Appendix A. Schematic Flow Diagrams of Production of Various Food Categories and Bottled Water

These generic process flow charts are intended to provide DOD auditors with potential steps in the manufacturing process where microbiological counts could increase with loss of process control or development of insanitary conditions. In addition, the flow charts illustrate where there are lethality steps that reduce numbers of indicator organisms and pathogens if present.

Steps for receiving and storing packaging materials were omitted to simplify the creation – and use – of the process flow diagrams. It is expected that a DOD-approved food processing plant would have appropriate control and documentation of these functions, either as part of product-specific HACCP plans, or as preventive and pre-requisite programs such as Standard Operating Procedures for receiving and storage. It was recognized that a finished food product could move through many storage and distribution facilities as part of the supply chain. The final two steps were denoted “store finished product” and “distribute finished product” to simplify the creation and use of the process flow diagrams.

The intent was to include those steps relevant of the manufacturing process relevant to microbial aspects of food rather than to include all possible aspects or combinations of receipt, processing, storage, and distribution of production. The Committee assumes that DOD personnel will be able to recognize the specific steps observed at a food processing plant from among the general manufacturing steps shown on the process flow diagrams.

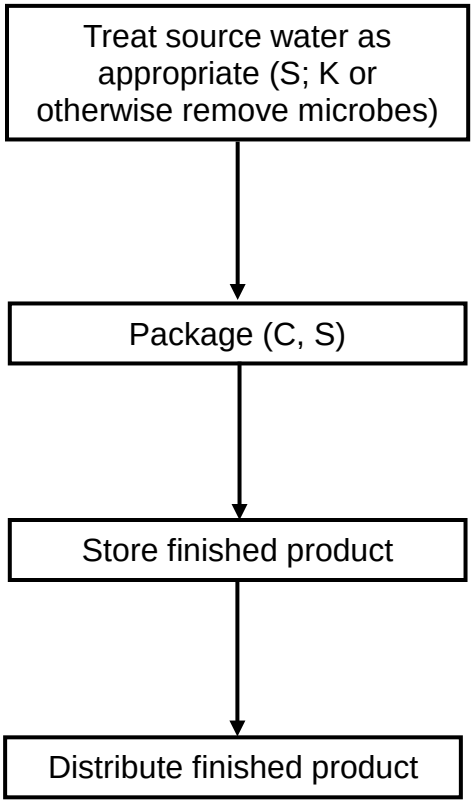
Steps may be followed by any of the following designations:

- C, a step at which significant contamination may occur when adequate process controls are not in place;
- G, a step in the process where growth of microorganisms can occur;
- K, a step where there is a pathogen kill step; and
- S, a point where sampling and testing by the supplier is recommended for verification or investigation.

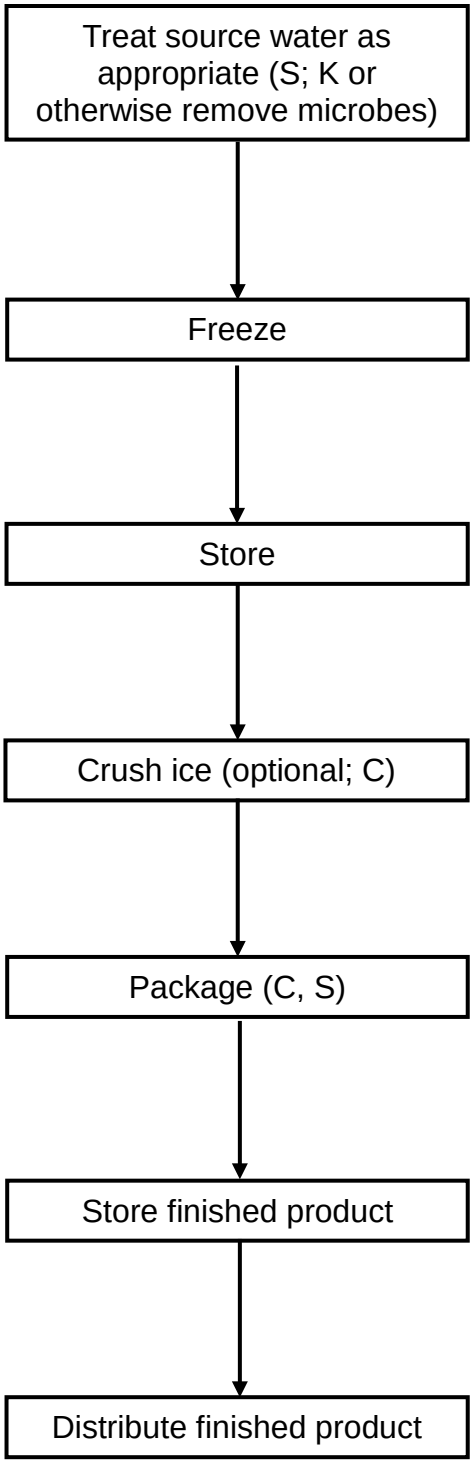
Programs for minimizing contamination at the identified steps include Good Agricultural Practices, Sanitation Standard Operating Procedures, Good Manufacturing Practices, and purchasing specifications. DOD personnel should use the process flow diagrams to review the general steps to manufacture the food product under evaluation. From the process flow diagram, DOD personnel should determine the step(s) at which verification sampling should be done by the supplier. When analysis of verification samples indicates that the supplier may have shortcomings in process or sanitation control, DOD personnel should use the process flow diagram to determine steps at which contamination might occur or steps at which a failure to achieve the expected destruction of bacteria may be occurring.

45

Flow Diagram A.1. BEVERAGES – BOTTLED WATER (ARTESIAN, MINERAL, PURIFIED, SPARKLING AND SPRING WATER)

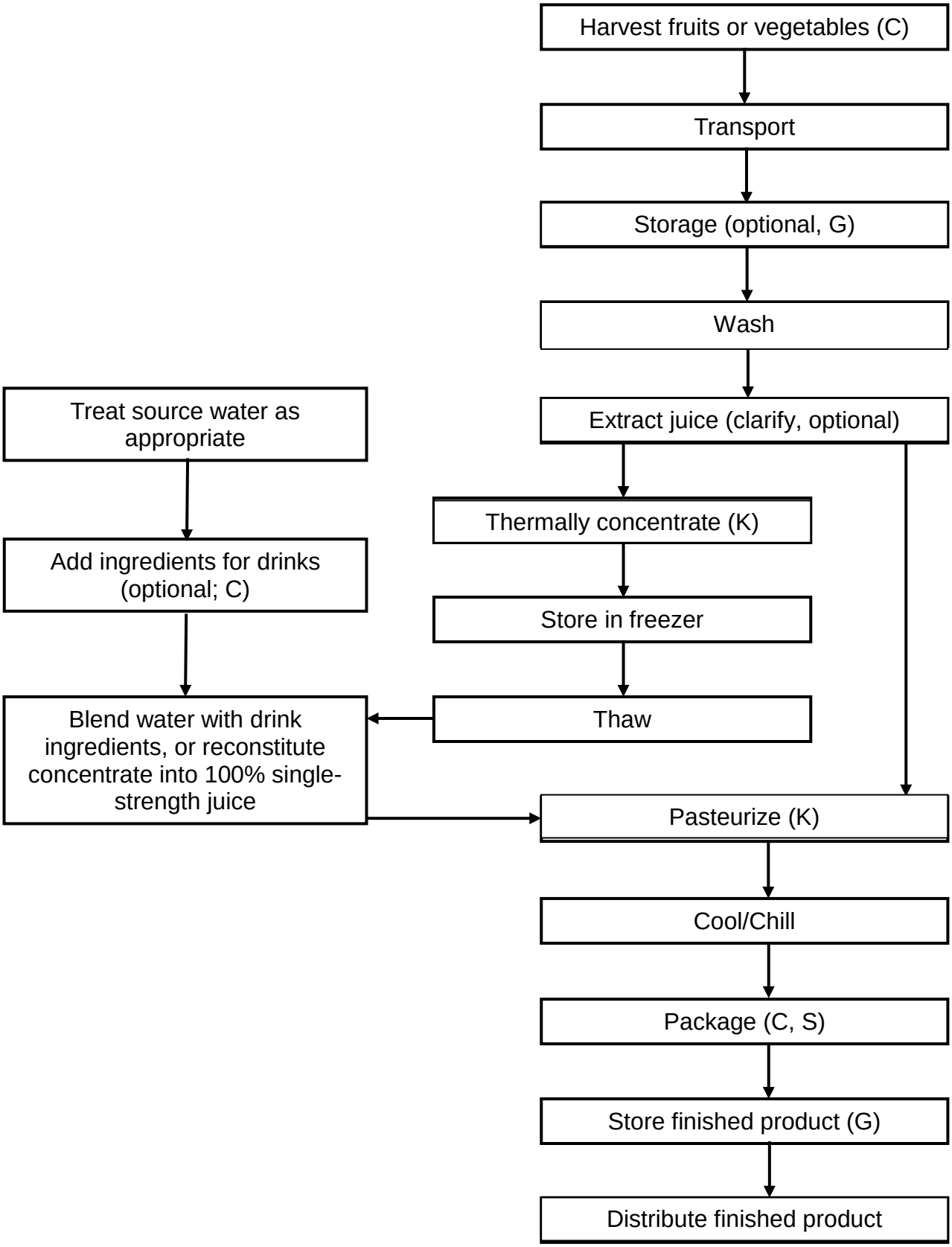


Flow Diagram A.2. BEVERAGES – ICE, PACKAGED

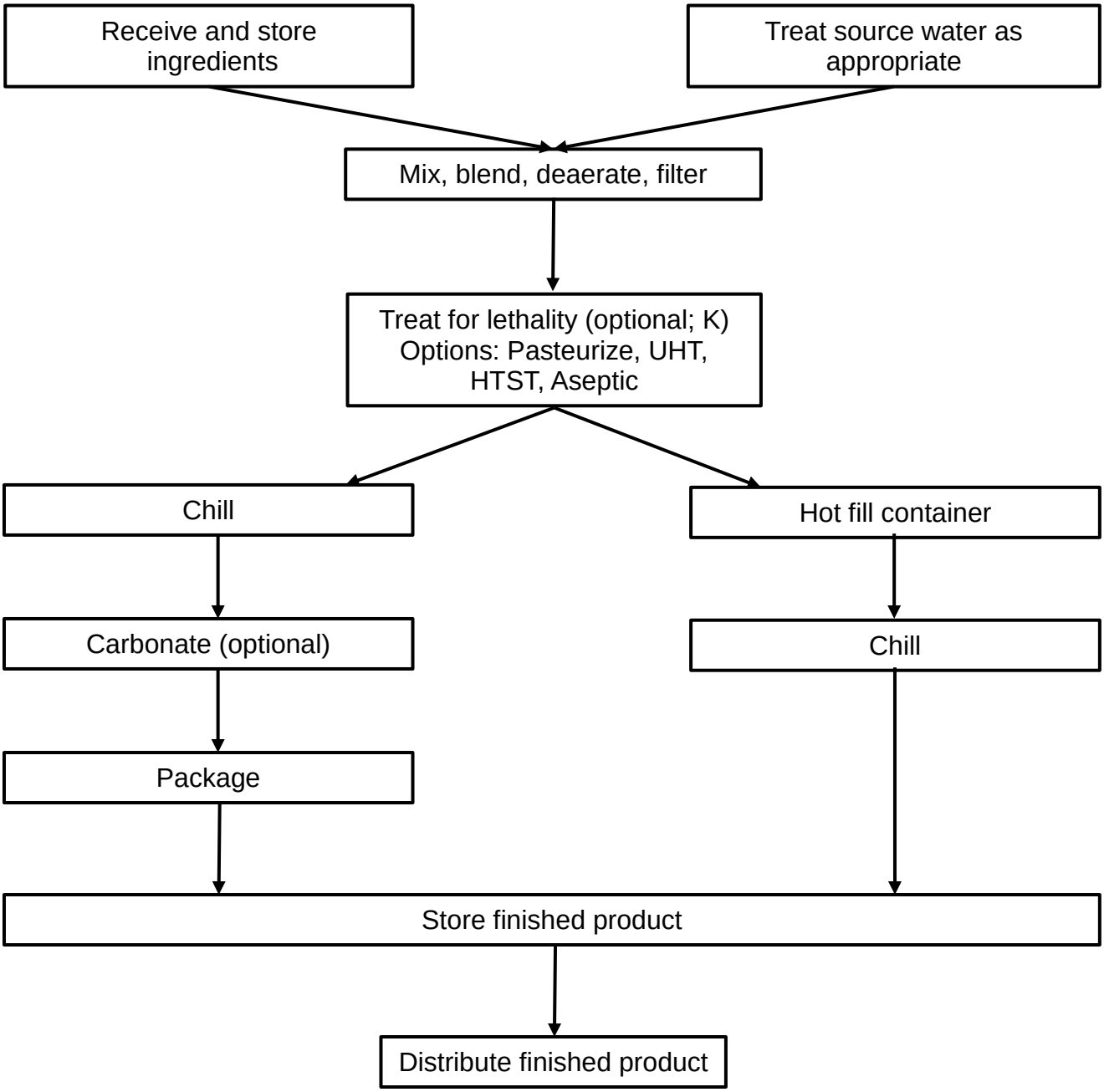


47

Flow Diagram A.3. BEVERAGES – JUICES AND DRINKS, PASTEURIZED, REFRIGERATED

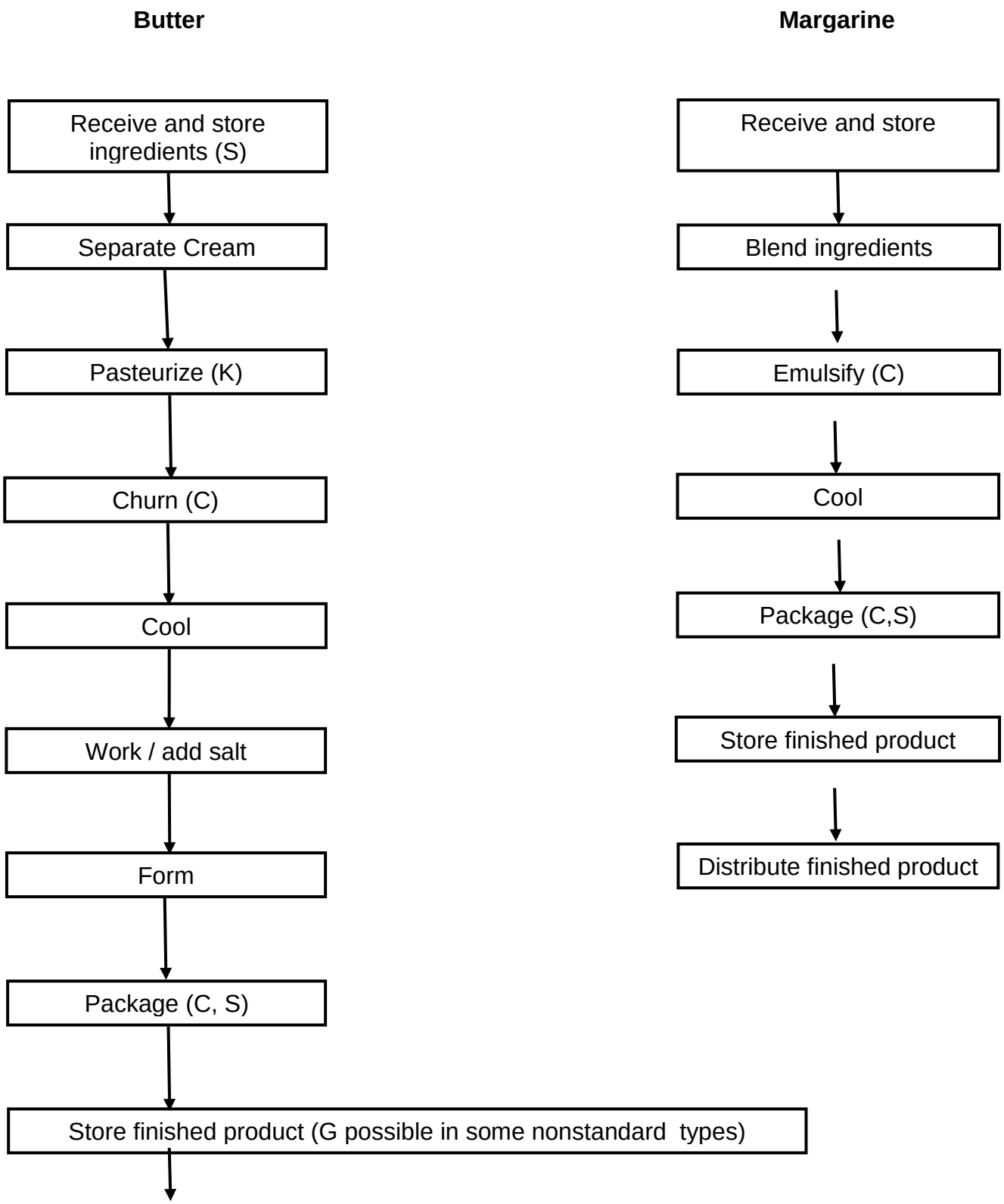


Flow Diagram A.4. BEVERAGES – SHELF STABLE



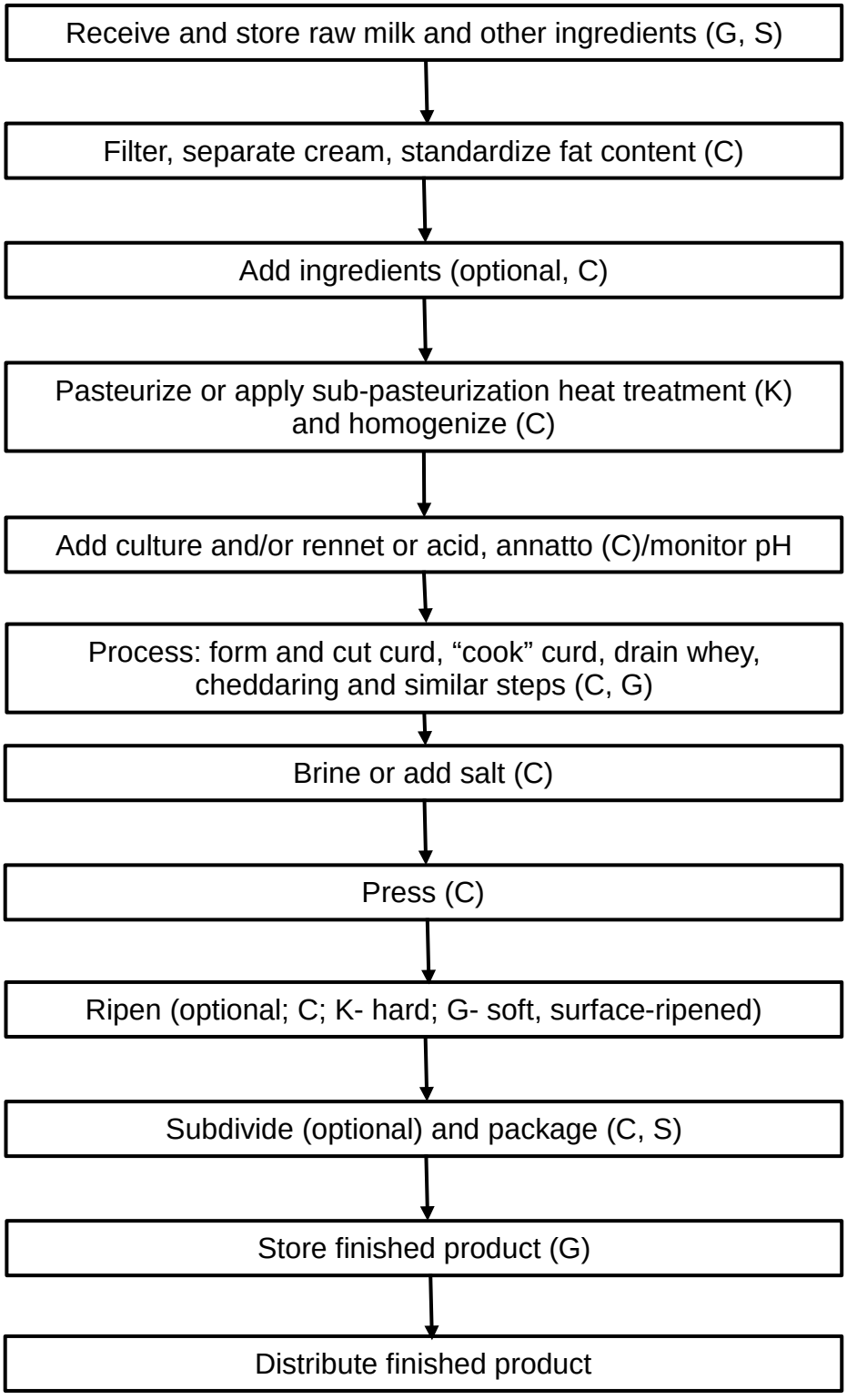
49

Flow Diagram A.5. DAIRY – BUTTER, MARGARINES



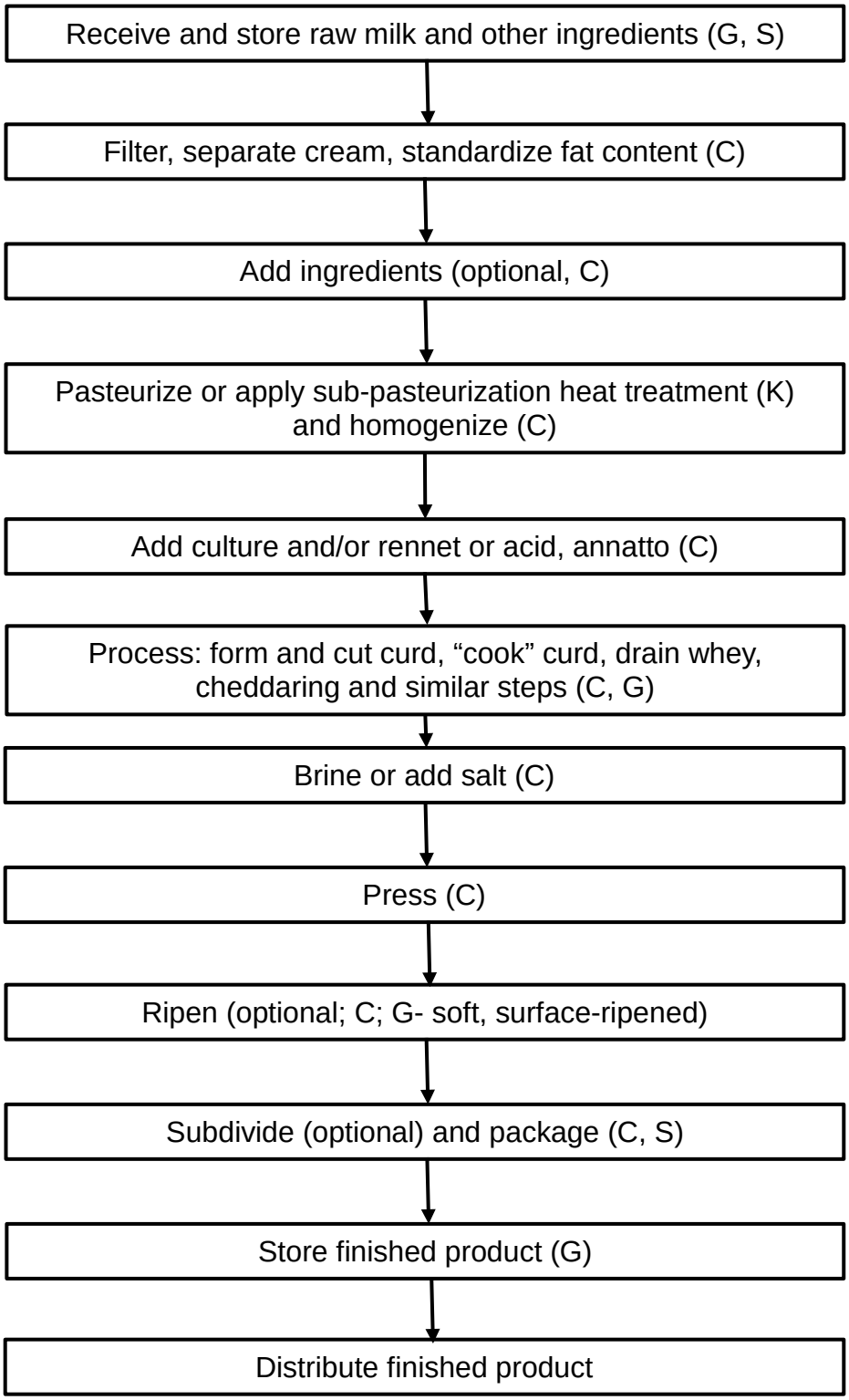
50

Flow Diagram A.6. DAIRY – CHEESE (HARD)



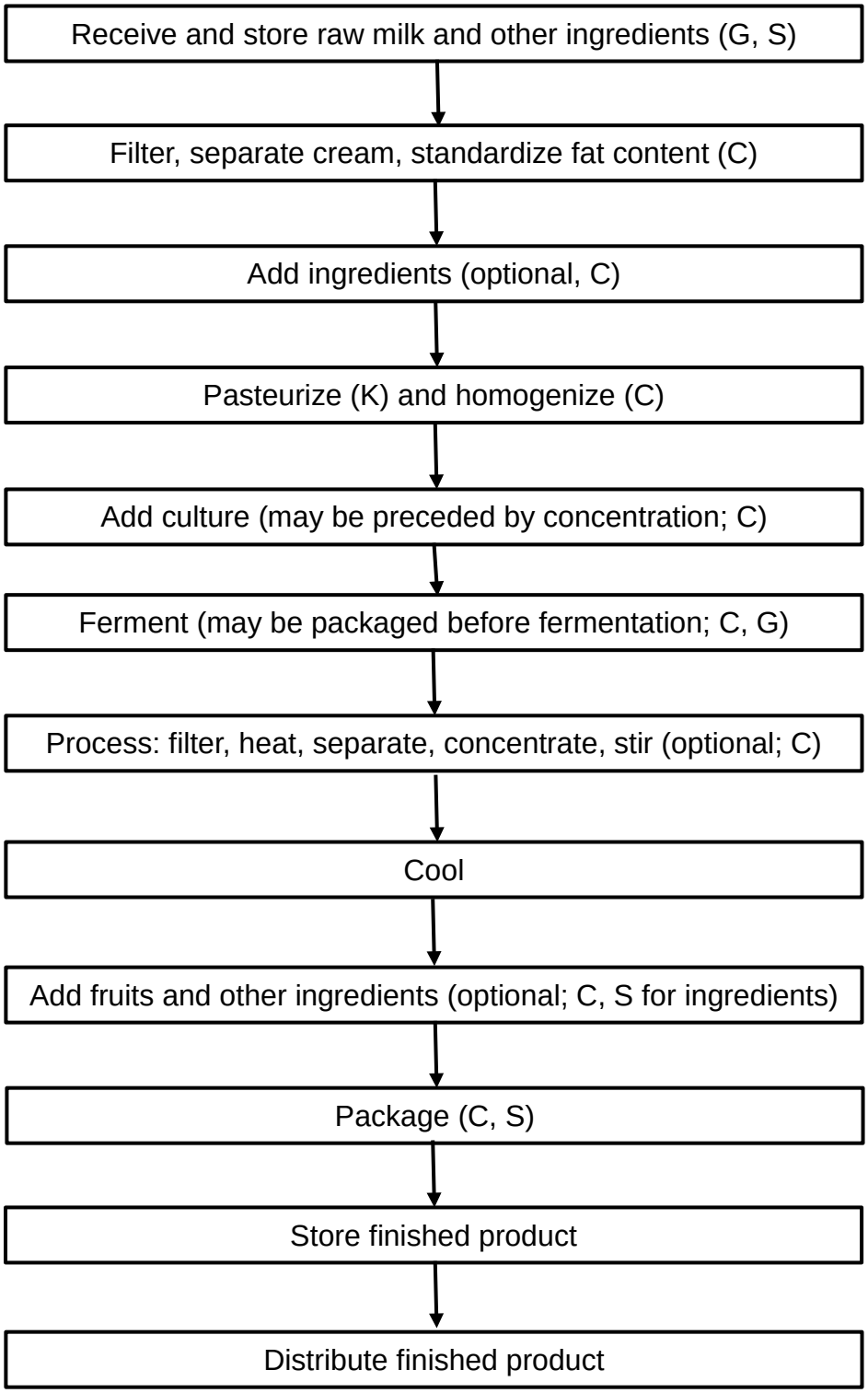
51

Flow Diagram A.7. DAIRY – CHEESE (SOFT, SEMI-SOFT AND SURFACE-RIPENED)



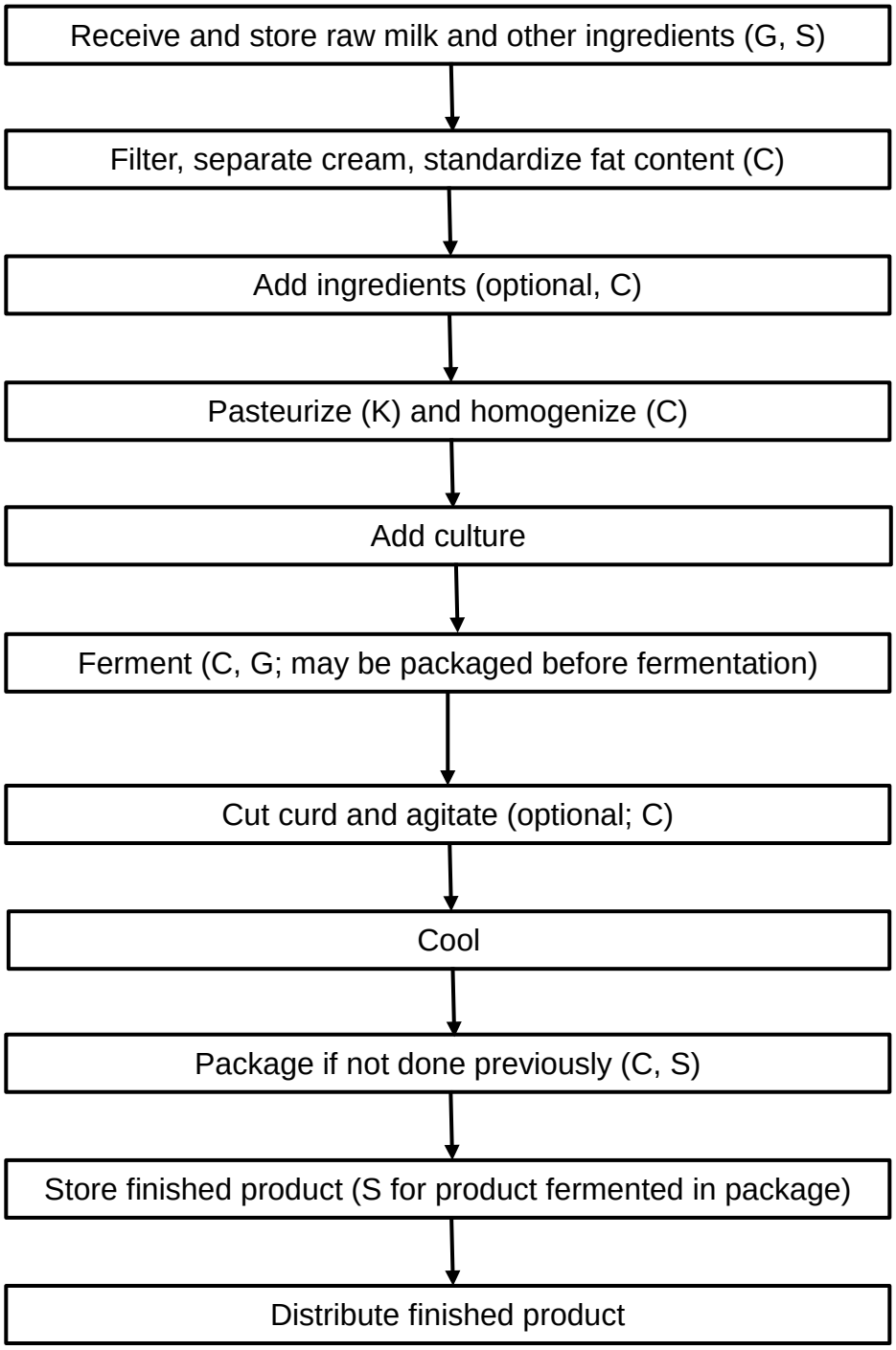
52

Flow Diagram A.8.a. DAIRY PRODUCTS Cultured pH<4.8 (Example – Yogurt)



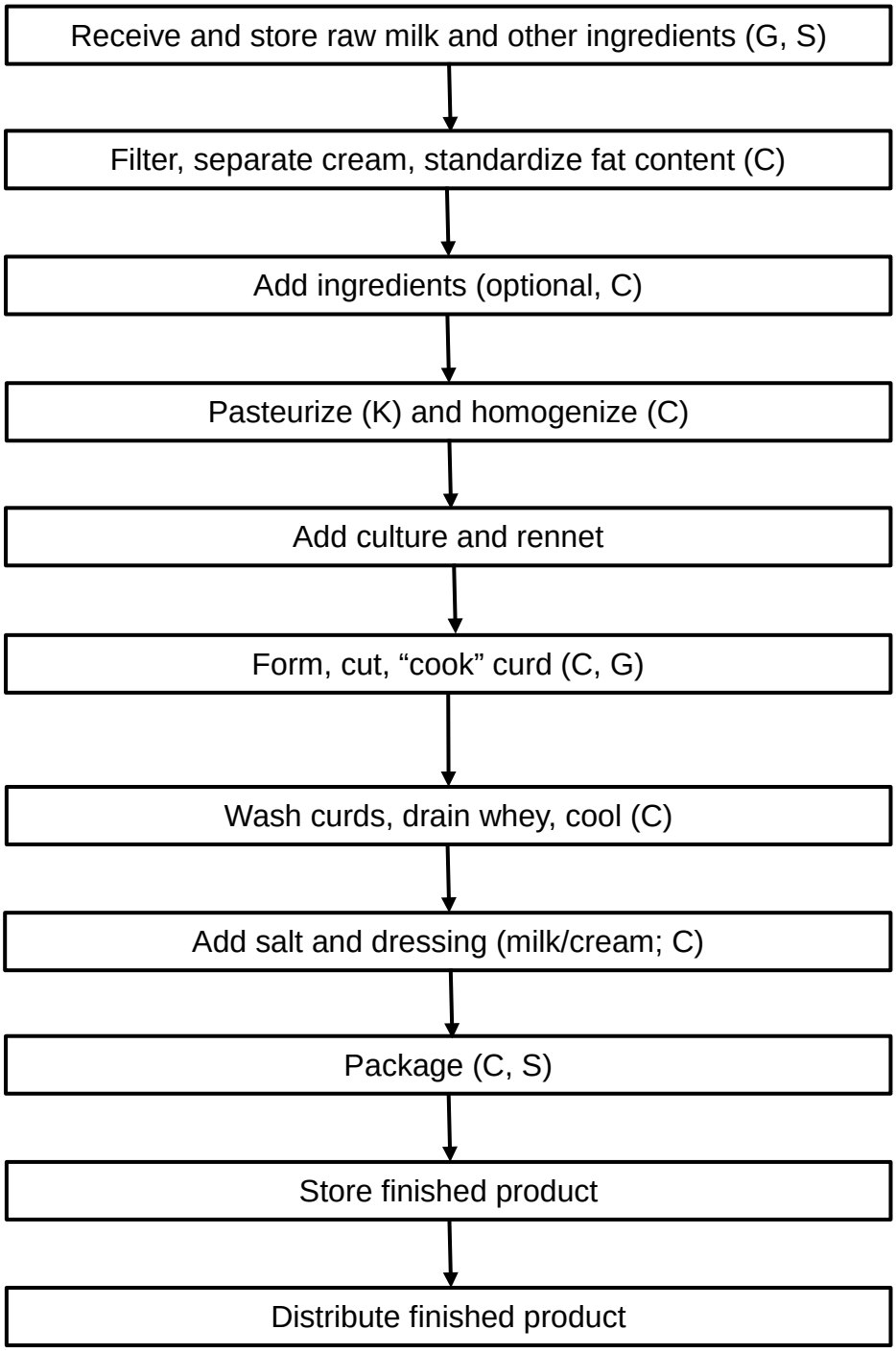
53

Flow Diagram A.8.b. DAIRY – CULTURED, pH<4.8 (Example – Sour Cream Buttermilk, etc.)



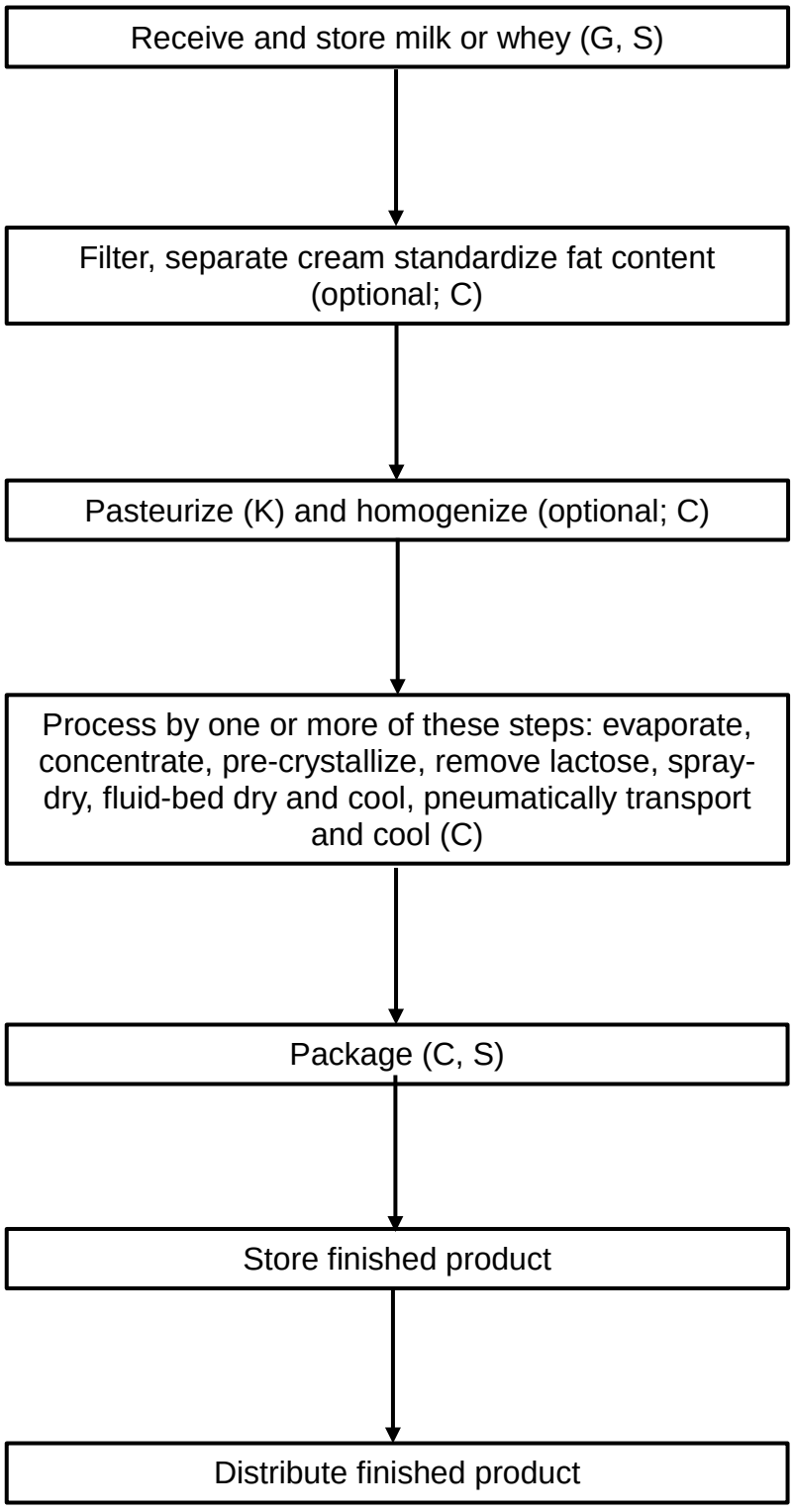
54

Flow Diagram A.9. DAIRY – CULTURED, pH>4.8 AND <5.4 (Example – Cottage Cheese)

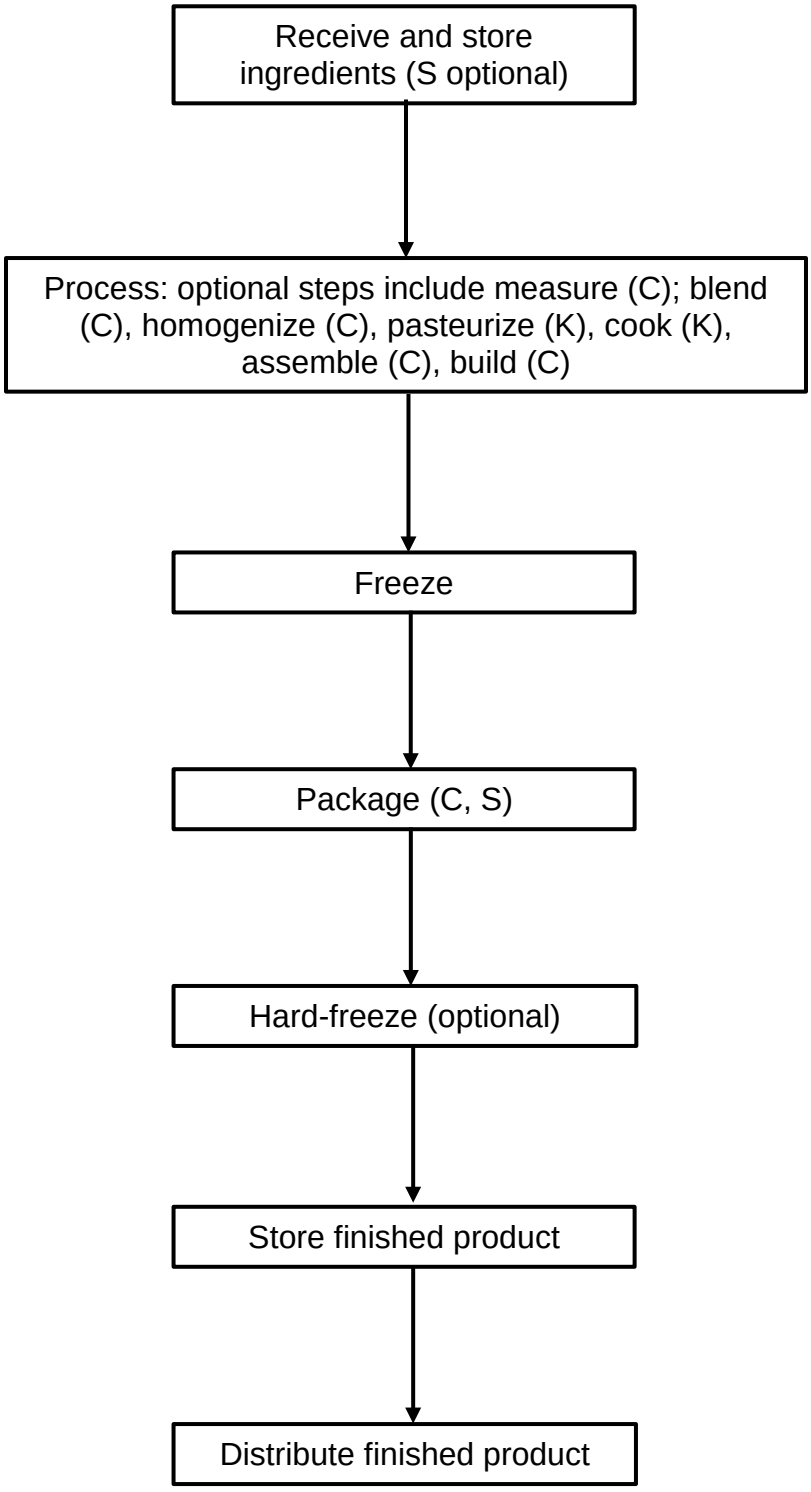


55

Flow Diagram A.10. DAIRY – DRIED PRODUCTS
(does not include dairy ingredients used to make infant formula)

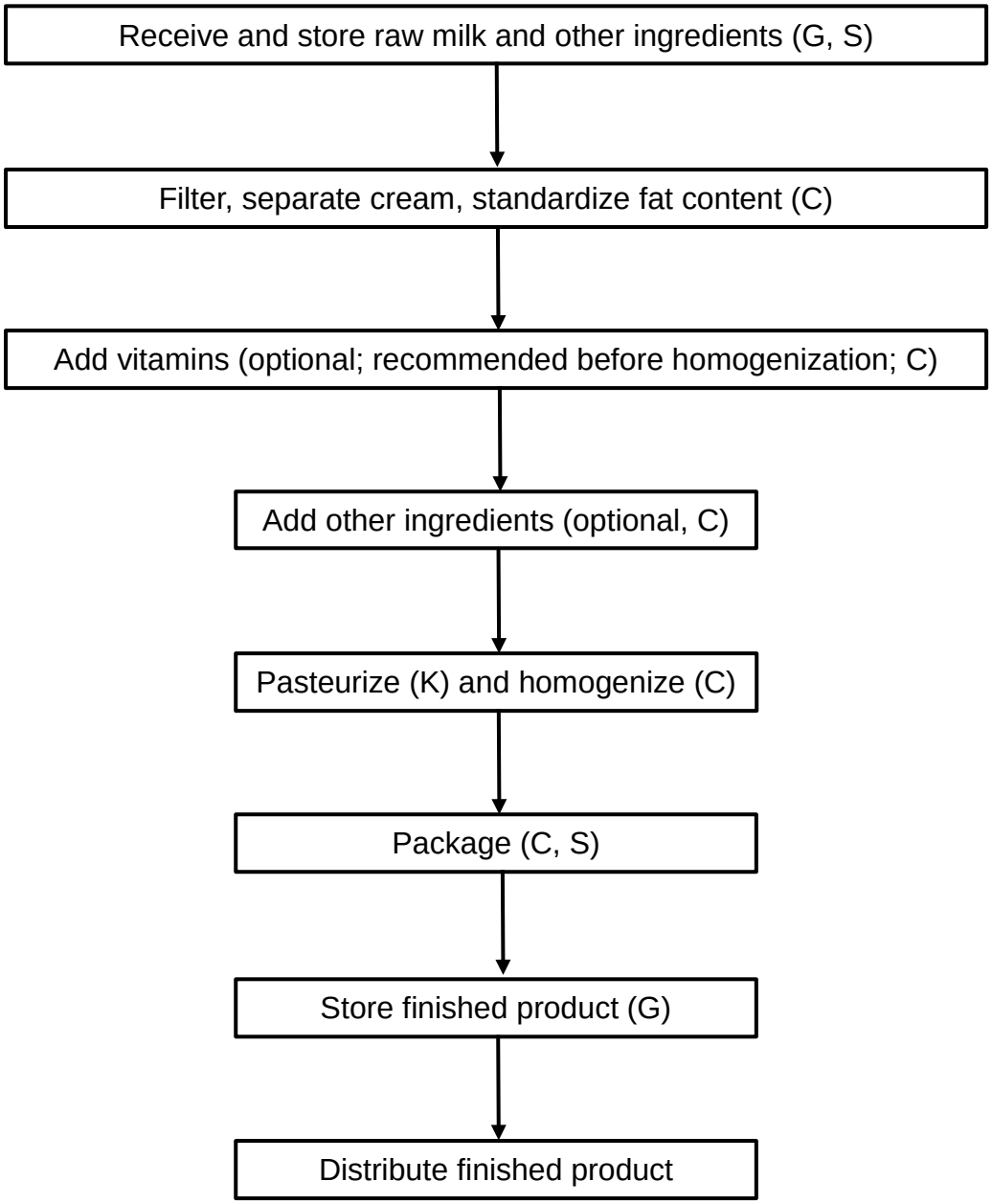


Flow Diagram A.11. DAIRY – FROZEN DESSERTS

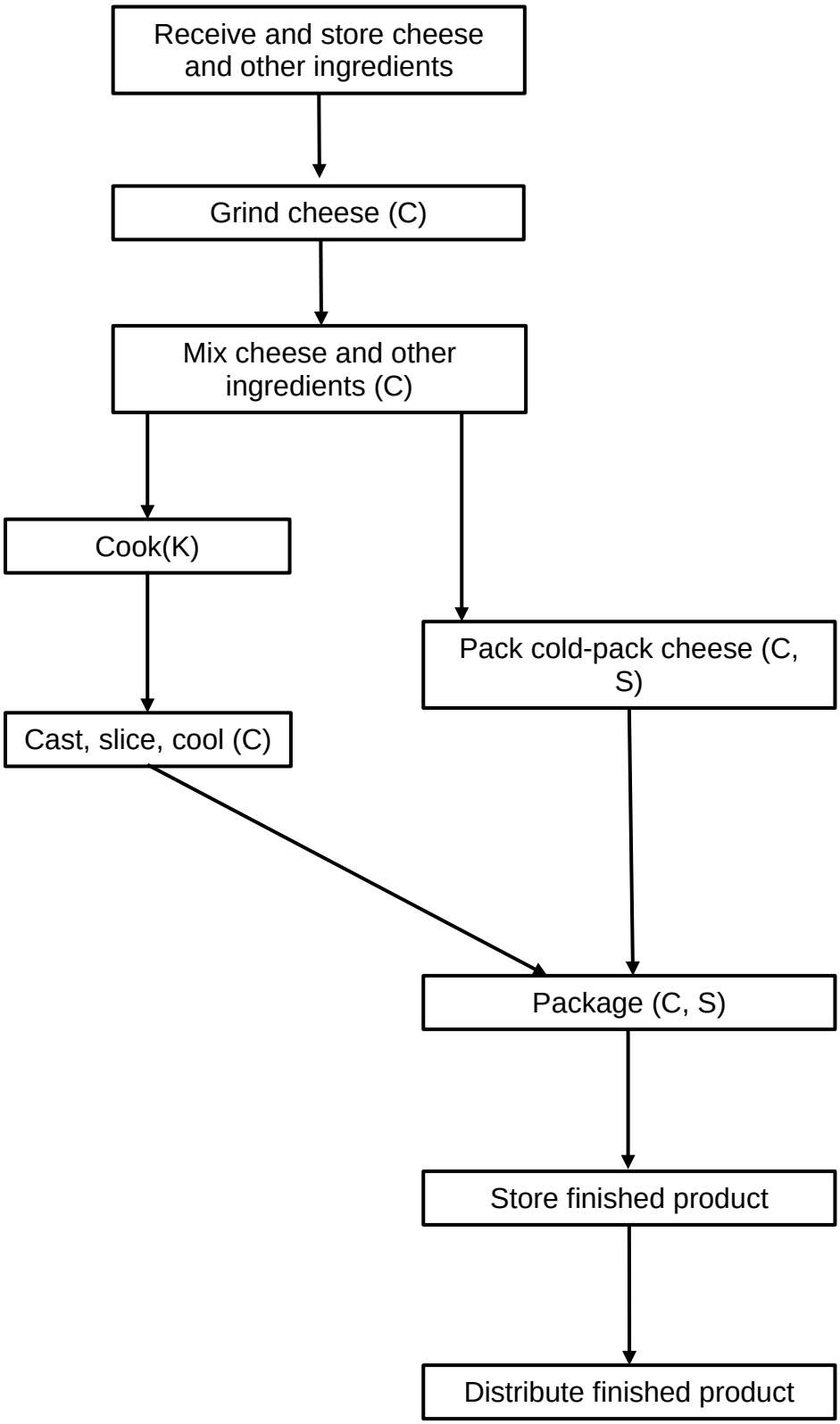


57

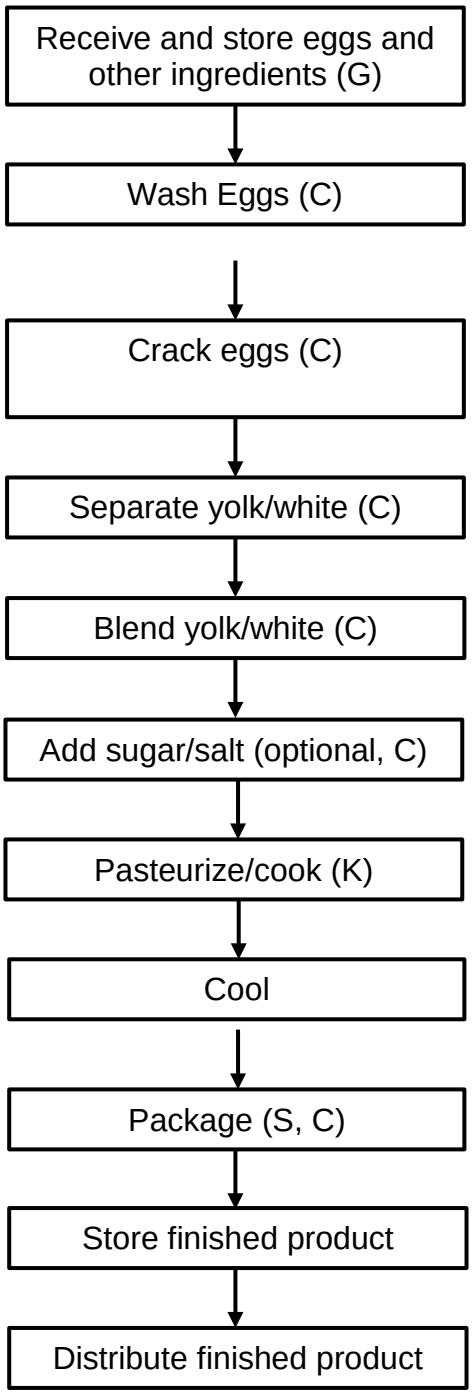
Flow Diagram A.12. DAIRY – MILK AND MILK PRODUCTS (Fluid)



Flow Diagram A.13. DAIRY – PROCESS CHEESE

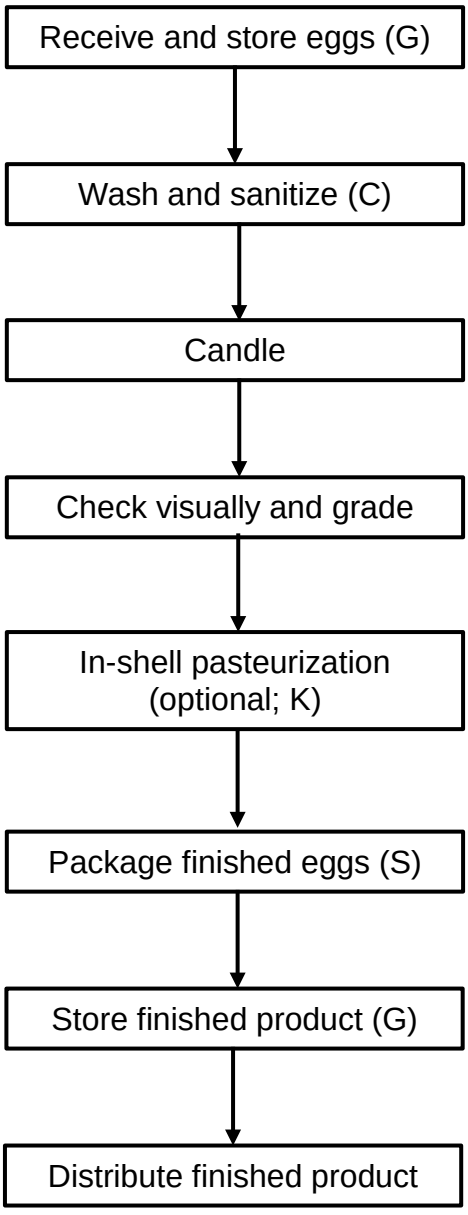


Flow Diagram A.14. EGG PRODUCTS – PASTEURIZED, PROCESSED



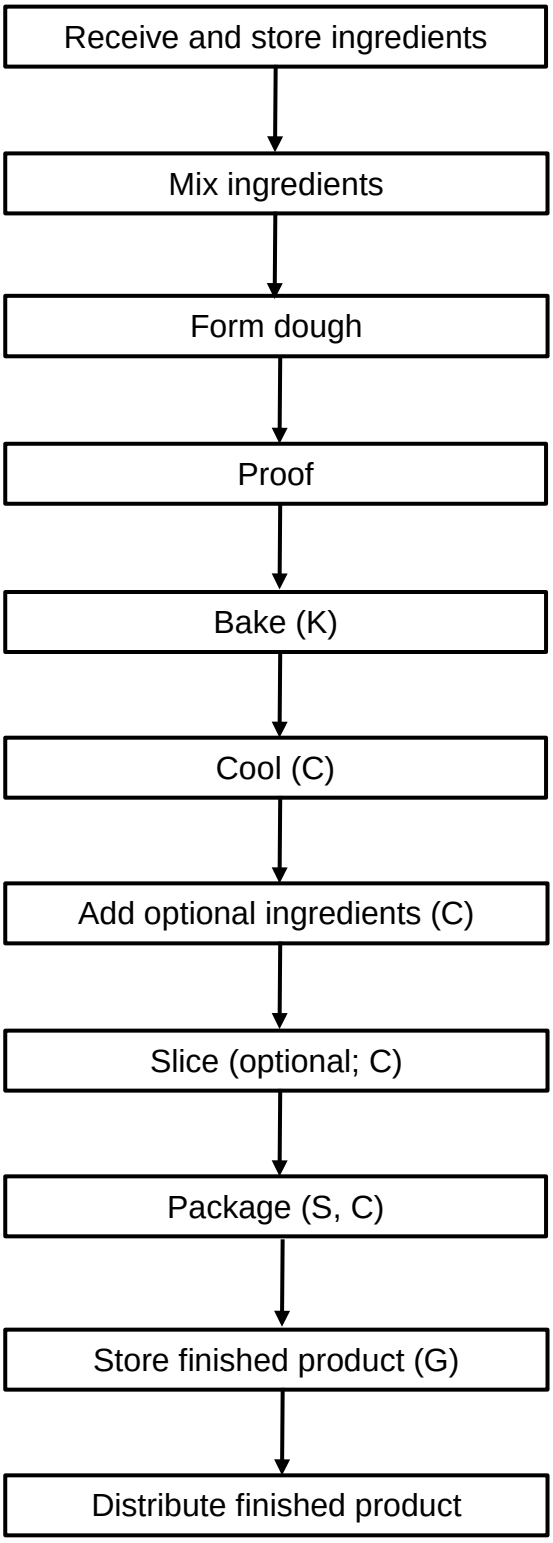
60

Flow Diagram A.15. EGG PRODUCTS – SHELL EGGS RAW



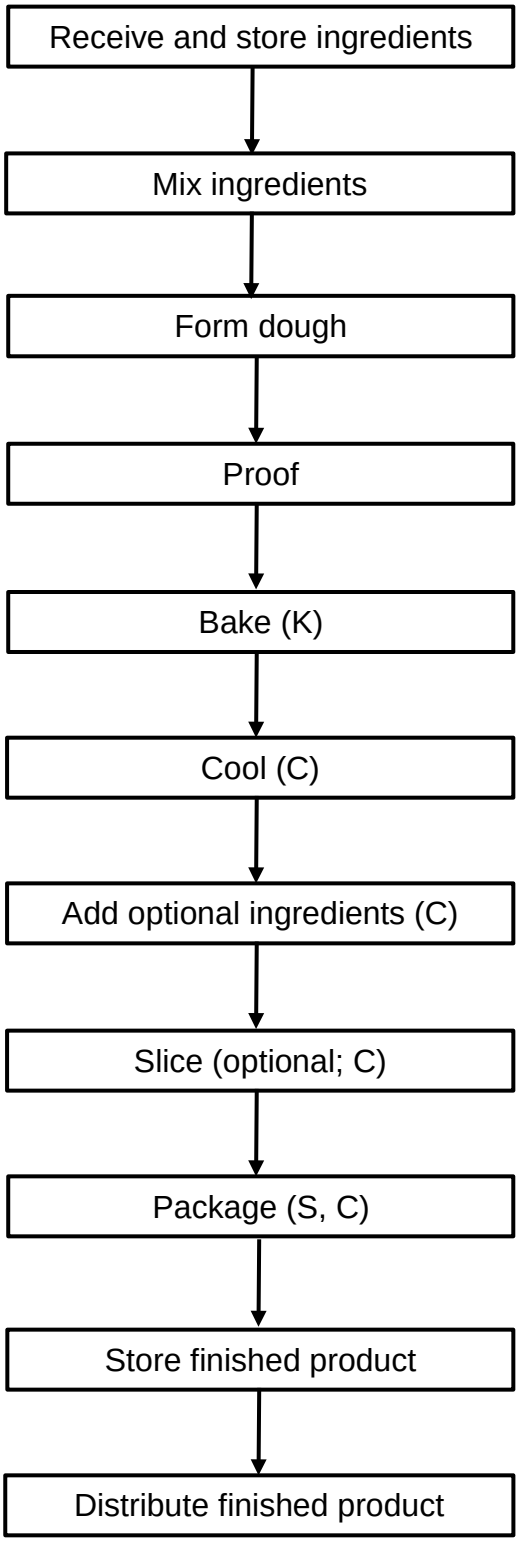
61

Flow Diagram A.16. GRAIN BASED PRODUCTS – BAKED ITEMS, RTE, REFRIGERATED OR TCS



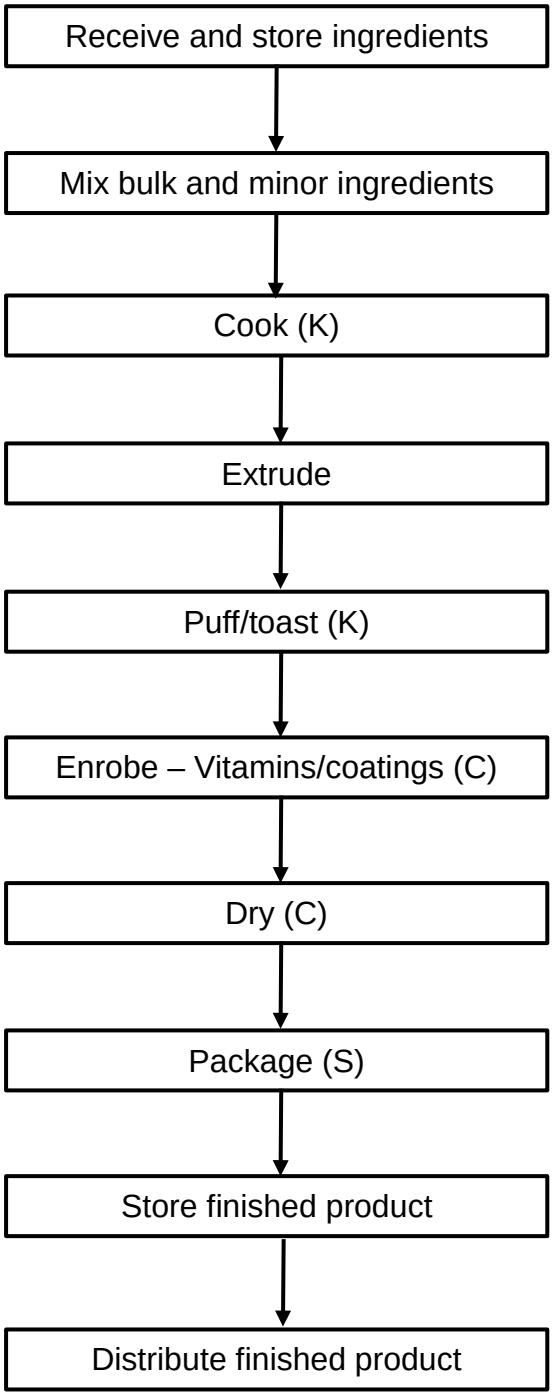
62

Flow Diagram A.17. GRAIN BASED PRODUCTS – BAKED ITEMS, RTE, SHELF STABLE, NON-TCS



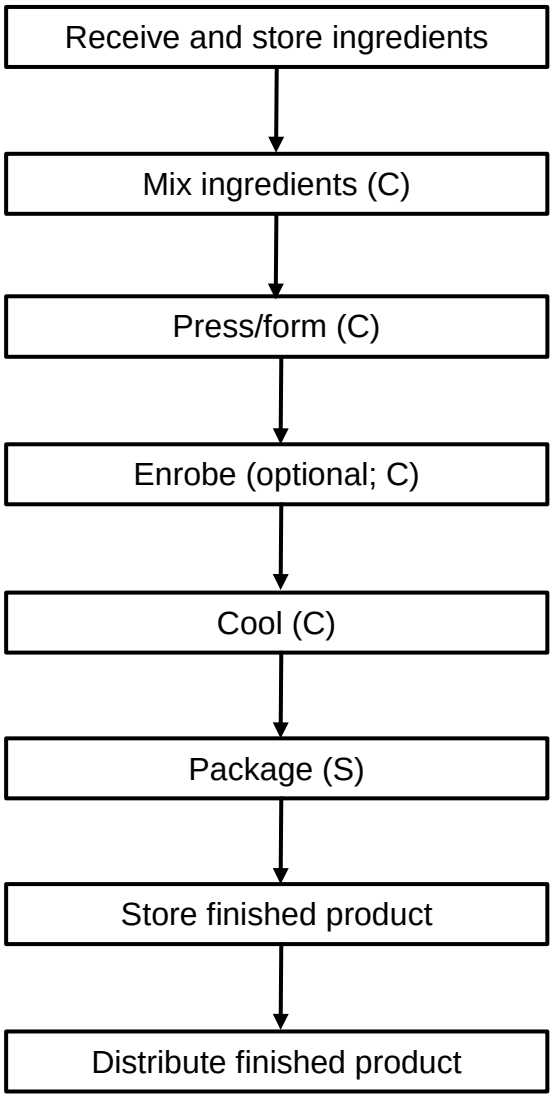
63

Flow Diagram A.18. GRAIN BASED PRODUCTS – RTE, CEREALS

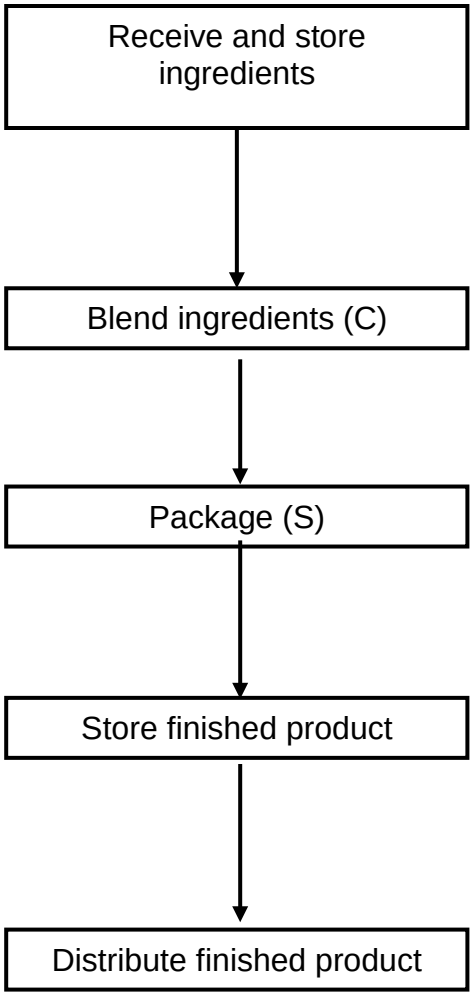


64

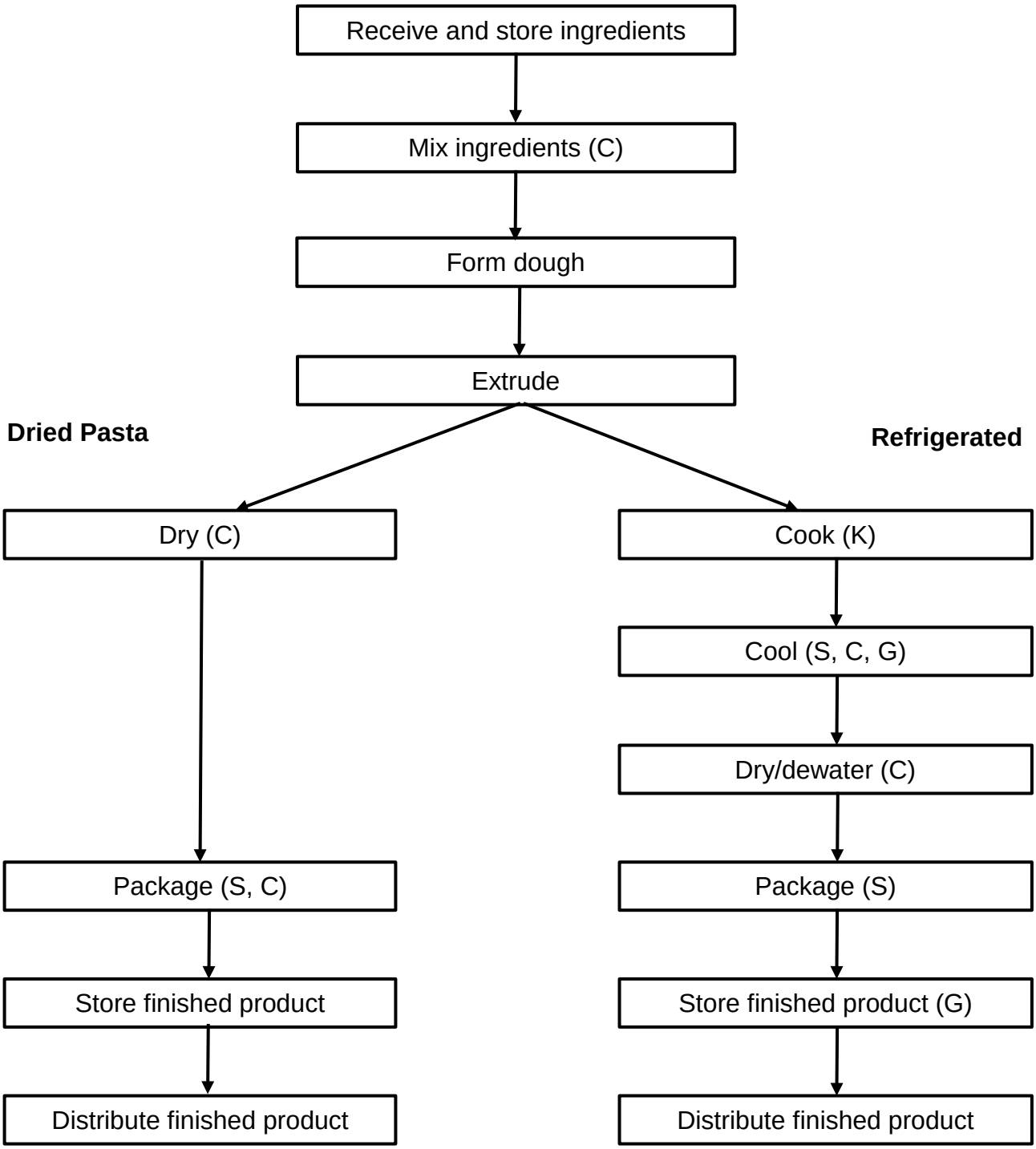
Flow Diagram A.19. GRAIN BASED PRODUCTS – RTE, COLD PRESSED BARS



65 Flow Diagram A.20. GRAIN BASED PRODUCTS – NON-RTE, DRY FLOUR BASED MIXES

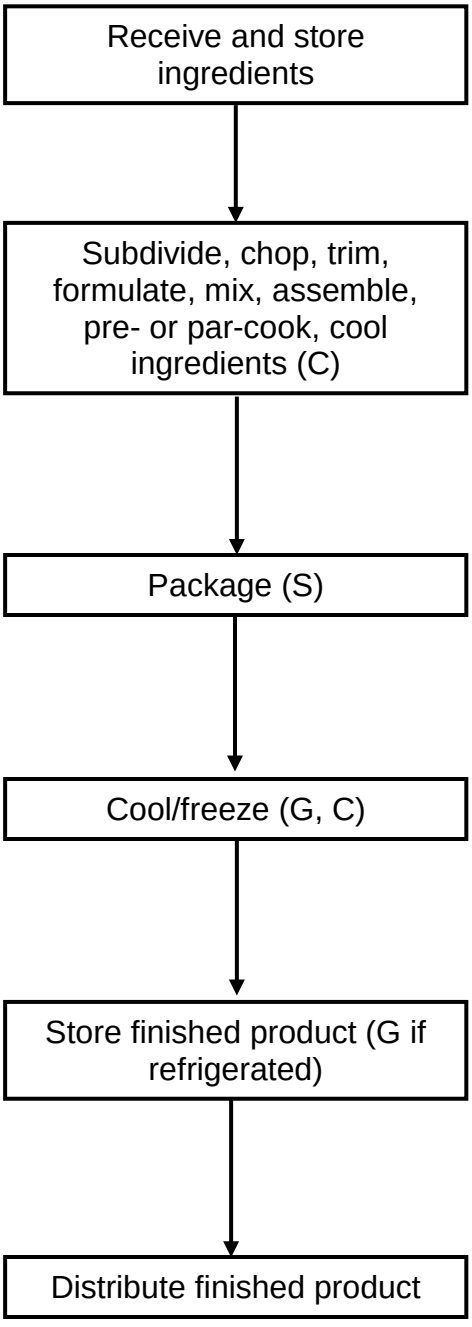


66 Flow Diagram A.21. GRAIN BASED PRODUCTS – NON RTE, PASTA, DRIED OR REFRIGERATED



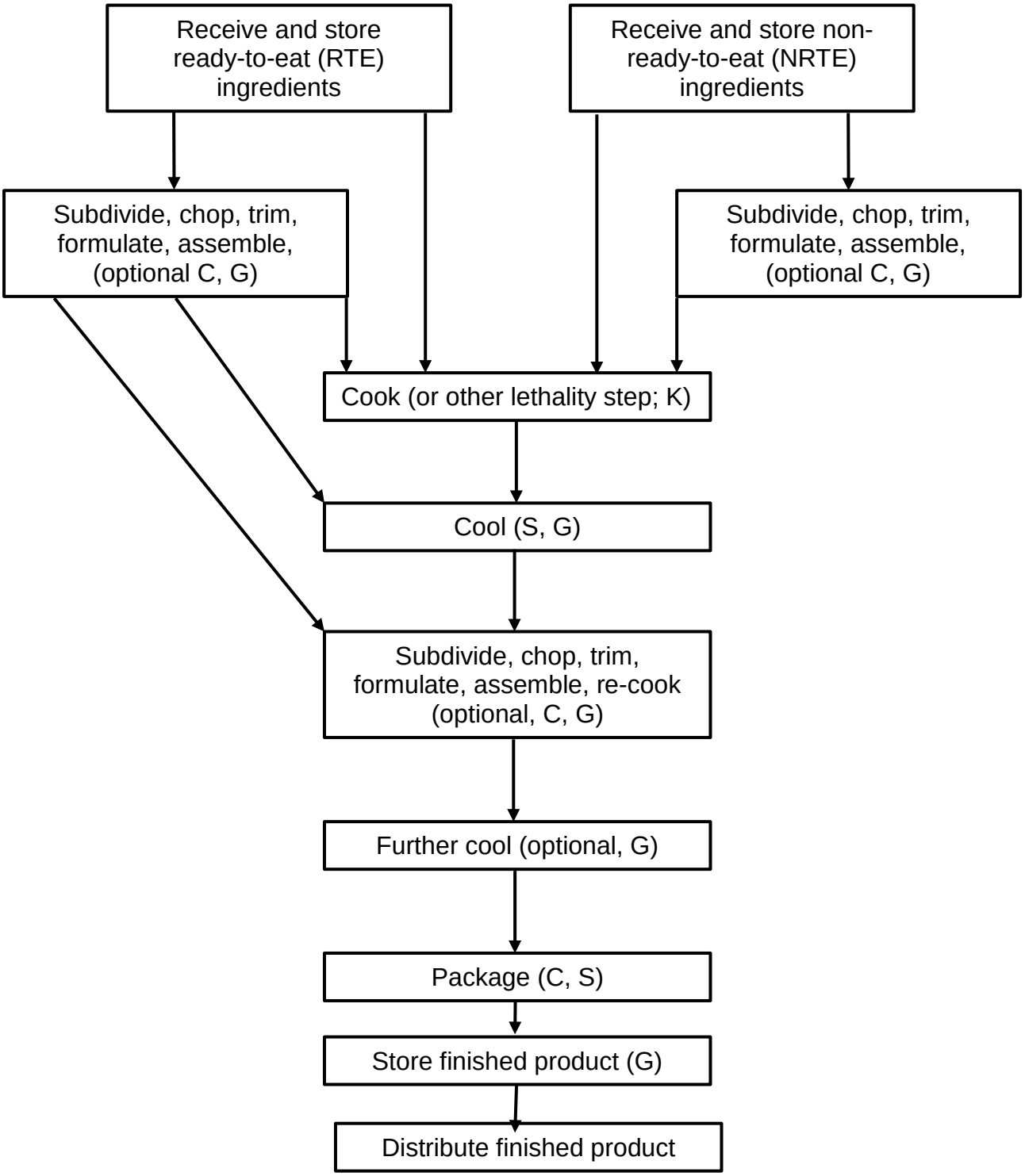
67

Flow Diagram A.22. MEALS AND ENTRÉES – NON-RTE, READY TO COOK (RTC) MEALS, INCLUDES RAW INGREDIENTS



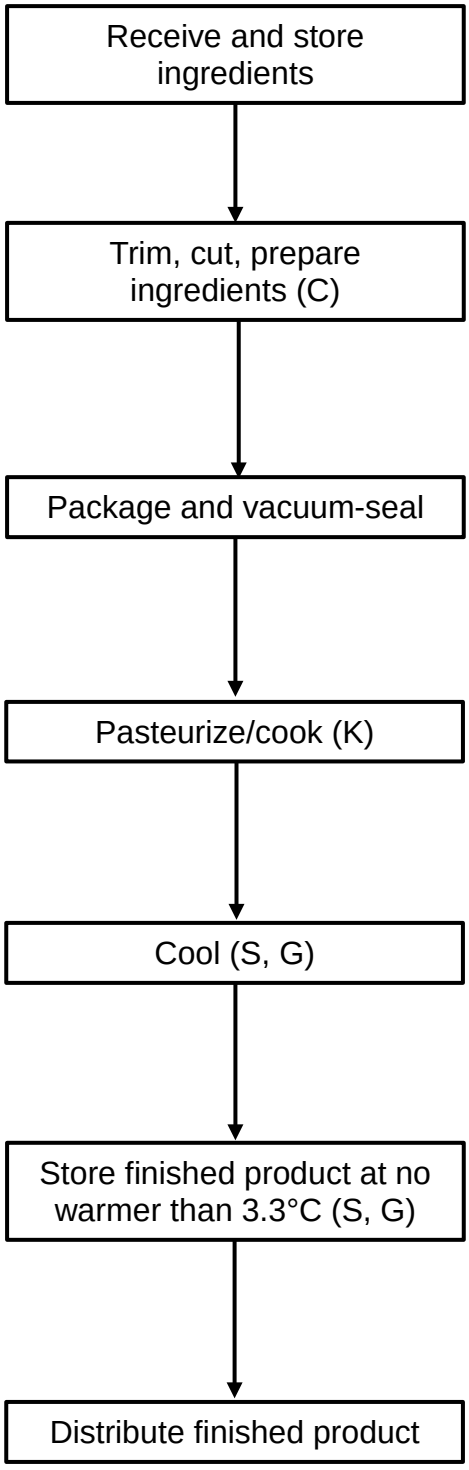
68

Flow Diagram A.23 MEALS AND ENTRÉES – RTE, DELI SALADS, SANDWICHES HEAT-EAT MEALS, SUSHI



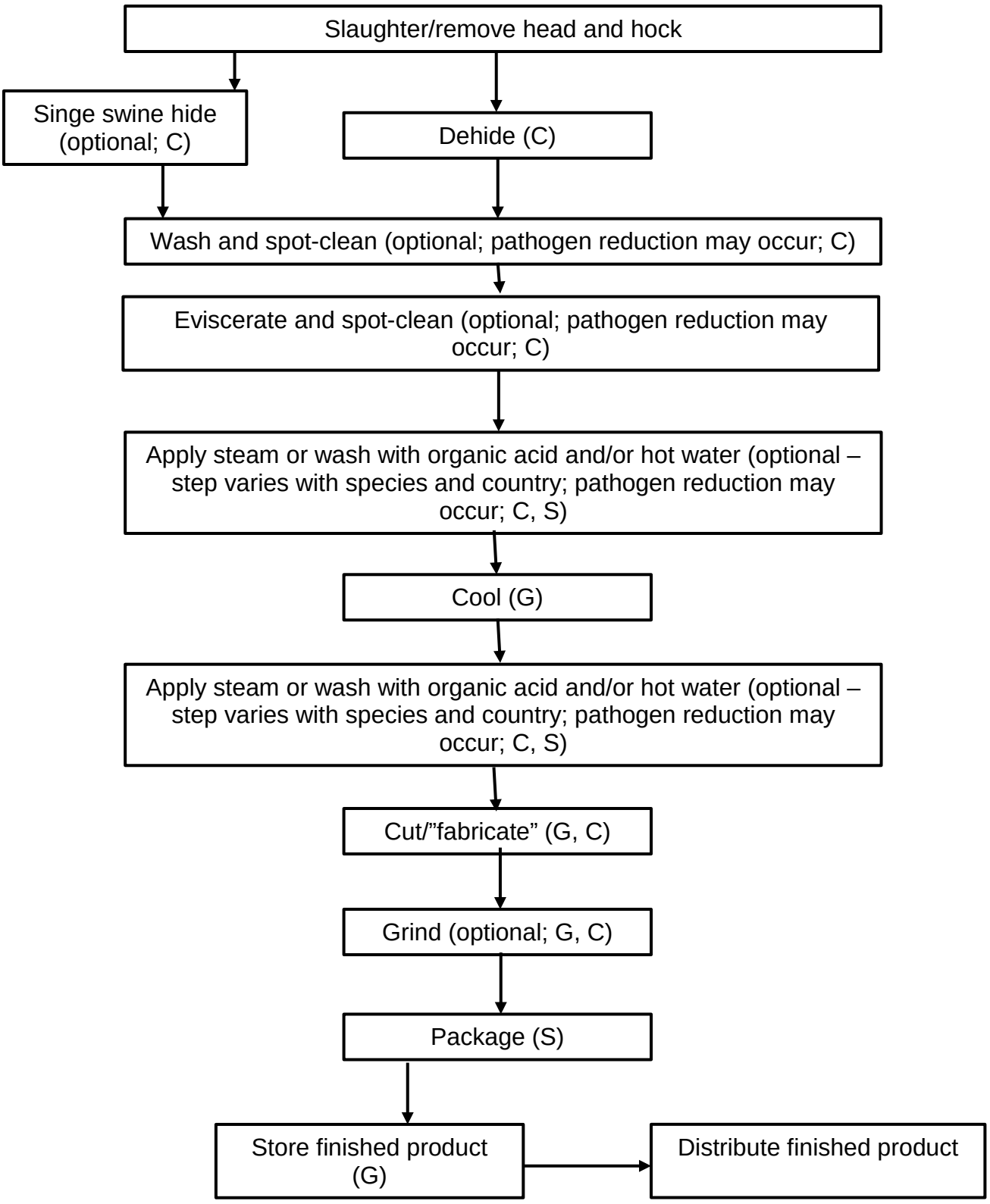
69

Flow Diagram A.24. MEALS AND ENTRÉES – SOUS VIDE, COOK AND CHILL



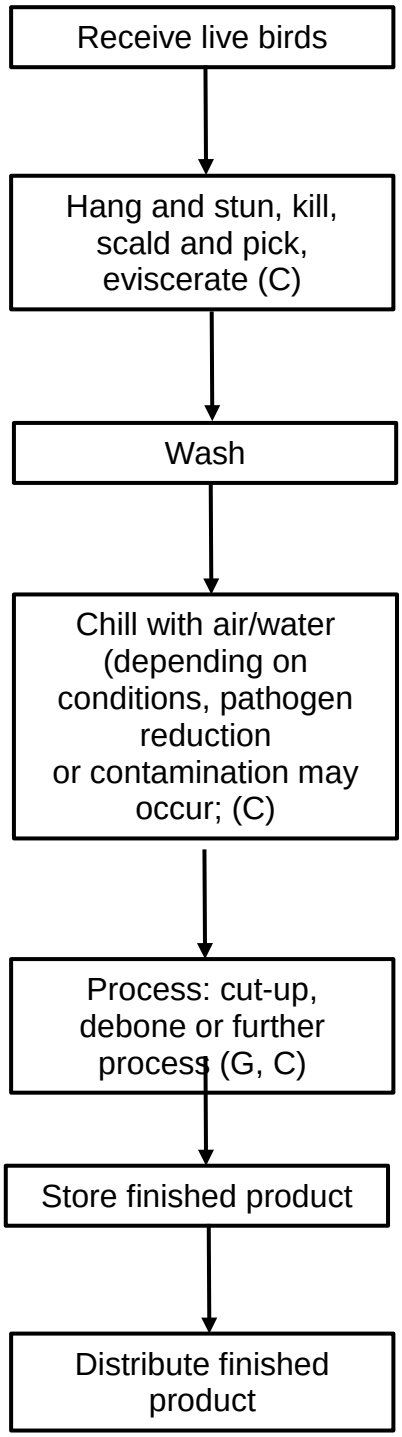
70

Flow Diagram A.25. MEAT, PORK AND POULTRY PRODUCTS – NON-RTE, BEEF AND PORK RAW, INTACT AND NON-INTACT

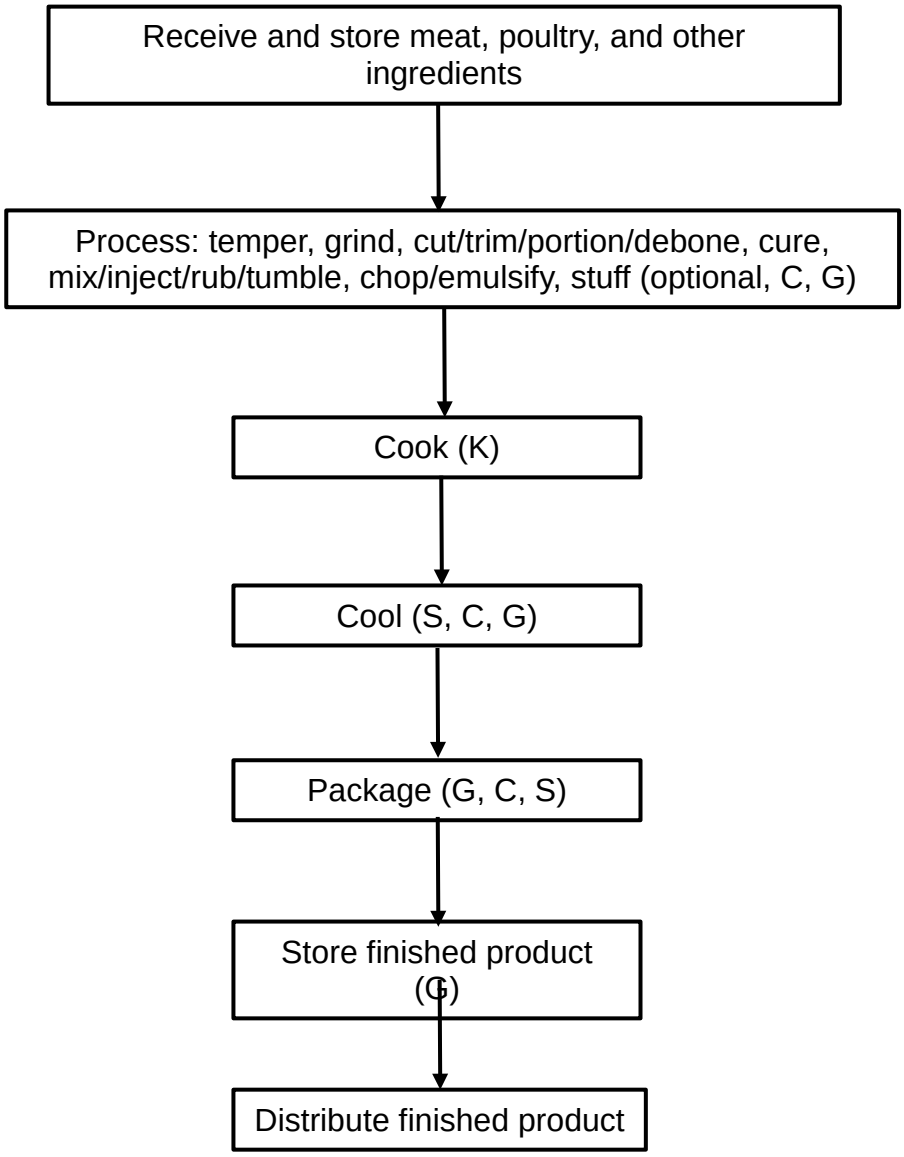


71

Flow Diagram A.26. MEAT, PORK AND POULTRY PRODUCTS – NON-RTE, POULTRY, RAW

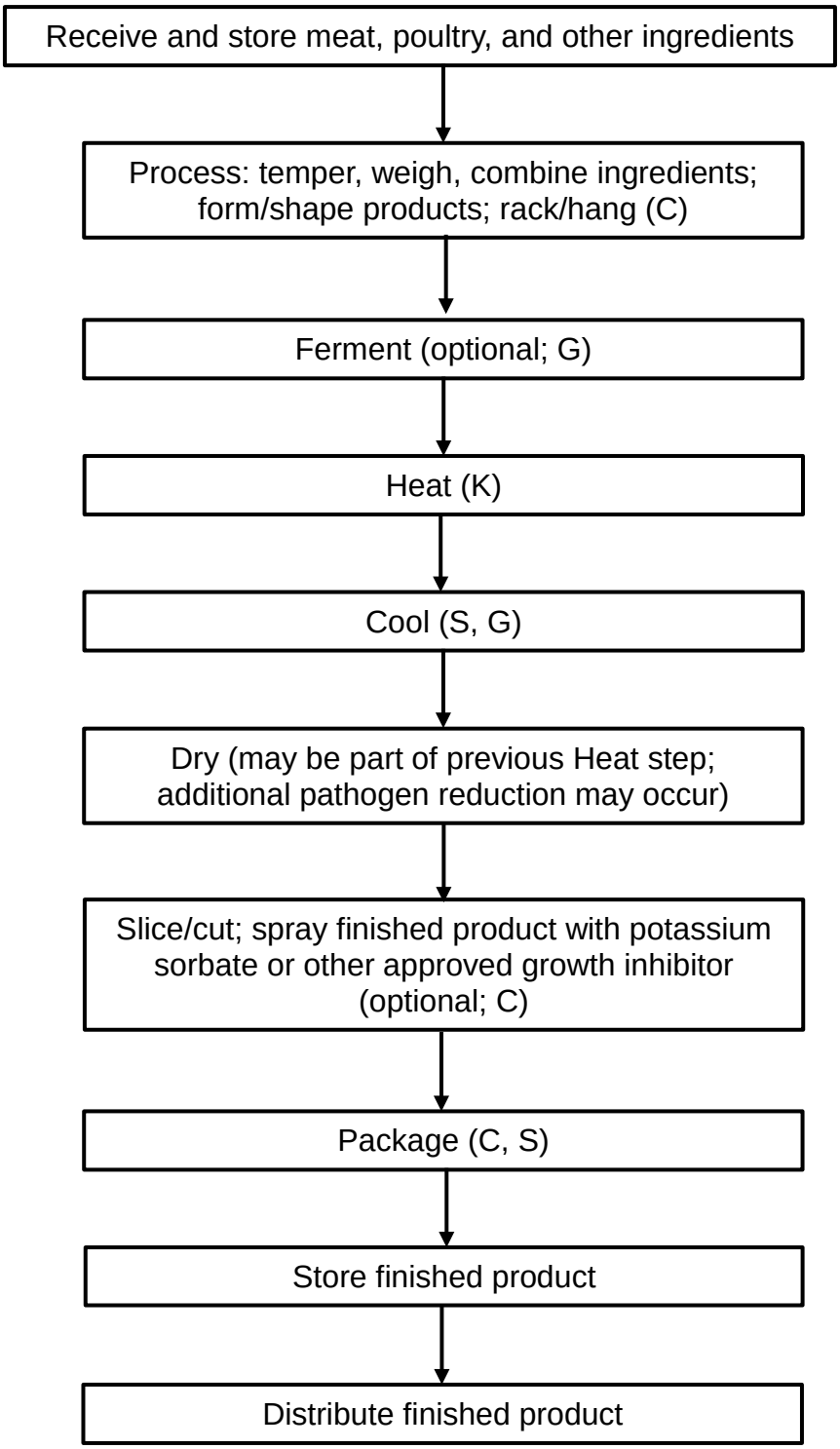


72 Flow Diagram A.27. MEAT, PORK AND POULTRY PRODUCTS – RTE, COOKED PERISHABLE



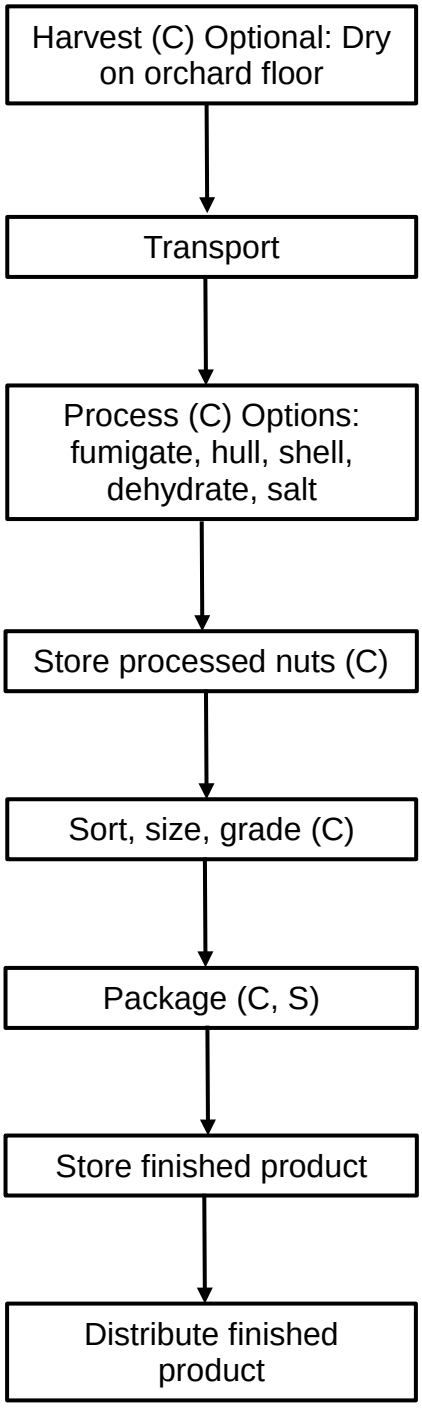
73

Flow Diagram A.28. MEAT, PORK AND POULTRY PRODUCTS – RTE FERMENTED AND DRIED, DRIED



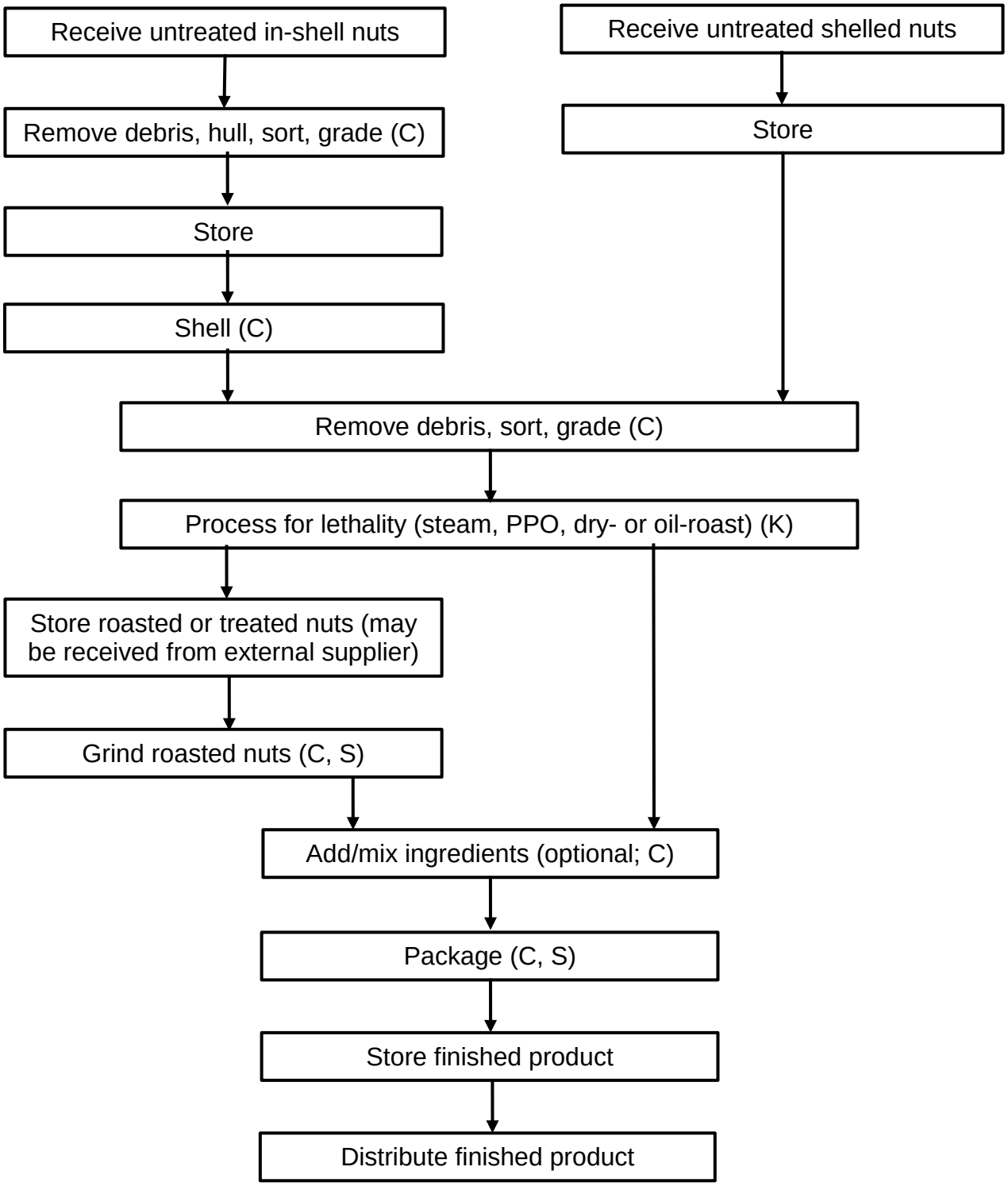
74

Flow Diagram A.29. NUTS AND NUT BUTTERS – NUTS, RTE, NOT PROCESSED FOR LETHALITY



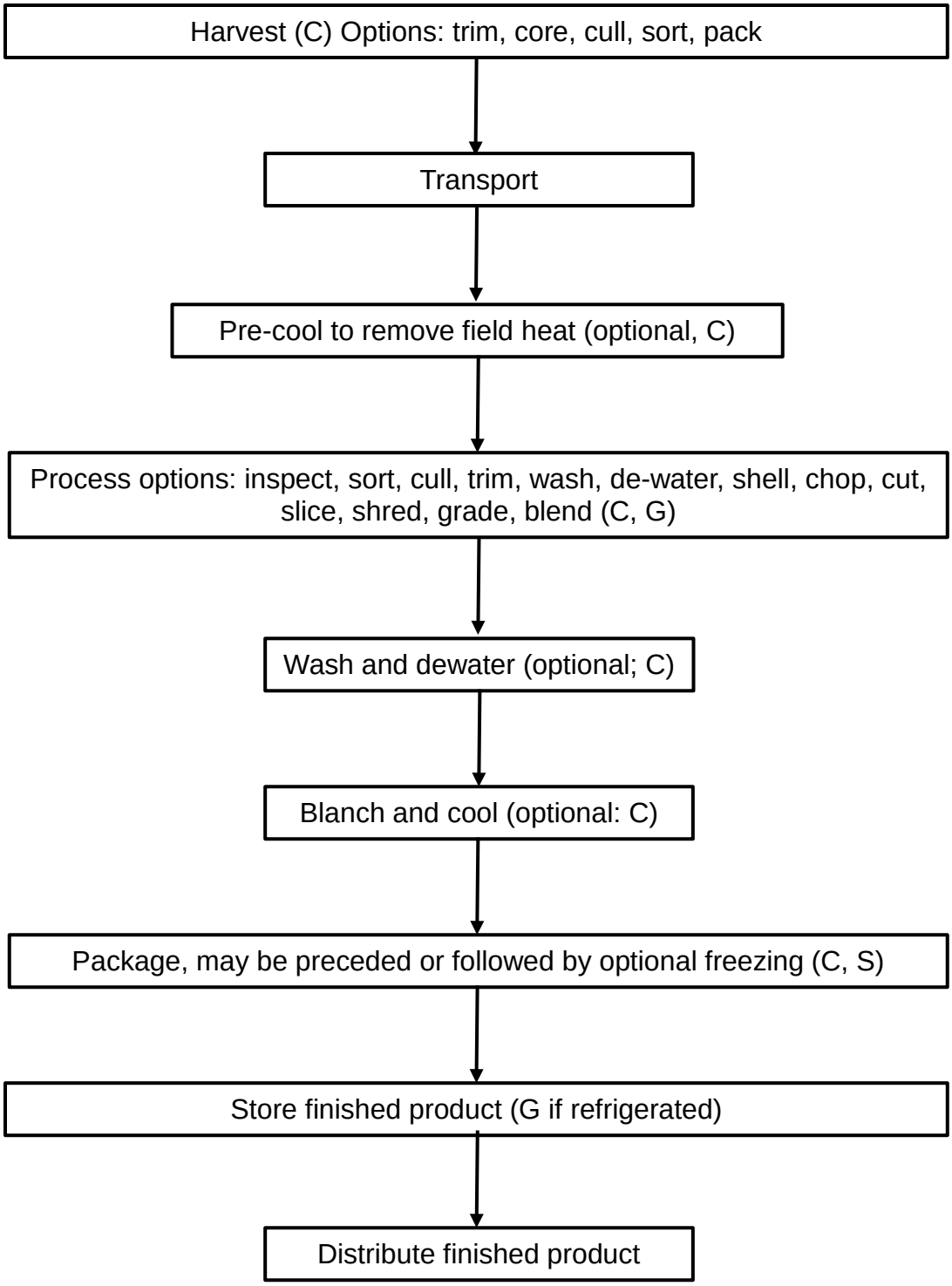
75

Flow Diagram A.30. NUTS AND NUT BUTTERS – RTE, PROCESSED FOR LETHALITY



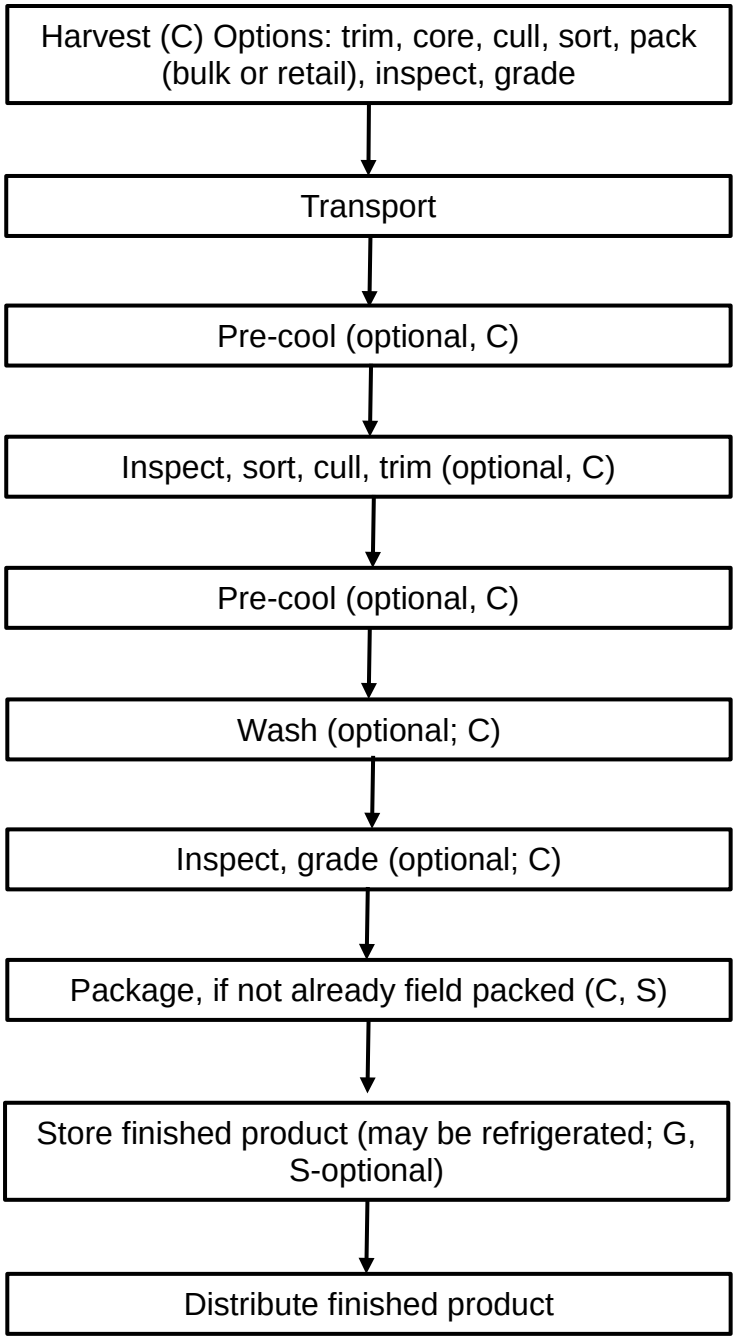
76

Flow Diagram A.31. PRODUCE – FRUITS AND VEGETABLES, CUT FROZEN, OR REFRIGERATED, MINIMALLY PROCESSED



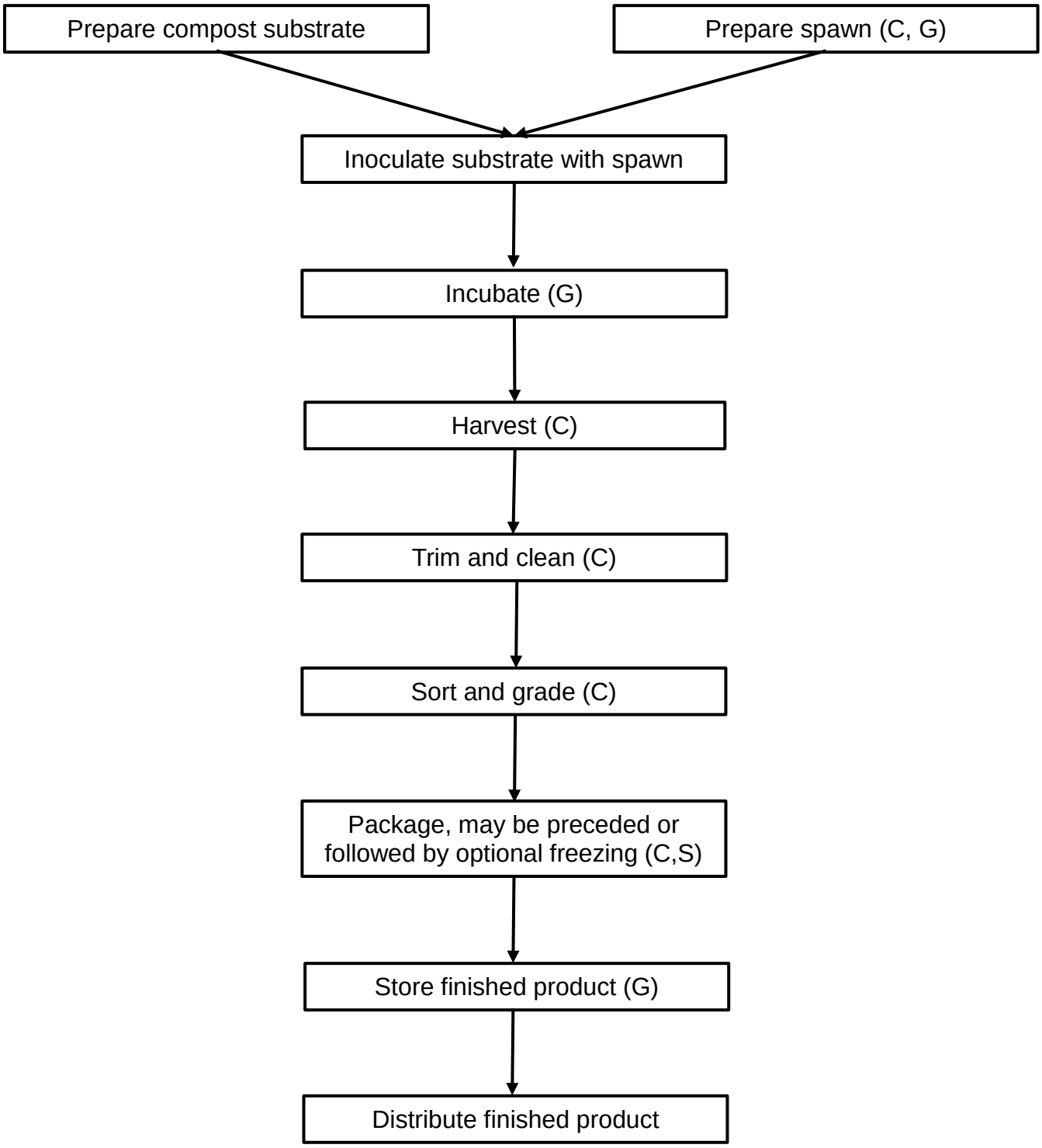
77

Flow Diagram A.32. PRODUCE – FRUITS AND VEGETABLES, WHOLE



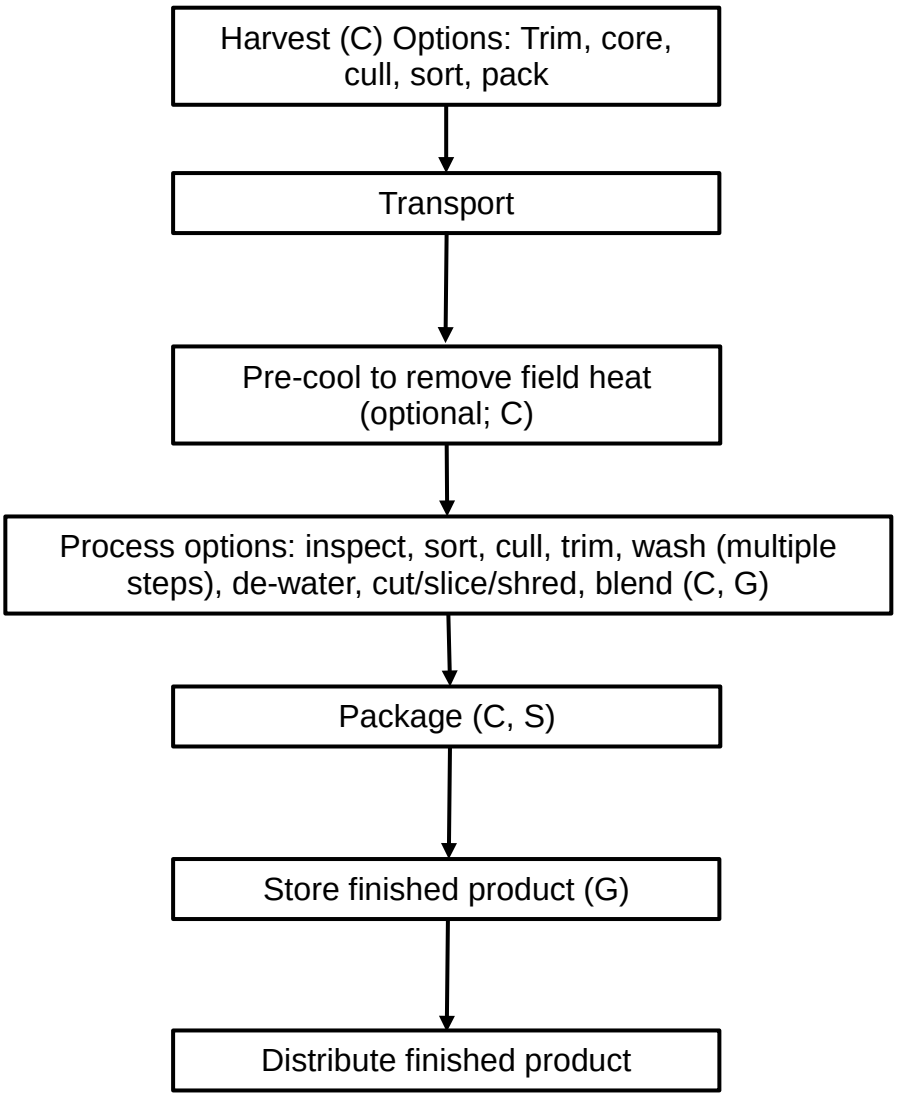
78

Flow Diagram A.33. PRODUCE – MUSHROOMS – FRESH OR FROZEN, WHOLE, SLICED, NOT CANNED OR MARINATED



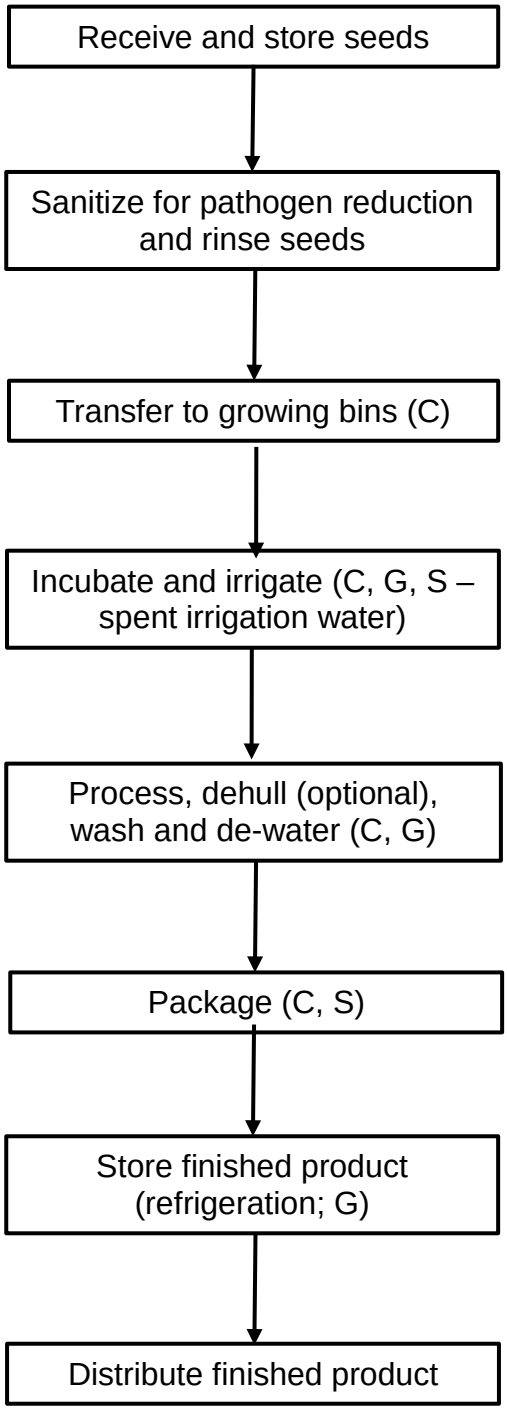
79

Flow Diagram A.34. PRODUCE – PACKAGED SALADS AND LEAFY GREENS



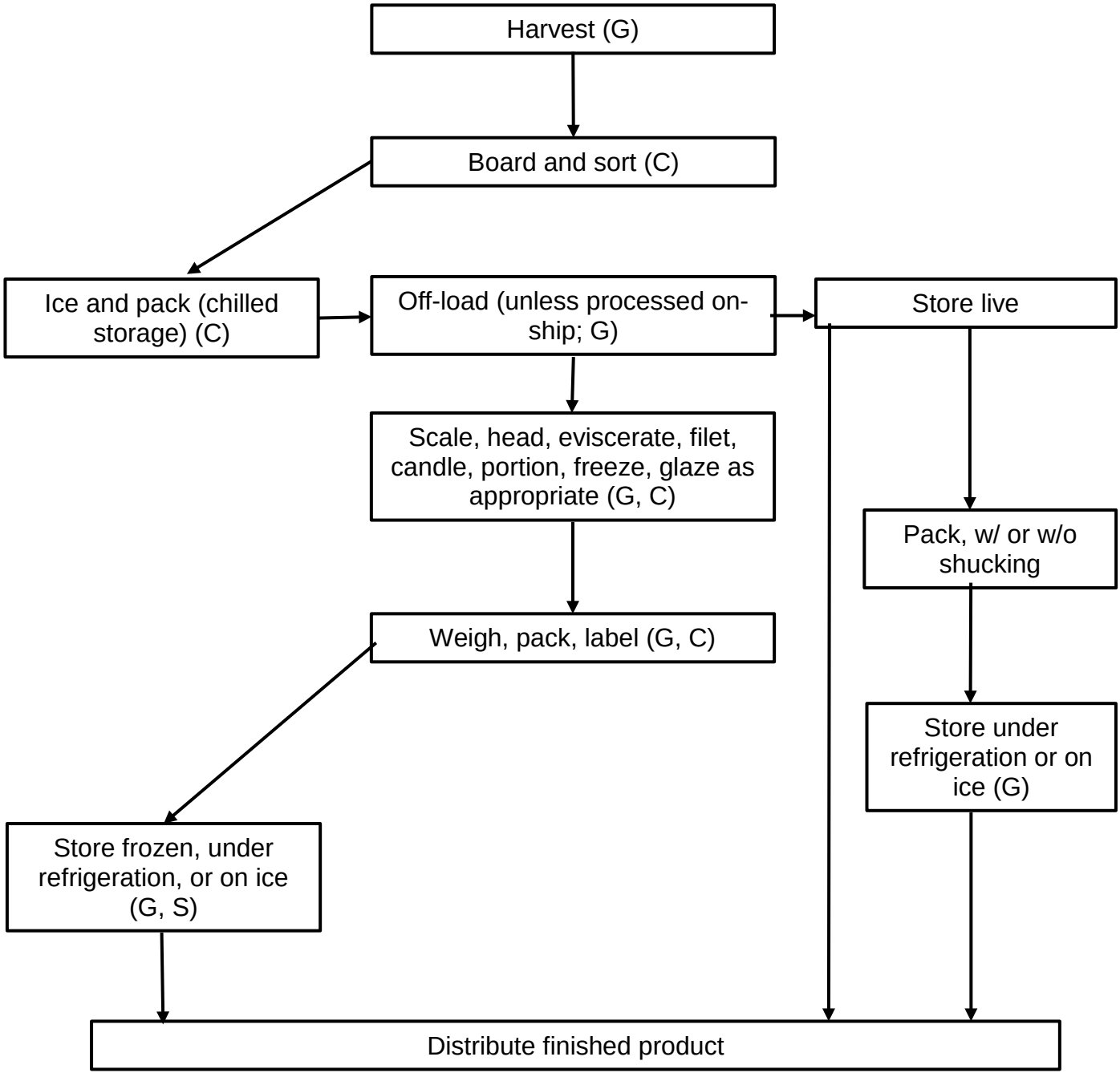
80

Flow Diagram A.35. PRODUCE – VEGETABLE SPROUTS



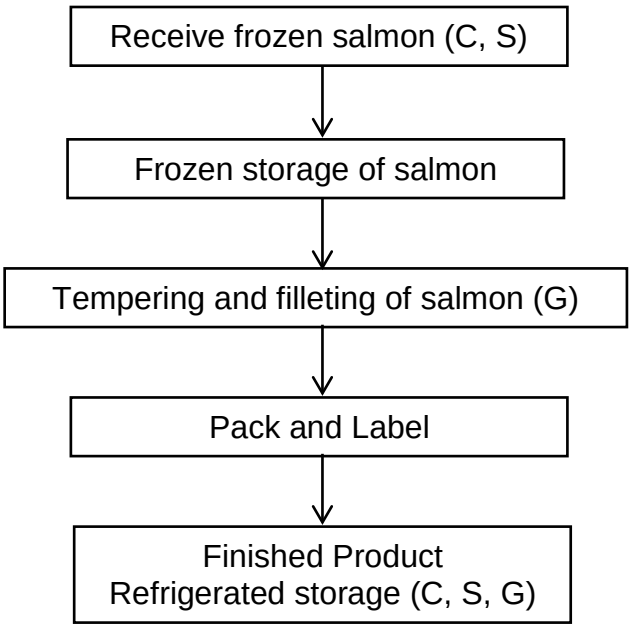
81

Flow Diagram A.36a. SEAFOOD – NON-RTE, RAW



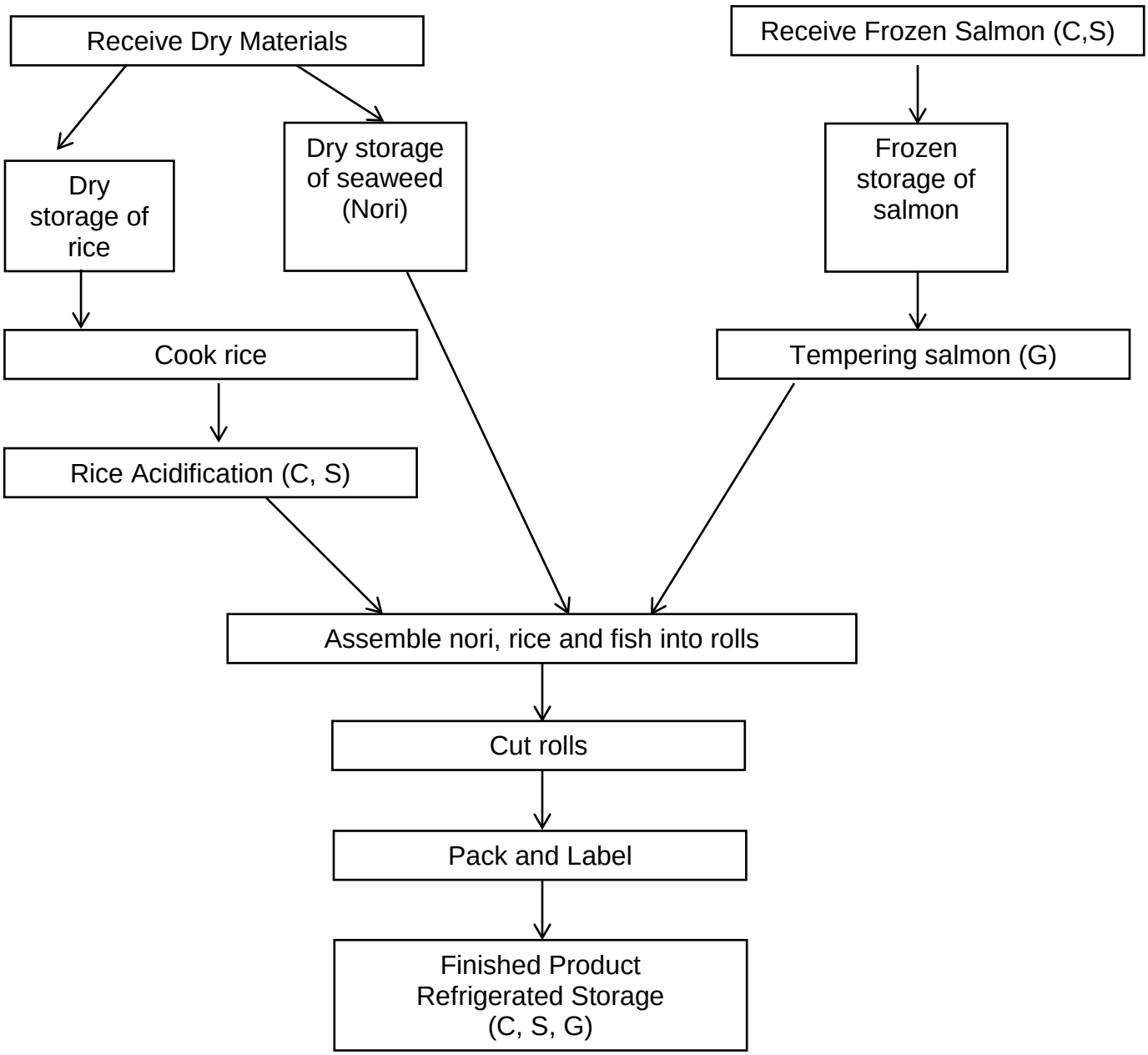
82

Flow Diagram A.36b. SEAFOOD –RAW
Wild Salmon Shashimi



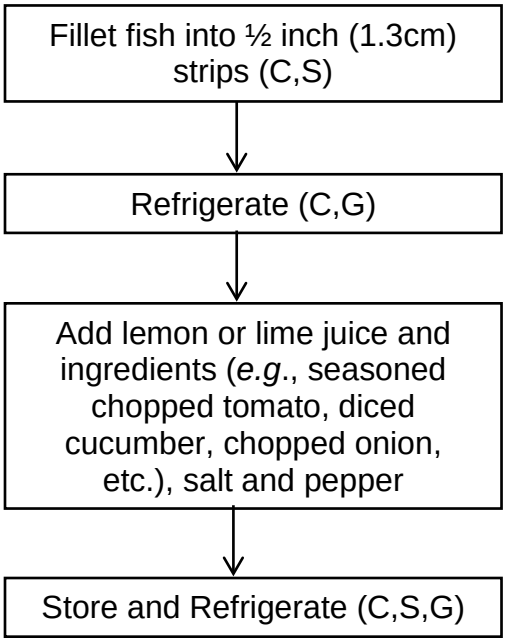
83

Flow Diagram A.36c. SEAFOOD –RAW
Wild Salmon Sushi



84

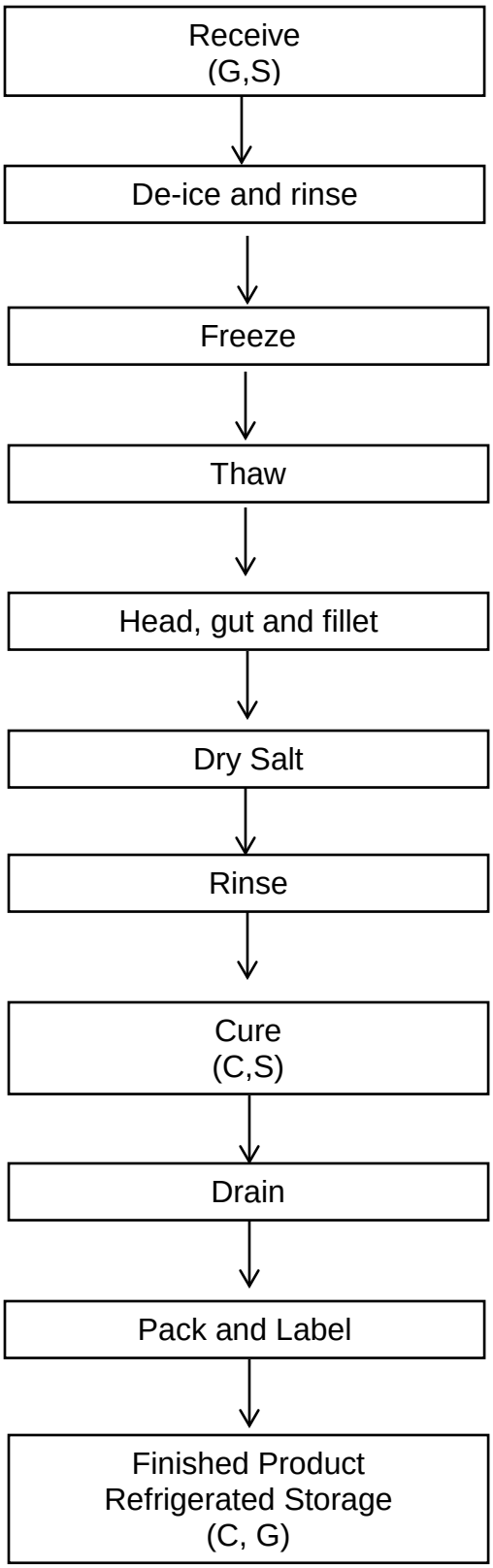
Flow Diagram A.36d. SEAFOOD –RAW
Ceviche



85

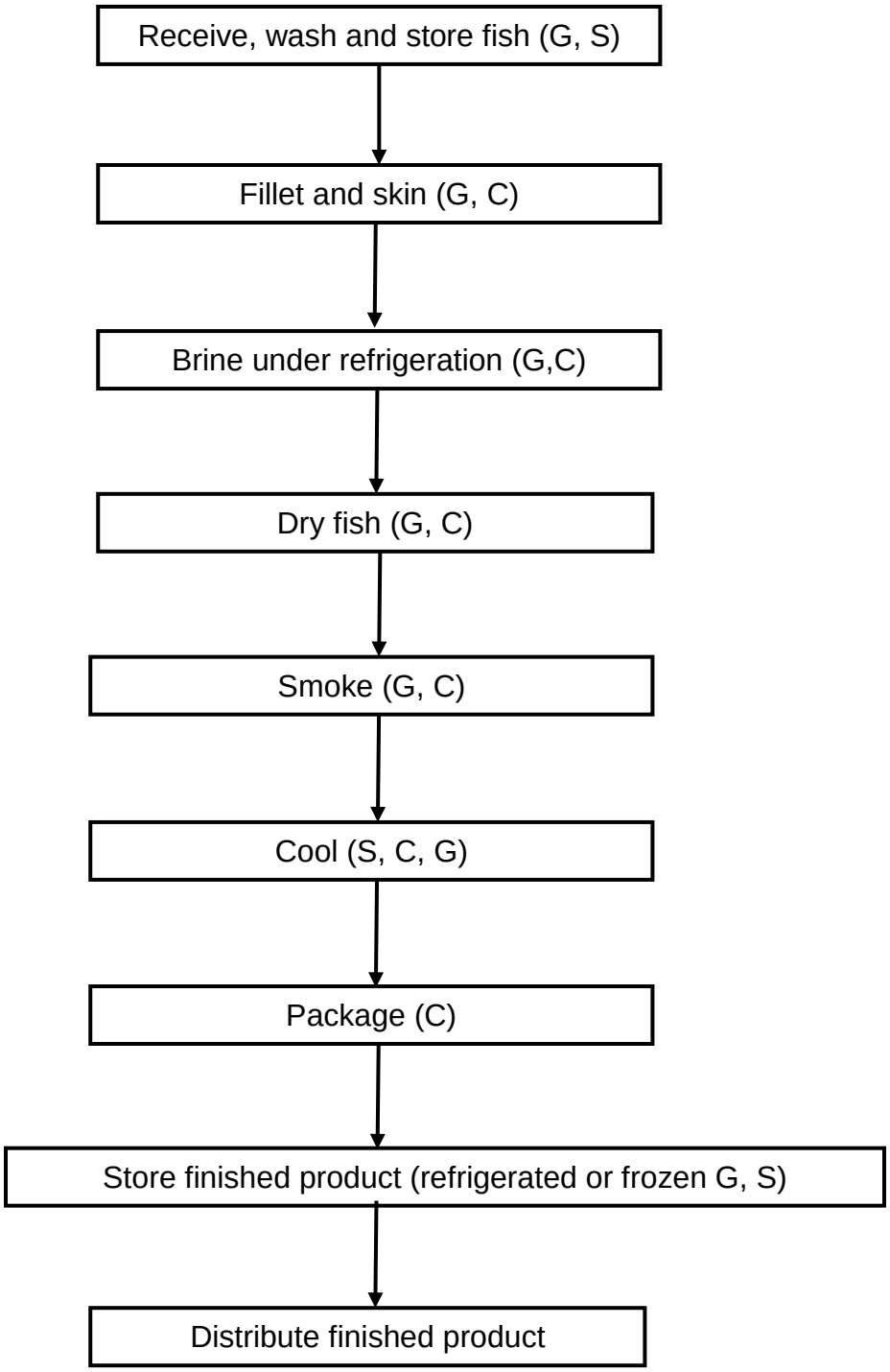
Flow Diagram A.36e. SEAFOOD –RAW

Pickled Herring Fillets



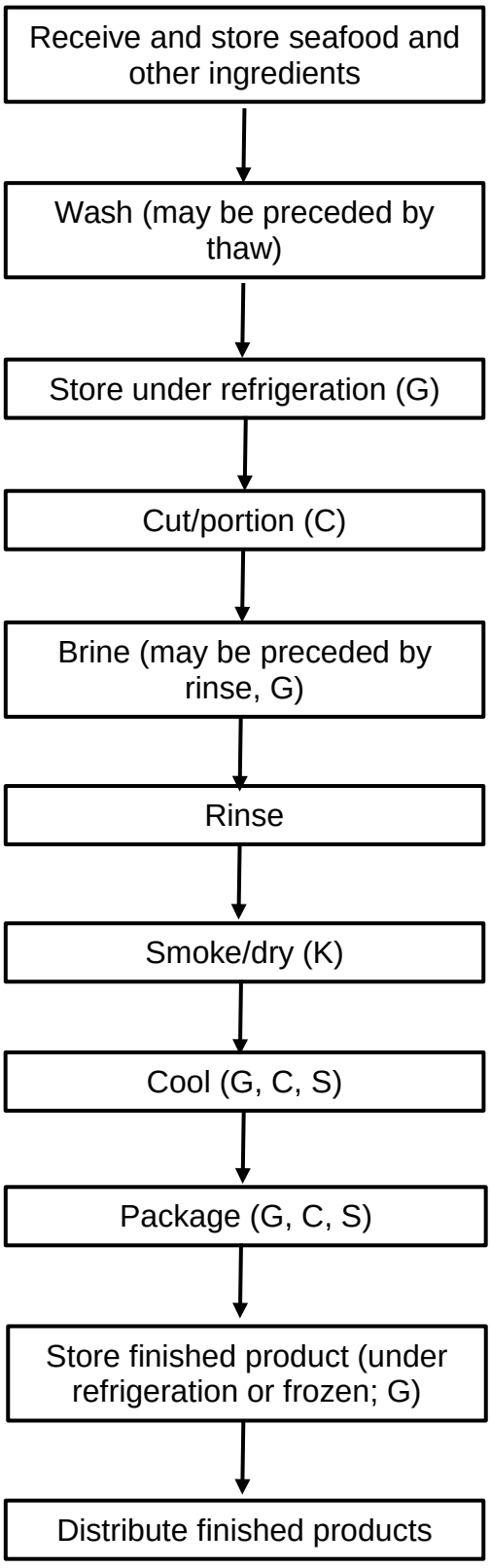
86

Flow Diagram A.37. SEAFOOD – RTE FISH, COLD SMOKED



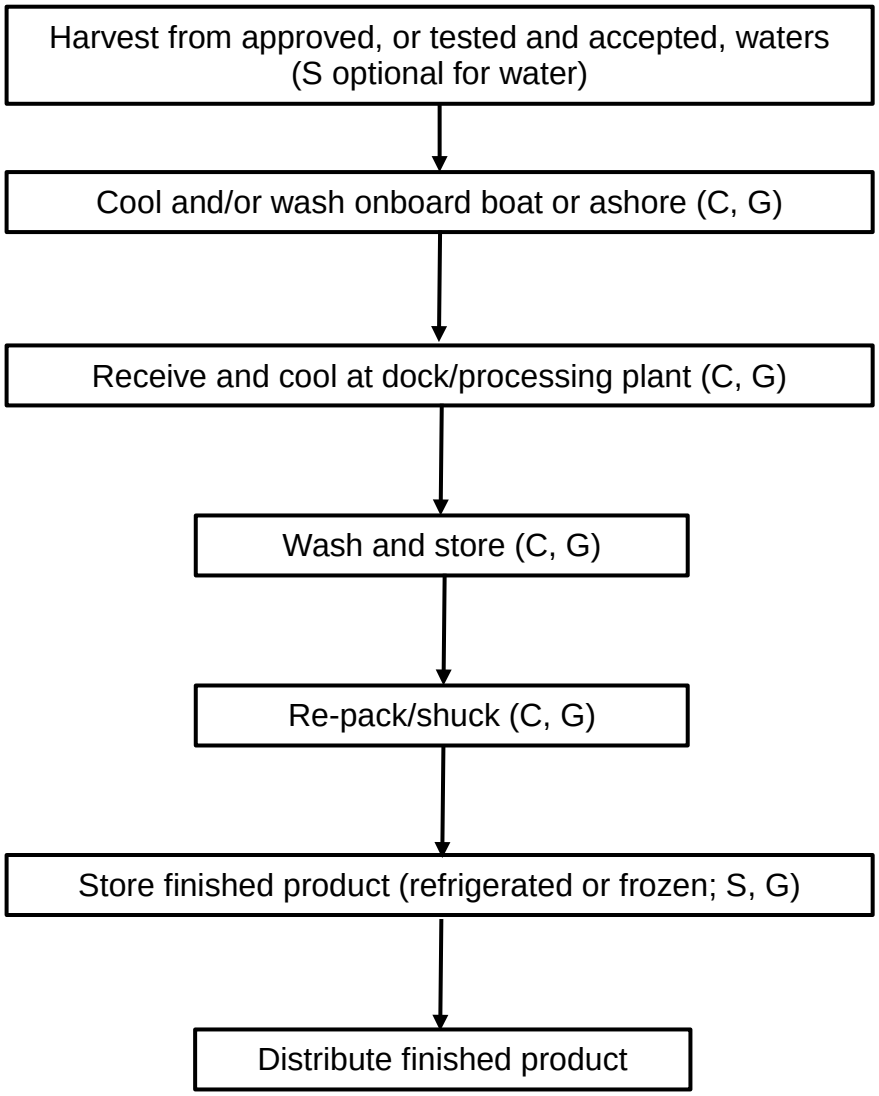
87
88

Flow Diagram A.38. SEAFOOD – RTE, FISH OR CRUSTACEAN, COOKED OR HOT SMOKED

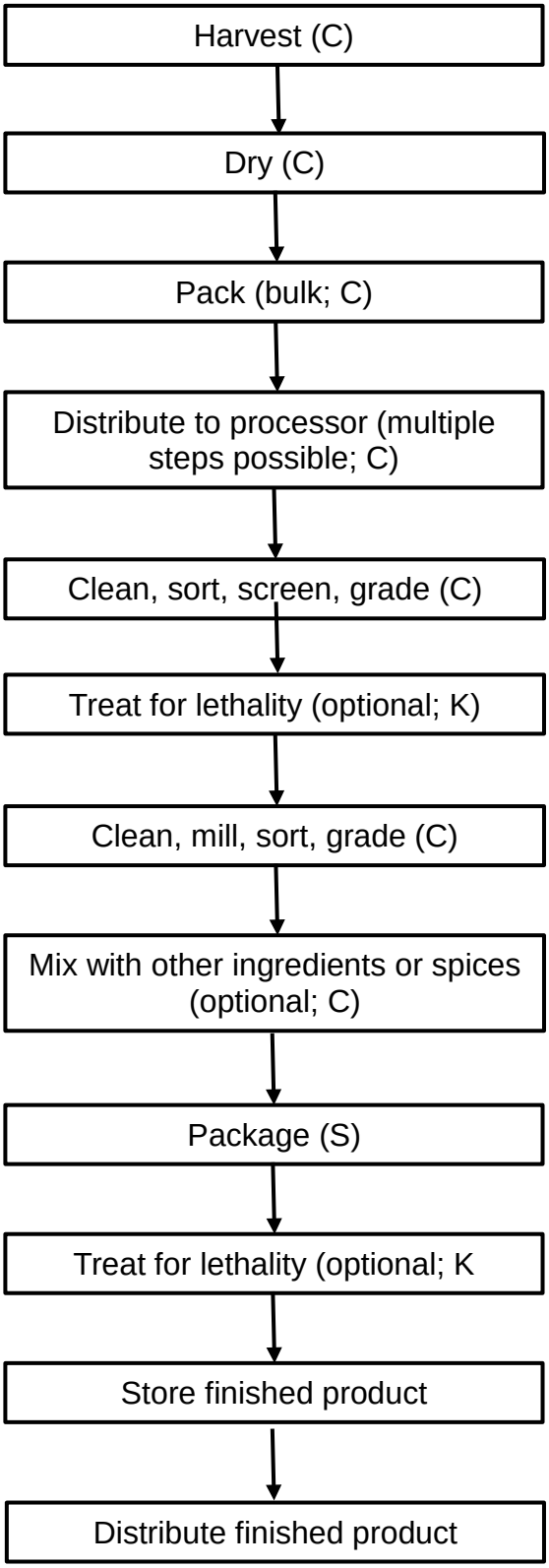


89

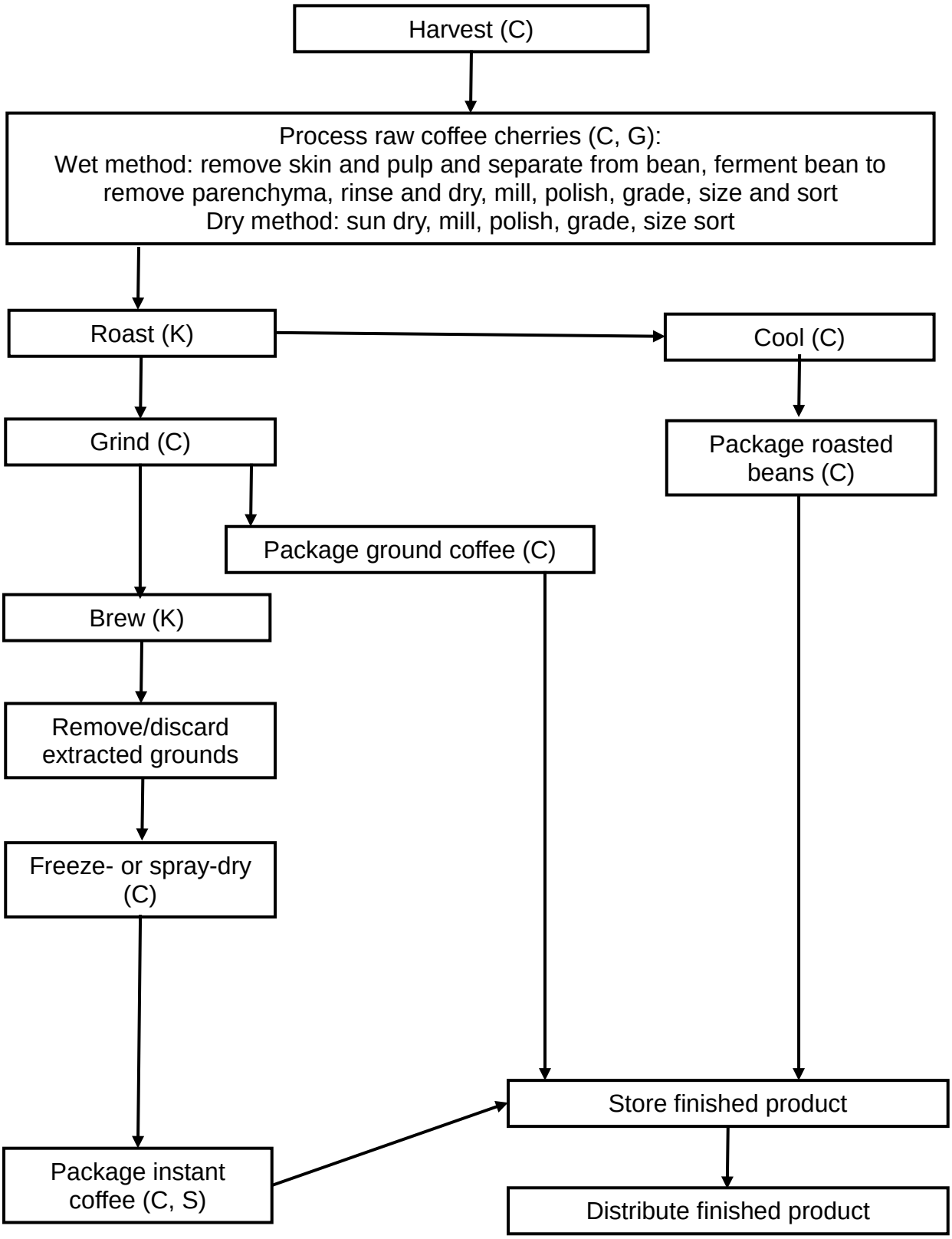
Flow Diagram A.39. SEAFOOD – RTE, RAW MOLLUSCAN SHELLFISH



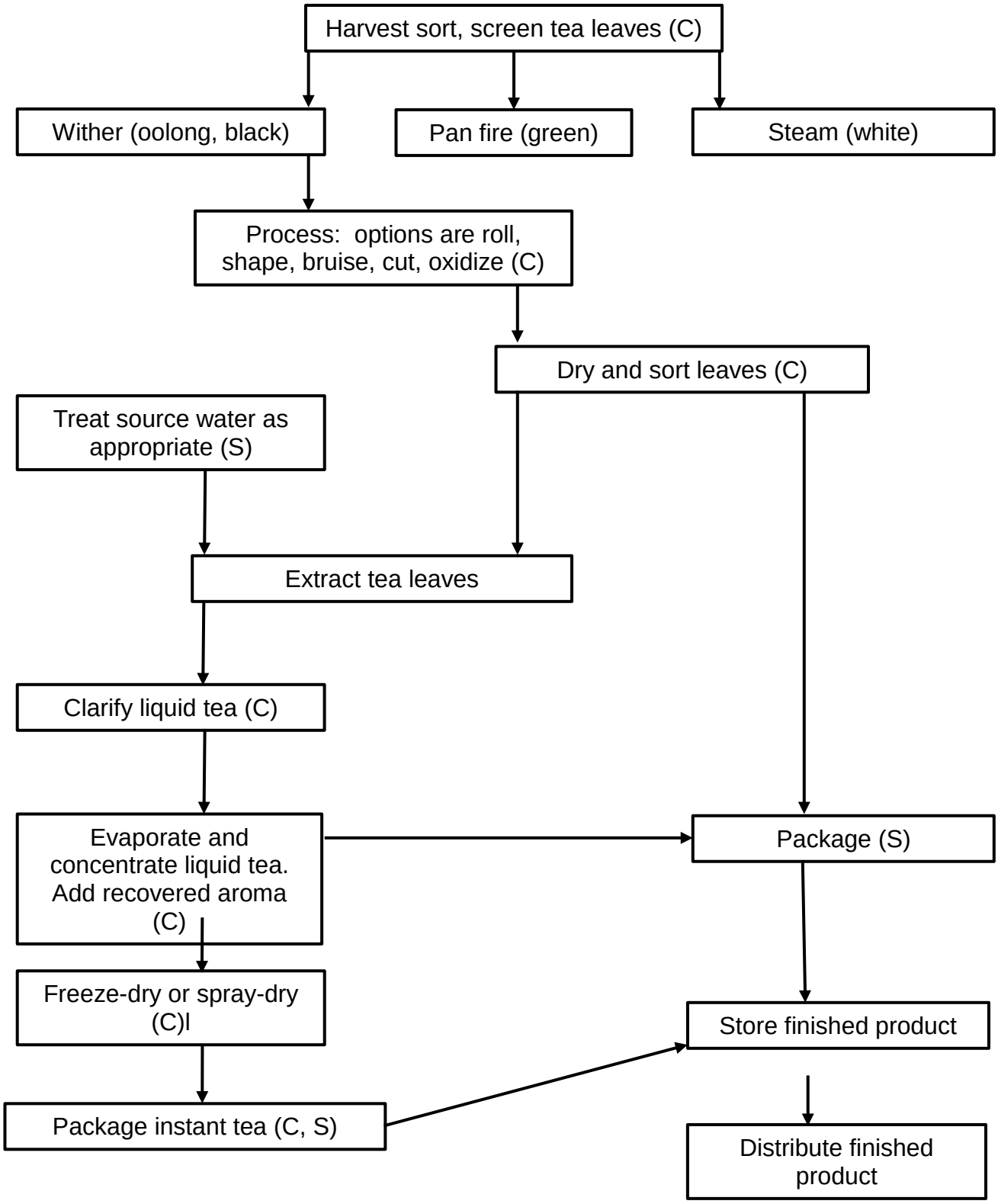
Flow Diagram A.40a. SPICES AND HERBS



Flow Diagram A.40b. BEVERAGES – COFFEE



Flow Diagram A.40c. BEVERAGES –



Appendix B: Statistical Process Control (SPC) Charts

Control charts are plots of process data collected over time used to determine if a process is in statistical control. It is important to note that there is a difference between a process being in statistical control and meeting specifications. A process is considered under statistical control if it is stable over time and the observed variation is due to common, chance causes inherent to the process (*e.g.*, background noise due to normal variation in ambient temperature and humidity) and there is no between-lot variation. A process is considered out of statistical control if shifts in the process central tendency (*e.g.*, mean), variability, or both result from uncommon sources associated with special or assignable causes (*e.g.*, equipment malfunction, a change in raw materials, or failure of a laboratory procedure). A food process being under statistical process control does not imply its capability with respect to meeting microbiological specifications. The ideal situation is when a process is both under statistical control and is capable of manufacturing products that meet specifications. However, a process can be in statistical control and not capable of satisfying specifications. For example, the process consistently generates substandard product. Alternatively, a process can be out of statistical control but capable of satisfying specifications. For example, the process is designed to be robust to deviations from the norm, such that it meets specifications despite high variability. Given seasonal and other sources of variability beyond a supplier's control, the latter situation may be particularly relevant to food production processes.

SPC charts can be classified as control charts for variables (*e.g.*, average and range charts) or control charts for attributes (*e.g.*, p charts). Microbiological food safety characteristics can be classified as variables or attributes. Microbiological concentration data expressed on a continuous numerical scale are classified as variable data. Microbiological presence/absence data or concentration data classified into numerical ranges (*e.g.*, $m < x \leq M$) are classified as attribute data.

Montgomery (Montgomery, 2005) cautions: "It is not possible to give an exact solution to the problem of control chart design, unless the analyst has detailed information about both the statistical characteristics of the control chart tests and the economic factors that affect the problem. A complete solution would require knowledge of the costs of investigating and possibly correcting the process in response to out-of-control signals, and the costs associated with producing a product that does not meet specifications. Given this kind of information, an economic decision model could be constructed to allow economically optimum control." However, such detailed information is not generally available for even a small subset of food production processes, and the available information is subject to considerable uncertainty, variability, and disagreement (*e.g.*, regarding consumer health impacts). Therefore, this discussion is limited to some general guidelines that will aid in SPC chart design rather than identifying optimal designs.

Control Charts for Variables

Control of variable characteristics requires managing both the central tendency and variability. Measures of central tendency include the mean (μ) and median. Measures of variability include the standard deviation (σ) and the range (*R*). The $\bar{x}$ chart is used to monitor control of the process average. Process variability can be monitored with a control chart for the standard deviation (*s* chart) or the range (*R* chart). Due to its simplicity, the *R* chart is widely used.

Suppose that the microbiological concentration data (*y*) from a food process are lognormally distributed such that the log-transformed data ($x = \log_{10}(y)$) are normally distributed with mean μ ($\log_{10}$ cfu/g) and standard deviation σ ($\log_{10}$ cfu/g). Estimates of μ and σ are based on an initial process capability study conducted when the process is considered under statistical control. Let *k* = number of lots (subgroups) sampled and *n* = number of samples per lot (subgroup). As a rule of thumb, Shewhart (Shewhart, 1986) suggested that "a sequence of not less than twenty five samples of size four" is the minimum requirement for concluding that a process is in a state of statistical control (*e.g.*, 4 samples per lot from 25 lots).

Let $\bar{x}_1, \bar{x}_2, \ldots, \bar{x}_k$ be the geometric ($\log_{10}$) sample means from each lot (subgroup). The estimate of process average (μ) is the grand mean ($\bar{\bar{x}}$):

$$\bar{\bar{x}} = \frac{\sum_{j=1}^{k} \bar{x}_j}{k}$$

The sample range (*R*) is the difference between the largest and smallest observations within each lot (subgroup): $R = x_{max} - x_{min}$. The average sample range ($\bar{R}$) provides an estimate of the process standard deviation (σ):

$$\bar{R} = \frac{\sum_{j=1}^{k} R_j}{k}$$

$$\hat{\sigma} = \frac{\bar{R}}{d_2}$$

Where d_2 is the expected mean of R/σ. Table B.1 provides calculated d2 values for n=2-25.

Table B.1. Factors for Control Charts for Variables Assuming a Normal Distribution

n	d2	d3	A2	D3	D4
2	1.128	0.853	1.880	0.000	3.267
3	1.693	0.888	1.023	0.000	2.575
4	2.059	0.880	0.729	0.000	2.282
5	2.326	0.864	0.577	0.000	2.114
6	2.534	0.848	0.483	0.000	2.004
7	2.704	0.833	0.419	0.076	1.924
8	2.847	0.820	0.373	0.136	1.864
9	2.970	0.808	0.337	0.184	1.816
10	3.078	0.797	0.308	0.223	1.777
11	3.173	0.787	0.285	0.256	1.744
12	3.258	0.778	0.266	0.283	1.717
13	3.336	0.770	0.249	0.307	1.693
14	3.407	0.763	0.235	0.328	1.672
15	3.472	0.756	0.223	0.347	1.653
16	3.532	0.750	0.212	0.363	1.637
17	3.588	0.744	0.203	0.378	1.622
18	3.640	0.739	0.194	0.391	1.609
19	3.689	0.733	0.187	0.404	1.596
20	3.735	0.729	0.180	0.415	1.585
21	3.778	0.724	0.173	0.425	1.575
22	3.819	0.720	0.167	0.435	1.565
23	3.858	0.716	0.162	0.443	1.557
24	3.895	0.712	0.157	0.452	1.548
25	3.931	0.708	0.153	0.459	1.541

By convention, statistical process control limits are based on μ ± 3σ, where 99.7% of values sampled from a normal distribution lie within a “Six Sigma” interval centered on the mean. Tabled values for factors for control charts for variables are typically based on the 3σ convention.

The $\bar{x}$ chart monitors between-lot variability in the process mean. The equations for constructing 3σ upper and lower control limits on the $\bar{x}$ chart are as follows:

$$UCL_{\bar{x}} = \bar{\bar{x}} + A_2\bar{R}$$
$$LCL_{\bar{x}} = \bar{\bar{x}} - A_2\bar{R}$$

where $A_2 = \frac{3}{d_2\sqrt{n}}$. Table B.1 provides A_2 values for n = 2 to 25. When 3σ control limits are used and the process is under statistical control, the probability of a sample mean being outside the $\bar{x}$ control limits simply due to random chance (the false-alarm rate (FAR)) is 0.3%. Note that the control limits are based on within-lot variability (σ) only (Montgomery, 2005). Thus the conventional limits treat any

between-lot variability ($\sigma_{\bar{x}}$) as indicating a lack of control, rather than a source of variation that may be intrinsic to the process. Achieving negligible between-lot variability may not be feasible in some food production processes. Even for relatively small sample sizes, the sampling distribution of the sample mean is approximately normal even if the underlying data are not; although the limit of quantitation presents a potential complication for microbiological data if the proportion of negative results is large (International Commission for the Microbiological Specifications of Foods (ICMSF), 2002). Montgomery (Montgomery, 2005) addresses monitoring processes with a high proportion of data such as those that fall outside the detection limit or are too numerous to count.

The *R* chart monitors within-lot variability. The equations for constructing 3σ upper and lower control limits on the *R* chart for process variability are as follows:

$$UCL_R = D_4\bar{R}$$
$$LCL_R = D_3\bar{R}$$

where $D_4 = 1 + \frac{3d_3}{d_2}$, $D_3 = \max\left[0, 1 - \frac{3d_3}{d_2}\right]$, and $d_3 = \frac{\sigma_R}{\sigma}$. Table B.1 provides d_3, D_3, and D_4 values for n = 2 to 25. Even for normally distributed data, the sampling distribution of *R* (with the standard deviation, σ_R) is non-negative and positively skewed. Therefore, the symmetric 3σ control limits for *R* are only approximate, and the actual FAR depends on *n* and the underlying distribution. In food safety, the concern would typically be about excessive variation (UCL_R), but insufficient variation (LCL_R) may indicate a problem with sampling or analytical procedures.

The data used to construct $\bar{x}$ and *R* charts also provide information about process capability. The two-tailed process capability index (C_p) is defined in terms of the upper and lower specification limits (USL and LSL):

$$C_p = \frac{USL - LSL}{6\sigma}$$

Note, however, that the equation for C_p only considers process variability. It implicitly assumes that the process is centered on a mean of (USL-LSL)/2. Compare to an upper-tail C_p:

$$C_p = (USL - \mu) / (3\,\sigma)$$

Further details about the statistical basis for control charts for variables are available in standard texts (*e.g.*, (Montgomery, 2005)). On-line calculators for control charts for variables are available from a variety of sources (*e.g.*, http://www.sqconline.com/).

When establishing control limits based on an initial process capability study, it may be reasonable to remove a few extreme sample values due to assignable causes from the dataset to better represent common cause variation of a stable process under statistical control. However, extreme values may simply be random outliers, and identifying an assignable cause for each extreme value may not be possible. Similarly, apparent patterns in small datasets (*e.g.*, a sequence of extreme values or trends) may be simply due to random variation. If the initial data indicate that process variability is not in statistical control, then the control limits on the $\bar{x}$ chart may not be meaningful. Therefore, beginning the analysis with the *R* chart can be useful. It is customary to treat the control limits obtained in the initial phase as provisional and to update and revise the control limits over time as additional information is acquired (Appendix I) and the process matures.

BIBLIOGRAPHY

International Commission for the Microbiological Specifications of Foods (ICMSF). 2002. Microorganisms in Foods 7: Microbiological Testing in Food Safety Management. Springer, New York.

Montgomery, D. C. 2005. Introduction to Quality Control. 5th ed. John Wiley & Sons, Hoboken, NJ.

Shewhart, W. A. 1986. Statistical Method from the Viewpoint of Quality Control. Dover Publications.

Appendix C: Process Control for Attributes (*p* charts)

There are a variety of process control charts for attributes. The *p* chart is widely used; it charts the fraction of non-conforming analytical units over a sampling sequence. The *p* chart is based on the binomial distribution, which assumes that there are only two possible outcomes for each observation (conforming or non-conforming), the proportion of non-conforming analytical units (*p*) is constant, the samples are independent (*e.g.*, defects do not cluster), and a fixed sample size (*n*). The sample proportion non-conforming ($\hat{p}$) is the ratio of the number of non-conforming analytical units (*d*) observed in a sample of size *n*:

$$\hat{p} = \frac{d}{n} \qquad \text{(eq. C.1)}$$

For the binomial distribution, the mean and variance of the sampling distribution of $\hat{p}$ are:

$$\mu_{\hat{p}} = p \qquad \text{(eq. C.2)}$$

and

$$\sigma_{\hat{p}}^2 = \frac{p(1-p)}{n} \qquad \text{(eq. C.3)}$$

respectively.

Assuming a constant sample size, the estimated average proportion non-conforming ($\bar{p}$) across lots (subgroups) is:

$$\bar{p} = \frac{\sum_{i=1}^{m} d_i}{mn} = \frac{\sum_{i=1}^{m} \hat{p}_i}{m} \qquad \text{(eq. C.4)}$$

where *m* = number of lots (subgroups) sampled and *n* = number of samples per lot (subgroup).

Conventionally, *p* chart control limits are based on a symmetric ± 3σ interval using a normal approximation to the binomial (Montgomery, 2005):

$$UCL = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}} \qquad \text{(eq. C.5)}$$

$$LCL = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}} \qquad \text{(eq. C.6)}$$

Note that equations C.5 and C.6 assume that $\bar{p}$ represents the desired target value of the proportion non-conforming for the process. In food safety, concern would normally focus on exceeding the upper control limit (UCL); however, observations below the lower control limit (LCL) could indicate problems with sampling and analytical procedures, or it could represent an opportunity on how to improve process quality. On-line calculators are available for computing conventional 3 sigma control limits for *p* charts (*e.g.*, http://www.sqconline.com/control-chart-calculator-attributes-discrete-data). It should be noted that the further the target value of *p* is from 0.5, the larger the sample size required for the normal approximation to be reasonable. As a general rule, the normal approximation is reasonable if $np \geq 5$ and $n(1-p) \geq 5$. In many food safety applications where the target value for *p* is substantially less

than 0.5, the sample size required for the normal approximation would be costly. More generally, even if an exact binomial method is used to calculate control limits, practical application of *p* charts is limited to cases where the target value for *p* is not very small (Table C.1). The sample size should be large enough to provide a reasonably high degree of confidence of observing at least one non-conforming unit (Montgomery, 2005). For example, if the target value for $p = 0.01$ and $n = 5$, the conventional upper control limit is 0.14 (eq. C.5). Consequently, observing a single non-conforming unit in the sample ($\hat{p} = 1/5 = 0.2$) would suggest a lack of process control.

Table C.1. Sample size requirements for *p* chart control limits

p target	n_1	n_2	n_3
0.01	500	299	230
0.02	250	149	114
0.03	167	99	76
0.04	125	74	57
0.05	100	59	45
0.10	50	29	22
0.20	25	14	11
0.30	17	9	7
0.40	13	6	5
0.50	10	5	4

n_1 = minimum sample size required for normal approximation
n_2 = sample size required for 95% confidence of observing at least one non-conforming unit
n_3 = sample size required for 90% confidence of observing at least one non-conforming unit

Standard texts provide additional details on constructing and interpreting *p* charts (*e.g.*, (Montgomery, 2005)).

BIBLIOGRAPHY

Montgomery, D. C. 2005. Introduction to Quality Control. 5th ed. John Wiley & Sons, Hoboken, NJ.

Appendix D. High-Event Period Process Control

A high-event period may be defined as a production period when the observed prevalence likely exceeds the expected or design prevalence. Here prevalence refers to an attribute – either presence/absence or concentration in a range (*e.g.*, cfu/g > M). The application of numerical criteria for identifying a high-event period is intended for cases where the prevalence is impracticably low for p-charts.

Suppose that the prevalence (p) is constant such that the number of positive test results (x) out of *n* independent samples follows a binomial distribution. Then we can determine combinations of x and *n* that are unlikely to occur by chance if the true prevalence is no more than the design prevalence. A sampling period would proceed until the testing results indicate a high-event period, or non-conformance with the design prevalence. After appropriate action is taken in response to the non-conformance, a new sampling period begins.

Tables D.1 and D.2 present the limits of conforming sample results for a false alarm rate (FAR) of 5% and 1%, respectively. From Table D.1, for example, if the number of positive test results observed is x = 4 out of *n* < 198, then there is less than a 5% chance of observing the data if the true prevalence is 1%. A 5% FAR might be appropriate for cases of low sampling frequency because a long sampling period may elapse before a producer receives an indication that the process is out of control.

Table D.1. High-Event Period Criteria for 5% False Alarm Rate

	Design prevalence (p)									
Positive Test Results (x)	0.005	0.01	0.015	0.02	0.025	0.03	0.035	0.04	0.045	0.05
	Samples (n) for given design prevalence									
1	71	35	24	18	14	12	10	9	8	7
2	164	82	55	41	33	27	23	21	18	16
3	274	137	91	69	55	46	39	35	31	28
4	395	198	132	99	79	66	57	50	44	40
5	523	262	175	131	105	88	75	66	59	53
6	658	329	220	165	132	110	95	83	74	67
7	797	399	266	200	160	134	115	101	90	81
8	940	471	314	236	189	158	135	119	106	95
9	1086	544	363	273	218	182	156	137	122	110
10	1235	618	413	310	248	207	178	156	139	125

Similarly from Table D.2, if the number of positive test results observed is x = 4 out of *n* < 129, then there is less than a 1% chance of observing the data if the true prevalence is 1%. A 1% FAR might be appropriate for cases of high

sampling frequency because a sampling period of limited duration would elapse before a producer receives an indication that the process is out of control.

Table D.2. High-Event Period Criteria for 1% False Alarm Rate

	Design prevalence (p)									
Acceptance Number (c)	0.005	0.01	0.015	0.02	0.025	0.03	0.035	0.04	0.045	0.05
	Samples (n) for given design prevalence									
1	30	15	10	7	6	5	4	4	3	3
2	88	44	29	22	18	15	13	11	10	9
3	165	83	56	42	34	28	24	21	19	17
4	257	129	86	65	52	44	37	33	29	27
5	359	180	120	90	73	61	52	46	41	37
6	468	235	157	118	95	79	68	60	53	48
7	583	292	195	147	118	99	85	74	66	60
8	704	353	236	177	142	119	102	90	80	72
9	829	415	278	209	167	140	120	105	94	85
10	957	480	320	241	193	161	139	122	108	98

Appendix E. Control Charts for Very Low Prevalence

Here 'very low prevalence' is taken to mean that less than 2% of the samples taken are found positive for the analyte. The testing is typically limited to presence/absence methods, and the finding of a positive is sufficient to implicate the underlying lot.

The statistic of interest for this scenario is the prevalence proportion of positive results, or, equivalently, the 'mean time between positives' ('MTBP').

E. coli O157:H7 Testing of Ground Beef

Lots of ground beef are tested for *E. coli* O157:H7. While positives may result in rejected lots, this testing can also be used for process control.

The observed prevalence depends on the analytical unit size. In order to be meaningful, the prevalence needs to be referenced to an analytical unit size, i.e., a prevalence of positives in X gram samples (e.g., 325 g). Guidelines for this example require that prevalence of positives should average no higher than 1 in 500 samples or 0.2%, or a MTBP of 500 samples or more (the LSL). Because the prevalence is so low, the nonparametric method is probably not viable for this scenario, as a long sampling history would be required to find even a 99th percentile. For this example we therefore use a parametric approach.

The normal operations are modeled as a Poisson process, with the MTBP following an exponential distribution, which has a standard deviation equal to the mean. Hypothetical data for 325-gram samples from several years indicate a process MTBP of 690 sampling units with a standard deviation of 730, not much different from 690, supporting the use of an exponential model.

A parametric 'g-Chart' is shown in Fig. E.1, with an upper control limit calculated as:

$$UCL = MTBP + 3\sqrt{[\ MTBP\ (MTBP + 1)} \qquad \text{(eq. E.1)}$$

$$= 2762$$

In the example, the LCL is zero. The factor '3' is based on the 3 sigma convention and corresponds to the 99.9th percentile (Alternatively, the exact exponential distribution quantiles could be used).

Also plotted is the exponentially weighted moving average (EWMA) of the MTBP data, with a smoothing constant of 0.1 and starting value $EWMA_0 = 690$:

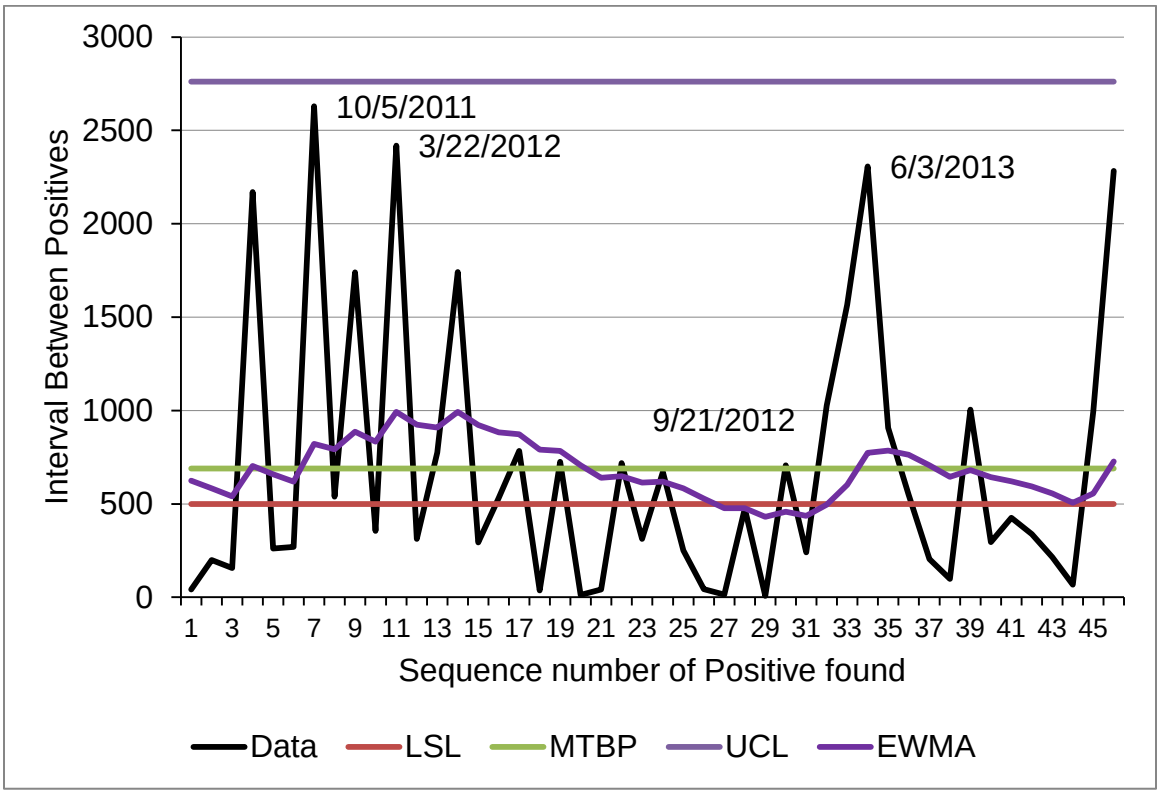
$$EWMA_{k+1} = EWMA_k + 0.10\ (MTBP_{k+1} - EWMA_k) \qquad \text{(eq. E.2)}$$

The EWMA smooths the rough curve and is helpful in visualizing the drift of the MTBP average.

The g-Chart helps define operational conditions that lead to relatively stable low prevalence. However, it has the limitation that it is an individual data trend chart and the LCL is absent. If the data line moves above the UCL, this suggests maintenance of this state of operations would result in lower prevalence, and should be investigated to see how this lower prevalence could be sustained. Also, if the data line exhibits a strong non-random pattern, this suggests a systematic cause, which should be investigated. Figure E.1. shows a saw-tooth appearance ('up' followed by 'down'), indicating negative autocorrelation.

Finally, we can supplement the control limits with a 'runs test', e.g., if a run of 11 or more MTBP data consecutively fall *below* the mean MTBP, then 'abnormal' operations are detected, and an assignable cause should be sought (for the exponential distribution, the mean is the 63rd percentile, so 0.63^{11} = 0.6% FAR). The longest run observed below the mean MTBP is 7 samples here, which falls within expectations for normal operations. As an alternative, a 'center-line' at 0.693 MTBP could be added, for which results under statistical control are equally likely to fall on either side. A run of 7 or more results on the either side of this center line represents detection of an abnormal change in the process that should be investigated for an assignable cause, i.e., for the exponential distribution, the median = 0.693 x mean, so 0.5^{7} = 0.8% FAR.

71



72
73
74 **Figure E.1**. g-Chart for hypothetical *E. coli* O157:H7 MTBP data.
75

Appendix F. Control Chart for Low Prevalence with Quantification

This scenario corresponds to prevalence (i.e., presence/absences followed by quantification of positive samples, or above or below limit of quantification) in the range 2% to 10% where samples provide quantitative estimates. These data can be used to create two different control charts, the g-Chart showing time between positive results, and an individuals chart with adjusted quantiles. As in Appendix E, the g-Chart helps define operational conditions that lead to relatively stable low prevalence. The individuals chart detects data that may indicate the presence of assignable causes that can support further investigation. The sampling can still be interpreted as the output of a Poisson process, and the prevalence and MTBP estimated. However, it is also assumed that positive results now occur often enough that they are routinely quantified.

The prevalence from history may be estimated as

$$p = (\#\ \text{positives}) / (\text{total}\ \#\ \text{samples}) \qquad \text{(eq. F.1.)}$$

and the MTBP as 1/p, or as the average of the between-positive sampling intervals as before.

The g-Chart will still be useful for maintaining normal prevalence (MTBP).

If the observed counts (not concentration) in quantitation are below 100 and a single dilution is used, the counts may be modeled as Poisson distributed. If the observed counts are 10 or more typically, or multiple dilutions or a most probable number (MPN) technique is used, the counts (or estimates in the case of MPN) may be modeled as normally distributed after a logarithmic transformation.

Processes that are in control may be characterized by a constant expected prevalence with incidental modest contamination. A Poisson distributed contamination may arise from isolated contamination events such as those caused by aerosolized particles. Lognormally distributed contamination may arise from splatters or surface-to-surface contact. Processes that are out of control may result from changes in prevalence of contamination, or increased counts when they occur.

Data are logarithmic-transform from the original concentration results:

$$y = \log_{10}(x + 0.3\ d) \qquad \text{(eq. F.2.)}$$

where '*x'* is the concentration estimated for the positive result, 'd' is the concentration corresponding to a single count result, and 'y' is the logarithmic metamer. For example, if the analytical portion is 1 ml, and there is a one decimal dilution, then a single count would result in an estimated concentration of

10 cfu/ml. Single count measurements (*i.e.*, =10 cfu/ml) would be transformed as 1.11 = $\log_{10}(10+0.3 \times 10)$.

Example: Coliforms in Soft Cheese

Lots of soft cheese (*e.g.*, Brie) are sampled and tested for coliform bacteria. Specifications require each lot should not exceed 1,000 CFU/25g test portion. History is comprised of 702 samples, of which 28 were positive, for a prevalence (p) of 3.99%. The MTBP was 24.4 samples with a standard deviation of 27.5 samples, close to the MTBP, supporting the exponential distribution assumption.

Figure F.1. shows the g-Chart, with an UCL exception at sample #309, and a run of 9 values below the MTBP line. The exception indicates better control is possible in normal operations, and this should be explored. The run of 9 below the MTBP line, although not an exception, is suggestive of a problem with control in this range of samples.

Contamination levels of individual samples may be plotted with an UCL based on an extreme quantile of normal operations. From the historical data, nonparametric quantiles were calculated and shown in the second column of Table F.1.

Table F.1. Quantile results from Soft Cheese history

Quantile Probability	Nonparametric quantile	Adjusted Quantile Probability	Normal Quantile
99%	2.30	74.9%	2.40
99.5%	2.60	87.5%	2.77
99.9%	3.65	97.49%	3.40
99.95%	3.84	98.75%	3.62

Note: All quantiles are for $\log_{10}$ transformed positive data using eq.(F.2).

The nonparametric quantiles are derived from the EDF of the 702-sample data. As a rule, these are very imprecise for probabilities greater than 701.5 / 702 = 99.9%.

Parametrically, we can represent the distribution as a mixture of a binomial distribution for prevalence and a truncated normal distribution for positive observations. The hurdle threshold for positive counts is $T = \log_{10}(10 + 3) = 1.11$. The observed average and standard deviation of the positive data for y were 1.87 and 0.783, resp. The estimated z-score from a standard normal distribution for the threshold is 1.11, with an associated probability of only 0.03, indicating a non-truncated distribution might be useful as a rough approximation.

In Table F.1, the ‘Adjusted Quantile Probability’ column is the desired quantile probability ‘P’ (given in the first column of the table) adjusted for prevalence p. The adjusted quantile probability P* is given by

$$P^* = [P - (1 - p)] / p \qquad \text{(eq. F.3.)}$$

Finally the normal distribution quantiles are the quantiles associated with P*.

Note that the nonparametric and normal quantiles are in excellent agreement here, supporting the lognormal assumption. The probability of obtaining less than a single count was about 0.1%, indicating no problem with bias at the low end.

Figure F.2. shows the individuals’ chart (‘i-Chart’) with associated UCLs for some soft cheese data. The SPC UCL line corresponds to the mean 1.87 plus 2.575 times the standard deviation of 0.783. This SPC UCL line represents the 99.5% quantile (normal vs. abnormal division) of the lognormally distributed positive result data, given that a positive result occurs. The Quantile UCL line represents the nonparametric 99.5% quantile across all results, including those which correspond to zero counts. The point at sample #12 exceeds both UCLs, indicating the point is unusual for observation as a result, and also unusual from the baseline normal distribution point of view. Sample #12 represents an unexpected shift in operations. The sample #24 result exceeds the Quantile UCL line, which means it is a rarity in sampling, but does not exceed the SPC UCL line, indicating it is not that unexpected from a positive data distribution point of view, so still represents normal operations (same distribution of positive results). This difference in interpretation between the nonparametric and parametric approaches shows another advantage (besides allowing the estimation of high probability quantiles using small samples) of the latter.

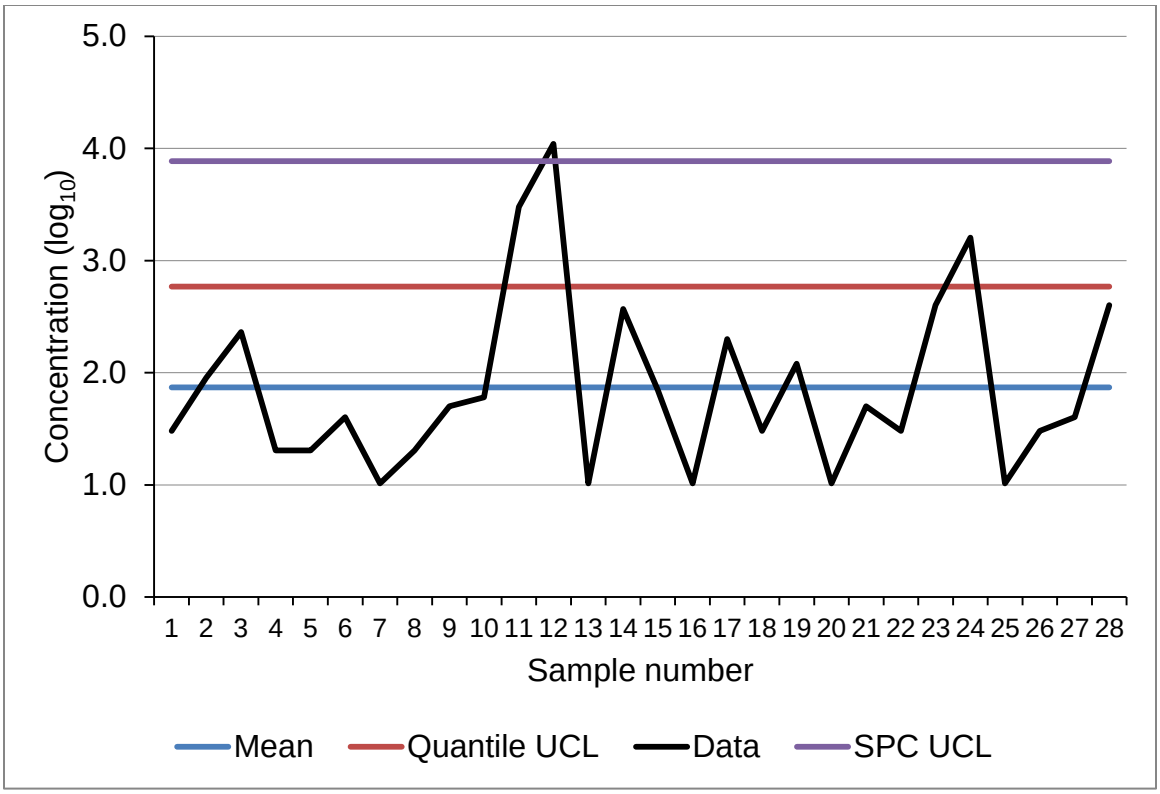


Figure F.1. g-Chart for coliforms in soft cheese. Note UCL exception around sample #309 and run of 9 values below the MTBP.

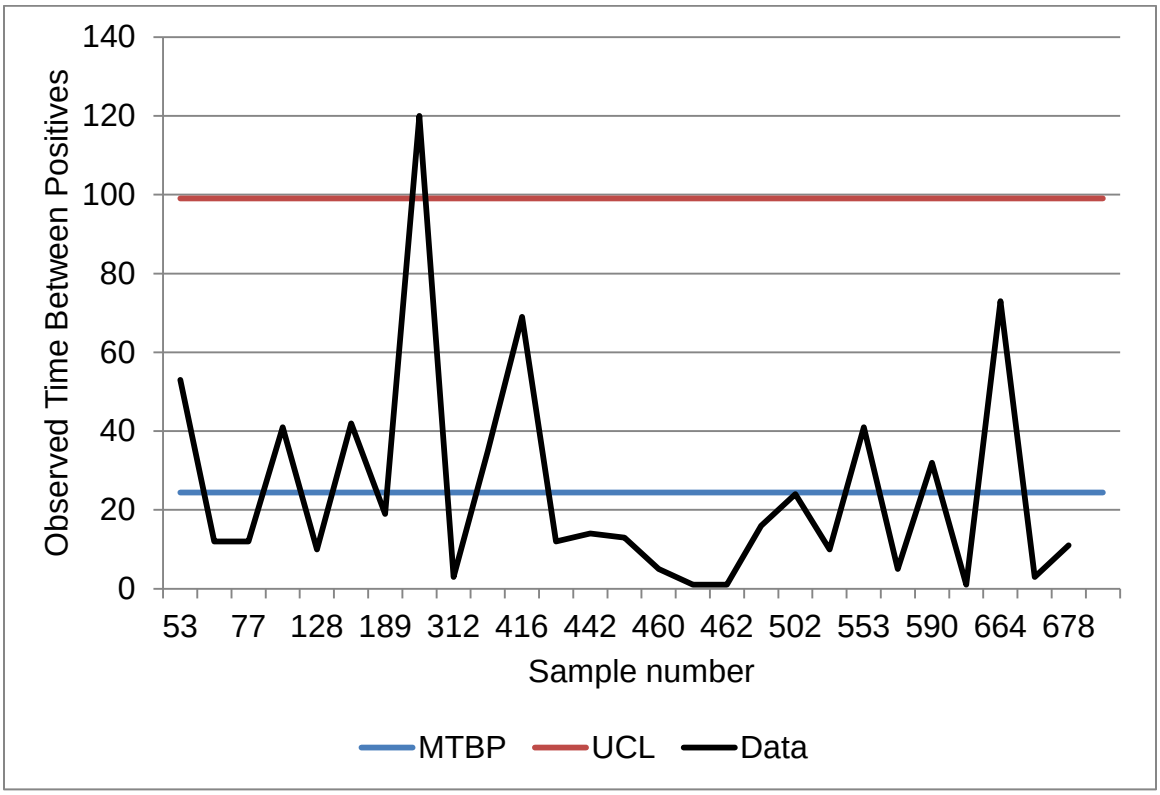


Figure F.2. Individuals chart (i-Chart) for positive samples observed for coliforms in Soft Cheese.

Appendix G. Control Chart for Moderate to High Prevalence with Quantitation

This example corresponds to prevalence in the range 10% to 95%. The sampling can be interpreted as the output of a Bernoulli process, and the prevalence estimated and controlled. It is also assumed that positive results are routinely quantitated.

Because of the moderate to high prevalence, rational subgroups (i.e., lots that represent test units belonging to a homogeneous population with the same constant population parameters) of samples may be combined to increase normality and provide better tools for prevalence SPC. If grouping is to be done by time period, equal sampling for each period is advised, and the sample size large enough to achieve an expected 5 positive results or more, and similarly for negative results. For example, if the mean prevalence is 20%, the sample size should be at least 5 / 0.2 = 25. If the mean prevalence is 80%, the sample size would also be 25.

SPC may be carried out by a 'p-Chart', where the control limits are given by

$$UCL = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}} \qquad \text{(eq. G.1.)}$$

$$LCL = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}} \qquad \text{(eq. G.2.)}$$

where 'n' is the rational subgroup sample size.

The SPC of the distribution of the positive result concentrations may be performing using an individuals' chart with control limits typically as

$$UCL = \mu + 3\ \sigma \qquad \text{(eq. G.3.)}$$

$$LCL = \mu - 3\ \sigma \qquad \text{(eq. G.4.)}$$

The values for ρ, σ and μ need to be determined from history or a process capability study.

Although there is fixed sample size during a time period (in this case, 40 samples per quarter), the number of positive results is a random variable, so a standard X-bar chart cannot be used.

Example: Aerobic Plate Counts in Ground Beef

Lots of ground beef in cold storage are sampled and tested for aerobic plate counts (APC). Assume the microbiological guidelines require that the APC should not exceed 10,000,000 CFU/g (*i.e.*, 7.0 on a $\log_{10}$(CFU) scale).

Data consist of 455 samples, of which 393 were positive (86.4% prevalence). The positive samples had average $\log_{10}$-transformed concentration of 5.19 with standard deviation of 1.34.

Table G.1. Quantile results from ground beef data

Quantile Probability	Nonparametric	Adjusted Quantile Probability	Normal Quantile
99%	8.00	98.84%	8.23
99.5%	8.07	99.42%	8.57
99.9%	8.28	99.88%	9.28
99.95%	8.31	99.94%	9.54

Note: All quantiles are for $\log_{10}$-transformed positive data.

The nonparametric quantiles from the expected distribution function (EDF) are precise up to 99.5%. The agreement between nonparametric and normal-based quantiles is good, but not perfect. The probability of getting less than one count under the normal distribution model is 2.2%, a small error which should be adjusted out by using a truncated normal distribution, but which we will ignore here.

Given a prevalence of 86%, the minimum sample size required for the normal approximation to be valid is 36. Based on this, sampling was carried out by quarter of the year, with 40 samples taken randomly each quarter. For each quarter, the proportion of the 40 samples with enumerative results >0 was calculated via eq. F.1 (Appendix F).

Figure G.1. shows a p-Chart for hypothetical data. Note the exceptions at periods #7 and #22, either of which would indicate a drop in prevalence of samples with enumerative results >0.

Figure G.2. shows an i-Chart for the samples with enumerative results >0 with control limits based on $\pm$ 3 σ. The data are under control with no exceptions.

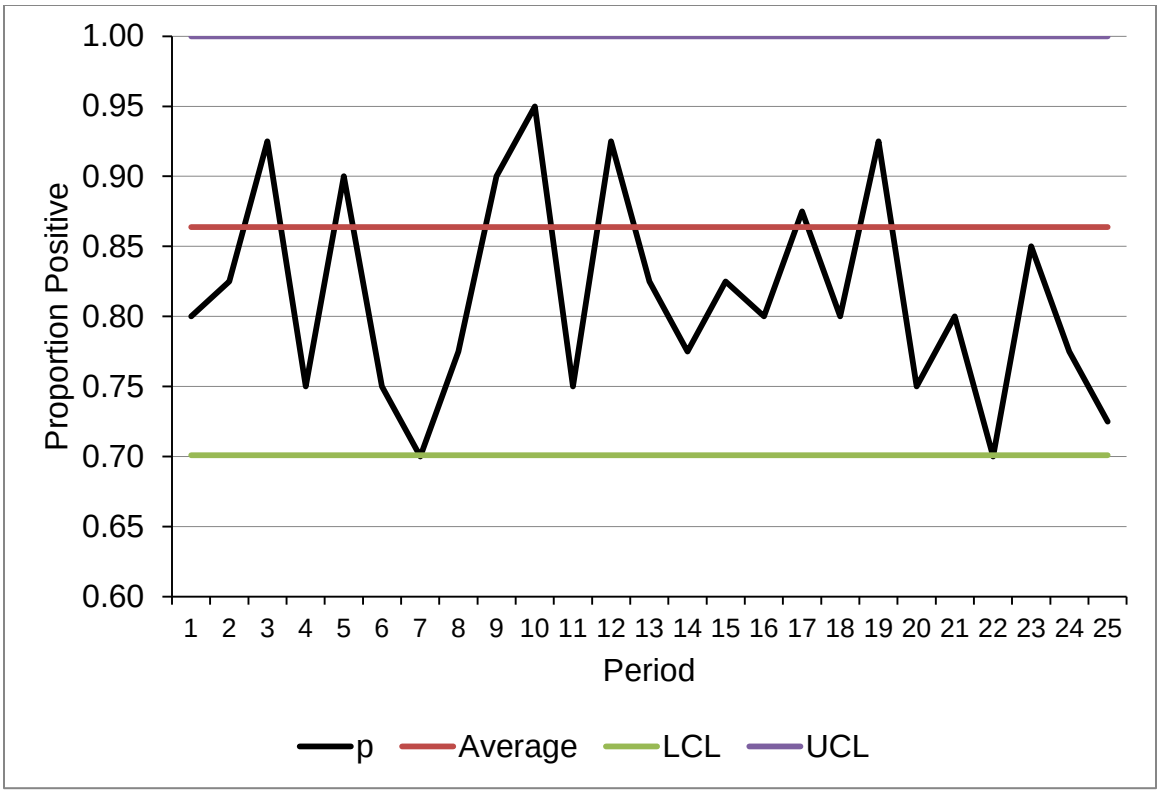


Figure G.1. p-Chart for aerobic plate count in ground beef. Note the exceptions at periods #7 and #22 which imply a drop in the proportion of samples with enumerative results >0 from that expected. There is also a general tendency to fall under the average.

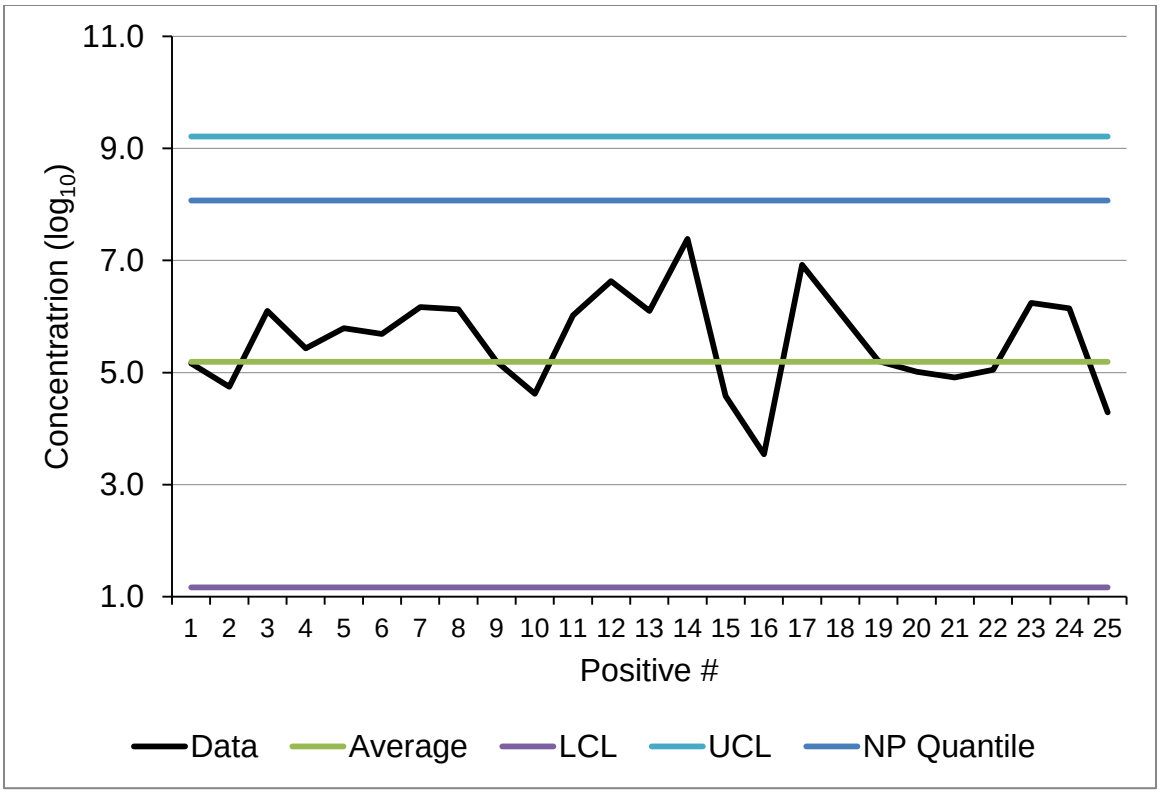


Figure G.2. Individuals' chart for aerobic plate count in ground beef.

Appendix H. Control Chart for Very High Prevalence with Quantitation

This example corresponds to prevalence in the range 95% to 100%. For this case, the number of samples with enumerative results equal to 0 is low enough to apply eq. F.2. (Appendix F).

Small rational subgroups (i.e., lots) are now possible, corresponding to shift, day, week, month or quarter, within which operations are expected to be consistent. The use of such subgroups allows control not only of the mean, but also the spread of the process.

The X-bar chart has control limits calculated as follows:

$$UCL_{ave} = \mu + A_2 R_{ave} \qquad \text{(eq. H.1.)}$$

$$LCL_{ave} = \mu - A_2 R_{ave} \qquad \text{(eq. H.2.)}$$

where the center line is μ (determined from historical data), *n* is the subgroup sample size, A_2 is a numerical factor available from standard control chart tables (Appendix B) and R_{ave} is the average range from the same historical dataset. The range R is the difference between the maximum and minimum values in a subgroup.

Variation is controlled by a R Chart, with control limits at

$$UCL_R = R_{ave} + D_4 R_{ave} \qquad \text{(eq. H.3.)}$$

$$LCL_R = 0 \text{ for } n < 6 \qquad \text{(eq. H.4.)}$$

where D_4 is obtained from the same table as A_2. For most purposes, n should be between 2 and 6, with 4 or 5 preferred. The Range Chart responds to changes in *within* subgroup variation.

Table H.1. shows various scenarios for using X-bar-R- control charts for microbial testing.

Table H.1. Average-Range statistical process control chart characteristics for different sampling time frames

Purpose	Verify a general good state of control at vendor output or customer receiving
Operation	1. Compare variation and level across periods to variation within periods. 2. Generally, start with long time-scale plans (higher numbers), with shorter time-scale plans used for tightened inspection or troubleshooting
Notes	1. Requires quantitative measurement result. 2. Each sampling unit may itself be a composite of specimens taken from the common time period, with a single combined test result
n	Sample size taken (fixed size)

I. Sample Within Production Shift, n > 2 (best used for tightened inspection or internal control)

Operation	Take sample of size 'n' from each production shift. Plot average and range of each sample	
	Average chart	*Range chart*
Purpose	Are the sample averages consistent across shifts and days, free of trends and disturbances?	Is the variation observed consistent within shift?
Assignable causes	1. Personnel changes between shifts/days. 2. Introduction of new raw material lots. 3. Management changes between shifts/days. 4. Staffing and volume issues between shifts. 5. New equipment or procedures between shifts/days.	1. New employees within shift. 2. New management within shift. 3. New equipment or procedures within shift.

II. Sample Within Production Day, n > 2 (best used for tightened inspection or internal control)

Operation	Take sample of size 'n' from each production day, across shifts. Plot average and range of each sample	
	Average chart	*Range chart*
Purpose	Are the sample averages consistent across days, free of trends and disturbances?	Is the variation observed consistent within and across different days' production?
Assignable causes	1. Personnel changes between days. 2. Introduction of new raw material lots. 3. Management changes between days. 4. Staffing and volume issues between days. 5. New equipment or procedures between days.	1. New employees within day. 2. New management within day. 3. New equipment or procedures within day.

III. Sample Within Production Week, n = 5, 6, 7 (normal inspection)

Operation	Take single unit from each production day during week, across shifts. The collection of results is the sample. Plot average and range of each sample.	
	Average chart	*Range chart*
Purpose	Average Chart PURPOSE:	Range Chart PURPOSE:

	Are the sample averages consistent across weeks, free of trends and disturbances?	Is the variation observed consistent within and across different weeks' production?
Assignable causes	ASSIGNABLE CAUSES: 1. Personnel changes between weeks. 2. Introduction of new raw material lots. 3. Management changes between weeks. 4. Staffing and volume issues between weeks. 5. New equipment or procedures between days	ASSIGNABLE CAUSES: 1. New employees within week. 2. New management within week. 3. New equipment or procedures within week. 4. Day of week volume or procedure effects.
IV. Sample Within Production 'Month', n = 4 (loosened inspection)		
Operation	Take single unit from each production week, across days and shifts. The collection of results is the sample. Plot average and range of each sample	
	Average chart	*Range chart*
Purpose	Are the sample averages consistent across months, free of trends and disturbances?	Is the variation observed consistent within and across different months' production?
Assignable causes	1. Personnel changes between months. 2. Introduction of new vendors. 3. Management changes between months. 4. Staffing and volume issues between months 5. New equipment or procedures between months. 6. Seasonal changes in raw materials and production volume	1. New employees within month. 2. New management within month. 3. New equipment or procedures within month. 4. New equipment or procedures within month

Example: *Aerobic Plate Count in Bagged Salad*

Received lots of bagged salad mixed are tested for APC. Five samples are taken per lot. Based on prior test data, the long-term average APC $\log_{10}$ concentration is 5.19 with standard deviation of 1.34 and an average range of 3.12.

Figure H.1. shows the Average Chart for recent data. No abnormal behavior is apparent.

Figure H.2. shows the Range Chart for the same data. Two exceptions at the UCL are prominent.

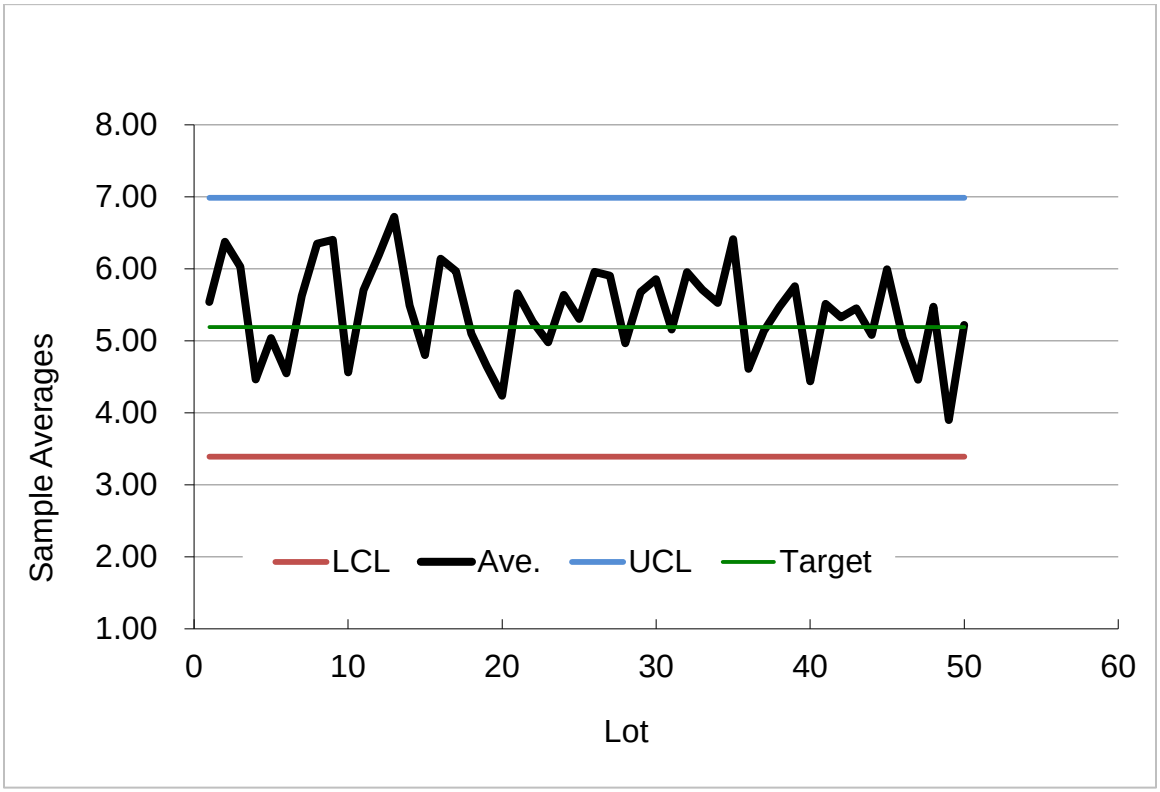


Figure H.1. Average Chart for APC in bagged salad mix.

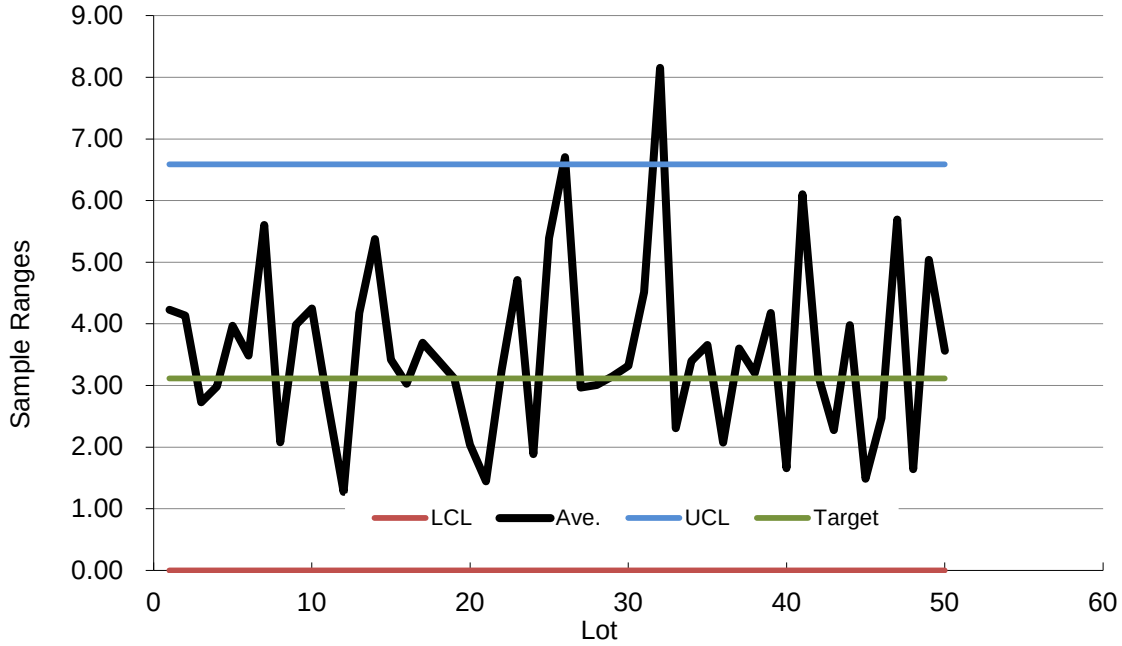


Figure H.2. Range Chart for APC in bagged salad mix. Note the two out-of-control points.

Appendix I. Number of Samples and Statistical Uncertainty about Setting Control Limits for X Bar Charts

There are no firm rules for how much data are needed to develop control charts. As the number of lots used to develop a control chart increases, the uncertainty about setting the control limits (too high or too low) decreases. However, there are diminishing returns to using more data.

For example, Figure I.1 is based on hypothetical data collected at a frequency of n = 5 samples per lot represented by a lognormal distribution with a geometric mean = 3 $\log_{10}$ cfu/g (1,000 cfu/g) and a standard deviation = 1 $\log_{10}$ cfu/g. The grand mean (G mean) is represented by the central solid line. The upper and lower 3 σ control limits for sample means are represented by dashed lines (UCL, and LCL, respectively). The uncertainties associated with the statistics due to random sampling variability are represented by dotted lines (90% confidence limits). Assuming the process is stable over time, as the number of lots (subgroups) used to develop an average control chart increases, the uncertainty about the control limits decreases. The result of using more lots (subgroups) to develop control limits is increased confidence that the limits are not set too high or too low relative to the intended design (3 sigma). Uncertainty about the control limits decreases more slowly than the uncertainty about the mean. This is due to greater random sampling error in measures of variability.

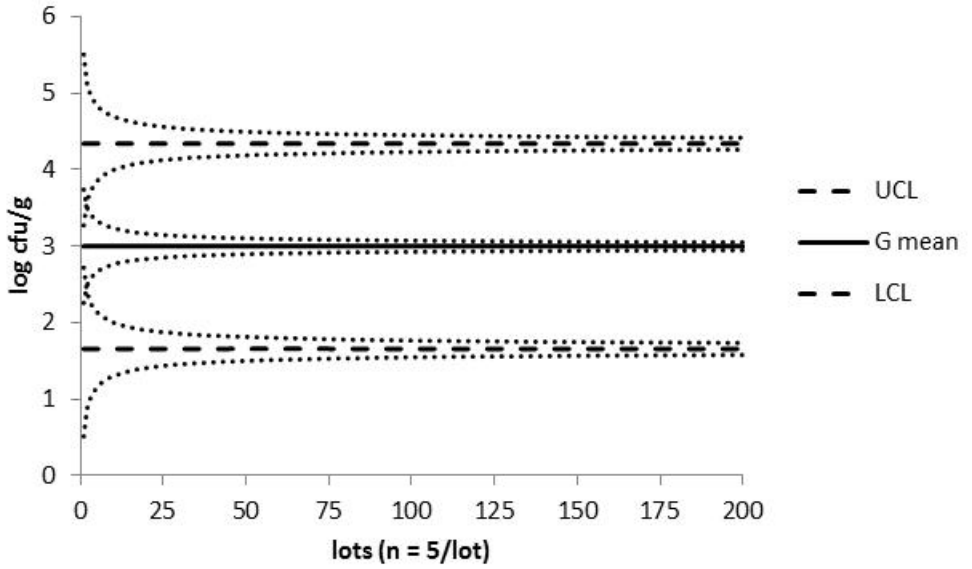


Figure I.1. Uncertainty about 3 Sigma Control Limits for Mean (μ = 3 $\log_{10}$ cfu/g, σ = 1 $\log_{10}$ cfu/g)

The uncertainty about the control limits depends on the number of samples per lot (n) as well as the number of lots (subgroups) used to develop the limits. Assuming a lognormal distribution with geometric mean = 3 $\log_{10}$ cfu/g (1,000

cfu/g) and a standard deviation = 1 $\log_{10}$ cfu/g, Figure I.2 compares the relationship between the uncertainty about average chart control limits and the number of lots used to develop the limits for n = 5 and n = 3 samples per lot (i.e., rational subgroup). Both cases show an initial rapid decrease in uncertainty in control limits followed by diminishing returns from additional lots. However, the control limit uncertainty for n = 3 samples per lot (subgroup) starts from a substantially higher level relative to n = 5 samples per lot (subgroup).

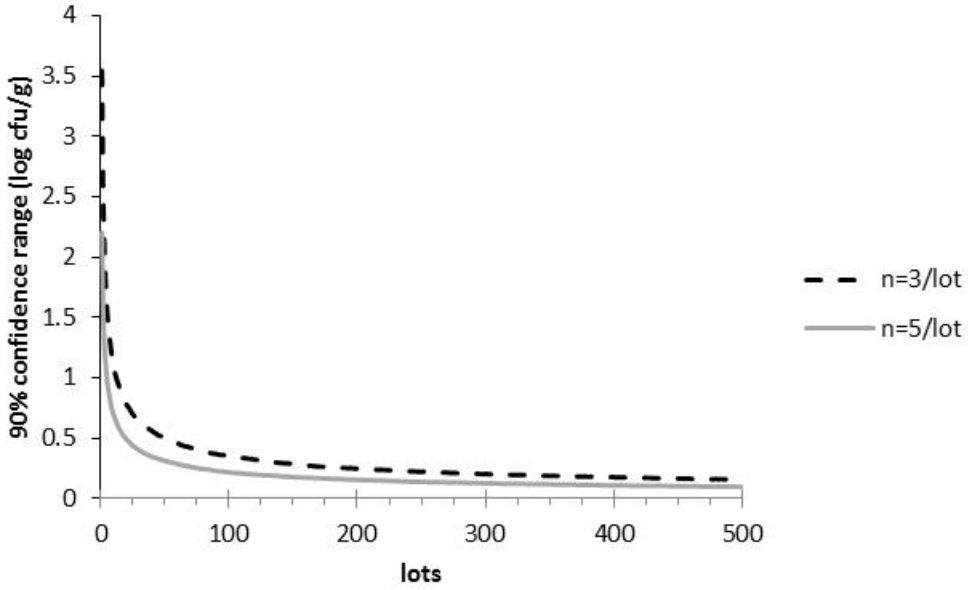


Figure I.2. 90% Confidence Range of 3 Sigma Control Limits for Mean (μ = 3 $\log_{10}$ cfu/g, σ= 1 $\log_{10}$ cfu/g)

It should be remembered that all data included in the dataset used to compute the control limits should be consistent with a tenable assumption of a time period of unchanging conditions (*e.g.*, the same season of raw materials, the same production process, the same equipment).

Appendix J. Microbiological and chemical limits for foods that are useful to assess process control and insanitary conditions.

Introduction

The microbiological and chemical limits provided in the following tables are useful for suppliers and DOD to assess process control and sanitary conditions associated with the production of various foods. The limits and sample size or procedures described in these tables are *not* regulatory limits, although in certain cases, they may reference regulatory limits.

The food categories correspond to those listed in Appendix A where flow diagrams for manufacturing of the foods are provided. The microbiological data for the various microorganisms or classes of microorganisms can be used to develop statistical process control (SPC) charts, as well as to gain an understanding of the microbiological quality and safety associated with the various products.

The environmental monitoring program (EMP) data have less utility for development of SPC charts because of the potential high number of monitoring sites, and thus, the longer time frame required for sufficient data for SPC charts. However, the EMP data have been correlated with food-product contamination (Kornacki, 2014) and have usefulness for assessing process control, cleaning and sanitation practices, targeting supplier and DOD resources, and for trending EMP data over time to assess continuous improvement.

Each table in Appendix J includes the microorganisms that are useful for assessing process control and sanitary conditions during production of foods within the given food category. The microbiological limits for these microorganisms are provided, as well as recommended actions to be taken if the limits are exceeded. In many instances, the actions include investigating to determine a root cause, developing and implementing corrective and preventive actions, and conducting follow-up sampling and testing to determine if the corrective and preventive actions have been effective. In all tables, where applicable, these actions are identified as “Investigate” and “Implement Corrective Actions” to simplify the actions listed. The investigative and corrective action processes likely will be unique to each situation.

Samples of the food may be taken at numerous points throughout production; these are considered as in-process samples. Samples taken at the end of the production line also may be tested, with results compared against the microbiological limits. In some cases, these finished product data may be useful to assist in the development of finished product microbiological criteria; however, initially, these data should be used to assess process control and sanitary conditions, and compared against the limits provided for each criterion. When samples are taken at the end of the production line and tested, and results exceed the limits, the recommended action may be to reject the lot of food represented by the sample. This will be especially true when the microorganism detected is a pathogen and the food will not receive further processing using a validated kill step.

The number of in-process, finished product, or environmental samples to take and test may not be given for all criteria in the tables. In general, taking more samples is better; and larger numbers of samples taken for pathogens can increase the confidence of detecting pathogens present at a low prevalence. Analytical unit weights for testing should be a minimum of 25 grams; for pathogen testing, the analytical unit (usually a composite weight) in the table may specify a particular weight (*e.g.*, 325 or 375 grams) and provide the weights for the individual samples contributing to the composite sample (*e.g.*, 15 X 25-gram samples to result in a 375-gram analytical unit). The body of the report and Appendix I discuss how sample numbers affect the design of SPC charts.

Table J.1. Microbiological Limits for Bottled Water

Notes: The bottled water category includes bottled water described as Artesian, Mineral, Purified, Sparkling or Spring.

Criteria & EMP Target Microorganism[a]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
Coliforms	<10 in 100 mL		Reject lot. Investigate; test for generic *E. coli*. Notify local authorities if they are involved in providing water treatment.	See 21 CFR 165.110 (b)(2)(i)(A) for applicable regulatory standards
E. coli (generic) or thermotolerant coliforms	Negative in 100 mL		Reject lot. Investigate. Notify local authorities if they are involved in providing water treatment. If water comes in contact with food, it is recommended that the food be destroyed or reprocessed to kill vegetative cells.	See 21 CFR 165.110 (b)(2)(i)(B) for applicable regulatory standards
Enterococcus		Negative in 250 mL	Investigate. Notify local authorities if they are involved in providing water treatment. If water comes in contact with food, it is recommended that the food be destroyed or reprocessed to kill vegetative cells.	Not routinely tested; however, some countries (in the EU) test for *Enterococcus* in lieu of coliforms.
Heterotrophic plate count		<100/mL @ 22°C <20/mL @ 37°C	Investigate. Notify local authorities if they are involved in providing water treatment.	Reject or divert for further processing; investigate, implement corrective action
Pseudomonas aeruginosa		Negative in 250 mL	Investigate. Notify local authorities if they are involved in providing water treatment.	Not routinely tested, but may be required by individual country's regulations
Parasites & Viruses		Negative	Investigate. Notify local authorities if they are involved in providing water treatment.	Unless there is a particular concern for parasites or viruses, testing typically is not done; this will be very situational and location-dependent.

[a] (Code of Federal Regulations, 2014b; European Communities, 2007; World Health Organization (WHO), 2013, 2014)

Table J. 2. Microbiological Limits for Ice, Packaged

Notes: Testing based on target microorganisms for bottled water.

Criteria & EMP Target Microorganism[b]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
Coliforms	<10 in 100mL		Investigate. Test generic *E. coli*. Notify local authorities if they are involved in providing water treatment for water becoming ice.	
E. coli (generic) or thermotolerant coliforms	Negative in 100 mL		Investigate. Notify local authorities if they are involved in providing water treatment for water becoming ice. If the ice is for direct consumption, it is recommended that the ice not be used. If ice comes in contact with food, it is recommended that the food be destroyed or reprocessed to kill vegetative cells.	
Pseudomonas aeruginosa		Negative in 250 mL	Investigate. Notify local authorities if they are involved in providing water treatment.	Not routinely tested, but may be required by individual country's regulations
Parasites & Viruses		Negative	Investigate. Notify local authorities if they are involved in providing water treatment for water becoming ice.	Unless there is a particular concern for parasites or viruses, testing typically is not done; this will be very situational and location-dependent.

[b] (Code of Federal Regulations, 2014b; European Communities, 2007; World Health Organization (WHO), 2013, 2014)

Table J. 3. Microbiological and Chemical Limits for Juices and Drinks, Pasteurized and Refrigerated

Notes: Examples of these products are orange juice, carrot juice, and some tea beverages. These products are pasteurized but must be kept refrigerated to prevent spoilage. Raw citrus juices sold in the U.S. will require additional testing (Subpart B, Juice HACCP regulations). Juices with a pH>4.6 should address control of *Clostridium botulinum*.

Criteria & EMP Target Microorganism[c]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
Coliforms	<10/mL		Investigate, implement corrective action	
E. coli (O157:H7 or other STEC)		Negative in 10 individual 25-g samples	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	This limit is based on the FDA Juice HACCP regulation requiring a 5-$\log_{10}$ reduction. Processors with demonstrated control may not need to test for *E. coli* O157:H7 except for periodic verification purposes.
Listeria spp. (EMP) [d]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	
Patulin (in apple juice)[e]		50 µg/kg	The presence of patulin in apple juice above the limit should lead to rejection of the product. Investigate and implement corrective action.	Different countries may have different regulatory requirements. A lower limit of10 µg/kg should be considered when apple juice products are intended for infants.
Salmonella (product)		Negative in 375 g	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	375 g analytical unit composed of 15 X 25-g samples This limit is based on the FDA Juice HACCP regulation requiring a 5-$\log_{10}$ reduction. Processors with demonstrated control may not need to test for *Salmonella* except for periodic verification purposes.

[c] (Code of Federal Regulations, 2014a; U. S. Department of Health and Human Services, 2004)
[d] (R.B. Tompkin, 2002; R. B. Tompkin, Scott, Bernard, Sveum, & Gombas, 1999)
[e] (U. S. Department of Health and Human Services, 2005c)

Table J.4. Microbiological and Chemical Limits for Shelf-stable Beverages

Notes: Examples of these products are carbonated beverages, commercial sterility/ultra-high temperature/aseptic beverages, and some juice drinks. Microbiological control is accomplished by one or more of the following: low pH, pasteurization (UHT), and carbonation

Criteria & EMP Target Microorganism	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
Patulin (in apple juice)[f]		50 µg/kg	The presence of patulin in apple juice above the limit should lead to rejection of the product. Investigate and implement corrective action.	Different countries may have different regulatory requirements. A lower limit of10 µg/kg should be considered when apple juice products are intended for infants.
Microbiological criteria (NA) [g]	NA	NA	NA	No microbiological testing recommended for this product

There are no microbiological limits set for shelf-stable beverages as these products are considered commercially-sterile (*i.e*., stable at room temperature under normal handling and storage conditions). Suppliers should be verifying the raw materials used in the formulation of these products before the process providing commercial sterility. Shelf-stable liquid products should be examined by means other than routine microbiological testing; if inspection finds bulging containers, pH changes, odors, etc., then further investigation is warranted.

[f] (U. S. Department of Health and Human Services, 2005c)
[g] (Elliott & Kataoka, 2013)

Table J.5. Microbiological Limits for Dairy- Butter, margarine

Notes: Either formulated with sufficient salt or lactic acid (for unsalted butter) to prevent growth or refrigerated; products containing added seasoning/herbs/spices may have additional requirements

Criteria & EMP Target Microorganism[h]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
Coliforms[i]	10/g		Investigate, implement corrective action	
Enterobacteriaceae[i]		10/g	Investigate, implement corrective action	Due to certain strains being able to survive milk pasteurization, enterococci are not widely adopted as indicators of process hygiene in the dairy industry[j]
Mold/Yeast		20/g	Investigate, implement corrective action	
Listeria spp. (EMP)[k]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	
S. aureus		100/g	Investigate, implement corrective action. if $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	

[h] (National Academies of Science, 2003)
[i] Coliforms or *Enterobacteriaceae* are acceptable for routine testing. (Kornacki, Gurtler, & Stawick, 2013)
[j] (Craven, Eyles, & Davey, 2003)
[k] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)

Table J.6. Microbiological Limits for Dairy-Cheese, Hard

Notes: Ex. Parmesan, Cheddar, a_w<0.95 and pH<5.6. All cheeses are made with pasteurized milk.

Criteria & EMP Target Microorganism[l]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
Coliforms	<100/g		Investigate, implement corrective action	
E. coli (generic)		<10/g	Investigate, implement corrective action; if >100/g, reject lot	
Listeria spp. (EMP) [m]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	
Listeria spp. (product)		Negative in 25 g	Reject lot	May be in-process vat sample due to the aging process for natural cheese
Salmonella		Negative in 375 g	Reject lot	May be in-process vat sample due to the aging process for natural cheese.
S. aureus		100/g	Investigate, implement corrective action. If $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	Test for toxin if slow acid development; if positive for toxin, destroy product

[l] (U.S. Department of Health and Human Services, 2010)
[m] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)

Table J.7. Microbiological Limits for Dairy-Cheese, Soft, Semi-Soft, Surface-Ripened

Notes: Ex. Brie, Fresh Mozzarella, a_w>0.95 and pH>5.4. All cheeses are made with pasteurized milk.

Criteria & EMP Target Microorganism[n]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
Coliforms	<100/g		Investigate, implement corrective action	
E. coli (generic)		<10/g	Investigate, implement corrective action; if >100/g, reject lot	
Listeria spp. (EMP) [o]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	
Listeria spp. (product)		Negative in 125 g	Reject lot	125-g analytical unit composed of 5 x 25-g samples
Salmonella		Negative in 375 g	Reject lot	
S. aureus		100/g	Investigate, implement corrective action. if $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	Test for toxin if slow acid development; if positive for toxin, destroy product.

[n] (Australia New Zealand Food Authority, 2014; Authority, 2014; U.S. Department of Health and Human Services, 2010)
[o] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)

Table J.8. Microbiological Limits for Dairy-Cultured, pH <4.8

Notes: Ex. Sour cream, yogurt, buttermilk; active pH control required

Criteria & EMP Target Microorganism[p]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
Coliforms	10/g		Investigate, implement corrective action; if >10/g and used for RTE foods, reject lot	
Listeria spp. (EMP)[q]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	
Mold/Yeast		10/g	Investigate, implement corrective action	The presence of mold and yeast may be influenced by added ingredients such as fruit purees and other inclusions. This needs to be considered in assessing mold and yeast populations as well as whether any detectable molds and yeast would grow in the product during its shelf life.
S. aureus		10^3/g	Investigate, implement corrective action. if $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	No testing recommended unless fermentation does not reach pH <4.8 in <8 h

[p] (U. S. Department of Health and Human Services, 2011b; U.S. Department of Health and Human Services, 2010)
[q] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)

Table J.9. Microbiological Limits for Dairy-Cultured, pH >4.8 and < 5.4

Notes: Ex. Cottage cheese, cream cheese, moisture >50%; active pH control required

Criteria & EMP Target Microorganism[r]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
Coliforms	10/g		Investigate, implement corrective action. If >10 /g and regulated under PMO, reject lot due to regulatory limit	
Listeria spp. (EMP) [s]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	
Mold/Yeast		10/g	Investigate, implement corrective action	The presence of mold and yeast may be influenced by added ingredients such as fruit purees and other inclusions. This needs to be considered in assessing mold and yeast populations as well as whether any detectable molds and yeast would grow in the product during its shelf life.
S. aureus		10^3/g	Investigate, implement corrective action. If $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	No testing recommended unless fermentation does not reach pH <4.8 in <8 h

[r] (Bradley, Houck, & Smukowski, 2013; U. S. Department of Health and Human Services, 2011b)
[s] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)

Table J.10. Microbiological Limits for Dairy-Dried Products

Notes: Ex. NFDM, whey powder. This does not cover dried dairy ingredients used in infant formula; those requirements are more stringent

Criteria & EMP Target Microorganism[t]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC/SPC	$1X10^4$/g		Investigate, implement corrective action	
B. cereus		100/g	Investigate, implement corrective action. if $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	
Coliforms[u]	10/g		Investigate, implement corrective action	
Enterobacteriaceae		10/g	Investigate, implement corrective action	
Listeria spp. (EMP) [v]		Negative for Zone 2 or 3	Investigate, consider Zone 1 and finished product testing, implement corrective actions	
S. aureus		100/g	Investigate, implement corrective action. if $\geq 10^2$ /g, reject lot due to potential for enterotoxin production	
Salmonella (EMP)[w]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	
Salmonella	Negative. in 375 g		Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	As an alternative sampling option to collecting and compositing 15-25 g samples (total 375 g), an auto sampler can be used to collect small amounts of samples throughout a production run for a total of 375g[x]

[t] (International Commission for the Microbiological Specifications for Foods (ICMSF), 2011; U. S. Department of Health and Human Services, 2011b; U.S. Department of Health and Human Services, 2010)
[u] Coliforms or *Enterobacteriaceae* are acceptable for routine testing. (Kornacki et al., 2013)
[v] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)
[w] (Chen et al., 2009a, 2009b; Grocery Manufacturers Association, 2009)
[x] Recommend 1500 g per lot when high volumes of product are produced per lot (or production day).

Table J.11. Microbiological Limits for Dairy-Frozen Desserts

Notes:

Criteria & EMP Target Microorganism[y]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC		See comments	Investigate, implement corrective action.	Populations may be influenced by ingredients; product specific APC limits need to be established based on baseline testing
Coliforms	100/g		Investigate, implement corrective action.	Populations may be influenced by ingredients
Salmonella (product)		Negative in 250 g	Reject lot; Investigate, implement corrective action.	250 g analytical unit composed of 10 x 25-g samples
Listeria spp. (EMP)	Negative for Zone 2 or 3		Investigate, consider Zone 1 and product testing, implement corrective action	

[y] (International Commission for the Microbiological Specifications for Foods (ICMSF), 2011)

Table J.12. Microbiological Limits for Dairy-Milk and Milk Products (Fluid)

Notes: Ex. Fluid milk, cream; Pasteurized, refrigerated; alkaline phosphatase negative (less than 2.0 micrograms phenol equivalent per g)

Criteria & EMP Target Microorganism[z]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC/SPC	2.0 x 10^4/g		Investigate, implement corrective action	
Coliforms[aa]	10/g		Investigate, implement corrective action. if >10 /g and regulated under PMO, reject lot due to regulatory limit	
Enterobacteriaceae		10/g	Investigate, implement corrective actions	
Listeria spp. (EMP) [bb]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and product testing, implement corrective action	
S. aureus		100/g	Investigate, implement corrective action. if $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	No testing recommended unless temperature abuse is suspected

[z] (Bradley et al., 2013; U. S. Department of Health and Human Services, 2011b)
[aa] Coliforms or *Enterobacteriaceae* are acceptable for routine testing. (Kornacki et al., 2013)
[bb] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)

Table J.13. Microbiological Limits for Dairy- Processed Cheese

Notes: Manufactured by heating cheese with water, emulsifier and other ingredients to kill vegetative pathogens; molten cheese may then be hot-filled into loaves or blocks and chilled or cut into individual slices for use; these cheeses are intended to be stored refrigerated. Shelf-stable hot-filled cheese spreads or cheese sauces must be formulated for safety to inhibit *Clostridium botulinum*.

Criteria & EMP Target Microorganism	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC/SPC	10^3/g		Investigate and implement corrective action.	Test for products which are not hot-filled directly into final container. APC limit may be adjusted subject to control chart associated with Statistical Process Control. Populations are predominantly sporeformers or heat-stable spoilage microorganisms.
Coliforms		<10/g	Investigate, implement corrective action	Test for products which are not hot-filled directly into final container
E. coli (generic)		<10/g	Investigate and implement corrective action	Test for products which are not hot-filled directly into final container
Listeria spp. (EMP) [cc]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	
S. aureus		<100/g	Investigate, implement corrective action. if $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	Test for products which are not hot-filled directly into final container
Salmonella (EMP)[dd]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	Test EMP in area where products are not hot-filled directly into final container
Salmonella (product)		Negative in 125 g	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	Test for products which are not hot-filled directly into final container

[cc] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)
[dd] (Chen et al., 2009a, 2009b; Grocery Manufacturers Association, 2009)

Table J.14. Microbiological Limits for Egg Products-Pasteurized, Processed

Notes:

Criteria & EMP Target Microorganism[ee]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC	10^4/g		Investigate, implement corrective action	
B. cereus		10^3/g	Investigate, implement corrective action. if $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	
Coliforms	10/g		Investigate, implement corrective action	
Enterobacteriaceae		100/g	Investigate, implement corrective action	
Listeria spp. (EMP) [ff]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	
Listeria spp. (product)		Negative in 100 g	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	
S. aureus	10/g		Investigate, implement corrective action. if $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	
Salmonella (EMP)[gg]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	
Salmonella (product)	Negative in 100 g		Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	

[ee] (Australia New Zealand Food Authority, 2014; European Commission, 2005; International Commission for the Microbiological Specifications for Foods (ICMSF), 2011; U. S. Department of Agriculture Food Safety Inspection Service, 2014c)
[ff] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)
[gg] (Chen et al., 2009a, 2009b; Grocery Manufacturers Association, 2009)

Table J.15. Microbiological Limits for Egg Products-Shell Eggs, Raw
Notes:

Criteria & EMP Target Microorganism[hh]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
Coliforms[ii]		10^3/g	Investigate, implement corrective action	
E. coli (generic)[ii]		10^3/g	Investigate, implement corrective action	
Enterobacteriaceae		10^4/g	Investigate, implement corrective action	
Salmonella (EMP)	Negative for Zone 2 or 3		If environment is positive for *Salmonella* Enteritidis, conduct egg sampling per FDA Final Rule 2009	*Salmonella* Enteritidis environmental testing

[hh] (U. S. Department of Health and Human Services, 2009)
[ii] Coliforms, *E. coli or Enterobacteriaceae* are acceptable for routine testing. (Kornacki et al., 2013)

Table J.16. Microbiological Limits for Grain-based products-RTE, baked items, refrigerated or TCS

Notes: Examples: focaccia, custard or cream-filled pastries, pies. Qualifying information: APC counts may be high due to containing ingredients prepared with starter culture

Criteria & EMP Target Microorganism	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
B. cereus		10^3/g	Investigate, implement corrective action. if $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	
Coliforms	100/g		Investigate process and implement corrective action	
E. coli (generic)		10/g	Investigate process and implement corrective action	
Listeria spp. (EMP) [jj]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	Periodic finished product testing (test/hold) for products which support growth of *L. monocytogenes*
S. aureus		10^3/g	Investigate, implement corrective action. if $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	
Salmonella[kk]		negative in 375 g	Reject lot. Investigate and implement corrective action	

[jj] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)
[kk] (Andrews, Jacobson, & Hammack, 2014)

Table J.17. Grain-based products-RTE, baked items, shelf stable, non-TCS

Notes: Examples: bread. If raw ingredients added after baking step, additional risks should be considered. ICMSF 8 does not recommend routine testing.
:

Criteria & EMP Target Microorganism[ll]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC		10^4/g	Investigate process and implement corrective action	Populations predominantly sporeformers
Coliforms[mm]		100/g	Investigate process and implement corrective action	
Enterobacteriaceae		100/g	Investigate process and implement corrective action	
Salmonella (product)		Negative in 125 g	Reject lot; investigate process and implement corrective action	*Salmonella* testing is appropriate if raw ingredients (e.g., nuts, raw flour)are added post-baking

[ll] (International Commission for the Microbiological Specifications for Foods (ICMSF), 2011)
[mm] Coliforms or *Enterobacteriaceae* are acceptable for routine testing. (Kornacki et al., 2013)

Table J.18. Microbiological Limits for Grain Based Products, RTE, cereals

Notes: Examples: breakfast cereals. Grain based product undergoes a lethality step; mycotoxin surveillance testing completed on incoming grains as pre-requisite program with limits based on individual country's regulations

Criteria & EMP Target Microorganism	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC		$5x10^4$/g	Investigate process and implement corrective action	
Coliforms[nn]		100/g	Investigate process and implement corrective action	
Enterobacteriaceae		100/g	Investigate process and implement corrective action	
Salmonella (EMP)[oo]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	If Zone 1 positive, reject lot
Salmonella		Negative in 375 g	Reject lot; investigate process and implement corrective action	375-g analytical composed of15 x 25-g samples

[nn] Coliforms or *Enterobacteriaceae* are acceptable for routine testing. (Kornacki et al., 2013)
[oo] (Chen et al., 2009a, 2009b; Grocery Manufacturers Association, 2009)

Table J.19. Microbiological Limits for Grain Based Products – RTE, cold-pressed bars

Notes; Ex. granola bars; Qualifying information: ingredients will undergo mycotoxin surveillance testing as appropriate; shelf-stable, a_w <0.85

Criteria & EMP Target Microorganism	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC		$5x10^4$/g	Investigate process and implement corrective action	
Coliforms[pp]		100/g	Investigate process and implement corrective action	
Enterobacteriaceae		100/g	Investigate process and implement corrective action	
Salmonella (EMP)[qq]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	
Salmonella		Negative in 375 g	Reject lot; investigate process and implement corrective action	375-g analytical unit composed of 15 x 25-g samples

[pp] Either coliform or *Enterobacteriaceae* testing is appropriate. (Kornacki et al., 2013)
[qq] (Chen et al., 2009a, 2009b; Grocery Manufacturers Association, 2009)

Table J.20. Microbiological Limits for Grain Based Products non-RTE, dry, flour based mixes

Notes: Flour can contain pathogens occasionally and should be subjected to a lethality step prior to consumption[rr]

Criteria & EMP Target Microorganism	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
Not Applicable (NA)	NA	NA	NA	No microbiological testing recommended for this product

[rr] (Sperber & North American Millers' Association Microbiology Working Group, 2007)

Table J.21. Microbiological Limits for Grain Based Products – Non-RTE, pasta, dried or refrigerated

Criteria & EMP Target Microorganism	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC		10^6/g		High APC counts for unheated products made with raw flour are not unexpected
E. coli (generic)		100/g	Investigate process and implement corrective action	Periodic testing recommended for refrigerated pasta
Listeria spp. (EMP) [ss]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	Recommended in facilities manufacturing refrigerated pasta
S. aureus		10^3/g	Investigate, implement corrective action. if $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	
Salmonella (EMP)[tt]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	Recommended in facilities manufacturing dried pasta
Salmonella		Negative in 125 g	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	

[ss] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)
[tt] (Chen et al., 2009a, 2009b; Grocery Manufacturers Association, 2009)

Table J.22. Microbiological and Chemical Limits for Meals and Entrees—Non-RTE, ready-to-cook meals, includes raw ingredients
Notes: This category includes a wide variety of products and processes that will influence appropriate testing choices.

Criteria & EMP Target Microorganism	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
B. cereus		10^3/g	Investigate, implement corrective action. if $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	Test if food contains components which are high risk for *B. cereus*, such as cooked rice
Coliforms[uu]		10^3/g	Investigate, implement corrective action	
E. coli (O157:H7 or other STEC)		Negative in 125 g	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	Testing if raw, non-intact beef component is present. Validated cooking instructions should be present on package. 125-g analytical unit composed of 5 x 25-g samples
Enterobacteriaceae		10^4/g	Investigate, implement corrective action	
S. aureus		10^3/g	Investigate, implement corrective action. if $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	
Salmonella (EMP)[vv]		Negative for Zone 2 or 3	Investigate, consider Zone 1 and finished product testing, implement corrective action	
Salmonella (product)		Negative in 375 g	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	375 g analytical unit composed of15 x 25-g samples
Histamine[ww]		50 ppm in 250 g	Reject lot; Investigate, implement corrective action	Histamine testing appropriate only when scombroid species are present; The FDA Hazards and Controls Guide lists a defect action level of 50ppm

[uu] Coliforms or *Enterobacteriaceae* are acceptable for routine testing. (Kornacki et al., 2013)
[vv] (Chen et al., 2009a, 2009b; Grocery Manufacturers Association, 2009)
[ww] (U. S. Department of Health and Human Services, 2011a)

Table J.23. Microbiological and Chemical Limits for Meals and Entrees--RTE, deli salads, sandwiches, heat-eat meals, sushi

Notes: Survey data indicates a wide range in microbial populations depending on specific food. Items may include ingredients which are raw.

Criteria & EMP Target Microorganism	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
B. cereus		10^3/g	Investigate, implement corrective action. If $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	Test if food contains components which are high risk for *B. cereus*, such as cooked rice
Coliforms[xx]		10^4/g	Investigate, implement corrective action	
E. coli (generic)	100/g		Investigate, implement corrective action	
Enterobacteriaceae		10^4/g	Investigate, implement corrective action	
Listeria spp. (EMP) [yy]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	
S. aureus		10^3/g	Investigate, implement corrective action. If $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	
Salmonella (EMP)[zz]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	
Salmonella (product)		Negative in 375 g	Reject lot; Investigate, implement corrective action	375-g analytical unit composed of 15 x 25-g samples
Histamine[aaa]		50 ppm in 250 g	Reject lot; Investigate, implement corrective action	Histamine testing appropriate only when scombroid species are present; The FDA Hazards and Controls Guide lists a defect action level of 50ppm.

[xx] Coliforms, *E. coli, or Enterobacteriaceae* are acceptable for routine testing. (Kornacki et al., 2013)
[yy] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)
[zz] (Chen et al., 2009a, 2009b; Grocery Manufacturers Association, 2009)
[aaa] (U. S. Department of Health and Human Services, 2011a)

Table J.24. Microbiological Limits for Meals and Entrees—RTE, sous-vide, cook and chill

Notes: These products receive a lethality treatment; presence of vegetative microbes represents post-process contamination. If not using validated *sous-vide* process for a 6-log reduction of non-proteolytic *Clostridium botulinum*, testing of vegetative microorganisms is warranted.

Criteria & EMP Target Microorganism	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC		10^3/g	Investigate, implement corrective action	
B. cereus		10^3/g	Investigate, implement corrective action. If $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	Test if food contains components which are high risk for *B. cereus*, such as cooked rice
Coliforms[bbb]		100/g	Investigate, implement corrective action	
E. coli (generic)	10/g		Investigate, implement corrective action; reject lot or divert for recooking if appropriate	
Enterobacteriaceae		100/g	Investigate, implement corrective action	
Clostridium perfringens[ccc]		500/g	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	If greater than 500 cfu/g, indicator of loss of process control or potential deviation from USDA cooling requirements

[bbb] Coliforms *or Enterobacteriaceae* are acceptable for routine testing. (Kornacki et al., 2013)
[ccc] (U. S. Department of Agriculture Food Safety Inspection Service, 1999; U.S. Department of Agriculture Food Safety Inspection Service, 1999)

Table J.25. Microbiological Limits for Meat—Beef and Pork, Non-RTE, raw (intact, non-intact)

Criteria & EMP Target Microorganism[ddd]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC		10^5/g	Investigate, implement corrective action	
Coliforms		10^3/g	Investigate, implement corrective action	
E.coli (generic)	500/g		Investigate, implement corrective action	
E. coli (O157:H7 and/or other STEC) [eee]		Negative in 325 g	Divert for lethality step, if appropriate, or reject. Investigate and implement corrective action	Test non-intact beef (ground, tenderized, enhanced) product and intact product intended to become non-intact
Enterobacteriaceae		10^4/g	Investigate, implement corrective action	
Salmonella (product)[fff]		See sampling for USDA-FSIS Performance Standards	Investigate, implement corrective action	Not used an accept/reject criterion; used for process control

[ddd] (National Advisory Committee on Microbiological Criteria for Foods, 2013; U.S. Department of Agriculture Agricultural Marketing Service (AMS), 2015)
[eee] (U. S. Department of Agriculture, 2011)
[fff] (U. S. Department of Agriculture Food Safety Inspection Service, 2014d)

Table J.26. Microbiological Limits for Meat—Poultry, Non-RTE, raw

Criteria & EMP Target Microorganism	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC		10^6/g	Investigate, implement corrective action	
Coliforms[ggg]		10^3/g	Investigate, implement corrective action	
E. coli (generic)		10^3/g	Investigate, implement corrective action	
Enterobacteriaceae		10^4/g	Investigate, implement corrective action	
Salmonella (product)[hhh]		See sampling for USDA-FSIS Performance Standards	Investigate, implement corrective action	Not used an accept/reject criterion; used for process control

[ggg] Coliforms, generic *E. coli*, *Enterobacteriaceae* are acceptable for testing. (Kornacki et al., 2013)
[hhh] (U. S. Department of Agriculture Food Safety Inspection Service, 2014d); *Campylobacter* is also proposed In the USDA-FSIS Performance Standards.

Table J.27. Microbiological Limits for Meat— RTE cooked, perishable

Notes: Ex. Includes beef, pork and poultry products, deli meats, frankfurters

Criteria & EMP Target Microorganism	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC		10^3/g	Investigate, implement corrective action	
Coliforms[iii]		100/g	Investigate, implement corrective action	
E. coli (generic)	10/g		Investigate, implement corrective action	
Enterobacteriaceae		100/g	Investigate, implement corrective action	
Listeria spp. (EMP) [jjj]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	
Listeria spp. (product)[kkk]		Negative in 125 g	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	125-g analytical unit composed of 5 x 25-g samples
Salmonella		Negative in 125 g	Investigate, implement corrective action	
Clostridium perfringens[lll]		500/g	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	If greater than 500 cfu/g, indicator of loss of process control or potential deviation from USDA cooling requirements

[iii] Either coliforms or *Enterobacteriaceae* are acceptable for testing. (Kornacki et al., 2013)
[jjj] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)
[kkk] (Authority, 2014; Canada Food Inspection Agency, 2012; U. S. Department of Agriculture Food Safety Inspection Service, 2014a; U.S. Department of Health and Human Services, 2008)
[lll] (U. S. Department of Agriculture Food Safety Inspection Service, 1999)

Table J.28. Microbiological Limits for Meat— RTE fermented, dried

Notes: Ex. Includes beef, pork and poultry products, Jerky, dried fermented sausage, dried acidified meat sticks; e.g. a_w <0.85 or pH <5.3 and a_w <0.92 for vacuum-packaged meat sticks. Products manufactured with a validated kill step for *E. coli* O157:H7 (beef) or *Salmonella* (pork, poultry) as appropriate for the given meat matrix

Criteria & EMP Target Microorganism[mmm]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
Coliforms[nnn]		100/g	Investigate, implement corrective action	
E. coli (generic)	10/g		Investigate, implement corrective action	
E. coli (O157:H7 or other STEC)		Negative in 125 g	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	125-g analytical unit composed of 5 x 25-g samples
Enterobacteriaceae		100/g	Investigate, implement corrective action	
S. aureus		10^3/g	Investigate, implement corrective action. If $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	Testing of in-process (uncooked) product may be appropriate if fermentation does not meet USDA-accepted guidelines for temperature-hours[ooo]
Salmonella		Negative in 125 g	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	125-g analytical unit composed of 5 x 25-g samples

[mmm] (U. S. Department of Agriculture Food Safety Inspection Service, 2014b)
[nnn] Either coliforms or *Enterobacteriaceae* are acceptable for testing. (Kornacki et al., 2013)
[ooo] (American Meat Institute Foundation, 1997)

Table J.29. Microbiological and Chemical Limits for Nuts and Nut Butters – RTE, Not processed for lethality

Notes: Ex.: include peanuts, tree nuts (*e.g.*, walnuts, almonds, pecans, pistachios, macadamia)

Criteria & EMP Target Microorganism	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
E. coli (generic)		0.36 MPN/g	Investigate, implement corrective action	If 2 of 10 samples are ≥0.36 MPN/g, the product is violative
Salmonella EMP[ppp]	Negative for Zone 2 and 3 surfaces		Investigate root cause of positive results, conduct vector sampling and repeat sampling until confirm negative results	
Salmonella (product)	Negative in 2 X 375-g samples		Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	Two 375-g analytical units derived from 30 x 25-g samples
Toxins – Aflatoxin B1[qqq]	20 ppb		Investigate, implement corrective action	This is routine testing for peanuts, pistachios & Brazil nuts, but non-routine for other nut types or situations

[ppp] (Chen et al., 2009a, 2009b; Grocery Manufacturers Association, 2009)
[qqq] (U. S. Department of Health and Human Services, 2005a, 2005b, 2005d, 2005e)

Table J.30. Microbiological and Chemical Limits for Nuts and Nut Butters – RTE, processed for lethality
Notes: Ex.: peanut butter, almond butter, roasted nuts

Criteria & EMP Target Microorganism	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
Salmonella EMP[rrr]	Negative for Zone 2 and 3 surfaces		Investigate root cause of positive results, conduct vector sampling and repeat sampling until confirm negative results	
Salmonella (product)	Negative in 2 x 375-g samples		Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	Two 375 g analytical units derived from 30 x 25-g samples
Toxins – Aflatoxin B1[sss]	20 ppb		Reject lot; investigate, implement corrective action	This is routine testing for peanuts, pistachios & Brazil nuts, but non-routine for other nut types or situations

[rrr] (Chen et al., 2009a, 2009b; Grocery Manufacturers Association, 2009)
[sss] (U. S. Department of Health and Human Services, 2005a, 2005b, 2005d, 2005e)

Table J.31. Microbiological Limits for Produce—Fruits and Vegetables, Cut, Frozen or Refrigerated

Notes: minimally processed

Criteria & EMP Target Microorganism[ttt]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
E. coli (generic)	100/g		Consider improvements in production hygiene and selection of raw materials	
E. coli (O157:H7 or other STEC)		Negative	Reject lot; investigate, implement corrective action	Depending on commodity, geographical location and use of GAPs
Listeria spp. (EMP) [uuu]	Negative zone 2 or 3		Consider zone 1 and finished product testing; implement corrective action	
Listeria spp. (finished product)		Negative	Reject lot; investigate, implement corrective action	Depending on commodity, geographical location and use of GAPs; Sample size may vary; e.g. 25 g
Salmonella (product)		Negative	Reject lot; investigate, implement corrective action	Depending on commodity, geographical location and use of GAPs; Sample size may vary; e.g. 25 g

[ttt] (Canada, 2008; European Commission, 2005)
[uuu] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)

Table J.32. Microbiological Limits for Produce—Fruits and Vegetables, Whole

Notes: Ex. products customarily consumed without cooking, tomatoes, cantaloupes, avocado, mangoes, apples, celery, carrots, berries, whole lettuce

Criteria & EMP Target Microorganism[vvv]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
E. coli (O157:H7 or other STEC)		Negative	Reject lot; investigate, implement corrective action	Depending on commodity, geographical location and use of GAPs; Sample size may vary; e.g. 25 g
Listeria spp. (EMP) [www]	Negative zone 2 or 3		Consider zone 1 and product testing; implement corrective action	
Salmonella (EMP)[xxx]	Negative zone 2 or 3		Consider zone 1 and finished product testing; implement corrective action	
Salmonella (product)		Negative	Reject lot; investigate, implement corrective action	Depending on commodity, geographical location and use of GAPs; Sample size may vary; e.g. 25 g

[vvv] (Canada, 2008; European Commission, 2005; International Commission for the Microbiological Specifications for Foods (ICMSF), 2011)
[www] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)
[xxx] (Chen et al., 2009a, 2009b; Grocery Manufacturers Association, 2009)

Table J.33. Microbiological Limits for Produce—Produce, Mushrooms

Notes: fresh, whole, sliced, not canned or marinated

Criteria & EMP Target Microorganism[yyy]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
E. coli (generic)		10^3/g	Investigate, implement corrective action	
E. coli (O157:H7 or other STEC)		Negative for 10 individual 25-g samples	Reject or divert for further processing if appropriate; investigate, implement corrective action	No composite testing
Enterobacteriaceae		10^4/g	Investigate, implement corrective action	
Listeria spp. (EMP) [zzz]	Negative zone 2 or 3		Consider zone 1 and finished product testing; implement corrective action	
S. aureus		10^3/g	Investigate, implement corrective action. If $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	
Salmonella (EMP)[aaaa]		Negative zone 2 or 3	Consider zone 1 and finished product testing; implement corrective action	
Salmonella (product)		Negative for 2 x 375-g composite samples	Reject or divert for further processing if appropriate; investigate, implement corrective action	Two 375-g analytical units composed of 30 x 25-g samples

[yyy] (Canada, 2008; European Commission, 2005)
[zzz] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)
[aaaa] (Chen et al., 2009a, 2009b; Grocery Manufacturers Association, 2009)

Table J.34. Microbiological Limits for Produce—Packaged Salads and Leafy Greens

Criteria & EMP Target Microorganism[bbbb]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
E. coli (generic)	100/g		Consider improvements in production hygiene and selection of raw materials	
E. coli (O157:H7 or other STEC)		Negative	Reject lot; investigate, implement corrective action	Sample size may vary e.g.25 g
Listeria spp. (EMP) [cccc]	Negative zone 2 or 3		Consider zone 1 and finished product testing; implement corrective action	
Listeria spp. (finished product)		Negative	Reject lot; investigate, implement corrective action	Sample size may vary; e.g. 25 g
Salmonella (finished product)		Negative	Reject lot; investigate, implement corrective action	Sample size may vary; e.g. 25 g

[bbbb] (International Commission for the Microbiological Specifications for Foods (ICMSF), 2011)
[cccc] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)

Table J.35. Microbiological Limits for Produce— vegetable sprouts

Criteria & EMP Target Microorganism[dddd]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
E. coli (generic)	10^3/g		Investigate, implement corrective action	
E. coli (O157:H7 or other STEC) product		Negative in 2 50-gm analytical units	Reject lot; investigate, implement corrective action	
E. coli (O157:H7 or other STEC) (spent irrigation water) [eeee]	Negative in 2 x 100-g analytical units		Reject lot; investigate, implement corrective action	
Listeria spp. (EMP) [ffff]	Negative zone 2 or 3		Consider zone 1 and finished product testing; implement corrective action	
Listeria spp. (product)[gggg]		Negative in 2 x 250-gm analytical units	Reject lot; investigate, implement corrective action	Each 250-g analytical unit composed of 5 x 50-g samples
Salmonella (product)		Negative in 30 x 50-gm analytical units	Reject lot; investigate, implement corrective action	
Salmonella (spent irrigation water) [cccc]	Negative in 2 x 375-gl analytical units		Reject lot; investigate, implement corrective action	

[dddd] (Health Canada, 2006; U.S. Food and Drug Administration, 1999)

[eeee] Sampling spent irrigation water; collect the total of 1-liter of spent irrigation water from various trays of growing sprouts. Two x 375-ml subsamples are used for Salmonella detection and 2 x 100-ml subsamples are used for detection of E. coli O157:H7.

[ffff] (R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)

[gggg] (Authority, 2014; Hitchens & Jinneman, 2013)

Table J.36. Microbiological and Chemical Limits for Seafood, Raw

Notes: Ex.: fish, shrimp, crabs. Verification testing for histamine in scombroid species only. The FDA Hazards and Controls Guide lists a defect action level of 50ppm. See Table J.37, J.38 and J. 39 if raw seafood may be used for applications without full cook such as for sushi or ceviche, additional testing may be appropriate.

Criteria & EMP Target Microorganism[hhhh]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
Coliforms		10^3/g	Investigate, implement corrective action	Routine testing is not recommended for a raw product that is not intended to be consumed raw.
Salmonella		Negative	Divert for reprocessing if appropriate or reject; investigate, implement corrective action	Consider sampling in facilities or countries where growing, harvesting or handling conditions result in significant prevalence of *Salmonella* in the product. Treat raw seafood as RTE food if it may be used for applications without full cook such as sushi or ceviche (See Table J.37 and J.38);Sample size may vary; e.g. 25 g.[iiii]
Histamine		50 ppm	Reject lot; investigate, implement corrective action	Scombroid species only; see sampling details [jjjj]

[hhhh] (Ahmed & Institute of Medicine (U.S.). Committee on Evaluation of the Safety of Fishery Products., 1991; Australia New Zealand Food Authority, 2001, 2014; International Commission for the Microbiological Specifications for Foods (ICMSF), 2011; U. S. Department of Health and Human Services, 2011a)

[iiii]Sample size may vary depending on intended usage, e.g. for sushi or ceviche without full cook (Andrews & Hammack, 2003)

[jjjj] (U. S. Department of Health and Human Services, 2011a)

Table J.37. Microbiological and Chemical Limits for Seafood--RTE, Fish, Cold Smoked

Notes: Verification testing for histamine in scombroid species only. The FDA Hazards and Controls Guide lists a defect action level of 50ppm

Criteria & EMP Target Microorganism[kkkk]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC (EMP)	10/cm^2		Investigate, implement corrective action	Routine testing for general status of cleaning and disinfection can be done by swab sampling and determining the aerobic plate count. Product contact surfaces should contain less than 10 CFU/cm^2
Listeria spp. (EMP) [llll]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	
Listeria monocytogenes (product)		Negative in 5 individual 25-g analytical units	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	
Salmonella		Negative	Divert for reprocessing if appropriate or reject; investigate, implement corrective action	Sample size may vary; e.g. 25 g
Histamine		50 ppm	Reject lot; investigate, implement corrective action	Scombroid species only; see sampling details[mmmm]

[kkkk] (International Commission for the Microbiological Specifications for Foods (ICMSF), 2011; U. S. Department of Health and Human Services, 2011a)
[llll] (Scott et al., 2005; R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)
[mmmm] (U. S. Department of Health and Human Services, 2011a)

Table J.38. Microbiological and Chemical Limits for Seafood-- RTE, cooked or hot smoked
Notes: Ex.: includes cooked and hot smoked products, cooked crabmeat, lobster meat, shrimp, crayfish, surimi, seafood salads, hot-smoked fish.
Histamine testing recommended for scombroid species only with Defect Action Level 50ppm

Criteria & EMP Target Microorganism[nnnn]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC		10^5/g	Investigate Source of Post Cook Handling and Storage Contamination	
Coliforms[oooo]		100/g	Investigate; implement corrective action	For cooked seafood other than shrimp and crabmeat
Coliforms[nnnn]		$5x10^3$/g	Investigate; implement corrective action	For cooked crabmeat- fresh (Handled after final cook)
Coliforms[nnnn]		10^3/g	Investigate; implement corrective action	For cooked shrimp (Handled after final cook)
Listeria spp. (EMP) [pppp]	Negative for Zone 2 or 3		Investigate, consider Zone 1 and finished product testing, implement corrective action	
Listeria monocytogenes (product)		Negative in 5 individual 25-g analytical units	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	
S. aureus	10^3/g		Investigate, implement corrective action. If $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	Routine testing is recommended especially for products that are handled after the final cook (kill) step
Salmonella		Negative	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	Validated cooking will destroy *Salmonella*; if HACCP plans are in place to control cooking and recontamination after cooking, there should be no need for routine testing. Testing could be done as a verification or investigation. Sample size may vary; e.g. 25 g
Histamine		50 ppm	Reject lot; investigate, implement corrective action	Scombroid species only; see sampling details[qqqq]

[nnnn] (Australia New Zealand Food Authority, 2014; International Commission for the Microbiological Specifications for Foods (ICMSF), 1986; U. S. Department of Health and Human Services, 2011a)
[oooo] (Buchanan, 1991)
[pppp] (Scott et al., 2005; R.B. Tompkin, 2002; R. B. Tompkin et al., 1999)
[qqqq] (U. S. Department of Health and Human Services, 2011a)

Table J.39. Microbiological Limits for Seafood--RTE, Raw Molluscan Shellfish

Notes: Ex.: molluscan shellfish such as oysters, clams, mussels, scallops intended to be eaten without a full cook. Shellfish must be from approved harvest waters from countries with MOU (*I.e.*, New Zealand, Mexico, Korea, Canada) with the United States. Shellfish from any other source should not be accepted by DOD. Investigational testing for aquatic toxins. While *V. vulnificus* and *parahaemolyticus* may be a concern in RTE, raw molluscan shellfish, no limits can be recommended at this time.

Criteria & EMP Target Microorganism[rrrr]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC		$1.5x10^6$/g	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	
Coliforms (fecal)		$3.3x10^2$/100g	Investigate; implement corrective action; enumerate generic *E. coli*	
E. coli (generic)		$3.3x10^2$/100g	Investigate; implement corrective action	

[rrrr] (National Advisory Committee on Microbiological Criteria for Foods, 1992; U. S. Department of Health and Human Services, 2011a) Each analytical unit is comprised of 10-12 individual shellfish composited into one unit. See text FDA Fish and Fishery Products Hazards and Controls Guidance for sampling procedure.

Table J.40. Microbiological Limits for Spices, Herbs, Coffee and Tea

Notes: defined as ready-to-eat

Criteria & EMP Target Microorganism[ssss]	Microbiological Limit		Recommended Action if Limit is Exceeded	Comments
	Routine	Non-Routine		
APC	10^5/g		Investigate	
B. cereus		10^4/g	Investigate, implement corrective action. if $\geq 10^4$ /g, reject lot due to potential for enterotoxin production	
Coliforms		10^4/g	Investigate, implement corrective action	
E. coli (generic)		10/g	Investigate, implement corrective action	
E. coli (O157:H7 or other STEC)		Negative	Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	Number and size of samples will vary depending on product
Mold/Yeast		10^4/g	Investigate, implement corrective action	
Salmonella (EMP)[tttt]	Negative zone 2 or 3		Consider zone 1 and finished product testing; implement corrective action	
Salmonella	Negative		Divert for reprocessing, if appropriate, or reject. Investigate and implement corrective action	Number and size of samples will vary depending on product; routine testing of *Salmonella* in roasted coffee may not be applicable
Mesophilic sporeformer		10^5/g	Investigate, implement corrective action	

[ssss] (Canada, 2008; Sagoo et al., 2009)
[tttt] (Chen et al., 2009a, 2009b; Grocery Manufacturers Association, 2009)

References:

Ahmed, F. E., & Institute of Medicine (U.S.). Committee on Evaluation of the Safety of Fishery Products. (1991). *Seafood safety* Retrieved from http://www.nap.edu/catalog/1612.html

American Meat Institute Foundation. (1997). Good Manufacturing Practices for Fermented Dry & Semi-Dry Sausage Products. Retrieved February 18, 2015, from http://www.meathaccp.wisc.edu/Model_Haccp_Plans/assets/GMP%20Dry%20Sausage.pdf

Andrews, W. H., & Hammack, T. S. (2003). BAM: Chapter 1. Food Sampling/Preparation of Sample Homogenate. *In Bacteriological Analytical Manual, Edition 8, Revision A, 1998.* Retrieved April 13, 2014, from http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm063335.htm

Andrews, W. H., Jacobson, A., & Hammack, T. (2014). BAM: Salmonella, Chapter 5 *FDA, Bacteriological Analytical Manual* (Vol. 2014).

Australia New Zealand Food Authority. (2001). Guidelines for the microbiological examination of ready-to-eat foods. Retrieved September 23, 2014, from http://www.foodstandards.gov.au/publications/pages/guidelinesformicrobi1306.aspx

Australia New Zealand Food Authority. (2014). Australia New Zealand Food Standards Code - Standard 1.6.1 - Microbiological Limits for Food. Retrieved January 12, 2015, from http://www.comlaw.gov.au/Series/F2008B00630

Authority, A. N. Z. F. (2014). Criteria for Listeria monocytogenes – Microbiological Limits for Foods.

Bradley, R. L., Houck, K., & Smukowski, M. (2013). Milk and milk products. In S. Doores, Y. Salfinger, & M. L. Tortorello (Eds.), *Compendium of Methods for Microbiological Examination of Foods* (5th ed.): American Public Health Association.

Buchanan, R. L. (1991). Microbiological criteria for cooked, ready-to-eat shrimp and crabmeat. *Journal of Food Technology, 45*(4), 157-160.

Canada Food Inspection Agency. (2012). Implementation of the 2011 Health Canada Policy on *Listeria monocytogenes* in Ready-to-Eat Foods. Retrieved September 19, 2014, from http://www.inspection.gc.ca/food/fish-and-seafood/product-inspection/fish-listeria/eng/1338572158747/1338572678417

Canada, H. (2008). Standards and Guidelines for Microbiological Safety of Food – An Interpretative Summary. Retrieved September 2014, 2014, from http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/volume1-eng.php

Chen, Y. H., Scott, V. N., Freier, T. A., Kuehm, J., Moorman, M., Meyer, J., . . . Banks, J. (2009a). Control of *Salmonella* in low-moisture foods II: Hygiene practices to minimize *Salmonella* contamination and growth. *Food Protection Trends, 29*, 435-445.

Chen, Y. H., Scott, V. N., Freier, T. A., Kuehm, J., Moorman, M., Meyer, J., . . . Banks, J. (2009b). Control of *Salmonella* in low-moisture foods III: Process validation and environmental monitoring. *Food Protection Trends, 29*, 493-508.

Code of Federal Regulations. (2014a). 21 CFR 120. Hazard Analysis and Critical Control Point (HACCP) Systems. Retrieved February 19, 2015, from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=120&showFR=1

Code of Federal Regulations. (2014b). 21 CFR 165. Requirements for Specific Standardized Beverages. Retrieved February 3, 2014, from http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=d26e287c93ddfdc1dcc06d9b896b5d5f&r=PART&n=21y2.0.1.1.38

Craven, H. M., Eyles, M. J., & Davey, J. A. (2003). Enteric indicator organisms in foods. In A. D. Hocking (Ed.), *Foodborne Microorganisms of Public Health Significance, 6th ed.* Tempe, Australia: Australian Institute of Food Science and Technology Inc.

Elliott, P. H., & Kataoka, A. (2013). Canned Foods - Test for Commercial Sterility. In S. Doores, Y. Salfinger, & M. L. Tortorello (Eds.), *Compendium of Methods for Microbiological Examination of Foods* (5th ed.): American Public Health Association.

European Commission. (2005). Microbiological Criteria for Foodstuff. Commission Regulation (EC) No. 2073/2005. Retrieved September 23, 2014, from http://www.fsai.ie/uploadedFiles/Reg2073_2005(1).pdf

European Communities. (2007). Drinking Water Regulations. Retrieved September 23, 2014, from http://www.irishstatutebook.ie/pdf/2007/en.si.2007.0278.pdf

Grocery Manufacturers Association. (2009). Control of *Salmonella* in low-moisture foods. Retrieved August 14, 2014, from http://www.gmaonline.org/downloads/technical-guidance-and-tools/SalmonellaControlGuidance.pdf

Health Canada. (2006). Health Products and Food Branch (HPFB) Guidance for Industry: Sample Collection and Testing for Sprouts and Spent Irrigation Water (pp. 1-18).

Hitchens, A. D., & Jinneman, K. (2013). BAM: Chapter 10. Detection and Enumeration of *Listeria monocytogenes,* Revised 2013 *FDA, Bacteriological Analytical Manual 8th Edition, Revision A, 1998. .* Retrieved April 13, 2014, from http://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm071400.htm

International Commission for the Microbiological Specifications for Foods (ICMSF). (1986). *Microorganisms in Foods 2: Sampling for Microbiological Analysis: Principles and Specific Applications* (2nd ed.). University of Toronto, Canada: University Toronto Press.

International Commission for the Microbiological Specifications for Foods (ICMSF). (2011). *Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance*. New York: Springer.

Kornacki, J. I. (2014). An Environmental Sampling Approach to Product Risk Assessment. *Food Safety Magazine*.

Kornacki, J. I., Gurtler, J. B., & Stawick, B. A. (2013). Enterobacteriaceae, Coliforms, and *Escherichia coli* as Quality and Safety Indicators, Updated September 2013. In Y. S. S. Doores, M. L.Tortorello (Ed.), *Compendium of Methods for the Microbiological Examination of Foods* (5th ed.). http://ajph.aphapublications.org/doi/book/10.2105/MBEF.0222: American Public Health Association.

National Academies of Science. (2003). Scientific Criteria and Performance Standards to Control Hazards in Dairy *Scientific Criteria to Ensure Safe Foods* (pp. 225-247). Washington, D.C.: Institute of Medicine. National Research Council of the National Academies.

National Advisory Committee on Microbiological Criteria for Foods. (1992). Microbiological criteria for raw molluscan shellfish. *J Food Prot, 55*(6), 463-480.

National Advisory Committee on Microbiological Criteria for Foods. (2013). Expedited response to the questions posed by the USDA agricultural marketing service to support ground beef purchase for the federal food and nutrition assistance programs. *J. Food Prot, 76*, 523-5237.

Sagoo, S. K., Little, C. L., Greenwood, M., Mithani, V., Grant, K. A., McLauchlin, J., . . . Threlfall, E. J. (2009). Assessment of the microbiological safety of dried spices and herbs from production and retail premises in the United Kingdom. *Food Microbiol, 26*(1), 39-43. doi: 10.1016/j.fm.2008.07.005

Scott, V. N., Wiedmann, M., Hicks, D., Collette, R., Jahncke, M. L., & Gall, K. (2005). Guidelines for *Listeria* testing of environmental, raw product and finished product samples in smoked seafood processing facilities. *Food Protection Trends, 25*(1), 23-34.

Sperber, W. H., & North American Millers' Association Microbiology Working Group. (2007). Role of microbiological guidelines in the production and commercial use of milled cereal grains: a practical approach for the 21st century. *J Food Prot, 70*(4), 1041-1053.

Tompkin, R. B. (2002). Control of *Listeria monocytogenes* in the food-processing environment. *J. Food Prot, 65*(4), 709-725.

Tompkin, R. B., Scott, V. N., Bernard, D. T., Sveum, W. H., & Gombas, K. S. (1999). Guidelines to prevent post-processing contamination from *Listeria monocytogenes*. *Dairy, Food and Environmental Sanitation, 19*(8), 551-562.

U. S. Department of Agriculture. (2011). Shiga-toxing Producing *Escherichia coli* in Certarin Raw Beef Products. *Federal Register, 76*(182), 58157-58165.

U. S. Department of Agriculture Food Safety Inspection Service. (1999). Appendix B: Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization). June 1999. *http://www.fsis.usda.gov/OPPDE/rdad/frpubs/95-033F/95-033F_Appendix%20B.htm*. Retrieved December 12, 2012

U. S. Department of Agriculture Food Safety Inspection Service. (2014a). Compliance guidelines to control *Listeria monocytogenes* in post-lethality exposed ready-to-eat meat and poultry products. Updated January 2014. Retrieved August 14, 2014, from http://www.fsis.usda.gov/wps/wcm/connect/d3373299-50e6-47d6-a577-e74a1e549fde/Controlling_LM_RTE_Guideline_0912?MOD=AJPERES

U. S. Department of Agriculture Food Safety Inspection Service. (2014b). FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments. Retrieved August 14, 2014, from

http://www.fsis.usda.gov/wps/wcm/connect/5fd4a01d-a381-4134-8b91-99617e56a90a/Compliance-Guideline-Jerky-2014.pdf?MOD=AJPERES

U. S. Department of Agriculture Food Safety Inspection Service. (2014c). FSIS Microbiological Testing Program for *Salmonella* in Pasteurized Egg Products, 1995–2013. Retrieved August 14, 2014, from http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/testing-program-for-rte-meat-and-poultry-products/microbiological-testing-program-for-pasteurized-egg-products/pasteurized-egg-products

U. S. Department of Agriculture Food Safety Inspection Service. (2014d). Pathogen Reduction – *Salmonella* and *Campylobacter* Performance Standards Verification Testing. Retrieved January 23, 2015, from http://www.fsis.usda.gov/wps/wcm/connect/b0790997-2e74-48bf-9799-85814bac9ceb/28_IM_PR_Sal_Campy.pdf?MOD=AJPERES

U. S. Department of Health and Human Services. (2004). Guidance for Industry Juice HACCP Hazards and Controls Guidance.

U. S. Department of Health and Human Services. (2005a). Aflatoxin in Peanuts and Peanut Products. CPG Sec. 570.375.

U. S. Department of Health and Human Services. (2005b). Brazil Nuts - Adulteration with Aflatoxin. CPG Sec. 570.200.

U. S. Department of Health and Human Services. (2005c). Patulin in Apple Juice, Apple Juice Concentrates and Apple Juice.

U. S. Department of Health and Human Services. (2005d). Pistachio Nuts - Aflatoxin Adulteration. CPG Sec. 570.500.

U. S. Department of Health and Human Services. (2005e). Tree Nuts - Adulteration with Filth, Involving the Presence of the Organism *Escherichia coli*. CPG Sec. 570.450.

U. S. Department of Health and Human Services. (2009). Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation: Final Rule. 21 CFR Parts 16 and 118, Federal Register 74(130).

U. S. Department of Health and Human Services. (2011a). Fish and Fishery Products Hazards and Controls Guidance - Fourth Edition. Retrieved August 14, 2014, from http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/seafood/ucm2018426.htm.

U. S. Department of Health and Human Services. (2011b). Grade “A” Pasteurized Milk Ordinance, Including Provisions from the Grade “A” Condensed and Dry Milk Products and Condensed and Dry Whey--Supplement I to the Grade “A” Pasteurized Milk Ordinance.

U.S. Department of Agriculture Agricultural Marketing Service (AMS). (2015). Microbiological Testing of AMS Purchased Meat, Poultry and Egg Commodities. . Retrieved February 22, 2015, from http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateA&navID=MicrobialTestingofCommodities&rightNav1=MicrobialTestingofCommodities&topNav=&leftNav=&page=FPPMicroDataReports&resultType=&acct=lsstd

U.S. Department of Agriculture Food Safety Inspection Service. (1999). Performance standards for the production of certain meat and poultry products. Retrieved October 18, 2014, from https://www.federalregister.gov/articles/1999/01/06/99-32/performance-standards-for-the-production-of-certain-meat-and-poultry-products

U.S. Department of Health and Human Services. (2008). Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods; Draft Guidance. Retrieved January 22, 2015, from http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm

U.S. Department of Health and Human Services. (2010). Compliance Policy Guide Sec. 527.300 Dairy Products - Microbial Contaminants and Alkaline Phosphatase Activity.

U.S. Food and Drug Administration. (1999). Guidance for industry: Sampling and microbial testing of spent irrigation water during sprout production. *Federal Register, 64*, 57896-57902.

World Health Organization (WHO). (2013). Report on regulations and standards for drinking water quality - draft 12. Retrieved April 14, 2014, from http://www.who.int/water_sanitation_health/regulations_and_standards_for_drinking-water_quality/en/

World Health Organization (WHO). (2014). Drinking- water quality. Retrieved September 19, 2014, from http://www.who.int/water_sanitation_health/dwq/en/

Appendix K. Sampling for Lot Acceptance or Rejection

In lot acceptance sampling, a sample of *n* units is drawn from a lot, and a characteristic of interest (*e.g.*, presence of a pathogen or concentration of an indicator organism) of the sample units is analyzed. The test portion or analytical unit may represent an entire sample unit (*e.g.*, enrichment of a 25-g sample), a composite of multiple sample units (*e.g.*, enrichment of sixty 6.25-g sample units into an approximate 375 g composite test portion), or a portion or aliquot of a sample unit (*e.g.*, enumeration of 1 ml of diluted homogenate prepared from a 25-g sample unit). Based on the sample results and the lot acceptance criteria, a lot disposition decision is made to either accept or reject the lot.

For lot acceptance sampling to have direct impact, lots must vary with respect to the analyte of interest. If the analyte is homogeneous among lots, sampling will accept some lots and reject others by chance alone, and the accepted lots are no better than the rejected lots. Lot acceptance sampling schemes may involve normal, tightened, or reduced inspection levels. Lot acceptance sampling may be applied lot-by-lot, or skip-lot sampling may be applied to less than 100% of lots. Conventional rules for switching between inspection levels depend on the history of supplier conformance to specifications and are available as guidelines for frequency and intensity of lot acceptance sampling schemes (e.g., MIL-STD-1916 [available at http://guidebook.dcma.mil/34/milstd1916(15).pdf], ISO 2859-1, ISO 2859-3, /ASQ Z1.4 [available at www.asq.org]).

Lot Acceptance Sampling for Attributes

Current microbiological lot acceptance sampling schemes are based on lot acceptance sampling for attributes. Both microbial presence/absence data obtained from enriched samples and quantitative concentration data divided into numerical ranges are classified as attributes. Two-class sampling plans are applicable where product quality is divided into two attribute classes. For sampling based on detection methods, the classes are presence or absence. For sampling based on enumeration methods, the classes are $x \leq m$ or $x > m$, where x is a measure of concentration (*e.g.*, cfu/g, cfu/ml, cfu/cm^2, as appropriate), and *m* is the microbiological limit separating acceptable from unacceptable concentrations. Three-class sampling plans are applicable where product quality is measured by enumeration methods and results are divided into three attribute classes: $x \leq m$, $m < x \leq M$, or $x > M$; where *m* is the limit for a marginally acceptable concentration (note the change in meaning from the 2-class plan), and *M* is the limit for an unacceptable concentration (*i.e.*, similar in meaning to m in the 2-class plan). Two- and three-class sampling plans also may be used for process control (International Commission for the Microbiological Specifications for Foods (ICMSF), 2011), but in the context of lot acceptance sampling, a consequence of non-conformance with a microbiological criterion is rejection of the lot represented by the samples.

Performance Characteristics of the Sampling Plans

The performance characteristics of microbiological lot acceptance sampling plans are generally described in terms of the probability of acceptance (p_a) for a given lot composition under specified microbiological limits. The operating characteristic (OC) curve plots the probability of accepting the lot versus a measure of its quality (*e.g.*, the proportion of analytical units exceeding a given limit). In practice, the probability of lot acceptance also depends on the sampling procedures and analytical methods specified under the microbiological criteria (*e.g.*, test sensitivity and specificity, percent recovery in enumeration, compositing). The statistical performance characteristics of a lot-acceptance sampling plan reflect the different probabilities of rejecting lots of different qualities. In addition to this direct, or curative, effect of a sampling plan, for a continuing series of lots presented for inspection, lot acceptance sampling also may have an indirect, or preventative, effect by exerting economic pressures on suppliers to prevent or limit the frequency and severity of non-conformance through process control measures (Whittle, 1954; Hill, 1960; International Organization for Standardization, 2007).

Two-Class Plans

For two-class sampling plans based on a maximum limit (*m*), the probability of lot acceptance (p_a) can be calculated directly from the proportion of non-conforming analytical units (*p*). For presence/absence sampling plans, *p* refers to the proportion of test-positive analytical units. For concentration-based sampling plans, *p* refers to the proportion of analytical units with cfu/g ≥ *m*. A two-class sampling plan is defined by the sample size *n* and the maximum number of non-conforming analytical units allowed (acceptance number) *c*. In general, the probability of lot acceptance (p_a) is the probability that the number of non-conforming independent sample units in the sample of *n* is less than or equal to *c*:

$$p_a = \sum_{i=0}^{i=c} C_i^n \, (p)^i (1-p)^{n-i} \qquad \text{(eq. K.1.)}$$

where $C_i^n = \frac{n!}{i!(n-i)!}$ (the binomial coefficient, or combination of n things taken i at a time), *p* is the proportion of non-conforming analytical units, *n* is the number of samples drawn from the lot, and *c* is the acceptance number.

Most two-class sampling plans for pathogens specify *c* = 0. In this case, p_a simplifies to:

$$p_a = (1-p)^n \qquad \text{(eq. K.2.)}$$

For presence/absence sampling plans, it is important to note that the proportion of test positives depends on the size of the analytical unit (test portion). If analytical units of different sizes are examined from the same food lot, the proportion of test positives will be lower for smaller analytical units. For example, for a given concentration, a 25-g

sample is less likely to contain at least one microorganism than a 100-g sample. Therefore, prevalence needs to be referenced to the size of the analytical unit (*e.g.*, prevalence in 25 grams). If the detection method is less than 100% sensitive, the apparent prevalence (proportion of test positives) is less than the true prevalence (actual proportion of positives). For concentration-based sampling plans, equations K.1. and K.2. assume that measurement error is negligible (~100% recovery) and that false positive results are very unlikely (~ 100% specificity). If measurement error is substantial, the probability of lot acceptance may be affected by the microbial distribution (not just the proportion of non-conforming sample units) because measurement error can result in misclassification of sample units above or below the limit (*m*).

Figure K.1. presents the operating characteristic curves for *c* = 0 two-class sampling plans over a range of sample sizes (*n*).

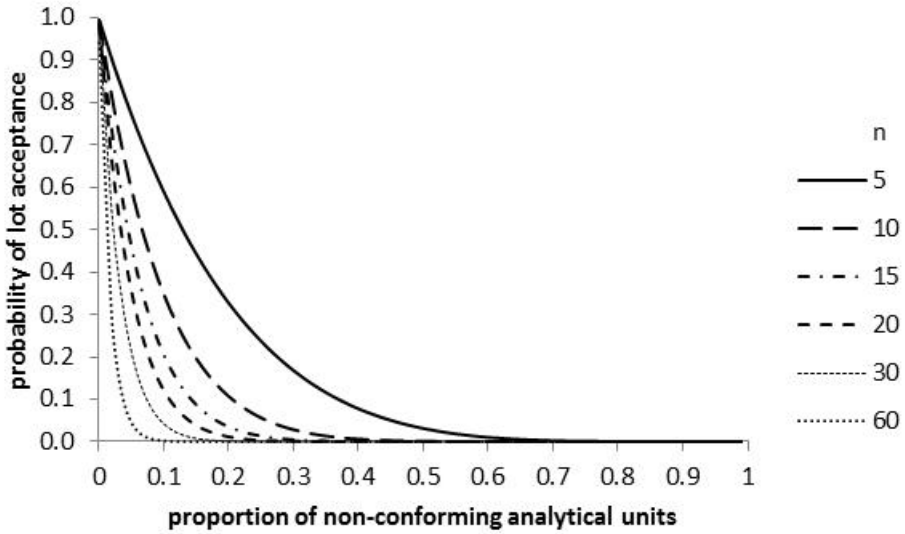


Figure K.1. Operating Characteristic Curves for Two-Class Sampling Plans with *c* = 0.

Table K.1. summarizes the performance of an *n* = 5, *c* = 0 two-class sampling plan with *m* = absence in 25 g with probability of acceptance (p_a) = 0.95, 0.5, and 0.05.

Table K.1. Summary Performance of *n* = 5, *c* = 0 Two-Class Sampling Plan

n	5
c	0
m	absence in 25 g
p_a	*p*
0.95	0.0102
0.50	0.1294
0.05	0.4507

Alternatively, the probability of acceptance for two-class sampling plans can be calculated based on an assumed statistical distribution of the microbial concentration in a lot. Assuming that the average concentration is lognormally distributed and that the number of cfu in an analytical unit varies randomly according to the Poisson distribution (a Poisson-Lognormal distribution), Table K.2. summarizes the performance of an n = 5, c = 0 two-class sampling plan with m = absence in 25 g. The values (probability of acceptance) shown in Table K.2. assume a perfect detection method (100% sensitivity and 100% specificity). The calculations can be performed using on-line resources (http://www.icmsf.org/publications/sampling_plans.html; http://www.fstools.org/sampling). For further details about the Poisson-Lognormal used by these on-line calculators, see (van Schothorst et al., 2009).

Table K.2. Performance of n = 5, c = 0, m = absence in 25-g Two-Class Sampling Plan

N	c	M	Probability of lot acceptance	stdev* = 0.25** (log_{10} cfu/g)	stdev = 0.50 (log_{10} cfu/g)	stdev = 0.80 (log_{10} cfu/g)	stdev = 1.2 (log_{10} cfu/g)
				Geometric mean concentration (log_{10} cfu/g)***			
5	0	absence in 25 g	0.95	-3.46	-3.67	-4.08	-4.81
			0.50	-2.32	-2.48	-2.74	-3.14
			0.05	-1.64	-1.69	-1.74	-1.79

Note: Probability of acceptance (p_a) values assume negligible measurement error.
*stdev = standard deviation
**In many applications, measurement error alone exceeds 0.25 log_{10} cfu/g. We include this standard deviation value to help the reader understand the derivation of values for sampling plans commonly presented in the literature (e.g., (International Commission for the Microbiological Specifications of Foods (ICMSF), 2002; International Commission for the Microbiological Specifications for Foods (ICMSF), 2011)).
***Technically, the geometric mean is the exponentiated mean of the logarithms of individual concentrations. For example, if the mean of the log-transformed values = -2 log_{10} cfu/g, the geometric mean = 0.01 cfu/g. However, because -2 log_{10} and 0.01 are equivalent, we adopt the common usage in the food microbiology literature of "geometric mean" to refer to the mean of the log-transformed values to differentiate it from the arithmetic mean on the original scale (cfu/g). For the lognormal distribution, the geometric mean represents the median because the normal distribution is symmetric.

It should be noted that in terms of consumer health risk, the arithmetic mean (the average, or expected value) concentration is more relevant than the geometric mean (median) concentration (International Life Sciences Institute-Europe (ILSI-Europe), 2010). Table K.3. presents the arithmetic mean concentration for the 5 percent probability of acceptance distributions in Table K.2.

Table K.3. Arithmetic Mean for Lognormal Distributions

geometric mean (log_{10} cfu/g)	standard deviation (log_{10} cfu/g)	arithmetic mean (cfu/g)
-1.64	0.25	0.0270

-1.69	0.50	0.0396
-1.74	0.80	0.0993
-1.79	1.20	0.7377

As an example interpretation of Table K.3, if the arithmetic mean concentration is 0.0396 cfu/g, a 25-g serving would contain an average of 1 cfu. Note that there is no direct correspondence between the probability of lot acceptance and the level of risk indicated by the arithmetic mean concentration. This illustrates that evaluating the food safety impact of sampling plans is not as straightforward as calculating their statistical operating characteristics.

Three-Class Plans

Three-class sampling plans are based on a marginal limit (*m*) and a maximum limit (*M*). A three-class sampling plan is defined by the sample size *n* and *c* the maximum number of marginal analytical units allowed, or acceptance number. (The acceptance number for analytical units exceeding *M* is zero.) For three-class sampling plans, the probability of lot acceptance (p_a) can be calculated directly from the proportion of marginally acceptable (p_m) and unacceptable (p_d) analytical units (Codex Alimentarius Commission, 2004):

$$p_a = \sum_{i=0}^{i=c} C_i^n \, (p_m)^i (1 - p_d - p_m)^{n-i} \qquad \text{(eq. K.3)}$$

where $C_i^n = \frac{n!}{i!(n-i)!}$ (the binomial coefficient), p_m is the proportion of marginally acceptable analytical units (with $m < x \leq M$), p_d is the proportion of analytical units with $x > M$, *n* is the number of samples drawn from the lot, and *c* is the acceptable number of marginal units.

Figure K.2 summarizes the operating characteristics of an $n = 5$, $c = 2$ three-class sampling plan for probability of acceptance (p_a) = 0.95, 0.5, and 0.05.

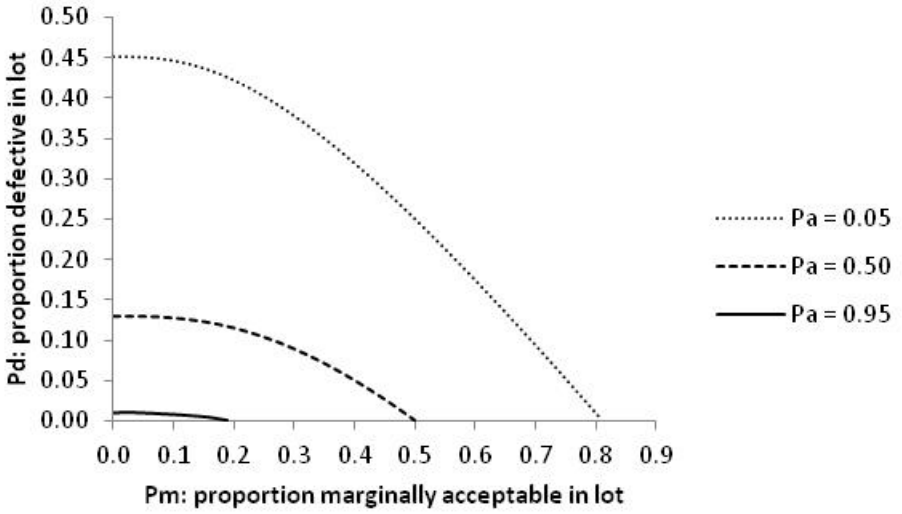


Figure K.2. Operating Characteristic Contours for Three-Class Plan: n = 5, c = 2

Table K.4 presents selected performance characteristics for an n = 5, c = 2 three-class sampling plan.

Table K.4. Performance Characteristics for n = 5, c = 2 Three-Class Sampling Plan: Probabilities of Acceptance (p_a) for Lots Containing Indicated Proportions p_d and p_m

Proportion unacceptable (p_d)	Proportion Marginal (p_m)								
	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45
0.90	<*	0.0000							
0.85	<	<	0.0000						
0.80	<	<	<	0.0000					
0.75	<	<	<	<	0.0000				
0.70	<	<	<	<	<	0.0000			
0.65	0.0051	<	<	<	<	<	0.0000		
0.60	0.0101	0.0092	0.0074	0.0051	<	<	<	0.0000	
0.55	0.0182	0.0170	0.0146	0.0111	0.0073	<	<	<	0.0000
0.50	0.0310	0.0294	0.0262	0.0213	0.0156	0.0099	0.0051	<	<
0.45	0.0500	0.0481	0.0438	0.0374	0.0294	0.0209	0.0129	0.0065	<
0.40	0.0774	0.0750	0.0697	0.0614	0.0508	0.0389	0.0270	0.0163	0.0080
0.35	0.1156	0.1127	0.1063	0.0959	0.0822	0.0663	0.0497	0.0338	0.0201
0.30	0.1675	0.1642	0.1564	0.1438	0.1267	0.1062	0.0840	0.0618	0.0414
0.25	0.2367	0.2327	0.2236	0.2084	0.1875	0.1620	0.1334	0.1039	0.0753
0.20	0.3270	0.3224	0.3117	0.2938	0.2687	0.2375	0.2018	0.1638	0.1258
0.15	0.4429	0.4377	0.4253	0.4044	0.3748	0.3373	0.2938	0.2463	0.1974
0.10	0.5896	0.5837	0.5695	0.5454	0.5108	0.4666	0.4143	0.3563	0.2952
0.05	0.7727	0.7661	0.7501	0.7225	0.6826	0.6310	0.5692	0.4995	0.4250

0.00	0.9988	0.9914	0.9734	0.9421	0.8965	0.8369	0.7648	0.6826	0.5931

	p_m								
p_d	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90
0.50	0.0000								
0.45	<	0.0000							
0.40	<	<	0.0000						
0.35	0.0098	<	<	0.0000					
0.30	0.0243	0.0117	<	<	0.0000				
0.25	0.0498	0.0289	0.0137	<	<	0.0000			
0.20	0.0902	0.0590	0.0339	0.0160	0.0053	<	0.0000		
0.15	0.1500	0.1064	0.0689	0.0393	0.0184	0.0060	<	0.0000	
0.10	0.2342	0.1762	0.1239	0.0797	0.0451	0.0210	0.0068	<	0.0000
0.05	0.3488	0.2742	0.2046	0.1428	0.0912	0.0513	0.0237	0.0077	<
0.00	0.5000	0.4069	0.3174	0.2352	0.1631	0.1035	0.0579	0.0266	0.0086

Note: Probability of acceptance (p_a) values calculated assuming negligible measurement error.
*p_a < 0.005.

Note that some combinations of p_m and p_d presented in Figure K.2. and Table K.4. may not be plausible for certain applications. For example, consider a three-class sampling plan for mesophilic aerobic bacteria in dried milk with $m = 10^4$ cfu/g, and $M = 10^6$ cfu/g. Based on Table K.3, $p_a = 0.05$ for the combination $p_m = 0.05$ and $p_d = 0.45$. However, if the distribution is lognormal, this combination of p_m and p_d values would imply a lot of dried milk with a geometric mean aerobic plate count of 4 $\log_{10}$ cfu/g (10,000 cfu/g), a standard deviation of 16 $\log_{10}$ cfu/g, and a maximum concentration in excess of 40 $\log_{10}$ cfu/g.

Alternatively, the probability of acceptance for three-class sampling plans can be calculated based on an assumed statistical distribution of the microbial concentration in a lot. In this case, eq. K.3. above is still used to calculate the probability of lot acceptance, but the marginal and unacceptable proportions (p_m and p_d) are derived from the assumed statistical distribution. Table K.5. summarizes the performance of n = 5, c = 2 three-class sampling plans based on assuming a lognormal distribution.

Table K.5. Performance of n = 5, c = 2 Three-Class Sampling Plans

n	c	m	M	Probability of lot acceptance	stdev* = 0.25 ($\log_{10}$ cfu/g)	stdev = 0.50 ($\log_{10}$ cfu/g)	stdev = 0.80 ($\log_{10}$ cfu/g)	stdev = 1.2 ($\log_{10}$ cfu/g)
					Geometric mean concentration ($\log_{10}$ cfu/g)			
5	2	10^4 cfu/g	10^6 cfu/g	0.95	3.78	3.56	3.29	2.82
		(4 $\log_{10}$	(6 $\log_{10}$	0.50	4.00	4.00	3.99	3.89
		cfu/g)	cfu/g)	0.05	4.22	4.44	4.68	4.90
5	2	<3MPN/g	9.8	0.95	0.25	-0.19	-0.87	-1.79
			MPN/g	0.50	0.47	0.33	0.05	-0.38

	0.05	0.68	0.76	0.79	0.78

*stdev = standard deviation

As an example of Table K.5. calculations, consider the lognormal distribution with geometric mean of 4.68 $\log_{10}$ cfu/g (47,863 cfu/g) and standard deviation of 0.8 $\log_{10}$ cfu/g (denoted by shaded cell of Table K.5.) For the first sampling plan, the marginal limit (m) of 4 $\log_{10}$ cfu/g is the 20^{th} percentile of the distribution. The maximum limit (M) of 6 $\log_{10}$ cfu/g is the 95^{th} percentile of the distribution. As a result, p_m = 0.95-0.20 = 0.75 and p_d = 1-0.95 = 0.05. Looking up these values in Table 3 (or inserting the values into eq. 3) results in probability of lot acceptance (p_a) = 0.05. The calculations can be performed using on-line resources (http://www.icmsf.org/publications/sampling_plans.html; http://www.fstools.org/sampling).

Impact of Lot Acceptance Sampling Plans

As noted above, the impact of lot acceptance sampling plans depends on variability among lots. The Food and Agriculture Organization/World Health Organization jointly supported development of a web-based analytical tool that can analyze the direct impact of lot acceptance sampling plans based on user-specified distributions of contamination between and within lots (http://www.fstools.org/sampling).

BIBLIOGRAPHY

Codex Alimentarius Commission. 2004. General Guidelines on Sampling.

Hill, I. D. 1960. The Economic Incentive Provided by Sampling Inspection. Journal of the Royal Statistical Society. Series C (Applied Statistics) 9: 69-81.

International Commission for the Microbiological Specifications for Foods (ICMSF). 2011. Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance. Springer, New York.

International Commission for the Microbiological Specifications of Foods (ICMSF). 2002. Microorganisms in Foods 7: Microbiological Testing in Food Safety Management. Springer, New York.

International Life Sciences Institute-Europe (ILSI-Europe). 2010. Impact of Microbial Distributions on Food Safety.

International Organization for Standardization. 2007. Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots — Part 1: Acceptance sampling. ISO, Geneva.

van Schothorst, M., M. H. Zwietering, T. Ross, R. L. Buchanan, and M. B. Cole. 2009. Relating microbiological criteria to food safety objectives and performance objectives. Food Control 20: 967-979.

Whittle, P. 1954. Optimum Preventative Sampling. Journal of the Operations Research Society of America 2: 197-203.

Appendix L. Design of 2-class and 3-class Sampling Plans

Two- and three-class sampling plans are attribute sampling plans where quantitative microbiological concentration data are divided into two or three classes, respectively. The key parameters of these plans are: 'n', the sample size; 'c_m', the acceptance number for sample units which exceed m in concentration; and 'c_M', the acceptance number for sample units which exceed M in concentration. The sample of n units is presumed to be a 'rational subgroup', such as units chosen from the same lot or time period of production.

Some additional notation that will be useful in the discussion of 2- and 3-class sampling plans are:

P_m: The percentile rank of m in *normal* production.
$Q_m = 1 - P_m$
P_M: The percentile rank of M in *normal* production.
$Q_M = 1 - P_M$
$y_m = \log_{10}(m + 0.3\ d)$, where 'd' is the dilution factor from counts to concentration
$y_M = \log_{10}(M + 0.3\ d)$, where 'd' is the dilution factor from counts to concentration

2-Class Sampling Plans

In a '2-Class' sampling plan, only the M quantile is used.

There are several approaches to designing a 2-class sampling plan.

Approach1: Given M and associated error fraction target, find n and c_M

This approach is used primarily in designing sampling plans *for acceptance testing*, and the focus is on the *false negative fraction* ('consumer's risk' or 'type II error' or 'β').

Here 'M' denotes a median concentration that, if exceeded, represents 'unacceptable' product which should be rejected with high reliability by the plan.

Subject matter expertise or specifications provides a value for M that should be rejected with high reliability ('Power' = 1 – β), say 95% or 99% or 99.9%. The parameters n and c_M are chosen to achieve the power required. For this purpose, M is presumed to be the median of the distribution of concentration for an unacceptably contaminated lot of product.

The probability of rejecting this type of unacceptable lot is

$$1 - \beta = P[(\# > M) > c_M] \quad \text{(L.1.)}$$

calculated from a binomial distribution with p = P[X ≤ M] = 0.50.

Some possible plans are:

Table L.1. 2-Class plans, given M as median of 'unacceptable' lots

n	c	Power Target	Power Actual
4	0	95.00%	93.75%
5	0	95.00%	96.88%
6	0	95.00%	98.44%
10	1	95.00%	98.93%
20	5	95.00%	97.93%
10	1	99.00%	98.93%
20	4	99.00%	99.41%
10	0	99.90%	99.90%
20	3	99.90%	99.87%

Note that this type of plan is based on specifications, so is not generally useful for SPC.

Approach 2: Given P_M and associated error fraction target, find n and c_M

This approach is used in designing sampling plans *for process control*, and the focus is on the *false positive fraction* (‘producer’s risk’ or ‘type I error’ or ‘α’ or ‘FAR’).

M here represents a specified high quantile of the concentration of ‘normal’ production. Its value is determined from its percentile rank P_M either nonparametrically or parametrically based on historical data. The parameters n and c_M are chosen to achieve the maximum false positive fraction α allowed, typically 1% or 0.1%, depending upon sampling rate. Note that M is presumed to be a high quantile of the distribution of concentration during ‘normal’ production under statistical process control.

The probability of a randomly chosen lot from normal production failing is

$$\alpha = P[(\# > M) > c_M] \quad \text{(eq. L.1.)}$$

calculated from a binomial distribution with n trials and $p = Q_M$.

Some possible plans are:

Table L.2. 2-Class plans, given M and α

n	c	α Target	Prob. ≤ M	α Actual
1	0	5.00%	95.00%	5.00%
2	1	5.00%	95.00%	0.25%
3	1	5.00%	95.00%	0.72%
5	1	5.00%	95.00%	2.26%
10	2	5.00%	95.00%	1.15%
1	0	1.00%	99.00%	1.00%
2	1	1.00%	99.00%	0.01%
3	1	1.00%	99.00%	0.03%
5	1	1.00%	99.00%	0.10%
10	1	1.00%	99.00%	0.43%
1	0	0.10%	99.90%	0.10%
2	1	0.10%	99.90%	0.00%
3	1	0.10%	99.90%	0.00%
5	1	0.10%	99.90%	0.00%
10	1	0.10%	99.90%	0.00%

Approach 3: Given n, c_M and error fraction target, find P_M

This approach results in achievement of an *exact* false positive fraction α, and again is used in designing sampling plans *for process control* with the focus on the *false positive fraction* ('producer's risk' or 'type I error' or 'α' or 'FAR').

M represents a high quantile of 'normal' production whose value is determined from its percentile rank P_M which solves the following equation

$$\alpha = P[(\# > M) > c_M] \qquad \text{(eq. L.2.)}$$

calculated from a binomial distribution with n trials and $p = Q_M$.

Some possible plans are:

Table L.3. 2-Class plans, given n, c and α

n	c	α Target	Prob. <= M	α Actual
1	0	5.00%	95.00%	5.00%
2	1	5.00%	77.65%	5.00%
3	1	5.00%	86.46%	5.00%
5	1	5.00%	92.36%	5.00%
10	2	5.00%	91.28%	5.00%
1	0	1.00%	99.00%	1.00%
2	1	1.00%	90.00%	1.00%
3	1	1.00%	94.10%	1.00%
5	1	1.00%	96.73%	1.00%
10	1	1.00%	98.45%	1.00%
1	0	0.10%	99.90%	0.10%
2	1	0.10%	96.80%	0.10%
3	1	0.10%	98.20%	0.10%
5	1	0.10%	99.00%	0.10%
10	1	0.10%	99.52%	0.10%

3-Class Sampling Plans

In a '3-Class' sampling plan, both the m and M quantiles are used.

We will discuss again the same three approaches to designing a 3-class sampling plan.

Approach 1: Given m, M and error fraction target, find n, c_m and c_M

This approach once again is used *for acceptance testing*, and the focus is on the *false negative fraction* ('consumer's risk' or 'type II error' or 'β').

Here 'M' again denotes the median concentration that, if exceeded, represents 'unacceptable' product that should be rejected with high reliability by the plan. The quantile 'm' denotes the median concentration that separates 'acceptable' from 'marginal' product. Presumably 'acceptable' product should be rejected infrequently.

Subject matter expertise or specifications provide a value for M that should be rejected with high reliability ('Power' = 1 – β), say 95% or 99% or 99.9%. Such expertise or specifications also provides the value for m that should be rejected 50% of the time (*i.e.*, the 'indifference' level). The parameters n, c_m and c_M are chosen to achieve the statistical power required.

The probability of rejecting unacceptable lots with median concentration M is determined from eq.(L.1.) and the probability of rejecting indifferent lots with median concentration m is

$$0.5 \sim P[(\# > m) > c_m] \qquad \text{(eq. L.3.)}$$

calculated from a binomial distribution with $p = P[X \leq m] = 0.50$.

Some possible plans are:

Table L.4. 3-Class plans, given m, M as median concentrations

n	m c	M c	M Power Target	M Power Actual	m Power Target	m Power Actual
4	1	0	95.00%	93.75%	50.00%	68.75%
5	2	0	95.00%	96.88%	50.00%	50.00%
6	2	0	95.00%	98.44%	50.00%	65.63%
7	3	1	95.00%	93.75%	50.00%	50.00%
10	4	1	95.00%	98.93%	50.00%	62.30%
7	3	0	99.00%	99.22%	50.00%	50.00%
10	4	1	99.00%	98.93%	50.00%	62.30%
10	4	0	99.90%	99.90%	50.00%	62.30%

Approach 2: Given P_m, P_M and error fraction target, find n, c_m and c_M

This approach is used primarily in designing sampling plans *for process control*, and the focus is on the *false positive fraction* ('producer's risk' or 'type I error' or 'α' or 'FAR').

M and m represent specified quantiles of the concentration of 'normal' production under statistical control, with m < M. Their values are determined from their percentile ranks P_m and P_M either nonparametrically or parametrically based on historical data. The parameters n, c_m and c_M are chosen to achieve the maximum false positive fraction α allowed, typically 1% or 0.1%, depending upon sampling rate.

The probability of a randomly chosen lot from normal production failing from both rejection rules for the special case that $c_M = 0$ is

$$1 - \alpha = \sum_{k=0}^{c} \binom{n}{k} u^k p^{n-k} \qquad \text{(eq. L.4.)}$$

where $p = P_m$ and $u = P_M - P_m$.

An additional design rule for 3-class plans is to make the rejection rules for m and M roughly of equal impact in the determination of the total false positive fraction. This can be achieved by determining P_M for the 2-class plan with sample size n and acceptance number $c_M = 0$ and half the false positive fraction α, and then choosing the parameters related to m. We assume therefore that P_M has been determined from

$$\alpha / 2 = P[(\# > M) > 0] \quad \text{(eq. L.5.)}$$

calculated from a binomial distribution with n trials and $p = Q_M$.

Some possible plans are:

Table L.5. 3-Class sampling plan given m and M probabilities

n	c	α Target	Probability ≤ m	Probability ≤ M	Exact α m + M
5	1	0.50%	98.50%	99.95%	0.454%
5	1	1.00%	97.50%	99.90%	1.047%
5	1	5.00%	94.50%	99.49%	4.720%
5	1	10.00%	91.50%	98.98%	9.650%
5	2	0.50%	93.50%	99.95%	0.493%
5	2	1.00%	91.50%	99.90%	1.019%
5	2	5.00%	85.00%	99.49%	4.894%
5	2	10.00%	80.00%	98.98%	9.919%
5	3	0.50%	85.00%	99.95%	0.470%
5	3	1.00%	81.00%	99.90%	1.041%
5	3	5.00%	71.00%	99.49%	5.028%
5	3	10.00%	64.50%	98.98%	10.045%

Approach 3: Given n, c_m, c_M and error fraction target, find P_m and P_M

This approach results in achievement of an *exact* false positive fraction α, and again is used in designing sampling plans *for process control* with the focus on the *false positive fraction* ('producer's risk' or 'type I error' or 'α' or 'FAR').

M and m again represent specified quantiles of the concentration of 'normal' production under statistical control, with m < M. Their values are determined from their percentile ranks P_m and P_M either nonparametrically or parametrically based on historical data. The parameters n, c_m and c_M are specified, and P_m and P_M chosen to achieve the maximum false positive fraction α allowed, typically 1% or 0.1%, depending upon sampling rate.

As in the section titled ‘Given P_m, P_M and error fraction target, find n, c_m and c_M’, we assume $c_M = 0$ to simplify the equations, and choose P_M to satisfy eq.(L.5.). The implicit eq.(L.4.) is then solved for P_m.

225 Some possible plans are:
226
227 Table L.6. Find m for 3-class plan from given α, M and σ

N	c	FAR Target	Probability ≤ M	Probability ≤ m
5	1	0.200%	99.980%	98.966%
5	1	0.200%	99.980%	98.966%
5	1	0.200%	99.980%	98.966%
5	1	0.500%	99.950%	98.342%
5	1	0.500%	99.950%	98.342%
5	1	0.500%	99.950%	98.342%
5	1	1.000%	99.900%	97.608%
5	1	1.000%	99.900%	97.608%
5	1	1.000%	99.900%	97.608%
5	1	5.000%	99.495%	94.176%
5	1	5.000%	99.495%	94.176%
5	1	5.000%	99.495%	94.176%
5	2	0.200%	99.980%	95.237%
5	2	0.200%	99.980%	95.237%
5	2	0.200%	99.980%	95.237%
5	2	0.500%	99.950%	93.436%
5	2	0.500%	99.950%	93.436%
5	2	0.500%	99.950%	93.436%
5	2	1.000%	99.900%	91.610%
5	2	1.000%	99.900%	91.610%
5	2	1.000%	99.900%	91.610%
5	2	5.000%	99.495%	84.770%
5	2	5.000%	99.495%	84.770%
5	2	5.000%	99.495%	84.770%
5	3	0.200%	99.980%	87.778%
5	3	0.200%	99.980%	87.778%
5	3	0.200%	99.980%	87.778%
5	3	0.500%	99.950%	84.500%
5	3	0.500%	99.950%	84.500%
5	3	0.500%	99.950%	84.500%
5	3	1.000%	99.900%	81.392%
5	3	1.000%	99.900%	81.392%
5	3	1.000%	99.900%	81.392%
5	3	5.000%	99.495%	71.088%
5	3	5.000%	99.495%	71.088%
5	3	5.000%	99.495%	71.088%

228

Approach 4: Finding m and M from P_m and P_M

The concentrations m and M may be determined nonparametrically as quantiles of an observed empirical cumulative distribution function (ECDF) at probabilities P_m and P_M. Acceptable accuracy requires the number of underlying observations $N \geq 2 / Q_M$. E.g., for $P_M = 99.9\%$, $Q_M = 1 - P_M = 0.001$ and the requirement is that $N \geq 2000$. Lack of available data typically limits this approach to $P_M = 99\%$ or less.

Extension to higher quantiles is possible by fitting available data to a parametric model, such as a normal distribution for the $\log_{10}$-transformed concentrations. Suppose this has been done, and the prevalence of zero results is P_0, and the mean and standard deviation of the $\log_{10}$-transformed concentrations are estimated at 'm' and 's'.

If the entire mixture ECDF (including zero results) is the desired basis for quantiles, compute adjusted quantiles for P_m and P_M as

$$P_m' = 1 - (1 - P_m) / (1 - P_0) \qquad \text{(eq. L.6.)}$$

$$P_M' = 1 - (1 - P_M) / (1 - P_0) \qquad \text{(eq. L.7.)}$$

Find y_m and y_M as the quantiles of the normal distribution with mean m and standard deviation s corresponding to P_m' and P_M'. Then compute m and M as the antilogs of y_m and y_M. Note that observed zero results are still used in applying the rejection rules.

Appendix M. Implied False Alarm Rate in a 3-class Sampling Plan Given m, M, n, c, and σ.

In addition to designing 3-class sampling plans to achieve a desired false alarm rate (FAR), we can also investigate the FAR implied by existing plans. We begin by assuming that the unacceptable concentration limit M is chosen according to some criterion and then evaluate the impact of different levels of process variability (σ) on the FAR under existing 3 class sampling plans.

M percentile criterion: First, assume that M is chosen to be an extreme percentile in the right hand tail of the distribution, such as the 99.5th percentile. This means that M is chosen such that p_d = 0.5% of individual samples have an unacceptable concentration. For a given sampling plan, the FAR attributable to M (FAR_M) = 1-(1-p_d)^n. This is simply the complement of eq. K.2. (Appendix K). For an n = 5 sampling plan, FAR_M = 2.5%. For a given sampling plan, the overall FAR is given by the complement of eq. K.3. (Appendix K). The overall FAR can be partitioned into portions attributable to M and m: FAR = FAR_M + FAR_m. Assuming a lognormal distribution, given p_d and σ_{log10} values, we can calculate p_m from existing sampling plans based on the ratio of the limits (M/m). Given a fixed M percentile, the implied μ_{log10} and percentile of the specified marginal limit value (m) will vary depending on the process variability (σ). This has important consequences for the FAR. Table M.1 presents the FARs implied by existing n = 5, c = 2 three-class sampling plans over a range of σ_{log10} values.

Table M.1. False alarm rates implied by existing 3-class sampling plans (M percentile)

n	c	log(M/m)	σ_{log10}	M percentile	FAR(%)	FAR_M(%)	FAR_m(%)
5	2	1	0.25	7.7	99.6	2.5	97.1
			0.50	71.8	15.8	2.5	13.3
			0.80	90.8	3.1	2.5	0.6
			1.20	95.9	2.5	2.5	0.0
5	2	2	0.25	0.0	100.0	2.5	97.5
			0.50	7.7	99.6	2.5	97.1
			0.80	53.0	45.2	2.5	42.8
			1.20	81.8	6.6	2.5	4.1

FAR_M criterion: Second, assume that M is chosen to achieve a desired FAR_M for a given sampling plan, such as the conventional 0.3%. For a given sampling plan, p_d = 1-(1-FAR_M)$^{1/n}$. For an n = 5 sampling plan, p_d = 0.05% (M = 99.95th percentile). Based on the same approach used to generate Table M.1, Table M.2 presents implied FAR.

Table M.2. False alarm rates implied by existing 3-class sampling plans (FAR_M)

n	c	log(M/m)	σ_{log10}	m percentile	FAR(%)	FAR_M(%)	FAR_m(%)
5	2	1	0.25	23.2%	91.4%	0.3%	91.2%
			0.50	89.8%	1.2%	0.3%	0.9%
			0.80	97.8%	0.3%	0.3%	0.0%
			1.20	99.3%	0.3%	0.3%	0.0%
5	2	2	0.25	0.0%	100.0%	0.3%	99.7%
			0.50	23.2%	91.4%	0.3%	91.2%
			0.80	77.9%	7.8%	0.3%	7.5%
			1.20	94.5%	0.4%	0.3%	0.1%

The take away message from Tables M.1 and M.2 is that designing 3-class sampling plans based on n, c, m, and M without considering process variability (σ) can result in highly inconsistent false alarm rates. On the other hand, the analysis in this section assumes that limits are based on reliable data from an ideal process that is under statistical control and capable of meeting microbiological specifications. If the m and M limit values are chosen instead on the basis of strong observed associations with certain concentrations being exceeded (*e.g.*, measurements exceeding M are associated with observed pasteurization process failures, measurements exceeding m and associated with significantly reduced shelf life), then frequent occurrences where the microbiological criteria were exceeded may indicate unsatisfactory process quality. Under such circumstances, the events would be mischaracterized as false alarms because the exceedances indicate a lack of process capability to meet microbiological specifications.