CHAPTER 11

Controlling the Microbiological Quality of Foods

In Chapter 10 we surveyed the different methods used in the microbiological examination of food and how these give us information about the size and composition of a food's microflora. We will now go on to describe how data obtained from such tests can be used to make decisions on microbiological quality and how accurate these judgements are likely to be. It will become apparent that reliance on this approach alone is an ineffective means of controlling quality so, finally, we will examine how best to ensure the production of consistently good microbiological quality products.

11.1 QUALITY AND CRITERIA

We all feel we know what is meant by quality and the difference between good quality and poor quality. One dictionary defines quality as the 'degree of excellence' possessed by a product, that is to say how good it is at serving its purpose. In terms of the microbiology of foods, quality comprises three aspects:

(1) *Safety*. A food must not contain levels of a pathogen or its toxin likely to cause illness when the food is consumed.
(2) *Acceptability/shelf-life*. A food must not contain levels of microorganisms sufficient to render it organoleptically spoiled in an unacceptably short time.
(3) *Consistency*. A food must be of consistent quality both with respect to safety and to shelf-life. The consumer will not accept products which display large batch-to-batch variations in shelf-life and is certainly not prepared to play Russian roulette with illness every time he or she eats a particular product.

Regulatory bodies and the food industry are the two groups most actively interested in determining and controlling the microbiological quality of foods. The regulatory authorities must do so to fulfil their statutory responsibility to protect the public from hazardous or inferior goods. The extent to which they intervene in food production and supply will depend of course upon the food laws of the country in which they operate. Commercial companies, both food producers and retailers, also have a major interest, since their association with products that are consistently good and safe will protect and enhance their good name and their market.

To distinguish food of acceptable quality from food of unacceptable quality requires the application of what are known as microbiological criteria. Three different types of microbiological criterion have been defined by The International Commission on Microbiological Specifications for Foods (ICMSF).

(1) A *microbiological standard* is a criterion specified in a law or regulation. It is a legal requirement that foods must meet and is enforceable by the appropriate regulatory agency.
(2) A *microbiological specification* is a criterion applied in commerce. It is a contractual condition of acceptance that is applied by a purchaser attempting to define the microbiological quality of a product or ingredient. Failure of the supplier to meet the specification will result in rejection of the batch or a lower price.
(3) A *microbiological guideline* is used to monitor the microbiological acceptability of a product or process. It differs from the standard and specification in that it is advisory rather than mandatory.

The ICMSF have also specified what should be included in a microbiological criterion as set out below:

(1) A statement of the food to which the criterion applies. Clearly foods differ in their origin, composition, and processing; will present different microbial habitats; and will therefore pose different spoilage and public health problems.
(2) A statement of the micro-organisms or toxins of concern. These may cover both spoilage and health aspects, but decisions on what to include must be realistic and based on a sound understanding of the microbial ecology of the food in question.
(3) Details of the analytical methods to be used to detect and quantify the micro-organisms/toxins. Preferred methods for standards or specifications would be those elaborated by international bodies, although less sensitive or less reproducible methods may be used for simplicity and speed in confirming compliance with guidelines.

(4) The number and size of samples to be taken from a batch of food or from a source of concern such as a point in a processing line.
(5) The microbiological limits appropriate to the product and the number of sample results which must conform with these limits for the product to be acceptable (*n*, *c*, *m*, and *M*, see Section 11.2). In this regard, it should be remembered that for certain food-borne pathogens such as *Staphylococcus aureus* or *Clostridium perfringens*, their mere presence does not necessarily indicate a hazard and specification of some numerical limits is necessary.

These last two points can present the greatest problem. In applying the microbiological criterion it is assumed that the analytical results obtained are an accurate reflection of the microbiological quality of the whole batch of food. How justified that extrapolation is will depend upon the accuracy and precison of the tests used and on how representative the samples were that were tested.

Micro-organisms are rarely distributed uniformly throughout a food, nor in fact are they usually distributed randomly. When micro-organisms are dispersed in a food material in the course of its production, some may die, some may be unable to grow and others may find themselves in microenvironments in which they can multiply. The resulting distribution, containing aggregates of cells, is described as a contagious distribution (Figure 11.1).

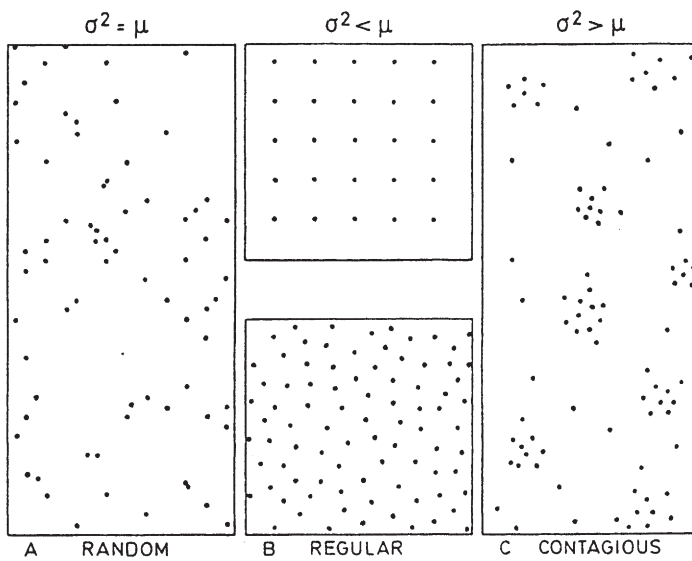

Figure 11.1 *Possible types of spatial distribution of micro-organisms in food* σ^2*, variance;* μ *mean*
(Reproduced with permission from Jarvis (1989))

As the number of samples tested increases, so does our confidence in the result but so too does the cost of testing. To be sure of the quality of the batch or lot we would have to test it all, but since microbiological testing is destructive, this would result in almost absolute confidence in the product quality but none left to sell. A compromise must therefore be struck between what is practicable and what gives the best estimate of lot quality.

11.2 SAMPLING SCHEMES

The sampling scheme most commonly applied in the microbiological testing of foods is that of sampling for attributes. It makes no assumption about the distribution of micro-organisms within the batch of food and is therefore particularly suited to situations where we have no knowledge of this; for example with imported foods at their port of entry.

11.2.1 Two-class Attributes Plans

In an attributes sampling scheme analytical results are assigned into classes; in the simplest type, the two-class scheme, samples are classified as acceptable or defective depending on the test result. A sample is described as defective if it is shown to contain more than a specified number of organisms or, in cases where a presence or absence test is applied, the target organism is detected.

A two-class sampling scheme is defined by three numbers:

n – the number of sample units to be tested;
m – the count above which the sample is regarded as defective. This term would not appear in schemes employing a presence/absence test since a positive result is sufficient for the sample to be defective;
c – the maximum allowable number of sample units which may exceed m before the lot is rejected.

Such schemes do not make full use of the numerical data obtained but simply classify sample units according to the test result. For example, if m is 10^4 cfu g^{-1}, those samples giving counts of 10^2, 9×10^3, and 1.2×10^4 would be considered acceptable, acceptable, and defective respectively, despite the fact that the first sample had a count almost 2 log cycles lower than the second and the difference in count between the second and third samples is relatively small.

Using this approach, results from a number of sample units can be classified according to the proportion defective and the frequency of occurrence of defective units described by a binomial distribution. If p represents the proportion of defective sample units in the whole lot, *i.e.* the probability of a single sample unit being defective, and q represents the proportion of acceptable units (the probability of a sample unit being

acceptable), then the probability distribution of the various possible outcomes is given by the expansion of the binomial:

$$(p+q)^n \tag{11.1}$$

Where n, the number of sample units examined, is small compared with the lot size.

Since, in a two-class plan, a sample can only be acceptable or defective then

$$p+q=1 \tag{11.2}$$

The probability that an event will occur x times out of n tests is given by:

$$P_{(x)} = (n!/(n-x)!\,x!)\,p^x q^{(n-x)} \tag{11.3}$$

or if we substitute $(1-p)$ for q:

$$P_{(x)} = (n!/(n-x)!\,x!)\,p^x(1-p)^{n-x} \tag{11.4}$$

If we have a sampling plan which does not permit any defective samples ($c=0$), then by putting $x=0$ into Equation (11.4) we obtain an expression for the probability of obtaining zero defective samples, *i.e.* the probability of accepting a lot containing a proportion p defective samples:

$$P_{acc} = (1-p)^n \tag{11.5}$$

It follows that the probability of rejection is:

$$P_{rej} = 1-(1-p)^n \tag{11.6}$$

We can use this equation to determine how effective such relatively simple sampling schemes are. For example, Table 11.1 shows how the frequency (probability) of finding a defective sample changes with the level of defectives in the lot as a whole and with the number of samples taken. This could apply to a *Salmonella*-testing scheme where detection of the organism in a single sample is sufficient for the whole lot to be rejected. If the incidence of *Salmonella* is 1% ($p=0.01$), a level

Table 11.1 *Acceptance and rejection thresholds in a sampling scheme*

Incidence of defectives[a] (%)	*No. of samples tested*					
	10		*20*		*100*	
	P_{acc}	P_{rej}	P_{acc}	P_{rej}	P_{acc}	P_{rej}
0.01	99.9	0.1	99.8	0.2	99.0	1.0
0.1	99.0	1.0	98.0	2.0	90.0	10.0
1	90.0	10.0	82.0	18.0	37.0	63.0
2	82.0	18.0	67.0	33.0	13.0	87.0
5	60.0	40.0	36.0	64.0	0.6	99.4
10	35.0	65.0	12.0	88.0	0.1	99.9

[a] *e.g.* Presence of *Salmonella* in a sample or surviving mesophiles in packs of an appertized food

corresponding to 40 positive 25 g samples in a lot of 1 tonne (4000×25g samples), then the lot would be accepted 90% of the time if 10 samples were tested on each occasion. When the number of samples taken at each testing is increased then the chances of rejection are increased, so that with 20 samples the lot would be accepted 82% of the time. If we went to testing 100 samples, we would accept the same lot only 37% of the time.

A statistically equivalent situation would be the testing of an appertized food for the presence of surviving organisms capable of spoiling the product, and where detection of one defective pack would mean rejection of the lot. Using Table 11.1 again, we can see that if there was a failure rate of one pack in a thousand ($p = 0.001$), even taking 100 packs for microbiological testing we would only reject a lot on one out of ten occasions. In fact we can calculate the number of packs it would be necessary to take in order to have a 95% probability of finding one defective sample ($P_{rej} = 0.95$). This is done simply by substituting in Equation (11.6) and solving for n. The answer, 2995, demonstrates why it is necessary to have alternatives to microbiological testing to control the quality of appertized foods.

The probabilities of acceptance or rejection associated with an attributes sampling plan can be calculated from the binomial distribution. For large batches of product these can also be represented graphically by what is known as an operating characteristic (OC) curve of the type shown in Figure 11.2. For each level of defectives in the lot, the probability of its acceptance or rejection using that plan can be read off the curve. Figure 11.3 demonstrates that as n increases for a given value of c, the stringency of the plan increases since a lot's overall quality must increase with n for it to have the same chance of being passed. If c is increased for a given value of n (Figure 11.4), so the plan becomes more lenient as lot quality can decrease but still retain the same chance of being accepted.

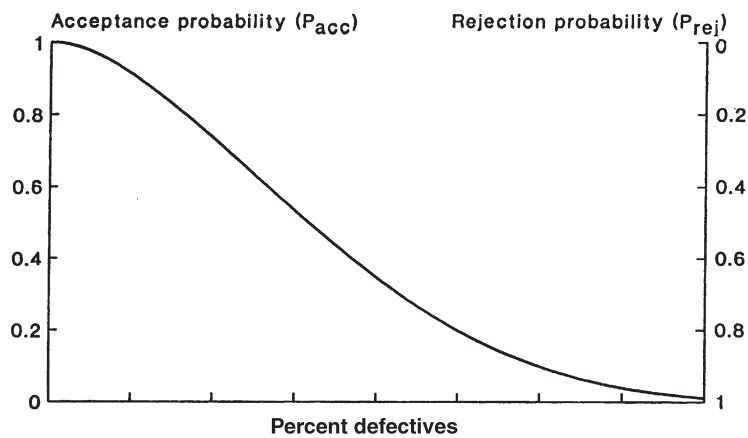

Figure 11.2 *An operating characteristic curve*

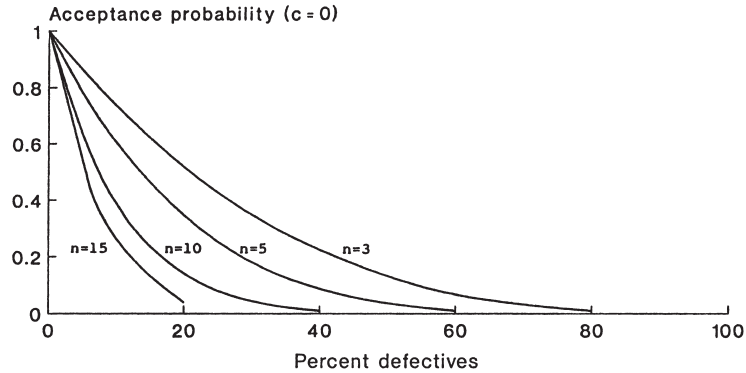

Figure 11.3 *Operating characteristic curves (increasing stringency).* c = *0,* n = *3, 5, 10, 15*

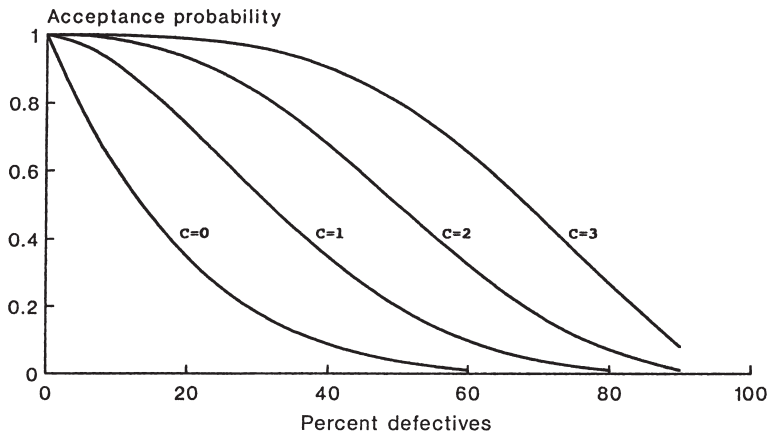

Figure 11.4 *Operating characteristic curves (decreasing stringency).* n = *5,* c = *0, 1, 2, 3*

The ideal OC curve would resemble Figure 11.5 with a vertical cut off at the maximum acceptable level of defectives. To achieve this would require testing an unacceptably high number of samples so the purchaser has to adopt a sampling plan which will accept lots defined as being of good quality most (*e.g.* 95%) of the time and has a high probability (*e.g.* 90%) of rejecting lots of poor quality (Figure 11.6). Two types of error are identifiable in this approach: the producer's risk that a lot of acceptable quality would be rejected (5%), and the consumer's or purchaser's risk that a lot of unacceptable quality would be accepted (10%). Lots of intermediate quality would be accepted at a frequency of between 10 and 95%.

11.2.2 Three-class Attributes Plans

Three-class attributes sampling plans introduce a further category and divide samples into three classes: acceptable, marginally acceptable, and

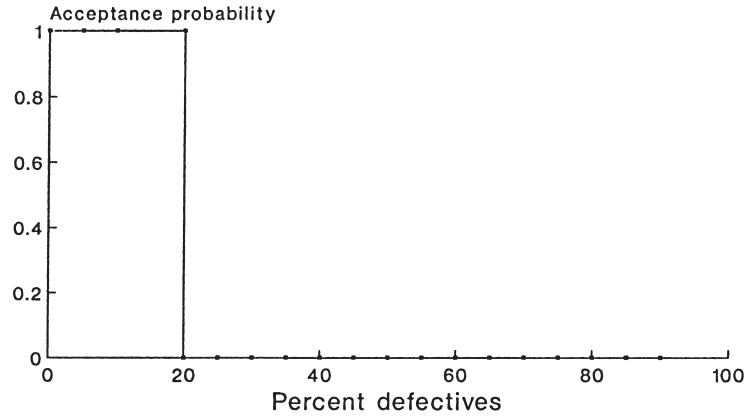

Figure 11.5 *An ideal operating characteristic curve*

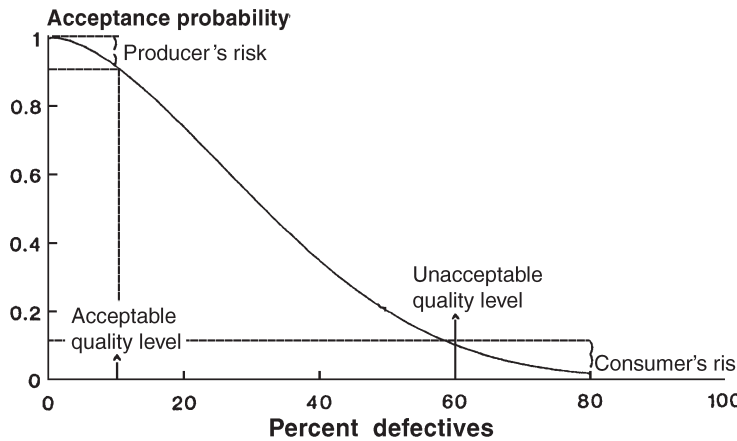

Figure 11.6 *Producer's and consumer's risk*

unacceptable. Use of this extra classification of marginally acceptable means that they are not used with presence or absence tests but only with microbiological count data. A three-class plan is defined by four numbers:

n – the number of samples to be taken from a lot;
M – a count which if exceeded by any of the test samples would lead to rejection of the lot;
m – a count which separates good quality from marginal quality and which most test samples should not exceed;
c – the maximum number of test samples which may fall into the marginally acceptable category before the lot is rejected.

As with the two-class plan increasing c or decreasing n increases the leniency of a three-class plan. OC curves for three-class plans can be derived from the trinomial distribution and describe a 3-dimensional

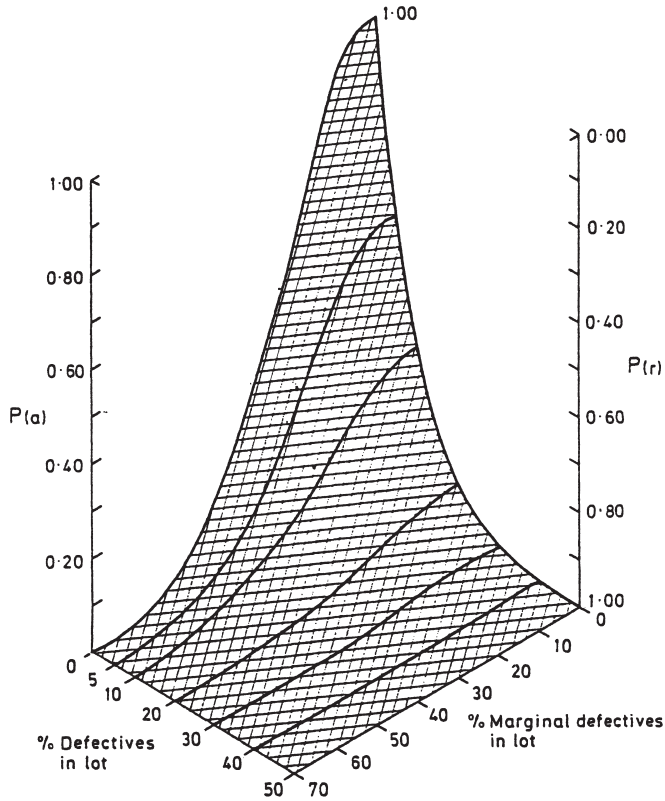

Figure 11.7 *Operating characteristic surface for a three-class plan.* n = *10,* c = *2* (Reproduced with permission from Jarvis (1989)

surface with axes defining the probability of acceptance/rejection, the proportion of marginally defectives in a lot, and the proportion of defectives in a lot (Figure 11.7).

Microbiological criteria using attributes sampling plans for different foods have been produced by a number of organizations and some examples of these are given in Table 11.2. As is clear, the stringency of the sampling plan varies with the type of food and the organism being sought.

In 2006 a regulation came into force in the countries of the EU (2073/2005) setting down microbiological criteria for some foods based on attribute plans. This consolidated a number of previous regulations and criteria. It also introduced two types of criterion: food safety criteria and process hygiene criteria. If foods fail to meet food safety criteria they should not be placed on the market or withdrawn from sale. Failure to meet process hygiene criteria is less serious but would necessitate a review of food safety management procedures with a view to improving product quality. The criteria are not intended as quality control measures in

Table 11.2 *Attributes sampling plans*

Product	*Organisms*	*Plan class*	n	m	M	c	*Source*
Ice cream	APC	3	5	10^5	10^6	2	Canada
	coliforms	3	5	10	10^3	1	
Dried milk	APC	3	5	5×10^4	2×10^5	2	International Dairy Federation
	coliforms	3	5	10	100	1	
	Salmonella	2	15	0	–	0	
Frozen raw crustaceans	APC	3	5	10^6	10^7	3	ICMSF
	E. coli	3	5	11	500	3	
	Staph. aureus[a]	3	5	10^3	10^4	2	
	Salmonella[a]	2	5	0	–	0	
	V. parahaemolyticus[a]	3	5	10^2	10^3	1	
Frozen cooked crustaceans	APC	3	5	5×10^5	10^7	2	ICMSF
	E. coli	3	5	11	500	2	
	Staph. aureus	2	5	10^3	–	0	
	Salmonella[a]	2	10	0	–	0	
	V. parahaemolyticus[a]	3	5	10^2	10^3	1	
Frozen fruits and vegetables pH > 4.5	*E. coli*	3	5	10^2	10^3	2	ICMSF
Minced meat	APC	3	5	5×10^5	5×10^6	2	EU
	E. coli	3	5	50	500	2	
	Staph. aureus	3	5	100	5000	2	
	Salmonella (25 g samples)	2	5	–	–	0	

[a] Additional tests
m and M values are expressed as cfu g^{-1}, APC = Aerobic Plate Count

themselves and they do not (with a few exceptions) specify any minimum frequency of testing, increased routine testing or the introduction of a positive release system. The intention is that they serve as a means of ensuring food safety management systems such as HACCP (see 11.6) are functioning correctly.

11.2.3 Choosing a Plan Stringency

Two important principles governing the choice of plan stringency are presented in Table 11.3. As the severity of the hazard being tested for increases, so too must the stringency of the sampling plan. For example, spoilage can be regarded as more of a risk to the product than to the consumer and so tests for indicators of shelf-life such as aerobic plate counts will have the most lenient sampling plans. Even though such plans may quite frequently pass products which are defective, they can still be effective in the sense that regular rejection of say 1 in 5 batches of product would represent a significant economic loss to the producer and would be a strong incentive to improve quality.

Table 11.3 *ICMSF suggested sampling plans*

	Conditions in which food is expected to be handled and consumed after sampling, in the usual course of events[a]		
Degree of concern relative to utility and health hazard	*Conditions reduce degree of concern*	*Conditions cause no change in concern*	*Conditions may increase concern*
No direct health hazard Utility, e.g. shelf-life and spoilage	Increase shelf-life 3-class $n = 5$, $c = 3$	No change 3-class $n = 5$, $c = 2$	Reduce shelf-life 3-class $n = 5$, $c = 1$
Health hazard Low, indirect (indicator)	Reduce hazard 3-class $n = 5$, $c = 3$	No change 3-class $n = 5$, $c = 2$	Increase hazard 3-class $n = 5$, $c = 1$
Moderate, direct, limited spread *e.g. Staph. aureus C. perfringens*	3-class $n = 5$, $c = 2$	3-class $n = 5$, $c = 1$	3-class $n = 10$, $c = 1$
Moderate, direct, potentially extensive spread *e.g. Salmonella*	2-class $n = 5$, $c = 0$	2-class $n = 10$, $c = 0$	2-class $n = 20$, $c = 0$
Severe, direct *e.g. C. botulinum S. typhi*	2-class $n = 15$, $c = 0$	2-class $n = 30$, $c = 0$	2-class $n = 60$, $c = 0$

[a] More stringent sampling plans would generally be used for sensitive foods destined for susceptible populations
Adapted from ICMSF (1986)

Interpretation of the significance of high numbers of indicator organisms will depend on the indicator and the food involved. Enterobacteriaceae or coliform counts can provide an indication of the adequacy of process hygiene, though they are naturally present in substantial numbers on several raw foods. *Escherichia coli* is indicative of faecal contamination and the possible presence of enteric pathogens, although there is no direct relationship and interpretation is not clear-cut. Because of these uncertainties, indicator tests are of only moderate stringency.

When looking for known pathogens, more stringent sampling plans are appropriate and these become more demanding as the severity of the illness the pathogen causes increases.

The conditions under which the food is to be handled after sampling must also be accommodated in any plan. For example, a sampling plan for *E. coli* in raw meats can be quite lenient since the organism is not uncommon in raw meats and the product will presumably be cooked before consumption, thus reducing the hazard. A more stringent plan is required for the same organism if the subsequent handling of a food will produce no change in the hazard; for example, ice cream which is stored frozen until consumption. The most stringent plan would be required for products where subsequent handling could increase the hazard. This would be the case with dried milk where the product could be reconstituted and held at temperatures which would allow microbial growth to resume.

Plan stringency should also take account of whether the food is to be consumed by particularly vulnerable groups of the population such as infants, the very old, or the very sick.

11.2.4 Variables Acceptance Sampling

Very often we have no idea how micro-organisms are distributed within a batch of food and have no alternative but to use an attributes sampling scheme which makes no assumption on this question. In many cases though, studies have found that micro-organisms are distributed log-normally, that is to say the logarithms of the counts from different samples conform to a normal distibution. For example, a survey of nearly 1300 batches of frozen and dried foods found that, on average, only 7.8% of batches did not conform to a log-normal distribution. When this is the case it is possible to use a variables acceptance sampling procedure which achieves better discrimination by making full use of the numerical data obtained from testing rather than just assigning test results into classes as is done in sampling by attributes.

The shape of a normal distribution curve is determined by the parameters μ, the population mean which determines the maximum height of the curve, and σ, the standard deviation of the distribution which

determines its spread. For any log count V in a log-normal distribution, a certain proportion of counts will lie above V determined by:

$$(V - \mu)/\sigma\,(= K) \tag{11.7}$$

where K is known as the standardized normal deviate.For example, when:

$K = 0\,(V = \mu)$ then 50% of values will lie above V;
$K = 1\,(V = \mu + \sigma)$ then 16% of values lie above V;
$K = 1.65\ (V = \mu + 1.65\sigma)$ then 5% of values lie above V.

Rearranging, we get:

$$\mu + K\sigma = V \tag{11.8}$$

If V is chosen to represent a log count related to a safety or quality limit and K determines the acceptable proportion of samples in excess of V then a lot would be acceptable if:

$$\mu + K\sigma \leq V \tag{11.9}$$

and unacceptable if:

$$\mu + K\sigma > V \tag{11.10}$$

In practice V is likely to be very close to the logarithm of M, used in three-class attribute plans.

Since we do not know μ or σ, we must use estimates derived from our testing, $\bar{x}$, the mean log count, and s, the sample standard deviation. K is replaced with a value k_1, derived from standard Tables, which makes allowance for our imprecision in estimating K and chosen to give a desired lowest probability for rejection of a lot having an unacceptable proportion of counts greater than V. This gives us the condition for rejection:

$$\bar{x} + k_1 s > V \tag{11.11}$$

Some k_1 values are presented in Table 11.4. If we decrease the desired minimum probability of rejection for a given proportion exceeding V, *i.e.* decrease the stringency of the plan, then k_1 decreases. Application of a variables plan for control purposes will give a lower producer's risk than the equivalent attributes scheme.

It is possible to apply the variables plan as a guideline to Good Manufacturing Practice (GMP). In this case the criterion is:

$$\bar{x} + k_2 s < v \tag{11.12}$$

where k_2 is derived from Tables and gives a certain minimum probability of acceptance provided less than a certain proportion exceeds v, a lower limit value characteristic of product produced under conditions of Good Manufacturing Practice (Table 11.4). The value v will be very similar to

Table 11.4 k *Values for setting specifications for variables sampling*

Safety/quality $\bar{x} + k_1 s > V$									
Probability of rejection	*Proportion exceeding* v	*No. of replicate samples*							
		3	4	5	6	7	8	9	10
0.95	0.05	7.7	5.1	4.2	3.7	3.4	3.2	3.0	2.9
	0.10	6.2	4.2	3.4	3.0	2.8	2.6	2.4	2.4
	0.30	3.3	2.3	1.9	1.6	1.5	1.4	1.3	1.3
	0.50	1.7	1.2	0.95	0.82	0.73	0.67	0.62	0.58
0.90	0.10	4.3	3.2	2.7	2.5	2.3	2.2	2.1	2.1
	0.25	2.6	2.0	1.7	1.5	1.4	1.4	1.3	1.3
GMP criterion $\bar{x}+k_2 s < v$									
Probability of acceptance	*Proportion exceeding* v								
0.95	0.10	0.33	0.44	0.52	0.57	0.62	0.66	0.69	0.71
	0.20	−0.13	0.02	0.11	0.17	0.22	0.26	0.29	0.31
	0.30	0.58	−0.36	−0.24	−0.16	−0.10	−0.06	−0.02	0
0.90	0.10	0.53	0.62	0.68	0.72	0.75	0.78	0.81	0.83
	0.20	0.11	0.21	0.27	0.32	0.35	0.38	0.41	0.43
	0.30	0.26	−0.13	−0.05	0.01	0.04	0.07	0.10	0.12

the logarithm of m used in the three-class attributes plan. If a lot were to fail a GMP criterion it would not lead to rejection of the lot but would alert the manufacturer to an apparent failure of GMP.

If we take a practical example, let us assume that the critical safety/quality limit is 10^7 cfu g^{-1} ($V = 7$), but that under conditions of GMP a level below 10^6 is usually attainable ($v = 6$). We are testing five samples from the lot and wish to be 95% certain to reject lots where more than 10% of samples exceed a count of 10^7. From Table 11.4, $k_1 = 3.4$ and our specification becomes:

$$\text{if } \bar{x} + 3.4s > 7 \text{ then reject.}$$

If we also wish to be 95% sure of accepting lots with less than 20% greater than our GMP limit then from Table 11.4, k_2 is 0.11 and our GMP criterion becomes:

$$\text{if } \bar{x} + 0.11s < 6 \text{ then accept.}$$

Three batches of product give the following log counts:

	A	**B**	**C**
	5.48	5.55	5.95
	5.23	5.30	6.12
	5.81	6.10	6.20
	5.97	5.75	5.65
	5.46	6.01	6.21
$\bar{x}$	5.59	5.74	6.03
s	0.30	0.33	0.23

Applying the safety/quality limit and GMP formulae, batches A and B are acceptable according to both criteria. Batch C, though acceptable with respect to the safety/quality limit, is not acceptable according to the GMP criterion and this may warrant further investigation.

11.3 QUALITY CONTROL USING MICROBIOLOGICAL CRITERIA

In the 1970s in Oregon in the United States standards were introduced governing the microbiological quality of ground meat in retail stores. After they had been in force for a few years an enquiry was conducted into their effect. The principal conclusion was that, although there was felt to have been a general improvement in sanitation and handling, the standards had produced no significant change in quality. There was no evidence that the bacterial load on ground meat or the risk of foodborne illness had been reduced and, on the debit side, significant costs had been incurred as a result of rejection of material not meeting the standard and

through the expense of microbiological testing. It was also felt that consumers had been misled, since their expectation had been that the introduction of standards would lead to an improvement in quality. As a result of this enquiry, the standards were revoked.

An interesting comparison is provided by the Milk Marketing Board's scheme of paying English and Welsh farmers on the basis of the bacterial count of the milk they supply (see Chapter 5). In this case, feedback of the results to farmers resulted in a dramatic decrease in the recorded count of milk over a period of just four months.

The difference in these two experiences can be ascribed to a number of reasons. Firstly, microbiological testing of milk is more likely to give an accurate reflection of microbiological quality in the batch as a whole since it is easier to obtain truly representative samples of a liquid. Also, much is known on how to produce raw milk hygienically so that bacterial contamination is minimized, farmers had simply not been assiduous in the application of these procedures until financial penalties acted as an incentive. Another crucial difference is that the standards in Oregon had applied later in the supply chain, at the point of sale. Earlier stages in meat production such as conditions of slaughter, dressing and storage make a major contribution to the microbiological quality of meat and the standards had done nothing to improve these. The enquiry had noted that there had been an improvement of hygiene at the retail level but since this produced no significant reduction in count it clearly indicates that the problem lay elsewhere.

These two cases indicate two important features of microbiological quality control. Namely the ineffectiveness of retrospective systems of quality control and the importance of control at source.

A system of retrospective quality control based on testing samples of a product and accepting or rejecting a lot on the basis of test results suffers from a number of limitations. We have already discussed the inhomogeneous distribution of micro-organisms in food, the problems of representative sampling and the producer's and purchaser's risks associated with any sampling plan. To minimize these risks requires plans entailing the testing of large numbers of samples and these entail high costs as a result of both the amount of product required to be tested and the costs of laboratory resources. Even with representative samples there is the problem of the relative inaccuracy of traditional microbiological methods and their long elapsed times. If results of laboratory tests are required before a product can be released for sale (a positive release system), then the product's useful shelf-life is reduced. Finally, a major weakness of retrospective systems of quality control is that they provide little in the way of remedial information. They help identify that there is a problem but often give little information as to where it has arisen and what is required for its solution. If a product has

high counts, is this due to poor quality raw materials, poor hygiene in the production process, poor conditions of storage, or some combination of all three?

The most effective way of controlling quality is through intervention at source, during the production process. On its own, any amount of testing will not improve product quality one jot, to do this requires action where the factors which determine quality operate, namely in the processing and supply chain itself.

11.4 CONTROL AT SOURCE

Control of processing . . . is of far greater importance than examination of the finished article.

Sir Graham Wilson

The traditional approach to control of microbiological quality at source has relied upon a combination of a well-trained workforce, rigorous inspection of facilities and supervision of operations, coupled with microbiological testing, not only of finished product, but also of ingredients, product in process, equipment, the environment, and personnel.

11.4.1 Training

Food handlers should be trained in the basic concepts and requirements of food and personal hygiene as well as those aspects particular to the specific food-processing operation. The level of training will vary depending on the type of operation and the precise job description of the employee, however some form of induction training with regular updating or refresher courses is an absolute minimum.

Training should give food handlers an understanding of the basic principles of hygiene, why it is necessary, and how to achieve it in practice. A core curriculum for any such course should emphasize:

(1) Micro-organisms as the main cause of food spoilage and foodborne illness and the characteristics of the common types of food poisoning.
(2) How to prevent food poisoning through the control of microbial growth, survival or contamination.
(3) Standards of personal hygiene required of food handlers. These are principally to avoid contamination of food with bacteria the food handler may harbour as part of the body's flora, *e.g Staph. aureus, Salmonella* or that they may bring in with them from the outside world, *e.g. Listeria, B. cereus*. Some do's and don'ts associated with good personal hygiene are listed in Table 11.5.

Table 11.5 *Some do's and don'ts of personal hygiene for food handlers*

DO

Wash your hands regularly throughout the day and especially:

–after going to the toilet;
–on entering a food room and before handling food or equipment;
–after handling raw foods;
–after combing or touching the hair;
–after eating, smoking, coughing or blowing the nose;
–after handling waste food, refuse or chemicals.

Keep fingernails short and clean.
Cover any cuts, spots or boils with a waterproof dressing.
Keep hair clean and covered to prevent hair/dandruff entering the food.
Always wear clean protective clothing (including footwear) in food processing areas.

DON'T
Do not smoke, chew gum, tobacco, betel nut, fingernails or anything else.
Do not taste food.
Do not spit, sneeze or cough over food.
Do not pick nose, ears or any other body site.
Do not wear jewellery when handling food.
Do not wear protective clothing outside the production areas.

(4) Principles of the handling and storage of foods such as the correct use of refrigerators and freezers, the importance of temperature monitoring, the need for stock rotation and the avoidance of cross-contamination.
(5) Correct cleaning procedures and the importance of the 'clean-as-you-go' philosophy.
(6) Knowledge of the common pests found in food premises and methods for their exclusion and control.
(7) An introduction to the requirements of current food legislation.

These topics should be illustrated and supplemented with material relevant to the specific type of food business and the foods being handled.

11.4.2 Facilities and Operations

The environment in which food processing is conducted is an important factor in determining product quality. The premises should be of sufficient size for the intended scale of operation and should be sited in areas which are free from problems such as a particular pest nuisance, objectionable odours, smoke or dust. The site should be well accessed by metalled roads and have supplies of power and potable water adequate to the intended purpose. Particular attention should also be paid to the provision of facilities for the efficient disposal of processing wastes.

Buildings must be of sound construction and kept in good repair to protect the raw materials, equipment, personnel and products within, and to prevent the ingress of pests. The grounds surrounding the plant should be well maintained with lawns cut regularly and a grass-free strip of gravel or tarmac around the buildings. Well-tended grounds will not only prove aesthetically pleasing but will help in the control of rodent pests. Landscaping features such as ponds are not advisable since they may encourage birds and insects.

It is important that the buildings provide a comfortable and pleasant working environment conducive to good hygienic practices. They should be well lit, well ventilated and of sufficient size to maintain the necessary separation between processes that could give rise to cross-contamination. Features such as control of temperature and relative humidity and a positive pressure of filtered air may be required in some process areas for the benefit of both personnel and product.

In processing areas, floors should be made of a durable material which is impervious, non-slip, washable, and free from cracks or crevices that may harbour contamination. Where appropriate, floors should be gently sloped to floor drains with trapped outlets. Internal walls should be smooth, impervious, easily cleaned and disinfected, and light coloured. The angle between floors and walls should be coved to facilitate cleaning. Ceilings should be light-coloured, easy to clean, and constructed to minimize condensation, mould growth and flaking. Pipework, light fittings and other services should be sited to avoid creating difficult-to-clean recesses or overhead condensation. A false ceiling separating processing areas from overhead services has sometimes been advocated though these are generally used only in particularly sensitive areas. Light fittings should be covered to protect food below in the event of a bulb or fluorescent tube shattering. Windows should have sills sloped away from the glass and, in some climates, should be covered with well-maintained fly screens. All entrances to the plant must be protected by close fitting, self-closing doors to prevent the ingress of birds and other pests. Air curtains may also be used to protect some work areas.

Toilets and changing facilities should be clean, comfortable, well lit and provide secure storage for employees' belongings. Toilets should not open directly on to food-processing areas and must be provided with hand-washing facilities supplied with hot water, soap and hand drying facilities. Ideally, taps and soap dispensers should be of the non-hand-operated type and single-use disposable towels or an air blower be provided for hand drying. Hand washing facilities should also be available elsewhere in the plant wherever the process demands.

The overall layout of the plant should ensure a smooth flow-through from raw materials reception and storage to product storage and dispatch. Areas may be designated as 'high risk' or 'low risk' depending on

the sensitivity of the materials being handled and the processes used. High-and low-risk areas of a production process should be physically separated, should use different sets of equipment and utensils, and workers should be prevented from passing from one area to the other without changing their protective clothing and washing their hands. The principal situation where such a separation would be required is between an area dealing with raw foods, particularly meat, and one handling the cooked or ready-to-eat product.

It should hardly need emphasizing that the same rules governing access, behaviour and the wearing of protective clothing also apply to management, visitors and anyone requiring to visit the processing areas.

11.4.3 Equipment

Equipment and its failings can be a source of product contamination and some notable examples are presented in Table 11.6. The main objectives of the design of hygienic food-processing equipment are to produce equipment that performs a prescribed task efficiently and economically while protecting the food under process from contamination. There is general agreement on the basic principles of hygienic design, as outlined by a number of bodies. Those given below are taken from the Institute of Food Science and Technology (UK) publication, 'Good Manufacturing Practice: A Guide to its Responsible Management' with slight modification.

(1) All surfaces in contact with food should be inert to the food under conditions of use and must not yield substances that might migrate to or be absorbed by the food.
(2) All surfaces in contact with the food should be microbiologically cleanable, smooth and non-porous so that particles are not caught in microscopic surface crevices, becoming difficult to dislodge and a potential source of contamination.
(3) All surfaces in contact with food must be visible for inspection, or the equipment must be readily dismantled for inspection, or it must be demonstrated that routine cleaning procedures eliminate the possibility of contamination.
(4) All surfaces in contact with food must be readily accessible for manual cleaning, or if clean-in-place techniques are used, it should be demonstrated that the results achieved without disassembly are equivalent to those obtained with disassembly and manual cleaning.
(5) All interior surfaces in contact with food should be so arranged that the equipment is self-emptying or self-draining. In the design of equipment it is important to avoid dead space or other

Table 11.6 *Examples of equipment-related spoilage or foodborne illness*

Equipment	*Problem*	*Consequences*	*Correction*
Grain silo	Areas of high moisture	Mouldy grain[a]	Proper ventilation and grain turnover
Can reformer	Holes in cans of salmon	Botulism	Proper maintenance of equipment
Gelatin injector	Welds difficult to clean	Salmonellosis from meat pies	Smooth weld
Wood smoke sticks	Bacteria surviving cleaning	Spoilage of sausage	Replace wood with metal
Heat exchanger (cooling side)	Cracked cooling unit permitting entrance of contaminated water	Salmonellosis from milk powder	Replace heat exchanger
Pump	Worn gasket	Spoilage of mayonnaise	Replace gaskets more frequently
Deaerator	Not properly cleaned or located in processing scheme	Contamination of pasteurized milk, enterotoxigenic cheese	Properly clean deaerator and move upstream of pasteurizer
Commercial oven	Poor heat distribution	Areas of under-cooking, rapid spoilage potential foodborne illness	Correct heat distribution in oven, monitor temperature to detect failure

[a] Moulds can produce a range of mycotoxins
From Shapton and Shapton (1991)

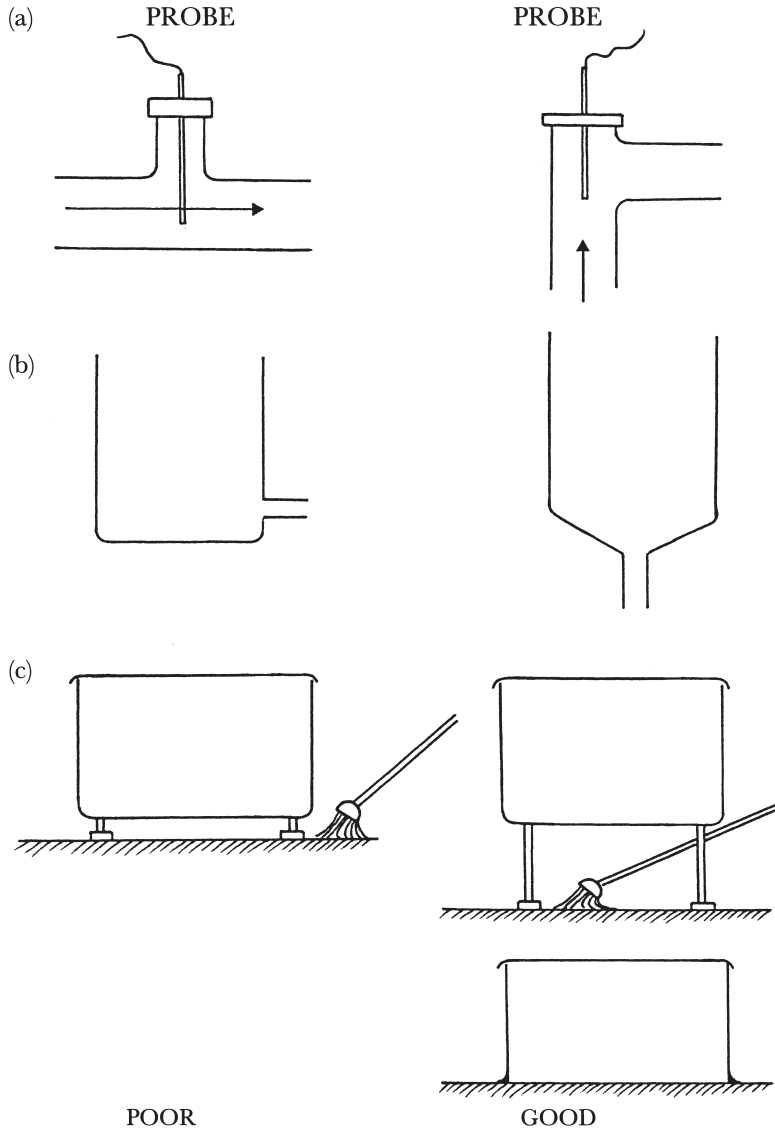

Figure 11.8 *Examples of poor and good equipment design. (a) Placement of probes, (b) avoidance of dead space, (c) avoidance of cleaning problems*

conditions which trap food and may allow microbial growth to take place (Figure 11.8).

(6) Equipment must be so designed to protect the contents from external contamination and should not contaminate the product from leaking glands, lubricant drips and the like; or through inappropriate modifications or adaptations.

(7) Exterior surfaces of equipment not in contact with food should be so arranged to prevent the harbouring of soils, micro-organisms or

pests in and on equipment, floors, walls and supports. For example, equipment should fit either flush with the floor or be raised sufficiently to allow the floor underneath to be readily cleaned.

(8) Where appropriate, equipment should be fitted with devices which monitor and record its performance by measuring factors such as temperature/time, flow, pH, weight.

11.4.4 Cleaning and Disinfection

In the course of its use, food processing equipment will become soiled with food residues. These may impair its performance by, for instance, impeding heat transfer, and can act as a source of microbiological contamination. Hygienic processing of food therefore requires that both premises and equipment are cleaned frequently and thoroughly to restore them to the desired degree of cleanliness. Cleaning should be treated as an integral part of the production process and not regarded as an end-of-shift chore liable to be hurried or superficial.

What appears to be clean visually can still harbour large numbers of viable micro-organisms which may contaminate the product. Cleaning operations in food processing have, therefore, two purposes:

(i) physical cleaning to remove 'soil' adhering to surfaces which can protect micro-organisms and serve as a source of nutrients; and
(ii) microbiological cleaning, also called sanitizing or disinfection, to reduce to acceptable levels the numbers of adhering micro-organisms which survive physical cleaning.

These are best accomplished as distinct operations in a two-stage cleaning process (Figure 11.9), although combined detergent/sanitizers are sometimes used for simplicity and where soiling is very light.

In a general cleaning/disinfecting procedure, gross debris should first be removed by brushing or scraping, possibly combined with a pre-rinse of clean, potable (drinking quality) water. This should be followed by a more thorough cleaning which requires the application of a detergent solution. The detailed composition of the detergent will depend on the nature of the soil to be removed, but a main component is likely to be a surfactant; a compound whose molecules contain both polar (hydrophilic) and nonpolar (hydrophobic) portions. Its purpose in detergent formulations is to reduce the surface tension of the aqueous phase, to improve its penetrating and wetting ability and contribute to other useful detergent properties such as emulsification, dispersion and suspension. There are three main types of surfactant,

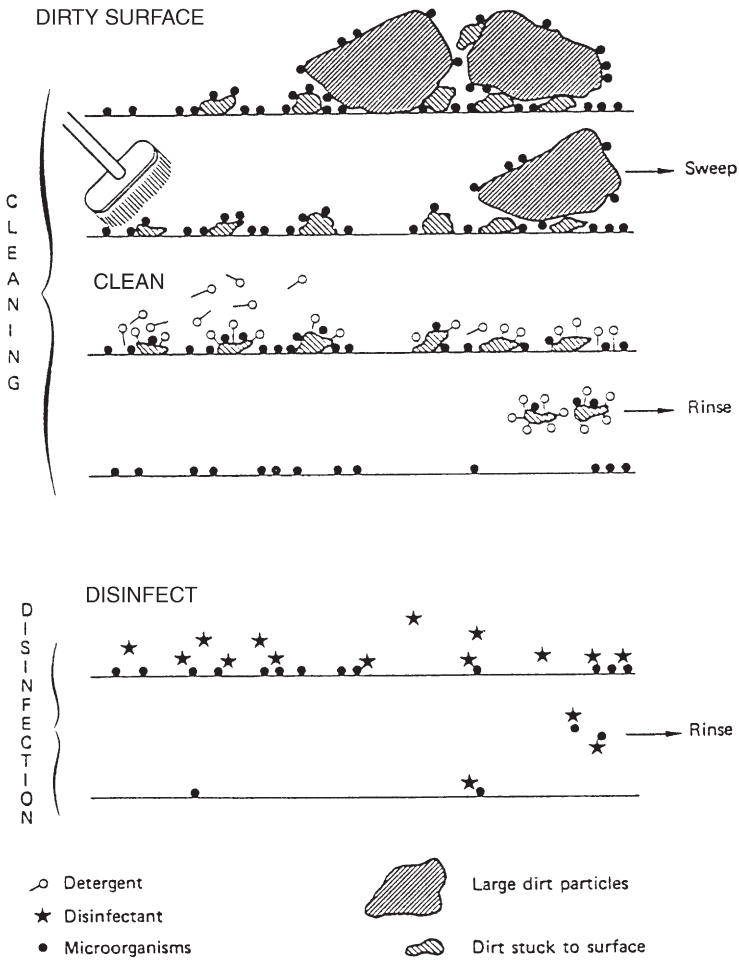

Figure 11.9 *Two-stage cleaning.*
(Reproduced with permission from WHO document VPH/83.42, copyright retained)

classified according to the nature of the hydrophilic portion of the molecule:

(i) *anionic* – in these, which include soaps, alkyl and alkylbenzene sulfonates and alcohol sulfates, the hydrophilic portion is a negatively charged ion produced in solution. They are incompatible with the use of quaternary ammonium compounds (QUATs) which are positively charged;
(ii) *non-ionic* – made by condensing ethylene oxide on to the polar end of a fatty acid, fatty alcohol or alkyl phenol;

(iii) *cationic* – quaternary ammonium compounds (QUATs) which have a positive charge in solution and are used mainly for their bacteriostatic and bacteriocidal activity rather than their cleaning properties.

Detergent preparations also often include alkalis such as sodium hydroxide, sodium silicates, or sodium carbonate which assist in solubilizing organic material such as fats and proteins. Acids are used in other formulations designed to remove the tenacious mineral scales such as milkstone which build up on surfaces, particularly heated ones, after repeated use.

Phosphates have a number of useful functions in detergents though their subsequent environmental impact can pose problems. Detergent performance is improved by sequestering agents which chelate calcium and magnesium ions and prevent the formation of precipitates. Polyphosphates are often used for this purpose, although ethylenediamine tetraacetic acid (EDTA) and gluconic acid are alternatives which have the advantages of heat stability and compatibility with QUATs. Polyphosphates also inhibit the redeposition of soil; a role for which sodium carboxymethyl cellulose is sometimes included.

Several other factors contribute to an effective cleaning procedure in addition to the physico-chemical activity of the detergent solution. Heat generally improves the efficiency of cleaning, particularly with fat-containing soils, although the temperature used must be compatible with the detergent, the soil type, and the processing surface being cleaned. Mechanical energy in the form of shear forces created by turbulence, scrubbing or some other form of agitation considerably assists in the cleaning process. For smaller items of equipment this can be done manually but for larger areas and pieces of equipment some form of power cleaning is necessary. This may involve the use of a high pressure low volume (HPLV) jet of water or detergent solution. HPLV systems operate at pressures in the range 40–100 bar ($kg\,cm^{-2}$) with flow rates between 5 and 90 $1\,min^{-1}$ and are best suited for cleaning equipment where it is necessary to direct a powerful jet into relatively inaccessible areas (though hygienic design should minimize these). They are also used to rinse off detergents applied to equipment in the form of gels or foams; systems which give longer contact times between detergent and soil than would be obtained simply by spraying with an aqueous detergent solution. Gel or foam cleaning is particularly suited to use with more recalcitrant soils and on non-horizontal equipment surfaces where conventional detergent solutions would quickly run off.

Low pressure/high volume (LPHV) cleaning (≈ 5 bar; $\approx 500\,l\,min^{-1}$) is suitable for areas with a low level of soiling with water soluble residues or washing light debris to a floor drain.

It is desirable that equipment is not left wet after cleaning since micro-organisms will be able to grow in any residual water film. This is best achieved by provision of sufficient drainage points and natural air drying, although drying with single-use tissues may be required in some circumstances.

Many micro-organisms will be removed along with the soil in the course of cleaning, but many may remain on an apparently clean surface. It is therefore necessary to disinfect equipment after cleaning. A most efficient means of doing this is through the application of moist heat, which has a distinct advantage over chemical disinfectants in that its efficacy is not impaired by residual organic matter. It does however require careful control to ensure that the required temperature is maintained long enough for it to be effective. This is most appropriate in enclosed systems and is not always practicable in other areas for which chemical disinfectants are the method of choice.

Six types of chemical disinfectant are most commonly used in food processing:

(1) chlorine and chlorine compounds
(2) iodophors
(3) quaternary ammonium compounds (QUATs)
(4) biguanides
(5) acid anionic surfactants
(6) amphoteric surfactants

Hydrogen peroxide and peracetic acid are also used in some applications such as the disinfection of packing materials.

Chemical disinfectants do not act specifically on a single aspect of a microbial cell's metabolism but have a more broadly based inhibitory effect. In the case of chlorine, iodophors and peracetic acid, they act as non-specific oxidizing agents oxidizing proteins and other key molecules within the cell, while others such as QUATs and amphoterics act as surfactants, disrupting the cell membrane's integrity. For this reason, development of microbial resistance requires quite complex cellular changes. This has been noted in capsulated Gram-negative bacteria where changes in the composition of the cell membrane have resulted in resistance to QUATs and amphoterics. Development of resistance by some pseudomonads to these agents can, however, be prevented by addition of a sequestering agent which is believed to interfere with calcium and magnesium binding in the outer membrane and capsule, making the cell more vulnerable. Acquisition of resistance to oxidizing disinfectants has not been observed.

The main considerations in choosing a chemical disinfectant for use in the food industry are:

(1) Its microbiological performance – the numbers and types of organisms to be killed.
(2) How toxic is it and what is its effect on the food?
(3) What is its effect on plant – does it stain or corrode equipment?
(4) Does it pose any hazard to staff using it?
(5) Is it adversely affected by residual soil?
(6) What are the optimal conditions for its use, *i.e.* temperature, contact time, pH, water hardness?
(7) How expensive is it?

Some of these characteristics are summarized in Table 11.7.

All disinfectants are deactivated to some extent by organic matter. This is why they are best used after thorough cleaning has removed most of the soil.

Chlorine in the form of hypochlorite solution is the cheapest effective disinfectant with a broad range of antimicrobial activity which includes spores. The active species is hypochlorous acid (HOCl) which is present in aqueous solutions at pH 5–8. It is corrosive to many metals including stainless steel although this can be minimized by using it at low concentrations, at alkaline pH, at low temperature and with short contact times. For most purposes an exposure of 15 minutes to a solution containing $100\,mg\,l^{-1}$ available chlorine at room temperature is sufficient.

Organochlorine disinfectants such as the chloramines are generally weaker antimicrobials but are more stable and less corrosive than hypochlorite allowing longer contact times to be used.

In iodophors, iodine is dissolved in water by complexing it with a non-ionic surfactant. Phosphoric acid is often included since the best bactericidal activity is observed under acidic conditions. To disinfect clean surfaces a solution containing $50\,mg\,l^{-1}$ available iodine at a $pH < 4$ is usually required. The amber colour of iodophors in solution has two useful functions: it provides a crude visual indication of the strength of the solution and it will stain organic and mineral soils yellow indicating where equipment has been inadequately cleaned. However, they can also stain plastics and can taint some foods.

QUATs are highly stable with a long shelf-life in concentrated form. They are non-corrosive and can therefore be used at higher temperatures and with longer contact times than other disinfectants. However, at low concentrations ($< 50\,mg\,l^{-1}$) and low temperatures they are less effective against Gram-negative bacteria. This is not usually a problem under normal conditions of use (150–250 $mg\,l^{-1}$; $> 40\,^{\circ}C$; contact time > 2 min),

Table 11.7 *Characteristics of common disinfectants used in the food industry*

	Steam	*Chlorine*	*Iodophors*	*QUATs*	*Amphoterics*	*Acid anionic*	*Peracetic acid*
Activity against:							
Vegetative bacteria							
Gram-positive	++	++	++	++	++	++	++
Gram-negative	++	++	++	+	+	++	++
Yeasts	++	++	++	++	++	++	++
Moulds	++	++	++	++	++	++	++
Bacterial spores	++	++	+	0	0	+	++
Adversely affected by soil	+	++	+	+	+	+	++
Corrosive	0	++	+	0	0	+	0
Possibility of tainting with poor rinsing	0	+	++	0	0	0	+
Active at neutral pH	+	+	0	+	+	0	0
Affected by water hardness	0	0	0	+	+	+	0
Instability in hot water	0	++	++	0	0	0	+

although incorrect usage could result in a build up of QUAT-resistant bacteria on equipment. Because of their surfactant properties, QUATs (and amphoterics) adhere to food-processing surfaces even after rinsing. This can be an advantage; in one study in a poultry plant, levels of bacteria on plant were shown to continue decreasing for nine hours after disinfection as a result of the effect of residual QUAT. In some areas though, it can be a problem; residual QUAT or amphoteric may inhibit starter culture activity in cheese and yoghurt production and can also affect head retention on beer.

Biguanides are similar to QUATs but have greater activity against Gram-negatives, although development of resistance has been noted here too.

Amphoterics are surfactants with a mixed anionic and cationic character which are far less affected by changes in pH than other disinfectants. Their high foaming characteristics make them unsuitable for some uses.

In modern food processing much equipment cleaning is automated in the form of cleaning-in-place (CIP) systems. These are most readily applied to cleaning and disinfecting plant which handles liquid foods and have therefore found widest application in the brewing and dairy industries, although they are now appearing in meat processing plants. A CIP system is a closed section of plant which can be cleaned by draining the product followed by circulation of a sequence of solutions and water rinses that clean and then disinfect the plant leaving it ready for resumed production. Though the initial capital investment is high, CIP offers a number of advantages. Its running costs are lower than traditional cleaning procedures since labour costs are low and it gives optimal use of detergents, disinfectants, water and steam. As it does not involve the dismantling of plant prior to cleaning, CIP minimizes unproductive 'down time' and the risk of equipment damage during disassembly. It is also safer since personnel are no longer required to perform the sometimes hazardous operations of climbing up on to, or into, equipment and, provided the system is correctly formulated, it gives a consistent result with little chance of human error.

To ensure cleaning and disinfecting procedures are achieving the desired result some form of assessment is necessary. The inadequacy of visual inspection of equipment to determine its microbiological status has already been alluded to. It is however worth noting that, with few exceptions, if a surface is visually dirty it is also likely to be microbiologically dirty. Culturing micro-organisms removed from a cleaned surface by swabbing, rinsing or a contact-transfer technique will give an indication of the level of contamination, but only after sufficient time has elapsed for the organisms to produce visible growth. Recently the use of ATP bioluminescence has found increasing use in this area. It provides a rapid measure of the hygienic status of a surface without having to

distinguish between microbial and non-microbial ATP since high levels of ATP, whatever the origin, will indicate inadequate cleaning and disinfection (see Section 10.5.3).

Cleaning dry process areas presents an entirely different problem from that discussed above. By their very nature these areas are inimical to microbial growth due to the absence of water. To introduce moisture in the name of hygiene could have exactly the opposite effect and give rise to microbiological problems. Cleaning in dry process areas should therefore be mechanical, using vacuum cleaners, wipes and brooms.

11.5 CODES OF GOOD MANUFACTURING PRACTICE

The features of control at source outlined above are often enshrined in official regulations or codes of Good Manufacturing Practice (GMP). GMP is defined as those procedures in a food-processing plant which consistently yield products of acceptable microbiological quality suitably monitored by laboratory and in-line tests. A code of GMP must define details of the process that are necessary to achieve this goal such as times, temperatures, *etc*., details of equipment, plant layout, disinfection (sanitation) and hygiene practices and laboratory tests.

Codes of GMP have been produced by a variety of organizations including national regulatory bodies, international organizations such as the Codex Alimentarius Commission as well as trade associations and professional bodies. They can be used by manufacturers as the basis for producing good quality product but may also be used by inspectors from regulatory bodies.

While they can be very useful, a frequent limitation is that in their desire to be widely applicable they tend to be imprecise. This leads to the use of phrases such as 'appropriate cleaning procedures', without specifying what these may be; 'cleaning as frequently as possible', without specifying a required frequency; 'undesirable organisms', without specifying which organisms. They also often fail to identify which are the most important requirements affecting food quality and which are of lesser importance. As a result, someone conducting, supervising or inspecting an operation is left uncertain as to what specifically is required to ensure that the operation is conducted in compliance with GMP.

This sort of information is often only available based on a detailed analysis of an individual processing operation.

11.6 THE HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) CONCEPT

In the food industry today approaches based on Good Manufacturing Practice are being largely superseded by application of the Hazard

Analysis Critical Control Point (HACCP) concept. This has improved on traditional practices by introducing a more systematic, rule-based approach for applying our knowledge of food microbiology to the control of microbiological quality. The same system can also be adopted with physical and chemical factors affecting food safety or acceptability, but here we will confine ourselves to microbiological hazards. It should also be remembered that HACCP is primarily a preventative approach to quality assurance and as such it is not just a tool to control quality during processing but can be used to design quality into new products during their development.

HACCP was originally developed as part of the United States space programme by the Pillsbury Company, the National Aeronautics and Space Administration (NASA) and the US Army Natick Laboratories who used it to apply the same zero defects philosophy to food for astronauts as to other items of their equipment. It is based on an engineering system known as the Failure Modes Analysis Scheme which examines a product and all its components asking the question 'What can go wrong?'.

In 1973 it was adopted by the US Food and Drug Administration for the inspection of low-acid canned food. It has since been more and more widely applied to all aspects of food production, food processing and food service, and to all scales of operation from large industrial concerns, through to cottage industries and even domestic food preparation.

The meaning of the terms *hazard* and *risk* in the HACCP system differs from their common everyday usage as synonyms. In HACCP, a *hazard* is a source of danger; defined as a biological, chemical or physical property with the potential to cause an adverse health effect. Individual hazards can be assessed in terms of their severity and risk. Clearly botulism is a far more severe hazard than say *Staphylococcus aureus* food poisoning. *Risk* is an estimate of the likely occurrence of a hazard so, although *C. botulinum* is a more severe hazard, epidemiological evidence shows that the risk it poses is generally very low.

Before HACCP can be applied, it is essential that good manufacturing and hygienic practices are already in place. Factors such as hygienically designed plant and premises, effective cleaning regimes, employee hygiene, pest control, *etc.* provide the necessary foundation on which a successful HACCP system can be built. When HACCP regulations were introduced in the United States to cover fish and fishery products (1995) and meat and poultry (1996), this requirement for prerequisites based on good manufacturing practice was built into the regulations in the form of prescribed Sanitation Standard Operating Procedures (SSOPs).

HACCP itself has evolved since its first formulation and has been the subject of considerable international discussion and debate. In recent

years however national and international bodies seem to have settled on an agreed definition based on seven essential principles of a HACCP system:

(1) Conduct a hazard analysis.
(2) Determine the Critical Control Points (CCPs).
(3) Establish critical limits.
(4) Establish a system to monitor control of the CCP.
(5) Establish corrective action to be taken when monitoring indicates that a particular CCP is not under control.
(6) Establish procedures to verify that the HACCP system is working effectively.
(7) Establish documentation concerning all procedures and records appropriate to these principles and their application.

To apply these principles in practice it is necessary to go through a series of steps outlined in Table 11.8.

A HACCP study is best conducted by a multidisciplinary team comprising a microbiologist, a process supervisor, an engineer and a quality assurance manager, all of whom will be able to bring their own particular expertise and experience to bear on the task in hand. Involvement of production personnel will also ensure identification with the plan by those who will have to implement it. It is important to decide on the terms of reference or scope of the HACCP plan. Experience suggests that best results are obtained when the study's terms of reference specify particular microbial hazards for consideration since this will allow the team to define specific controls. The choice of hazard considered will depend on whether there is epidemiological evidence linking a particular micro-organism with the food in question. In the absence of such evidence, factors such as the

Table 11.8 *Steps in the application of HACCP*

1	Assemble the HACCP team	
2	Describe the product	
3	Identify intended use	
4	Construct flow diagram	
5	On-site confirmation of flow diagram	
6	List all potential hazards	**Principle 1**
	Conduct a hazard analysis	
	Determine control measures	
7	Determine CCPs	**Principle 2**
8	Establish critical limit for each CCP	**Principle 3**
9	Establish a monitoring system for each CCP	**Principle 4**
10	Establish corrective action for deviations that may occur	**Principle 5**
11	Estabish verification procedures	**Principle 6**
12	Estabish documentation and record keeping	**Principle 7**

product's physical and chemical characteristics and the way it is eventually used by the consumer must provide the basis for selection.

The HACCP team produces a full description of the product, its composition and intended use, and conducts a detailed evaluation of the entire process to produce a flow diagram. This must cover all process steps under the manufacturer's control but may also extend beyond this, from before the raw materials enter the plant to the product's eventual consumption. If the eventual consumers include a high proportion of a particularly vulnerable group of the population such as infants, the elderly or sick this too should be identified.

The flow diagram must contain details of all raw materials, all processing, holding and packaging stages, a complete time–temperature history, and details of factors such as pH and a_w that will influence microbial growth and survival. Additional information covering plant layout, design and capacity of process equipment and storage facilities, cleaning and sanitation procedures will also be necessary to assess the possible risks of contamination.

Once completed, it is important that the accuracy of the final document is verified in a separate assessment during which the process is inspected on-site using the flow diagram as a guide.

11.6.1 Hazard Analysis

Hazard Analysis determines which hazards could pose a realistic threat to the safety of those consuming the product and must therefore be controlled by the production process. It is best approached in a systematic way by working through a list of raw materials, ingredients and steps in processing, packaging, distribution and storage, listing alongside each the hazards that might reasonably be expected to occur. It must identify:

(i) raw materials or ingredients that may contain micro-organisms or metabolites of concern, the likely occurrence of these hazards and the severity of their adverse health effects;
(ii) the potential for contamination at different stages in processing:
(iii) intermediates and products whose physical and chemical characteristics permit microbial growth and/or survival, or the production and persistence of toxic metabolites; and
(iv) measures that will control hazards such as process steps which are lethal or bacteriostatic.

Clearly, the expertise of the food microbiologist plays a key role at this stage; for example, helping the team distinguish between raw materials/ingredients that are microbiologically sensitive, *e.g.* meat, eggs, nuts and

those which are not, *e.g.* sugar, vinegar, *etc.* The use of quantitative tools such as predictive models to calculate the potential for growth or the extent of survival at each step can also provide the hazard analysis with valuable information.

11.6.2 Identification of Critical Control Points (CCPs)

Once the hazard analysis has produced a list of the potential hazards, where they could occur, and measures that would control them, critical control points (CCPs) are identified. A CCP is defined as a location, step or procedure at which some degree of control can be exercised over a microbial hazard; that is, the hazard can be either prevented, eliminated, or reduced to acceptable levels. Loss of control at a CCP would result in an unacceptable risk to the consumer or product.

A raw material could be a CCP if it is likely to contain a microbial hazard and subsequent processing, including correct consumer use, will not guarantee its control. Specific processing steps such as cooking, chilling, freezing, or some feature of formulation may be CCPs, as could aspects of plant layout, cleaning and disinfection procedures, or employee hygiene. Many are self-evident, but decision trees can be used to help in their identification (Figure 11.10).

The questions in the decision tree should be asked for each hazard at each step in the process. Though it is necessary to consider hazards individually it will emerge that some points in a process are CCPs for more than one hazard. For example, using the decision tree, pasteurization will be a critical control point for VTEC, *L. monocytogenes, Salmonella* and *Campylobacter* in the processing of milk. Though chill storage of the milk prior to pasteurization is clearly beneficial, since it will reduce or prevent the growth of these and other organisms, it will not be a CCP for these particular hazards since they are eliminated by subsequent pasteurization. Chilling would, however, be a CCP with regard to *Staph. aureus* because by preventing growth of the organism, it will prevent production of heat resistant toxin that could survive pasteurization.

If a hazard is identified at a step where control is necessary for safety, and there is no control measure at that or any subsequent step, then the product or process should be modified to include a control measure.

11.6.3 Establishment of CCP Critical Limits

For each of the CCPs identified, criteria must be specified that will indicate that the process is under control at that point. These will usually

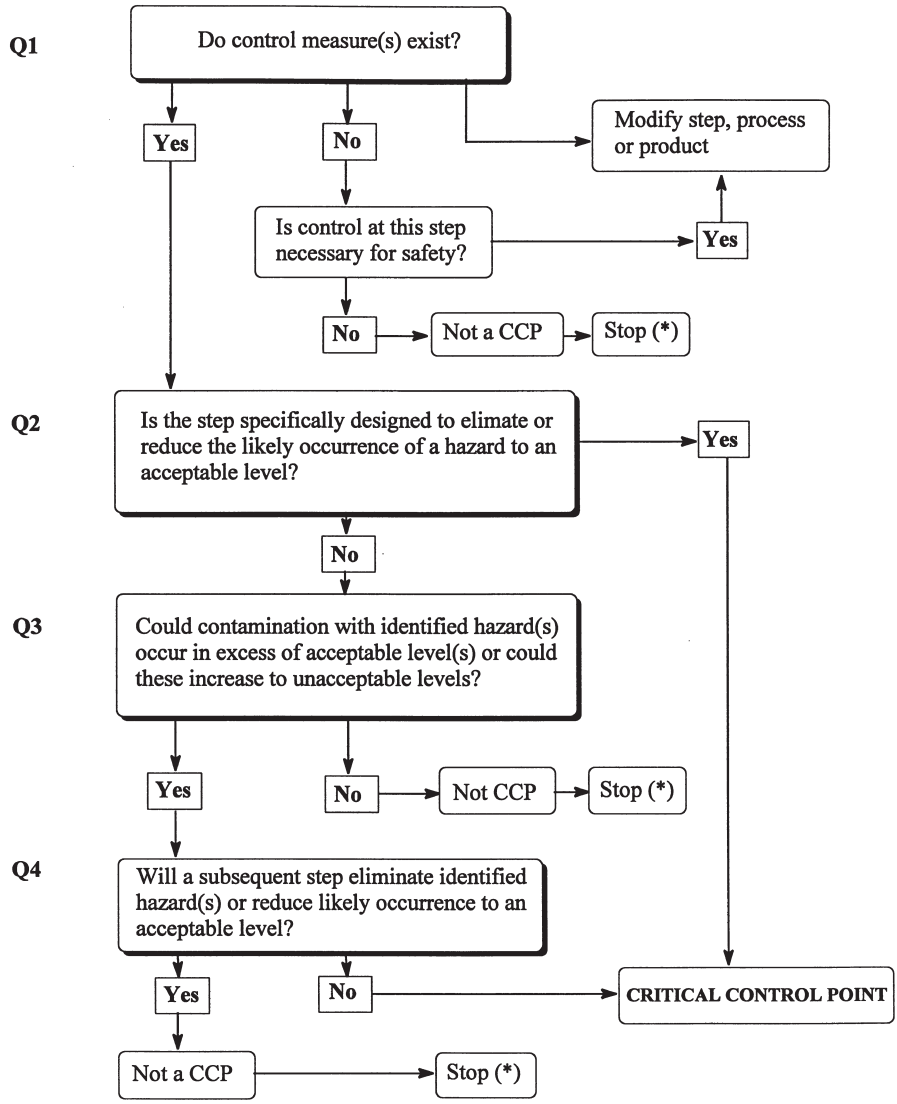

Figure 11.10 *Example of decision tree to identify CCPs (answer questions in sequence)*

take the form of critical limits (with tolerances where appropriate) necessary to achieve control of the hazard. Criteria may include:

(i) *physical parameters* such as temperature/time, humidity, quantity of product in a pack, dimensions of can seams, or depth of product in trays to be chilled;
(ii) *chemical parameters* such as pH in fermented or acidified foods, a_w in intermediate-moisture foods, salt concentra-

tion, available chlorine in can cooling water, or level of preservative;

(iii) *sensory information* such as texture, appearance, or odour; or,

(iv) *management factors* such as the correct labelling of products with instructions for use and handling, or efficient stock rotation.

Critical limits can be derived from a number of sources such as in-house expertise, published data, expert advice, mathematical models or from experiments conducted specifically to provide this information.

11.6.4 Monitoring Procedures for CCPs

Crucial to the application of criteria at CCPs is the introduction of monitoring procedures to confirm and record that control is maintained. It is important to remember that the assurance given by monitoring procedures will only be as good as the methods used and these too must be regularly tested and calibrated.

To achieve the on-line control of a processing operation, monitoring procedures should wherever possible be continuous and give 'real time' measurement of the status of a CCP. In some cases, the availability of appropriate monitoring procedures could govern the choice of criteria. If continuous monitoring is not possible then it should be of a frequency sufficient to guarantee detection of deviations from critical limits, and those limits should be set taking into account the errors involved in periodic sampling.

The long elapsed times involved in obtaining microbiological data means that microbiological criteria are not generally used for routine monitoring of CCPs, other than perhaps the testing of incoming raw materials. Microbiological testing does however play an important part in verification.

Records should be kept of the performance of CCPs. These will assist in process verification and can also be analysed for trends which could lead to a loss of process control in the future. Early recognition of such a trend would allow pre-emptive remedial action to be taken.

11.6.5 Protocols for CCP Deviations

When routine monitoring indicates that a CCP is out of control there should be clearly described procedures for its restoration, who is responsible for taking action and for recording the action taken. In addition to measures to restore the process, it should also prescribe what should be done with product produced while the CCP was out of control.

11.6.6 Verification

Verification is the process of checking that a HACCP plan is being applied correctly and working effectively. It is an essential feature of quality control based on HACCP and is used both when a system is first introduced and to review existing systems. Verification uses supplementary information to that gathered in the normal operation of the system and this can include extensive microbiological testing. To verify that criteria or critical limits applied at CCPs are satisfactory will often require microbiological and other, more searching, forms of testing. For example, microbial levels may need to be determined on equipment where day-to-day monitoring of cleaning procedures is based on visual inspection alone, or the precise lethality of a prescribed heat process may have to be measured. In normal operation, only limited end product testing is required because of the safeguards built into the process itself, but more detailed qualitative and quantitative microbiological analyses of final product and product-in-process may be required in a verification programme. Supplementary testing must be accompanied by a detailed on-site review of the original HACCP plan and the processing records.

One of the great strengths of the HACCP approach is its specificity to individual production facilities. Differences in layout, equipment and/or ingredients between plants producing the same product could mean that different CCPs are identified. Similarly, small changes in any aspect of the same production process could lead to verification identifying new CCPs or weaknesses in existing criteria or monitoring procedures.

11.6.7 Record Keeping

The HACCP scheme should be fully documented and kept on file. Documentation should include details of the HACCP team and their responsibilities; material from the Hazard Analysis such as the product description and process flow diagram; details of the CCPs – the hazards associated with them and critical limits; monitoring systems and corrective action; procedures for record keeping and for verification of the HACCP system. This should be accompanied by associated process records obtained during operation of the scheme. It will also include material such as documentation to verify suppliers' compliance with the processor's requirements, records from all monitored CCPs, validation records and employee training records.

Because of its highly specific and detailed nature, it is not possible to present here a full HACCP system for particular food products. But by way of illustration, Figure 11.11 shows the flow diagram of a process for the production of a yoghurt flavoured by the addition of fruit or nut puree with critical control points identified.

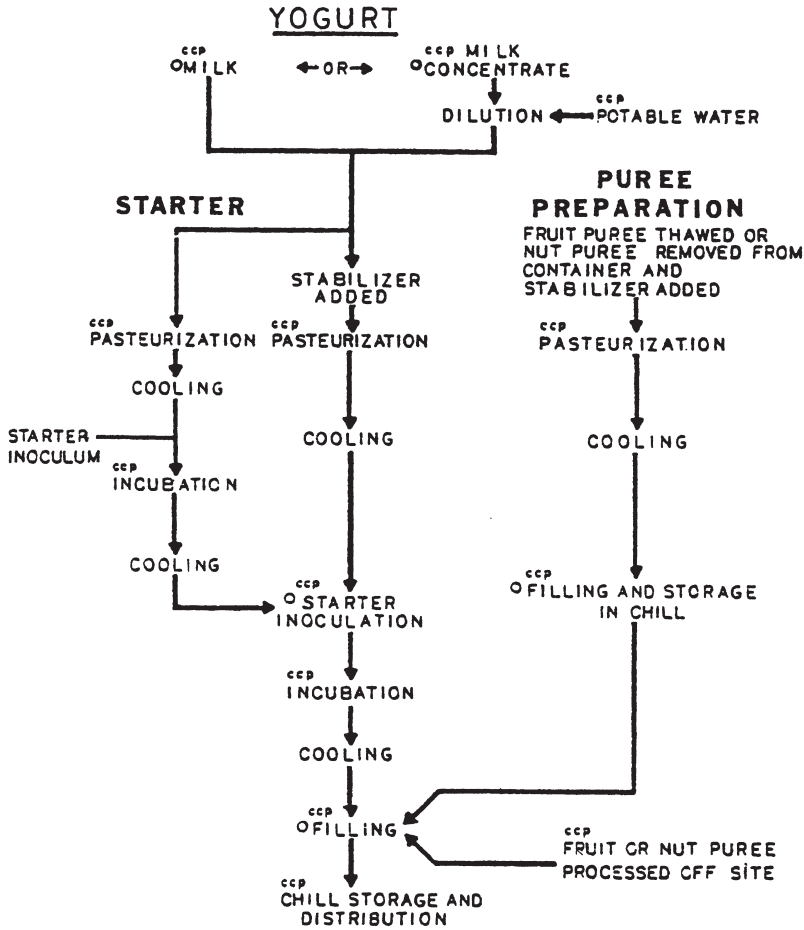

Figure 11.11 *Flow diagram and CCPs for yoghurt with fruit or nut puree. CCP, critical control point; O, major contamination source*
(Reproduced with permission from Shapton and Shapton (1991))

Here the microbiological safety hazards are the presence of pathogens or their toxins. The final product has a pH of 3.9–4.2 and, stored at chill temperatures, it will not permit pathogen growth and will in fact have a moderate lethal effect depending on the pathogen considered. The properties of the product will however have no effect on preformed toxins introduced during processing.

Control of pathogens in the product is obtained by pasteurization of the milk and by ensuring a satisfactory fermentation to give pH $<$ 4.3 so CCPs will be located at points critical to achieving these goals. For example, incoming milk must be tested for antibiotic residues which may inhibit starter-culture activity, and the time and temperature of heat treatment, and factors governing the fermentation such as temperature and starter composition, must all be strictly controlled and monitored.

The possibility that the fruit or nut puree may contain pre-formed toxins is a matter which is under the control of the supplier. The pH of the fruit puree is likely to control any possibility of growth and toxin production by bacterial pathogens, although mycotoxins might be a concern. To control yeasts which could reduce the product's shelf-life, it may be necessary to specify the heat process given to the fruit puree and to store it at chill temperatures prior to use. Nut puree requires more stringent control because of its higher pH. The supplier should provide evidence that it has received a botulinum cook and that the nuts used in its preparation were of good quality and free from aflatoxin.

The US Department of Agriculture has produced a generic HACCP analysis of the production of raw beef (Figure 11.12). Such documents can provide a useful guide to a HACCP team but care must be taken that unique factors applying to the operation under study are not overlooked.

Clearly the full rigours of the HACCP approach are disproportionate to the needs and capabilities of many small food businesses. Since these make up a substantial part of the food industry in most countries, particularly in the food service sector, simplified HACCP-based programmes have been developed for such cases. One example of this is the "Safer Food Better Business" scheme developed by the UK's Food Standards Agency.

11.7 QUALITY SYSTEMS: BS 5750 AND ISO 9000 SERIES

In line with the thinking described above, there has been a change in the way standards are being used in quality management. They have moved away from being specific and prescriptive to being more conceptual in approach. This is best illustrated by the British Standard BS 5750 and its International Standards Organization (ISO) equivalent, the ISO 9000 series, on Quality Systems which are applicable to any processing or productive activity.

A quality system is a means of ensuring that products of a defined quality are produced consistently and it represents an organized commitment to quality. Quality systems work by requiring documented evidence at all stages, from product research and development, through raw materials purchase, to supply to the customer, that quality is rigorously controlled. In the food industry which is increasingly pursuing certification under such standards, HACCP documentation can play an essential role in this as evidence of a commitment to quality.

Factories can achieve approval under BS 5750 from a certifying body such as the British Standards Institution. Quality assessors study the company's 'quality manual' to ensure it meets all the requirements of the standard and then make a detailed on-site assessment of actual practices

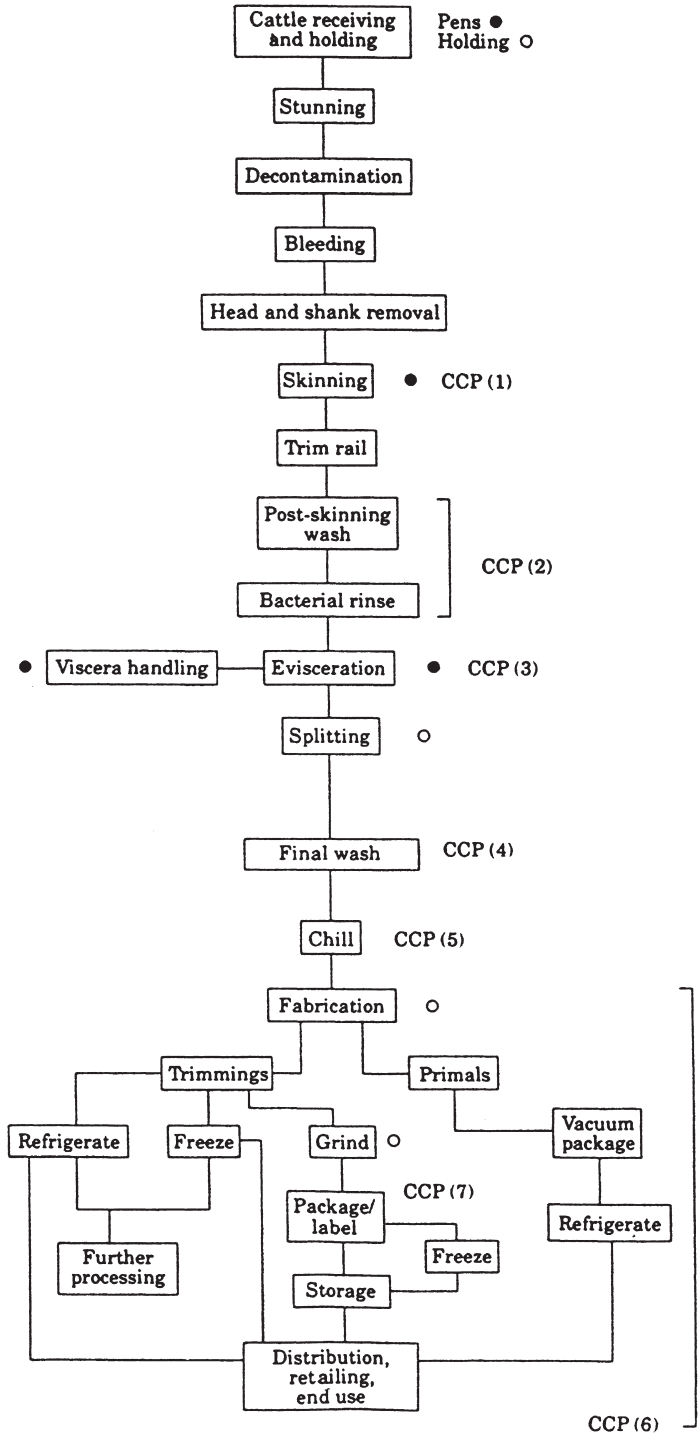

Figure 11.12 *Generic HACCP for raw beef*
(Reproduced with permission from Food Microbiology, 1993, **10**, 449–488. Academic Press)

to verify that prescribed procedures are understood and followed. Following certification, regular follow-up visits are made to ensure continued conformance with the standard.

The value to a company of seeking this outside endorsement of their quality systems is that it provides objective evidence to potential customers of the company's commitment to quality and can therefore pay substantial commercial dividends.

11.8 RISK ANALYSIS

Regulatory authorities established by governments are charged with the task of protecting the public from unsafe food and to do this they must be able to assess foodborne risks and implement strategies for their control. In the past, governments have adopted a variety of approaches to achieve this, largely subjective and based on local interests and conditions. Increasingly, however, there is a move to more systematic and unified approaches to the problem. In part, this has been driven by perceived weaknesses in existing systems, increasing concerns about the safety of food and the need for cost effective strategies to prevent and, where necessary, to reduce the risk from foodborne hazards. A major impetus behind the introduction of transparent, science-based approaches to risk management has however been the needs of international commerce.

Food and food products are important items of international trade and the loss of export markets can have a serious economic impact on producing countries. It is therefore important to be sure that when one country rejects imported food on the grounds that it is unsafe this is being done for sound scientific reasons rather than simply to erect a trade barrier to protect domestic producers or to penalise the exporting country. For this reason world trade agreements under the General Agreement on Tariffs and Trade (GATT), now the World Trade Organization (WTO), have recognized that so-called Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade should be transparent and based on sound scientific principles. In particular:

> Members shall ensure that their SPS measures are based on an assessment. . .of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organisations.

Risk assessment is the scientific component of an overall system known as risk analysis (Figure 11.13). Risk assessment should provide an estimate, preferably quantitative, of the probability of occurrence and the severity of adverse health effects resulting from human exposure to

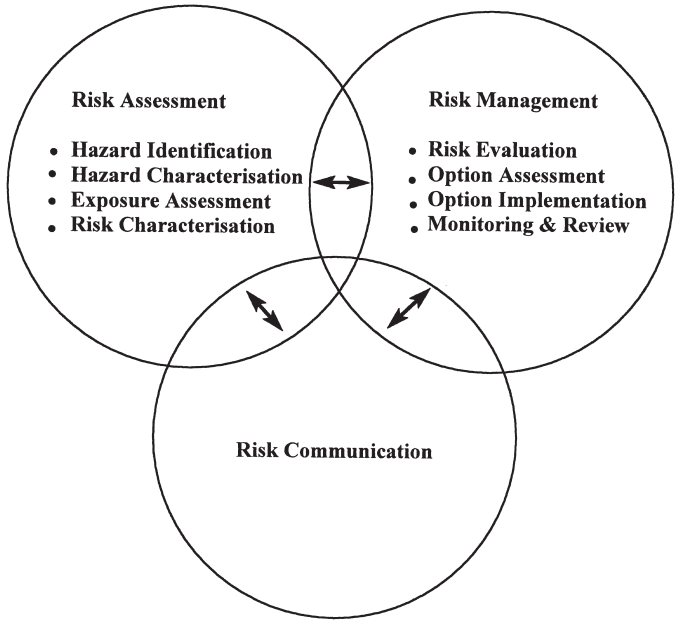

Figure 11.13 *Risk Analysis*
(Adapted form Lammerding, J. Food protection 1997, 1420–1425)

foodborne hazards, known as the risk estimate. There are four steps in risk assessment.

(1) *Hazard identification* is similar to the hazard analysis stage in HACCP and must identify the agents that are hazards to health and that may be present in a particular food. These will be the focus of subsequent stages in the risk assessment process. As with HACCP, these hazards may be chemical, physical or biological, though in this case we are concerned with micro-organisms and their toxins.
(2) *Exposure assessment* is a qualitative/quantitative evaluation of the likely intake of a hazardous agent. This must employ information on consumption patterns, *i.e.* the amounts of a particular food consumed by individuals, taking into account any variation with factors such as age, socio-economic status, religion, *etc.* It must also estimate the level of the microbial hazard in the food at the time of consumption – information that could be obtained from survey data and the use of predictive models describing the growth/survival of the organisms under likely conditions of storage and processing prior to consumption.
(3) *Hazard characterization* is the qualitative and/or quantitative evaluation of the adverse effects associated with the particular

hazard. Dose–response models which relate the number of micro-organisms ingested and the likelihood and severity of clinical illness are a valuable tool, but development of such models for foodborne pathogens is still in its early stages. There are very limited scientific data available compared with chemical hazards and there are additional difficulties arising from the complexity of micro-organisms. Some dose–response data have been obtained from studies conducted with volunteers, but these can be a crude model of the real situation since the volunteers all tend to be healthy adults. Other complicating factors can be the wide variation in virulence between different strains of the same organism, variation of virulence with the organism's physiological state and the important role played by the food vehicle in modulating the ability of the organism to cause infection. Alternative approaches have used information from disease outbreaks to generate more realistic dose–response models, but this is an area where considerable developments are likely over the next few years.

(4) *Risk characterization* integrates the results from the previous three stages to give an estimate, including attendant uncertainties, of the probability and severity of illness in a given population. The accuracy of the estimate can be assessed by comparison with independent epidemiological data where available.

Risk management (Figure 11.13) is the process of deciding, in collaboration with risk assessors, which risk assessments should be undertaken and then weighing policy alternatives to accept, minimize or reduce assessed risks. Risk managers have to decide what level of risk is acceptable (zero risk is an unachievable objective), assess the costs and benefits of different control options and if required select and implement appropriate controls, including regulatory measures. Management also includes the subsequent evaluation of the effectiveness of the measures taken and their review, if necessary.

The final component in risk analysis is risk communication – the interactive exchange of information and opinions between risk assessors, risk managers, consumers and other interested parties. This is an integral part of risk analysis and has a number of goals including the promotion of awareness, understanding, consistency and transparency.

Following an assessment of risk and its management options, it may be possible to define a food safety objective – a statement of the frequency or the maximum concentration of a microbiological hazard in a food that is considered to give an acceptable level of consumer protection. This can then be used by the food industry as a goal to be delivered through the application of good hygienic practices and HACCP. With this we reach something of a high point in the

development of food microbiology to date. Management systems of the type described help ensure effective decision making and the integrated application of our increasing knowledge of foodborne micro-organisms, their detection and control. This in its turn can help deliver a varied, safe and reliable food supply, making a significant contribution to the overall quality of our lives.