THE DEVELOPMENT AND EVALUATION OF MICROBIOLOGICAL STANDARDS FOR FOODS

JOHN H. B. CHRISTIAN
CSIRO Division of Food Research
North Ryde, NSW, Australia

ABSTRACT

Major requirements in establishing microbiological standards for foods are to avoid unnecessary standards and to make the necessary standards meaningful. Careful consideration of the Codex Alimentarius "General principles for the establishment and application of microbiological criteria for foods" will help to avoid unnecessary standards. The establishment of meaningful criteria requires a clear understanding of what aspects of microbiological quality are to be controlled. It is also essential that the requirements of potential customers are taken into account. Extensive and appropriate data must be obtained on the microbiology of the food produced under conditions of good manufacturing practice. Evaluation of standards requires constant monitoring of microbiological data. The microbiology of a food is greatly influenced by manufacturing processes and standards may have to be revised if a process is altered. Conflicting assessments of food against the same standard may indicate a need for more suitable methods. The application of microbiological standards is expensive. Standards should therefore be few and effective.

The development of microbiological standards for foods springs from a natural desire to ensure the microbiological safety and quality of our food supply. However, the achievement of practical and effective standards is difficult. Bad standards are very easy to set, but the application of any standard is expensive and for a bad standard it will be particularly so. Bad standards do not give an acceptable cost benefit — they cost too much for what little they may achieve.

The failings apparent in bad standards include:

(a) Irrelevance in respect of the food — where there is no practical microbiological hazard posed by the food in relation to either safety or quality.

(b) Irrelevance in respect of the microorganism — when the organism that is monitored for the standard is not a problem in the food, e.g. because it does not grow in it, or because it is destroyed in the process.

(c) Impractical to monitor a hazard microbiologically, e.g. routine examination of heat-processed canned foods for Clostridium botulinum.

(d) Imprecise or meaningless, e.g. the traditional standard for many foods "pathogens shall be absent". One can neither test for all pathogens nor ensure absence.

The Development And Evaluation Of Microbiological Standards For Foods

How then do we avoid bad standards and develop good ones? The Codex Alimentarius Commission responded to this problem by developing "General Principles for the Establishment and Application of Microbiological Criteria for Foods", criteria covering standards, specifications and guidelines. Although tailored to the needs of the Codex Alimentarius, these principles can be modified to assist in the development of criteria for other purposes. Standards are, of course, mandatory criteria which may stand alone, without being part of Codes of Good Manufacturing Practice (GMP), Codes of Hygienic Practice, or commercial agreements. In this paper our main concern is with standards for foods in international trade.

The General Principles list a number of general considerations which must be explored at the beginning of the standard-setting exercise. The main one is that a definite need for a standard must be established. This is best provided by epidemiological data indicating that the product has been a significant hazard to health or that it is particularly prone to microbial attack and deterioration. Such evidence will not exist for a new product or process, in which case the potential to cause microbiological problems must be assessed. This is done by examination of the product and consideration of the factors that will influence microbial growth or death in the product. When this substitute for epidemiological data must be depended upon, re-evaluation is essential, as will be discussed later.

Establishing a need will usually also establish which are the microorganisms of concern. An examination of the raw materials for the presence of such organisms is appropriate and of the process for its effects on those organisms. Even though GMP may be adhered to, the use of raw materials with different microbial loads or of differing processes can give different microbial profiles in the final product. Thus shrimps and prawns from different regions may have quite different aerobic plate counts after cooking. Similarly the incidence of salmonelae on poultry carcasses will to a large extent reflect the Salmonella status of the live birds. The nature of the microorganisms of concern can be influenced also by geography or by national practices. Thus Vibrio parahaemolyticus is most likely to cause problems in seafoods from tropical and subtropical waters and from temperature waters in the summertime. Salmonelae are unlikely to be a hazard even in improperly fermented sausage where a heat treatment is employed to destroy trichinelae in pork.

The risks of post-processing contamination and growth must also be considered. The standard should be technically attainable by GMP so that it does not encourage the use of objectionable treatments in attempts to reduce microorganisms to the level demanded.

Most important is consideration of the category of consumers for whom the food is intended — are they an average, relatively health population, or are they a sensitive group that includes the very young, the very old, or the ill or debilitated?

Cost-benefit aspects have already been mentioned. They represent important and difficult considerations in the setting of standards.

Coming now to the components of the standard itself, the General Principles state that a microbiological criterion for a particular food should consist of:

1. a statement of the microorganisms and parasites of concern, and/or their toxins;
2. the appropriate analytical methods;
3. a plan defining the number of samples to be taken, the size of the sample unit and other sampling details;
(4) the microbiological limits appropriate to the food, and

(5) the number of sample units that should conform to these limits.

The microorganisms included in a standard should be widely accepted as relevant — as pathogens, as indicator organisms or as spoilage organisms — to the particular food and technology. Organisms whose significance in the food is in doubt should not be included. The mere finding, with a presence-absence test, of certain organisms known to cause food-borne illness, such as *Staphylococcus aureus*, *Clostridium perfringens* and *Vibrio parahaemolyticus*, does not necessarily indicate a health hazard. Numbers are most important.

Indicator organisms may be sought as indicating either unsatisfactory manufacturing practice or the presence of a pathogen — particularly one which cannot readily be estimated directly, such as a virus. Pathogens should always be tested for directly when this is practicable.

There is often difficulty in deciding how many microorganisms (or groups) should be included in a standard. Examples of differences of opinion abound. National standards for several foods (as at 1974) are listed in Annex IV of FAO/WHO (1975). For dried milk one country, Country A, advocated four tests and Country B one, while for precooked frozen shrimps and prawns the situation was reversed — Country A listed one test and Country B seven. This presumably reflects national concern based on experience. Another observation is that some countries consistently prescribe more tests in their criteria than do others.

Just how many tests are necessary can be difficult to reach agreement on — there are cases where the inclusion of one test in a standard has been argued for years. However there are two clear penalties for including too many tests — it is uneconomic to apply more tests with no increase in assurance of safety or quality, and elaborate or extensive testing procedures are likely to be applied less frequently than relatively simple ones. *This will result in less cost, but also in less benefit.*

The appropriate analytical methods, which should be stated in the standard, must be standard methods that have been subjected to wide testing and that are in general use. It can be most important for the standard methods to be used in collecting data on which numerical limits in a standard are to be based.

As one cannot test an entire consignment of food, a sampling plan is essential. This has to take account of both the distribution of microorganisms in foods and the variability associated with microbiological methods — testing only one sample from a lot of food is simply not good enough. Consideration of those aspects gave rise to 2- and 3-class attributes sampling plans. These are of particular relevance for examining food-stuffs in international trade, where very little may be known, at port of entry, of the treatments the food has received or of the distribution of microorganisms within any particular consignment.

In these attributes sampling plans, the number of samples to be tested is chosen and reflects the hazard posed by the particular organism in the particular food. For indicator and total plate counts, 3-class plans are generally used in which there are four factors: “n”, the number of samples to be examined, “m”, an acceptable count, with values above it being marginally acceptable or unacceptable, “M”, the count separating marginally acceptable from unacceptable, and “c”, the number of samples which may exceed m. None may exceed M. The 2-class plan provides presence and absence criteria most commonly for pathogens such as salmonellae. In such plans, n, c and m are used,
with \( m \) being a value below which the sample is acceptable and above which it is not. Typical sampling plans are as follows:

A 3-class attributes sampling plan for aerobic plate count
\[
\begin{align*}
  n &= 5, \quad c = 1, \quad m = 10^5, \quad M = 10^6
\end{align*}
\]
A 2-class attributes sampling plan for Salmonella
\[
\begin{align*}
  n &= 10, \quad c = 0, \quad m = 0
\end{align*}
\]

Such sampling plans are to be applied to the testing of each lot. A particularly important provision is that the number of samples tested shall be as stated in the sampling plan and shall not be exceeded. Thus a lot which passed the Salmonella test in the example (not detected in ten samples), might fail if 20 samples were tested. This, however, would not be a “standard”, because the conditions of testing had been changed. Similarly, the size of the analytical samples, the amount actually cultured, must be standardized. For Salmonella testing the sample size, which should be stated in the standard, is usually 2.5 g.

With respect to the microbial limits, there is no fixed relationship between \( m \) and \( M \). In general, \( m \) values should be based on data obtained for foods produced under conditions of GMP and \( M \) values on expert opinion as to the acceptable upper limit. The stringency of a standard derives from the values given to \( n \) and \( c \), a standard being made more severe by increasing \( n \) or by decreasing \( c \). In an attempt to systematize the use of \( n \) and \( c \), the International Commission on Microbiological Specifications for Foods (ICMSF) has developed the concept of Case as it relates to microbiological testing of foods. This takes into account, when setting these two values, both the degree of hazard represented by the organism for which the test is devised and the influence of future likely treatment of the food on that hazard (ICMSF, 1974).

If a food fails to meet such a standard, it is important to have in the standard guidance as to the fate of such food. The options may include sorting, reprocessing and destruction.

A final requirement of the General Principles is that criteria should be reviewed and, if necessary, revised at three-year intervals. This brings us to the evaluation of standards.

A first consideration is whether the food concerned has proved to cause less problems since introduction of the standard. If not, has the standard been applied? If it has not been applied, why? Are the tests too slow, too difficult or too expensive?

Many foods rarely cause problems, yet history has shown that they have been hazardous in the past. If no problems have arisen since a standard was applied, a revision is still necessary, on economic grounds, to check on the severity of the standard. If no sample has failed the standard, is it serving any useful purpose? Should it be tightened or removed? If a very high proportion of samples fail, say 10 per cent, is the standard too strict, causing unacceptable economic loss and a waste of good food, or are the process and the manufacturing practices incapable of producing an acceptable food?

To answer such questions, large amounts of reliable data are generally essential. With international standards, this means data from most of all countries exporting the product. It is highly desirable that these data be derived from application of the standard being evaluated, following it in every detail of sampling plan and methodology. It is difficult to make valid comparisons of data obtained with different sampling plans.

An opportunity to observe how recommended criteria may change as a result of experience is provided by the current revision of the book “Microbiology of Foods 2. Sampling for microbiological analysis: Principles and specific applications” (ICMSF,
1974). The revised edition should be published late in 1985. The sampling plans and limits for seafoods have been simplified by consolidating eleven categories and subcategories into six. *Escherichia coli* limits, using recently-developed membrane techniques, have replaced Most Probable Number (MPN) limits for fecal coliforms, with appropriate small adjustments of $m$ and $M$ values. Tests for *Staphylococcus aureus* are now optional except for cooked crustaceans.

Criteria for *Salmonella* contamination of raw meat and poultry have been deleted, because no meaningful criterion could be met using currently acceptable technology. In criteria for dried milk, *Salmonella* has replaced *Staphylococcus aureus*, in response to epidemiological trends since the first edition was prepared. For both egg and milk products, *Salmonella* criteria have been expanded to take account not only of likely subsequent handling practices but also the sensitivity of the likely consumers.

Having discussed the development of microbiological standards, it must be emphasized that no practical system of examination can provide complete certainty that a desired bacteriological state has been attained. It can indicate this only with a particular degree of probability. In some cases this probability is barely adequate, e.g., in attempts to detect salmonellae. In others it would be totally inadequate, as in routine testing for *Clostridium botulinum* in canned foods. A much better assurance of microbiological acceptability is achieved by control of microbiological hazards at source.

One method control at source is the Hazard Analysis Critical Control Point (HACCP) system (WHO/ICMSF, 1982). This consists of (a) an assessment of hazards associated with growing, harvesting, processing/manufacturing, distribution, marketing, preparation and/or use of a given raw material or food product; (b) determination of critical control points required to control any identified hazard(s); and (c) establishment of procedures to monitor critical control points. The HACCP system offers a more specific and critical approach to control of microbiological hazards than that achievable by traditional inspection and quality control procedures.

Briefly, hazard analysis involves an evaluation of all procedures concerned with production, distribution and use of raw materials and food products (a) to identify raw materials and foods that may contain poisonous substances, pathogens or large numbers of food spoilage organisms, and/or that can support microbial growth, (b) the find sources and specific points of contamination by observing each step in the food chain and (c) to determine the potential for microbes to survive or multiply during stages from production to preparation for consumption.

A Critical Control Point (CCP) is a location or a process which, if not correctly controlled, could lead to unacceptable contamination, survival, or growth of pathogens or spoilage organisms. Thus CCPs are points at which the hazards identified above can be contained. They may involve, for example, microbiological examination of raw materials, prevention of contamination, a heat process or a product formulation.

Monitoring is then necessary to ensure that the CCPs are really under control. This may be by visual inspection, or, more commonly, chemical, physical or microbiological testing.

The successful application of such a system reduces greatly, and may even eliminate, the need for microbiological testing of the end-product. When end-product testing is mandatory, e.g., examination of certain high-risk foods for *Salmonella*, or where foods in international trade will be tested for compliance with the standards we have discussed earlier, use of the HACCP system greatly increases assurance that the product is of the microbiological quality demanded.
References

