This guidance represents the Food and Drug Administration’s (FDA’s) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

This appendix contains a decision tree that may be used to assist you with the identification of critical control points (CCPs). You should not rely exclusively on the decision tree, because error may result.

The following decision tree is derived from one that was developed by the National Advisory Committee on Microbiological Criteria for Foods.
Q1: Does this step involve a hazard of sufficient risk and severity to warrant its control?

YES

NO

Q2: Does control measure for the hazard exist at this step?

YES

NO

Modify this step, process or product

Is control at this step necessary for Safety?

YES

NO

NOT A CCP

STOP

Q3. Is control at this step necessary to prevent, eliminate or reduce the risk of the hazard to consumers?

YES

NO

STOP

NOT A CCP

Appendix 3: Critical Control Point Decision

Tree A3 - 2 (June 2021)
BIBLIOGRAPHY

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of [Insert date], FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after [Insert date].

NOTES:

Appendix 3: Critical Control Point Decision
Tree A3 - 4 (June 2021)