

Permit with introductory note

Environment Protection Act (CAP 549)
Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L.549.77)

Crystal Pharma Ltd.
BLB 200,
Bulebel Industrial Estate,
Żejtun, ŻTN 3000

Permit number
IP 0005/07/D

Contents

Introductory note	3
Permit	6
Conditions	7
1 General.....	7
2 Closure and Decommissioning: Permitted Dismantling Works.....	11
3 Operating Conditions	14
4 Records.....	17
5 Reporting.....	18
6 Notification.....	18
7 Interpretation.....	19
Schedule 1 – Notification of abnormal emissions.....	21
Schedule 2 – Site Plan	22
Schedule 3 – Waste Log	23
Schedule 4 - Submission of Certifications and Documentation	24
End of Permit	24

This page has been intentionally left blank

Introductory note

This introductory note does not form part of the Permit

The following Permit is issued under Regulation 7 of the Industrial Emissions (Framework) Regulations, (S.L. 549.76) (“the Industrial Emissions (Framework) Regulations”), Regulation 16(3) and 16(4) of the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L.549.77) (“the Industrial Emissions (IPPC) Regulations”). Previous authorisations permitted the installation to carry out activities covered by the description in Section 4.5 in Schedule 1 of the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L.549.77) (“the Industrial Emissions (IPPC) Regulations”), to the extent authorised by the Permit, i.e.

“Production on an industrial scale by chemical or biological processing of pharmaceutical products including intermediates”.

Although, this activity is now prohibited the permit is nonetheless subject to the condition implied by Regulation 8 the Industrial Emissions (IPPC) Regulations, S.L.549.77 which require the Operator to use the best available techniques for preventing or, where that is not practicable, reducing emissions from the installation during the decommissioning process.

In some sections, the permit conditions require the Operator to use Best Available Techniques (BAT), in each of the aspects of the management of the installation, to prevent and where that is not practicable to reduce emissions. These conditions do not explain what is BAT.

A non-technical description of the installation’s previous activity is given in the original application.

The main activity of the installation is described as follows:

Decommissioning and dismantling of specified plants as specified in the IPPC application

Note that the Permit requires the submission of certain information to the Competent Authority as per subsequent specific conditions. In addition, the Competent Authority has the power to seek further information at any time under regulation 11 of the Industrial Emissions (Framework) Regulations, S.L. 549.76 provided that it acts reasonably.

Other IPPC Permits relating to this installation

Permit holder	Permit Number	Date of Issue
<i>Not applicable</i>		

Superseded Licences/Authorisations/Consents relating to this installation

Holder	Reference Number	Date of Issue
<i>Solea Pharma Ltd.</i>	<i>IP 0005/07/A</i>	<i>14 May 2009</i>
<i>Solea Pharma Ltd.</i>	<i>IP 0005/07/B</i>	<i>22 September 2011</i>
<i>Crystal Pharma Ltd.</i>	<i>IP 0003/06/C</i>	<i>5 October 2015</i>

Public Registers

This IPPC Permit and application is available to the public through the Competent Authority in accordance with the requirements of the Industrial Emissions (IPPC) Regulations. The applicant has made a request for certain information of a commercial nature to be withheld from the public. ERA has been supplied with all this information and has accepted the request of the applicant, because it was deemed to be commercially confidential.

Variations to the Permit

This Permit may be varied by the Authority at any time in the future (by the Authority serving a Variation Notice on the Operator). If the Operator wants any of the Conditions of the Permit to be changed, a formal application must be submitted to the Competent Authority. The **Status Log** within the Introductory Note to any such Variation Notice will include summary details of this Permit, variations issued up to that point in time and state whether a consolidated version of the Permit has been issued.

Any change in operations shall only be implemented following the issue of a variation of the permit by the Authority.

Transfer of the Permit or part of the Permit

The Authority may, on the joint application of an operator and a proposed transferee, transfer to the proposed transferee the environmental permit. The transfer of the permit will not relieve any of the operators from their environmental obligations and liabilities.

Status Log

Detail	Date	Comment
<i>Application IP 0005/07</i>	<i>Received between May & July 2007 (in various parts).</i>	<i>Not 'duly made'</i>
<i>Response to request for information</i>	<i>Request dated 06 September 2007</i>	<i>Response dated 27 September 2007 & 17 October 2007 'Duly made': 12 December 2007</i>
<i>Response to request for information</i>	<i>Request dated 12 December 2007</i>	<i>Response received 10 January 2008 Consolidated version received 07 February 2008</i>
<i>Proposal for monitoring of gaseous emissions</i>	<i>Proposal submitted 23 January 2008</i>	<i>Proposal accepted by MEPA 28 January 2008</i>
<i>Response to request for information</i>	<i>Request dated 30 January 2008</i>	<i>Response received 07 July 2008</i>
<i>Response to request for information on HVAC system</i>	<i>Request dated 08 May 2008</i>	<i>Response received 26 May 2008</i>
<i>Public consultation</i>	<i>Commenced on 14 February 2008</i>	<i>Concluded on 15 March 2008</i>
<i>Permit determined (IP 0005/07/A)</i>	<i>Permit determined: 27 November 2008</i>	<i>Permit issued: 14 May 2009</i>
<i>Application for renewal of the IPPC permit IP 0005/07</i>	<i>Request dated 18 June 2010</i>	<i>Response received by March 2011</i>
<i>Public consultation</i>	<i>Commenced on 19 March 2011</i>	<i>Concluded on 18 April 2011</i>
<i>Permit determined (IP 0005/07/B)</i>	<i>Permit determined: 21 July 2011 Permit issued: 22 September 2011</i>	<i>Permit expires on 22 September 2015</i>
<i>Application for variation of</i>	<i>Request dated 25 September</i>	<i>Response received on 04</i>

<i>the IPPC permit IP 0005/07 (to include an additional emission point from the plant)</i>	2012	December 2012
<i>Public consultation</i>	<i>Commenced on 08 December 2012</i>	<i>Concluded on 16 January 2013</i>
<i>Permit determined (IP 0005/07/C)</i>	<i>Permit determined: 22 January 2015</i>	
<i>Permit Issued</i>	05 October 2015	<i>Permit expired on 22 September 2015, however it was renewed on 5 October 2015 until the subsequent application for variation and renewal was determined</i>
<i>Application for the variation of the IPPC permit 0005/07 (to include the installation of a water purification system and the modification of an emission point)</i>	<i>Request dated 27 July 2015</i>	<i>Application withdrawn by applicant on 4 August 2017</i>
<i>Application for full surrender of the IPPC permit</i>	<i>Request dated 27th September 2017</i>	<i>Response received between November 2017 and February 2018</i>
<i>Public consultation</i>	<i>Commenced on 22nd February 2018</i>	<i>Concluded 8th March 2018</i>
<i>Permit determined (IP 0005/07/D)</i>	27 April 2018	
<i>Permit issued</i>	11 May 2018	<i>Permit expires: 11 May 2020</i>

End of Introductory Note

Permit

Industrial Emissions (Framework) Regulations, S.L.549.76; Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L. 549.77).

Permit number
IP 0005/07/D

The Environment and Resources Authority (hereinafter the Authority; the Competent Authority or ERA) in exercise of its powers under Regulation 7 of the Industrial Emissions (Framework) Regulations, (S.L. 549.76) (“the Industrial Emissions (Framework) Regulations”), hereby authorises:

Crystal Pharma Ltd. (hereinafter “the Operator” or “the Permit Holder”),
Of / Whose Registered Office (or principal place of business) is at:

BLB 200, Bulebel Industrial Estate, Żejtun, ŻTN 3000
(Company registration number: **C21609**)

to carry out decommissioning and dismantling of the installation as described in the IPPC application at:

Crystal Pharma Ltd. BLB 200, Bulebel Industrial Estate, Żejtun, ŻTN 3000

to the extent authorised by and subject to the conditions of this Permit.

Environment and Resources Authority APPROVAL Board No. _____ Held on _____ Chairman _____ Secretary _____	Date Issued: 11 May 2018
---	---------------------------------

Conditions

1 General

These permit conditions shall be read in conjunction with the original IPPC application received between May and July 2007, the applications for renewal and variation as subsequently clarified and recorded in the Status Log and the application for surrender dated 27th September 2017, which form an integral part of these permit conditions.

The conditions requested by other Authorities shall be enforced by the Authority which requested such conditions.

1.1 Permitted Activities

- 1.1.1 The Operator is authorised to carry out the activities and the associated activities specified in Table 1.1.1.

Table 1.1.1

Activity listed in Schedule 1 of the Industrial Emissions (IPPC) Regulations / Associated Activity	Description of specified activity	Limits of specified activity
Associated activity of storage, treatment and disposal/recycling of waste materials	Handling, storage, treatment and disposal/recovery of wastes from installation.	From generation of waste to disposal or recycling onsite or offsite.
Decommissioning and Dismantling	Decommissioning of the structures outlined in the IPPC application submitted on 21 February 2018	From the decommissioning as per approved method statements to the appropriate disposal of all resulting wastes

1.2 Site

- 1.2.1 The activities authorised under condition 1.1.1 shall not extend beyond the Site, as shown on the Site Plan in Schedule 3 to this Permit.

1.3 Overarching Management Condition

- 1.3.1 The Environment Management System (EMS) shall be maintained until such time that the Authority confirms in writing that permit is fully surrendered.

1.4 Improvement Programme

- 1.4.1 The Operator shall complete the improvements specified in Table 1.4.1 by the date specified in that table, and shall send written notification of the date of completion of each requirement to the Authority within 10 working days of the completion of each such requirement.

Table 1.4.1: Improvement programme		
Reference	Requirement	Date
4	Submission of a letter notifying the Authority of the completion of the dismantling works	Within 1 week of completion of works
5	Submission of certification by an independent, warranted civil engineer or engineer showing that any catchment pits, reservoirs and bunds on site have been visually inspected and ascertained free from visual surface contamination	Within 1 month of completion of works
6	The submission of the finalised schedule 3 form to be updated and submitted to ERA compiled for each waste stream arising from the dismantling of the structures listed in the IPPC application.	Within 2 months of completion of works

1.5 Operational Changes

1.5.1 The Operator shall seek the Authority's written agreement to any operational change as defined by S.L. 549.77 including any deviations from the approved method statements, by sending to the Authority: written notice of the details of the proposed change, including an assessment of its possible effects (including changes in emissions and waste production) on risks to the environment and to public health from the Permitted Installation; any relevant supporting assessments and drawings; and the proposed implementation date

1.5.2 Any such change shall not be implemented until agreed to in writing by the Authority. As from the agreed implementation date, the Operator shall operate the Permitted Installation in accordance with that change, and relevant provisions in the Application shall be deemed to be amended.

1.5.3 The Director of Environment and Resources and any officials to whom this role is delegated are hereby authorised to make decisions on variations to this permit, with the exception of the following cases:

- a. variations which could lead to significant impact on human health or the environment;
- b. Any change in the nature or functioning or an extension of an installation where the change or extension in itself reaches the capacity thresholds set out in Schedule 1 of the Industrial Emissions (IPPC) Regulations;
- c. Variations covered by the Environmental Impact Assessment Regulations;
- d. Aspects of the operations specifically prohibited by this permit;
- e. Changes to fees;
- f. Renewal of the validity of this permit.

1.6 Off-site Conditions

1.6.1 The Permit holder shall ensure that no chemicals or waste escape to the environment especially when transporting such materials offsite or onsite.

1.7 General Considerations

- 1.7.1 The conditions and obligations of this permit are without prejudice to any other regulation, code of practice, conditions or requirements requested by other Authorities or entities, including but not limited to, the Planning Authority, Occupational Health and Safety Authority, Transport Malta, the Regulator for Energy and Water Services (REWS) and the Environmental Health Directorate.
- 1.7.2 This permit is granted saving third party rights. The operator is not excused from obtaining any other permission required by law.
- 1.7.3 A copy of this permit shall be available at all times at the site office, including any variation notices of amendments to it.
- 1.7.4 The Permitted Installation shall be managed, controlled, supervised and operated by staff that are aware of the importance of environmental protection and suitably trained on the requirements of this Permit, in particular on those permit conditions relevant to their duties. All staff shall be provided with adequate training and written operating instructions to enable them to effectively carry out their duties.
- 1.7.5 The company shall maintain a register of third party complaints. The register shall record the name and address of the complainant(s), the date, location, source and nature of the complaint and the corrective action undertaken, where such action proves necessary.
- 1.7.6 In case of any monitoring requirements specified in this permit, there shall be provided safe means of access to enable sampling/monitoring to be carried out by the Authority if necessary.
- 1.7.7 All persons have a duty of care to protect the environment. The Operator shall become familiar with his legal obligations and good environmental practice.
- 1.7.8 The site shall be maintained in a tidy condition, free from litter and waste (whether arising from own activities or external sources).
- 1.7.9 The Operator is to be fully liable and responsible for managing the site in all its various aspects and to supervise the full adherence with all the conditions of this permit.
- 1.7.10 The Authority may carry out regular compliance checks that vary in frequency according to the site's compliance with the permit conditions. Any such checks carried out by the Authority are to be made at the Permit Holder's financial expense.
- 1.7.11 The Authority's representatives are empowered to inspect every part of the site and ask for any closed or locked areas to be opened. They are also entitled to be given any proof, documentation, plans, receipts or any other records which these Authority representatives may request.
- 1.7.12 The Authority may request additional monitoring and/or review of operational practices and/or commission audits on the installation as deemed necessary to address any circumstances that may affect the quality of the surrounding environment. Any required monitoring and audits shall be carried out at the expense of the operator.
- 1.7.13 The Authority may add, amend, substitute or revoke any of the conditions of this permit after notifying the Permit Holder of its intention and after describing the changes to the Permit Holder. This, without prejudice to any prevailing circumstances that would preclude the Authority from following such a procedure.

- 1.7.14 The Authority may suspend or revoke this permit or part of this permit where significant mismanagement of the site is observed or any of the permit conditions are not respected after a written warning is given by the Authority or in any eventuality that gives the Authority enough reason to suspend/revoke this permit.
- 1.7.15 Any incident including accidental release of liquid, solid or gaseous materials from the site that could be regarded as causing environmental damage, or as posing a threat of environmental damage, shall be reported as soon as possible and not later than within 24 hours to ERA, without prejudice to the emergency plan of the installation and Health and Safety.
- 1.7.16 The Operator shall undertake all necessary measures and precautions to prevent spillage of raw materials, intermediates, products, waste and any other materials.

1.8 Follow up on land and groundwater risk testing and quantitative risk assessment

- 1.8.1 Further to the report submitted to the Authority containing the results of the Land & groundwater testing and the Quantitative Risk Assessment carried out at Crystal Pharma Ltd. as part of the full surrender of the IPPC permit (IP 0005/07), the Operator shall, following completion of works, seal the site so as to ensure that any rainwater on site does not soak into the ground thus cause the possibility for further leaching of any contaminants within the substrate into the ground.
- 1.8.2 Once the site is sealed and made impermeable as per condition 1.8.1, the operator shall submit certification by an independent warranted engineer that the site has been rendered impermeable.
- 1.8.3 Further to conditions 1.8.1 and 1.8.2, any follow up actions requested by the Authority in writing shall be construed as forming part of the conditions of this permit and shall be read in conjunction with these permit conditions and subject to the associated provisions of the permit including the Bank Guarantee.

2.1 Operating Conditions

- 2.1.1 The operator is **not** authorised to carry out any of the activities or associated activities listed in table 2.1.1

Table 2.1.1	
Activity listed in Schedule 1 of the Industrial Emissions (IPPC) Regulations / Associated Activity	Description of prohibited specified activity
Section 4.5: Production of basic pharmaceutical products (Active Pharmaceutical Ingredients – APIs) by a chemical process	Synthesis of active pharmaceutical ingredients (APIs).

Associated activity of utilities	Reverse osmosis plant. Diesel boiler to produce steam and hot water. Emergency electricity generator for provision of electricity in case of power failure.
Associated activity of waste oil recovery/disposal	Oil ring pumps for solvent recovery from the vapours induced when creating vacuum in the plant

2.2 Permitted Dismantling works

- 2.2.1 This permit addresses the decommissioning, dismantling, and removal of structures as described in the site closure plan (section 4) in the IPPC application submitted on 21 February 2018.
- 2.2.2 All works shall be in line with the final approved method statements unless otherwise stipulated in writing by the Competent Authority.
- 2.2.3 The transport & disposal of hazardous waste locally shall be subject to a permit from ERA and shall follow the hazardous waste consignment note procedure while transport & disposal of hazardous waste abroad shall follow the requirements of S.L 549.65.
- 2.2.4 The operator shall be responsible for ensuring that containment measures through best available techniques are applied to ensure that any proposed works resulting the least possible damage and disturbance to the surrounding land.
- 2.2.5 The Operator shall ensure that the closure and decommissioning is carried out so as to prevent or minimise any pollution risk, including the generation of waste.
- 2.2.6 Any actions identified in the Site Closure Report shall be implemented within 12 months of final cessation or decommissioning of the Permitted activities or part thereof.
- 2.2.7 As part of the Site Closure Report, the Operator shall submit certification by an independent, warranted civil engineer or engineer showing that any catchment pits, reservoirs and bunds on site have been visually inspected and ascertained free from visual surface contamination.
- 2.2.8 Applicable waste management considerations detailed in section 2.2 shall be applied at all times. This shall also address the temporary storage of any wastes generated from dismantling on site pending removal during the full decommissioning of the site.
- 2.2.9 Upon completion of all dismantling works the operator shall provide an update of the table provided in Schedule 3. This shall include any additions of unforeseen wastes which may not have been identified during the decontamination/dismantling activities.
- 2.2.10 Further to condition 2.2.9, the authority may request the testing of any residual/unclassified wastes aimed at determining waste characterisation. These shall be carried out and submitted to the authority for approval prior to removal from the site.
- 2.2.11 The provisions of this permit shall apply to the site until such time that the site is

deemed fit for after use by the Environment and Resources Authority

- 2.2.12 Upon completion of all dismantling works the operator shall provide an update of the table provided in Schedule 3. This shall include any additions of unforeseen wastes which may have been identified during the dismantling process.

2.3 Waste recovery or disposal during decommissioning

General

- 2.3.1 All operations concerning the management of waste are subject to the Waste Management Regulations (S.L.549.63) and the Waste Management (Activity Registration) Regulations (S.L. 549.45).
- 2.3.2 The Operator shall be committed to reduce waste generation where possible.
- 2.3.3 The operator is to prevent litter or other wastes escaping from the site boundaries, particularly during loading/unloading. Any such escape of waste shall be collected immediately upon detection.
- 2.3.4 End-of-waste criteria must be met for any waste to be classified as a product. In such cases, the operator shall comply with relevant criteria set by legislation. In the absence of any relevant legislation, the operator shall follow the procedure laid down in Regulation 6 of S.L. 549.63.
- 2.3.5 Packaging and containers containing significant residual quantities of chemicals shall be regarded as hazardous waste and stored in dedicated waste management areas.
- 2.3.6 On-site disposal of wastes by any means including burning, disposal to drain or surface water, burying or deposition on land is prohibited, unless specifically approved by a permit from the Authority or the Water Services Corporation (WSC).

Storage

- 2.3.8 All wastes shall be stored within the designated and controlled storage area(s) prior to ultimate disposal; wastes to be recycled should be stored in a designated labelled container or area and not mixed with other wastes. The Operator shall ensure adequate protection and containment of all wastes.
- 2.3.9 Waste to be recycled shall be stored in a designated container or area and shall not be mixed with other wastes.
- 2.3.10 Waste produced at the Permitted Installation shall be recycled, reused or recovered unless technically and/or economically impossible. When practical recyclable wastes should be segregated to facilitate recycling.
- 2.3.11 Unless approved in writing by the Authority, the Operator is prohibited from mixing a hazardous waste of one Category with a hazardous waste of another category or with any other non-hazardous waste.
- 2.3.12 Liquid and hazardous wastes shall be stored in a labelled, closed container(s) within a designated and controlled storage area(s) prior to ultimate disposal which shall be appropriately contained to ensure no contamination of the environment in case of spillage. Wastes of different natures and having different European Waste Catalogue codes as established by Commission Decision 2000/532/EC and any subsequent amendments should not be mixed in the same container.

- 2.3.13 Drums and containers of chemicals/oils shall be stored in designated and secure storage areas. Storage areas shall be bunded or otherwise designed so that surface and ground waters cannot be contaminated by spillages.
- 2.3.14 All storage of materials or waste shall take place only in locations where thorough clean-up and site reinstatement can be readily undertaken.
- 2.3.15 All wastes leaving the site after storage and/or processing must only be sent to facilities licensed to accept the individual waste stream, either locally or abroad.
- 2.3.16 No storage of waste destined for recovery is permitted for a period exceeding 3 years
- 2.3.17 No storage of waste destined for disposal is permitted for a period exceeding 12 months
- 2.3.18 No storage of waste is permitted on property outside the site premises.
- 2.3.19 The Operator shall ensure that waste transferred to another person is packaged and labelled in accordance with national, European and any other standards which are in force in relation to such labelling. While awaiting collection, recovery or disposal all waste shall be stored in designated areas protected, as may be appropriate, against spillage, leachate run-off and accidental damage. The waste is to be clearly labelled and appropriately segregated.

Transport

- 2.3.20 Transboundary movement of waste shall be carried out in accordance with the following regulations, as amended from time to time:
 - i. Regulation (EC) N° 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste;
 - ii. Commission Regulation (EC) N° 1418/2007 of 29 November 2007 concerning the export for recovery of certain waste listed in Annex III or IIIA to Regulation (EC) N° 1013/2006 of the European Parliament and of the Council to certain countries to which the OECD Decision on the control of transboundary movements of waste does not apply; and
 - iii. Any other applicable legislation.
- 2.3.21 Waste sent off-site for recovery or disposal shall be conveyed only by an authorised waste carrier as per Activity 38 of Schedule 1 of S.L. 549.45. The waste shall be transported only from the site of the activity to the site of recovery/disposal in a manner which shall not adversely affect the environment and in accordance with all relevant National and European legislation.
- 2.3.22 Each movement of hazardous waste to authorised facilities shall be covered by a valid consignment permit obtainable from the Authority. Each movement shall also be covered by a consignment note obtainable from the Authority.
- 2.3.23 Independent of any Environment Management System, the Operator shall be responsible for making use of the services of an ADR (The European Agreement concerning the International Carriage of Dangerous Goods by Road) certified carrier for transport of chemicals and hazardous wastes on land.

Records

- 2.3.24 Records shall be maintained for the disposal of all hazardous waste, including quantities, dates, contractor name and manner of disposal. The records should be maintained for a period of 5 years and be made available for inspection by

the Authority upon request.

- 2.3.25 The Operator shall ensure to keep records for every consignment of wastes removed from the Site indicating the EWC Code, description, quantities, date of removal, contractor name (including for transport), consignment note number (where applicable) and manner and place of final disposal/recovery.
- 2.3.26 A full record which shall be open to inspection by authorised persons of the Authority at all times, shall be kept by the Operator on matters relating to the waste management operations and practices at this site. This record shall as a minimum contain details of the following:
 - 2.3.26.1 The tonnages and EWC Codes for the waste materials removed off site as per Schedule 1 of S.L. 549.63.
 - 2.3.26.2 The names of the Company and carrier of the waste and their Permit details (either waste registration or waste management permit).
 - 2.3.26.3 Details of the ultimate disposal/recovery destination facility for the waste and its appropriateness to accept the consigned waste stream, to include its Waste Management Permit details and number
 - 2.3.26.4 Written confirmation of the acceptance and disposal/recovery of any hazardous waste consignments sent off-site.
 - 2.3.26.5 Details of all wastes consigned abroad for disposal or recovery and classified as Green, Amber or Red in accordance with the EU Transfrontier Shipment of waste regulations (Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste, as may be amended from time to time.) The rationale for the classification must form part of the record
 - 2.3.26.6 Details of any approved waste mixing as per condition 2.2.11

3 Operating Conditions

3.1 Emissions to Air

- 3.1.1 No emissions to air from the Permitted Installation are allowed.

3.2 Discharges to surface waters

- 3.2.1 No discharges to surface water shall take place from the installation.

3.3 Discharges to sewers

- 3.3.1 The Operator shall also abide by the conditions of the Sewer Discharge Permit, as is regulated by the Water Services Corporation and the provisions of the Sewer Discharge Control Regulations, (S.L.545.08).
- 3.3.2 Where any of the parameters stipulated by the WSC are exceeded, the operator shall ensure that any follow up actions requested by the WSC are implemented.
- 3.3.3 No discharges of trade effluent into the sewer (whether from off-site or on-site discharge points) are allowed, unless specifically authorised by the Water Services Corporation. Prior to any discharge of trade effluent, the operator must provide evidence of authorisation from the Water Services Corporation to the Authority.

3.3.4 Any liquid waste resulting from flushing or cleaning of plant and equipment shall not be disposed via the sewers unless specifically approved by the Water services corporation. In cases where such discharges are prohibited, any effluent shall be collected and considered as hazardous waste.

3.3.5 Rainwater shall be segregated from all process areas that are potentially contaminated with raw materials, intermediates and/or products.

3.3.6 Rainwater shall not be discharged into the sewer or cesspits.

3.4 Discharges to groundwater

3.4.1 The operator shall not allow the introduction into groundwater of any substance included in the Regulations for the Protection of Groundwater against pollution and deterioration (SL 549.53).

3.4.2 Further to condition 3.4.1 the operator shall not allow any discharges to groundwater.

3.4.3 The dismantling and decommissioning works at the installation shall not hinder the achievement of good chemical and quantitative status of groundwater as prescribed under the Water Policy Framework Regulations, S.L. 549.100.

3.5 Fugitive emissions of substances to water and sewer

3.5.1 Subject to condition 3.5.2, the Operator shall use BAT so as to prevent or where that is not practicable to reduce fugitive emissions of substances to water (including to groundwater) and sewer from the Permitted Installation, in particular from:

- All structures under or over ground;
- Surfacing;
- Storage areas;
- Bunded areas.

3.5.2 Any accidental release of substances shall be duly treated prior to discharge into the sewers (subject to clearance from the WSC), or disposed as waste. Records shall be kept of such discharges, including the volume discharged and other parameters, as agreed with the Water Services Corporation, as per the Sewer Discharge Permit.

3.6 Odour

3.6.1 The Operator prevent or where that is not practicable to reduce odorous emissions from the Permitted Installation, in particular by controlling the storage conditions of odorous materials and controlling dismantling and decommissioning works to minimise the generation of odour.

3.6.2 There shall be no significant offensive odour, as perceived by an Authorised Officer of the Competent Authority, outside the boundary of the permitted installation.

3.6.3 In case of complaints regarding odours which upon investigations are verified, the operator shall take all measures necessary so as to address such complaints provided always that any techniques used by the Operator to eliminate odorous emissions shall be approved by the Authority prior to their implementation.

3.7 Emissions to Land

3.7.1 No emission from the Permitted Installation shall be made to land.

- 3.7.2 In the event of contamination of land, the operator shall notify the Authority within 24 hours. In such cases, a decontamination plan shall be forwarded to the Authority for approval and shall be executed within a time frame agreed with the Authority.

3.8 Noise

- 3.8.1 The Operator shall use BAT so as to prevent or where that is not practicable to reduce emissions of noise from the Permitted Installation, in particular by ensuring appropriate timing of noisy activities and vehicle movements.
- 3.8.2 Alarms/sirens/release valves shall only be tested between the hours of 10.00 and 17.00 Monday to Friday and not on any Public Holiday.

3.9 Management and Technically Competent Person

Incidents and Complaints

- 3.9.1 The Operator shall maintain and implement written procedures for:
- 3.9.1.1 Taking prompt remedial action, investigating and reporting to the Competent Authority actual or potential non-compliance if such events occur
 - 3.9.1.2 Investigating incidents and prompt implementation of appropriate actions; and
 - 3.9.1.3 Ensuring that detailed records are made of all such actions and investigations.
- 3.9.2 The Operator shall record and investigate complaints concerning the Permitted Installation's effects or alleged effects on the environment and public health. The record shall give the date and nature of complaint, time of complaint, name of complainant (if given), a summary of any investigation and the results of such investigation and any actions taken.

Attendance of Technically Competent Person(s)

- 3.9.3 The Permitted Installation shall be managed by staff who are suitably trained and fully conversant with the requirements of this Permit.
- 3.9.4 Attendance of the Technically Competent Person(s) at the Site shall be recorded arrival and departure.
- 3.9.5 During the dismantling operations the Technically Competent Person/s shall be physically in attendance at the Site.

Changes in Technically Competent Persons

- 3.9.6 Any changes in Technically Competent Management (Person/s) and the name of any incoming person together with evidence that such person has the required technical competence shall be submitted to the Authority in writing within 5 working days of the change in management.
- 3.9.7 In the event of any short or long periods of sick leave or vacation leave taken by the TCP for a period exceeding 10 days, the Operator is obliged to find a replacement for that member of staff immediately without delay.
- 3.9.8 In the event of the death, dismissal, resignation or leave of the Technically Competent Management of the Site, the Permit Holder shall immediately inform the Authority, and prove to the Authority that the Permit Holder is actively seeking a replacement.

3.10 Accident prevention and control

- 3.10.1 In the case of an accident, the Operator shall follow the Emergency Plan, as approved by the Civil Protection Department.
- 3.10.2 The Operator shall maintain and implement all health and safety measures in compliance with Act XXVII of 2000; Occupational Health and Safety Authority Chapter 424 and all relevant subsidiary legislation
- 3.10.3 The Operator shall have sufficient employees trained to deal with any emergency that may arise, e.g. fire-fighting and first aid.
- 3.10.4 The Operator is to keep the Authority updated on any major changes in operations that may impact on the health and safety of the employees.
- 3.10.5 The Operator is to make available Health and Safety documentation upon request by Occupational Health and Safety Officers.
- 3.10.6 During decommissioning, dismantling and demolition processes the Civil Protection Department shall be formally informed 24 hrs prior to the commencement of any high risk works
- 3.10.7 Decommissioning, dismantling and demolition works are to be coordinated in such a way so as to ensure that access to fire trucks is not impaired.
- 3.10.8 The Operator is to ascertain that the fire hydrant system is left active until the dismantling works are complete.
- 3.10.9 Spillages of hazardous materials or wastes shall be cleared up immediately to prevent escape to drain, surface water or land. Where applicable this shall be carried out by the application of absorbent materials. All sand and other material shall be disposed of as approved by the responsible authority.

4 Records

- 4.1 The Operator shall ensure that all records required to be made by this Permit or by the previous permit covering operations within the installation (IP 0005/07/C) and any other records made by it in relation to the operation of the Permitted Installation shall:-
 - 4.1.1 be made available for inspection by the Authority upon request;
 - 4.1.2 be supplied to the Authority on demand and without charge and in the format requested;
 - 4.1.3 be legible;
 - 4.1.4 Indicate any amendments which have been made and shall include the original record wherever possible; and
 - 4.1.5 be retained at the Permitted Installation, or other location agreed by the Authority in writing, for a minimum period of 5 years from the date when the records were made, unless otherwise agreed in writing.
- 4.2 A daily operations log shall be kept on site in which the following information shall be recorded on a daily basis:
 - 4.2.1 Any incidents that took place on site such as mechanical faults in the machinery or equipment used on site for the dismantling operations, any spills, fires, etc and the remedial action taken

- 4.2.2 Any other incidents that the permit holder deems important to record.
- 4.2.3 Total amount of waste in kilos (Kg) removed from site for disposal, recovery, recycling or further treatment.

Each record shall be compiled within 24 hours of the relevant event. The records kept in the daily operations log shall be available for inspection at any time when the Authority representatives request to inspect them

5 Reporting

- 5.1.1 All reports and written and/or verbal notifications required by this Permit and notifications required by Regulation 7 of the Industrial Emissions (IPPC) Regulations shall be made and sent to the Authority using the contact details notified in writing to the Operator by the Authority.

6 Notifications

- 6.1.1 The Operator shall notify the Authority without delay of any accident which has caused, is causing or has the potential to cause significant pollution and a public health risk
- 6.1.2 When submitting notifications under 6.1.1 the operator shall send to the Authority the information listed in Schedule 1 to this Permit within 24 hours of such notification.
- 6.1.3 The Operator shall notify the following matters to the Authority in writing within 10 working days of their occurrence:-
 - 6.1.3.1 Where the Operator is a registered company:-
 - a Any change in the Operator's trading name, registered name or registered office address;
 - b Any change to particulars of the Operator's ultimate holding company (including details of an ultimate holding company where an Operator has become a subsidiary); and
 - c Any steps taken with a view to the Operator going into administration, entering into a company voluntary arrangement or being wound up.
 - 6.1.3.2 Where the Operator is a corporate body other than a registered company:
 - a Any change in the Operator's name or address; and
 - b Any steps taken with a view to the dissolution of the Operator
 - 6.1.3.3 In any other case: -
 - a The death of any of the named Operators (where the Operator consists of more than one named individual);
 - b Any change in the Operator's name(s) or address(es);
 - c Any steps taken with a view to the Operator, or any one of them, going into bankruptcy, entering into a composition or arrangement with creditors, or, in the case them being in a partnership, dissolving the partnership

7 Interpretation

7.1.1 In this Permit the following expressions shall have the following meanings assigned to them, except where the context otherwise requires. All other terms shall have the same meaning as that assigned to them in the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L. 549.77), or any statutory provisions or regulations amending or replacing them:

“Application” means the application for this Permit, together with any response to a notice served under Regulation 5 to the Industrial Emissions (IPPC) Regulations and any operational change agreed under the conditions of this Permit.

“Authorised Officer” means any officer of the Authority authorised in writing pursuant to Part X of the Environment Protection Act 2001 to exercise any of the powers specified in Part X of that Act;.

“Background concentration” means such concentration of that substance as is present in:

- water supplied to the site; or
- where more than 50% of the water used at the site is directly abstracted from ground or surface water on site, the abstracted water; or
- where the Permitted Installation uses no significant amount of supplied or abstracted water, the precipitation onto the site.

“BAT” means best available techniques, which means the most effective and advanced stage of development of activities and their methods of operation which indicates the practical suitability of particular techniques to prevent and where that is not practicable to reduce emissions and the impact on the environment as a whole. For these purposes: “available techniques” means “those techniques which have been developed on a scale which allows implementation in the relevant industrial sector, under economically and technically viable conditions, taking into consideration the cost and advantages, whether or not the techniques are used or produced in Malta, as long as they are reasonably accessible to the operator”; “best” means “in relation to techniques, the most effective in achieving a high general level of protection of the environment as a whole” and “techniques” “includes both the technology used and the way in which the installation is designed, built, maintained, operated and decommissioned.”

“BREF” means the latest version of the BAT reference document available from the website of the European Integrated Pollution Prevention and Control Bureau (<http://eippcb.jrc.es/pages/Factivities.htm>)

“Engineer” for engineering works specified in these conditions, means a person who works in the relevant branch of engineering and possesses a warrant to carry out the profession of an engineer in Malta.

“Fugitive emission” means an emission to air or water (including sewer) from the Permitted Installation which is not controlled by an emission or background concentration limit

“Groundwater” means all water which is below the surface of the ground in the saturation zone and in direct contact with the ground or subsoil.

“Hazardous Waste” means hazardous waste as defined in The Waste Regulations, (S.L.549.65), and any statutory provisions or regulations amending or replacing them.

“Industrial Emissions (IPPC) Regulations” means the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L.549.77) and words and expressions defined in the Industrial Emissions (IPPC) Regulations shall have the same meanings when used in this Permit save to the extent they are specifically defined in this Permit. It shall include any future amendments or superseding legislation.

“Malta” means the Island of Malta, the Island of Gozo and the other islands of the Maltese Archipelago, including the territorial waters thereof.

“Monitoring” includes the taking and analysis of samples, instrumental measurements (periodic and continual), calibrations, examinations, tests and surveys.

“Permitted Installation” means the activities and the limits to those activities described in Table 1.1.1 of this Permit.

“Sewer” or *“Public sewerage system”* means the sewerage system owned by the Water Services Corporation.

“Staff” includes employees, directors or other officers of the Operator, and any other person under the Operator’s direct or indirect control, including contractors.

“Surface water” means inland waters, except groundwater; transitional waters and coastal waters

“Technically Competent Person” means a person possessing the qualifications, experience and technical competence to abide by the conditions of the Permit;

“Technically Competent Management” means the Technically Competent Person or Persons in control of the day-to-day activities authorised by the Permit and carried on at the Site;

“The Authority” or *“the Competent Authority”* or *“ERA”* means the Environment and Resources Authority or such other body or person as the Minister responsible for the environment may by order in the Gazette prescribe;

“The Permit Holder” means the Permit Holder specified in the Permit or other person to whom the Permit has been transferred in accordance with the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L. 549.77), and any statutory provisions or regulations amending or replacing them;

“The Operator” means a person who is in occupation of the Site and has responsibility for carrying out day to day activities at the Site and to whom the Permit has been issued and / or transferred;

“The Regulations” means the Industrial Emissions (Framework Regulations, 2013 (549.76) (“the Industrial Emissions (Framework) Regulations and the Industrial Emissions (IPPC) Regulations (549.77) (“the Industrial Emissions (IPPC) Regulations;

“Year” or *“reporting year”* means calendar year ending 31 December.

- 7.1.2 Where any condition of this Permit refers to the whole or parts of different documents, in the event of any conflict between the wording of such documents, the wording of the document(s) with the most recent date shall prevail to the extent of such conflict

Schedule 1

Notification of abnormal emissions and significant adverse environmental effects

This page outlines the information that the Operator must provide to satisfy conditions 5.1.1 and 5.1.2 of this Permit.

Units of measurement used in information supplied under Part A and B requirements shall be appropriate to the circumstances of the emission. Where appropriate, a comparison should be made of actual emissions and authorised emission limits.

If any information is considered commercially confidential, it should be separated from non-confidential information, supplied on a separate sheet and accompanied by an application for commercial confidentiality under the provisions of the Industrial Emissions (IPPC) Regulations.

Part A

Permit Number	
Name of Operator	
Location of Installation	
Location of the emission	
Time and date of the emission	

Substance(s) emitted	Media (e.g. air, groundwater)	Best estimate of the quantity or the rate of emission (include units)	Time between which the emission took place

Measures taken, or intended to be taken, to stop the emission	
--	--

Part B

Any more accurate information on the matters for notification under Part A.	
Measures taken, or intended to be taken, to prevent a recurrence of the incident.	
Measures taken, or intended to be taken, to rectify, limit or prevent any pollution of the environment or harm or any public health risk which has been or may be caused by the emission.	
The dates of any unauthorised emissions from the installation in the preceding 24 months.	

Name of TCP/ delegate ⁱ	
Post	
Signature	
Date	

ⁱ authorised to sign on behalf of Operator

Schedule 2 Site Plan

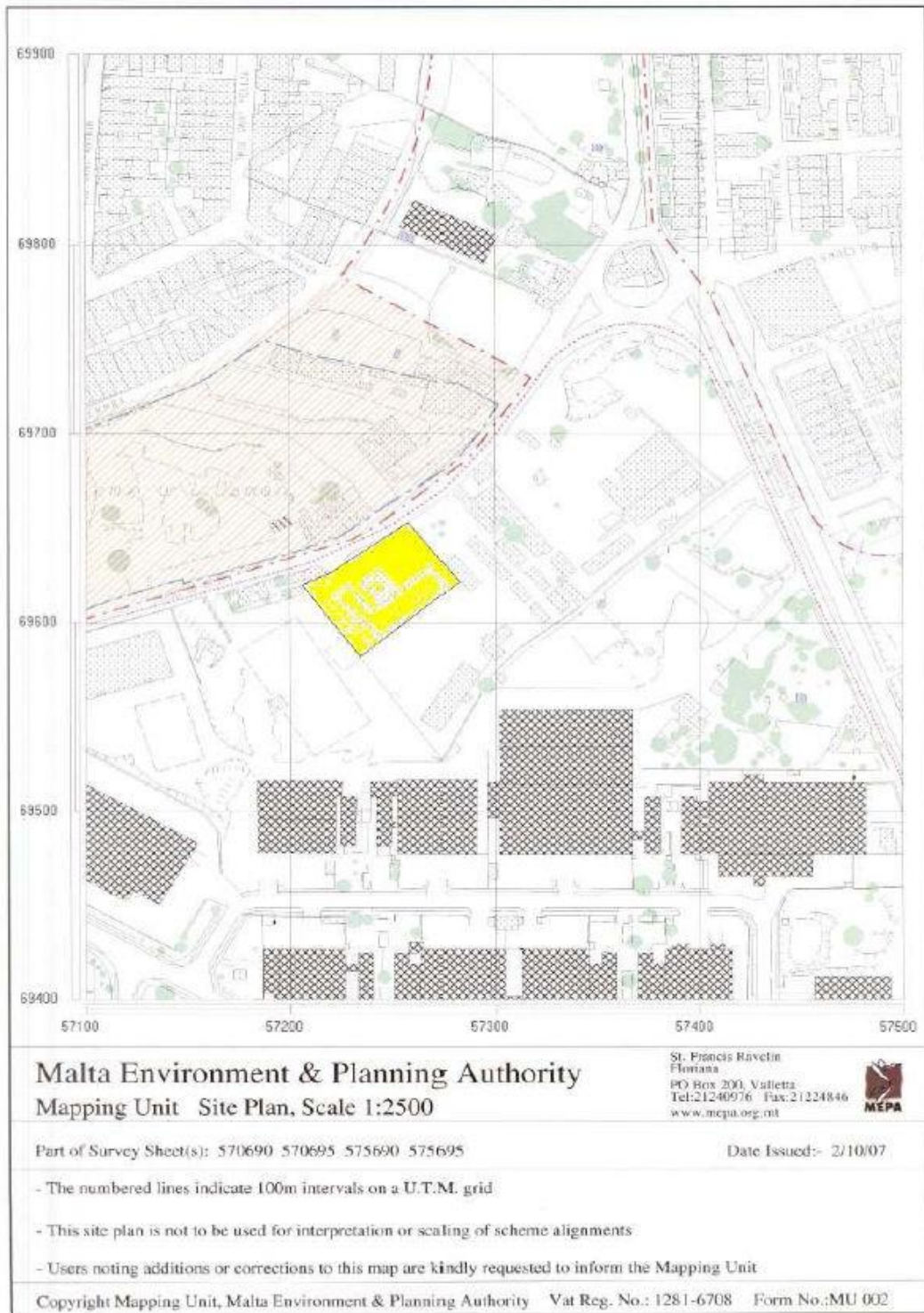


Fig. S3.1: Site of permitted installation, showing the extent of area (highlighted in yellow, outlined in black) for carrying out of the activities specified in condition 1.1.1. The extent of the site boundary is indicative and should not be used for interpretation purposes.

**Schedule 3
List of wastes estimated and generated**

No	Type of Waste	EWC code (from Commission decision 2000/532/EC establishing a list of wastes)	Quantity projected	Quantity generated	Waste carrier reg. No. Waste broker reg. No	Permitted disposal facility / Permit number or details of overseas disposal site (including consignment note/ TFS permit Number [if applicable]).	Method of storage and containment for wastes to be retained on site
W 1							
W 2							
W 3							
W 4							
W 5							
Continue as required							

Schedule 4
Submission of Certifications and Documentation

Please attach a supporting document with the following:

Reference in Permit	
1.4	Improvement Programme Items as per Table 1.4
1.8.3	Certification that the site has been rendered impermeable following completion of works.

END OF PERMIT