Health Canada Santé Canada

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

Bureau of Chemical Safety

Food Directorate

Bureau d'innocuité des produits chimiques

Direction des aliments

Guidelines for Incidental Additive Submissions - Guideline No. 4

Revised: June 1, 2010

Our Mission

To ensure chemicals are not present in foods at levels that may cause adverse health effects to Canadians.

Notre Mission

Veiller à ce que les produits chimiques ne soient pas présents dans les aliments à des niveaux pouvant entraîner des effets néfastes sur la santé des canadiennes et des canadiens.

Canada

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1. Purpose

These guidelines have been prepared to assist manufacturers in the preparation of submissions to the Bureau of Chemical Safety (BCS), Food Directorate, Health Products and Food Branch, Health Canada, respecting the acceptability of incidental additive products intended for use in food processing plants, under the authority of the ***Food and Drugs Act and Regulations***.

The following information is provided for guidance purposes only in order to facilitate the evaluation of incidental additives for use in food processing establishments.

2. Regulations of Incidental Additives under the Food and Drugs Act

While not defined under the *Food and Drugs Act* (FDA), incidental additives may be regarded, for administrative purposes, as those substances which are used in food processing plants and which may potentially become adventitious residues in foods. They can include products that are regulated as drugs or cosmetics under *Food and Drug Regulations* (FDR) but specifically exclude food additives and food packaging materials.

With the exception of certain products, which are regulated under specific regulations, such as disinfectants, cosmetics, natural health products, etc., there are no sections of the *Food and Drugs Act* and *Regulations,* which specifically require the pre-clearance of incidental additives for use in food processing plants. However, if these substances are misused, resulting in contamination of foods thereby creating a potential health risk to consumers, such an action would be considered to be in violation of Section 4(a) of the Act, which states, "**No person shall sell an article of food that has in or upon it any poisonous or harmful substance**"

As an example, the following products are considered to be incidental additives when they are used in food processing establishments:

. Sanitizers
. Disinfectants (sporicides, bactericides, virucides, fungicides)
. Cleaning agents for food equipment and food handling areas (including bacterial enzyme, drain, membrane and other cleaners)
. Detergents (dish and laundry)
. Hand products (cleaners, antiseptic, lotions, barrier creams, etc.)
. Odour control agents
. Boiler water treatment compounds
. Cooling and closed re-circulating water treatment compounds
. Potable or processing water treatment compounds
. Lubricants, release agents, solvents and related compounds
. Antifoaming agents for incidental use with food contact
. Heat exchangers/refrigerants
. Air treatment compounds
. Etc.

3. Working with other federal governmental organizations

Health Canada ensures that products for use in food premises are safe and effective when used according to the manufacturer instructions. Upon request, the Bureau of Chemical Safety (BCS) assesses the safety of the intended incidental additives that may come in direct contact with food in food processing establishments. However, while pre-market assessments of incidental additives products can be done on a voluntary basis by the BCS, under different use conditions, pre-market clearance may be a mandatory requirement under other legislations as presented below. Therefore, petitioners are required to contact the following governmental entities for the pre-clearance of their products, according to their respective intended application before submitting applications to the BCS. Please note that their contact information is presented in reference in **Appendix I.**

3.1 Pest Management Regulatory Agency (PMRA)

Petitioners wishing to use pesticides (sporicide, bactericide, virucide, fungicide, etc.) on non-food contact surfaces in food processing establishments, are also required to request an evaluation of safety (to humans, environment, etc.) and the efficacy of their product from the Pest Management Regulatory Agency (PMRA) of Health Canada before submitting their products to the Bureau of Chemical Safety.

Pesticides, sold or used in Canada, are regulated nationally under the *Pest Control Products Act* (PCPA). The PMRA is responsible for administering this legislation, registering pest control products, re-evaluating registered products and setting pesticide maximum residue limits (MRLs) on food. For more information about PMRA of Health Canada, you can visit the PMRA website at http://www.hc-sc.gc.ca/cps-spc/pest/index-eng.php

3.2 Therapeutic Products Directorate (TPD) and Natural Health Products Directorate (NHPD)

3.2.1 Disinfectants

Any disinfectant product (sporicide, bactericide, virucide and fungicide) intended to be used in food premises and having a therapeutic effect (preventing or controlling diseases) is considered to be a **drug**. For such products companies must contact the Submission and Information Policy Division of the Bureau of Policy and Coordination of the Therapeutic Products Directorate of Health Canada for Drug Identification Number (DIN) registration of their product. For more information on disinfectant drugs guidelines, you can visit the TPD website at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/disinfect-desinfect/disinf_desinf-eng.php

3.2.2 Human-use Antiseptics Products

Any human-use antiseptic product intended to be used in **food premises** and having a therapeutic effect (preventing or controlling diseases by reduction of organisms on skin) is considered to be a drug under the *Food and Drugs Act*.

The Bureau of Chemical Safety works in partnership with the Natural Health Products Directorate (NHPD) and the Therapeutic Products Directorate (TPD) to ensure the safety and efficacy of antiseptic products intended to be used in food processing establishments. The NHPD and TPD are responsible for the mandatory pre-market assessment of human-use antiseptic products.

Hence, for products containing ingredients that meet the definition of Schedule 1 of the *Natural Health Products Regulations (NHPR),* sponsors are required to submit an application for a Natural Product Number (NPN) with the Natural Health Products Directorate as per Section 5 of the Natural Health Products Regulations (*NHPR)*. Sponsors of antiseptic products for human use containing ingredients other than those that meet the definition of Schedule 1 of the *NHPR* are required to file an application for a Drug Identification Number (DIN) with the Therapeutic Products Directorate as per Part C, Section C.01.014 of the *Food and Drug Regulations*. For more information on Human-Use Antiseptic Drugs Guidance, you can visit the TPD website at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/antiseptic_guide_ld-eng.php

3.3. Healthy Environments and Consumer Safety Branch (HECS)

3.3.1 Cosmetics

Petitioners of cosmetic products (hand cleansers, lotions, etc.) intended for use in **food premises** should also contact the Cosmetics Division of the Consumer Product Safety Directorate of the Healthy Environments and Consumer Safety Branch of Health Canada to provide a cosmetic notification form within 10 days of first sale of the product in Canada. These cosmetics must meet all applicable requirements under the *Food and Drugs Act*, and the *Cosmetic Regulations* to ensure that they are notified to Health Canada, properly labelled and safe to use and do not pose any health risk to consumers.

The Cosmetic Regulations of the *Food and Drugs Act* require that cosmetics sold in Canada must be manufactured, prepared, preserved, packed and stored under sanitary conditions. For more information on requirements for cosmetics, you can visit the following web site at www.healthcanada.gc.ca/cosmetics

3.3.2 Process Water treatment compounds

Process water is potable water which is used in food processing plants and which may or may not directly contact food items and/or may be incorporated into food products (e.g., water used for general cleaning, cooking, blanching, fuming, washing foods, etc).

The chemical ingredients used in the formulation of treatment compounds for water intended for food contact application should meet the specifications set out by the ***Food Chemicals Codex*** in order to avoid or minimize unwanted impurities and this application is assessed by the Food Additive and Contaminants Section of the Bureau of Chemical Safety.

The process water so treated must meet standards set out in the latest Guidelines for Canadian Drinking Water Quality. Drinking water is primarily an area of provincial and territorial jurisdiction in Canada, but Health Canada's role is critical in all Canadian jurisdictions. Health Canada's Water Air and Climate Change Bureau works in collaboration with the provinces and territories to develop the *Guidelines for Canadian Drinking Water Quality*. Health Canada provides scientific expertise and national leadership on issues related to drinking water safety, whereas provincial and territorial governments are responsible for establishing regulations and requirements regarding the quality of drinking water. Provinces and territories use the guidelines as a basis to develop their own enforceable requirements for drinking water quality, either directly by reference or through their own regulatory or licensing process. For products used in the treatment of drinking water, Health Canada recommends the use of products that have been certified as meeting the appropriate health-based standard by an accredited certification body. A complete list of accredited certification bodies can be found on the website of the accreditation organization, the Standards Council of Canada, at www.scc.ca

3.3.3 Air treatment compounds

Petitioners wishing to use air treatments such as ozone, hydrogen peroxide or other gaseous antimicrobial agents in food processing establishments, are required to contact the Pest Management Regulatory Agency (PMRA) to inquire about the safety and efficacy of their products as antimicrobials before submitted them to the Bureau of Chemical Safety.

If the air treatment compounds are intended to be used in food holding premises where unpackaged fresh food (e.g. fruits and vegetables) or unpackaged meat are present then petitioners are required to contact the Food Additives and Contaminants Section of the Chemical Health Hazard Assessment Division, Bureau of Chemical Safety to inquire about the safety of these treatments to food.

The use of air treatment compounds in food processing establishment also requires the consideration of health risks to employees. Petitioners should contact their province where the facility is located to determine any related occupational health and safety requirements.

3.4 Incidental Additives Used in Federally Registered Food Establishments

In the case of products intended for use in federally registered food establishments operating under other Acts and Regulations that are administered by the Canadian Food Inspection Agency (CFIA), manufacturers and suppliers of those products should be aware that as of July 2, 2014, the CFIA no longer requires industry to pre-register non-food chemicals in the *Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products* . However, operators of federally registered food establishments still remain responsible for using products that are safe and suitable for their intended use and that meet all regulatory requirements. For more information on CFIA's requirements, please visit the Agency's website.

4. Submissions and No-objection Letters (NOL)

Under the authority of the provisions of Section 4(a) of the *Food and Drugs Act*, and with the express intent of assisting food manufacturers in averting violations thereof, the Bureau of Chemical Safety (BCS) evaluates on a case-by-case basis the acceptability of various incidental additive products **voluntarily** submitted by manufacturers wishing to supply their products to food processors. Requests for such evaluations are called **Submissions**.

For products considered acceptable by the BCS, **No-Objection Letters** are issued, which may then be presented by the product manufacturers to prospective food processor customers. Letters expressing favourable BCS opinions are called "No Objection Letters"

A no-objection letter does not constitute an approval of the product under the *Food and Drugs Act and Regulations*. It is simply an opinion expressed by the BCS on the acceptability of the product, based on the information available at the time of its evaluation. Issuance of a no-objection letter does not relieve the product user (food processor) from their responsibilities relating to Section 4(a) of the Act. There is no fee attached to obtaining a no objection letter.

A no objection letter has no expiry date. It is considered valid as long as the composition, the intended use and the labelling content remain as described in the initial submission's application. Petitioners are responsible for notifying the BCS of any changes that may affect the validity of the no objection status. However, the BCS reserves the right to rescind the no objection status of any given product should information come to light showing that its use may potentially pose a health risk to consumers.

5. Information Requirements[1] for Incidental Additive Submissions

In order to evaluate the safety of use of incidental additive products in food plants, BCS requires that petitioners submit the following information. All such information is held in confidence and is used for evaluation purposes only. These are initial requirements only. Evaluation of submitted information will dictate if any clarification and/or additional information are required.

5.1. Application/Checklist Form for Incidental Additive Submissions

Please submit a completed Application/Checklist Form (Appendix II) to include the following:

(a) The product trade name and code number (if applicable) under which the product will be marketed in Canada;

(b) The intended end-use and technical function of the product with an indication if there is an incidental food contact in food plants. For example: lubricant with incidental food contact, lubricant with no food contact, boiler water additive where the water or the steam produced may come in contact with foods or will not come in contact with food products, cooling re-circulating water treatment, cleaner, sanitizer/disinfectant with or without a

[1] Use of the term "requirement" is not intended to mean required by law.

potable water rinse after the treatment, hand sanitizer with or without a potable water rinse, etc.

(c) Full disclosure of the formulation of the product including chemical and bacterial (if applicable) ingredients. This information should be in the form of a complete quantitative list of all ingredients used in its manufacture (pre-reaction formula) and in the final product's formulation (post-reaction formula, where applicable), taking into account that the percentage of components of the full formulation should add up to 100%. Each chemical ingredient should be clearly identified by its proper chemical name, the CAS number (Chemical Abstracts Service) registry number, trade name and supplier. Each bacterial ingredient should be identified by the scientific name of organism (i.e., *Genus species*) and source/origin number.

(d) Copy of the label or draft label of the product bearing information such as a descriptive name of the product and a statement denoting its technical function, a listing of the major ingredients (active and non-active), direction for use including dilution factor, a potable water rinse (if applicable), the use of the product in food plants and the name and address of the manufacturer or distributor including postal code (see Part 5.3).

5.2. Additional Information

(a) The regulatory references of compliance with other government agencies (e.g., US Code of Federal Regulation (21CFR), the European Union (EU) Regulations on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Domestic Substances List (DSL), National Sanitation Foundation (NSF) International, Food Contact Premarket Notification (FCN), Material Safety Data Sheets (MSDS), or other certification bodies will be useful. Please note that they are not sufficient for assessment purposes.

(b) **For boiler water additives**, where steam carryover may contact foods: the condition of use of the boiler water (i.e., temperature, pressure, pH, number of cycles, etc.) and concentration levels of volatile ingredients (estimated or measured) and/or their breakdown products under normal boiler operating conditions when the steam carryover contacts food are required.

(c) The residual amount of the product that will remain on food contact surfaces after application (e.g., **sanitizers, disinfectants, lubricants with incidental food contact,** etc.) when precautionary safety measures, such as potable water rinse and thorough drainage of excess of the product, are undertaken, or the quantity of the product that may be incidentally transferred to foods and/or its worst-case Estimated Dietary Intake resulting from the use of the product. This information should be in the form of actual analytical data or theoretical estimates based on the proposed use level of the product. Food Contact Notification (FCN) and/or Threshold of Regulation calculation and documentation are useful.

(d) Any information that is used to estimate the dietary exposure such as market penetration of the product, type of food involved (if known) where the product is intended to be used in food plants, etc.

(e) **Toxicological data**. The submission for new formulations or uses that significantly increase potential exposures should include all unpublished and published studies relevant to the safety assessment of the incidental additive. In the case of unpublished studies, full reports complete with the primary data, should be included with the submission, when available. Sufficient details should also be provided to ascertain that study protocols conform with the testing guidelines published by the Organization for Economic Co-operation and Development and were conducted according to good laboratory practice.

The toxicological data submitted must be sufficient to demonstrate the safety of the incidental additive under the proposed conditions of use. In the case of inherently toxic incidental additives such as sanitizers and disinfectants, a complete set of toxicological studies would normally be required, unless the formulation in question has been previously cleared by Health Canada (i.e., PMRA). This would include acute, repeated-dose and chronic oral toxicity/ carcinogenicity studies, reproductive and development toxicity studies as well as genotoxicity studies. Special studies on metabolism and pharmacokinetics or to examine specific types of toxic effects may also be required to complete the safety assessment.

(f) **Microbiological data** is required to support the efficacy and safety of: i) agents used to inhibit or inactivate food-borne pathogens (bacteria, viruses, yeast, molds, parasites) and ii) new and/or novel food formulations, additives, ingredients (including antimicrobial agents, sanitizers, disinfectants, rinses, washes, etc.). The submission for new and/or novel food formulations, additives, ingredients, or processing aids should include adequate data, published or unpublished, with details on any bacterial ingredients used in the formulation(s) which support the safety and efficacy of the product of interest when used under the same conditions.

Please be advised that illegible submissions will be immediately returned to petitioners without further consideration. It is strongly urged that all submissions be typed for clarity.

Please note that, under Section 20 (1) (b) of the *Access to Information Act*, the information submitted above will be used in confidence for our evaluation purposes of your submission only and will not be shared with any third party unless advised otherwise by your company and/or your supplier(s) with a written notice.

5.3. Labelling Guide for incidental additive products used in food processing establishments

A label or draft label bearing the following information:

(a) Descriptive name of the product and, immediately adjacent to the brand name, a statement prominently shown and denoting the function and specific intended use of the product in food processing plants.

(b) A list of major ingredients; if there is an active ingredients list on the label and the ingredients with high concentrations in the product are non-active, they should be declared under a separate heading such as CONTAINS or INGREDIENTS.

(c) Name and address of the manufacturer or distributor including postal code.

(d) Direction for use of the product in food premises including dilutions factor(s) (e.g. X ml of the product per YL of water), the amount of time of contact with surfaces under treatment, type of surfaces (non-porous, porous, food contact surfaces, floors, etc.), where applicable, or a statement to the effect such as "This product is to be used as recommended by a responsible company representative", and any precautionary statements necessary to avoid contamination of food as follows:

- "Avoid contamination of food during application and storage" or "Do not contaminate food during the use and storage of the product" for cleaners, sanitizers, deodorizers, lubricants with no food contact, and others.
- Maximum concentrations of active ingredients (e.g. quaternary ammonium compounds, chlorine, iodophors, anionic surfactants, hydrogen peroxide, peracetic acid, etc. concentrations in non-rinse sanitizers (see Table 1), or amines concentrations in the steam produced (see Table 2) in a boiler water systems, and restrictions (e.g. amines containing boiler water additives with milk products (see Section 7).
- "Not for use in Potable Water systems" for certain water treatment compounds.
- "Use under well ventilated conditions" for aerosols and solvents.
- A potable water rinse statement for food contact surfaces.
- "Do not add directly to food" for lubricants with incidental food contact.

(e) Food premises use statement such as "For Food Plants and Other Industrial Use Only".

(f) A net content.

(g) **Unacceptable Claims:** The statements "non-toxic" and "safe" when applied to handling of a product are not acceptable on labels, as they are considered to be misleading at the user level and may suggest that the product can be added directly to food. The claims "Approved by Health Canada" or "Approved by CFIA" are also not acceptable on the labels.

Note: Additional labelling may be required for disinfectants and human-use antiseptic products as per the *Food and Drug Regulations* and the *Natural Health Products Regulations*.

6. The use of cleaning and sanitizing agents in food processing establishments

The use of cleaning agents on food contact surfaces should at all times be followed by a thorough rinse with potable water. It is recommended that cleaners, which cannot be effectively removed by rinsing with potable water, not be used on food contact surfaces. If, however, such a cleaner is required then its use should be followed by a secondary cleaning step with a detergent-type product previously issued a LONO by Health Canada. The use of disinfectants and sanitizing agents on food contact surfaces also is followed with a potable water rinse. In order to be ensured of an optimum sanitizing effect, this final water rinse may be delayed until the sanitizing effect has been reached.

In certain circumstances, it is recognised that the use of a final sanitizing rinse without a subsequent potable water rinse is preferable. The following chemical substances (see Table 1) used in sanitizers without potable water rinse will be considered to be acceptable for this purpose:

Table 1. Maximum concentrations of some chemical substances used in the formulation of sanitizers on food contact surfaces in food premises.

N	Chemical Substance	Maximum Concentrations of Chemical Substances
1	Chlorine releasing compounds, e.g., hypochlorites	200 ppm of available chlorine
2	Quaternary ammonium chlorides	200 ppm of available active quaternary ammonium compounds
3	Iodophors	25 ppm, expressed as titratable iodine
4	Hydrogen peroxide, peracetic acid	1100 ppm of hydrogen peroxide acetic acid solutions

Other types of sanitizing agents, evaluated on case-by-case basis, may also be considered acceptable for use on food contact surfaces without potable water rinse. The acceptability of new and ingredients at higher concentration, and ingredients of concern used in the formulation of sanitizers will be subject to a new assessment.

The use of a sanitizing agent on food contact surfaces without a potable water rinse is subject to the following additional requirements:

a) the food contact surfaces should be hard and non-porous in nature;

b) the food contact surfaces should be previously cleaned and rinsed with potable water prior to sanitizing; and

c) the surfaces should be thoroughly drained to remove excess residues of the sanitizing agent prior to re-use of the surfaces or equipments in food processing operations.

Products should not be used without a potable water rinse on porous surfaces or on equipment, which is constructed in such a manner that effective drainage is not possible.

It should be noted that for sanitizers/disinfectants used on food contact surfaces without a potable water rinse, BCS will require additional information such as the residual amount of the product

that will remain on food contact surfaces after application or the quantity of the product that may be incidentally transferred to foods and/or its worst-case Estimated Dietary Intake resulting from the use of the product (see Part 5.2 (c) and (d)).

Please also note that the dilution factor(s) and maximum concentrations of chemical substances used as sanitizing agents specified above should be presented on the labels of the products under "Direction for use" (see Section 5.3 (d)).

7. The use of boiler water additives in food processing establishments

Boiler water additives (BWA), which are intended for use in food premises, are evaluated on a case-by-case basis, taking into consideration the merits of each individual submission based on its chemical formulation, recommended conditions for use, including dosage rates and product labelling. Concentration limitations have been set for the following chemicals used in boiler water systems (see Table 2):

Table 2. Maximum concentrations of additives used in boiler water systems.

N	Boiler Water Additives	Maximum Concentration of Additives
1	2-amino-2-methyl-1-propanol	15 ppm in the steam
2	Cyclohexylamine	10 ppm in the steam
3	Diethylaminoethanol	15 ppm in the steam
4	Morpholine	10 ppm in the steam
5	Octadecylamine	3 ppm in the steam
6	N,N-bis (2-hydroxyethyl) alkyl (C12-C18) amine derived from coconut oil	2 ppm in the steam
7	Trisodium nitrilotriacetate	5 ppm in boiler feed water

Steam treated with the above chemicals is not considered to be acceptable for use in the processing of milk and milk products. There is no objection to the use of blends of chemicals listed above provided that the **total amine concentration of steam does not exceed 25 ppm**.

It should be noted that the detailed direction for use, the maximum concentrations of additives used in boiler water systems specified above, and restrictions statements (e.g. the steam so treated does not contact milk or other dairy products) should be presented on the labels of the products under "Direction for use" (see Section 5.3 (d)).

Certain other non-volatile chemical substances are commonly used for the treatment of boiler water in food premises. Although no specific maximum concentrations have been established for these substances, their acceptability for a particular use should be determined only after an individual evaluation based on the information submitted by the manufacturer.

The use of boiler water additives in food premises is subject to the following requirements:

a) the amount of the product used is not in excess of that required for its functional purpose; and

b) the amount of steam in contact with food does not exceed that required to produce the intended effect in or on the food.

Please note that to promote handling of preparations containing sodium sulfite, sodium bisulfite, sodium metabisulfite, and sodium nitrite in a manner as to prevent their use in meat products, such preparations must be adequately decharacterized. The preparation is considered to be acceptable if the sulfite, bisulfite, metabisulfite and nitrite ions present are decharacterized by 33% of its weight of sodium hydroxide; by 50% of its weight of trisodium phosphate, by 100% of its weight of sodium carbonate; or if the preparation contains not less than 5% percent tannin, lignin, sodium lignosulfonate, or sodium humate.

Please note that for boiler water additives, where steam carryover may contact foods, BCS will require additional information such as the condition of use of the boiler water (i.e. temperature, pressure, pH, number of cycles, etc) and concentration levels of volatile ingredients (estimated or measured) and/or their breakdown products under normal boiler operating conditions when the steam carryover contacts food are required (see Part 5.2 (b)).

8. Exempted Products

The following is a list of exempted product categories for which it is not necessary to seek a "no objection letter" for use in food processing establishments. Submissions received for products, which fall in these categories will not be evaluated by the Bureau of Chemical Safety:

(i) Products used in offices or similar non-food processing areas. Examples: furniture waxes and polishes, upholstery or rug shampoos or cleaners, toilet bowl and urinal cleaners.

(ii) Products used in cafeterias or lunchrooms. Examples: rinse additives, tarnish removers.

(iii) Products used in heating systems. Examples: fuel additives, fire-box or cleaners.

(iv) Products used outdoors only for sewage or waste water systems. Examples: grease solvents for traps or lines, odour control compounds in lagoons or holding ponds.

(v) Products used in cooling towers or evaporative condensers located outside of food processing facilities. Examples: corrosion inhibitors, algaecides, (must bear P.C.P. registration number) and cleaning compounds.

(vi) Products used on the exterior of buildings or adjacent areas. Examples: tar, asphalt or mortar solvents, surface finishing materials, de-icing compounds.

(vii) Products used for the cleaning or maintenance of the exterior of food processing plant use vehicles. Examples: car washes or shampoos, tire cleaners, body brighteners.

(viii) Products used on non-food contact equipment or machinery in electrical rooms, machine shops, etc. outside of food handling areas.

(ix) In-plant laundry products used on work apparel and other material, which do not directly contact food in their applications.

(x) Cleaners, deodorizers and related products used in non-food handling areas in the plant.

(xi) Products for treating closed steam lines, cooling water systems where the treated steam/water will not contact food or food contact surfaces.

(xii) Cosmetic products (Health Canada's Cosmetics Division must be notified) used by employees at the end of their working shift or by employees not engaged in food handling application.

Although these exempted products are not subject to the review of the Bureau of Chemical Safety, it is expected that:

(a) The products will be properly labelled.

(b) The products will not be stored in food handling areas.

(c) The use of the products will not directly or indirectly contaminate food products during application and storage.

Appendix I: Contact Information

Governmental Agency	Name, Title, Division, Address, Phone/Fax Numbers
Bureau of Chemical Safety, (BCS) **Food Directorate** **Food Packaging Materials and Incidental Additives Section**	Manager Food Packaging Materials & Incidental Additives Section Chemical Health Hazard Assessment Division Health Canada 251 Sir Frederick Banting Driveway Postal Locator 2201C Ottawa, Ontario, K1A 0K9 Canada Email: hc.fpmia-meaai.sc@canada.ca
Bureau of Chemical Safety, (BCS) **Food Directorate** **Food Additives and Contaminants Section**	Manager Food Additives and Contaminants Section Chemical Health Hazard Assessment Division A.L.# 2201C 251 Sir Frederick Banting Dr. Ottawa, Ontario, K1A 0K9 Phone: 613-957-1827 Fax: 613- 990-1543
Non-prescription Drug Evaluation Division, Therapeutic Product Directorate (TPD)	Manager Non-prescription Drug Evaluation Division A.L. # 0202D 101 Tunney's Pasture Dr. Ottawa, Ontario, K1A 0B9 Phone: 613-954-6740 or 613-941-2510 Fax: 613-946-9614
Disinfectant Unit Therapeutic Product Directorate (TPD)	Submission and Information Policy Division Bureau of Policy and Coordination A.L. # 0201A1 Finance Building Tunney's Pasture Ottawa, Ontario, K1A 1B9 Phone: 613 – 941- 0827 Fax: 613- 941-0825
Consumer Product Safety Bureau, **Healthy Environments and Consumers Safety Branch**	Notification Officer Cosmetics Division Consumer Product Safety Bureau A.L. # 3504D 123 Slater Street, Ottawa, Ontario, K1A 0K9 Phone: 613-952-8523 Fax: 613-952-3039

Natural Health Products Directorate (NHPD)	Manager A.L. # 3300B Submission Management Division, NHPD 2936 Baseline Rd, Ottawa, Ontario, K1A 0K9 Phone: 613-946-1685 Fax: 613-954-2877
Pest Management Regulatory Agency (PMRA)	Pest Management Information Service Pest Management Regulatory Agency Health Canada 2720 Riverside Drive Ottawa, Ontario, K1A 0K9 Address Locator: 6606D2 E-mail: pmra.infoserv@hc-sc.gc.ca Telephone: 613-736-3799 Toll-free: 1-800-267-6315 Facsimile: 613-736-3798 Teletypewriter: 1-800-267-1245 (Health Canada)

Appendix II: Application/Checklist Form for Incidental Additive Submissions

(see Part 5. Information requirements for incidental additive submissions)

NOTE: Please type or print clearly the content of this form. Complete one application form per product. *
The submission package should be mailed to the Manager of Food Packaging Materials and Incidental Additives Section, Chemical Health Hazard Assessment Division, Bureau of Chemical Safety, Health Canada, 251 Sir Frederick Banting Driveway, Postal Locator 2201C, Ottawa, Ontario, Canada, K1A 0K9.

□ Part 1. Applicant Information

Company name: _____
Address: _____
_____
City: _____Country: _____Postal Code: _____
Phone: _____ Fax: _____
E-mail: _____
Contact Name: Mr./ Ms._____
Position title _____

□ Part 2. Product Information (Note: Product name must be the same as it appears on the label. See Part 5.1)

□ 2.1. Trade name and code number under which the product will be marketed in Canada

□ 2.2. The intended end-use and technical function of the product. Please indicate incidental food

contact (where applicable) in food plants: e.g. lubricant with incidental food contact or with no food contact, degreaser, boiler water additive where the water or the steam produced may come in contact with foods or will not come in contact with food products, recirculating cooling water treatment, cleaner, sanitizer/disinfectant with or without a potable water rinse after the treatment, hand cleaner, hand sanitizer with or without a potable water rinse, etc.

☐ **Part 3. Formulation Information**** Chemical formulation of the product should be in the form of a complete quantitative list of all ingredients used in its manufacture (pre-reaction formula) and in the final product's formulation (post-reaction formula, where applicable), taking into account that the percentage of components of the chemical formulation should add up to 100%. Each chemical ingredient should be clearly identified by its proper chemical name, the CAS number (Chemical Abstracts Service Registry Number), trade name and supplier.

Trade name/ grade	Name of supplier(s) (include alternate suppliers)	Chemical name	CAS registry number	% by weight	Regulatory Reference (CFR, NSF, FCN, etc.), if any (See Part 5.2 a)
				Total: 100%	

☐ **Part 4. Submit copy of the label or draft label of the product (see Part 5.3 Labelling Guide).**

☐ **Part 5. Additional information attached:** i.e.: MSDS, FCN, technical data, product specification, etc.

Signature Date:

Please note that, under Section 20 (1) (b) of the *Access to Information Act*, the information submitted above will be used in strict confidence for our evaluation purposes of your submission only and will not be shared with any third party unless advised otherwise by your company and/or your supplier(s) with a written notice.

* BCS would ask that you submit no more than five products at a time.

** If the formulation of the product contains chemical and bacterial ingredients, it is recommended that full disclosure of the composition of the product be provided. This information should be in the form of a complete quantitative list of all chemical and bacterial ingredients used in its manufacture, taking into account that the percentage of components of full formulation should add up to 100%. Each chemical ingredient should be clearly identified by its proper chemical name, the CAS number, trade name and supplier, and each bacterial ingredient - by the scientific name of organism and source/origin number (See Part 5.1 (c)).