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Opinion Article

An Assessment of the US and UN Safety Precautions for Pesticides in Milk by Labeling Medicine Alarm Strategy for all Dairy Animal Products

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Abstract

Concurrent outbreaks of diseases in ruminants have currently focused attentions on the significance of animal feed and human food contamination with mycotoxins in the induction of malignant diseases and cancer. Many data indicate that even very small quantities of pesticides are carcinogenic; however, to date no data clearly show that significant levels of these formulas are reaching the consuming public through milk. We believe at this time, we need additional toxicology studies with cows, particularly dealing with the reproductive cycle, to elucidate the effects of long-term ingestion of these compounds by the newborn and the aged and ill of the population. This paper is based solely on our opinion about the development of pesticides safety precautions in light of the American and US regulations where we noticed no conclusions are attempted on the public health significance of the published data at this time. The potential impact of this research could be advisable to the American Dairy Science Association, U. S. Department of Agriculture and the Food and Drug Administration, and many national authorities in the world. Our observations have showed a progress being made on the reduction of levels (not incidence) of pesticides of milk and milk products during the past few decades. This has been brought about through active educational and enforcement programs by federal and state regulatory agencies, together with educational efforts directed to dairymen and processors. Enforcement by prominent agencies as Federal Food and Drug Administration continues to be on a basis of administrative action levels. No finite tolerances have as yet been established for commonly occurring pesticide residues in dairy products. Therefore, this study is expected to report shortly recommendations to FDA on such enforcement policies.

Keywords: Safety Precautions; Pesticides; Chemical Industry; Health; Dairy

Study Opinion

The objectives of the Federal Food, Drug, and Cosmetic Act are to ensure a national food supply that is safe and wholesome as well as honestly and informatively labeled. At the time of its passage in 1938 the law stood as a landmark in modern-day food regulation. In the light of the tremendous technological developments and economic trends over the past 50 yr., it has been necessary to make major amendments in the law to prevent its becoming obsolete. Two such amendments were the Pesticide Amendment of 1954 and the Food Additives Amendment of 1958. Both were in recognition of the spectacular increase in the use of chemicals in national economies and to ensure that this use is surrounded by sufficient safeguards to protect the public health.

It has been stated that since 1939 till 2018, sales in the chemical industry have increased fivefold and that today the industry stands fourth in size among all the industries of the country. Hundreds of thousands of chemical entities produced, more than 10,000 of which are being manufactured for commercial use. Indeed, we are living in a chemist's world. To appreciate the validity of that statement one has only to view the magnitude of the problem of developing adequate analytical methods to detect a countless number of complex compounds in use today or proposed to be used in or on foods and to understand that the assurance of the safety of national food supply cannot be given without the problem's solution.

The research contributions of the drug and insecticide branches of the chemical industry have had a profound effect on world-wide health and economic gains. Outstanding among the drug achievements has

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been the discovery and mass production of penicillin. Notable among insecticide achievements was the discovery and mass production of DDT beginning in World War II. While the health and economic gains from these developments have been tremendous, this must not blind us to their potentialities for harm.

These useful chemicals are today presenting you and us with a major problem in insuring that they are properly used. The two governmental agencies primarily responsible for the proper and adequate labeling of these commodities to insure safe use are the U. S. Department of Agriculture and the Food and Drug Administration. The Food and Drug Administration and State and local authorities have the responsibility to deal with situations arising out of their misuse.

The U. S. Department of Agriculture enforces the Federal Insecticide, Fungicide, and Rodenticide Act of 1947. Labels for all economic poisons must be registered with the Department before they are shipped in interstate commerce. Following the directions for use on labels of pesticides thus registered should yield products without illegal residues. Dairymen and growers of agricultural commodities have one simple rule to follow-use pesticides according to label directions-on the crops or kinds of animals specified, in the amount specified, and at the times specified.

The Food and Drug Administration enforces tile labeling provisions of the Federal Food, Drug, and Cosmetic Act, which require, among other things, adequate directions for proper use and warnings against misuse in the labeling of drugs [1].

Accordingly, pesticides and drugs in interstate commerce coming into the hands of farmers and dairymen for their use contain the kind of label instructions and warnings that, if followed, will insure the production of an uncontaminated milk supply. Specifically, U. S. Department of Agriculture registered labels for DDT and other pesticide preparations warn against use of the chemical on or around dairy animals and against feeding treated forage to dairy animals. The labeling of penicillin preparations for the treatment of diseased dairy animals warns milk producers to reject milk from such animals.

The Pesticide Amendment to the Federal Food, Drug, and Cosmetic Act will be 64 yr. old next month. The Food and Drug Administration has the responsibility for the establishment and enforcement of tolerance regulations promulgated under its authority. During these 64 yr. more than 21,000 tolerances or exemptions from the requirement of tolerances have been established for more than 100 pesticide chemicals. A considerable number of petitions were not favorably acted upon, since it was found upon review that scientific data were not available to support a conclusion of safety of the tolerances or exemptions requested.

A basic part of a pesticide tolerance petition for consideration is full reports of investigations made with respect to the safety of the pesticide chemical. In the event the petition requests or the Secretary of Health, Education, and Welfare deems necessary, the petition and other data before the Secretary may be referred to an advisory committee for a report and recommendation on the proposal in the petition.

The amendment requires that the petitioner describe the analytical methods by which determinations of reported residues were made. Before we can conclude that a tolerance will be safe we must make certain that we have a means for enforcing it. We think it would be poor public health policy to make a rule allowing toxic materials to be used in foods in safe amounts and not have any mechanics for checking upon the quantities present to make certain they do not exceed the safe levels.

As part of our review of the methods described in the petition for determination of residues of the pesticide, we wish, in most cases, to try out the methods in our own laboratories. As more tolerances are established to permit an increasing number of pesticide chemicals on food crops, the problem becomes more difficult, because we must be able to determine residues of each new pesticide chemical not only in the presence of interfering plant extractives but also in the presence of other pesticide chemicals which may legally be present on the same crop.

During the past year more emphasis has been placed upon methods try-out and more attention is being given to the specificity of the methods to identify and measure residues at tolerance levels. New tools and techniques are continually being added to the armament of the chemist, and solutions to the extremely difficult problems in the determination of pesticide residues are being worked out.

Some time ago a scientific advisory committee was appointed to study a proposal that residues of methoxychlor not to exceed 0.25 p.p.m, be permitted in milk. Methoxychlor was being proposed as a pesticide for use on dairy animals and it was contemplated that milk residues would result there from. After a study of the available data the scientists recommended against the proposal. The committee felt that in view of the importance of milk in the diet a greater margin of safety must be established in fixing a tolerance for pesticides in milk than would be the case for any other food in the human diet.

Since the days around the year 1906, when formaldehyde was used to preserve milk, it has been the consistent policy of food and health officials generally to oppose the addition, in any amount, of poisonous or deleterious substances to milk. This philosophy still prevails in the current century. However, if additional research should show that there is a reasonable basis to propose a tolerance for pesticide residues in milk which would not endanger the public health, the Food and Drug Administration is required by law to give it consideration. If a proposal was made for a specific level of a particular pesticide in milk and if the proposal was supported by compelling evidence of safety, the Food and Drug Administration, under the law, would have no alternative to establishing a tolerance.

Since there is now no legal tolerance for any pesticide residue in milk, the interstate shipment of milk containing such a residue is illegal under the Act and the milk itself is subject to seizure. Inasmuch as milk contaminated with pesticides is illegal, contaminated products processed from it are illegal.

Likewise, residues of antibiotics, in any amount, in milk are illegal. Such residues result from a failure, through ignorance or through deliberation, to reject milk from treated animals for recommended periods after treatment. What are the public health implications of antibiotics in milk? Some time ago the Food and Drug Administration asked a group of outstanding experts in the field of antibiotics to study the question. It was their conclusion that while there should be no antibiotics in milk, penicillin presents the major health problem. It was concluded that allergic reactions ranging from mild to fatal may occur to particularly sensitive persons from drinking milk contaminated with penicillin.

We are not unmindful of the rumors of the addition of penicillin to milk to lower bacterial counts. There are also reports, thus far unconfirmed, of the addition of penicillinase to milk so that the milk wilt not show a positive test for penicillin [2]. Since it is a protein the likelihood of allergic reaction must be anticipated. Anaphylactic type allergic reactions have been attributed to penicillinase. The addition of this enzyme to milk constitutes the addition of a food additive for which there is no sanction under the law. Consequently, such a practice is illegal and if encountered will be dealt with just as promptly and forthrightly as we would expect to deal with the direct addition of penicillin to milk for the reduction of bacteria count. Aside from the matter of the penicillin and penicillinase residues making milk illegal, we should point out that the Act also outlaws milk from sick animals; therefore, chemically contaminated milk from treated cows has two counts against it under the law.

Any question concerning direct additives to fluid milk or processed dairy products must be approached under the provisions of the Food Additives Amendment. This Amendment was enacted September 6, 1958, and became fully effective March 6, 1960. Its passage followed a period of years in which extensive consideration had been given by the U.S. Congress to the need for better consumer protection in this area. Basically, it has shifted the responsibility for determining the safety of food ingredients to those who propose to market and use them, and requires that the determination be reached before ingredients of unknown or unrecognized safety may be used. It provided authority to administratively extend the effective date of March 6, 1960, in individual cases up to 1 yr., in order to be applied later on in the novel century. On the basis of a finding on any proposal that it would involve no undue risk to the public health and that conditions exist which necessitate the prescribing of such an additional period.

A large number of additives through official publications [3,4] have been generally recognized as safe and, hence, not subject to the amendment. Also, extensions have been granted a considerable number of others, permitting their continued use to March, 2020, or until a regulation on its issued, whichever is sooner. How do all these developments affect the dairy industry? First of all, we should consider that there are legal standards of identity for butter and for more than 60 cheese and cheese products in which unauthorized ingredients, irrespective of any question of safety, may not be legally used. We hope, incidentally, it is safe to again predict there will be a standard for ice cream soon.

If and when proposals are made for the amendment of an identity standard or the promulgation of a new one any additive proposed to be used will have to first meet the test of the Food Additives Amendment before it can be considered for use in the standardized product.

The important question for the dairy products manufacturer to decide is whether any substance being added either directly by him or indirectly through an intermediate, to his product is a food additive. If not, then obviously he is not concerned with this Amendment. In addition, if what he adds is generally recognized as safe then he still need not be concerned with this Amendment. But if he is adding substances directly to his product, or if substances are being added indirectly, which are not generally recognized as safe, and are not covered by prior sanctions, then he is concerned.

We have received a great many inquiries about how guaranty protection can be obtained to avoid responsibility for using an additive which has not had appropriate safety clearance. We have concluded that under a precedent court decision a food processor cannot protect himself from responsibility of complying with the law by obtaining a guaranty from the supplier of the chemical he is using. The guaranty would go only to the additive itself and not to the finished processed food. It seems prudent, however, for the food manufacturer to request assurance from his supplier that he has complied with the Food Additives Amendment. Your chemical or packaging supplier should be able to tell you whether the materials used by them are or are not on the approved lists. If you should obtain a guaranty from your supplier and later ship food which is adulterated by a food additive, your obtaining the guaranty would be taken into account by us in deciding whether to recommend criminal prosecution, even though the guaranty itself would not be lawfully binding on the Administration.

Having defined the problem of milk contaminated with pesticides and antibiotics, how have we approached it to bring about correction? First, believing that the educational approach is a basic part of a sound regulatory program, we spent a considerable amount of time and effort in studying the Extension Service of the U. S. Department of Agriculture, dairy associations, state people experiences in the past 100 years, and others in a wide-spread campaign aimed at the education of the dairy farmer in the proper use of pesticides and drugs and the implications arising out of their misuse. We have just issued a flyer to this effect and various dairy industry groups are distributing it to milk stations to send to patrons with their milk cheeks.

Many efforts have been exploited to amend drug regulations to call for better, more informative labeling of antibiotic preparations. Further amendments are in process to clear up questions that have arisen on injectables. We made several surveys to determine the incidence of these contaminants in milk to measure as best we could the results of our efforts. The last one in 2017 (unpublished work) showed a significant percentage of the samples examined to contain residues, thus reflecting that our efforts had not been wholly successful. We then proceeded to develop a new and quicker test for antibiotics. We organized and conducted a number of schools to teach antibiotic and pesticide methods to cooperating officials and industry representatives. We are aware that nowadays officials are stepping up certain activities in the examination of feeds for illegal residues of pesticides.

We noticed that the U. S. Department of Agriculture, State authorities, and many international authorities have warned about the danger of feeding agricultural by-products or crop wastes such as apple pomace, pea vine silage, trimming and stripping from produce crops to dairy cows. Seizure has been made on some of these high residue articles shipped in interstate commerce. We have repeatedly emphasized in many public statements that the production, acceptance, and shipping of contaminated milk is illegal and can lead to serious trouble.

How do you and we convince all concerned this is so? As a regulatory agency, once we have carried out what appears to be a sound educational program and our surveys show there is still a problem, we have left only the remedy of the application of the sanctions provided by the law. It is unfortunate but true that this step seems just as basic to a program to bring about compliance as does the educational approach. They go hand in hand one without the other will not be successful.

The Pesticide and Food Additive Amendments, like the rest of the Federal Food, Drug, and Cosmetic Act, call for investigational and enforcement policies consistent with the way we have gone about administering the other sections of the law over the years. So we are now engaged in a regulatory program that has brought some seizures of butter and evaporated and condensed milk because of their contamination with pesticides.

There have been no regulatory actions against milk or milk products contaminated with antibiotics. All reports from industry, State officials, and our own field people are very encouraging about the progress that has been made here. This is not to say that there should be any lessening of your efforts to inform and educate those who are responsible for the proper use of antibiotic preparations.

There is still much to be done in this whole area and primarily the program, if it is to be really successful, has to be one of education and self-policing with prevention your goal not correction by the regulatory official.

You, as a responsible scientific group in the dairy industry, stand in a unique position to render an important public service in such a program.

We think the practical value of every social invention or material discovery depends upon its being adequately interpreted to the masses. Besides, the future of scientific progress depends as much on the interpretive mind as it does upon the creative mind. The interpreter stands between the layman, whose knowledge of all things is indefinite and the scientist whose knowledge about one thing is authoritative. The scientist advances knowledge. The interpreter advances progress. History affords abundant evidence that civilization has advanced in direct ratio to the efficiency with which the thought of the thinkers has been translated into the language of the masses.

Who can better serve as interpreters in this present climate to bridge the gap between the scientific fraternity and the dairy industry in this tremendously important field than the membership of this Association? It is most gratifying

and noteworthy to see in the June, 2018, issues of journals, the establishment of a new section could entitle Interpretive Summaries of Papers, reflecting your recognition of an opportunity for public service.

Conclusion

Consequently, there is no simple, short-term cure for our mutual problem. We have much hard work ahead of us. The Food and Drug Administration pledges reasonable enforcement approaches and policies consistent with the broad objectives of the law. We solicit your continued support in the attainment of those goals so important to the consumer and your industry.

References

1. Aljerf L (2017) Syrian medical legislation impacts stories on pharmacy in the millennium. Chronicles of Pharmaceutical Science 1(5): 307-311.
2. Ismail F, Adeloju SB (2015) Comparison of single layer and bilayer biosensors based on crosslinking of penicillinase for potentiometric detection of penicillin in milk and antibiotics. Electroanalysis 27(6): 1523-1531.
3. Fardet A, Rock E (2017) In vitro and in vivo antioxidant potential of milks, yoghurts, fermented milks and cheeses: a narrative review of evidence. Nutrition Research Reviews 1-19.
4. Martínez-López B, Gontard N, Peyron S (2017) Worst case prediction of additives migration from polystyrene for food safety purposes: a model update. Food Additives & Contaminants: Part A 35(3): 563-576.