in focus

Navigating the complexity of Canadian regulations for antimicrobial products

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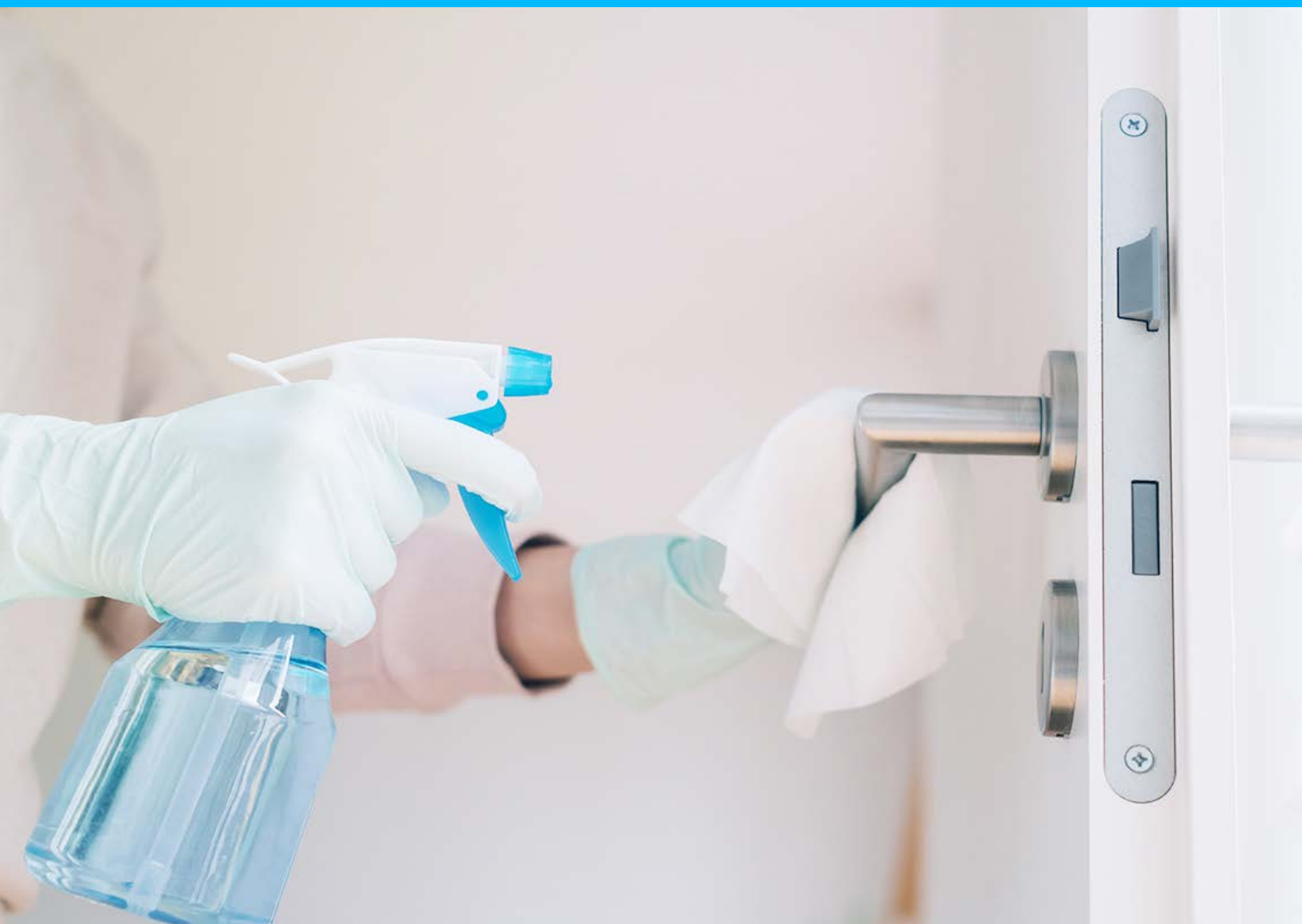
a **science group** company

Launching an antimicrobial product in Canada can be a complex undertaking. While Health Canada oversees all regulatory matters at a strategic level, the practicalities are handled by various agencies, each of which has different requirements. When developing a new product or looking to import a product for the first time, it's important to understand how it is categorized by Health Canada, and which regulations will apply. In this paper, we look at situations where antimicrobial products are classified as 'pesticides', 'drugs' or 'incidental additives' in Canada, offering guidance on registration and authorization requirements.



Defining antimicrobial products in Canada

Under Canadian legislation, antimicrobial products fall into two principal categories: 'pesticides' or 'drugs'. Depending on this classification, they are regulated under Health Canada's Pest Control Products Act (PCPA) or Food and Drugs Act (FDA) respectively.

The situation becomes more complex for antimicrobial products intended for use in food processing establishments. These products can also fall within the 'incidental additives' category which is regulated by Health Canada's Food Directorate.

Understanding where your product sits in relation to these regulations is essential, as it impacts a wide range of factors. Compliance activities such as pre-market assessment, registration, licensing and supporting documentation, as well as product packaging and labeling requirements, all vary depending on a product's classification.

However, determining the most appropriate category – then ensuring a product meets its requirements – is not always straightforward. This is particularly challenging for new market entrants or companies looking to import antimicrobial goods into Canada for the first time.

Health Canada, which has oversight of all three agencies, considers three key factors in the classification of an antimicrobial product:

1. Composition
2. Ingredients' history of use
3. Product representation (use, function, marketing, label claims).

Providing adequate and acceptable information related to these factors plays a key role in obtaining the necessary approvals to market antimicrobial products. In this paper we look at the specific product classifications and requirements of each of the three agencies in turn. Our aim is to offer some insight into the way antimicrobial products are regulated in Canada.

Health Canada regulates antimicrobial products under the Pest Control Products Act (PCPA) or the Food and Drugs Act (FDA); some products intended for use in food processing applications are also covered by the Food Directorate.

Health Canada's Pest Control Products Act

In Canada, a pest control product is defined as any product, device, organism, substance or thing that is manufactured, represented, sold or used as a means for directly or indirectly controlling, preventing, destroying, mitigating, attracting or repelling any pest.

Within this category, Health Canada's Pest Management Regulatory Agency (PMRA) regulates the following antimicrobial product types:

- Treated articles (fibre, textile, leather, rubber, plastic, wood)
- Preservatives
- Sanitizers
- Slimicides for industrial process fluids
- Swimming pool and spa bactericides and algaecides
- Antifouling paints

Antimicrobials which qualify as pest control products must be properly registered in Canada before they can be sold there. A product's technical active ingredient needs to be registered for its specific intended use.

Before such products are sold in Canada, their technical active ingredient (TGAI) must be registered for their specific use, otherwise known as 'use site category' (USC).

The registration process involves the submission of documentation, including scientific data, to support the safety, efficacy, and quality of the product. Efficacy data and 'weight of evidence' information are essential requirements for all product types.

A key mandate of the PCPA is ensuring transparency in the pesticide registration system, and its Pesticide Public Registry sets out to achieve this. Regulatory and policy documents available via the registry's website offer detailed guidance for pesticide manufacturers. It's also possible to search existing applications for pest control product registration or amendment, as well as information on approved products and active ingredients. TSG can assist with consultation of the registry's public databases if required.

Registering antimicrobials with the PCPA

Documentation requirements for PCPA registration of an antimicrobial pest control product vary depending on the type of registration sought. Typically, submissions must include:

- English and French labels
- Chemistry
- Toxicology
- Exposure (occupational & consumer)
- Value (efficacy)

For some USCs, the PCPA also requires information on environmental chemistry, including fate and toxicology.

Once a submission has been made, the PMRA conducts a pre-market assessment. This involves evaluating the information for any health or environmental hazards then determining whether the product offers value to the Canadian market.

If the registration is successful, the product receives a unique Pest Control Products (PCP) Number which must be displayed on the approved product label.

Health Canada's Food and Drugs Act

Certain antimicrobial products are regulated as drugs under Health Canada's FDA because they decrease the chance of transmitting disease. Under Canadian regulation, drug products include prescription and non-prescription pharmaceuticals, disinfectants and sanitizers with disinfectant claims.

The FDA defines a 'drug' as any substance or mixture of substances manufactured, sold or represented for use in:

a The diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms

b Restoring, correcting, modifying organic functions

c Disinfection in premises in which food is manufactured, prepared or kept

Alongside these overarching categories, an 'antimicrobial agent' is defined as a drug that is capable of destroying pathogenic micro-organisms and that is labeled as being for use in the disinfection of environmental surfaces or medical devices that:

a Are not invasive devices as defined in those regulations, and

b Are intended to come into contact with intact skin only

Products which fall into one or more of these category definitions need to be authorized ahead of sale in Canada. A submission must be made to Health Canada for a thorough assessment of safety, efficacy, and quality.

Disinfectants and disinfectant/sanitizer combination products for use on hard surfaces are regulated by the Natural and Non-prescription Health Products Directorate (NNHPD). The same is true of consumer medical goods with antimicrobial claims, such as toothbrushes or bandages. The NNHPD must review ingredients, uses, and claims before these products can be marketed.

Products which fall under the FDA's remit must be authorized before they can be sold in Canada.

Obtaining FDA authorization for antimicrobial products

To apply for market authorization, a manufacturer must present substantive scientific evidence to support the safety, efficacy, and quality of a given product. Claims made on the product label also need to be authorized.

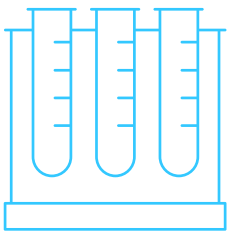
The monograph approach

Canada's NNHPD product licensing system uses monographs for many natural health products and some non-prescription and disinfectant drugs. The approval process is expedited for products that are fully aligned with a monograph as critical information is preapproved.

New Drug Submissions

If a product's active ingredient is not currently recognized for its proposed use, the registration is considered a New Drug Submission. In this situation, extensive evidence must be included with the submission. This encompasses chemistry, toxicology, and efficacy test data, as well as specific manufacturing and processing details. The FDA's exact requirements vary depending on the type of registration sought. However, they are generally consistent with those of the US Environmental Protection Agency (EPA).

It's useful to establish whether your product is covered by a monograph at the earliest possible stage. Likewise, if it will be considered a New Drug Submission, getting a head-start on scientific testing will help streamline the authorization process.



Health Canada's Food Directorate

Canada's FDA defines 'food' as including any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.

In addition to this, substances used in food processing facilities with the potential to leave trace residues in foods are regulated as 'incidental additives'. So, in a food processing context, the following product types fall under the regulation:

- Sanitizers
- 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.)
- Odor 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

Under the Safe Food for Canadians Regulations, food businesses hold responsibility for ensuring safe use of these products. They must demonstrate that the commodities and processes which they handle are compliant, and that products covered by the incidental additives regulation are used as per manufacturer instructions.

It is important to note that any disinfectant product proposed for use in food processing and manufacture which has a therapeutic effect (preventing or controlling diseases) is considered a drug. As such, an application would have to be made to the NNHPD for Drug Identification Number (DIN) registration.

Hand care products, detergents and cleaning agents are among the items that may be classified as incidental additives when used in a food processing context.

Antimicrobials with incidental food contact

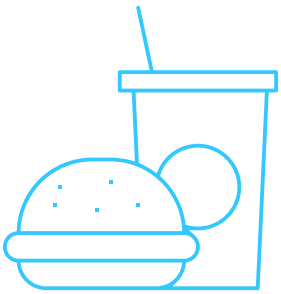
While incidental additives are not specifically defined as food or drugs by the FDA, their use falls under the authority of FDA Regulations. The compliance of food businesses in this respect is verified by the Canadian Food Inspection Agency (CFIA) via inspection and surveillance. Food businesses are also encouraged to implement their own Supplier Food Safety Assurance Programs to help ensure all items they procure are safe and suitable for use, including non-food chemicals.

The Bureau of Chemical Safety

Manufacturers of products for treating food processing equipment (e.g. conveyor belts, plastic utensils, food packaging materials and cutting boards) must ensure they are suitable for food contact applications.

The Bureau of Chemical Safety (BCS) can offer assistance here. As part of Health Canada's Food Directorate, the BCS works to ensure that foods do not contain chemicals at levels that could lead to adverse health impacts. Manufacturers can voluntarily seek advice regarding the acceptability of products they wish to sell to the food industry. Upon review of information submitted, the BCS will issue a letter of no-objection if it deems that the product does not pose an unacceptable health risk.

BCS safety assessments are conducted on a case-by-case basis and take the individual merits of the product into consideration.



Food businesses are responsible for ensuring the safe use of products classified as incidental additives. However, the manufacturer must ensure the product is suitable for use in food applications when used as directed.

Incidental additive exemptions

Several product categories are not evaluated by the BCS, and no-objection letters are not issued for their use in food processing establishments. Broadly speaking, this relates to products that are not used on food contact surfaces or by people handling food. The categories include:

- Products used in non-food processing areas (e.g. offices or staff cafeterias), such as furniture waxes and rinse additives
- Products used on the exterior of buildings or on vehicles used by a food processing plant, such as tar, de-icing compounds, and car shampoo
- Products used in heating or wastewater systems, such as fuel additives or odor control compounds
- Products for treating closed steam lines or cooling water systems where the treated steam/water will not contact food or food contact surfaces
- Cosmetic products used by employees at the end of their working shift or by employees not engaged in food handling applications

Although these exempted products are not subject to review by the BCS, it is expected that they will be properly labeled and not stored in food handling areas. Care must be taken to ensure the products do not contaminate food products during application or storage.

Products for use in areas of food processing plants which don't handle food are largely exempt from the incidental additives regulation. However, they must be stored and used in a manner that ensures contamination cannot occur.

Final thoughts

Regulations surrounding the sale and use of antimicrobial products are necessarily strict and inevitably complex. When planning to launch a product in Canada, it pays to take time to understand the associated requirements at the earliest possible stage. It's important to consider the three key factors that Health Canada uses to classify antimicrobial products: composition, ingredients' history of use, and product representation. This has a direct impact on which agency the product will be regulated under, impacting everything from pre-market assessment and registration to packaging and labeling requirements.

How TSG can help

TSG has extensive experience working on the registration process for antimicrobial products in Canada. Our consultants are well-versed in the various jurisdictional boundaries and have extensive experience helping manufacturers find the most appropriate pathway to market. Our services include:

- Strategic guidance to assess the regulatory jurisdiction of your product
- Assistance with preparing and submitting registrations to the appropriate CAN regulatory bodies
- Development of a strategy for addressing data requirements
- Assistance with developing and reviewing labels and label claims

About TSG Consulting ¬

TSG Consulting provides companies with high quality regulatory and scientific consulting services.

We help clients worldwide address the technical and regulatory issues in taking their products to market in multiple jurisdictions. Our scientific expertise, regulatory knowledge and understanding of local nuances enable our clients to navigate the complex and ever-changing regulatory landscape across the globe.

We serve a number of key markets and industry sectors including agricultural, industrial, consumer, food and beverage, animal health, and medical. Our teams comprise scientists and regulatory experts – many of whom have previously held positions at regulatory agencies, departments, and in industry.

This combination of science, regulatory expertise and knowledge of how institutions and industry operate provides our clients with superior and well-rounded guidance. TSG Consulting has offices in France, Germany, Spain, UK, USA and Canada. TSG is a Science Group (London listed) company.

info@tsgconsulting.com

www.tsgconsulting.com

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- Regulatory & Compliance: helping clients in highly regulated markets to launch, market and defend products internationally, navigating the frequently complex and fragmented regulatory ecosystems.
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info@sciencegroup.com

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