THE DEVELOPMENT OF MICROBIOLOGICAL STANDARDS FOR FOODS

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In recent years, there have been many reports on microbiological standards for foods and their significance (1, 3, 7, 9, 10, 13, 14, 15, 16, 17). The topic has prompted a certain degree of controversy and arguments for and against such standards. All authors have indicated that microbiological standards should be applied with great caution. Microbiological standards have been proposed to measure the following attributes of a food: (a) the sanitary conditions under which the food was processed, (b) the keeping quality, and (c) the presence or absence of pathogens or other organisms that may indicate the presence of pathogens.

ADVANTAGES OF STANDARDS

Though the pros and cons of microbiological standards in measuring these attributes have been extensively presented (2, 5, 8, 11), it is useful to review briefly some of these arguments. The proponents for microbiological standards for foods have presented the following points:

1. It has been shown, through experience, that as soon as microbiological standards are issued (even on an arbitrary basis), there is an improvement in the microbiological status of the food to which the standards have been applied. The establishment of standards has stimulated improvements in plant sanitation and quality control. Standards supplement programs of plant inspection and promote comprehensive sanitation programs.

2. Defects in the plant may be missed in a physical inspection of the food establishment. These defects may be uncovered in a bacteriological examination of some type related to raw or finished products or to food handling equipment.

3. Microbiological tests can serve as the final check on sanitation of the food and the food process.

4. While low bacterial counts do not guarantee the safety of the food, the presumption of safety is on the side of foods that are consistently within established microbiological standards. Hobbs (12) has noted that, generally, those foods suspected of causing food poisoning have counts of greater than one million per g, and usually greater than 10 million per g. Bacterial counts for the majority of normal food stuffs are approximately 100,000 per g or less.

5. Low bacterial counts in certain foods are attainable.

6. Microbiological standards can serve as indicators of keeping quality. It has been demonstrated that low bacterial counts will enhance shelf life, and that the bacterial count may reflect the degree of decomposition of a food. However, in order for a standard to be meaningful, relative to keeping quality, it must take into account specific types of organisms which will spoil the particular food, and the specific conditions of storage that prevail.

7. Standards are especially useful in the control of foods which are manufactured at a distance, and over which the regulatory authority has no opportunity of control through physical plant inspection.

LIMITATIONS OF STANDARDS

The objections to microbiological standards for foods are based on the following arguments:

1. The establishment of a numerical microbiological standard may be arbitrary and more or less dependent on a loose correlation with some other factors. Therefore, the standard may be unrelated to the sanitation status of the food.

2. There are defects in bacteriological tests. Present methods of sampling and analyses of foods are inadequate. There are statistical inconsistencies in the sampling of foods and bacteriological procedures for foods are not uniform or well established. Laboratory results may not be reproducible and many more samples than are usually collected are needed for drawing inferences which are statistically significant.

3. There can not be any universal microbiological standard for all foods, and a separate standard must be arrived at for each food or class of food. In addition, microbiological standards may not be feasible for many types of foods.

4. Various processing phases and storage phases that the foods undergo influence the viable count. If only the final phase of the food chain is tested, insanitary handling before heat treatment or other bactericidal processing may be covered up. A food which has been handled poorly in the initial phases of production may be given a final treatment that will permit it to meet a bacteriological standard.

5. The food is usually taken off the market or consumed before the bacteriological tests are completed, therefore, the tests have only retrospective significance.

Development of Food Standards

6. Microbiological standards will be expensive and difficult to administer and may not find acceptance in the courts of law.

If the list of advantages and objections is examined, it is found that they fall into these classifications:

1. Scientific or theoretical validity—are the standards based on verified data?
2. Technical—are standards technically feasible?
3. Administrative—can standards be employed in a regulatory food program?
4. Legal—will standards have legal acceptance?

Scientific Validity

The first premise to examine is the basic question of standards in environmental health rather than microbiological standards for foods. Standards have existed in environmental health for many years and over the years have been supported by some and rejected by others.

Environmental health standards should be related to the enhancement of the public health. However, there are great differences between the objectives of various standards. Some of the existing standards in environmental health are concerned with insuring the elements of simple survival, such as limits of concentration of toxic gases. Others are concerned with the prevention of disease, such as water quality standards. Others are concerned with maintaining a favorable environment for man, such as light intensity standards, and some are concerned with the maintenance of comfort.

The key problem in the establishment of standards is to meet the tests of soundness and objectivity whether the standards are for pollutants in air, microbiological quality of foods, radiation exposure, or chemicals in water. Of the hundreds of quantitative standards that already exist in the area of public health, how many can meet these rigid tests? Shuval (18) has raised some basic questions relative to the establishment of quantitative standards. These questions are:

- Do the standards have a scientific basis?
- Can the standards be justified as necessary for the protection of public health?
- Are there other conditions operative in addition to scientific validity and public health necessity?
- Are standards overly rigid?
- Have the standards been influenced by political or economic considerations or by local factors?
- Can standards be kept up-to-date in the light of an advancing technology or are they continually doomed to obsolescence?

Therefore, any discussion of standards raises problems beyond those related to science and technology. The establishment of standards raises questions relative to philosophy and morality, strategy and tactics, and economics and law.

Technical Problems

Leaving the realm of theory and descending into the "every day world," we are still confronted with some very basic technical problems relating to the implementation of microbiological standards. For instance, one of the most difficult and controversial areas in the establishment of microbiological standards concerns the role of indicators of fecal contamination. Tests based upon the detection of fecal indicators of sanitation have serious limitations (5, 6, 23). Tests for the detection of potential pathogens should not be used in the routine testing of foods, but should be limited to exploratory surveys of new and existing food products to assess their potential as sources of food-borne disease.

Other technical problems are related to improvement and clarification of standard laboratory methodology, including methods of collecting samples, size of samples, statistics of sampling, culture media, incubation temperatures, and quantitative detection of pathogens or indicator organisms of demonstrated sanitary significance.

The main purpose of a microbiological standard is to give information relative to the sanitary conditions, practices, and processes in the plant; and to the likelihood that the food may or may not present a health hazard. In order to do this, the development of a microbiological standard must be based on an observed numerical count when the acceptable standards of sanitation specified in the code are followed. It is important that microbiological tests and standards not become a mere "numbers" game, rather, standards should be as objective and meaningful as possible. Standards are more likely to be objective if field inspection services are teamed with laboratory services to correlate and identify the sanitation factors, the food components and the particular food processes which influence the microbiological quality of a food at each stage.

Administrative Considerations

Environmental health standards do not arise of themselves. There must be a need for such standards, and this need must be successfully communicated to a competent governmental, or professional, or scientific organization so they will start on the arduous task of developing standards. The role and expectation of the program administrator is critical to the development of standards in environmental health. On one hand, the administrator operates
within a wide area of discretion. On the other hand, legislative bodies, courts, and administrators have been interested in clearly defined quantitative limits in order to have a greater uniformity in the administration and interpretation of public health laws. It has been suggested that the development of objectivity in standards will result in less need for dependence on individual determinations and subjective judgments. Some administrators have looked to microbiological standards as authoritative guides that may substitute for professional judgment and thus relieve them of troublesome decisions. Wolman (24) has said that many administrators are searching for mathematical certainty in the solution of complex problems related to the environment, despite the fact that there is a high degree of uncertainty in the underlying scientific principles that are involved in establishing such standards. Such administrators hope that they will be able to solve these problems by some formula which has universal applicability. This, of course, is a delusion since there will always be the need for continued use of sound professional judgment based on experience and understanding in the application of standards.

LEGAL

If and when microbiological standards for foods come into wide use, we can expect that they will be tested in the courts. Tobey (22) notes that although the courts have been liberal in upholding all reasonable regulations on milk and food, the judiciary has also recognized the existence of certain constitutional limitations upon the scope and extent of such control, especially when the legal rights of individuals under the federal and state constitutions have been or are likely to be infringed. Tobey (22) notes that "... the health officer who confiscates and destroys private property such as milk in a summary manner must be able to prove the impurity of the milk in a court of action, should it arise ... . Similar precautions must be observed by health officers in taking samples of milk and milk products for analysis. Where, for example, only one of twenty cans of milk was tested in a supply which was to be commingled, it was held that there was insufficient evidence to convict." The established legal principles regarding state and municipal control of foods in general are the same as those set forth for dairy products.

Whether microbiological standards for various foods will be upheld in the courts will depend on their demonstrated objectivity, the lack of capriciousness, and the way they are applied by the regulatory agency. The latter is probably the determining factor. For instance, there is doubt whether standards can be used by regulatory agencies for the acceptance or rejection of food. This type of surveillance is more applicable for a continuous industry quality control program than for an official regulatory program, where the sampling is done on an intermittent basis and extremely small numbers of samples are taken. An exception to this may be made in those cases where the processing plant is beyond the control of the regulatory authority and when sampling constitutes the only method of gathering information on the safety and quality of the food. In this instance, greater use should be made of reciprocal arrangements between departments, so that the regulatory agency receiving a food product may be informed of the results of sanitary inspections of the food plant made by the agency where the manufacturer is located. This inspection information in combination with bacteriological tests at the point of receiving the food would have validity.

DISCUSSION

There are a limited number of microbiological standards and criteria in current use (11). This insufficiency of explicit standards is reflected in the scope of present day laboratory programs in food sanitation. Referring specifically to local regulatory agencies, these laboratory services have been limited to the endless routine testing of milk and milk products and a few other foods, and the occasional investigation of a food borne disease outbreak.

When the administrator is confronted with a laboratory report showing a high bacterial count in a milk sample, he knows the course of action to take since there are well established standards. But what action does the administrator take when confronted with standard plate counts in foods such as ground beef, and chicken salad, which may run into the millions? To all intents and purposes these foods appeared to be wholesome and edible when sampled. Upon receiving the laboratory report, the administrator must make some interpretation as a guide to action. One cannot escape from standards and criteria, be they implicit or explicit. Standards and criteria are part of the decision making process in government.

Recognizing that local regulatory agency budgets do not allow for routine testing of all food that might warrant such sampling, the program administrator should increase the scope of food testing. However, there should be a change of emphasis from the routine testing of foods to field research and evaluation surveys of foods. Laboratory services in food bacteriology should be used as a diagnostic tool to collect information relative to acceptable processing techniques and potential hazards of a wide variety of foods rather than the continual and repetitive sampling of a few foods. A rational approach requires the correlation of plant inspection data with laboratory
data. Field studies of the sanitary conditions in food plants should be related to bacteriological findings. This has not always been the case in the derivation of microbiological standards for foods. For the most part, the regulatory microbiological standards in current use have been based either on arbitrary indices which have been established and modified through subsequent experience, or they have been arrived at retrospectively, based on performance studies of food products already on the market. This is not to say that standards derived in this way are not valid. It is not necessary to wait until all uncertainties are settled before microbiological standards are proposed and established. Legislative bodies, courts and administrators do not require perfect knowledge. However, what is required is the absence of capriciousness in the establishment and enforcement of standards. Confidence in the use of microbiological standards by regulatory agencies and by food industries will be proportionate to demonstrated objectivity of standards.

CONCLUSIONS

There is a need by administrators for microbiological standards for foods. The greater the objectivity of these standards, the more useful they will be. Standards should be developed only after a careful study of field conditions and through correlation of results of plant inspections with laboratory data. The approach in establishing microbiological standards should, therefore, be ecological and epidemiological. The ecological concept is one which studies the relation between living organisms and their environment; the epidemiological method is one which comprises an orderly approach to the study of causes and effects. Local regulatory agencies that combine field inspection services and laboratory services can do a great deal of field research to help arrive at objective standards.

The very nature of the food chain requires that there be close intergovernmental cooperation. No single level of government can muster enough resources to do a complete job of food protection.

Metropolitan health departments should conduct microbiological evaluations of foods for they are well situated to carry on this type of field activity. However, much of the data from these efforts will be lost unless there is a method for the information to be readily disseminated. To do this a suggested method is to have the major local health departments organize an information network so that these findings may be made available to each other. The Public Health Service could take a major role in establishing an information exchange or clearing house for information on microbiological standards for foods. At the same time, more use should be made of reciprocal arrangements and agreements between food protection agencies. A governmental unit receiving a food product could be informed of the results of food plant inspections made by the control agency where the manufacturer is located.

Standards will continue to be used by administrators of environmental health programs and use of microbiological standards for foods will increase. There have been misuses and abuses of such standards in the past. The future of microbiological standards will depend as much on the equitable and rational application by environmental health administrators as on the scientific validity of the standards.

REFERENCES

SELECTION OF A MEDIUM FOR THE ISOLATION AND ENUMERATION OF ENTEROCOCCI IN DAIRY PRODUCTS

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Ten media, commonly used for the detection and isolation of streptococci of sanitary significance in water, dairy and other food products, were compared to establish a plating medium for the enumeration of enterococci in dairy products. To make all media suitable for comparison by the agar plate method, agar was added to those media which initially were recommended for use as broths. Criteria used in selecting the medium were high recovery, selectivity but not undue inhibition of enterococci and ease in obtaining and interpreting results.

The recovery data of three different platings of enterococcus cultures were statistically analyzed. In this manner, one medium was eliminated on the basis of low recovery. Six of the remaining nine media were eliminated because they permitted the growth of non-enterococcus cultures. Two of the three media then remaining were eliminated because they allowed one S. hoores culture to grow. In addition, these media showed considerable variation in size and color of enterococcus colonies.

The medium selected, the Citrate azide medium of Reinbold, Swern and Hussong (13), was modified by increasing the azide concentration. This did not result in undue inhibitory effects. It was further tested by obtaining recovery data for 158 known enterococcus cultures. High selectivity was demonstrated by showing that 408 colonial isolates from plates of raw milk, cheese and butter could be identified as enterococci.

Coliform bacteria are widely used as indicator organisms for pollution in water, food and dairy products. Some investigators have proposed that the enterococcus group of bacteria could serve as a supplement or substitute for the same purpose. While coliforms may be isolated easily and confirmed by relatively simple bacteriological techniques, the multiplicity of detection procedures and poor agreement among various methods for the quantitative enumeration of enterococci present serious handicaps to their systematic study.

This study was undertaken to establish a plating medium which would be suitable for the detection and enumeration of enterococci in dairy products. Criteria used in selecting the medium were high recovery, selectivity but not inhibition of enterococci, and ease in obtaining and interpreting results.

Since the discovery of the suppression of growth of Gram-negative bacteria with sodium azide by Hartmann (6), many investigators have used this substance in media for the isolation of fecal streptococci. Thallous acetate also has been used for this purpose. White and Sherman (18) devised a medium, Penicillin azide agar, for the enumeration of enterococci from raw milk. They reported that the medium, although completely selective, partially inhibited the growth of *Streptococcus durans*. Studies on the reduction of tetrazolium by lactic acid bacteria have been made by many workers. Laxminarayan and Iya (9) compared the dye-reducing activities of dif-