



PPI POSITION PAPER

On-Farm Grading of Cucumbers is Considered a Farming Operation and is Not Subject to the cGMP and Preventive Control Requirements of Part 117

Many PPI member companies have grading stations where the freshly harvested cucumbers are sized, graded, and sorted. State and federal regulators conducting inspections of PPI member companies will frequently raise questions about the design and construction of grading stations and assert the grading stations do not meet the cGMP requirements of 21 CFR Part 117. It is the PPI position that grading stations are part of farming and are not subject to the cGMP requirements of 21 CFR Parts 110 or 117.

Establishments that engage in the manufacturing, processing, packing, or holding of food for consumption in the United States are required to register.¹ Registered establishments are subject to the cGMP and Preventive Controls requirements of Part 117, unless exempt. Establishments engaged in farming operations are specifically exempt from the registration requirements.² This means that a farm can engage in packing and holding of raw agricultural commodities and be exempt from the registration and preventive control requirements when the activity is considered part of the “farming operations.” Grading is an activity that falls within the definition of “farming operations.”

Grading operations frequently involve the use of water in protecting and transporting the fresh produce. For example, a cucumber grading station generally involves a collection vessel that is filled with water. The trailer carrying the recently picked cucumbers will use gravity to transfer the fresh cucumber into the collection vessel. The collection vessel is filled with fresh water at the beginning of the day. The water protects the cucumber from damage and bruising when it is being dumped into the vessel. A conveyor belt will then transport the cucumbers from the collection water into a grading station where the cucumbers can be sized and sorted according to the specifications established for each Grade. The cucumber vine and cucumber grow on the ground and will contain the dust and dirt that is present given these growing conditions. The water in the collection vessel will dissolve the dirt on the recently harvested cucumbers and will become discolored after the first load of cucumbers are dumped into the vessel. While the water in the collection vessel is discolored, it is unnecessary and harmful to the process to add sanitizing chemicals to the water. The cucumbers are in the water for a limited amount of time and they are being exposed to the microflora found naturally in the field. The addition of sanitizing agents is unnecessary and would be harmful if applied to the water for cucumbers. Many of the cucumbers will be sent to processors for fermentation where the cucumber is placed in a fermentation tank with a salt water brine for fermentation. The fermentation process relies on the natural microflora found on the pickle. The addition of a sanitizing agent to the collection water would destroy the microflora and would prevent proper fermentation of these cucumbers. A review of the relevant precedent establishes the Grading process is part of “farming” and does not trigger facility registration or the application of the GMPs found in 21 CFR Parts 110 or 117.

The preamble to the final rule specifically clarifies that “grading” is a packing activity that when done on a farm is considered a farming activity. FDA states, “sorting, culling, and grading RACs can be either a holding activity or a packing activity.”³ FDA also states,

¹ See, [21 CFR 1.225](#).

² See, [21 CFR 1.227](#).

³ See, 80 Fed. Reg 55908, 55933 (Sept. 17, 2015) (accessed Oct 26, 2023 at: [80 FR 55908, 55933](#)).





“we have previously classified several on-farm activities in more than one way ([79 FR 58524 at 58538 and 58571](#)) depending on when the activity occurs. For example, sorting, culling, and grading RACs can occur during both packing and holding activities.”⁴

Language from the preamble to the proposed rule also supports this finding, specifically:

“Just as there are some activities that are performed incidental to storing a food, there are some activities that are performed incidental to packing a food. For example, sorting, culling, and grading RACs could be an activity incidental to packing on a farm or farm mixed-type facility, whereas off-farm some sorting or similar activities such as culling or grading may be required to ensure that like items are packed together, or to remove damaged items.”⁵

The proposed rule also listed the following as an organizing principle to the revision of the definition of farm:

“Activities that involve RACs and that farms traditionally do for the purposes of growing RACs, removing them from the growing areas, and preparing them for use as a food RAC, and for packing, holding and transporting them, should all be within the definition of ‘farm.’”⁶

It is the PPI position that grading stations are considered part of the farming operations. Grading activities, similar to other activities conducted on the farm are subject to good agricultural practice. The grading activities and grading stations, however, are not subject to the registration requirements, the cGMP requirements of 21 CFR Part 110, or the cGMP and preventive control requirements of 21 CFR Part 117.

⁴ See, 80 Fed. Reg. at 55933.

⁵ See, 79 Fed. Reg. 58524, 58537-8 (Sept. 29, 2014) (accessed on Oct. 26, 2023 at: [79 FR 58524, 58537-8](#)).

⁶ See, 79 Fed. Reg. 58524, 58538 (Sept. 29, 2014) (accessed on Oct. 26, 2023 at: [79 FR 58524, 58537](#)).

