

**Environmental Assessment
Registration Document**

For

**Microbial Fermentation Facility
At a New Building to be Constructed Adjacent to 14 Clyde Avenue in
the City of Mount Pearl**

Submitted to:

**Minister of Environment and Conservation
(Pursuant to Part X of the Environmental Protection Act)**

Proponent:

**6574262 Canada Inc. (Operating as ICUS)
Bldg 1A Unit 303 King's Bridge Court
St. John's NL A1C 2R2**

Date:

May 17, 2010

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NAME OF UNDERTAKING:**Microbial Fermentation Facility (MFF)****PROPONENT:**

- (i) 6574262 Canada Inc. (Operating as ICUS)
NOTE: ICUS is an acronym derived from the words Italy, Canada, and the US
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THE UNDERTAKING:**(i) Nature of the Undertaking:**

The project being undertaken is the establishment of a Microbial Fermentation Facility (MFF). Microbials are microorganisms that are used in the agricultural industry to increase crop yields through natural means, and to improve crop health and vigour thus reducing crop diseases. They are often referred to as inoculants or microbial biocontrol agents and are commonly used in commercial agriculture all over the world today. The MFF is a fermentation facility that will produce up to 1.5 tonnes of dry material in the first year and up to 5-10 tonnes at maximum capacity. The input materials are all food grade and no hazardous waste materials, effluents, odours, noise or other negative environmental issues are associated with the operations of the business. Nearly 100% of the input materials are used in the process, and the only potential spent material or waste generated will be 1% to 5% (maximum of 500 kilograms per year) of the feed media of corn, rice or dried mushrooms that may not be consumed by the organisms. This material is all food-grade and can be recycled in the process, sold as mulch, or transferred to the landfill. Our goal is to recycle all spent material. The organisms are safe and

normally exist in soils throughout Canada and other parts of the world. They are ubiquitous, and can even be found in agricultural soils in Newfoundland. Some of these organisms tend to be highly specific in their effects on crops. ICUS has acquired from Agriculture and Agri-Food Canada and other agencies specific organisms that will be of benefit to grain and legume growers in Canada and the US. The three key species of organisms acquired by the company include *Rhizobia*, *Trichoderma* and *Clonostachys*. The MFF will produce these products for export to the US and mainland Canada. The shipping will be by closed-cab transport trucks as partial loads, backhauls on outgoing large trailers, or by smaller closed-cab vehicles.

ICUS intends to establish the MFF in Donovan's Industrial Park in a new building under construction on the N.C. Hutton Holdings Limited property adjacent to an existing building at 14 Clyde Avenue, also owned by N.C. Hutton Holdings Limited. The site is zoned Light Industrial (LI) and a discretionary use application needs to be made to the City of Mount Pearl for final approval.

Purpose/Rationale/Need for the Undertaking:

Initially, for the first two years ICUS will produce two organisms that will be sold to a Company in the United States called Advanced Biological Marketing (ABM) – website <http://abm1st.com/>. These two organisms are a *Rhizobia* used as an inoculant for soybeans to increase yields and a *Trichoderma* used as an inoculant in wheat and canola for increasing yields and reducing the need for adding nitrogen to crops. Inoculants in the United States are considered completely harmless and do not require any type of license or registration from the USDA or US EPA.

In Canada, the Canadian Food Inspection Agency (CFIA) deals with the registration of inoculants, and the Pest Management Regulatory Agency (PMRA) deals with the registration of biocontrol agents. Before these products can be sold in Canada for application to Canadian crops a company needs to obtain a registration. ICUS is in the process of carrying out the field trials and other studies to register products for sale in Canada, but we will not be in a position to market in Canada for at least two years; after we obtain the registrations. Agriculture and Agri-Food Canada (AAFC) has been assisting ICUS for the last two years with product registrations in Canada and have provided funding to support the effort. Viterra, <http://www.viterra.ca/>, a major distributor in western Canada, and organic growers in Quebec (represented by <http://www.moulinsdesoulanges.com/>) are performing field trials in 2010 to assist with the registration activities. These groups are interested in distributing the products in Canada once a registration is obtained.

The products that we will sell to our US customer are already produced and sold in the United States. ABM has been selling Excalibre (a *Rhizobia* inoculant) for soybeans for 7 years now and the current supply comes from producers in the US and Argentina which ICUS will replace. ABM has also been selling T22 (a *Trichoderma* inoculant) for wheat and corn for at least 3

years and the supply comes from a plant in upstate New York by a Company called BioWorks, another producer that ICUS will replace. ABM's products are well established in the US market.

(ii) Geographical Location

The proposed location is in Donovan's Industrial Park, Mount Pearl, in a new building under construction on the N.C. Hutton Holdings Limited property adjacent to an existing building at 14 Clyde Avenue. The site is zoned Light Industrial (LI) which allows for the use that we are proposing for this location, although a discretionary use application needs to be made to the City of Mount Pearl for final approval.

The facilities in the area are all zoned LI. There are no residential properties near the proposed site. Access is off Clyde Avenue via one major driveway for all buildings on the larger site owned by N.C. Hutton Holdings Limited. Only 3-5 parking spaces are required for the new use, and this is easily accommodated in the current parking layout.

Location maps and other details are included below. The location map (Figure 1) shows the location relative to streets in the area, and the layout plan and property view (Figure 2) shows the proposed building plan and the view from Clyde Avenue of adjacent properties. The building will be approximately 10,000 square feet. There will be 2 loading doors for transport trailers. The building has the requirements that will suit our purposes, after upgrades are completed.

There are no other options being explored at this time.

Figure 1: Location Map by Google Maps (2010)

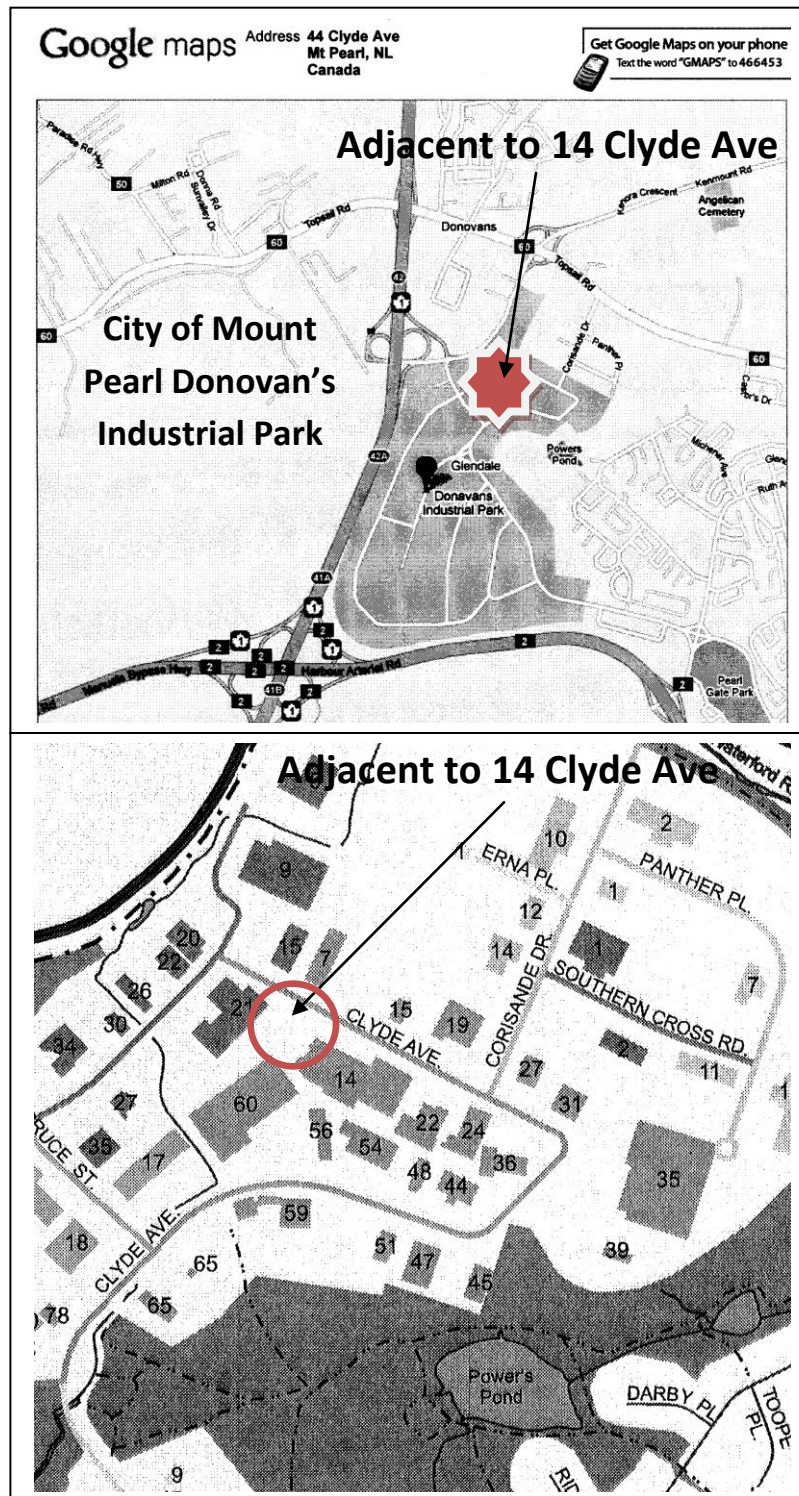
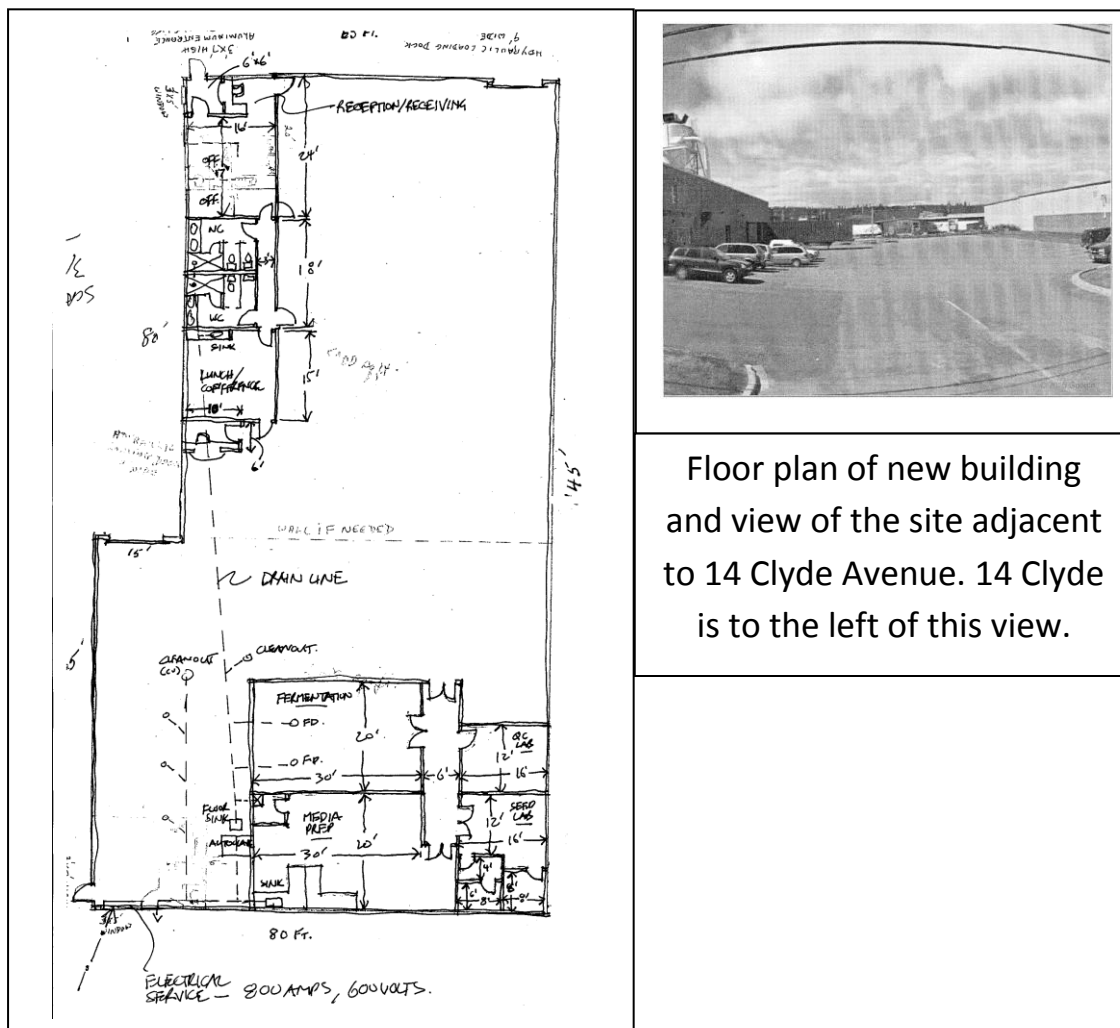


Figure 2: Building Layout and Property View:



(iii) Physical Features

No residential areas are located nearby and properties adjacent to this site are all commercial or industrial. The site is fully serviced and has paved areas and well designed loading points that are easy to access, and sufficient parking. There are no water bodies or reserves or other vegetation or wildlife habitats close to the site.

There are no emissions, effluents, or odours generated by the process and no waste disposal or storage is required on-site. There are no processing or other activities outside of the building and loading/offloading will occur 4 to 5 times a year at loading docks/doors only. There will not be any impact on the neighbouring area from the activities of the operation.

(iv) Construction:

The facility will be a 10,000 square foot steel prefabricated warehouse building adjacent to 14 Clyde Avenue, Mount Pearl. The warehouse portion will have approximately 25 feet of clear internal space with two loading doors. The space will have sufficient electrical capacity and other requirements that will suit our purposes, although some leasehold improvements will be required. Leasehold improvements include interior construction (new), HVAC, electrical, and plumbing to allow for offices, equipment hook-up and operation, and cleaning.

The new construction will include approximately 1,800 square feet of clean room processing area on the ground floor inside the warehouse to house fermentation equipment and the QC lab. There will also be approximately 560 square feet of reception, offices, washrooms, and a conference/lunch room in the building. The main warehouse building is a steel structure with a concrete floor and sheet steel walls. The equipment required in the facility includes:

- **Media Preparation:**
 - Sink, fume hood, autoclave, washer, refrigerator, balances and miscellaneous
- **Seed Production Lab:**
 - Biosafety cabinet, Refrig/freezer, microscope, shaker, plate counter.
- **QC Lab:**
 - Biosafety cabinet, -80C freezer, refrig/freezer, incubator, microscope, miscellaneous.
- **Fermentation Suite:**
 - 20L seed fermenter, 400L seed fermenter, 3000L production fermenter, media process tank (500L to 1500L)
- **Downstream Processing Suite:**
 - Filtration system, buffer and process tanks, chromatography system
- **Filling and Packaging:**
 - Ribbon blender, blow/fill/seal/pouch filler
- **Mech/Utilites:**
 - HVAC, chiller, boiler, compressed air, steam generator, vacuum system, pumps.

Leasehold renovations will begin in July 2010 and end in September 2010 and will require approximately 2 months to complete. There will not be any airborne emissions, liquid effluents, or solid waste materials that could impact the area during construction, and there are no known potential causes of resource conflicts.

(v) **Operation:**

ICUS intends to produce microbes (microorganisms) that are used in agriculture as inoculants for increasing crop yields, and as biocontrol agents for increasing plant health and reducing disease. The organisms are safe and exist in the soil naturally throughout the world. ICUS initially will sell two products to Advanced Biological Marketing in the US (<http://abm1st.com/>), including an inoculant for soybeans to increase yields and an inoculant for wheat and canola for increasing yields. Inoculants in the United States are considered completely harmless and do not require any type of license or registration as previously noted. In Canada, the Canadian Food Inspection Agency (CFIA) deals with the registration of inoculants, and the Pest Management Regulatory Agency (PMRA) deals with the registration of microbial biopesticides. ICUS is preparing for Canadian registrations over the next two years (discussed previously).

ICUS will produce approximately 1,500 kilograms (1.5 tonnes) of product in the first year, and at maximum capacity in 5 years the target is 10,000 kilograms (10 tonnes) per year. The production space houses small seed fermentation vessels and one 3,000 L production vessel in a class 100 clean room. These are roughly the sizes of vessels that a micro-brewery or small production winery would use. Downstream processing equipment includes filtration (concentrating/drying), blending and bag-filling equipment. It is critical to keep undesired contaminants from entering the products so it is necessary to operate in a relatively sterile environment (low level clean room with HEPA filters) to keep the air around our production area clean and fresh.

The process involves growing the organisms in seed vessels, transferring to a production vessel and growing enough material to move to the final downstream processing area where drying, formulating and packaging is carried out. There are no hazardous emissions or harmful waste materials generated by the process. The materials that act as the food source for the organisms will be mostly digested leaving little or nothing behind as a waste material. Leftover corn or rice (undigested media) will be recycled as the food source for the next batch. Limited acids/bases (maximum 55 gallon drum) will be stored on site and will be diluted to be used for cleaning the equipment. The drums will provide up to a 6 month supply. After cleaning the waste is further neutralized before disposal in the city drain. The input materials are all safe and/or food grade as noted below:

Ingredients:

- **Organisms:** The organisms come from Canadian and/or US farm soils. One organism for example, was isolated from Manitoba farm soils by an Agriculture and Agri-Food Canada scientist and ICUS is licensing the organism. A small quantity of frozen organisms will be stored onsite in freezers as starter cultures including: a *Bradyrhizobia*

for soybeans, a *Trichoderma* for grain crops, and a *Clonostachys* for soybeans and grain crops.

- **Other ingredients:** Yeast extract, cellulose, corn, rice, or dried mushrooms to grow the organisms, cellulose and starch as formulating agents, and filtered water.

Environmental Impact (External Environment):

The facility will not generate any air emissions or effluents, and the process will not produce odours or noise. The only material that may generate some minor odour is yeast extract used as part of the growth media. Only about one kilogram per batch run is used, and the facility therefore may generate a slight yeast odour similar to a bread making/baking facility. There are no special exhaust fans, and no special ventilation requirements. As noted the only requirement will be an HVAC system with HEPA's to control the intake of air to maintain a sterile production area, but no specialized exhaust systems, stacks, or other exterior ventilation equipment is required.

Streams and lakes, along with birds and other wildlife will not be impacted in any way by the operation. The process is a completely closed circuit system, entirely internal, and does not produce any outputs that could affect the exterior environment. There will not be any large crates or packing materials on the outside of the building and there are no known vehicle loading issues. The products are packed in small plastic totes of 50 to 100 liters in size, shrink wrapped and placed on wooden pallets for loading. These are loaded onto a closed cab transport truck for shipment. The product is a dry powder and is always prepacked and sealed prior to shipping. Two similar plants by Novozymes, and Becker-Underwood exist in Saskatchewan. These plants have been producing microbials for approximately ten years in the region without any issues.

Diagrams of the process illustrating the "no-impact" potential of the operation are shown in Figure 3, Figure 4, and Figure 5:

NOTE: Figure 3 is based on a bench top system and changes in the final process have eliminated the centrifuge and fluid-bed dryer, and by recycling the substrate as growth media, waste sources can be eliminated almost entirely. Even if some waste remains it is suitable as animal feed material or for compost.

Figure 3: Mass Balances (per 4 kg of product using bench-top process).

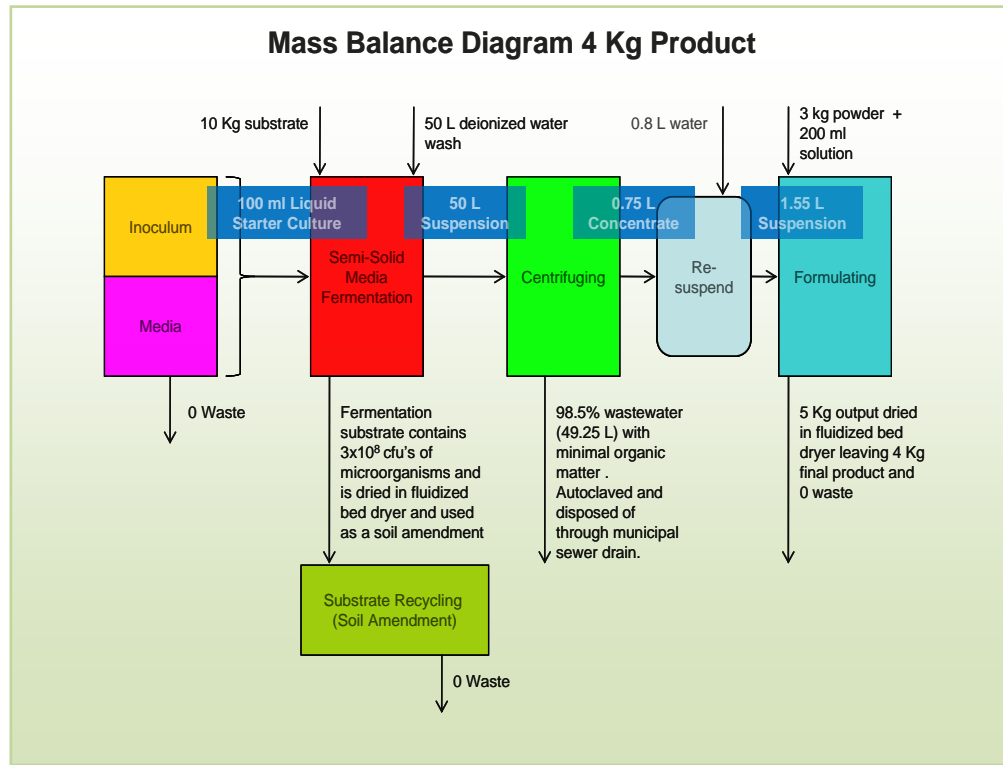


Figure 4: Process

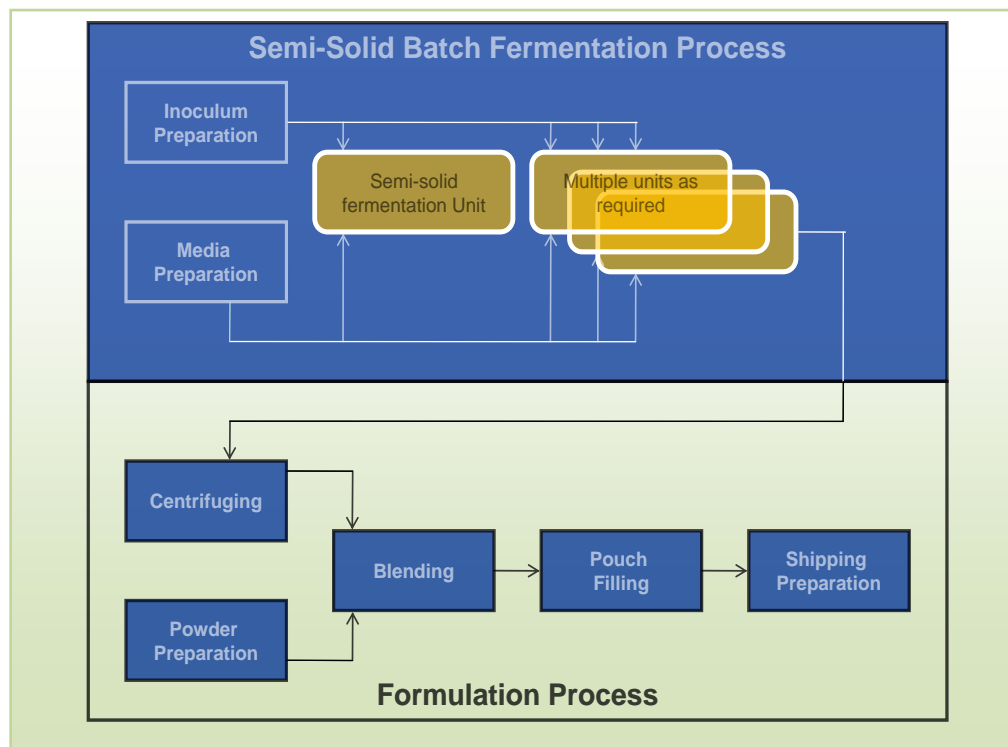
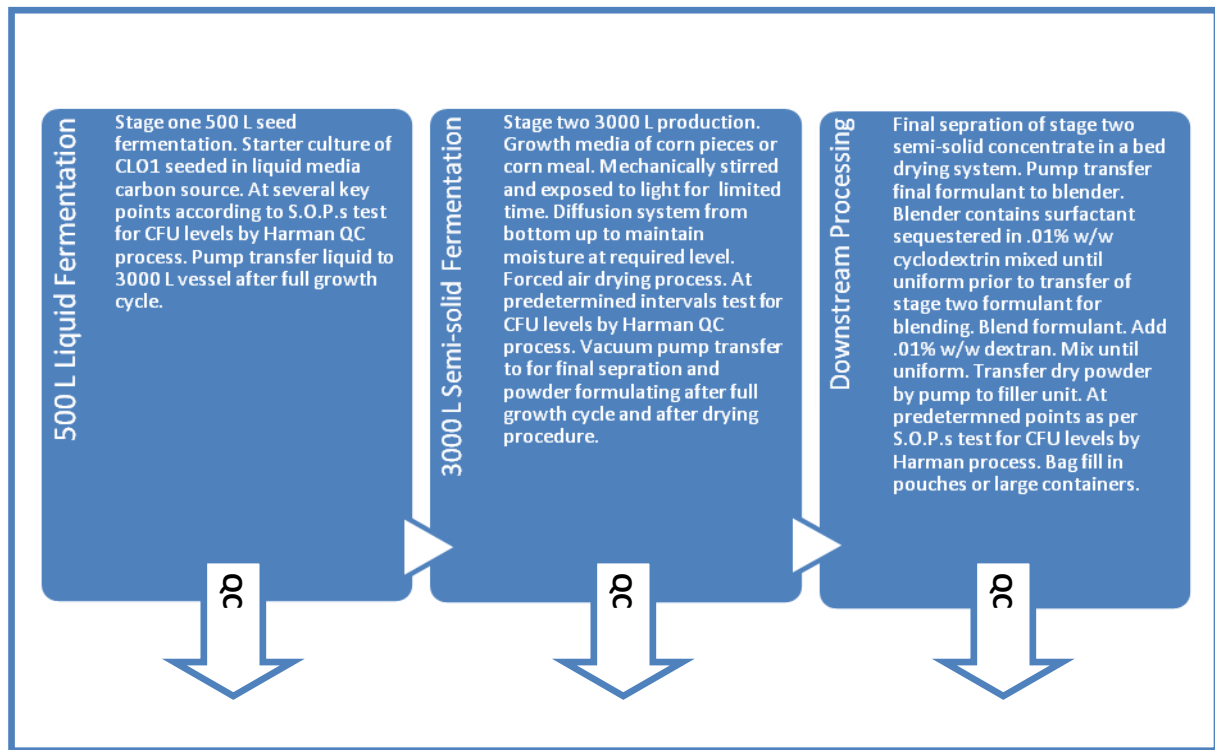


Figure 5: Process Details



Plant Operations:

The plant will operate on day shift only and will employ 3 technical staff for the first year. The peak period will be from October to March 2010 just prior to the planting season. In year two it is expected that 2 additional staff will be required and the production will be spread more evenly over the year. The process description follows:

Seed Production: Master Seed cultures will be stored in plastic cryogenic vials frozen at a temperature no warmer than -20°C. Working Seed is propagated in shakeflasks and dispensed into vials under local Class 100 conditions (laminar flow hood or biosafety cabinet). After dispensing, the working seed is removed for frozen storage at no warmer than -20°C.

Media Preparation: Small scale media prep services include cleaning of glassware and portable equipment, media formulation, sterilization, and clean staging. Small volumes of media are prepared for shake flasks, QC plates, and fermentation additions. Media is dispensed into clean glassware or addition vessels as required, and sterilized with an autoclave. Media is then stored.

Seed Propagation: The manufacturing process begins with cell propagation of the working seed. One vial of working seed is removed from storage,

thawed out and transferred into a sterile glass shake flask containing the growth media (under local Class 100 conditions). The shake flask is resealed, and placed in a temperature controlled shaker at 28°C. When the culture has reached log-growth, the seed is expanded by dispensing the culture into several more sterile shake flasks under Class 100 conditions using aseptic technique. These flasks are resealed and removed from the Class 100 area and placed into the temperature controlled shaker. Once the target seed volume reaches the log-growth stage, it is removed from the incubated shaker and once again taken to the Class 100 area. The shake flasks are pooled into a sterile stainless steel addition vessel.

Fermentation Suite: The small scale liquid fermenter (cleaned-in-place) is manually batched with media and automatically steam sterilized. After steady state conditions are reached for temperature, pH, and dissolved oxygen, the addition vessels for transfer materials are connected to the addition ports via flex hose. After sterilizing with clean steam, the contents are added to the fermenter via air overpressure. When the culture has reached maturity, a transfer line is connected from the bottom outlet valve on the liquid seed fermenter to the semi-solid production fermenter inlet valve array, and the entire transfer line is sterilized with clean steam. The production scale semi-solid fermenter (cleaned-in-place) is manually batched with growth media and automatically steam sterilized using the automated control system. After reaching steady state conditions the contents of the seed fermenter are transferred to the production fermenter via air overpressure. When the culture has reached maturity, additional air will be introduced into the fermenter vessel to dry the material. Drying the culture promotes sporulation and makes the final product more friable.

Downstream Processing: The dried culture will be removed from the production fermenter via vacuum transport directly to a ribbon blender. The ribbon blender will break up the friable clumps into a relatively uniform powder. Then the additional dry formulation ingredients will be fed to the ribbon blender, to create the final formulated product. The final product is then packaged into foil or plastic pouches using a blow, fill, and seal filler.

(vi) Occupations:

There will be 3 employees hired in the first year including a Plant Manager and two Production Technicians (one will also act as the QC Technician). In the second year 3 additional employees (2 more Production Technicians and a Facilities Engineer) will be hired for 6 employees in total by the end of the second year. The breakdown is:

- Production Technicians (Laboratory Technicians, Laboratory Demonstrators, or Industrial Technicians/Technologists or Classification

- 9461 Process Control and Machine Operators, Food and Beverage Processing)
- QC Technician (Classification: 2211 Chemical Technologists and Technicians)
- Plant Manager (Classification: 0911 Manufacturing Managers)
- Facilities Engineer (7351 Stationary Engineers and Auxiliary Equipment Operators)

ICUS is an equal opportunity employer.

APPROVAL OF THE UNDERTAKING:

Use of the products in the field/on farms in Canada requires registrations in Canada. The Canadian Food Inspection Agency (CFIA) deals with the registration of inoculants, and the Pest Management Regulatory Agency (PMRA) deals with the registration of biocontrol agents. Before these products can be sold in Canada, a company needs to obtain a registration. ICUS is in the process of carrying out the field trials and other studies to register products for sale in Canada, but we will not be in a position to market in Canada for at least two years; after we obtain the registrations. No registrations are required for inoculants in the United States and the first two years of production will be exported to the US.

FUNDING:

Funding is already in-place and is being used to order equipment and operate, including the organization of leaseholds and facility planning as described in this EA. Funding came from ACOA, The Province (Department of Business) and a private investor. Leaseholds are anticipated to cost approximately \$150,000.

SCHEDULE:

The project needs to begin between June 2010 and July 2010, and needs to finish by October 2010 when production launch is scheduled. The start dates are based on leasing timeframes proposed to the landlord, and the leasehold renovations schedule. The finish date is dictated by the requirement to meet our US supply contract.

By: Gordon Genge, May 17, 2010

