Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

Summary of Comments Received on Health Canada's Proposed Document *Validation of Ready-to-Eat Foods for Changing the Classification of a Category 1 into a Category 2A or 2B Food –in relation to Health Canada's Policy on Listeria monocytogenes in Ready-to-Eat Foods (2011)* – October-November, 2011

November 2012

Bureau of Microbial Hazards
Food Directorate
Health Products and Food Branch

Canada

Background

After the 2008 deli-meat listeriosis outbreak, Health Canada started a review/update of its *Policy on Listeria monocytogenes in Ready-to-Eat Foods* incorporating the latest science available. In 2011, further to the publication of this policy, a document initially entitled *Validation of Food Safety Measures to Limit or Prevent the Growth of Listeria monocytogenes in Ready-to-Eat Foods* and now renamed *Validation of Ready-to-Eat Foods for Changing the Classification of a Category 1 into a Category 2A or 2B Food – in relation to Health Canada's Policy on Listeria monocytogenes in Ready-to-Eat Foods (2011)*, was drafted. The purpose of this latter document is to assist processors and importers of ready-to-eat (RTE) foods with the validation of the classification of their RTE products into either Category 2A or Category 2B, as defined in Health Canada's *Policy on Listeria monocytogenes in Ready-to-Eat Foods* (Health Canada, 2011).

On October 17, 2011, the proposed draft mentioned above was sent out electronically to targeted stakeholders (i.e., ~775 individuals) by Health Canada's Bureau of Microbial Hazards (BMH), Food Directorate, in order to obtain their comments. Comments were accepted until November 28, 2011.

Summary of comments

Health Canada received input from various stakeholders representing governments, industry, academia and professional organizations, including:

Governments:
Agriculture and Agri-Food Canada
Alberta Agriculture and Rural Development
British Columbia Centre for Disease Control
Canadian Food Inspection Agency
Health Canada (other sections)
Ministère de l'Agriculture, des Pêcheries et de l'Alimentation du Québec
Ontario Ministry of Agriculture, Food and Rural Affairs
Public Health Agency of Canada
United States Food and Drug Administration - Center for Food Safety and Applied Nutrition

Industry:
Aliments ED Foods
Griffith Laboratories Canada
Maple Leaf Foods Inc.
Merinov
Premium Brands
Purac America
Silliker

Academia

University of Waterloo

Professional organizations
Canadian Meat Council
Canadian Poultry and Egg Processors Council
Canadian Produce Marketing Association
Further Poultry Processors Association of Canada

Stakeholders generally supported the proposed document. Key issues that were identified by stakeholders during the comment period are highlighted below.

1) **Is there a need to validate refrigerated RTE foods having stated shelf-lives of ≤ 5 days? How is Health Canada's *Policy on Listeria monocytogenes in Ready-to-Eat Foods (2011)* applicable to these RTE foods?**

   Refrigerated RTE products having stated shelf-lives of ≤ 5 days produced in a food manufacturing facility are covered by Health Canada's *Policy on Listeria monocytogenes in Ready-to-Eat Foods* (Health Canada, 2011). As stipulated in Section 1 of the document *Validation of Ready-to-Eat Foods for Changing the Classification of Category 1 into a Category 2A or 2B Food - in relation to Health Canada's Policy on Listeria monocytogenes in Ready-to-Eat Foods (2011),* no validation studies are required for these products; they are by default considered as a Category 2A food (Health Canada, 2012a). This being said, these establishments must produce safe foods as per the *Food and Drugs Act* and its *Regulations.* In relation to Health Canada's *Policy on Listeria monocytogenes in Ready-to-Eat Foods (2011),* an environmental monitoring program should be included (i.e., Figures 1-2-3 of the policy) and the compliance criteria (i.e., action level for *L. monocytogenes*: > 100 CFU/g and level of priority for oversight: medium to low) from Table 1 of the policy would apply.

   Refrigerated RTE products having stated shelf-lives of ≤ 5 days made and sold by a food retail or food service establishments are not covered by Health Canada's *Policy on Listeria monocytogenes in Ready-to-Eat Foods* (Health Canada, 2011). Therefore the document *Validation of Ready-to-Eat Foods for Changing the Classification of Category 1 into a Category 2A or 2B food - in relation to Health Canada's Policy on Listeria monocytogenes in Ready-to-Eat Foods (2011)* would not be applicable for these RTE products (Health Canada, 2012a). This being said, these establishments must produce safe foods as per the *Food and Drugs Act* and its *Regulations*. If these RTE foods are ever to be tested, compliance criteria (i.e., Table 1 of the policy) could apply. The final decision (i.e., nature of concern) would be determined on a case-by-case basis through a health risk assessment (HRA) done by Health Canada.

2) **For Category 2A classification (i.e., for a RTE product known to occasionally contain low levels of *L. monocytogenes* and has a processing step achieving < 5-log reduction in numbers of *L. monocytogenes* from non-thermal treatment(s) or no kill step altogether),**

one of the key process parameters is the concentration of *L. monocytogenes* at the beginning of the shelf-life of the RTE product (time = 0). What are the recommended testing frequencies for Category 2A RTE products, at time=0, to confirm that the concentration of *L. monocytogenes*, if present, does not exceed the inoculum level (i.e., < 10-30 CFU/g) used in the supporting challenge study provided to relevant regulatory authority?

The purpose of the document *Validation of Ready-to-Eat Foods for Changing the Classification of Category 1 into a Category 2A or 2B Food - in relation to Health Canada's Policy on Listeria monocytogenes in Ready-to-Eat Foods (2011)* is to provide general guidance (Health Canada, 2012a). Specifics are left to the discretion of the regulatory program. However, such frequencies should be representative of production process (e.g., in terms of volume and types of lots).

3) **In the document *Validation of Ready-to-Eat Foods for Changing the Classification of Category 1 into a Category 2A or 2B Food - in relation to Health Canada's Policy on Listeria monocytogenes in Ready-to-Eat Foods (2011)*, it is stated: "*The validation documentation will be evaluated and the final classification of the RTE product will be confirmed by the relevant regulatory authority*". Who precisely is the "relevant regulatory authority"?**

The Canadian Food Inspection Agency (CFIA) and/or provincial/territorial governments are considered relevant regulatory authorities in this particular context. Health Canada recognizes that certain provincial/territorial governments may have limited expertise, resources, and processes to accomplish this task. To this effect, these provincial/territorial governments should contact the CFIA to collaborate on the evaluation/confirmation of the RTE product classification (i.e., CFIA - Food Safety Division). Note that the confirmed classification of RTE products must be made available to any regulatory authority upon request. Documents are/will be available to assist regulatory authorities in the evaluation of any validation documentation provided by RTE food processors or importers, as applicable, to ultimately confirm the categorization of RTE products, as per Health Canada's *Policy on Listeria monocytogenes in Ready-to-Eat Foods* (Health Canada, 2011; Health Canada, 2012b (to be published); Health Canada, 2012c (to be published)).

4) **How can the "validation" studies, for a change in product categorization (i.e., from a Category 1 to a Category 2) be performed by small and very small processors which, most often, have limited resources (i.e., financial, scientific/technical knowledge/expertise, etc.)?**

It is important to note that the "validation" studies required to change the classification of a Category 1 into a Category 2A or 2B RTE food (in relation to Health Canada's *Policy on Listeria monocytogenes in Ready-to-Eat Foods* (Health Canada, 2011)) are not a condition of sale for RTE products. Instead, the RTE product which has a refrigerated stated shelf-life greater than 5 days and for which insufficient, inadequate or no validation information is

provided to consider it as either Category 2A or 2B RTE product, or for which its categorization (as 2A or 2B) has not been confirmed by the relevant regulatory authority, will be classified by default as a Category 1. As such, the compliance criteria for Category 1 RTE food from Health Canada's *Policy on Listeria monocytogenes in Ready-to-Eat Foods (2011)* would apply (i.e., action level for *L. monocytogenes*: detected in 125g and level of priority for oversight: high; as per Table 1 of the policy).

At a minimum, all food processing establishments should know the physico-chemical parameters of their RTE products, their intended shelf-lives and storage conditions. In order to evaluate if any of these parameters are critical limits that could potentially result in a Category 2 (A or B) classification without the need to provide extensive validation studies, processors would need to determine if the characteristics of their final RTE products are:

- pH < 4.4, regardless of a_w → Validation not required, by default Category 2B
- A_w < 0.92, regardless of pH → Validation not required, by default Category 2B
- Combination of pH < 5.0 and a_w < 0.94 → Validation not required, by default Category 2B
- Frozen storage (until consumption) → Validation not required, by default Category 2B
- Stated refrigerated shelf-life of ≤ 5 days → Validation not required, by default Category 2A

If any of the above scenarios are applicable throughout the stated shelf-lives of RTE products, processors would need to ensure (and provide evidence) that these parameters are met consistently, as they would be critical limits.

Alternatively, if food processors feel that their RTE products could potentially be classified as a Category 2A or 2B, they may choose to hire a competent consultant/specialized laboratory to assemble/perform supporting validation information/studies justifying RTE food placement in Category 2 (A or B, as applicable). These validation documentations would need to be submitted to and confirmed by a relevant regulatory authority.

5) In the context of a change in RTE product categorization (i.e., Category 1 to Category 2),

a) should laboratory challenge testing be performed on RTE products for which publications exist (i.e., growth of *L. monocytogenes* in these particular RTE foods throughout their stated shelf-lives have been documented)?

b) should laboratory challenge testing be performed on RTE products for which submission data have been presented to Health Canada in the context of an approved food additive (i.e., antibacterial agent – Class 2 preservative)?

a) For a product representing the highest risk for *L. monocytogenes* growth (within a grouping), it would be very unlikely that all the processing parameters/product specifications would be explicitly described in a peer-reviewed scientific publication and thus match the RTE product

under investigation. Product formulation has a key influence on growth of micro-organisms; however, this is often considered proprietary information. Unless the processing company is part of the authorship for the publication, sufficient information on product formulation is unlikely. This being said, it will be under very strict circumstances that no laboratory challenge testing would be required for product representing the worst case scenario within a grouping. However, a relevant literature review can help design experimental protocols for the product(s) under investigation, for the purpose of changing from Category 1 to Category 2.

As specified under Sections 3.2(d) and 4.2(d) of the document *Validation of Ready-to-Eat Foods for Changing the Classification of Category 1 into a Category 2A or 2B Food - in relation to Health Canada's Policy on Listeria monocytogenes in Ready-to-Eat Foods (2011)*, for RTE products being grouped under one product representing the highest risk for *L. monocytogenes* growth, no laboratory challenge testing needs to be performed, as long as an acceptable rationale for grouping and modelling is provided.

b) The reviews for approval of antibacterial agents are being done independently of guidance provided in Health Canada's *Policy on Listeria monocytogenes in Ready-to-Eat Foods* (Health Canada, 2011). Data contained in these food additive submissions are proprietary information. Those reviews are not to be made public, hence cannot be used by a third party. Food additive submissions are assessed, through a pre-market assessment, for safety and technical efficacy. The above technical effect could be in line with categorization of RTE products expressed in Health Canada's *Policy on Listeria monocytogenes in Ready-to-Eat Foods (2011)*, but this is not required for approval. Details regarding the specific efficacy of a food additive (e.g., against a specific micro-organism) are not mentioned in the *Lists of Permitted Food Additives*. (Health Canada, 2012d; Health Canada, 2012e). It is not possible to predict the impact of a specific antibacterial agent on the growth of *L. monocytogenes* in a specific RTE product solely from these public references.

6) What is the rationale for requesting a 10-30 CFU/g inoculation range in challenge studies targeted for Category 2A RTE foods? Why are higher inoculums (i.e., > 100 CFU/g) acceptable in challenge test studies for any RTE products aiming for Category 2B status (i.e., growth of *L. monocytogenes* to be less than a 0.5 log CFU/g increase throughout the stated shelf-life)?

First of all, it is important to note that the durable life of a RTE product is to be determined, as stipulated in Section B.01.001 of Division 1, Part B (Foods) of the *Food and Drugs Regulations* (Government of Canada, 2012). This shelf-life determination should be established prior to performing challenge test studies (not the reverse).

For Category 2A determination:
The 30 CFU/g upper limit was chosen on the basis of the food safety outcome to be reached by these specific RTE products. This upper limit will provide useful data that are relevant to the compliance criteria for Category 2A products. This compliance criteria states: the level of

L. monocytogenes, when present, should be limited to a maximum of 100 CFU/g throughout the stated shelf-life of the RTE product. This means, if the product is inoculated with 30 CFU/g at time=0 and the counts anytime throughout the shelf-life are 100 CFU/g (within compliance criteria), a 0.5 log CFU/g increase occurred throughout the stated shelf-life (i.e., mathematically speaking, an initial inoculum of 30 CFU/g that increases by 0.5 log CFU/g will result in a final count of 95 CFU/g). Thus, in order to remain at a maximum of 100 CFU/g throughout the stated shelf-life, any inoculum > 30 CFU/g would provide less than a 0.5 log CFU/g increase throughout shelf-life; and hence would result in meeting the Category 2B food safety outcome.

The 10 CFU/g lower limit was determined based on expert advice, which was further supported by opinions received during the consultation period on the *Validation of Ready-to-Eat Foods for Changing the Classification of Category 1 into a Category 2A or 2B Food - in relation to Health Canada's Policy on Listeria monocytogenes in Ready-to-Eat Foods (2011)* document. It is to be noted that scientific information about the actual level of contamination of RTE products with *L. monocytogenes* that could potentially be categorized under 2A (e.g., refrigerated cold smoked fish, fresh-cut produce) at time=0 is limited, as many authors report data as either only the presence/absence of *L. monocytogenes*, counts at undefined times during the shelf-life, or counts using a method with a higher limit of detection. Furthermore, since it is difficult to inoculate *L. monocytogenes* at a finite concentration in a product, Health Canada suggested the range of 10-30 CFU/g for inoculation. Note that with the new version of analytical method MFLP-74, *Enumeration of Listeria monocytogenes in Foods* (Pagotto *et al*., 2011), the limit of detection has been improved (i.e., *L. monocytogenes* counts can be reported to < 5 CFU/g, depending on the dilution being used). Hence, counts of 10-30 CFU/g are easily obtainable with this enumeration method.

For Category 2B determination:
The limitation of growth for *L. monocytogenes* to a maximum increase of 0.5 log CFU/g throughout the stated shelf-life of a RTE food (to represent a RTE food in which growth of *L. monocytogenes* will not occur) is in line with the International Codex Alimentarius Commission standard (CAC, 2009). To this end, the < 0.5 log CFU/g increase also takes into account a measurement of uncertainty. Due to the nature of the food safety outcome (i.e., < 0.5 log CFU/g increase throughout the stated shelf-life), the initial level of inoculum can vary, so long as, for example, it does not overload the preservative system/natural hurdles associated with the product and that the concentrations can be easily enumerated. See Health Canada's document *Listeria monocytogenes Challenge Testing of Refrigerated Ready-to-Eat Foods* for more details (Health Canada, 2012f).

Nonetheless, it is important to remember that the compliance criteria for RTE foods falling under Category 2A and 2B is ≤ 100 CFU/g throughout the stated shelf-life, as presented in Table 1 of Health Canada's *Policy on Listeria monocytogenes in Ready-to-Eat Foods* (Health Canada, 2011).

7) Why must validation challenge test studies be performed at a minimum temperature of 7°C, in relation to requesting a change in the categorization of a RTE food product (i.e., from a Category 1 into a Category 2A or 2B)?

This requirement can be found in the *Listeria monocytogenes Challenge Testing of Refrigerated RTE Foods* (Health Canada, 2012f).

The choice of incubation temperatures should reflect reasonable foreseeable conditions of distribution, storage and use, that is anticipated storage conditions and possible temperature abuse. Health Canada considers that 7°C is more representative of the cold chain for foods stored both in retail establishments and in consumer homes. As such, validation challenge test studies must be performed at a minimum temperature of 7°C.

Performing challenge studies at 7°C throughout the stated shelf-life duration provides useful information. If *L. monocytogenes* counts remain within the food safety outcome limits under these latter conditions, it would indicate a certain margin of safety, and hence a re-categorization of the RTE food product may be considered by the relevant regulatory authority. If *L. monocytogenes* counts are found to be above the food safety outcome limits in these conditions, it could indicate that there is a reasonable probability that *L. monocytogenes* could be found in such a RTE product, during regulatory/industry inspection, at a concentration above the compliance limit. Therefore, re-formulation and/or re-evaluation of the shelf-life of these RTE products may be considered, since a re-categorization of these RTE products will not be granted by the relevant regulatory authority.

8) Are all elements raised in the document *Listeria monocytogenes Challenge Testing of Refrigerated Ready-to-Eat Foods* (Health Canada, 2012f), considered requirements in challenge test studies performed with the goal of validating RTE food(s) for a change in classification from a Category 1 into a Category 2A or 2B?

The document *Listeria monocytogenes Challenge Testing of Refrigerated Ready-to-Eat Foods* was not drafted specifically for the sole purpose of providing requirements to manufacturers/importers/laboratories that wish to design challenge test studies for a change in RTE product's categorization in relation to Health Canada's *Policy on Listeria monocytogenes in Ready-to-Eat Foods* (Health Canada, 2011). As stated in section 1 of the document *Listeria monocytogenes Challenge Testing of Refrigerated Ready-to-Eat Foods* (Health Canada, 2012f), the goals are to recommend an experimental design for challenge test studies to determine the potential for growth of *L. monocytogenes* in refrigerated RTE foods (i.e., can a RTE food support or not the growth of *L. monocytogenes*), and to provide guidance on how to assess the efficacy of lethality treatments for *L. monocytogenes* in RTE foods. Consequently, much of the information contained in this document is applicable to challenge test studies performed with the goal of validating RTE food(s) for a change in classification from a Category 1 into a Category 2A or 2B. In fact, the majority of elements raised in this document should be performed for such a purpose. Please note that in the context of re-categorization, the relevant regulatory authority reserve the right to request a

scientific rationale to support omission or modification of recommended parameters. Based on the rationales provided, it may have an impact on the acceptance of the challenge test studies, and hence re-categorization of the RTE food product(s).

Please also note that there are 2 requirements expressed in the document *Listeria monocytogenes Challenge Testing of Refrigerated Ready-to-Eat Foods* (Health Canada, 2012f), which must be met in re-categorization validation challenge test studies. They are:

- a minimum of three lots of products must be tested for *L. monocytogenes* in triplicate at each sampling time (i.e., minimum of 5 time points throughout the stated shelf-life of the product, including time zero and at end of shelf-life) (section 5.3).

AND

- studies must be performed at a temperature of 7^{o}C or above (section 5.7)

If these requirements are not followed by the petitioner, it would automatically lead to the rejection of the challenge test studies which is one of the mandatory tasks in the validation of RTE foods for changing the classification of a Category 1 into a Category 2A or 2B food (Health Canada, 2012a).

One example of an element raised in the *Listeria monocytogenes Challenge Testing of Refrigerated Ready-to-Eat Foods* document that is not considered a requirement in the context of validation for the re-categorisation of a RTE food product (i.e., Category 1 into Category 2A or 2B), is the sampling at time points past the end of the stated shelf-life for the product. Performing the challenge test study for counts of *L. monocytogenes* up to 1.5 times the stated shelf-life of the product would be considered as providing informative additional data (e.g., perhaps in the context of a research paper), but in the specific context of validation for a re-categorisation, this 1.5 times shelf-life data would not have a direct impact on the final decision made by the relevant regulatory authority.

Furthermore, it is important to note that other requirements for validating RTE foods for a change in classification from a Category 1 into a Category 2A or 2B are also expressed in the document *Validation of Ready-to-Eat Foods for Changing the Classification of Category 1 into a Category 2A or 2B Food - in relation to Health Canada's Policy on Listeria monocytogenes in Ready-to-Eat Foods (2011)* (Health Canada, 2012a). For example, an inoculation level of 10-30 CFU/g must be used for a challenge study attempting to demonstrate Category 2A classification while the inoculation level to be used for the challenge test study for attempting to demonstrate Category 2B classification has not been pre-set by regulatory authorities (also see response to question #6). In addition, please note that prior to performing the challenge test study for attempting to demonstrate Category 2A classification, one must ensure that the product under consideration complies to the pre-requisite for such categorisation (i.e., the processing of initial ingredients for the product RTE food does not involve a heat treatment and achieves a < 5-log reduction in numbers of *L. monocytogenes*).

9) In the context of "modeling", how does one group RTE products and subsequently determine the highest risk RTE product with which to perform the mandatory laboratory challenge study?

Since it may not be practical to conduct laboratory challenge studies for each RTE product being manufactured by a processor, it could potentially be acceptable to group comparable RTE products. The groupings should consider, for example, the type of products (e.g., same type using different flavourings or different types that are closely related), and their i) composition (e.g., pH, a_w, use of permitted antibacterial agents), ii) packaging and iii) shelf-life duration. Those parameters should be comparable, that is, the growth of *L. monocytogenes* in the grouped RTE products should be very similar when their growth profiles are compared.

A rationale, supported by scientific evidence, needs to be provided to justify the grouping of RTE products, as well as for the selection of the highest risk RTE product, for *L. monocytogenes* growth, within the group (i.e., the one RTE product for which a laboratory challenge study will be performed). As such, modeling, prior to conducting the challenge study, could be a useful tool in this determination. It should be noted that, subsequent to the laboratory challenge study, the output data of the mathematical model, when applied to the RTE product selected for the challenge study, can indicate a higher level of risk than the findings of the challenge study done on the highest risk RTE product, especially if the modeling was done in broth under ideal growing conditions. In fact, the provisions under which the microbiological mathematical models were generated must be suitable for the RTE foods under investigation. Thus, the predicted microbiological behavior from a model should be conservative and overestimate the microbial growth rate of *L. monocytogenes* in the RTE product which underwent the challenge test study. As mentioned above, mathematical models can often be built from results obtained by experiments performed in culture media. The translation to what happens in real life situations, i.e., in "actual" RTE product, needs to be investigated.

10) Would it be acceptable that Food Industry Associations collect data from their members and submit collective validation information, to the relevant regulatory authorities, for a change in the classification of Category 1 type RTE foods into a Category 2A or 2B?

This approach could potentially be acceptable. The Association's submission would be subjected to the same requirements to provide scientific evidence as an independent processor/importer's submission (i.e., submissions need to be product specific with the possibility of grouping, given acceptable supporting rationales). These submissions would undergo the same regulatory review process. Documents to assist regulatory authorities in the evaluation of any validation documentation provided by RTE food processors/importers/associations, as applicable, to ultimately confirm the categorization of RTE products, as per Health Canada's *Policy on Listeria monocytogenes in Ready-to-Eat Foods,* are/will be available (Health Canada, 2011; Health Canada, 2012b (to be published);

Health Canada, 2012c (to be published)). The outcome of any such evaluations could be made public, in agreement with the Association.

11) Why are the applications of post-process lethality treatments, such as high pressure processing (HPP) and surface heat pasteurization, not being recognized as an option for a change in RTE product categorization (i.e., from a Category 1 to a Category 2)?

The growth potential of *L. monocytogenes* in/on a food is the basis for the categorization of RTE foods (i.e., Category 1, 2A or 2B) in Health Canada's *Policy on Listeria monocytogenes in Ready-to-Eat Foods* (Health Canada, 2011). The sole application of HPP or surface heat pasteurization (steam, hot water, radiant oven heating, infrared technology) as a post-process lethality treatment to a RTE food would not affect the ability of that particular food to support the growth of *L. monocytogenes* (i.e., if the growth of *L. monocytogenes* is possible in a specific RTE product, it would also be possible in that same RTE product having received an HPP or surface heat pasteurization treatment). Based on this rationale, no change in food product categorization can be entertained on the sole basis of the application of these post-process lethality treatments. This being said, HPP and surface heat pasteurization treatments could still be effective food safety measures that can be additionally applied to certain RTE foods. With the use of such treatments, the probability of *L. monocytogenes* contamination should be less compared to the same product that has not received a post-process lethality treatment. Therefore, the level of priority for industry control, as well as regulatory inspection and compliance activities, could vary within the same Category of RTE food products, resulting in a lower overall priority for such products.

References

Codex Alimentarius Commission (2009). Proposed Draft Microbiological Criteria for *Listeria monocytogenes* in Ready-to-Eat Foods. - ALINORM 09/32/13 - Appendix II - Step 5. Accessed on October 23, 2012.

Government of Canada (2012). Food and Drug Regulations. Part B (Foods). Division 1. Accessed on October 23, 2012.

Health Canada (2011). Policy on *Listeria monocytogenes* in Ready-to-Eat Foods. Accessed on October 23, 2012.

Health Canada (2012a). Validation of Ready-to-Eat Foods for Changing the Classification of Category 1 into a Category 2A or 2B Food - in relation to Health Canada's *Policy on Listeria monocytogenes in Ready-to-Eat Foods (2011)*.

Health Canada (2012b). Instructions for the Completion of the Validation Process Linked to Health Canada's *Policy on Listeria monocytogenes in Ready-to-Eat Foods (2011)*. To be published (title to be confirmed).

Health Canada (2012c). Data Requirements and Submission Templates for the Validation of Ready-to-Eat Foods for Changing the Classification of a Category 1 into a Category 2A or 2B Food. To be published (title to be confirmed).

Health Canada (2012d). Lists of Permitted Food Additives. Accessed on November 25, 2012.

Health Canada (2012e). Food Additives that May Currently be Used as Class 2 Preservatives to Potentially Control the Growth of *Listeria monocytogenes* in Ready-to-Eat Foods Sold in Canada.

Health Canada (2012f). *Listeria monocytogenes* Challenge Testing of Refrigerated Ready-to-Eat Foods.

Pagotto, F., Trottier, Y-L., Upham, J., and Iugovaz, I. (2011). MFLP-74. Enumeration of *Listeria monocytogenes* in Foods. In: Compendium of Analytical Methods, Vol. 3 Accessed on October 23, 2012.