

SUMMARY OF COMMENTS/RECOMMENDATIONS

PROPONENT: Pfizer Canada Inc.
PROPOSAL NAME: Pfizer Global Supply - Brandon
CLASS OF DEVELOPMENT: 1
TYPE OF DEVELOPMENT: Manufacturing
CLIENT FILE NO.: 5642.00

OVERVIEW:

Manitoba Conservation and Water Stewardship received a Proposal on April 15, 2013 and additional information on May 28, 2013 for the continued operation of a Pharmaceutical manufacturing facility located at 720 – 17th Street East in Brandon, Manitoba. The facility manufactures pharmaceutical quality estrogens by an extraction process from pregnant mares' urine, with subsequent processing of the extracted estrogens into active pharmaceutical ingredients.

On April 18, 2013 the Department placed copies of the Proposal in the Public Registries located at The Legislative Library, 200 Vaughn Street, Winnipeg, the Millennium Public Library in Winnipeg, the Manitoba Eco-Network and the Western Manitoba Regional library, 1 – 710 Rosser Avenue, in Brandon and Online Registry at <http://www.gov.mb.ca/conservation/eal/registries/index.html>. Copies of the Proposal were provided to the Technical Advisory Committee (TAC) members. A notice of the Environment Act proposal was also placed in the Brandon Sun on April 20, 2013. The newspaper and TAC notifications invited responses until May 21, 2013.

COMMENTS FROM THE PUBLIC:

No Comments.

COMMENTS FROM THE TECHNICAL ADVISORY COMMITTEE:

Canadian Environmental Assessment Agency

No Comments.

Manitoba Agriculture – Land Use Branch

No Response.

Manitoba Conservation and Water Stewardship – Sustainable Resource Management Branch

No Concerns.

Manitoba Conservation and Water Stewardship – Compliance and Enforcement Branch

No Response.

Manitoba Conservation and Water Stewardship – Programs and Strategies Branch – Air Quality Section

No Response.

Manitoba Conservation and Water Stewardship – Wildlife Branch

No Concerns.

Manitoba Conservation and Water Stewardship – Parks and Protected Spaces Branch

The Branch has no comments or concerns as it does not affect any parks or protected spaces.

Manitoba Conservation and Water Stewardship – Forestry Branch

No Response.

Manitoba Conservation and Water Stewardship – Aboriginal Relations Branch

No Response.

Manitoba Conservation and Water Stewardship – Lands Branch

No Concerns.

Manitoba Conservation and Water Stewardship – Water Quality Management Section

Would it be possible to request a copy of the proponent's emergency management and spill response plans? Most of my comments pertain to this area, so where their own protocols are sufficient, it would be helpful to couch licence terms in their words.

Disposition

Clause 25 to 27 and 36 to 38 of the draft Environment Act Licence addresses issues regarding spill containment and emergency response plan.

Manitoba Conservation and Water Stewardship – Groundwater Management Section

No Response.

Manitoba Conservation and Water Stewardship– Fisheries Branch

Fisheries Branch has reviewed this request to license the continued operation of Pfizer Pharmaceuticals, a pharmaceutical manufacturing facility located at 720 17th St E in the City of Brandon. The facility has been operating since 1966 and it manufactures pharmaceutical quality estrogens by an extraction process from pregnant mare urine with subsequent processing of the extracted estrogens into active pharmaceutical ingredients. Wastewater from the process is trucked to the City of Brandon under an Industrial Discharge License. Process equipment rinse

water and sanitary waste is discharged to the City of Brandon's wastewater treatment system. Potable water from the City of Brandon is used at the facility. Containment is provided for the six underground storage tanks that are used for storing bulk materials use in the process and waste materials derived from the process; as well as at the concrete truck pads and; all drums filled with liquid controlled products.

Based on the information provided it would appear that there should be limited fisheries concerns with the continued operation of this facility.

Manitoba Conservation and Water Stewardship – Office of Drinking Water

No Concerns

Manitoba Conservation and Water Stewardship– Water Use Licensing Section

No Response

Manitoba Conservation and Water Stewardship – Water Control Works Licensing Section

No Response

Manitoba Conservation and Water Stewardship– Climate Green Initiative Branch

No Response.

Manitoba Culture, Heritage and Tourism – Heritage Branch

No Response.

Manitoba Innovation Energy and Mines – Energy Development Branch

No Response.

Manitoba Innovation Energy and Mines – Petroleum Branch

No Response.

Manitoba Infrastructure and Transportation – Flood Forecasting Branch

No Response.

Manitoba Infrastructure and Transportation – Highway Planning and Design Branch

No Concerns.

Manitoba Intergovernmental Affairs

No Concerns.

Manitoba Health – Environmental Health Unit

Our office has reviewed the proposal. Overall, it appears that Pfizer Global Supply (PGS) has addressed most environmental health concerns. Here are a few comments that are worth considering or need to be addressed:

- *Page 7, 5th paragraph, 3rd line makes mention of a ‘cafeteria’ on site that supports production. If this is a facility where meals are prepared for workers, contractors, sub-contractors or visitors to the site, it is defined as a “food handling establishment’ under Manitoba Regulation 339/88R under The Public Health Act. Our departmental records and database system indicate that this establishment has not been registered or permitted pursuant to that legislation and has probably gone undetected because it is located inside a secure industrial complex. PGS will be required to register this facility by contacting the Brandon Health Protection Unit Office at (204) 726-6601. The registration form and associated regulation, guidelines are available on-line at: www.manitoba.ca/healthprotection If the ‘cafeteria’ is a simple lunch room where people consume food they brought from home or ordered in from off site, then a permit is not required, but the status of this facility needs to be clarified with the local Public Health Inspector for the area (726-6601).*
- *Pages 13 and 17 note the following: some of the emissions are not disclosed as they are classified as ‘confidential’ pursuant to the ‘Proprietary Information Protection Agreement’ that is in place. Some of these undisclosed materials are reported as being within 65%-89.9% of air quality limits, which suggests to regulators and the public that limit excursions could occur in the future if industrial processes fail or experience a lapse. The reported emissions from proprietary compounds cannot be commented on as the substances are not known to this reviewer. The reviewer is relying on Conservation staff to understand the proprietary compounds, their health and environmental effects, and the compliance of the emissions of these substances with accepted environmental standards.*
- *Section VIII.7 on page 17 states that the proponent is not aware of any odour complaints regarding this site during the course of its operations. These portions of the environmental impact statement raise the following questions and/or concerns:*
 - a. *As a best practices approach, does PGS maintain a log of all reported odour or nuisance complaints and does it confirm that there have been no reported incidents, excursions of odour- nuisance complaints since 1966? Similarly, does Manitoba Conservation record similar events and what does that log indicate? If such a process does not exist, it certainly should be incorporated as a clause in the Environment Act Licence (EAL) and all incidents should be made ‘reportable’ to Manitoba Conservation and the local Medical Officer of Health.*
 - b. *Manitoba Conservation operates an ambient air quality monitoring station on the adjacent property at the Assiniboine Community College Campus. This would suggest that there may have been a history of nuisance odours or emissions concerns in the past. If so, what were the concerns and is this station still needed and what parameters are being monitored? Do they include monitoring for the undisclosed emissions associated with ‘Materials A-G’? If not, will the EAL formally require PGS to monitor for these emissions and report them on routine basis to Manitoba*

Conservation? Will the EAL licence prescribe limits for these undisclosed materials/parameters?

- c. PGS has not stated what if any health impacts are generally associated with these undisclosed materials and what type of preventative measures or processes they have in places to prevent or mitigate emissions associated with loss of process control (i.e. reduced production/emissions strategies, treatment/abatement technologies) Will the plant be measuring ambient air in the production facility, for safety of the worker? Will the plant emissions from combustions be monitored routinely?*
 - d. What is the formal process that PGS proposes to use in the event that odour complaints are received? A clear & effective process should be outlined in the EAL that involves PGS, Manitoba Conservation officials and the Medical Officer of Health for the area.*
- *Section VIII, 10 Endocrine Disrupting Compounds (EDCs)*
 - a. This part of the proposal indicates that wastes are directed to the City of Brandon municipal wastewater treatment facility. While this does not affect PGS' proposal for EA licensing, it does raise the issue of EDCs emissions in the City of Brandon's wastewater effluent being discharged to the environment. Does that EAL contain suitable monitoring, reporting and limits for the effective environmental management of the EDCs and/or related xenoestrogen compounds from other potential sources?*

Proponent Response (Sept 18, 2013):

- Thank you for this heads up. We passed this information on to the operator. The operator submitted an application to Manitoba Health's Brandon office, a Public Health Inspector has inspected the cafeteria, and we understand that a permit is being processed.
- Emissions in the Emission Modelling Report were calculated for the maximum emissions at the facility's maximum production capacity. The calculations represent the "worst case" emissions.

The 65.5% -89.9% emission rates described in the question occur during the unloading of that material into site storage tanks. This represents the "worst case" emissions for those materials. The storage tanks must be vented to allow displacement of the tanks' headspace during the unloading of the delivery tanker trucks. The tanks are vented for the approximately two hours per load as the material is allowed to gravity flow into the tank. The reported maximum emission rates would be for approximately 8 hours per year for the material estimated at 65.5% of emission rate and approximately 12 hours per year for the material estimated at 89.9% of emission rate. At current production levels emissions would be at the calculated rates for the materials for approximately 2 hours per year for each material.

The unloading of these materials is independent of site processing. Consequently, we consider the likelihood that we would exceed the Ontario limits to be low.

- The PGS Brandon site has a documented site procedure, "Handling Internal and External Environmental Complaints", to receive and document such complaints. PGS Brandon has no record of public complaint of odour or noise at the facility.

- PGS Brandon follows applicable occupational hygiene guidelines to manage occupational exposures to materials in use at our facility. The Brandon site routinely monitors colleague occupational exposures to the various production materials. The sample collection, analysis and interpretation are conducted by third party certified Occupational Hygienists and laboratories. Occupational hygiene testing results are provided to site colleagues as required under Manitoba Labour regulation.

PGS Brandon maintains an End-Of-Line Condenser on the Plant A production process to collect, chill and condense volatile compounds prior to venting. The collected condensate is sent to organic waste for eventual incineration at a licensed third party hazardous waste incinerator. The Plant B facility collects, condenses and recycles approximately 99.3% of a main proprietary material thereby reducing air emissions from that process. The site is currently installing a carbon capture system to reduce emissions occurring during the filling of storage tanks, as previously outlined. Storage tanks and process vessels are nitrogen blanketed to reduce material evaporation and therefore emissions. Ventilation in product production areas is equipped with HEPA filtration to prevent the exhaust of particulate pharmaceutically active material.

Natural gas fired boilers, used to provide heat and steam for our facilities, are the only combustion units at the site. The submitted boiler emission data was calculated at the simultaneous operation of all boilers, including backup boilers, at 100% rated capacity.

In light of the foregoing systems, PGS Brandon does not believe additional monitoring is required.

- As noted previously, the PGS Brandon site has a written procedure to process odour and noise complaints and the site has no records of such complaints. PGS Brandon proposes to incorporate notification to Manitoba Conservation of odour complaints into its existing “Handling Internal and External Environmental Complaints” procedure.
- We understand that the City of Brandon is required to implement an EDC monitoring program for its treated wastewater as part of the environmental licensing of the new industrial Waste Water Plant. We believe that The City’s EDC monitoring program will address this comment.

Disposition

The branch reviewed the response provided by the proponent and had no further comments. In addition Clauses 9, 11, 12 to 14, 17 and 30 of the draft Environment Act Licence address air emission limits, odour, emission control equipment, emission monitoring and issues related to the emergency response plan.

Manitoba Labour – Office of Fire Commissioner

The Office of the Fire Commissioner has no concerns with the proposed application for an environmental license for this facility.

We recognize that this facility has been in operation since 1966, and that PGS Brandon maintains active membership in the Brandon Emergency Support Team (BEST) and works cooperatively with the City and other industrial partners through this organization to develop community preparedness action plans for potential emergencies and spills.

Manitoba Labour – Work Place Safety & Health

No Response

PUBLIC HEARING:

A public hearing is not recommended.

CROWN-ABORIGINAL CONSULTATION:

The Government of Manitoba recognizes that it has a duty to consult in a meaningful way with First Nations, Métis communities and other Aboriginal communities when any proposed provincial law, regulation, decision or action may infringe upon or adversely affect the exercise of a treaty or Aboriginal right of that First Nation, Métis community or other Aboriginal community.

This facility is an existing operation located on a private land with the city of Brandon. There would be no infringement of aboriginal or treaty rights under Section 35 of the Constitution Act, 1982. Therefore, it is concluded that Crown-Aboriginal consultation is not required for the project.

RECOMMENDATION:

The Proponent should be issued a Licence for the continued operation of a Pharmaceutical manufacturing facility in accordance with the specifications, terms and conditions of the attached draft Licence. Enforcement of the Licence should be assigned to the Environmental Compliance and Enforcement Branch of Manitoba Conservation and Water Stewardship.

A draft Environment Act Licence is attached for the Director's consideration.

Prepared by:

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