PPI POSITION PAPER

Open Fermentation Tanks Are Acceptable Under cGMPs

Many PPI member companies ferment pickles in uncovered outdoor fermentation tanks. We are aware of state and federal regulators that have raised questions about the use of open fermentation tanks for fermenting pickles. PPI has prepared this position paper to support the use of uncovered outdoor fermentation tanks under the current Good Manufacturing Practice (cGMP) regulations found at 21 CFR Part 110 and the cGMP and the preventive control regulations found at 21 CFR Part 117.

The FDA current Good Manufacturing Practice (cGMP) regulations address outdoor bulk vessels such as fermentation tanks. The regulations state a plant must:

> "Permit the taking of proper precautions to protect food in installed outdoor bulk vessels by any effective means, including:
>
> (i) Using protective coverings.
>
> (ii) Controlling areas over and around the vessels to eliminate harborages for pests.
>
> (iii) Checking on a regular basis for pests and pest infestation.
>
> (iv) Skimming the fermentation vessels, as necessary."[1]

Importantly, the plain language of the regulations does not require outdoor fermentation tanks to have a protective covering but merely identifies protective coverings as an example of a mitigation measure that may be appropriate in some instances. Moreover, a review of FDA statements reveals it is appropriate and necessary for pickle fermentation tanks to remain open. PPI submitted comments to the proposed rule that would establish the requirements in 21 CFR Part 117. PPI's comments highlighted the flexibility of this provision and emphasized that such flexibility is necessary. Fermentation of brined vegetables is one of the oldest technologies and the practice has evolved little over the past thousand years. As PPI explained in its comment, the high salt concentration, utilization of sugar by the lactic acid bacteria and other microbiota, and production of high concentrations of organic acid renders the fermentations free of pathogens and prevents the survival of competing bacteria. Closed fermentation tanks, therefore, are not necessary for food safety. More importantly, open top fermentation tanks allow UV light to inhibit the formation of aerobic film yeast which helps control the pH of the tank and supports food safety.

FDA did not address the PPI comment in the preamble to the final regulation, however a review of the preamble to the original 1986 final regulation establishing the cGMP regulations in 21 CFR Part 110

[1] *See*, 21 CFR 117.20(b)(3). The corollary provision in 21 CFR 110.20(b)(2) has the same "effective means" language in paragraphs (i)-(iv) but the language of the regulation uses the term "outdoor bulk fermentation vessels" rather than "installed outdoor bulk vessels." An outdoor fermentation tank would fit within both of these descriptions.

1101 17th Street NW Suite 700
Washington DC 20036
P 202-293-5800
www.ilovepickles.org

reveals support for the use of open fermentation tanks. In the preamble to the original cGMP rule, FDA addressed a comment from the wine industry related to 21 CFR 110.20(b)(3) which stated "all new wine fermenters are closed, but that some members of the industry still use open fermenters. A requirement that they be covered or replaced would create a genuine hardship for many of the smaller wineries."[2] FDA's response to this comment confirms that the rule does not prohibit the use of open fermentation tanks:

> "This paragraph of the regulations requires that manufacturers take proper precautions for protecting products in outdoor bulk fermentation vessels. The paragraph does not require that any specific practice be followed. Rather, the paragraph merely suggests what practices may be appropriate, i.e., using protective coverings; controlling areas over and around the vessels to eliminate harborages for pests; checking on a regular basis for pests and pest infestation; and skimming the fermentation vessels, as necessary."[3]

FDA's 1986 response reinforces the PPI position that outdoor bulk fermentation tanks do not have to have a protective covering under the cGMP requirements.

It is PPIs position that the cGMPs provide sufficient flexibility to allow for the use of open top fermentation tanks for fermenting vegetables. Further, PPI recognizes that open top fermentation tanks and exposure to UV light can help prevent the development of potentially hazardous yeasts and control product pH.

[2] *See*, 51 Fed. Reg. 22458, 22465 (June 19, 1986) (available at: 51 FR 22458, 22465.)
[3] *Id*.