TECHNICAL NOTE

Project	**AbbVie Ireland IE Licence Application 2018**
Subject	**Site Closure Plan**
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1.0 INTRODUCTION

AbbVie Ireland NL B.V has decided to develop an integrated biochemical suite at their facility at Ballytivnan Sligo. The purpose of this development is to design a facility to manufacture special medicines for treating illnesses (like cancer) in a highly controlled and contained environment.

The main process includes the linking of a bio-pharmaceutical molecule to a cytotoxic molecule providing effective delivery of the medicine within the patient. The project will consist of internal demolition of part of the existing redundant manufacturing facility, which is located to the west of the new Warehouse, to make way for the proposed biochemical suite.

The facility intends to operate 7 days per week, 24 hours per day. The total number of staff on site once the new bio-chemical pharmaceutical suite is fully operational is anticipated to be approximately 280 persons.

In support of the Industrial Emissions (IE) licence application, the following is an outline of the closure activities should they be required after the IE licence has been granted and the facility is operational.

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2.0 CLOSURE TASKS AND PROGRAMMES

2.1 Closure Declaration

Based on the information provided in the Soil and Groundwater Baseline Assessment (Attachment 4.8.2), clean closure of the facility is likely. There are no known contamination issues at the facility. Whilst the facility was previously owned by Abbott Nutrition, and therefore there is a small potential for legacy contamination at the site, the recent soil and groundwater sampling for the facility suggest that there is no existing legacy contamination.

Upon cessation of activities at the facility there will be no further wastewater emissions to sewer or emissions to atmosphere. There will also be no substances with the potential to release fugitive emissions remaining on site once the facility is closed.

2.2 Scope of the Closure Plan

The scope of this plan addresses the key issues, which would occur in an orderly shutdown of all the site activities on a phased basis over an estimated time period of approximately six months.

The scope of the plan includes the following primary activities:

- Setting up a management structure to oversee the closure;
- Cancellation of incoming raw materials and cessation of all production activities;
- All products dispatched off-site for sale and all excess raw materials run-down or removed from site;
- Full decontamination and decommissioning of all production equipment and building surfaces;
- All storage areas fully emptied and stored material transported off-site or disposed of. Decontamination, decommissioning and verification of all site utility services;
- Disposal or recovery of all waste materials in a manner that complies with regulatory requirements;
- Management and retention of all relevant records relating to movement, transfer or disposal of waste throughout the closure process - available for review by the Agency; and
- Independent verification and certification of clean closure status.

2.3 Criteria for Successful Closure

The principal criteria against which successful closure will be gauged are as follows:

- All buildings and facilities will be uncontaminated and secured from unauthorised access;
- There will be no constraints on future land use due to residual contamination or structures;
- Materials/wastes arising from decommissioning will be handled, packaged, stored and disposed of or recovered in such a manner that;
    - Equipment or uncontaminated materials can be sold for re-use or sold for scrap or;
    - Contaminated materials will be disposed of using authorised hazardous waste contractors.

- All relevant documents relating to waste, material movements or disposal will be managed and retained throughout the closure process;
- Sufficient funds will be available to cover the full cost of closure;
- The Environmental Management System (EMS) in place at the facility will be implemented and remain in place throughout the closure process; and
- Agency agreement that the site has been returned to a satisfactory state – in comparison to the Soil/Water Baseline Report for the facility.

The basis of the closure plan is to ensure that, upon completion of implementation of the plan, the AbbVie facility would be in a suitable state for future industrial use and would not pose a risk to public health and safety or the environment.

It is not intended to remove all structures or systems from the site. In general, specialized equipment, pipelines and storage tanks will be sold for reuse, where possible, or disposed of off-site. The facility buildings and common external utility features will remain in a suitable condition for future site users.

Assuming an orderly shutdown, AbbVie will use key staff resources to form a team to manage and execute the requirements of this Closure Plan, supplemented where appropriate by external resources. This closure team will be responsible for managing and executing the complete plan.

2.4 Roles and Responsibilities during Closure

The following personnel outlined in Table 1 will have specific responsibility in the event of closure of the site. In the case of an orderly shutdown, the Site Lead, in discussions with the AbbVie management, will determine if and when the facility is to be closed and will have ultimate responsibility for ensuring a clean site closure occurs.

Personnel	Area of Responsibility as part of Closure Plan
Site Lead	The Site Lead will have ultimate responsibility for overseeing the closure process.
Engineering Lead	The Engineering Lead will have responsibility for implementing the Closure Plan. He/she will assign tasks for the process and ensure that closure is carried out as per this strategy. His/her primary responsibilities will include: ○ Responsibility for decommissioning of all plant, equipment and for the process of sale or disposal of the equipment once decommissioned; ○ Responsibility for the management of non-plant related closure aspects i.e. overseeing the decontamination process and direction of all residual raw materials and waste for disposal off site. (Process Engineers will be retained for an appropriate period of time to assist with production close out)
EHS Lead and EHS Engineer	The Environmental Health & Safety (EHS) lead accompanied by the EHS Engineer will be responsible for ensuring site closure processes are carried out with minimal impact on the environment and with no residual risk to the environment following closure of the site. The EHS lead will provide correspondence and liaison with the Agency during the closure process. He/she will be responsible for coordination

	of external consultants to carry out environmental monitoring and closure audit. He/she will ensure all waste documentation is maintained and daily inspections are carried out during closure. They will be responsible for correct waste storage and disposal/recovery. During decommissioning, all documentation relating to all movements of materials/machinery whether disposed of or sold for reuse must be maintained. In addition, certificates for cleaning of all tanks, bund drains etc. must be maintained.
Maintenance and Warehouse Staff	A number of maintenance technicians will be retained for the active phase of decommissioning of the plant. At least 2 no. Warehouse operators will be retained to remove the majority of the wastes.

Table 1 *Roles and Responsibilities of AbbVie staff as part of the Closure Plan*

2.5 Procedure to Achieve the Stated Criteria

This section outlines the phased procedures to be followed in the event of a site closure:

- Stage 1 – Production decommissioning, including transfer of residuals to on-site storage;
- Stage 2 – Removal of excess raw materials and final product from site;
- Stage 3 – Removal of production related hazardous/non-hazardous wastes from site;
- Stage 4 – Contract cleaning of tanks, bunds, sump and interceptors;
- Stage 5 – Removal of non-process related materials and non-hazardous wastes;
- Stage 6 – Decommissioning of non-essential site services;
- Stage 7 – Decommissioning of ducts and vents;
- Stage 8 – Decommissioning of the Waste Water drainage system and monitoring station;
- Stage 9 – Removal of residual hazardous materials (non-process related);
- Stage 10 – Decommissioning of remaining site services; and
- Stage 11 – Documentation and certification of decommissioning and decontamination.

Stage 1 – Production decommissioning, including transfer of residuals to on-site storage

Task 1: Cancellation of incoming materials

It is assumed that any shutdown of the site will be a well-planned event. This implies that the shut-down date will be known well in advance and that both process schedules and inputs of raw materials have been planned with the shut-down already factored in.

All contracts relating to the delivery of supplies and materials will be cancelled. All contracts other than those that are concerned with the Closure Plan or related to safety of personnel or the environment will be terminated.

It is noted that in the event of a sudden closure, running down the quantities of raw materials on site will not be possible and the quantities to be removed may be up to the maximum storage volume of any particular tank.

Task 2: Transfer all raw materials and finished product to the Warehouse

Following cessation of production, it is assumed that all raw materials that had already been transferred from the Warehouse to the production building would be processed. Any residual raw materials and finished product will be labelled and transferred from the production building back to the Warehouse.

Chemical storage throughout the production building and in the laboratories will be transferred to a designated area in the Warehouse. An inventory of the materials should be taken, and it should be identified if any materials are suitable for return to suppliers.

Task 3: Transfer all production solid wastes, hazardous and non-hazardous to waste storage area

This task will include the specific transfer of hazardous and non-hazardous solid waste to appropriate storage on-site, as follows:

(a) Transfer of solid hazardous waste stored in sealed and labelled containers to the waste storage area;
(b) Transfer of contaminated containers, contaminated empty drums, Intermediate Bulk Container (IBC's) and other packaging to the waste storage area;
(c) Transfer of non-hazardous solid waste from the production building, admin building and canteen building to the waste storage area; and
(d) Removal of general waste to the waste storage area.

Task 4: Cleaning and decontamination of process equipment

This task specifically includes:

- Completion of cleaning and decontamination procedures for all production equipment;
- Removal, as necessary, of lubricating oils and greases from machinery;
- Cleaning of production building materials in contact with any product, Active Pharmaceutical Ingredients (API) or raw material;
- Purging of transfer lines and vessels in contact with materials, as appropriate; and
- Washing of all external surface areas and floors in the process area.

There may be some parts of the general ductwork system that require decommissioning and subsequent cleaning, removal and disposal by licensed contractors.

Production cleaning and decontamination programs will be routine and Standard Operating Procedures (SOPs) exist for cleaning of process vessels, bioreactors and IBCs used in the production process. Regular cleaning and decontamination will be in place during operations with specific cleaning requirements between campaigns.

High high strength wastewater (hazardous) will be directed to a bunded sunken bulk storage tank and then tankered offsite for disposal. Low strength wastewater (non-hazardous) will be directed to a bunded sunken bulk storage tank and then discharged directly to the foul network.

Task 5: Decontamination Testing

Designed on a case by case basis, a testing protocol will be implemented to include sampling of representative areas of the cleaned plant, equipment and vessels using wipe/swab sampling of the equipment, followed by analysis for the detection of the various APIs.

Equipment, plant or vessels which do not meet the required criteria will be disposed of off-site as hazardous waste using licensed waste management contractors.

Task 6: Isolate from steam, compressed air, heating & air conditioning (HVAC) and other utilities available

There are no specific residuals associated with this stage as this is just a physical disconnection step. However, some utilities may be retained for later decommissioning stages. At a minimum, it is envisaged that the following steps will be carried out:

(a) Water: Potable water supplies to the processing area may be isolated by shutting down the pumps at the potable water break tanks;
(b) Steam: Steam lines can be isolated by closing the main steam distribution valves;
(c) Nitrogen: Nitrogen lines may be isolated by closing the main nitrogen distribution valves;
(d) Air: Airlines may be isolated by closing the main air distribution valve; and,
(e) Electricity: Power supplies may be isolated at the main transformer switches.

Stage 2 – Removal of excess raw materials and final product from site

Task 1: Dispatch of finished product from final production to customers

The storage containers with finished product are likely to be very valuable, therefore it can be assumed that all will be either sold to customers or dispatched to another AbbVie facility.

Task 2: Shipping of excess raw material off-site

Raw material purchase is planned on a schedule directly related to the planned production schedule. As the date for plant shut-down will be known in advance, it is assumed that stocks of raw materials will be reduced accordingly. There will be options for removal of this material off-site including return of raw material to

suppliers, transfer of materials to other AbbVie sites or other pharmaceutical companies in Ireland or transfer to recovery/recycling companies. Treating the material as a hazardous waste is a “worst case” scenario.

Stage 3 – Removal of production related hazardous/non-hazardous wastes from site

At this point, all substances that can be considered waste, either hazardous or non-hazardous, will have been placed in designated areas. The waste may include raw materials (detailed in Stage 2) that cannot be returned to suppliers or sold on to interested third parties.

In the case of hazardous waste disposal, all requirements of the IE Licence will be applied, especially in relation to hazardous waste that is not typically generated at the facility. Therefore, the management of some of this material may require the prior written approval of the Agency before the waste can be removed from the site.

Stage 3 will include the following tasks:

- Administrative organisation of shipments;
- Removal of the waste in accordance with appropriate National and EU Legislation; and
- Administrative organisation of relevant paper work. All waste shipments during this period will be documented according to EPA Guidelines. This will facilitate the requirement to have stated criteria for validation of decommissioning.

The estimated volumes of waste materials are based on discussions with AbbVie and review of the most significant items to be disposed of. In the case of liquid waste and tank/vessel washwater volumes, it is assumed that the total volume of liquid waste from the decontamination process will be the tank/vessel capacity +5% for washwater generation.

Stage 4 – Contract cleaning of tanks, bunds, sump and interceptors;

Cleaning of tanks/vessels

This stage is started when bulk tanks are emptied. There a limited number of sunken bulk storage tanks namely:

- High high strength wastewater (60,000L)
- Low strength wastewater (30,000L)
- Diesel belly tank for emergency generator (10,000L)
- Liquid nitrogen tank (10,000L);
- Liquid petroleum gas (LPG) tank (30,000L).

There are also 8 no. existing large plastics storage silos located to the south of the existing site.

Cleaning of bunds, sumps, interceptors and drainage

There are bunds, sumps and a significant process drainage network at the facility associated with material storage areas, production, utilities and abatement equipment.

It is expected that most of the rinses from bulk storage, sumps, bund and process drainage washing may not be suitable for diversion as wastewater to the foul network and will mostly likely be disposed of using a licenced / permitted contractor.

Stage 5 – Removal of additional raw materials and wastes

Hazardous materials stored in the chemstore, raw materials in the Warehouse, and other materials stored in the laboratory and in the production areas will either be returned to the suppliers or disposed of as hazardous waste by a suitable waste contractor.

Decontamination of the chemstore will be required prior to its removal from the site. Washwater generated will be disposed of as waste using a licenced / permitted contractor.

In addition, there will be other non-hazardous residual materials such as:

- Plastics and packaging;
- Mechanical parts;
- Protective clothing; and
- Miscellaneous.

Each major area of the site will have segregated skips allocated for the above non-hazardous waste.

Both hazardous and non-hazardous non-process materials will be removed and disposed of in accordance with the facility's IE Licence requirements.

Stage 6 – Decommissioning of non-essential site services/utilities

This stage of decommissioning will apply to the following primary site utilities:

(a) Chillers;
(b) 10 no. Boilers;
(c) Cooling towers and water dosing equipment;
(d) Water treatment systems;
(e) Emergency generator;
(f) Laboratories;
(g) Canteen; and
(h) Administration rooms.

Chillers
Process cooling for the production building will be provided by chillers using propylene glycol as the cooling medium (process chilled glycol). This will be drained down into a designated IBC which would then be removed offsite for disposal or recovery by an appropriate contactor.

Boilers
It is anticipated that the LPG fired steam boilers will be rendered safe and will be left active and maintained by a specialist contractor (for a short-term period or until the site is sold).

Water Treatment Systems
Water for Injection (WFI) is required for the formulation of the final product. The generation system is located in the utilities room.

Cooling Towers
Cooling water is provided by three cooling towers. These are located external to the new bio-chemical suite.

Emergency/Back-up Generators
At present 1 emergency generator is proposed for the new bio-chemical facility. It will likely be maintained by a specialist contractor until the plant is sold to an interested third party or scrapped depending on age/condition at the time of closure.

Laboratories
In a planned closure, it is assumed that most of the laboratory equipment will be sold, with the only significant costs arising from expired chemicals and general laboratory waste disposal.

Administration and Canteen
The facility has administration areas, offices and a canteen. It is assumed that only partial administration facilities will be required for the remaining site decommissioning operations and the successful completion of the Closure Plan.

Outside of the waste paper and other recyclables, the only anticipated difficult residuals associated with decommissioning of the administration buildings include office waste electrical and electronic equipment (WEEE). Due to the short life span of most office electronic equipment and sensitivity of the equipment due to confidential data, it is assumed that all electronic equipment will be considered waste.

Fire Protection System
An L2/L3 type fire detection and alarm system is in place throughout the building including either smoke or heat detectors as appropriate. All air handling units have duct smoke detectors connected to and monitored by the alarm system.

The existing facility is equipped with an automatic sprinkler valve control system to effectively deal with any emergency situation that may occur. The water going to the sprinkler system is fed from the ring main which is filled by the mains supply. Hydrants outside the building are fed direct from Town mains.

Portable fire extinguishers are in place around the building and will be used by suitable trained personnel. These comply with the requirements of The Fire Services Act 1981 and the Safety Health and Welfare at Work Act 1989 and IS 291: 2013 The Use, Siting, Inspection and Maintenance of Portable Fire Extinguishers.

Fans, Pumps and Motors
There are many fans, pumps and motors located throughout the site. These will be maintained until such time as AbbVie operations resume or until the plant is sold to an interested third party.

Stage 7 – Decommissioning of ducts and vents

All ducts, vents, and pipework connecting various equipment and areas of the site will be cleaned and decontaminated by a specialist cleaning contractor. Aqueous waste streams produced by cleaning of ducts and vents will either be discharged to the foul network or tankered offsite for disposal.

Stage 8 – Decommissioning of the Wastewater Drainage System

All wastewater generated during decommissioning of the site will be tankered offsite for disposal if the wastewater has come into contact with hazardous process high high strength wastewater. If the wastewater is sanitary waste or low strength

wastewater, and therefore has no hazardous content, it will be directed to the foul network.

The tasks involved with the decommissioning the wastewater drainage system itself will be:

(a) Flush all process lines to the wastewater drainage system with fresh water;
(b) Treat washings of the low strength wastewater drainage lines through the balancing and pH adjustment stage;
(c) Wash the low strength wastewater sunken sump tank and sunken bulk tank;
(d) Discharge treated wastewater to the foul sewer;
(e) Empty high high strength wastewater sunken sump and bulk storage tanks and organise disposal of high high strength wastewater through a hazardous waste contractor;
(f) Decommission tanks and associated pipelines and pump stations.
(g) Decommission final discharge monitoring point (SE1).

Stage 9 – Removal of residual hazardous materials (non-process related)

Any other hazardous materials identified during the closure will be stored in appropriate receptacles and will be disposed of by a licenced / permitted contractor.

Stage 10 – Decommissioning of remaining (essential) utilities

This stage of decommissioning will apply to the following site utilities:

(a) Air compressors - There is one air compressor system – this will be decommissioned by AbbVie maintenance staff.
(b) Electrical substation - 38kV electrical substation will be rendered safe and it is assumed that decommissioning will be carried out by AbbVie maintenance staff.

Stage 11 – Documentation and certification of decommissioning and decontamination

All transfers of raw materials, product and waste materials off-site will be appropriately recorded and maintained throughout the process for verification. Records of sales for value products will be kept for inspection and waste transfer documentation and consignment notes will be maintained on site for the duration of the decommissioning process and will be available after closure if required.

2.6 Stormwater Drainage and Surface Water Protection during Decommissioning

The following protection measures will be implemented during decommissioning:

- Dismantling of equipment will take place indoors, where possible, isolated from any stormwater collection points;
- All loading and unloading of vehicles as part of the decommissioning process will be isolated from stormwater collection points;
- All waste oils/greases drained from equipment will be stored in containers in bunded areas;
- The facility's procedures for accident prevention and emergency response will be adhered to in the event of any potential spill; and

- Additional spill kit equipment will be brought on site during decommissioning works.

2.7 Contaminated Land Treatment, Removal and/or Disposal

There is no known contamination of soil at the facility and, by implementing the procedures outlined in this report, it is not anticipated that any contamination will occur as a result of the decommissioning process. The areas of the site where decontamination of equipment will take place are bunded and covered in hard-standing so any potential hazardous material spills can be quickly managed and contained.

2.8 Closure Plan Validation

An Independent Closure Audit (ICA) of the site will be undertaken prior to cessation of operations and actual decommissioning of the facility. The audit will compile an accurate inventory of all plant, equipment and wastes on the site. This inventory will be used as a benchmark against which successful decommissioning will be assessed.

2.9 Environmental Monitoring

Once production at the facility ceases and boilers are decommissioned, there will be no significant emissions to atmosphere at the facility so monitoring of emissions will not be required. Ambient dust, PM_{10} and other monitoring of air emissions, which may arise during decommissioning or decontamination works for closure, will be conducted upon request by the Agency.

Environmental monitoring of emissions to sewer will be carried out in accordance with the facility IE Licence (once granted) over the course of the six-month closure period.

Noise monitoring will be currently carried out at least annually at the facility once operational. Following closure of the facility, there will be no noise sources at the site, therefore it is not proposed to carry out regular noise monitoring.

Weekly visual inspection of the stormwater drainage discharges (via manholes at SW1, SW2 and SW3) will continue for the duration of the closure period and the frequency of inspection will be increased depending on closure activities.

Groundwater monitoring of wells will be carried out in accordance with the requirements of the facility IE Licence and will continue as scheduled for the duration of the closure period. Following closure, monitoring for the parameters listed in the IE Licence will continue to be carried out annually for two years.

2.10 Closure Validation Audit

The Agency will require the following list of information for a site which proposes to close in the immediate future:

- Submit name of person(s) completing closure audit for approval;
- Identify environmental liabilities or remediation issues with proposals on how these shall be dealt with post closure;
- Proposal for revised sampling analysis and reporting arrangements on foot of changes on-site for agreement with the Agency;

- Submit name of person(s) completing contaminated land/hydrogeological investigation; and
- Submit names of all proposed waste handling procedures during closure i.e. waste contractors, proposed final destination etc. for approval.

2.11 Closure Validation Report and Test Programme

As required by the IE Licence, a final validation report for the site will be required to be submitted to the Agency within three months of execution of the Closure Plan. The report will present all of the information required to demonstrate that the criteria for successful closure (Section 3.3) has been achieved as well as the information necessary for making an application for surrender of IE Licence, where appropriate.

In terms of the test programme, it is proposed to comprise the sampling and analysis presented in Table 2 as a minimum. It is anticipated that this scope will be refined and agreed with the Agency in advance of the assessment following confirmation of closure.

Media	No of Samples/Parameters	Description/Locations
Soil	Samples at varying depths for soil chemistry for all known contaminants used/present on site at the time of closure.	To be agreed with the Agency.
Groundwater	Samples for chemical characterization including all known contaminants used/present on site at the time of closure.	Annual sampling for two years post-closure.
Sewer	Sampling as per IE licence requirements over the 6-month closure period	SE1
Surface Water Drainage	At minimum, weekly visual inspection during closure period.	SW1, SW2 and SW3
Ambient Dust and PM_{10}	Sampling at a number of locations (upwind and downwind) for total dust and PM_{10}.	To be agreed with the Agency.

Table 2 *Proposed sampling and analysis plan for the facility during and after closure*

2.12 Closure Validation Certificate

AbbVie and its consultants will carry out the above tests and investigations and submit certification, as requested by the Agency, to confirm that there is no continuing risk to the environment.

3.0 FINANCIAL PROVISION

The cost of implementing the Closure Plan will be borne by AbbVie Ireland NL B.V in the event of closure of the facility.