# **Environment Act Proposal for**



Pfizer Global Supply-Brandon, a Division of Pfizer Canada Inc 720 17<sup>th</sup> Street East Brandon, Manitoba

March 12, 2013

## **Table of Contents**

Exec	utive Sur	mmary	3
I.	Certifica	ate of Title	3
II.	Owner o	of Mineral Rights	4
III.	Existing	Land Use	4
IV.	Land Us	se Designation	4
V.	Previous	s Studies	5
VI.	VI.1 E	alBackgroundDescription of Facility	5
VII.	Storage	of Gasoline and Associated Products	10
VIII.	VIII.1 Lc VIII.2 Ai VIII.3 W VIII.4 W VIII.6 Gi VIII.7 Oc VIII.8 Nc VIII.9 Li VIII.10 E	al Impacts of the Facility coation  r dater dastewater daste reen House Gas Emissions. dour oise ght Endocrine Disrupting Compounds Dzone Depleting Compounds	11 13 14 15 17 17 18 18
IX.	IX.1 Spi	I Protection Measures	20
Appe	ndix A:	Legal Description	
Appe	ndix B:	City Of Brandon Zoning Designation Drawings	

Appendix C: Site Plans and Drawings

## **Executive Summary**

This proposal is filed as application for a license in accordance with Manitoba Regulation 164/88 for the Pfizer Canada Inc. facilities located at 720-17th Street East, Brandon, Manitoba. The application is for the Pfizer Global Supply-Brandon, a Division of Pfizer Canada Inc (PGS Brandon) operation which has existed at this site since 1966. The original plant was constructed prior to Manitoba licensing regulations. The information contained in the application was prepared by PGS Brandon for the specific purpose of application for Environmental Licence and represents PGS Brandon's understanding of the requirements of the Province of Manitoba for such application.

Environmental impacts considered for this application are generated by operational processes and support operations at the Brandon site. PGS Brandon's operations consist of a proprietary trade secret process to extract estrogens from pregnant mares' urine (PMU) with subsequent processing of the extracted estrogens into active pharmaceutical ingredients. The process has been refined over its long history at the Brandon site to develop a safe and environmentally sound manufacturing operation. Reducing PGS Brandon's environmental footprint through reductions in resource use and waste generation is integrated into all production and capital planning as required by Pfizer corporate policy.

Pfizer is committed to protecting the natural environment through proactive management of its operations and seeks continuous improvement in its environmental protection programs. Operations at PGS Brandon have been effectively managed over more than 45 years so as to minimize residual environmental impact. In Pfizer's opinion, the PGS Brandon facility and operations do not pose a significant environment impact and the company requests that the Province consider granting a licence under this completed application.

## I. Certificate of Title

The legal name of the proponent is "Pfizer Canada Inc". A copy of the Certificates of Title showing the legal description of the property is provided in Appendix A.

The PGS Brandon facility is on property registered to Pfizer Canada Inc located at 720-17th Street East, Brandon, Manitoba. The location of this property is identified as Parcel One and Parcel Two in Appendix A1: Parcel 1 is the portion of Sixteenth Street East which is bounded on the north by southerly limit of van Horne Avenue East and which is bounded on the south by the northerly limit of College Avenue East, together with all of the lane in Block 24 of Plan 10 BLTO NE ¼ 13-10-19, Parcel Two is described as Lots 21 to 40 Block 23 and Lots 1 to 40 Block

24 of Plan 10 BLTO NE ¼ 13-10-19 WPM, Appendix A2 as Lot 5 Plan 1489 BLTO in Section 13-10-19, Appendix A3 as Lots 13-28 Block 17 of Plan 285 BLTO NW ¼ 18-10-18 WPM.

# II. Owner of Mineral Rights

The owner of mineral rights beneath the land described Parcel One in Appendix A1 is Her Majesty the Queen in Right of the Province of Manitoba. The owner of the mineral rights beneath the surface of Parcel Two in Appendix A1 is the City of Brandon. The ownership of the minerals beneath the surface of the land in Appendices A2 and A3 are the same as the surface owner, Pfizer Canada Inc, as there is no reference in the legal description to mines and minerals.

# III. Existing Land Use

The existing land use on which the site is located is industrial. The existing land use on land adjoining the site is industrial and educational/institutional and open space. No change in land use will be made for the purposes of this development.

The nearest residential receptor is approximately 350 m north-northeast of the PGS Brandon site's north property line and consists of a single residential property with outbuildings, corral and pasture. Behlen Industries, an industrial steel fabrication business, is on PGS Brandon's south boundary. Inventronics Limited, a steel enclosure fabricator, borders PGS Brandon's west side. The Manitoba Fire College is across College Avenue to the immediate north. PGS Brandon owns a paved parking lot immediately east of the facility across 17<sup>th</sup> Street East.

# IV. Land Use Designation

The City of Brandon's land use zoning designations for the subject site and surrounding area are provided in the Brandon and Area Planning Zone maps 50 and 51 in Appendix B1 and B2. Portions of the City of Brandon's zoning bylaw on zone map interpretation are found in Appendix B3. The PGS Brandon site is designated as MR, Industrial Restricted. Property immediately to the south is designated MG, Industrial General. Property immediately to the east is zoned as MR, Industrial Restricted and OS, Open Space. Property immediately to the north is designated EI, Educational and Industrial. The property to the west is designated as MR, Industrial Restricted, and MG, Industrial General.

No change will be made to the site zoning for the purposes of the facility and this license application.

## V. Previous Studies

No authorizations have been received from other government agencies, other than City of Brandon zoning and building permit approvals for the original 1966 facility.

PGS Brandon discharges its wastewater under a City of Brandon Industrial Discharge License (number 93-001).

In 1989, six underground liquid raw material storage tanks were removed and replaced with underground tanks in an interior coated concrete secondary containment vault. This work was recorded (file number 1374) with Manitoba Environment and Workplace Safety and Health.

In 2010, PGS Brandon received a Permit to Operate a Petroleum Storage Facility, Permit # 34079, for a vaulted storage tank deemed to contain an allied petroleum product under Manitoba Storage and Handling of Petroleum Products and Allied Products Regulation

## VI. Proposed Development

This application is for an existing pharmaceutical manufacturing facility which has been in continuous operation since 1966.

## VI.1 Background

PGS Brandon, through legacy companies Ayerst and Wyeth Organics, developed the current site as a facility to extract estrogens from PMU in 1966. The original plant, PGS Brandon Plant A, was constructed in 1966. An additional plant, Plant B was constructed in 1992-94. Plant A's estrogens extraction operations ceased in 2005 and Plant A was redeveloped to process the estrogens extracted in Plant B into two Active Pharmaceutical Ingredients, APIs. Manitoba Conservation has requested that Pfizer submit an application for a license as part of a province-wide effort to license industrial facilities in the province. As a result, this proposal is filed for application for a license in accordance with Manitoba Regulation 164/88 for the operation of the Pfizer facility at the subject site.

## VI.2 Description of Facility

The development is a bulk pharmaceutical manufacturing facility with two production plants. The site plan is shown in Appendix C1. The PGS Brandon site footprint is approximately 4.45 hectares or 11 acres, ringed by security fence. Of the total site area, physical structures cover

1.012 hectares (2.5 acres). The majority of the remaining site is paved with asphalt. There are small sections of grassed areas bordering the interior of fenced perimeter.

PGS Brandon's operations consist of a proprietary process to extract natural estrogens present in pregnant mares' urine (PMU). The extraction process is conducted in the Brandon Plant B. The extracted natural estrogens are processed into active pharmaceutical ingredients (APIs) in the Brandon Plant A. Two APIs are manufactured, a dry powder and a liquid concentrate. The bulk API's are shipped to other Pfizer sites around the world for use in hormone therapy medicines for the treatment of post-menopausal conditions. The Brandon facility has laboratory and administrative support functions which are located primarily in Plant A.

## VI.3 Hours of Operation

Plant B contains the primary production process, and is currently operated from November to March on a 24 hour Sunday to Friday shift schedule. Production is limited to the November-March period to process urine collected from the mares during their seasonal pregnancy.

The API processing in Plant A is operated on a 24 hour, seven day per week schedule based on specific API demand within the Pfizer network.

Laboratory and Administrative operations are, generally, business hours, Monday to Friday.

## VI.4 Method of Operation

Plant B is operated as the primary production plant, extracting estrogens from the Pregnant Mare Urine (PMU). Plant A contains two post-processing steps and is used for office, lab, and warehouse/storage purposes. Figure VI.4.1 and Tables VI.4.1 and VI.4.2 provide an outline of the inputs and outputs of the facility. Facility inputs include PMU, various proprietary raw materials used in production, water for cleaning, nitrogen to maintain inert atmospheres in production vessels, electricity to operate equipment and natural gas used to fire the facility boilers.

Operational processes at Plant B are as follows:

- The PMU is delivered in closed tanker trucks. Solids in the PMU are separated using a centrifuge and are removed to a licensed waste disposal facility.
- Estrogens are extracted from PMU using a proprietary trade secret process.
- The estrogens-rich stream is concentrated and purified using low heat and various raw materials, including water.

• The product is dried at low heat into solid granular form, bagged, enclosed in drums and stored indoors.

There are two post-processing steps in Plant A and these are as follows:

- Dry product (from Plant B) is dry blended to meet various product specifications.
   The blender is entirely enclosed and no liquid agents are used. The dry product is bagged, enclosed in drums and stored indoors. The product is shipped to other Pfizer sites for further processing.
- Dry product is reconstituted into an aqueous form for use in several pharmaceutical products. Materials, including water, are used for extraction and purification in the process. The liquid product is stored indoors in bladders enclosed in drums prior to shipment to other Pfizer sites for processing into cream or intravenous medicines.

Supporting the production operations are several Quality Control laboratories that use small quantities of laboratory chemicals. Included in the Labs is a Canadian Food Inspection Agency permitted Level 2 Microbiology lab. A small maintenance shop, janitorial activities and cafeteria also support production.

Utility operations consist of two boilers in Plant B and three boilers in Plant A. The boilers are operated using natural gas. #2 fuel oil serves as alternate fuel in event of disruption in gas supply. The site has two backup diesel powered generators to provide emergency electrical power for product coolers. The site maintains two diesel emergency fire pumps to provide water for fire suppression in event of failure in the City's water supply. The site maintains a 1136 cubic meter underground water cistern or reservoir as supply for that emergency system.

Electricity is fed to the site from two separate Manitoba Hydro feeds; one each for Plant A and Plant B. The Plant A transformer is 2000 kVA and the Plant B transformer is 1500 kVA.

In addition to the product, the following is generated:

- Spent Pregnant Mare Urine (SPMU) is PMU from which estrogens have been extracted and combined with rinse water in an approximate 1:3 ratio of urine to water. This waste is transported by tanker truck to the City of Brandon Wastewater Treatment facilities for treatment under an agreement with the City.
- Process residuals (solid and liquid, non-hazardous and hazardous) are handled by licensed haulers and disposed, or recycled, to licensed facilities audited and approved for use by Pfizer.
- Biohazard material from the Public Health Agency Canada permitted Class 2
   Microbiology laboratory is transported and disposed of by a licensed biohazard waste company.

- Process equipment rinse water and sanitary waste from bathrooms are discharged to the City of Brandon wastewater treatment system.
- Volatile Organic Compounds (VOCs) and natural gas combustion products are discharged to the atmosphere from various processes (associated with production operations, material transfers, and tank breathing) and supporting operations (including boilers and material storage).

Production process details, including the process solvents used, are proprietary. Manitoba Conservation has access to this information in accordance with the Proprietary Information Protection Agreement, Brandon PMU Facility Protection Proprietary Information and Trade Secrets.

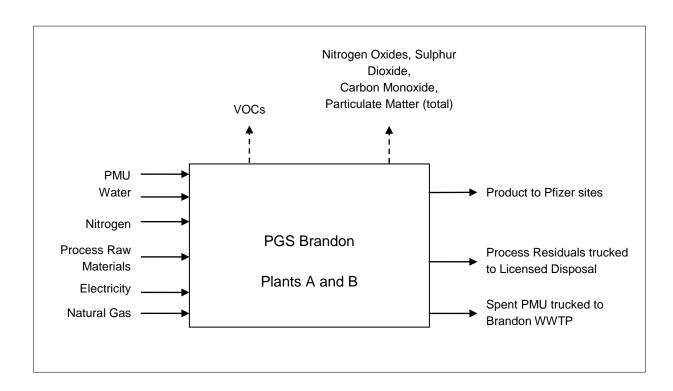


Figure VI.4.1: Facility Inputs and Outputs

**Table VI.4.1: Process Inputs** 

INPUT	SOURCE	2009	2010	2011	2012
Potable Water	City of Brandon	107,888 m3	111,151 m3	93,823 m3	70,434 m3
Electricity	Manitoba Hydro	12,290 MWh	12,634 MWh	9,693 MWh	8,671 MWh
Natural Gas	Manitoba Hydro	2,780,675 m3	2,688,513 m3	2,310,102 m3	2,115,492 m3
Pregnant Mare Urine	Rancher Network	4,331 m3	2,438 m3	1,117 m3	1,143 m3

**Table VI.4.2: Process Outputs** 

OUTPUT	DESTINATION	2009	2010	2011	2012
Product	Pfizer Customers	Business Critical	Business Critical	Business Critical	Business Critical
Spent PMU	City of Brandon Waste Water Treatment	11,224 m3	6,960 m3	3,181 m3	3,103 m3
Scrapped Product	Incineration	2.28 t	0	0	0
Hazardous Waste	Hazardous Waste Landfill	1.04 t	1.0 t	14.8 t	34.3 t
Hazardous Waste	Incineration	244.00 t	379.01 t	364.21 t	289.3 t
Medical/ Biological Waste	Incineration	5.53 t	5.61 t	4.25 t	2.56 t

Recyclables (Metal, cardboard, glass, plastic)	Various Approved Recyclers	39.57 t	30.81 t	39.68 t	40.51 t
Recycled Raw Material	Recycled and Reused on Site	Not Available	716.36 t	433.13 t	342.52 t
Non-Hazardous Solid Waste	City of Brandon Landfill	59.48 t	81.78 t	102.5 t	81.4 t
Carbon Dioxide	Atmosphere	5,520 tCO2eq	5,338 tCO2eq	4,576 tCO2eq	4,188 tCO2eq
Volatile Organic Compounds	Atmosphere	1.185 t	1.185 t	1.273 t	.63 t
Ozone Depleting Compounds	Atmosphere	.041 t	0 t	0 t	0 t

## VII. Storage of Gasoline and Associated Products

Both plants use underground storage tanks (UST) for storing bulk materials used in the process and waste materials derived from the process. The locations of above and underground storage tanks are shown in Appendix C.

Some of the process chemicals are considered allied petroleum products under MR 188/2001, Storage and Handling of Petroleum Products and Allied Products. PGS Brandon has a current Manitoba Conservation Permit to Operate a Petroleum Storage Facility, Permit Number 34079, for those tanks containing products considered allied petroleum products under the legislation.

The storage tanks are equipped with conservation vents and are blanketed with nitrogen to minimize evaporative losses. The tanks are provided with monitored secondary containment to contain spills.

Drums containing production materials are stored in a separate building supplied with secondary spill containment on the property. Small containers are stored in designated lab and warehouse areas with appropriate secondary spill containment.

## VIII. Potential Impacts of the Facility

#### VIII.1 Location

The site's physical presence displaces the natural environment and its associated plants and wildlife. The site, in isolation, has minimal environmental impact as it provides low quality habitat. The site had been developed from its natural state before the existing plant was constructed in 1966. The site is located within the City of Brandon's zoned industrial land and is surrounded on three sides by industrial development with a major City traffic corridor on the remaining side.

The site is maintained to provide minimal attraction to birds and animals thereby preventing human activity- wildlife conflict such as animal migration across roads and highways to the site. The main plant site maintains a chain link security fence which keeps medium to large animals off the property. There is no standing water, potential food source or cover habitat to attract wildlife. All raw materials are stored in doors or in closed tanks. All site waste is secured in closed containers and removed on a minimum weekly basis by contract waste companies. The site's rodent control program targeting mice, rats and ground squirrels reduces potential prey populations.

#### VIII.2 Air

Emission rates for specific materials cannot be provided in this public application to protect the nature of the proprietary unit operations and the identity of the proprietary materials. Manitoba Conservation has access to this information in accordance with Proprietary Information Protection Agreement, Brandon PMU Facility Protection Proprietary Information and Trade Secrets.

Emissions and advanced dispersion modelling for the PGS Brandon site to determine the facility's compliance with Manitoba Conservation air quality criteria was prepared by MNB Environmental Engineering Inc., Maryhill Ontario. MNB's study indicates emissions meet Manitoba Conservation ambient air quality limits and applicable Ontario regulatory limits under the study's assumed production levels and plant emission controls efficiencies and therefore pose minimal environmental impact.

The total site maximum emission rates for Plants A and B are shown in Table 2.1

**Table VIII.2.1: Site Maximum Emission Rates** 

Substance	CAS Number	Maximum Emission Rate (grams/second)			
Jubstance	CAS Number	Plant A	Plant B	Total	
Material A	Confidential	0.0000	0.0362	0.0362	
Material B	Confidential	0.0000	0.6464	0.6464	
Material C	Confidential	0.1778	0.4494	0.6272	
Material D	Confidential	0.0006	0.0347	0.353	
Material E	Confidential	0.0003	0.0000	0.0003	
Material F	Confidential	0.0106	0.0000	0.0106	
Material G	Confidential	0.5973	0.0000	0.5973	
Carbon Monoxide	630-08-0	0.3889	0.4444	0.8333	
Nitrogen Oxides	10102-44-0	0.5000	0.5556	1.0556	
Sulphur Dioxide	7446-09-5	0.0031	0.0033	0.0064	
Particulate Matter (total)	-	0.0389	0.0389	0.0778	

Emissions used in the modelling assume simultaneous operation, at the full productive capacity, of the two plants. These maximum emission rates were calculated based on a mass balance approach using standard engineering estimates. The emission modelling assumes capture of Plant B tank farm passive emissions during truck unloading and the operation of the Plant A vent condenser when the Plant A post-processing step (i.e., the reconstitution to a liquid product) is operating.

Maximum emissions for natural gas combustion were calculated based on all combustion units operating simultaneously at 100% of their rated capacities (i.e., three boilers in Plant A and two boilers in Plant B). US EPA AP-42 emission factors were applied to calculate the emission rates of combustion products from the burners. These emission factors were selected according to combustor type and size. With a maximum unit heat input of 20.3 MMBtu/hr, all units fall into the category of "Small Boilers" (under 100 MMBtu/hr).

MNB conducted the emission dispersion analysis using the latest AERMOD dispersion modelling program from Lakes Environmental, Version 6.8.6. The AERMOD program is an AMS/EPA Regulatory modelling assessment. AERMOD fully incorporates the PRIME building downwash algorithms, local terrain and advanced meteorological turbulence calculations. The model was run with the Multi-Chemical Run utility using the regulatory default option with one

hour averaging times for five years of representative weather station data. The maximum of the 9th highest hourly concentration for each year was used per Section 6.6 of the Air Dispersion Modelling Guideline for Ontario (Version 2.0) prepared by the Ontario Ministry of Environment.

The AERMOD Dispersion Modelling results are given in Table VIII.2.2. The values represent the maximum ground level concentrations (GLC) for specific material emissions generated at 100% process and boiler operation. The results assume that emissions from the Plant B underground tank farm are abated with a 90% capture with carbon filters. As shown, emissions as modeled are within the applicable air quality limits.

Table VIII.2.2: Emission Summary Results

Substance	CAS Number Maximum GLC (µg/m³)		Air Quality Limit (µg/m³)	Percentage of Limit
Material A	Confidential	Confidential	Confidential	89.9%
Material B	Confidential	Confidential	Confidential	2.9%
Material C	Confidential	Confidential	Confidential	65.5%
Material D	Confidential	Confidential	Confidential	0.0%
Material E	Confidential	Confidential	Confidential	0.0%
Material F	Confidential	Confidential	Confidential	35.2%
Material G	Confidential	Confidential	Confidential	9.2%
Carbon Monoxide	630-08-0	238.310	35000	0.7%
Nitrogen Oxides	10102-44-0	297.890	400	74.5%
Sulphur Dioxide	7446-09-5	0.000	900	0.0%
Particulate Matter (total)		20.847	120	6.9%

#### VIII.3 Water

The site is located on an extensive unconfined surficial sand aquifer. Pollutants spilled or discharged on the ground can quickly migrate downward and impact the groundwater. PGS Brandon has no record of any spill defined as reportable under Manitoba Conservation's regulations at the facility.

PGS Brandon has taken reasonable measures to prevent potential impacts to surface and ground water from its operations. Secondary containment is required for the loading and unloading of any liquid controlled product in bulk form under site and Pfizer policy. The site has three permanent concrete truck containment pads piped to spill collection tanks and a portable containment pad for set up and use under trucks unloading in other areas. Secondary containment is required for all drums filled with liquid controlled products. All floor drains within

production facilities are constructed so as to prevent spilled liquid from entering sanitary sewer or are directed to spill containment sumps or tanks. All tanks and exterior piping are provided with secondary containment or are double walled. There are no ground water wells on the site. Rain and snow melt runoff are directed to the City of Brandon's storm water drainage system over the site's paved lot. Runoff can be collected to prevent potential contamination in event that a spill breaches provided containment measures.

In 2012, PGS Brandon purchased approximately 70,000 m3 of potable water supplied by the City of Brandon from its water source, the Assiniboine River and delivered to the site by the City's metered water distribution system. The bulk of the water is returned to the basin after treatment in the City of Brandon's wastewater treatment facilities. The returned water meets the standards established by the Province for treated wastewater effluent. Some process vessel and piping initial rinse water is directed to hazardous waste which is incinerated by an approved waste handler. The water lost from the Assiniboine basin from the Brandon site operation is less than 250 m3 per year, or approximately 700 liters per day. This loss is believed to pose minimal environmental impact.

A potential impact to surface water and waterways from the PGS Brandon operation is from a possible trucking accident involving material in transport to and from the facility where the trucked material is released into the environment along a provincial roadway. PGS Brandon, as directed by Pfizer corporate policy, requires carrier suitability for the transport of all materials to and from the site. All carriers of dangerous goods or hazardous waste must meet Manitoba licensing requirements, maintain valid insurance, are registered to transport the manifested material and provide drivers certified in the Transportation of Dangerous Goods.

## VIII.4 Wastewater

Non-process wastewater generated from toilets, lunch rooms, laboratory and janitorial sinks, boiler, cooling tower blowdown, and non-contact cooling water is discharged to the City of Brandon sewer system under an Industrial Discharge License (number 93-001). There are no limitations on flow or parameter monitoring requirements. The City of Brandon monitors its treated effluent discharge regularly.

Process wastewater, primarily from Plant B, is collected and transported in tanker trucks to the City of Brandon's licensed wastewater treatment facility. This wastewater is composed predominantly of spent PMU, and includes equipment wash water. The following are typical characteristics of the process wastewater:

Biological Oxygen Demand 30,000 mg/L Chemical Oxygen Demand 50,000 mg/L

Total Suspended Solids	3,000 mg/L
Total Kjeldahl Nitrogen	6,000 mg/L
Ammonia Nitrogen	1,000 mg/L
Total Phosphorus	10 mg/L
рН	10.3
Volume	82000 m3/yr (max)

An Agreement between the City of Brandon and PGS Brandon allows this process wastewater to be delivered to the City for treatment. It is biologically treated using conventional wastewater treatment techniques and discharged to the Assiniboine River pursuant to the City of Brandon treatment facility's license, No. 2351 S2.

PGS Brandon has signed an Agreement with the City of Brandon for Pfizer capital participation in the joint Industrial Waste Water Treatment Plant (I-WWTP) currently under development. All PGS wastewater will be treated by the City of Brandon I-WWTP under the City's Environmental permit for that facility when it is completed, which is currently scheduled for 2013.

No adverse environmental impacts are expected from non-process and process wastewater generated from the facility.

#### VIII.5 Waste

PGS Brandon generates approximately 120 tonnes of non-hazardous solid waste annually. This waste is composed of packaging materials, general office waste, scrap equipment and cafeteria waste. PGS Brandon recycles approximately 40 tonnes of its non-hazardous solid waste annually. Recycled material includes scrap metal, paper, cardboard, plastics, glass, batteries, florescent light bulbs and e-waste. Recycled e-waste, metals, batteries, paper and florescent bulbs are directed to Pfizer audited and approved private recyclers. All other recyclable materials are directed to the City of Brandon recycle program. Remaining non-hazardous solid waste is disposed to the City of Brandon's landfill, License No. 3011.17.

PGS Brandon is a Manitoba registered hazardous waste generator, MBG11351. PGS Brandon disposes approximately 300 tonnes of hazardous waste annually, primarily high BTU liquid waste directed to a licensed hazardous waste incinerator. The site's Quality laboratories generate quantities of spent and expired lab chemicals sent for incineration. Brandon occasionally generates small amounts of solid hazardous waste from construction activities that includes items such as asbestos. In addition to regular hazardous waste, PGS Brandon generates waste that does not meet the regulatory definition of hazardous waste but is sent to hazardous waste disposal facilities as required by Pfizer corporate environment policy. This

waste is material that has been in contact with estrogens: personal protective equipment, packaging, solids centrifuged from the spent PMU, and scrapped product.

Hazardous solid and liquid wastes and their handling methods are described in Table 3. All hazardous wastes and special wastes are collected, segregated appropriately, and then transported for treatment and disposal at licensed hazardous waste facilities. Such facilities are regularly audited by Pfizer to ensure they operate to regulatory and Pfizer requirements. Hence, no adverse environmental impacts are expected from these solid and liquid wastes generated at the Brandon facility.

**Table 3: Hazardous Wastes** 

type	Name	Class	Handling
solid	PMU solids	N/A	Collected in indoor bins and trucked to licensed hazardous waste disposal facility.
	dust, bags, protective clothing containing natural estrogens	N/A	Collected in containers and trucked to licensed hazardous waste disposal facility.
liquid	waste solvents	211	Collected in storage tanks and hauled in tanker trucks to licensed hazardous waste disposal facility.
	production residue	211	Collected in containers and trucked to licenced hazardous waste disposal facility.
		211	Collected in containers
	lab wastes	241	and trucked to licenced hazardous or biohazard waste disposal facility.

<u>Note:</u> The components of the hazardous wastes cannot be identified to protect the identity of the proprietary solvents. Manitoba Conservation has access to this information in accordance with Proprietary Information Protection Agreement, Brandon PMU Facility Protection Proprietary Information and Trade Secrets.

Currently, approximately 3 tonnes of biohazard waste is generated in Quality Control Microbiology laboratory annually. This waste consists of culture plates with standard test organisms used to assess potential contamination of potable water, equipment and product.

Biohazard waste is segregated from all other waste and is transported and destroyed by an approved biohazard waste disposal company.

#### VIII.6 Green House Gas Emissions

PGS Brandon operations emitted approximately 4200 tCO2eq in 2012 which represents a downward trend in produced CO2 emissions. These emissions are calculated from site electricity and natural gas consumption using CO2 emission factors. Natural gas combustion in the site's boilers is the main source of CO2 emissions. The boilers are used for building heating and steam generation for production process. Electricity, used for motors, controls and lighting, is purchased from Manitoba Hydro and is assumed to be almost exclusively generated by hydroelectric means.

PGS Brandon operates two motor vehicles and one fuel-powered forklift on an as-needed basis. The CO2 contribution of these vehicles is low due to their occasional use. Employee vehicles used for daily work commutes contributes to CO2 emissions as do the emissions from contracted trucking transporting material to, and from, the site. These emissions are not included in this application.

Pfizer is committed to reducing its green house gas footprint. The company establishes reduction targets for all its sites and monitors for site target attainment. PGS Brandon works with its utility provider to meet CO2 reduction targets through reduced energy consumption, level loading, equipment replacement and efficiency engineering.

#### VIII.7 Odour

The Brandon process is conducted in a closed system and is tightly controlled and monitored due the requirements of pharmaceutical production. All exterior raw material storage tanks are blanketed with nitrogen to prevent evaporative loss that may produce odour. Plant A emissions are vented through the end-of-line vent condenser to capture emissions and their potential odours.

The site is unaware of any odour complaints regarding the site.

#### VIII.8 Noise

Noise produced at the site is compatible with industrial zoning. All industrial processes are within the site's buildings and are not audible to the outside environment. Rooftop HVAC units

produce the most sustained sound at the site. Tractor trailer traffic, site snow clearing, and potential construction activity produce the highest levels of sound. Delivery activity is generally conducted during daytime hours, Monday to Friday. Occasional snow removal is the only significant night time noise generation from site operations.

The site is unaware of any noise complaint regarding the site.

## VIII.9 Light

The site maintains site lighting consistent with an industrial facility. There are 17 high pressure sodium lamps to provide security lighting in paved areas within the fenced compound. There are an additional 9 pole lamps in the parking lot to the east of the fence portion of the facility. Plant B has no exterior lighting above the two story level. A small portion of Plant A has exterior lighting to the three story level with the remaining exterior lighting at two and one story levels. No lighting is directed up into the sky or toward neighbouring property.

The site is unaware of any lighting complaint regarding the site.

## VIII.10 Endocrine Disrupting Compounds (EDCs)

PGS Brandon's process removes existing conjugated estrogens found naturally in pregnant mare urine. The extraction process is not 100% efficient so residual estrogens are present in the spent PMU after processing. Currently, the spent PMU is treated at City of Brandon municipal wastewater treatment facilities where the residual estrogens are degraded through bacterial action during a prolonged hydraulic retention period. Treatment methodology will change upon completion and commissioning of the City of Brandon industrial wastewater treatment plant. The City of Brandon anticipates higher removal rates for estrogens in the industrial facility than in the current municipal treatment system. The City will develop a plan to monitor estrogens in the treated effluent from the industrial treatment facility under the terms of their Environmental Permit. Pfizer will continue to work with the City to ensure estrogens in treated effluent meet science-based standards.

PGS Brandon is committed to assuring that its manufacturing processes minimize EDCs released to the environment and that its discharges are controlled appropriately. The site utilizes specialized HEPA filtered ventilation systems, directs equipment initial rinse water to hazardous waste and employs HEPA vacuum cleaning to prevent residual particulate estrogens from being washed to sanitary sewer or released to atmosphere. PGS Brandon continues to seek improved extraction efficiencies in its process to increase yield and reduce residual estrogens in the spent PMU.

## VIII.11 Ozone Depleting Compounds (ODCs)

The Brandon facility has maintenance procedures and controls for all equipment containing ODCs (both Primary ODCs and HCFCs) to ensure appropriate on-site management to prevent ODC escape into the environment. This program includes: ensuring servicing is undertaken only by licensed personnel, preventing unintentional venting during servicing, ensuring recycled ODCs are used where possible, ensuring primary ODCs and HCFCs are captured and properly managed during decommissioning and that primary ODCs being destroyed at decommissioning.

PGS Brandon currently maintains an inventory of 9760 kilograms of refrigerant in its coolers and HVAC systems. The site has approximately 9090 kg of R-507 and 548 kg of R-134A refrigerants with the largest single reservoir being 2275 kg. R-22 type refrigerant accounts for approximately 122 kg of the inventoried volume. The largest single R-22 reservoir contains less than 19 kg. The remaining R-22 refrigerant is held in a number of small air conditioning units with capacities of less than 7 kg. The use of R-22 at PGS Brandon will be eliminated through equipment retirement; the site had approximately 26 kg removed during an HVAC upgrade in a portion of its facilities in 2011.

#### IX. General Protection Measures

PGS Brandon incorporates into their operations an Environmental, Health and Safety (EHS) management system that provides the framework to reduce and mitigate impacts on the environment. Environmental safeguards are integrated into engineering standards for all equipment and processes and include electronic leak detection, monitoring and alarm systems, and secondary containment of containers, vessels and piping. Protection of the environment is built into standard operating procedures (SOPs) for normal operation, start-up, shutdown, emergency situations and waste handling.

Pfizer's environmental management practices place emphasis on prevention and incorporates continuous improvement in operational equipment and processes. Pfizer establishes environmental targets for PGS Brandon aimed at reducing resource consumption and waste generation and monitors progress towards those targets. PGS Brandon is subject to audit by Pfizer corporate for environmental performance to evaluate whether the Brandon operation meets all regulatory and corporate requirements.

Hazardous materials are disposed per Section VIII.3. Pfizer audits its contracted third party hazardous or special waste disposal facilities to ensure those facilities are in compliance with their licence requirements and Pfizer corporate standards.

## IX.1 Spill and Emergency Management

Protection from leaks and spills is provided by spill containment systems. These systems incorporate safeguards such as:

- Secondary containment
- Lined trenches and sumps to capture spills and divert them to containment tanks
- Monitors and alarms (such as LEL, high levels)
- Spill/leak detection (such as sump level alarms, loss-of-vacuum in double-wall tanks).

Production and spill containment equipment are kept in good working condition by a preventative maintenance program to minimize the risk of spill occurrence and the impact of a spill should one occur.

The facility established and maintains a process to identify potential emergency events involving site operations and supporting activities. To effectively manage spills and other emergencies, PGS Brandon maintains the following documented site procedures:

- Emergency Preparedness and Management System
- A fire, spill and medical response plan (Emergency Response Contingency Plan)
  that includes colleague training from the Manitoba Emergency Service College in
  spill containment and clean up
- Procedures for handling chemical spills in Production and in Lab areas- Chemical Spill Plan

PGS Brandon maintains active membership in the Brandon Emergency Support Team, B.E.S.T., and works co-operatively with the City and other industrial partners through this organization to develop community preparedness action plans for potential emergencies and spills.

#### IX.2 Pollution Control Equipment

#### IX.2.a Dust Collector

In Plant B, a dust collector is used in the product drying room ventilation exhaust system. The dust collector has a design flow rate of 55 m3/s and has a particulate control efficiency of 99.99% for particulates  $0.3 \ \mu m$  or greater.

The dust collector is on a regular preventative maintenance schedule, and the pressure drop across the filters is monitored on a differential-pressure gauge. Approximately 5 kg of dust is collected from the dust collector per year. The collected dust is disposed under the requirements for special or hazardous waste as described in Section VIII.5.

#### IX.2.b End-of-Line Vent Condenser

In Plant A, a pair of vent condensers collects volatile organic compound (VOC) emissions from the post-processing operation where dry product is reconstituted into a liquid form. Process equipment vents are piped through the vent condensers. The condensers provide cooling to – 15C and trap VOC's by chilling them to the point of condensation into liquid. This condensate is collected in a waste receiver and is periodically pumped to an underground waste storage tank. Waste materials are liquid hazardous waste disposed as described in Section VIII.5.

## IX.2.c Plant B Tank Farm VOC Removal System

PGS Brandon is committed to providing a VOC removal system on its Plant B underground storage tanks to provide efficient capture of VOC's emitted during filling operations. This system will be sized to provide a capture efficiency that meets the 90% removal assumption in the MBN air emission and modeling report. The capture system will be designed and installed in accordance with PGS corporate standards and provincial regulations. This project is under development through the Pfizer capital program for the PGS Brandon site with construction schedule to start in April 2013.

## **APPENDIX A- Certificates of Title**

A1: Title No: 2491855/2 for Plant A, .PDF appendix\_a1 A2: Title No: 2491854/2for Plant B, .PDF appendix a2

A3: Title No: 2491862/2 for East Parking Lot, PDF appendix\_a3

#### **APPENDIX B- Site Zoning**

B1: Brandon Area Planning Map 51, .PDF appendix b1 cob zonemap50

B2: Brandon Area Planning Map 50, .PDF appendix\_b1\_cob\_zonemap50

B3: City of Brandon Zoning Codes, .PDF appendix\_b3\_zonemap\_interpretation

## **APPENDIX C**

C1: Site Plan with Property Lines, .PDF appendix\_c1\_pfizer\_siteplan

C2: Plant A Emission Points, .PDF appendix\_c2\_plant\_a\_emission\_points

C3: Plant B Emission Points, .PDF appendix\_c3\_plant\_b\_emission\_points