Frequently asked technical questions on the 2004 version of the "Policy on *Listeria monocytogenes* in ready-to-eat foods"

Bureau of Microbial Hazards
Food Directorate
Health Products and Food Branch

April 2010

Canada

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1) What is the scientific relationship between the Good Manufacturing Practices[0] (GMPs) status and the level of *Listeria monocytogenes* in the product?
A: The assumption would be that if there is environmental contamination with *Listeria monocytogenes* in the plant, the final product is more likely to be contaminated by the pathogen. However, this cannot always be reflected during sampling, since only a small number of sample units (n=5) are being analysed. Therefore, an evaluation of GMPs becomes necessary, with the assumption that if GMPs are not adequate, there is more chance for *L. monocytogenes* to be present in the plant environment and hence in the final product.

2) Is there guidance regarding the method to use for swab sampling?
A: Yes, as written in section 4.2 of the MFHPB-30 method from the Compendium of Analytical method, the analyst should follow the environmental sampling procedures given in MFLP-41A and B. The website address for the Compendium of Analytical method is:
http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/index-eng.php

3) In Figure 1 of the policy, will consideration be given as to which sites will be chosen for the composite sample?
A: Yes, consideration will be given to the sites for composite sampling. It is up to the inspection staff (meaning the regulatory authority) to determine if criteria or guidelines should be provided to the inspector for the sites to be swabbed.

4) Would new methods being developed and validated on an ongoing basis be acceptable to use for testing? Note that many laboratories use rapid screening kits for environmental testing for *Listeria*.
A: Yes, as indicated in Figure I and Table II in the policy, methods that are equivalent to those published in the Compendium of Analytical methods would be considered acceptable to use for testing.

5) Why is it necessary to test the final product if non-product contact surfaces are positive, but contact surfaces are negative?
A: Industry should work towards the elimination of *Listeria monocytogenes* from non-product contact surfaces, as the organism may eventually spread to product contact surfaces and finished products. We feel that testing end-product(s) after 3 positive results from non-product contact surfaces, is a reasonable end point. Please refer to Figure 1 in the policy.

6) How were the action levels established in Table I determined?

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[01] The term GMPs in the text is used as a generic term and includes all key conditions and control measures necessary for manufacturers to ensure the safety and the suitability of food during manufacturing.

A: The action levels were established a number of years ago based on outbreak data, some in-house data, plus international scientific expert opinion. Since only limited resources are available to regulatory agencies and the industry, it is much more effective to direct resources at foods where *L. monocytogenes* is likely to be present and grow to high levels, rather than targeting all ready-to-eat foods. For foods that are produced under adequate GMPs and do not support the growth of *L. monocytogenes*, a maximum of 100 cfu/g is part of the Canadian policy, and is a criterion that is also accepted in several European countries. The incidence of listeriosis reported in these industrialized countries since the non-zero criterion was adopted, is similar to the incidence in the U.S. (which have currently a "zero tolerance" policy in place for *L. monocytogenes* in foods). On the other hand, if there is inadequate, absent, or no information on GMPs for foods that do not support the growth of *L. monocytogenes*, the situation represents a Health Risk 2 concern if *L. monocytogenes* is found in the product.

7) How do you determine and define products as being made for a targeted population? Who would make that determination? Should products that are "targeted" to susceptible populations automatically be Category 1 or 2 in the event of positive testing, regardless of product characteristics?

A: The CFIA and Health Canada will determine if a product is targeted for susceptible individuals on a case-by-case basis. An example could be prepared luncheon meat for schoolboys and schoolgirls. If products are targeted to susceptible populations, the level of concern may change if the organism of concern, *Listeria monocytogenes*, is detected. This product would be considered a Health Risk 2 or Health Risk 1, but not a Health Risk 3. Please refer to the last paragraph of section 2 and to subscripts "k and l" from Table I of the policy.

8) In Figure 1 of the policy, which products will be analysed under "test end-products immediately" (the exact day the inspector returns to the establishment)?

A: As described in Figure 1 of the policy, if GMPs are adequate, testing would be done on previously made product(s) from the same production lot or lots on the same day that the plant environmental samples were originally taken, i.e., on the inspector's second or third trip to the plant (depending if *Listeria monocytogenes* is found on product or non-product contact surfaces). This means that the inspector would have to obtain the food sample(s) either from product currently being stored or held in the processing plant, or possibly directly from the retail level. If GMP's are inadequate, the above would still apply, except that in each case, there would be one less visit by the inspector before end product testing would be started.