantly need a published finite tolerance independent of the sensitivity of analytical methods and based rather on considerations of public health, of product safety, and on the very practical aspect of preserving the availability in the American dietary of essential dairy foods.

True, the promulgation of such a finite tolerance would require publication, and there would be some outcry from people or parties who do not fully understand the situation. But, as has often been said, it is better to be punished early than to permit a situation to exist which will almost surely lead to stricter enforcement policies, seizures of dairy products in technical violation, with far worse resulting publicity.

How might we determine a satisfactory level for such a finite tolerance for the DDT group of pesticides? Let us consider the present action level of 1.25 ppm fat basis. Data from many laboratories, including FDA, indicate that this level probably is within reach of achievement by the industry, provided that a continuing, persistent program of education to dairymen is carried out.

Furthermore, in the recent World Health Organization—Food and Agricultural Organization report, the no-effect level for DDT in rats is 1 ppm, or 0.05 mg/kg over the lifetime of the animal. Applying a tenfold safety factor for the human, this no-effect level is postulated as 0.005 mg/kg. If we translate this into a practical example, a 4.5 kg-infant consuming 500 calories per day, of which 330 calories were from milk containing the full 1.25 ppm of residue, would ingest precisely this amount, i.e., the no-effect level for the human, applying the tenfold safety factor. Since the infant consumes far more milk per unit of body weight than does the human at any other age, 1.25 may, therefore, be a reasonable, safe level for such a finite tolerance.

Since DDT and its analogues constitute a
major part of the total residue problem in milk, this group of compounds could well be the first for which a petition to FDA for a finite tolerance could be filed. California has taken the initiative and filed such a petition. Then, as data develop with respect to the other problem residues, similar petitions could follow for FDA action, with full consideration of the incidence, levels, toxicity, and other factors related to the setting of an appropriate and justifiable tolerance for the respective compounds.

It is recognized, of course, that FDA can bring about modification of tolerances, whether these be administrative or published and finite, the important difference being that the former can be changed simply by notification; whereas, to change the latter entails publication and an opportunity for due consideration and negotiation. This, in our opinion, is essential protection for all parties affected—the public, FDA, and industry.

A challenge to the dairy industry. I urge all of you in industry, in universities, in government to be aware of and give effort to the resolution of this problem.

Why is it that milk is subjected to such scrutiny—such meticulous appraisal, when it comes to promulgating a tolerance for pesticide residues—particularly DDT, for which tolerances have been established on most all other basic agricultural products and at levels up to 100 times what we are suggesting?

Of course there is an answer to this. We recognize and are proud that milk holds a unique position in the food supply. It is the basic food of infants, it is used liberally in the diets of the aged and ill. It is consumed more frequently and in larger amounts by the total population than any other agricultural commodity. It deserves special consideration. The margins of safety should be greater, but not to the extent of excluding milk from the category of basic agricultural foods.

Have sentimental illusions of uniqueness or purity or both, isolated milk from a realistic common sense approach to the pesticide problem?

The law provides that, where the need is established, a tolerance shall be promulgated. This should be interpreted as a real tolerance—a finite level based on adequate considerations of safety—not a flexible zero based on methodology.

There is one real issue. Is there a finite level of a given pesticide in milk (DDT for a starter) which 1) is safe under prevailing patterns of milk consumption, and 2) is as low as achievable under the best commercial practices of which our industry is capable? If the answer to this question is yes, and I am sure it is, let us agree and try to achieve it.

References