

HOGAN & HARTSON

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061-HFA 305
Rockville, MD 20852

Dear Sir or Madam:

On behalf of a coalition of fifteen leading trade associations, attached is a Citizen Petition requesting a regulatory limit for *Listeria monocytogenes* in ready-to-eat foods that do not support its growth. The requested limit is 100 colony forming units (CFU)/gram in prepared foods held at or below -1°C, prepared foods with pH values less than 4.4, prepared foods with water activity less than 0.92, and other prepared foods for which credible scientific evidence demonstrates that *L. monocytogenes* will not grow.

The requested regulatory limit would establish a science-based standard for the control of *L. monocytogenes* that allows the Food and Drug Administration and the food industry to focus resources on cell numbers of public health significance, encourages aggressive environmental sampling, and facilitates development of new control measures to inhibit growth, among other benefits. A targeted, risk-based approach to *L. monocytogenes* is consistent with the findings of the recent Food Safety and Inspection Service risk assessment and the *Listeria monocytogenes* action plan.

As required by 21 C.F.R. § 10.20, four copies of the petition and one copy of the references are enclosed. An electronic copy in a PDF format is also attached for your convenience. We ask that the fifth copy be date-stamped and returned via the awaiting messenger.

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If there are any questions or concerns, please do not hesitate to contact me at 202-637-5856 or Ann Boeckman at 202-637-5770. Thank you for your time and consideration.

Respectfully submitted,



Gary Jay Kushner

Enclosures