



AMERICAN  
SOCIETY FOR  
MICROBIOLOGY

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The American Society for Microbiology (ASM) is submitting comments in response to the Food and Drug Administration (FDA) notice requesting comments on the petition to establish a regulatory limit on *Listeria monocytogenes* in the Federal Register, Vol. 69, No. 100 on May 24, 2004, Docket No. 2003P-0574. The following comments were developed by the ASM Committee on Agriculture and Food Microbiology, of the Public and Scientific Affairs Board.

The ASM is the largest single life science society with more than 42,000 members, including scientists in academic, industrial, clinical, and government institutions, working in areas related to basic and applied research, the prevention and treatment of infectious diseases, laboratory and diagnostic medicine, the environment, and water and food safety. The ASM applauds FDA efforts to reduce the incidence of foodborne illness, including illness caused by *L. monocytogenes*, and to protect the safety of the food supply.

The FDA has announced that a citizen petition has been filed by fifteen trade associations requesting that FDA amend the current regulations in 21 CFR part 109, "Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Material," to establish a regulatory limit for *L. monocytogenes* of 100 colony forming units per gram in foods that do not support growth of the microorganism. The petition asserts that the requested regulatory limit would establish a science-based standard for the presence of *L. monocytogenes* in such foods, noting that this request is based on new and emerging evidence that consumer protection is a function of the organism's cell numbers in food, and not its mere presence.

**Comment: The ASM has reviewed the petition and agrees that consumer protection is a function of the number of *L. monocytogenes* cells in a food. The petition provides a compelling argument based on the FDA/FSIS risk assessment, the FAO/WHO risk assessment and a peer-reviewed article (Chen et al., 2003) that supports this assertion. The petition compares a number of scenarios: one in which the number of *L. monocytogenes* in foods is capped at 100 colony forming units (CFU) per gram, but the prevalence is unchanged, and another in which the number of *L. monocytogenes* is unchanged, but the prevalence is reduced by 50%. In the former example, the number of listeriosis cases is expected to decrease by more than 99.5%, whereas in the latter example the number of cases would only decrease by 50%.**

It has been argued, however, that if ‘zero tolerance’ limit were relaxed, food producers might relax their *L. monocytogenes* surveillance in no-growth foods and that this would result in increased prevalence of foods containing low doses of *L. monocytogenes*. The question that arises whether the scale of that increased prevalence (and perhaps increased contamination levels) would actually *increase* the overall risk compared to the *status quo*. Chen, *et al.* also address this situation, and simulated a scenario where prevalence increased by 100% while the maximum number of *L. monocytogenes* was held at 100 CFU/g. In this case the number of listeriosis cases fell by 98.9% (instead of 99.5%).

In a much more extreme example, the FAO/WHO Risk Assessment simulated a scenario where no foods exceeded 100 CFU/g but 100% of ready to eat foods were contaminated with 100 CFU/g at the time of consumption. This truly represents the ‘worst case’, relaxing the zero tolerance while achieving 100% compliance with the proposed tolerance. Under this scenario (based essentially on US data) the predicted number of listeriosis cases fell roughly 50%.

To sum up: depending on changes in prevalence, a change from “zero tolerance” to 100 CFU/g is expected to result in a decrease in listeriosis between 50% and 99.5%. The ASM finds the logic, reasoning and statistical techniques used to derive these conclusions to be sound and based on the best currently available science, and suggest that a change to the tolerance will result in a net public health benefit, even under the most conservative assumptions.

The petition further asserts that a regulatory limit will permit FDA and the food industry to distinguish products for which increased scrutiny is prudent from those for which greater attention will not yield a corresponding benefit to public health.

**Comment:** The ASM believes that this assertion follows logically from the prior assertion. Namely, if not all foods represent an equal risk, and those foods containing significantly more *L. monocytogenes* represent a significantly greater risk, it logically follows that more effort should be directed at removing highly contaminated foods from the marketplace. For example, (if we assume an exponential dose-response model) a food which contains  $10^8$  *L. monocytogenes* CFU/gm represents a risk one million times greater than a food containing  $10^2$  *L. monocytogenes* CFU/gm, so that finding and removing one package that contains  $10^8$  *L. monocytogenes* CFU/gm represents the same level of risk reduction as finding and removing one million packages that contain  $10^2$  *L. monocytogenes* CFU/gm.

The average contamination rate of ready-to-eat foods on the market is approximately 2% (Gombas et al., 2003). Using sampling and testing to control this (and enforce a zero tolerance) will require an extremely large number of samples. For example, even if 2% of a lot is contaminated, there is a 67% probability that even if 20 samples are taken they will all be negative - and the lot falsely accepted. Hence, it follows logically that consumer safety is not ensured by the combination of "zero tolerance" and sampling/testing. Seen from a societal point of view, controlling preservation levels (concentrations of salt, lactate, diacetate etc) is much cheaper and more efficient than tracing a sporadic bacterial contamination.

As the petition notes, a risk-based approach to addressing the occurrence of *L. monocytogenes* is consistent with the comprehensive risk assessment undertaken by FDA and the U.S. Department of Agriculture’s Food Safety and Inspection Service. In addition, the ASM notes that taking a risk-based approach to microbial food safety is also consistent with activities occurring in international settings (i.e. FAO/WHO).

**The ASM also agrees that this change should encourage: (i) innovative development of foods that don't support *L. monocytogenes* growth, (ii) the use of routine and/or aggressive sampling programs, (iii) provide better quantitative data on *L. monocytogenes* contamination in foods and provide a basis for validating technologies that kill or inhibit the growth of *L. monocytogenes* in foods.**

In addition, the petition asserts that there is general scientific agreement that low levels of *L. monocytogenes* are not uncommon in the food supply and that such low levels are regularly consumed without apparent harm.

**Comment: The ASM agrees that an international consensus regarding foods that do not support growth is emerging, and that Canada, Denmark, the United Kingdom, Australia, and New Zealand all have either formal or informal regulatory limits for *L. monocytogenes* that depart from a "zero tolerance" approach. If indeed "zero tolerance" for *L. monocytogenes* is not sound science, it may be viewed as a trade barrier and a failure of the United States to meet its obligations under the Sanitary and Phytosanitary Measures Agreement of the Uruguay Round of Trade Agreements.**

**In summary, the ASM supports the request that FDA amend the current regulations in 21 CFR part 109 to establish a regulatory limit for *L. monocytogenes* of 100 colony forming units per gram in foods that do not support growth of the microorganism. Such a regulatory limit is supported by the current scientific understanding of foodborne disease caused by *L. monocytogenes* and is consistent with a general approach to risk and science-based standards for food safety.**

Sincerely,

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## References

Chen, Y.H., Ross, E.H., Scott, V.N., and Gombas, D.E., 2003. *Listeria monocytogenes*: Low levels equal low risk. J. Food Protect. 66, 570-577.

Gombas, D.E., Chen, Y.H., Clavero, R.S., and Scott, V.N., 2003. Survey of *Listeria monocytogenes* in ready-to-eat foods. J. Food Protect. 66, 559-569.

Food and Agriculture Organization of the United Nations and World Health Organization (FAO/WHO). Risk Assessment of *Listeria monocytogenes* in ready-to-eat foods.

[http://www.fao.org/es/esn/food/risk\\_mra\\_riskassessment\\_listeria\\_en.stm](http://www.fao.org/es/esn/food/risk_mra_riskassessment_listeria_en.stm)

Docket notice:

<http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2004/pdf/04-11597.pdf>

Petition: <http://www.fda.gov/ohrms/dockets/dailys/03/dec03/122403/03p-0574-cp00001-02-vol1.pdf>