HEALTH PRODUCTS STEWARDSHIP ASSOCIATION

New Brunswick Pharmaceuticals and Sharps Stewardship Plan

2023-2027

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Terms and Definitions

Brand Owner	A person who: (i) is a manufacturer of pharmaceutical products or medical sharps, (ii) is a distributor of pharmaceutical products or medical sharps, (iii) is an owner or licensee of a registered or unregistered trademark under which pharmaceutical products or medical sharps are sold, offered for sale, or distributed, or (iv) if a pharmaceutical product or medical sharp is imported into the province, is the first person to sell the pharmaceutical product or medical sharp.
Collection Location	A location, typically a retail pharmacy, registered with HPSA to collect the pharmaceutical product and medical sharp waste returned by consumers. Referred to as "return facility" in the Regulation.
Commercial waste agreement	An agreement with a waste management service provider to manage Industrial, Commercial, or Institutional (IC&I) waste (e.g., a commercial waste agreement to manage medical sharp wastes from immunization/flu shots, COVID-19 vaccines)
Consumer	A person who uses a pharmaceutical product or medical sharp for their own purpose or that of their companion animal, and not for the purpose of resale.
Cytotoxic waste	Waste containing substances with genotoxic properties (e.g., waste containing cytostatic drugs – often used in cancer therapy; genotoxic chemicals)
Material type	For this Stewardship Plan, two types of materials are defined: - Material type 1: Pharmaceutical waste (which include prescription drugs, over-the-counter drugs and natural health products waste) - Material type 2: Sharp waste.
Medical Sharp	A needle, safety-engineered needle, lancet or other similar instrument designed for medical purposes to puncture the skin of a consumer or their companion animal and includes anything affixed to the medical sharp, including a syringe. Also referred to as ‘’sharp’ in this document.
Pharmaceutical Product	A drug as defined in section 2 of the Food and Drugs Act (Canada) and a natural health product as defined in subsection 1(1) of the Natural Health Products Regulations made under that Act, but does not include: (a) a food as defined in section 2 of the Food and Drugs Act (Canada), (b) a cosmetic as defined in section 2 of the Food and Drugs Act (Canada), (c) a drug that is a radiopharmaceutical as defined in Part C of the Food and Drug Regulations made under the Food and Drugs Act (Canada) (d) a drug for veterinary use except for a drug for veterinary use in a consumer's companion animal, (e) a topical substance that does not contain an antibiotic, antifungal or analgesic, or (f) a drug that is represented as being solely for use as a disinfectant on hard non-porous surfaces. Also referred to as ‘pharmaceutical’ and 'medication' in this document.

Acronyms

- CL: Collection Location
- DIN: Drug Identification Number
- DIN-HM: Homeopathic Medicine Number
- EPR: Extended Producer Responsibility
- HPSA: Health Products Stewardship Association
- IC&I: Industrial, Commercial, and Institutional
- NB: New Brunswick
- NBPA: New Brunswick Pharmacists' Association
- NBPSP: New Brunswick Pharmaceuticals and Sharps Program
- NHP: Natural Health Product
- NPN: Natural Product Number
- OTC: Over The Counter drug
- PRO: Producer Responsibility Organization
- RFP: Request For Proposal
- RNB: Recycle New Brunswick
- RX: Prescription drug

Introduction

Health Products Stewardship Association (**HPSA**) is a federally incorporated, not-for-profit Producer Responsibility Organization (PRO) formed over twenty (20) years ago in response to Extended Producer Responsibility (EPR) regulations pertaining to pharmaceutical products (**pharmaceuticals)** and medical sharps (**sharps**).

HPSA currently operates seven (7) programs in four (4) provinces where EPR regulations exist. The knowledge and network built over the years have helped educate Canadians about the pharmaceutical product and medical sharp waste, proper storage at home, safe return and end-of-life management.

HPSA operates under the general principles of:

- **Harmonization:** harmonization with other jurisdictions where programs already exist to create efficiencies in program management and deliveries.
- **No-cross subsidization**: costs of a program shall only be charged to the Brand Owners selling the specific product in the specific province.
- **Level-playing field:** costs associated with the program shall be charged based on the Brand Owner's market share in the program.

HPSA has been designated as an agent per section 50.74 of New Brunswick (NB) Regulation 2022-73, amending NB Regulation 2008-54 (which, consolidated, is referred to as '**the Regulation**') by its members who are obligated under the Regulation as Brand Owners in New Brunswick.

HPSA is thus submitting the New Brunswick Pharmaceuticals and Sharps Stewardship Plan on behalf of its members. The Plan details the New Brunswick Pharmaceuticals and Sharps Program (**NBPSP**) (**Program**) that manages two material types:

- Material type 1: Pharmaceutical waste, which includes prescription drugs (**RX**), over-the-counter drugs (**OTC**) and natural health products (**NHP**) waste.
- Material type 2: Sharp waste.

The list of HPSA members on whose behalf the plan is submitted is included in *Appendix A.*

In compliance with the Regulation, the NBPSP shall provide all New Brunswick residents with province-wide access to collection locations (CLs).

The Plan criteria and requirements for the proposed Program under the Regulation are outlined in *Appendix B.*

Efforts shall be made by HPSA to educate obligated parties of their responsibility and to pursue compliance (see page 8).
Of note the proposed Plan was submitted to HPSA members and the New Brunswick Pharmacists' Association (NBPA) for their feedback. Comments received were addressed in the version of the proposed Plan submitted to Recycle New Brunswick (RNB).

I. Program Management

HPSA has appointed a bilingual Programs Director who is responsible for all aspects of the Program, including:

- Relationship with Recycle New Brunswick (RNB).
- Relationship with stakeholders such as NBPA, municipalities, patient specific associations, other Collection Locations associations and other relevant stakeholders in the province.
- Establishment and maintenance of a Collection Location network for the Program in New Brunswick.
- Establishment and maintenance of an infrastructure for the delivery of clean supplies to the Collection Location network and transportation of waste collected from the Collection Location network to the final disposal facility.
- Bilingual promotion, education, and awareness campaigns for New Brunswick residents.

HPSA commits to hire a New Brunswick bilingual resident to support the Program management. HPSA shall be responsible for the strategic planning of the activities in New Brunswick, general financial operations, as well as overseeing the operational aspect of the Program delivery when harmonization with other provinces leads to cost efficiencies. The bilingual Programs Director is a member of the executive management team of HPSA.

Recycle New Brunswick (RNB) Advisory Committee

HPSA shall work cooperatively with RNB in identifying the stakeholders for the RNB-led Industry Advisory Committee meetings.

II. Program Funding

NBPSP shall be fully funded by HPSA members selling RX, OTC and NHP and sharps in New Brunswick based on the obligated parties' market share.

The fees charged to HPSA members shall reflect the true cost of managing each material type designated by the Regulation. The fees provide sustainable funding for collection, transportation, storage, and processing/disposal (including recovery of energy and disposal), communications and public awareness campaign, compliance/administration, and relevant audits.

To ensure long-term sustainability, HPSA shall be developing a contingency reserve for the Program, with relevant provision for each material type, in the event that collection, transportation, storage and processing costs exceed the funds available. This can happen in times of economic downturn or other unforeseen events, nevertheless requiring an uninterrupted, responsible service to continue. The contingency reserve shall not equal more than twelve (12) months of operating costs. The Program shall be audited annually by an independent external auditor from a performance and financial perspective.

In line with HPSA general principles, there is no cross-subsidization between material types operational and financial distinct management features.

HPSA operates a "return to retail" approach whereby the public returns pharmaceutical product and medical sharp waste to pharmacies or approved alternate Collection Locations. Collection Locations' participation in the HPSA network is voluntary.

The Regulation requires that Brand Owners register directly with Recycle New Brunswick. As the designated agent for Brand Owners, HPSA shall continue to communicate with its members to educate them of their responsibility and to pursue compliance. In the event of noncompliance, files will be referred to Recycle NB only after efforts have been made by HPSA to get them into the compliance and a detailed summary will identify efforts made by HPSA.

III. Program Products

A. Definitions

The products covered by the Program are defined in the Regulation and are referenced below:

Pharmaceuticals (RX, OTC and NHP) Category

"A drug as defined in section 2 of the Food and Drugs Act (Canada) and a natural health product as defined in subsection 1(1) of the Natural Health Products Regulations made under that Act,".

The pharmaceuticals category shall generally include:

- Any pharmaceutical product approved by Health Canada, with a Drug Identification Number (DIN) and sold in New Brunswick (RX or OTC).

- Any natural health product (NHP) approved by Health Canada, with a Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) and sold in New Brunswick.

NOT included in the pharmaceuticals category are:

- a food as defined in section 2 of the *Food and Drugs Act* (Canada).
- a cosmetic as defined in section 2 of the *Food and Drugs Act* (Canada).
- a drug that is a radiopharmaceutical as defined in Part C of the *Food and Drug Regulations* made under the *Food and Drugs Act* (Canada).
- a drug for veterinary use except for a drug for veterinary use in a consumer's companion animal.
- a topical substance that does not contain an antibiotic, antifungal or analgesic; or
- a drug that is represented as being solely for use as a disinfectant on hard non-porous surfaces.

No returned product intended for industrial, commercial, or institutional (IC&I) use shall be included in the Program. In other words, any pharmaceutical product used/administered by a health care practitioner shall remain under the proper collection and disposal procedures of a commercial waste agreement.

Sharps Category

"*A needle, safety engineered needle, lancet or other similar instrument that is designed, for medical purposes, to puncture the skin of a consumer or their companion animal and includes anything affixed to the medical sharp, including a syringe.*"

Examples of products that are included in the sharps category are (list not exhaustive):

- Infusion sets with needle attached.
- Lancets, including safety lancets.
- Needle tips.
- Needles, including safety needles.
- Pen with needle attached.
- Pen needles.
- Prefilled cartridges with needle attached.
- Pre-filled syringes with needle attached.
- Safety pens with needle attached.
- Syringes with needle attached.

No returned product intended for industrial, commercial, or institutional (IC&I) use shall be included in the Program. In other words, any sharp used in the context of an immunization campaign and/or administered by a health care practitioner (e.g., flu/influenza, COVID) shall remain under the proper collection and disposal procedures of a commercial waste agreement.

B. Description of Material Types

Regulatory requirement:

(n) a description of the material types that shall be used for performance measures and targets and annual reporting purposes;

As detailed in the section below, the collection of pharmaceutical and sharp waste shall be done using separate containers for each type of waste (RX, OTC and NHP waste on one side – material type 1, and medical sharp waste on the other side – material type 2). Several federal and provincial acts, regulations and guidelines dictate the storage, transport, consolidation and disposal of these wastes.

Material type 1: RX, OTC and NHP waste

Health Canada Guidance Document: Handling and destruction of post-consumer returns containing controlled substances (CS-GD-021)[1] states that "*Effective April 1, 2018, Health Canada no longer requires that pharmacists record the name of the drug product, strength and quantity for post-consumer returns. Consequently, there is no requirement to separate post-consumer returned controlled drugs and substances from other post-consumer returned prescription or non-prescription medications.*"

As a consequence, the material type 1 consist of the bulk of prescription drugs, other-the-counter drugs and natural health products brought back comingled by the consumers, which may contain opioids and controlled drugs and substances.

[1] https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/controlled-substances/compliance-monitoring/compliance-monitoring-controlled-substances/post-consumer-returns.html

Material type 2: sharp waste

Unused or used sharps that have been in contact with blood or with a biological liquid or tissue. Due to the possibility of the use of the sharps to administer cytotoxic drugs, the sharp waste may be labelled as cytotoxic.

Disposal of the above-mentioned waste is as follows:

- Pharmaceutical waste and cytotoxic sharp waste are being incinerated.
- Non-cytotoxic sharp waste is being autoclaved.

For performance measures and targets and annual reporting purposes, there shall be two material types as described above:

- Material type 1: RX, OTC and NHP waste.
- Material type 2: (cytotoxic and non-cytotoxic) sharp waste.

C. Expected Quantity Sold and Expected Quantity Collected

Regulatory requirement:

(b) information on the expected quantity or weight of pharmaceutical products and medical sharps, by material type, to be distributed within the Province and the expected quantity or weight of pharmaceutical product and medical sharp waste, by material type, to be collected or processed;

Pharmaceuticals (RX, OTC and NHP) and corresponding waste

An estimate of extended units of RX to be distributed in 2024 within the province has been assessed at 6.5 million.

An estimate of OTC sales in 2024 within the province has been assessed at $ 5 million.
An estimate of NHP sales in 2024 within the province has been assessed at $ 7 million.

In 2024, HPSA commits to modify its reporting process to provide Recycle NB the necessary regulatory reporting information.

Regarding the expected quantity or weight of pharmaceutical waste, based on the maturity of the Program, extrapolation for New Brunswick population, the number of pharmacies in the province as well as average weight collected in other provinces, and the below mentioned annual growth rate of approximately 5% of the market, HPSA anticipates collecting the following quantities over the duration of the Plan:

Waste type	2024	2025	2026	2027
RX + OTX + NHP waste (kg)	10,000	10,500	11,025	11,576

Sharps and corresponding waste

The following figures are expected quantities of sharps distributed in the province:

Product type	2024	2025	2026	2027
Medical sharps (kg)	27,000	28,350	29,767	31,256

Regarding the expected quantity or weight of sharp waste, based on the maturity of the Program, the New Brunswick population, the number of pharmacies in the province as well as average weight collected in other provinces, HPSA anticipates collecting (with an annual growth rate of approximatively 5%):

Waste type	2024	2025	2026	2027
Medical sharp waste (kg)	13,500	14,175	14,884	15,628

IV. Plan Details

Regulatory requirement:

(a) the plan for the collection, transportation, storage and processing of pharmaceutical product and medical sharp waste within the Province, including the pharmaceutical product and medical sharp waste of other brand owners;

Regulatory requirement:

(c) information on the province-wide collection system, including information with respect to return facilities, by material type, to be used by the consumer;

Regulatory Requirement:

(d) a description of how existing collection and processing systems were considered to maximize waste diversion in the Province;

Any “Orphan” and “Free Rider” products are accepted. “Orphan” products are products produced by a Brand Owner that either no longer exists or no longer produces such products. “Free Rider” products are products imported or distributed by an obligated Brand Owner that is not a registered member of HPSA. “Free riders” will be identified via the monitoring of products sold in the province and will be approached for return into compliance.

A. Collection System

HPSA commits to:

- having 50 % (i.e. 117, based on January 1, 2023 statistics[2]) of the licensed community pharmacies in New Brunswick, (ensuring that each regional service commission region has the appropriate accessibility), enrolled in the Program within one month of the Program start date.
- reporting to RNB on a quarterly basis on any new Collection Location enrolled in the Program.

1. Retail Pharmacies as main Collection Locations and alternate Collection Locations

Considering the specific nature of the pharmaceutical and sharp waste, the expertise gained from managing similar programs in other Canadian provinces and the fact that New Brunswick community pharmacies already provide take-back program, the use of community pharmacies as the most relevant Collection Locations were considered as the best way to maximize waste diversion (from disposal in households) in the province.
Pharmacies are a logical and safe system for the public to return pharmaceutical and sharp waste. Many have extended hours, offering a convenient place for consumer take-back year-round.

HPSA shall approve any Collection Location not being a retail pharmacy (alternate Collection Location) that would like to offer a collection of pharmaceutical product or medical sharp waste under the NBPSP.

Ahead of the NBPSP implementation day and before the collection of any pharmaceutical or sharp waste can begin, every Collection Location shall have an agreement (Collection Location Agreement) in place with HPSA regarding the collection and storage of pharmaceutical and sharp waste, meet Collection Location standards and have access to HPSA's portal.

Below are some of the general terms and conditions applicable for a retail pharmacy to be registered as an HPSA Collection Location:

- In the case of retail pharmacies, Collection Locations shall have a valid provincial pharmacy license issued by the College of Pharmacists of New Brunswick.
- A valid commercial waste agreement (CWA) proof shall be submitted to HPSA.
- A Collection Location shall provide the ability to drop off products during regular business hours and at no cost to consumers.
- A Collection Location shall display and spread public awareness through promotional and educational HPSA Program materials.
- A licensed pharmacist or pharmacy technician (key employees in community pharmacies) shall be present when a consumer drops off pharmaceutical and/or sharp waste.
- Pharmaceutical or sharp waste managed under an IC&I contract, from hospitals, institutions, doctor's offices, or pharmacy operations are not acceptable.
- Key employees working at the Collection Location shall be knowledgeable about the Program offered to consumers.
- Sharps containers shall be segregated from commercial pharmaceutical waste.
- Temporary storage duration of pharmaceutical waste and sharp waste respective containers at the Collection Location will depend on the mode of pick-up by the waste management service provider (scheduled vs. ad-hoc phone call).

[2] https://www.napra.ca/resources/national-statistics/

Specific Instructions for the material type 1:

- Collection Locations shall be supplied with one or more HPSA-labelled pharmaceuticals containers (2023: 60L green olive container) at no cost.
- The HPSA-labelled pharmaceuticals container is to be placed behind the counter of a dispensary.
- There is no limitation on the quantity of pharmaceuticals that a consumer can drop off.
- Any consumer pharmaceutical waste returns shall be placed into the HPSA-labelled pharmaceuticals container.
- All secondary packaging should be recycled where facilities exist and are available in a particular region.
- The only exceptions to this rule are liquid pharmaceutical products, gels, and powder that can be placed in their original vials (primary packaging) directly in the pharmaceuticals container.

Specific instructions for the material type 2:

- Collection Locations shall be supplied with HPSA-labelled sharps containers at no cost.
- Pharmacists or pharmacy technicians distribute HPSA-labelled sharps containers at no cost to any member of the public requesting one.
- Collection Locations should only accept sharp waste contained in a hard-shell container labelled with the biohazardous infectious materials pictogram, whether it is an HPSA-labelled sharps container or not.
- Sharps containers containing sharp waste from the administration of cytotoxic drugs shall be labelled with a cytotoxic label. Collection Location is being supplied cytotoxic labels at no cost on demand.
- Upon receiving sharps containers, pharmacists should ensure that the tops of the containers are locked and placed inside an HPSA-labelled return overpacking.

The voluntary participation of retail pharmacies and pharmacists, as well as potential alternate Collection Locations, is essential to the success of the Program. HPSA commits to working closely with New Brunswick Pharmacists' Association to support its pharmacists and staff, as well as alternate Collection Location owners/operators or related association(s), during the transition to the HPSA-led collection network, and moving forward, to ensure continued participation and awareness of the Program.

2. Collection in Remote and Rural Communities

Regulatory Requirement

(f) the plan for the provision of services to remote or rural areas;

HPSA shall pay particular attention to ensure remote and rural communities are adequately serviced by its Program. HPSA is aware of the key features of New Brunswick territory and population specificities, with for example islands with accessibility challenges.

HPSA shall conduct an assessment of its Collection Locations network reach and accessibility to ensure that it meets the needs of all residents of New Brunswick. Similar to its approach developed in other provinces, HPSA shall map out its Collection Locations network and of that of the population densities, and shall establish targets with regards to the reach of Collection Locations for urban areas and rural areas. HPSA shall undertake a regular mapping exercise to map out accessibility in the province and identify service gaps. HPSA shall report on a yearly basis the accessibility improvements of remote and rural communities, together with action plans to improve the performance of the Program.

HPSA shall consider the opportunity to onboard alternate Collection Location in remote and indigenous communities, with a partnership approach to respond to communities' needs.

3. Geographical Area for Collection

Regulatory Requirement

(e) the geographical areas that shall be used for annual reporting purposes;

For annual reporting purposes, HPSA shall be using the twelve (12) Regional Service Commission Regions:

#	Regional Service Commissions
1	Northwest Regional Service Commission
2	Restigouche Regional Service Commission
3	Chaleur Regional Service Commission
4	Peninsule Acadienne Regional Service Commission
5	Greater Miramichi Regional Service Commission
6	Kent Regional Service Commission
7	Southeast Regional Service Commission
8	Regional Service Commission 8
9	Fundy Regional Service Commission
10	Southwest New Brunswick Service Commission
11	Regional Service Commission 11
12	Western Valley Regional Service Commission

B. Transportation

As per HPSA's general service provider agreement, all requirements of federal, provincial and/or local rules and regulations such as the Canadian *Transportation of Dangerous Goods Act*, 1992 (S.C. 1992, c. 34) and New Brunswick's *Transportation of Dangerous Goods Act (*RSNB 2011, c 232)(CCSM c.D12) and associated regulations shall be adhered to by the waste management service provider(s) for the pick-up, transportation and storage of pharmaceutical and sharp waste collected under the HPSA Program.

Any supporting documentation relating to the above is required during HPSA's Request for Proposal.

C. Storage

There may be two "storage" steps considered in this Program:

- "Storage" at the Collection Location (i.e., at the retail pharmacy or at the alternative Collection Location). The "storage" of wastes at Collection Locations shall be done using pharmaceuticals containers and sharps containers for material types 1 and 2 waste respectively, under the responsibility of a health practitioner. Security is being required as per Health Canada Directive on Physical Security Requirements for opioids and controlled substances and described in the Collection Location Agreement. Storage duration at Collection Locations may vary depending on how quickly the pharmaceutical containers and medical sharps containers are filled up.

- "Storage" may be performed by the waste management service provider at a consolidation site, with relevant permits, where returns from several Collection Locations may be grouped. From experience, storage duration is low as the pharmaceuticals containers are emptied, washed and reintroduced into the market.

Storage permit requirements shall be always complied with.

D. Processing/Disposal

Regulatory Requirement

(k) a description of how pharmaceutical product and medical sharp waste shall be managed, by material type, in a manner that employs environmental, human health and safety standards that meet or are more strict than applicable laws;

No existing processing facility in New Brunswick was considered for the two material types, as none exist at the time of submission of the plan, to the knowledge of HPSA. Based on our understanding, current processing is as follows: material types are mixed with pharmacy IC&I waste and collected by a waste management service provider. The waste is exported outside of the province for incineration.

HPSA only partners with waste management service providers with proven track records of using established, approved, and verifiable procedures for the final treatment and processing of pharmaceutical and sharp waste in compliance with all applicable environmental regulations. Existing waste management service providers and their current processing systems for currently processed similar wastes shall be contacted to respond to the request for proposal.

The below descriptions of how material types 1 and 2 shall be managed, for reference purpose, are excerpts from the World Health Organization Safe management of wastes from health-care activities, second edition handbook ('WHO handbook')[3]:

- Non-cytotoxic sharp waste shall be treated using a high-pressure steam sterilization process (typically a commercial autoclave) or high temperature incineration.

  "*A typical operation for an autoclave involves the following:*
  • ***Waste collection****: Infectious waste bags are placed in a metal cart or bin. The cart or bin should be lined with a plastic liner to prevent waste from sticking to the sides of the container.*
  • ***Pre-heating*** *(for autoclaves with steam jackets): Steam is introduced into the outside jacket of the autoclave.*
  • ***Waste loading****: The metal cart or bin is loaded into the autoclave chamber. With every load, a colour-changing indicator is attached to the outer surface of the waste bag in the middle of the waste load to monitor treatment. The entry (or charging) door is closed, sealing the chamber.*
  • ***Air evacuation****: Air is removed through gravity displacement, pre-vacuuming or pulse vacuuming.*
  • ***Steam treatment****: Steam is introduced into the chamber until the required pressure or temperature is reached. Additional steam is automatically fed into the chamber to maintain the*

[3] World Health Organization. (2014). Safe management of wastes from health-care activities. 2nd edition. https://apps.who.int/iris/rest/bitstreams/304722/retrieve

temperature and pressure for a set time. Pressure pulsing autoclaves vary the pressure according to a set process cycle.

*• **Steam discharge**: Steam is vented from the chamber, usually through a condenser, to reduce the pressure and temperature. In some systems, a post-vacuum cycle is used to remove residual steam and to dry the waste.*

*• **Unloading**: Usually, additional time is provided to allow the waste to cool down further, after which the treated waste is removed and the indicator strip is checked. The process is repeated if the color change on the indicator shows that the treatment cycle was insufficient.*

*• **Documentation**: A written log is maintained to record the date, time and operator name; type and approximate amount of waste treated; and post-treatment confirmation results from any automated equipment recording or temperature–pressure monitoring indicator, such as the indicator strip.*

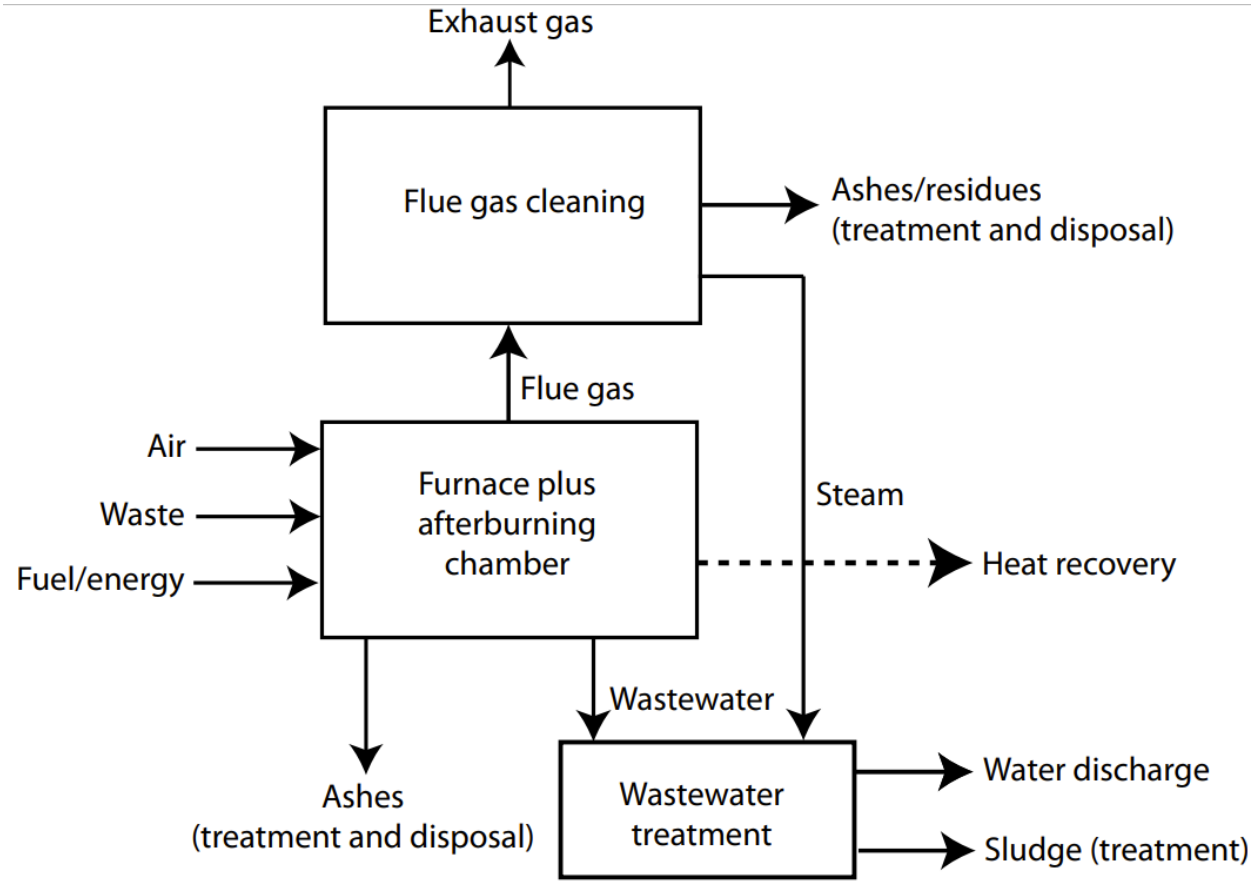
*• **Mechanical treatment**: If desired, the treated waste may be fed into a shredder or compactor before disposal in a landfill."*[4]

It is to be noted that a waste-to-energy process of the treated waste may be performed instead of landfilling, depending on environmental considerations.

- RX, OTC and NHP waste and cytotoxic sharp waste shall be treated by high temperature incineration.

"*Incinerators range from extremely sophisticated, high-temperature operating plants to very basic combustion units. All types of incinerators, if operated properly, should eliminate pathogens from waste and reduce waste to a small volume of ash. Incineration equipment should be chosen on the basis of the available resources and the local situation, balancing the public health benefits of pathogen elimination against the technical requirements needed to avoid the health impacts of air or groundwater pollution from the by-products of waste combustion.*"[5]

[4] Ibid, p.110
[5] Ibid, p.119



Source: Adapted by Jorge Emmanuel from UNEP (2006)

Figure 8.3 Simplified flow scheme of the incineration process

Figure from the WHO handbook[6].

- A waste-to-energy facility permitted to handle municipal solid waste shall be the preferred post-processing treatment method for non-cytotoxic sharp waste that has been rendered non-infectious through steam sterilization (classified as treated medical waste), where environmentally preferable, or for pharmaceutical and cytotoxic waste that has been incinerated.

All effluents from any process (e.g. exhaust gas, ashes/residues, water discharge) shall meet regulatory requirements or thresholds prescribed in environmental permits of the facilities.

Other treatment processes might be possible or under development (e.g., microwave treatment technologies). HPSA shall engage with stakeholders with regard to the opportunities to use such technologies in the future.

[6] Ibid, p.117

Regulatory Requirement

(j) the location of any long-term storage, containment or final treatment and processing facilities for pharmaceutical products and medical sharps;

HPSA does not expect any long-term storage or containment for pharmaceutical and sharp waste. The final treatment and processing facility/facilities locations shall be established via the contracting of the waste management service provider(s) and shall be communicated in HPSA's annual report. HPSA intends to use existing facilities whenever this constitutes the best option based on the analysis of the responses to the RFP. Of note, the waste management service provider(s) may propose alternative disposal site(s) located outside of the NB province, as long as they meet all relevant regulatory requirements.

V. Promotion and Education

Regulatory requirement:

(i) the communications plan to inform consumers of the stewardship plan, including the consumer's reasonable and free access to collection methods;

HPSA's communication campaign objectives shall be to educate New Brunswick residents on the safe handling and return of the pharmaceutical and sharp waste and ensure environmental and health protection for everyone.

To measure the progress and ensure consumers are aware of the Program and safe disposal techniques, it is HPSA's intent to conduct a biennial consumer awareness and behaviour survey, with a baseline in 2025. Based on the learnings from the survey, HPSA shall develop a tailored promotion and education plan to guarantee awareness increase and behaviour change.

A. Communication Methods

HPSA shall use various communication tools and approaches to raise awareness of proper disposal techniques of pharmaceutical and sharp waste.

An annual communications plan shall be submitted to RNB on or before December 15th of the preceding year.

Consumer Education

- HPSA shall develop social media content to educate New Brunswick residents on how and when to safely return their pharmaceutical and sharp waste. Social media content could include:
    - reminders of safe storage at home and return to Collection Locations;
    - mini campaigns to promote safe pharmaceutical and sharp waste return; as well as
    - reminders of the Collection Location map.
- HPSA shall develop a bank of educational content in various formats (step-by-step *how to dispose of* infographics, video instructions) that shall be shared with pharmacy banners, pharmacies, New

Brunswick Pharmacists' Association, and alternate Collection Locations to support consumer awareness and education building. Resources shall be available on HPSA's website.
- HPSA shall plan campaigns, such as data-based content, to get organic media coverage (earned media).

Program Accessibility

HPSA shall offer a Collection Location map on its website – a geo-localized map to find the closest Collection Location by submitting a postal code. HPSA shall collaborate with RNB to transmit relevant data so the Collection Location map can also be displayed on the RNB website.

Pharmacy and alternate Collection Location Education/Support

HPSA shall outfit community pharmacies and alternate Collection Locations with Program guides and consumer educational materials to increase the Program and consumer awareness and ensure consumers are well-informed on how to properly return their pharmaceutical and sharp waste.

B. Partnerships

HPSA shall partner with organizations interested in collaborating to promote health and safety of consumers holding pharmaceutical and sharp waste.

Prospective partners:

- **New Brunswick Pharmacists' Association** – planning webinars and/or educational events for pharmacists with the purpose of familiarizing them with the Program guidelines.
- **Retailers** – pharmacy banners and community pharmacies.
- **Producer Responsibility Organizations managing other programs** – Leveraging opportunities to combine communication efforts with existing programs.
- **Municipal and District Partnerships** – Seeking opportunities to partner with local governments, including links from local government websites to the HPSA website, and inclusion of Program information on recycling and disposal-specific web pages, as well as the availability of Program materials at the local government level.
- **Indigenous organizations** – Engagement with indigenous communities of New Brunswick to understand specific needs and provide relevant services.
- **Industry-Related Organizations** – HPSA shall partner with patient-specific associations (diabetes, arthritis) and alternate Collection Locations associations to increase the knowledge of pharmaceutical and sharp waste disposal.

VI. Environmental Impacts

A. Research & Development (R&D)

Regulatory requirement:

(h) information on current and future research and development activities in the Province related to the management of pharmaceutical products and medical sharps;

No current research and development activities in New Brunswick were identified during the process of the NBPSP development.

HPSA shall discuss with the relevant stakeholders (including waste management service providers and universities) on possible future R&D activities in the province, aiming to reduce environmental impacts of the management of pharmaceutical and sharp waste. Examples of R&D activities may be on reducing environmental impacts from processing activities by pre-treating waste to minimize hazardous waste incineration when feasible.

B. Hierarchy

Regulatory Requirement:

(g) the plan for the management of pharmaceutical product and medical sharp waste, by material type, in adherence to the following order of preference:

(i) recycling;
(ii) recovery of energy; and
(iii) disposal in compliance with the Act;

Whenever possible, minimizing the generation of hazardous healthcare waste is the best practice to prevent the occurrence of risks from the waste. Pharmaceutical products shall thus be consumed adequately to avoid leftovers or expired drugs.

The Regulation prescribes the order of preference for the management of the designated materials as explicated by Section 50.76 (g). However, given the requirements on managing pharmaceutical and sharp waste, recycling is currently impossible to apply. HPSA intends to use recovery of energy when the incinerator allows it, otherwise it intends to use the disposal in compliance with the Act.

Material type 1: RX, OTC and NHP Waste

There is currently no reuse or recycling application for post-consumer pharmaceutical waste.

Processing Requirements:

- Post-consumer pharmaceutical waste collected shall be treated by high temperature incineration.
- To ensure safety, mitigate the risk of diversion and to maximize the efficiency of the thermal treatment process, pharmaceutical waste shall be contained in leak-resistant and diversion-resistant secondary packaging (i.e., plastic pharmaceutical waste liners).

- Waste-to-energy is the preferred treatment method for post-consumer pharmaceutical waste, as it enables the use of the calorific potential of the waste to generate power or heat (via steam).
- Processors shall be licensed by the appropriate provincial government authority and have a provincial registration number, where required. Processors that currently service pharmacies for the elimination of pharmaceutical and sharp waste in the New Brunswick market shall be contacted to respond to the RFP.

HPSA is committing to ensure that its operational procedures include internal audits to ensure proper tracking mechanisms and chain of custody documentation are in place from the point of collection to final destruction – including the appropriate certificates of destruction.

Material type 2: Sharp Waste

As a designated material, medical sharps have unique characteristics that other designated materials do not. For example:

- Sharps are used as a delivery device in a healthcare-related application.
- They are used only once and then discarded: because of contact with human tissue, sharps are potentially infectious and are considered biomedical waste.
- Some sharps are used to inject drugs with chemotherapeutic properties and are therefore considered more hazardous than biomedical sharps. These sharps are classified as cytotoxic (genotoxic) waste.

There are no readily available options to reduce the waste generated when using a sharp device. Due to the unique health hazards associated with sharp waste, reuse or recycling are therefore not an option.

HPSA is committing to ensure that its operational procedures include internal audits to ensure proper tracking mechanisms and chain of custody documentation are in place from the point of collection to final destruction – including the appropriate certificates of destruction.

State-of-the-art practices, from environmental, human health and safety standpoints, are required from all actors dealing with sharp waste through requirements described in the Collection Location agreements and agreements with waste management services provider(s). Non-cytotoxic sharp waste may be autoclaved to treat their potential for infection, becoming non-hazardous waste. Cytotoxic sharps must be incinerated.

C. Environmental Impacts Reduction and Emergency Reporting

Regulatory Requirement:

(l) the plan for the elimination or reduction of the environmental impacts of pharmaceutical product and medical sharp waste, by material type;

Environmental impacts from unproperly managed consumer pharmaceutical and sharp waste, if not collected and processed adequately, are pollutions of waterways and soils via inadequate disposal by households (sinks, toilets, regular household waste stream). The OECD Report on Management of Pharmaceutical Household Waste[7], provides further information on:

[7] https://www.oecd-ilibrary.org/environment/management-of-pharmaceutical-household-waste_3854026c-en

- The ways the pharmaceuticals may enter the environment (e.g., when conventional wastewater treatment plant are not designed to remove them, when sludges from these wastewater plants are applied on land for agricultural use, or from leachate – if not well managed, from landfills).
- Their impacts: "*certain pharmaceuticals have been proven to cause adverse effects to ecosystems when entering environmental systems, including increased mortality in aquatic species and changes to physiology, behaviour or reproduction. The discharge of antibiotics can also lead to mutations in animals and the development of antimicrobial resistant bacteria.*"

This OECD report provides examples of measured effects of certain pharmaceutical residues on aquatic organisms in laboratory studies, such as reduced growth or behaviour changes.

HPSA, via its communication campaign to households on proper return at pharmacies and alternate Collection Locations, and on adequate processing, shall help reduce the above-cited environmental impacts from pharmaceutical and sharp waste.

As per the PRO Emergency Reporting Clause, should HPSA discover an environmental emergency, HPSA shall immediately notify, whether during normal hours or after hours, Recycle NB and the appropriate department of the New Brunswick Department of Environment.

D. Greenhouse Gas Impacts

Regulatory Requirement:

(m) a description of greenhouse gas emission impacts that shall result from the implementation of the stewardship plan and opportunities for reducing those impacts;

Implementing the proposed NBPSP may lead to an increase in the volume of collected materials, in turn leading to an increase in the transportation and processing of waste.

Although certain environmental impacts would be reduced (see above section C.), this increase in transportation and waste processing may lead to increased greenhouse gas (GHG) emissions from these activities.

Opportunities for reducing those impacts may be found in transportation management (e.g., optimization of an itinerary to reduce mileage between Collection Locations and to the consolidation/elimination site, electric fleet) and finding, where possible, local processing facilities (with the aim to reduce transport emissions) or processing methods that may reduce GHG emissions.

HPSA commits to develop, by end of 2025, calculation methods for:

- The estimate of the carbon footprint of the materials life cycle with boundaries being from the collection location until the final waste disposal step, per material type.
- The estimate of the total GHG yearly emission of the NBPSP.

Further analysis and improvement opportunities with emissions reductions quantifications and costs/revenues can be developed at a later stage.

The standards to be considered for use might include:

- United States Environmental Protection Agency (EPA) Waste Reduction Model (WARM)[8].
- World Resources Institute (WRI) and World Business Council for Sustainable Development (WBCSD) Product Life Cycle Accounting and Reporting Standard, part of the Greenhouse Gas Protocol[9].
- International Standard Organization (ISO) Standard 14067:2018(en) Greenhouse gases — Carbon footprint of products — Requirements and guidelines for quantification[10].

[8] https://www.epa.gov/warm
[9] https://ghgprotocol.org/product-standard
[10] https://www.iso.org/obp/ui/#iso:std:iso:14067:ed-1:v1:en

VII. Dispute Resolution Procedure

Regulatory requirement:

(o) a dispute resolution procedure to deal with disputes arising between the brand owner and a service provider.

If a Dispute arises between HPSA (representing its members) and a service provider, the party seeking resolution of the Dispute may initiate Dispute Resolution by way of the following steps.

Step 1: Notice of Concern

If a Dispute arises which the staff representatives of each party have been unable to resolve through discussion, the party wishing to initiate the Dispute Resolution procedures must notify the other party in writing. The notification will summarize the nature of the Dispute, the key facts, and include any relevant documentation.

Step 2: Informal Discussion

Within 30 days of receipt of the written notice under Step 1, the parties will meet to:

i. clarify the nature of the Dispute;
ii. request any further documentation in relation to the Dispute; and
iii. arrange for and facilitate a meeting to attempt in good faith to resolve the Dispute with representatives of the service provider and HPSA.

Step 3: Management Discussion

If the Dispute remains unresolved following the Informal Discussion, one of the parties may, within 30 days of the completion of the Informal Discussion, notify the other party in writing summarizing the aspects of the Dispute which remain outstanding following the Informal Discussion.
Within 30 days of receipt of such written notice, the parties will arrange for and facilitate a meeting between senior representatives of the service provider and HPSA to attempt in good faith to resolve the Dispute.

Step 4: Arbitration

Any arbitration will occur under the Arbitration Act (New Brunswick), RSNB 2014, c 100, and the legal seat and location of arbitration shall be Fredericton, New Brunswick, Canada. The arbitral tribunal shall be comprised of one arbitrator. Within thirty (30) days of receipt of a party's request for arbitration, the parties shall jointly agree upon an arbitrator. If the parties cannot agree on an arbitrator, each party shall submit two names of potential arbitrators, and the identity of the arbitrator shall be chosen from the four possible names by random draw observed by both parties. An arbitration will be scheduled to take place on a date to be determined by the arbitrator, in consultation with the parties who shall divide the time equally to present their positions to the arbitrator. The decision of the arbitrator shall be final and binding. Each Party shall bear its own costs of the arbitration and shall share equally the fees and disbursements of the arbitral tribunal and any other related costs of the arbitration, regardless of the outcome. The arbitrator shall have no jurisdiction to award costs in favour of either party.

Appendix A – Producers/HPSA Members

AA Pharma Inc.
Abbott Diabetes Care
AbbVie Corporation
ACCORD HEALTHCARE
Advanced Orthomolecular Research Inc
Advantage Solutions
Alcon Canada Inc.
Amgen Canada Inc.
Amway Canada Corporation
Apotex Inc.
Aralez Pharmaceuticals Canada Inc., d/b/a Miravo Healthcare
Ascensia Diabetes Care Canada Inc.
Astellas Pharma Canada, Inc.
AstraZeneca Canada Inc.
Atrium Innovation Inc.
Aurium Pharma Inc
Auro Pharma Inc
Auto Control Medical
Aventix Animal Health
Bausch & Lomb Corporation
Bausch Health Canada Inc.
Baxter Canada
Bayer Inc.
BGP Pharma
Bimeda-MTC Animal Health Inc.
Bioforce Canada Inc.
Biogen Canada Inc
BioSyent Pharma Inc.
Blistex Corporation
Body Plus Nutritional Products Inc.
Boehringer Ingelheim Animal Health Canada Inc
Boehringer Ingelheim Canada Ltd
Boiron Canada Inc
Bristol-Myers Squibb
Canadian Custom Packaging Company
Cardinal Health
Celex Laboratories Inc.
Ceva Animal Health Inc.
Champion Alstoe Animal Health/Sante Animale Inc.
Church & Dwight Canada
Cipher Pharmaceuticals Inc.
Clorox Company of Canada
Costco Wholesale Canada Ltd.
D Drops Company
Dechra Veterinary Products Inc
Domrex Pharma Inc.
Dr. Reddy's Laboratories
Duchesnay
Eisai Limited
Elanco Canada Ltd
Eli Lilly Canada Inc.
Embecta Nova Scotia Company
EMD SERONO
Exzell Pharma
Ferring Inc.
Fresenius Kabi Canada Ltd.
Galderma Canada Inc.
General Nutrition Centres Canada
Generic Medical Partners Inc./Partenaires Medicaux Generiques Inc.
Gilead Sciences Canada Inc.
GlaxoSmithKline Consumer Healthcare ULC
GlaxoSmithKline Inc.
Haleon
Health First Network Association Inc.
Herbalife of Canada Ltd
HLS Therapeutics
Hoffmann-La Roche Limited
Horopito Inc.
HPI Health Products/Lakota
Indivior Canada Ltd.
Intervet Canada Corp
IVC Vita Health
Jamieson Laboratories
Jamp Pharma Corporation
Janssen Inc.
Johnson & Johnson Inc, Canada
Laboratoire Atlas Inc.
Laboratoire Nicar
Leadiant Biosciences Inc.
LE GROUPE JEAN COUTU (PJC) INC.
LEO Pharma Inc.
LifeScan Canada ULC
Loblaw Inc.
London Drugs Ltd
Lundbeck Canada
Mannatech Canada
MARCAN PHARMACEUTICALS INC
McCarthy & Sons Service
McKesson Canada Corporation

Mead Johnson Nutrition (Canada) Co.
Medexus Pharmaceuticals Inc.
Merck Canada Inc.
Methapharm Inc.
Mint Pharmaceuticals Inc.
Mylan Pharmaceuticals ULC
Natural Factors Nutritional Products Ltd.
Nature's Sunshine Products of Canada Ltd.
Nestlé Canada Inc.
New Chapter Canada, Inc.
Novartis Pharmaceuticals Canada Inc.
Novo Nordisk Canada Inc.
Omega Alpha Pharmaceuticals Inc.
Organika Health Products Inc
Organon Canada Inc.
Otsuka Canada Pharmaceuticals Inc.
Paladin Labs Inc.
Pascoe Canada Inc.
Pattison Food Group Ltd.
Pfizer Canada ULC
Pharmasave Drugs (National) Ltd.
Pharmascience Inc.
PLATINUM NATURALS LTD.
Procter & Gamble Inc.
Purdue Pharma Inc.
Puresource Corp
RB Health (Canada) Inc.
REXALL PHARMACY GROUP ULC
ROCHE DIABETES CARE, DIVISION OF HOFFMAN-LA ROCHE LIMITED
Sandoz Canada inc
Sanis Health Inc.
Sanofi Consumer Health Canada
Sanofi-Aventis Inc.
Seaford Pharmaceuticals
Servier Canada Inc.
Shaklee Canada Inc.
Shoppers Drug Mart
Sivem Pharmaceuticals ULC
Sobeys Capital Incorporated
Sobi Canada entity of (Swedish Orphan Biovitrum)
St Francis Herb Farm Inc.
Stella Pharmaceutical Canada Inc.
Stericycle ULC
SteriMax Inc.
Sun Pharma Canada
Sunovion Pharmaceuticals Canada Inc
Takeda Canada Inc
Tanta Pharmaceuticals Inc.
Taro Pharmaceuticals Inc.
Teva Canada Limited
Tremblay Harrison Inc.
Trillium Health Care Products
UCB Canada
UniPHARM Wholesale Drugs
USANA Canada Co
Valeo Pharma Inc
Vertex Pharmaceuticals Incorporated
VETOQUINOL N.-A. INC.
Virbac Corporation
Vita Health Products Inc.
Wal-Mart Pharmacy (NS) Limited
Wellspring Pharmaceutical
Westcoast Naturals
Wholesale Medical Network Inc
WN Pharmaceuticals Ltd.
Xediton Pharmaceuticals Inc.
Zoetis Canada Inc.

Appendix B – Stewardship Plan Reference

Contents of pharmaceuticals and sharps stewardship plan as per Regulation Section 50.76.

	Required in the Plan	Location in the Plan
(a)	the plan for the collection, transportation, storage and processing of pharmaceutical product and medical sharp waste within the Province, including the pharmaceutical product and medical sharp waste of other brand owners;	Section IV.
(b)	information on the expected quantity or weight of pharmaceutical products and medical sharps, by material type, to be distributed within the Province and the expected quantity or weight of pharmaceutical product and medical sharp waste, by material type, to be collected or processed;	Section III. C.
(c)	information on the province-wide collection system, including information with respect to return facilities, by material type, to be used by the consumer;	Section IV.
(d)	a description of how existing collection and processing systems were considered to maximize waste diversion in the Province;	Section IV.
(e)	the geographical areas that shall be used for annual reporting purposes;	Section IV. A. 3.
(f)	the plan for the provision of services to remote or rural areas;	Section IV. A. 2.
(g)	the plan for the management of pharmaceutical product and medical sharp waste, by material type, in adherence to the following order of preference: (i) recycling; (ii) recovery of energy; and (iii) disposal in compliance with the Act;	Section VI. B.
(h)	information on current and future research and development activities in the Province related to the management of pharmaceutical products and medical sharps;	Section VI. A.
(i)	the communications plan to inform consumers of the stewardship plan, including the consumer's reasonable and free access to collection methods;	Section V.
(j)	the location of any long-term storage, containment or final treatment and processing facilities for pharmaceutical products and medical sharps;	Section IV. C.
(k)	a description of how pharmaceutical product and medical sharp waste shall be managed, by material type, in a manner that employs environmental, human health and safety standards that meet or are more strict than applicable laws	Section IV. D.
(l)	the plan for the elimination or reduction of the environmental impacts of pharmaceutical product and medical sharp waste, by material type;	Section VI. C.

(m)	a description of greenhouse gas emission impacts that shall result from the implementation of the stewardship plan and opportunities for reducing those impacts;	Section VI. D.
(n)	a description of the material types that shall be used for performance measures and targets and annual reporting purposes; and	Section III. B.
(o)	a dispute resolution procedure to deal with disputes arising between the brand owner and a service provider.	Section VII.