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CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

### **Microbeads in Toiletries Regulations**

P.C. 2017-570 June 2, 2017

Whereas, pursuant to subsection 332(1) (see footnote a) of the Canadian Environmental Protection Act, 1999 (see footnote b), the Minister of the Environment published in the Canada Gazette, Part I, on November 5, 2016, a copy of the proposed Microbeads in Toiletries Regulations, substantially in the annexed form, and persons were given an opportunity to file comments with respect to the proposed Regulations or to file a notice of objection requesting that a board of review be established and stating the reasons for the objection;

Whereas, pursuant to subsection 93(3) of that Act, the National Advisory Committee has been given an opportunity to provide its advice under section 6 (see footnote c) of that Act;

And whereas, in the opinion of the Governor in Council, pursuant to subsection 93(4) of that Act, the proposed Regulations do not regulate an aspect of a substance that is regulated by or under any other Act of Parliament in a manner that provides, in the opinion of the Governor in Council, sufficient protection to the environment and human health;

Therefore, His Excellency the Governor General in Council, on the recommendation of the Minister of the Environment and the Minister of Health, pursuant to subsection 93(1) of the *Canadian Environmental Protection Act, 1999* (see footnote d), makes the annexed *Microbeads in Toiletries Regulations*.

# **Microbeads in Toiletries Regulations**

### Interpretation

#### **Definitions**

**1** The following definitions apply in these Regulations.

*microbeads* means the plastic microbeads set out in item 133 of the List of Toxic Substances in Schedule 1 to the *Canadian Environmental Protection Act, 1999.* (*microbilles*)

**toiletries** means any personal hair, skin, teeth or mouth care products for cleansing or hygiene, including exfoliants and any of those products that is also a *natural health product* as defined in the *Natural Health Products Regulations* or a non-prescription drug. (*produit de toilette*)

### **Application**

### Non-application

**2** These Regulations do not apply to *prescription drugs* within the meaning of section A.01.010 of the *Food and Drug Regulations*.

#### **Prohibitions**

### Manufacture and importation

**3 (1)** A person must not manufacture or import any toiletries that contain microbeads, unless the toiletries are also natural health products or non-prescription drugs, in which case the prohibition applies on or after July 1, 2018.

#### Sale

(2) A person must not sell any toiletries that contain microbeads on or after July 1, 2018, unless the toiletries are also natural health products or non-prescription drugs, in which case the prohibition applies on or after July 1, 2019.

### Exemption — toiletries in transit

**4** No person contravenes subsection 3(1) if the toiletries are in transit through Canada, from a place outside Canada to another place outside Canada.

#### **Presence of Microbeads**

# **Accredited laboratory**

- **5 (1)** Any determination of the presence of microbeads performed for the purposes of these Regulations must be performed by a laboratory that is accredited
  - (a) under the International Organization for Standardization standard ISO/IEC 17025, entitled *General requirements for the competence of testing and calibration laboratories*, by an accrediting body that is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement; or
  - **(b)** under the *Environment Quality Act*, CQLR, c. Q-2.

### Accreditation

# (2) The accreditation must

- (a) be valid at the time the determination of the presence of microbeads is performed; and
- **(b)** if a method has been recognized by a standards development organization in respect of the determination of the presence of microbeads, include that determination within its scope.

#### Standards of good practice

(3) If there is no method that has been recognized by a standards development organization in respect of the determination of the presence of microbeads, the determination must be performed in accordance with generally accepted standards of good scientific practice at the time that it is performed.

#### **Consequential Amendment**

# **Designated Regulatory Provisions**

6 The schedule to the *Regulations Designating Regulatory Provisions for Purposes of Enforcement* (Canadian Environmental Protection Act, 1999) (see footnote 1) is amended by adding the following in numerical order:

|      | Column 1                             | Column 2                     |
|------|--------------------------------------|------------------------------|
| Item | Regulations                          | Provisions                   |
| 29   | Microbeads in Toiletries Regulations | (a) subsections 3(1) and (2) |

#### **Coming into Force**

#### January 1, 2018

7 These Regulations come into force on January 1, 2018, but if they are registered after that day, they come into force on the day on which they are registered.

#### **REGULATORY IMPACT ANALYSIS STATEMENT**

(This statement is not part of the Regulations.)

#### Issues

The environmental burden from plastic litter continues to increase globally, posing environmental issues with complex challenges. Plastic waste entering freshwater and marine ecosystems can come from various sources such as plastic bags, bottles and microplastics (see footnote 2) including plastic microbeads.

Some toiletries (see footnote 3) that are used to exfoliate or cleanse the human body, hereafter referred to as "toiletries" contain plastic microbeads. These toiletries get washed down the drain when used by consumers and enter wastewater treatment plants. After wastewater treatment, a portion of plastic microbeads is expected to reach and accumulate in freshwater and marine ecosystems across Canada. Plastic microbeads have been reported in coastal British Columbia, the Great Lakes, the St. Lawrence River, and in coastal Atlantic Canada. The scientific literature (see footnote 4) indicates that microplastics are readily taken up by a variety of non-human organisms and have shown adverse short-

term and long-term effects in aquatic organisms such as marine mammals, fish, invertebrates and fisheating birds.

Although voluntary actions have been taken by industry to phase out the use of plastic microbeads in toiletries, there is a risk of reintroduction or continued import of toiletries that contain plastic microbeads in Canada. Therefore, under the authority of the *Canadian Environmental Protection Act,* 1999 (CEPA), the Government of Canada (the Government) is prohibiting the manufacture, import, and sale (see footnote 5) of toiletries that contain plastic microbeads.

#### **Background**

Recognizing the risks that plastic microbeads pose to the environment, on March 24, 2015, the House of Commons voted unanimously for the Government to take immediate measures to add plastic microbeads to the List of Toxic Substances in Schedule 1 of CEPA. As a result of the resolution of the House, the Department of the Environment (the Department) completed a scientific review and analysis of over 130 scientific papers, as well as a consultation with experts on the impacts of plastic microbeads on the environment. The science review concluded that plastic microbeads should be considered toxic to the environment under paragraph 64(a) of CEPA, as they are entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity.

On June 23, 2015, the Canadian Council of Ministers of the Environment (CCME), consisting of federal, provincial and territorial environment ministers, acknowledged efforts by industry to eliminate the use of plastic microbeads in consumer products and supported the Government's scientific review of plastic microbeads. It was recognized that provinces and territories may take additional complementary actions to restrict the use of plastic microbeads. (see footnote 6)

On June 29, 2016, "Plastic microbeads that are ≤ 5 mm in size" were added to the List of Toxic Substances in Schedule 1 of CEPA to enable the Government to propose regulations to manage the environmental risk associated with the use of toiletries that contain plastic microbeads.

On November 5, 2016, under the authority of CEPA, the proposed Regulations to prohibit the manufacture, import, and sale of toiletries that contain plastic microbeads were published in the *Canada Gazette*, Part I, for a 75-day comment period. (see footnote 7) Public comments were considered in the development of the Regulations.

# Substance description, uses and sources of release

Plastic microbeads can vary in chemical composition, size, shape, density, and function, and are manufactured for specific purposes. They can be used in a variety of applications (see footnote 8), including toiletries. Plastic microbeads can either be chemically or physically stable (i.e. when used as abrasives, exfoliates or cleansers) or unstable (e.g. when designed to break down due to a physical or chemical trigger to release other chemicals). Stable plastic microbeads are most likely to remain for a long time in the environment.

The plastic microbeads that are the focus of these Regulations are solid plastic particles known to be equal to or less than 5 mm in size (in the largest external dimension) that are added to toiletries, including non-prescription drugs (see footnote 9) and natural health products. (see footnote 10) Some examples of these toiletries include facial or body scrubs, bath products, facial cleansers, and toothpastes. These plastic microbeads are eventually washed down the drain when consumers use toiletries that contain them. As plastic microbeads are too small to be entirely captured by wastewater treatment plants, a portion of these plastic microbeads continually enters the aquatic environment in Canada.

Plastic microbeads have been found, along with other microplastics, in surface waters, sediments, and in aquatic organisms. A study by Dris et al., (2015) in Paris, France, found that of the total amount of microplastics entering wastewater treatment, a significant amount (about 10%) was expected to be released into the environment. (see footnote 11) In Canada, they have been reported in coastal British Columbia, the Great Lakes, the St. Lawrence, and in coastal Atlantic Canada. Plastics, including microplastics, have also been measured on the shores of Lake Huron, Lake Erie, and Lake St. Clair. (see footnote 12)

According to the submissions of 46 Canadian companies that were received in response to a survey notice issued under section 71 of CEPA (see footnote 13) in 2014, 37 were importers, 7 were manufacturers and 2 were both importers and manufacturers of toiletries that contain plastic microbeads. These companies imported toiletries that contained less than 100 000 kg of plastic microbeads and exported toiletries that contained between 1 000 and 10 000 kg of plastic microbeads. In the same year, Canadian manufacturers produced toiletries that contained approximately 10 000 kg of plastic microbeads.

### Risk management actions in other jurisdictions

Plastic microbeads have been identified as a concern by numerous international organizations. (see footnote 14) International activities on the management of marine litter, which includes microplastics and plastic microbeads, are under way by several United Nations bodies and organizations, the Asia-Pacific Economic Cooperation, the United Nations Convention on Biological Diversity, and the G7, among others.

The issue of marine litter, including microplastics and plastic microbeads, has garnered increased attention and interest in international fora. Canada participates in varied capacities in a number of international efforts related to this issue. For example, in June 2015, G7 countries adopted the *G7 Action Plan to Combat Marine Litter*, which identified priority actions to effectively reduce marine litter by focusing on four key areas: land-based sources; sea-based sources; removal; and education, research and outreach. One action specifically targets microbeads: "encouraging industry to develop sustainable packaging and remove ingredients from products to gain environmental benefits, such as by a voluntary phase-out of microbeads."

The United Nations, through several of its competent bodies and organizations, is also addressing the sources and impacts of marine litter and microplastics, and is taking action to manage this global

problem. The United Nations Environment Programme's (UNEP) Global Programme of Action for the Protection of the Marine Environment from Land-based Activities and the Regional Seas Programme have been developing and implementing extensive activities on the management of marine litter on a global and regional scale. The Government participated as an advisory group member in UNEP's 2016 study on marine plastic litter and microplastics.

The Government continues to work with international partners such as through various bodies under the United Nations and the G7 and domestic partners to address the broader issue of marine litter and microplastics pollution.

#### **Actions in the United States**

Nine states in the United States (U.S.): Illinois, Colorado, Wisconsin, Indiana, Maine, Maryland, New Jersey, Connecticut and California, have passed laws that prohibit the selling and manufacturing of microbeads in personal care products. On December 28, 2015, the *Microbead-Free Waters Act of 2015* (H.R. 1321) was signed into federal law as an amendment of the *Federal Food, Drug, and Cosmetic Act*. The law will place restrictions on the manufacture or introduction, or delivery for introduction, into interstate commerce, of rinse-off cosmetic products containing plastic microbeads. (see footnote 15) The restrictions on rinse-off cosmetic products containing microbeads will come into effect on July 1, 2017, for manufacture, and on July 1, 2018, for introduction or delivery for introduction into interstate commerce. For non-prescription drugs, the timelines are July 1, 2018, for manufacture, and July 1, 2019, for introduction, or delivery for introduction, into interstate commerce.

#### Actions in Europe

On December 9, 2014, the European Union Commission Decision 2014/893/EU established that rinse-off products containing microbeads are no longer allowed to use the European Union Ecolabel. The European Union Ecolabel is recognized throughout Europe as a trusted identifier of products with a reduced environmental impact.

In the subsequent weeks, Austria, Belgium, the Netherlands, Luxembourg, and Sweden jointly called upon the Environment Council (ENV) in Brussels to institute a full ban on the addition of microbeads to toiletries. According to a petition response issued on April 29, 2015, an arm of the European Union Commission is gathering the necessary information and evidence for developing options to achieve a reduction of microplastics in cosmetic products. As well, a study to support the European Commission in developing measures to combat marine litter was published in January 2016. (see footnote 16) The study provided recommendations on actions that could be taken by the European Commission to achieve a reduction in microplastic pollution.

In addition, the Swedish Chemicals Agency, Kemi, proposed a ban on rinse-off cosmetics containing microbeads. Kemi is working in tandem with the Swedish Environmental Protection Agency to identify significant sources of microbead releases into the aquatic environment and to develop regulatory actions to reduce them.

Since the publication of the proposed Regulations, other governments have announced plans to take risk management actions on microbeads including France, the United Kingdom, Scotland, Ireland and Italy.

#### Actions in Australia

In 2015, New South Wales and South Australia agreed to lead work on a jurisdictional phase-out of microbeads. The current proposal gives Australian companies the option of voluntarily removing microbeads from their products by July 2018. The Australian Environment Minister announced that the federal government will take action to institute a formal ban if, by July 1, 2017, it is clear that the voluntary phase-out will not achieve its objectives.

#### Other countries

New Zealand, Taiwan and South Korea have also announced plans to take actions on microbeads.

#### **Objectives**

The objective of the Regulations is to contribute to the protection of the environment by reducing the quantity of plastic microbeads entering Canadian freshwater and marine ecosystems.

### Description

The Regulations will prohibit the manufacture, import, and sale of toiletries that contain plastic microbeads, including non-prescription drugs and natural health products. The types of toiletries covered include products such as bath and body products, skin cleansers and toothpaste. The Regulations will not apply to prescription drugs. For the purposes of the Regulations, plastic microbeads include any plastic particle equal to or less than 5 mm in size, which can vary in chemical composition, size, shape and density.

As of January 1, 2018, the manufacture and import of toiletries that contain plastic microbeads will be prohibited unless the toiletries are also natural health products or non-prescription drugs, in which case the prohibition will begin July 1, 2018.

As of July 1, 2018, the sale of toiletries that contain plastic microbeads will be prohibited, unless the toiletries are also natural health products or non-prescription drugs, in which case the prohibition will begin July 1, 2019.

Regulatees are not required to submit reports or conduct product testing to comply with the Regulations. However, if a determination of the presence of plastic microbeads in a toiletry is required for enforcement purposes, it must be performed by an accredited laboratory. This requirement will inform regulatees of the quality standards that will be used by an enforcement officer to determine compliance.

The Regulations will not apply to a toiletry that contains plastic microbeads and that is in transit through Canada, from a place outside Canada to another place outside Canada.

The Regulations will also make consequential amendments to the *Regulations Designating Regulatory Provisions for Purposes of Enforcement (Canadian Environmental Protection Act, 1999)* [the Designation Regulations]. (see footnote 17) The Designation Regulations designate the regulatory provisions from CEPA regulations that are subject to an increased fine scheme following an offence involving harm or risk of harm to the environment, or obstruction of authority.

#### **Benefits and costs**

#### **Benefits to the Canadian environment**

In laboratory studies, plastic microbeads have been shown to have adverse short-term and long-term effects in aquatic organisms. Scientific literature indicates that plastic microbeads are readily taken up by a variety of organisms, such as fish, mussels, and several types of zooplankton. Some studies have shown that microplastics, which include plastic microbeads, can impede feeding behaviour in aquatic species, leading to reduced body growth and reproduction. Additionally, similarly to organic matter, plastic microbeads can adsorb persistent organic pollutants (POPs) such as polychlorinated biphenyls (PCBs) and dichlorodiphenyltrichloroethane (DDT) from the marine environment and are harmful to organisms that eat them.

Plastic microbeads have been measured along with other microplastics in surface water, in sediments, and in aquatic organisms in Canada. As evidence suggests that wastewater treatment plants are not able to remove all plastic microbeads, they are expected to keep accumulating in the aquatic ecosystem in Canada. Plastic microbeads are expected to reside in the environment for a long time, and continuous release of the substance to the environment from toiletries sent down the drain is expected to result in long term adverse effects on biological diversity and ecosystems (i.e. freshwater and marine).

Although most of the benefits associated with eliminating plastic microbeads from toiletries are due to the voluntary phase-out of the substance by industry, the Regulations will require that plastic microbeads be no longer used and are not reintroduced into toiletries available in Canada.

# **Costs to businesses**

#### **Plastics sector**

The plastics sector comprises mainly small and medium-sized enterprises, 95% of which are Canadian-owned. Plastics are used by virtually every end-use segment of the economy. The unique attributes of plastics (including processability, light weight and corrosion resistance) have led to the creation of new products, and plastics have also displaced paper, glass and metal from traditional applications. Although there is a wide range of plastic products, three major product lines dominate: about 39% of shipments are packaging, 33% are construction products, and 14% are automotive components (the remaining 14% is for other products). In addition to being produced by companies within the defined plastic products industry, plastic production is a secondary activity of firms in other industry groups (for example plastic toys and furniture) and for internal consumption such as plastic bottles made in-house by a shampoo manufacturer.

Plastic producers also produce plastic microbeads for specific purposes, by varying their chemical composition, size, shape, and density. Plastic microbeads are not only used in toiletries but also in industrial settings (e.g. plastic blasting at shipyards, textile printing and automotive moulding), for antislip and anti-blocking applications, as well as in medical applications.

Based on the information received through a survey conducted under section 71 of CEPA, it is estimated that in 2014, about 10 000 kg of plastic microbeads were used in the manufacture of toiletries in Canada. Assuming this volume of plastic microbeads was all purchased from the plastic industry in Canada and a range of prices up to \$30 per kilogram, (see footnote 18) microbeads sales would be less than or equal to \$300 000 a year, in an industry that generated more than \$29 billion in manufacturing revenues in 2016, according to Statistics Canada. (see footnote 19) Moreover, given that some of this quantity was likely imported and given industry commitments to voluntarily phase out plastic microbeads from toiletries, the impact of the Regulations on the sector is expected to be minimal.

#### Personal care product sector

The Canadian Cosmetic Toiletry and Fragrance Association notes (see footnote 20) that Canadians purchase over \$5.4 billion of personal care products each year, including products such as deodorant, shampoo, skin care products, make-up, fragrances, sunscreens and cavity-fighting toothpastes. It also notes that each year, the Canadian personal care product industry creates an average of over 7 000 new products.

The Regulations are not expected to significantly impact the personal care product sector in Canada, as information provided to the Government in March 2016 suggested that toiletries that do not contain plastic microbeads were already becoming available to consumers in Canada. A number of Canadian manufacturers of toiletries have indicated that they already sell toiletries that do not contain plastic microbeads, (see footnote 21) and a majority of Canadian manufacturers communicated their plan to voluntarily phase out the use of plastic microbeads in toiletries by the time the prohibitions come into effect. These manufacturers are responsible for 99% of the total amount of plastic microbeads used in 2014 to manufacture toiletries. Several importers indicate that they already have access to toiletries that do not contain plastic microbeads at similar costs to toiletries that contain plastic microbeads. In addition, given actions taken in other jurisdictions (in particular the United States), the Department anticipates increasing availability of imported toiletries that do not contain plastic microbeads in Canada. However, if an importer wishes to test whether or not a toiletry contains plastic microbeads, there may be a one-time cost but it is expected to be minimal. In Canada, cosmetic products are required to have mandatory ingredient labelling as per the Cosmetic Regulations, which may help importers identify if plastic ingredients, such as polyethylene, are used in these exfoliating or cleansing products.

Given normal inventory turnover cycles and expected timing of the regulatory requirements, no cost to retail businesses is expected related to residual toiletries that could no longer be sold, as a sell through period is allowed. The Department anticipates that this should be sufficient to allow for the sale of products and the elimination of inventory.

#### **Cost to consumers**

Given the availability and the anticipated increasing availability of toiletries that do not contain plastic microbeads (via domestic manufacture and import), the Regulations are not expected to have any impact on consumers' access to a variety of toiletries or the cost associated with them.

#### **Costs to Government**

The costs associated with enforcement activities are estimated to be less than \$400 000 for the first five years after the Regulations are enacted. These costs are associated with verification of compliance with the Regulations, which will include site visits, sample analysis and review of written transit documents.

Costs associated with compliance promotion activities are estimated to be less than \$150 000 and are associated with posting of information on the Department's website, including frequently asked questions, responding to information or clarification requests, and through mail outs to stakeholders.

#### "One-for-One" Rule

The "One-for-One" Rule does not apply, as the Regulations will not impose any administrative burden on businesses.

#### **Small business lens**

The small business lens does not apply, as identified small businesses (manufacturers and importers) are expected to be in compliance with the Regulations by the time they are enacted and as there are no ongoing direct compliance or administrative costs associated with the Regulations.

### Consultation

On February 9, 2016, the Department published a consultation document for a 30-day public comment period, outlining the key elements of the regulatory proposal. There were more than 1 200 comments received and most of them were in support of the proposed Regulations. Key comments included a request to align regulatory timing with the United States to prevent potential for dumping of products in Canada; consideration of alternative risk management measures; and scope of products and materials covered. Other comments were on alternative risk management measures, consumer awareness and the information used to support the regulatory impact assessment of the proposed Regulations.

Based on the feedback received on the consultation document, the coming-into-force dates included in the proposed Regulations were adjusted.

Summaries of all comments that were received and the Department's responses, including details about how these comments were considered are included in the Regulatory Impact Analysis Statement (RIAS) that was published with the proposed Regulations in the *Canada Gazette*, Part I, on November 5, 2016. (see footnote 22)

The proposed Regulations were subject to a 75-day public comment period. Comments were received from 29 organizations and individuals: 16 from environmental non-governmental organizations (ENGOs), three from other governments, two from industry associations, and eight from Canadian citizens.

The CEPA National Advisory Committee (CEPA NAC) (see footnote 23) and relevant federal government departments were also consulted on the proposed Regulations. One CEPA NAC member advised the Department to consider other sources of microbeads in personal care products in addition to those that exfoliate or cleanse.

All comments are summarized below by topic and were considered in the development of the Regulations. Some of these comments were also addressed in the RIAS of the proposed Regulations.

### **Support for the Regulations**

The majority of stakeholders (toiletries sector, provincial governments, ENGOs, and consumers) were supportive of the proposed Regulations.

### **Scope of the Regulations**

### Other products containing plastic microbeads

Six ENGOs, two government stakeholders and several citizens requested that the Regulations take into account all products containing plastic microbeads that could enter the wastewater system in Canada. Several of these stakeholders indicated that consumer and industrial products such as cleaning supplies, wet wipes, and anti-slip coatings are all potential sources of plastic microbeads that may reach the environment in all parts of Canada. As well, one provincial government advised the consideration of other toiletries that may contain plastic microbeads, in addition to those that are used to exfoliate or cleanse. Stakeholders provided the examples of sunscreens and moisturizers that are not intended to be rinse-off products but may have negative impacts on the environment.

Response: Information on other sources that contribute to plastic microbeads in the environment is still emerging. There is sufficient evidence that plastic microbeads in toiletries that rinse off and wash down household drains are contributing to plastic pollution in our rivers and lakes. Accordingly Canada, like other jurisdictions (e.g. United States), is taking action to prohibit plastic microbeads in toiletries that are used to exfoliate or cleanse the human body. The Government continues to work with international partners (such as through various bodies under the United Nations and the G7) and domestic partners to address the broader issue of marine litter and microplastics pollution

## Other products contributing to microplastic pollution

Several stakeholders requested that the Regulations take into account all products that may contribute to microplastic pollution such as flushable wipes, commercial and industrial products such as paint products, styrofoam dock floatation products and single use plastics such as plastic plates, cups, cutlery, straws and stirrers.

Response: The Government is committed to preventing pollution, including plastics, in marine and freshwater ecosystems. The current regulatory approach is to manage the risk associated with plastic microbeads in toiletries. In Canada, a variety of approaches, regulatory and non-regulatory, are used to address plastic pollution and to prevent both macro- and microplastic debris from entering Canadian waters.

Responsibility for waste management in Canada is shared among federal, provincial, territorial and municipal governments. Implementation of waste reduction programs is led by provinces, territories and municipalities. These jurisdictions have programs in place for a wide range of products to address their local priorities, including tackling disposal of plastics, for example, fees or bans on single-use plastic bags. Therefore, a nation-wide ban on single-use plastics under a federal initiative is not being considered at this time. The federal government is, however, working collaboratively with provincial and territorial governments, through the CCME, to find solutions to waste management problems. In 2014, federal, provincial and territorial environment ministers adopted a shared Waste Vision and committed to taking action within their jurisdictions, in concordance with the CCME Action Plan for Waste, to improve Canada's record on reducing and recycling waste. The jurisdictions work collaboratively through the CCME to deliver guidance, recommendations or other products to support improved diversion of waste from landfills.

In 2009, environment ministers adopted the Canada-wide Action Plan for Extended Producer Responsibility and the Canada-wide Strategy for Sustainable Packaging to improve waste diversion and increase recycling across Canada. Extended producer responsibility (EPR) is a policy approach in which a producer's responsibility, physical and/or financial, for a product is extended to the post-consumer stage of a product's life cycle. All provinces have EPR regulations in place for a variety of products including: packaging, printed materials, electronic equipment, etc. These regulations generally target manufacturers, importers and/or distributors, and set performance targets for recycling specific product categories and rigorous governance requirements.

At the international level, Canada recently committed to address marine litter including the adoption of the *G7 Action Plan to Combat Marine Litter* and United Nations Sustainable Development Goal 14, which calls on the prevention and significant reduction of marine pollution, including debris, by 2025.

#### **Definitions**

To help address stakeholders concerns on definitions, as written in the Regulations, the Department will develop and distribute compliance promotion materials (e.g. a fact sheet or website material) to ensure that the regulated community is aware of the requirements of the Regulations within the first year after the Regulations are enacted.

### Definition of "toiletry"

Two industry associations expressed concerns with the use of the term "toiletry", given different terminology in the U.S. legislative approach. They requested that the qualifier "intended to be rinsed off" be added to the definition.

*Response*: The scope of the products covered under the Regulations is the same as that of the United States. Some differences in terminology exist due to differing legislative drafting protocols and authorities. As a result, these Regulations define the product itself, not how the consumer may choose to use the product. The Department will be distributing compliance promotion materials (e.g. fact sheets or website materials) to provide clarity to regulated parties regarding the scope of products covered.

### **Alignment with Health Canada Self-Care Product Framework**

One association requested consistency with any future changes to definitions that may happen under the Department of Health's consultations on its framework for self-care products. (see footnote 24)

Response: The Department will keep abreast of the Department of Health's evolving work to modernize its approach to self-care products, including natural health products, cosmetics and over-the-counter drugs. However, as this work is still at an early consultation stage, delaying the Regulations to better align with any potential change on self-care products' definitions was not deemed as a viable option. As appropriate, the Department will seek amendments to harmonize the terminology in the Regulations in order to reflect changes that may be made to the Department of Health's legislation and/or regulations, and that may impact these Regulations.

#### Non-prescription drug

One industry association questioned whether the term "Non-Prescription Drug" is defined in legislation.

*Response*: The term "Non-Prescription Drug" is not defined in the Regulations. However, in Canada a non-prescription drug is a pharmaceutical product that treats or prevents diseases or symptoms but that also does not fall under the definition of a prescription drug within the meaning of section A.01.010 of the *Food and Drug Regulations*. (see footnote 25)

# **Exemptions**

One ENGO requested that there not be an exemption for toiletries in transit through Canada.

*Response*: The Regulations are considered to be technical regulations under the World Trade Organization (WTO) Agreement on Trade Facilitation (TFA), which came into force on February 22, 2017. Article 11.8 of the TFA prohibits the application of technical regulations to goods moving through a WTO Member's territory from a point outside its territory to another foreign point (i.e. goods in transit).

### **Bioplastics and other new alternatives**

Five ENGOs requested that the Regulations prohibit bioplastic microbeads and also requested that other alternatives for plastic microbeads be assessed prior to being allowed for use in consumer products. In addition, one industry association raised concerns that the prohibition of bioplastic microbeads precludes the development of innovative biodegradable polymers that may not be a risk to human health or the environment.

Response: The Department agrees with the five ENGOs and has not exempted biopolymers, such as polylactic acid (PLA) plastic, poly-hydroxy-alkanoate (PHA) or poly-hydroxy-butyrate (PHB), in the regulatory approach. Several studies have been undertaken on biodegradable plastics which support this approach, including a study conducted by the California Department of Resources, Recycling and Recovery (see footnote 26) that showed that while certain alternatives may biodegrade to some extent over a period of a year, a significant percentage (20–50%) of these plastics will remain in the aquatic environment. In addition, a recently published United Nations Environment Programme (UNEP) report titled Biodegradable Plastics & Marine Litter concluded that "biodegradable plastics will not play a significant role in reducing marine litter." This is consistent with the U.S. legislative approach, which also does not exempt bioplastics.

With respect to other new alternatives to plastic microbeads, non-plastic alternatives that are currently on the Canadian market without existing prohibitions or controls may be used. However, if alternatives are substances new to Canada, the Government uses a preventative approach to managing the risks these may pose to humans or the environment. Under the *New Substances Notification Regulations* (Chemicals and Polymers) and the New Substances Notification Regulations (Organisms) of CEPA, the Department of Health and the Department of the Environment assess the potential risks that activities and uses of new substances (including organisms) may pose to Canadians or the environment before they are introduced into the Canadian marketplace.

### **Laboratory standards and testing**

One industry association requested that this section be removed from the Regulations as they believe it is unnecessary and complicates the Regulations. Another industry association indicated that it is unclear when certification from an accredited laboratory is required and by whom.

Several ENGOS urged the Department to provide more information regarding the methodology, quality standards and testing that will be used to determine the presence or absence of plastic microbeads.

Response: The Regulations are clear that regulatees are not required to submit reports or conduct product testing to comply with the Regulations; however, if a determination of the presence of plastic microbeads is required for enforcement purposes, it must be performed by an accredited laboratory. This requirement serves to inform regulatees of the laboratory standards that will be used by an enforcement officer to determine compliance with the regulatory provisions.

As part of its compliance promotion activities, the Department plans to share the methodology with stakeholders prior to the coming into force of the Regulations.

### **Coming into force**

# Advancing the coming-into-force dates

Nine ENGOs and several Canadian citizens urged the Canadian Government to expedite the Regulations. One of these ENGOs submitted a Notice of Objection (see footnote 27) to the coming-into-force timelines and requested that the Regulations come into force one year earlier on January 1, 2017. Five

additional ENGOs requested that the prohibition of manufacture, import, and sale of all toiletries, including natural health products and non-prescription drugs be advanced to July 1, 2017.

*Response*: Normal regulatory development timelines were streamlined wherever possible to ensure the timely implementation of the Regulations. Both CEPA and the *Cabinet Directive on Regulatory Management* requires Departments to publish proposed regulations in the *Canada Gazette*, Part I, for a public comment period, and then to take the comments received into consideration.

In addition, these Regulations are considered to be technical regulations under the WTO Agreement on Technical Barriers to Trade. Parties to the Agreement must leave a "reasonable interval" (generally understood as six months) between the publication and entry into force of such regulations.

The first coming-into-force date of January 1, 2018 was determined to take these obligations into account and to provide industry stakeholders time to source or reformulate toiletries to comply with the Regulations.

### **Dumping of products**

Several ENGOs expressed concerns that the first coming-into-force date in the Regulations is six months after that of the United States and that this could result in the dumping of products in Canada.

*Response*: Although the first prohibition on manufacture will come into force six months after that of the United States (January 2018 vs. July 2017), the date of the prohibition of sales of toiletries that contain plastic microbeads will be aligned with that in the United States (July 2018). Given that sales of the products in both countries will be banned at the same time, dumping is not expected.

### **Delaying the coming-into-force dates**

One industry association recommended that the Department allow an extra year for all coming-into-force dates in order for industry to comply with the Regulations. Another industry association indicated support for most of the coming-into-force dates in the Regulations but requested that the coming-into-force date for the sale of toiletries that are not also non-prescription drugs or natural health products be extended from July 1, 2018 to January 1, 2019.

Response: The majority of plastic microbeads from affected toiletries are expected to have been phased out before the Regulations are enacted. Information provided to the Government in March 2016 indicated that manufacturers accounting for 99% of the total amount of plastic microbeads used in 2014 to manufacture toiletries will have phased out the use of plastic microbeads in toiletries by the time the prohibitions come into effect. Furthermore, several importers indicated that they already have access to toiletries that do not contain plastic microbeads at similar costs to toiletries that contain plastic microbeads. Based on the available evidence, it was determined that the Regulations provide a reasonable amount of time for those few businesses that require time to deplete their inventories and therefore granting more time to comply with the Regulations was not deemed necessary.

In addition, the coming-into-force date for the sale prohibitions has been aligned with those of the United States to provide a level playing field for Canadian and American businesses.

### Potential stockpiles, export and disposal of toiletries that contain plastic microbeads

Several ENGOs recommended that the Regulations require companies to develop sustainable disposal procedures and establish take-back programs to encourage consumers to return toiletries. They also requested that the Government provide guidance to consumers on the proper disposal of these products.

Several ENGOs urged the Government to consider recall strategies to ensure toiletries containing plastic microbeads are not available on the Canadian market after the Regulations are in force.

One ENGO requested that the Canadian Government ensure that the existing stock of toiletries that contain plastic microbeads not be exported outside of the country.

*Response*: At the time of coming into force of the prohibitions on sale, there is not expected to be any remaining inventory. By the time the prohibitions come into effect, the manufacturers that accounted for 99% of the plastic microbeads used in 2014 to manufacture toiletries will have phased out their use. As a result, stockpiles are expected to be negligible and this is expected to minimize the likelihood of products being exported from Canada. Take-back programs are therefore not being contemplated.

While individuals can continue to use toiletries that contain plastic microbeads, as part of compliance promotion materials, information will be provided on how individuals can dispose of the toiletries if they wish to do so prior to the Regulations coming into force. If they wish to dispose of these toiletries, the Department recommends that toiletries that contain plastic microbeads be disposed of in the garbage. This will help to contain and manage toiletries that contain plastic microbeads in an environmentally sound manner, for example, in a landfill. If the toiletries that contain plastic microbeads are packaged in a recyclable container, the contents may be emptied in the garbage and recycled according to the provincial/territorial or municipal waste management standards. Disposing of toiletries that contain plastic microbeads down the drain is not recommended, as plastic microbeads are not fully removed from wastewater during treatment and will enter the environment through wastewater systems.

### **Environmental monitoring**

Several ENGOs recommended that the Government develop environmental monitoring and public reporting on plastic microbeads in the environment, including in fish and shellfish. They also recommended that the Government monitor the health implications of human ingestion of fish and shellfish contaminated by microbeads.

*Response*: No concerns related to human health were identified in the science review. Microplastics are, however, an area of emerging and evolving science, and the Government continues to follow scientific developments on this issue. The Department of Health will continue to review any new information on sources of exposure to plastic microbeads, including seafood, to determine the possible implications to

human health. Should a health risk be identified from any food, appropriate risk management actions would be developed by the Department of Health and the Canadian Food Inspection Agency.

The Department takes its role in achieving a clean, safe and sustainable environment seriously and it will continue to work with international partners such as through the United Nations and the G7 and domestic partners to address the broader issue of marine litter and microplastics.

### **Regulatory cooperation**

The Regulations are harmonized with measures in place in the United States, to the extent feasible given different legislative authorities and timelines.

Definition of plastic microbeads: In the United States, under the Microbead-Free Waters Act of 2015, plastic microbeads are referred to as "any solid plastic particle that is less than five millimetres in size and is intended to be used to exfoliate or cleanse the human body or any part thereof." In Canada, microbeads mean any plastic microbeads that are ≤ 5 mm in size. The plastic microbeads that are the focus of the Regulations are solid plastic particles known to be equal to or less than 5 mm in size (in the largest external dimension) which are added to toiletries, including non-prescription drugs and natural health products. The prohibitions in the Regulations are with respect to all such plastic microbeads in toiletries irrespective of why the microbeads are present in the regulated products.

Scope of application: The scope of the products covered under each phase of the microbeads prohibitions in Canada is the same as that in the United States. However, some differences in terminology exist due to differing legislative drafting protocols and authorities.

- The U.S. Microbead-Free Waters Act of 2015 applies to "rinse-off" cosmetics that contain intentionally added plastic microbeads, including toothpaste. Cosmetics under the U.S. Federal Food, Drug, and Cosmetic Act (see footnote 28) are defined as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance."
- Some differences in terminology exist due to differing legislative drafting protocols and authorities. As a result, these regulations define the product itself, not how the consumer may choose to use the product: the Regulations instead prohibit toiletries that contain plastic microbeads, with toiletries defined as "any personal hair, skin, teeth or mouth care products for cleansing or hygiene, including exfoliants and any of those products that is also a natural health product as defined in the Natural Health Products Regulations or a non-prescription drug."
- The United States also prohibits rinse-off "non-prescription drugs" that contain plastic microbeads. The scope of this term, under U.S. law, includes what in Canada are referred to as "non-prescription drugs" and "natural health products." In brief, "rinse-off cosmetics and non-prescription drugs" in the United States is equivalent to "toiletries including non-prescription drugs and natural health products" in Canada.

Timelines: The Regulations introduce the prohibition on toiletries that contain plastic microbeads in two phases. Phase one prohibits toiletries that contain plastic microbeads, excluding non-prescription drugs and natural health products and phase two prohibits all toiletries that contain plastic microbeads, including non-prescription drugs and natural health products. Each of these phases includes two coming-into-force dates: first, for manufacture and import; and second, for sale. Under the U.S. Microbead-Free Waters Act of 2015, the two coming-into-force dates (i.e. for the prohibition of "rinse-off" cosmetics and non-prescription drugs that contain plastic microbeads) apply to manufacture, followed by interstate commerce.

- The first coming-into-force date for each phase will, in Canada, apply to manufacture and import, to ensure a level playing field for Canadian manufacturers and importers.
- The second coming-into-force date for each phase will apply to sales which are expected to achieve the same result as the U.S. prohibition on interstate commerce. According to the U.S. Food and Drug Administration, it is rare that a product on the U.S. market is not interstate commerce, as at least some ingredients or packaging most likely originates from outside of the state, or outside of the country. (see footnote 29)

In Canada, the first coming-into-force date for phase one is six months later than in the United States, in order to meet the requirement of the WTO Technical Barriers to Trade Agreement to leave a reasonable interval between publication of the instrument and its coming-into-force date. The remaining coming-into-force dates are aligned with the U.S. law.

### Rationale

The environmental impact from plastic litter continues to increase globally. Plastic waste entering freshwater and marine ecosystems can come from various sources, from plastic bags and bottles to microplastics (including plastic microbeads). The plastic microbeads that are the focus of the Regulations are used in toiletries. Plastic microbeads in toiletries are eventually washed down the drain when consumers use them. As plastic microbeads are expected to reside in the environment for a long time and are too small to be entirely captured by wastewater treatment plants, there is a portion that enters and is expected to accumulate in the aquatic environment. In Canada, plastic microbeads have been reported in coastal British Columbia, the Great Lakes, the St. Lawrence, and in coastal Atlantic Canada.

Scientific literature indicates that plastic microbeads are readily taken up by a variety of non-human organisms and have adverse short-term and long-term effects on aquatic organisms as plastic microbeads can impede feeding behaviour, leading to reduced body growth and reproduction.

Given industry's anticipated voluntary phase out of plastic microbeads from toiletries, Canadian manufacturers, importers and consumers are not expected to be significantly impacted by the Regulations; however, the Regulations will mitigate the risk of re-introduction or continued import of plastic microbeads in toiletries in the future. Therefore, the Government is prohibiting the manufacture, import, and sale of toiletries that contain plastic microbeads in Canada.

Consequential amendments to the *Designation Regulations* will allow for the effective enforcement of the Regulations, and promote compliance.

### Strategic environmental assessment

The Regulations have been developed under the Government's Chemical Management Plan (CMP). The strategic environmental assessment (SEA) for the CMP (see footnote 30) concluded that such regulatory provisions will contribute to its goals of protecting and enhancing the quality of the water so that it is clean, safe and secure for all Canadians and supports healthy ecosystems, and also support the Federal Sustainable Development Strategy goals for protecting and enhancing the quality of the water. (see footnote 31)

### Implementation, enforcement and service standards

### <u>Implementation</u>

An intensive compliance promotion approach will be adopted by the Department within the first year after the publication of the Regulations, to ensure their effective and efficient implementation. The Department will develop and distribute compliance promotion materials (e.g. a fact sheet or web site material) to ensure that the regulated community is aware of the requirements of the Regulations. Working relationships have been established with industry and industry associations involved in the manufacture, import and sale of products covered by the Regulations. The Department will work with these organizations to ensure that the appropriate information is available to interested parties. As the regulated community becomes more familiar with the requirements of the Regulations, these activities are expected to decline to a maintenance level.

### **Enforcement**

The Regulations are made under CEPA, so enforcement officers will, when verifying compliance with the Regulations, act in accordance with the *Compliance and Enforcement Policy for CEPA (1999)* [hereinafter, the Policy].

Verification of compliance with the Regulations will include, among other inspection activities, sample analysis, site visits and review of written transit documents. When, following an inspection or an investigation, an enforcement officer discovers an alleged violation, the officer would choose the appropriate enforcement action based on the following factors, as outlined in the Policy:

- Nature of the alleged violation: This includes consideration of the damage, the intent of the alleged violator, whether it is a repeat violation, and whether an attempt has been made to conceal information or otherwise subvert the objectives and requirements of CEPA;
- Effectiveness in achieving the desired result with the alleged violator: The desired result is compliance within the shortest possible time and with no further repetition of the violation. Factors to be considered include the violator's history of compliance with CEPA, willingness to cooperate with enforcement officers, and evidence of corrective action already taken; and

• Consistency: Enforcement officers will consider how similar situations have been handled in determining the measures to be taken to enforce CEPA.

Subject to the enforcement officer's discretion, the following responses are available to deal with alleged violations of CEPA and its regulations:

- Warnings;
- Directions;
- Tickets;
- Ministerial orders;
- Environmental protection compliance orders;
- Detention orders for ships;
- Injunctions;
- Prosecutions;
- · Environmental protection alternative measures; and
- Court orders following convictions and civil suits by the Crown to recover costs.

More information on the Policy is available at the following address: https://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=5082BFBE-1.

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#### • <u>Footnote a</u>

S.C. 2004, c. 15, s. 31

### • Footnote b

S.C. 1999, c. 33

#### • Footnote c

S.C. 2015, c. 3, par. 172(d)

# • Footnote d

S.C. 1999, c. 33

## • Footnote 1

SOR/2012-134

#### • Footnote 2

Smaller particles of plastic are broadly referred to as microplastics.

### • Footnote 3

For the purposes of these Regulations, toiletries mean any personal hair, skin, teeth or mouth care products for cleansing or hygiene, including exfoliants and any of those products that is also a natural health product as defined in the *Natural Health Products Regulations* or a non-prescription drug.

# • Footnote 4

For more information on the scientific literature, please see the Science Summary report on microbeads at https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=ADDA4C5F-1.

#### • Footnote 5

CEPA defines the term « sell » to include to offer for sale.

# • Footnote 6

For more information, please see http://www.scics.ca/en/product-produit/news-release-environment-ministers-reaffirm-their-commitment-to-fight-climate-change/.

#### • Footnote 7

For more information, please see http://gazette.gc.ca/rp-pr/p1/2016/2016-11-05/html/reg2-eng.php.

## • Footnote 8

Plastic microbeads are also used in industrial settings for plastic blasting at shipyards, garments and car parts, oil and gas exploration, textile printing, and automotive molding. Other plastic products that use microbeads include anti-slip and anti-blocking applications and medical applications (biotechnology and biomedical research).

#### • Footnote 9

For the purpose of the Regulations, a non-prescription drug would be a pharmaceutical product that treats or prevents diseases or symptoms but that also does not fall under the definition of a prescription drug within the meaning of section A.01.010 of the *Food and Drug Regulations*.

#### • Footnote 10

Natural health products are defined under the *Natural Health Products Regulations*. For more information, please see http://laws-lois.justice.gc.ca/PDF/SOR-2003-196.pdf, page 2.

#### • Footnote 11

For more information on this study, please see the Science Summary report on microbeads at http://www.ec.gc.ca/ese-ees/ADDA4C5F-F397-48D5-AD17-63F989EBD0E5/Microbeads\_Science%20Summary\_EN.pdf, page 11.

# • Footnote 12

For more information on the presence of microplastics in Canada, please see the Science Summary report, page 15.

#### Footnote 13

For more information on section 71 of CEPA, please see http://www.ec.gc.ca/lcpe-cepa/26A03BFA-C67E-4322-AFCA-2C40015E741C/lcpe-cepa 201310125 loi-bill.pdf, page 41.

#### Footnote 14

"Microplastics in the ocean: a global assessment," GESAMP, 2015.

### • Footnote 15

Under the Act of Congress (H.R. 1321), the term "plastic microbeads" means any solid plastic particle that is less than 5 mm in size and is intended to be used to exfoliate or cleanse the human body or any part thereof.

#### Footnote 16

For more information, please see: http://www.eunomia.co.uk/reports-tools/study-to-support-the-development-of-measures-to-combat-a-range-of-marine-litter-sources/.

### • Footnote 17

For more information, please see http://laws-lois.justice.gc.ca/PDF/SOR-2012-134.pdf.

#### • Footnote 18

These values are based on information received in March 2016, from industry, in response to a follow-up questionnaire to a survey conducted in 2015 under section 71 of CEPA.

# Footnote 19

For more information, please see http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/manuf11-eng.htm.

#### Footnote 20

http://www.cctfa.ca/site/consumerinfo/Consumer\_Information.htm, as accessed on June 1, 2016.

#### Footnote 21

The main category of alternatives that can be used to replace plastic microbeads in toiletries comprises natural exfoliates such as apricot seeds, walnut shells, bamboo, sugar, salt, almonds and oatmeal.

#### Footnote 22

For more information about the comments and Government's responses to these comments, please see http://gazette.gc.ca/rp-pr/p1/2016/2016-11-05/html/reg2-eng.php.

### • Footnote 23

CEPA NAC provides a platform for ensuring a full and open sharing of information between the federal, provincial, territorial, and aboriginal governments on all matters related to the protection of the environment and the management of toxic substances. It is the main intergovernmental forum for the purpose of enabling national action and avoiding duplication in regulatory activity among governments within Canada.

#### Footnote 24

For more information, please visit https://www.canada.ca/en/health-canada/programs/consultation-regulation-self-careproducts/consulting-canadians-regulation-self-care-products-canada.html.

### • Footnote 25

For more information, please see http://laws-lois.justice.gc.ca/PDF/C.R.C., c. 870.pdf, page 2.

### • Footnote 26

For more information, please see: www.calrecycle.ca.gov/publications/Documents/1435%5C20121435.pdf.

#### Footnote 27

The provisions of the *Canadian Environmental Protection Act, 1999* regarding Notices of Objection (section 332) provide that, within 60 days after the publication of a proposed regulation, any person may file comments with respect to the Regulations or a Notice of Objection requesting that a board of review be established, stating the reasons for the objection.

## Footnote 28

For more information, please see

https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/federalfooddrugandcosmeticac tfdcact/default.htm.

### • Footnote 29

For more information, please see https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074248.htm#Interst ate\_Commerce.

# Footnote 30

Cabinet Directive on the Environmental Assessment of Policy, Plan and Program Proposals. Canadian Environmental Assessment Agency: http://www.ceaa.gc.ca/default.asp?lang=En&n=B3186435-1.

### • Footnote 31

The public statement regarding the strategic environmental assessment for the Chemical Management Plan is available at the following address: http://www.chemicalsubstanceschimiques.gc.ca/plan/sea-ees-eng.php.

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