



November 21, 2016

Biljana Mihajlovic, M.Sc.
Scientific Evaluator, Health Products and Food Branch
Health Canada
Government of Canada
Email: biljana.mihajlovic@hc-sc.gc.ca

SUBJECT: Health Canada's Proposed Microbiological Criteria for Water
in Sealed Containers and Prepackaged Ice

Dear Ms. Mihajlovic:

For several decades, the CBWA has appreciated the support and development of bottled water regulations in Canada that support healthy hydration and exports throughout the world. We look forward to continuing our positive collaboration that has maintained Canada's bottled water preeminent.

CBWA reaffirms our support for the continuing use of coliforms and *E. coli* as the most accurate indicator organism of the microbiological safety of bottled water. As part of our Model Code of Quality we observe a standard of zero presence of either in our products.

CBWA agrees with continuing the existing standard for **coliform**, as it is simply a method of interpretation depending on sample size and dilution. Total coliforms are not health indicator but indicators of suboptimum process control¹.

Total coliforms are a group of bacteria that are naturally found on plants and in soils, water, and in the intestines of humans and warm-blooded animals. Because total coliforms are widespread in the environment, they can be used as one of the many operational tools to determine the efficacy of a drinking water treatment system².

The bottled water industry in Canada has multi-barrier process controls and verification of each batch of bottled water produced.

CBWA agrees with continuing the existing standard for **E. Coli** since it is based on sound and widely recognized science, and in line with the current "*Guidelines for Canadian Drinking Water Quality*". In addition, the proposed *E. Coli* standard is in line with the current Codex Standard for bottled drinking water which refers to the World Health Organization's (WHO) drinking water guidelines³.

However, we do not support adopting limits or testing requirements of either Aerobic Colony Counts (ACC --also referred to "Heterotrophic Plate Counts" – HPC) or *Pseudomonas aeruginosa*.

AEROBIC COLONY COUNTS (ACC)

While CBWA agrees that ACC (also known as Heterotrophic Plate Count, or HPC) can be, under certain circumstances, a helpful GMP indicator in the case of bottled water in the taste and odor realm, we affirm that scientific consensus is clearly established that HPC/ACC should not be a regulatory tool.

We concur with scientists who have long established and strongly recognize that the measurement of HPC/ACC at market level has no relation with public health or the safety of the product. Bottled water is not sold as sterile. Any residual microflora is not indicative or accurate as an indicator of bottled water quality or safety. Any presence of HPC/ACC in "market level" samples does not correlate to unsafe or "out of compliance" product.

¹ Allen, M.J., and S.C. Edberg. (1997) *The public health significance of bacterial indicators in drinking water*. In: *Coliforms and E. coli*, D. Kay and C. Fricker (eds), *The Royal Society of Chemistry*, pp 176-181

² http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/water-eau/coliforms-coliformes/coliforms-coliformes-eng.pdf

³ Edberg, S.C., E.W. Rice, R.J. Karlin, and M.J. Allen. (2000) *Escherichia coli: the best biological drinking water indicator for public health protection*. *Journal of Applied Microbiology* 88:106S-116S, 2000.

While it may be representative to use HPC/ACC to evaluate the quality of “distribution line and reservoirs” for municipal drinking water, such concerns are not applicable to bottled water products. This is because the presence of HPC/ACC in bottled water at “market level” is only reflective of the innocuous and normal growth of the harmless residual micro-flora present at the time of bottling. The relevant health standard for “market level” bottled water products is the absence of *E. coli*.

The bottled water industry, working with national governments, have adopted methods of testing for *E. coli* that eliminate concern over the interference of HPC/ACC with the sensitivity of the methods used for the detection of *E. coli*.

Concerns over any potential link between the presence of HPC/ACC and an increased exposure to large numbers of opportunistic pathogens have been addressed and determined by WHO to not be a threat to public health. We refer you to the report of the *World Health Organization, April 2002, Expert Meeting on Heterotrophic Plate Count Measurement in Drinking Water Safety Management*. The most relevant quote about HPC from the document is:

“There is no evidence that HPC values alone directly relate to health risk either from epidemiological studies or from correlation with occurrence of waterborne pathogens”

Additionally, the same report states:

“There are increasing numbers of persons who are immunocompromised to various degrees and types living in communities, including some patients discharged to 'home care'. Normal "drinking water" is not always suitable for all such individuals for all uses (e.g. wound irrigation). This relates to water safety in general and not growth or HPC organisms in particular. Public health authorities should provide advice to at-risk groups in general and by practitioners responsible for individuals discharged to home care.

Where the drinking water supply meets international norms such as WHO Guidelines for Drinking Water Quality, only those people with severe changes from normal as determined by their physicians or medical agencies (e.g. an absolute neutrophil count < 500/ μ l are considered immunosuppressed to the extent that they may require specially processed drinking water.” (emphasis added)

Therefore, we submit that the presence of HPC/ACC in bottled water is not relevant to the public health for the general market to whom bottled water is marketed.

CBWA notes that the Canadian Drinking Water Guidelines clearly indicate that "No MAC is specified for heterotrophic plate count (HPC/ACC) bacteria in water supplied by public, semipublic, or private drinking water systems". The basis for the above is explained in a Guideline Technical Document entitled "Bacterial Waterborne Pathogens - Current and Emerging Organisms of Concern"⁴.

Specifically pages 2 & 3:

“The heterotrophic plate count (HPC) test is another method for monitoring the overall bacteriological quality of drinking water. HPC results are not an indicator of water safety and, as such, should not be used as an indicator of adverse human health effects. Each system will have a certain baseline HPC level and range, depending on site-specific characteristics: increases in concentrations above baseline levels should be corrected.” (emphasis added)

Summary: Based on the above, CBWA respectfully asks that Health Canada remove from consideration the establishment of a microbiological guideline pertaining to Aerobic Colony Count (ACC) in bottled water.

⁴ Prepared by the Federal-Provincial-Territorial Committee on Drinking Water of the Federal-Provincial-Territorial Committee on Health and the Environment, Health Canada, Ottawa, Ontario, February 2006, http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/water-eau/pathogens-pathogenes/pathogenes-pathogenes-eng.pdf

PSEUDOMONAS AERUGINOSA

CBWA believes that Health Canada’s current guideline proposals are not in line with the “*Making it Clear*” objectives. CBWA does not support a guideline for *Pseudomonas aeruginosa* as outlined in the table below.

Parameter (per 100 ml)	Standard				Sampling ² Class	Health Risk
	n	c	m	M		
<i>Pseudomonas aeruginosa</i>	5	0	0/100mL	-	2	3

Here are our concerns:

1. Harmonization of Regulations

Inclusion for *Pseudomonas aeruginosa* would not harmonize Canadian regulations with other governments and organizations: U.S.A., World Health Organization, Codex Alimentarius Commission⁵:

- CBWA notes that neither the US regulations nor the World Health Organization have any standard or guideline for *Pseudomonas aeruginosa* in bottled water. This decision not to regulate came from both organizations after much study and discussions.
- While the *Codex Alimentarius* standard for "natural mineral water" contains a requirement for *Pseudomonas aeruginosa*, such requirement does not exist in the *Codex Alimentarius* standard for "bottled water other than natural mineral water"⁶ that is applicable to most bottled water sold in Canada. We believe applying a narrow *Codex* standard applicable only to Natural Mineral water to all types of bottled waters in Canada would be inconsistent with CODEX and our closest export market, the United States.
- It must be emphasized that even when *Pseudomonas aeruginosa* is mentioned in any regulation, it is as an aesthetic (e.g., taste and odor) but not as a health risk.
- CBWA notes that the most recent version of the Guidelines for Canadian Drinking Water Quality does not include any standard or guideline for *Pseudomonas aeruginosa*.
- We also point to the Federal/Provincial/Territorial Drinking Water Committee chaired by Health Canada that has currently no plan to evaluate *Pseudomonas aeruginosa* for inclusion in the "*Guidelines for Canadian Drinking Water Quality*".
- The Canadian Drinking Water Guidelines do not mention *Pseudomonas aeruginosa* as a priority or as an emerging pathogen⁷. Including a guideline for *Pseudomonas aeruginosa* for bottled water will result in a contradiction with the Guidelines for Canadian Drinking Water Quality.

2. Testing Methods

Regulating *Pseudomonas aeruginosa* will not improve public health because the test methods lend themselves to false positives which may generate insecurity and inhibit trade.

⁵ From the document entitled “Making It Clear”, published by Health Canada: Why update the regulations?

⁶ *General Standard for Bottled /Packaged drinking waters (other than Natural Mineral Water), Codex STAN 227-2001 and the associated GMP code: Code of Hygienic Practice for Bottled /Packaged drinking waters (other than Natural Mineral Water), CAC/RCP 48-2001*

⁷ *Guidance on Waterborne Bacterial Pathogens – 2013*, [http://healthy Canadaians.gc.ca/publications/healthy-living-vie-saine/water-pathogens-pathogenes-eau/alt/water-pathogens-pathogenes-eau-eng.pdf](http://healthy Canadians.gc.ca/publications/healthy-living-vie-saine/water-pathogens-pathogenes-eau/alt/water-pathogens-pathogenes-eau-eng.pdf)

3. Protection of the Immunocompromised Population

CBWA notes that Health Canada's document entitled "Standards and Guidelines for Microbiological Safety of Food — An Interpretive Summary"⁸ dated April 2008 classifies *Pseudomonas aeruginosa* as a Health Risk Level 3. Health Canada's own definition of a Health Risk Level 3 is that there exists no probable health consequence resulting from the ingestion of food containing this micro-organism; we quote the referenced document: "*Health Risk 3 (HR3): This represents a situation where there is a reasonable probability that the consumption/exposure to a food is not likely to result in any adverse health consequence.*"

The same document does refer to the protection of immunocompromised individuals in the case of some foods but never in the case of *Pseudomonas aeruginosa*".

This same document when referring to the protection of immunocompromised individuals always refers to raising a Health Risk Level 2 to a Health Risk 1, never from a Health Risk Level 3 to a Health Risk 2: but, Health Canada's Rationale dated January 7, 2009 announces that the latter event would apply but only in the case of *Pseudomonas aeruginosa* and only for one food, bottled water.

This same document associates a 2-class sampling plan to the *Pseudomonas aeruginosa* guideline which equates to a zero tolerance criteria. Surprisingly, this means that bottled water is the only food type having Health Risk level 3 guidelines (*Pseudomonas aeruginosa* and *Aeromonas hydrophila*) associated with a zero tolerance criteria (2-class sampling plan); this is odd since this situation does not prevail for other foods, not even food for infants. Health Canada's Rationale dated January 7, 2009 explains that the zero tolerance criteria are justified in the case of *Pseudomonas aeruginosa* because the presence of this micro-organism at low levels can reach high levels during storage; but this event is equally possible for some, if not all, Health Risk 3 guidelines respecting other foods.

CBWA request further explanation as to the scientific basis of the concerns expressed relative to the protection of immunocompromised individuals in relation to a potential guideline for *Pseudomonas aeruginosa* while considering the classification at a Health Risk Level 3 and for one food only, bottled water and associated with a zero tolerance criteria.

4. Lack of Scientific Information to Support *Pseudomonas aeruginosa*

CBWA is not aware of any scientific information that would support setting a guideline for *Pseudomonas aeruginosa* in bottled water.

The Federal/Provincial/Territorial Drinking Water Committee chaired by Health Canada does not currently classify *Pseudomonas aeruginosa* within the priority emerging pathogens.

The World Health Organization (WHO) has performed extensive reviews and has found no need for a requirement on *Pseudomonas aeruginosa* in drinking water.

The US FDA, in their most recent adoption of Preventive Controls chose to leave the microbiological requirements for bottled water unchanged.

Summary: CBWA is not aware of any scientific information supporting a guideline for *Pseudomonas aeruginosa* in bottled water.

5. Inspection Tool/Indicator

In addition, CBWA believes that the risk of inadequate characterization of *Pseudomonas aeruginosa* in "in market" samples i.e. confusion between *Pseudomonas aeruginosa* and *Pseudomonas sp.* has the high potential to lead to unwarranted and inappropriate regulatory action.

Summary: *Pseudomonas aeruginosa* is not a definitive tool for "inspection purposes" at market level. While CBWA agrees that *Pseudomonas aeruginosa* is not present in ground water not under surface water influence, it is not an accurate indicator of "serious contamination by pollution." Specifically, CBWA maintains that the appropriate indicators of fecal contamination are E coli and coliforms.

⁸ Official Methods for the Microbiological Analysis of Foods, <http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/volume1-eng.php>



CONCLUSION

CBWA respectfully asks that Health Canada remove from consideration establishing of a microbiological guideline pertaining to Aerobic Colony Count (ACC) and *Pseudomonas aeruginosa* in bottled water.

CBWA maintains that the appropriate indicators of fecal and environmental contaminations are E coli and coliforms. The citations and evidence we have referenced support Health Canada in leaving the microbiological limits unchanged for bottled water.

Sincerely,

A handwritten signature in black ink, appearing to read "Lawrence Henderson", written over a horizontal line.

Dr. Lawrence Henderson
CBWA Technical Committee Co-Chairman

A handwritten signature in black ink, appearing to read "John Fudge", written over a horizontal line.

John Fudge
CBWA Technical Committee Co-Chairman

A handwritten signature in black ink, appearing to read "John Worsnop", written over a horizontal line.

John Worsnop
CBWA Chairman of the Board

A handwritten signature in black ink, appearing to read "Elizabeth Griswold", written over a horizontal line.

Elizabeth Griswold
CBWA Executive Director

Canadian Bottled Water Association

7357 Woodbine Avenue
Suite 617
Markham, Ontario
L3R 6L3
Telephone: (416) 618-1763
Email: griswold@cbwa.ca

cc: CBWA Board of Directors
CBWA Technical Committee



ABOUT CBWA

The CBWA is a trade association consisting of 60 bottler and supplier members representing the bottled water industry in Canada. The CBWA has developed its own Bottled Water Model Code (Code of Standards) to which all member companies must comply. CBWA bottler members are also subject to annual third-party inspections to ensure adherence to the CBWA Bottled Water Model Code. Our trade association believes in applying the principals of good sound data-supported science.

The CBWA also works closely with other organizations throughout the world to ensure that the industry is at the forefront of industry related science and food safety. The relationships are:

- International Council of Bottled Water Associations
- International Bottled Water Association
- Quebec Bottled Water Association
- European Federation of Bottled Waters
- Australian Bottled Water Institute
- China Beverage Industry Association
- Latin American Bottled Water Association
- Associação Brasileira da Industria de Águas Minerais
- NSF International
- World Health Organization (WHO)
- Codex Alimentarius (NGO: ICBWA)
- Drinking Water Research Foundation