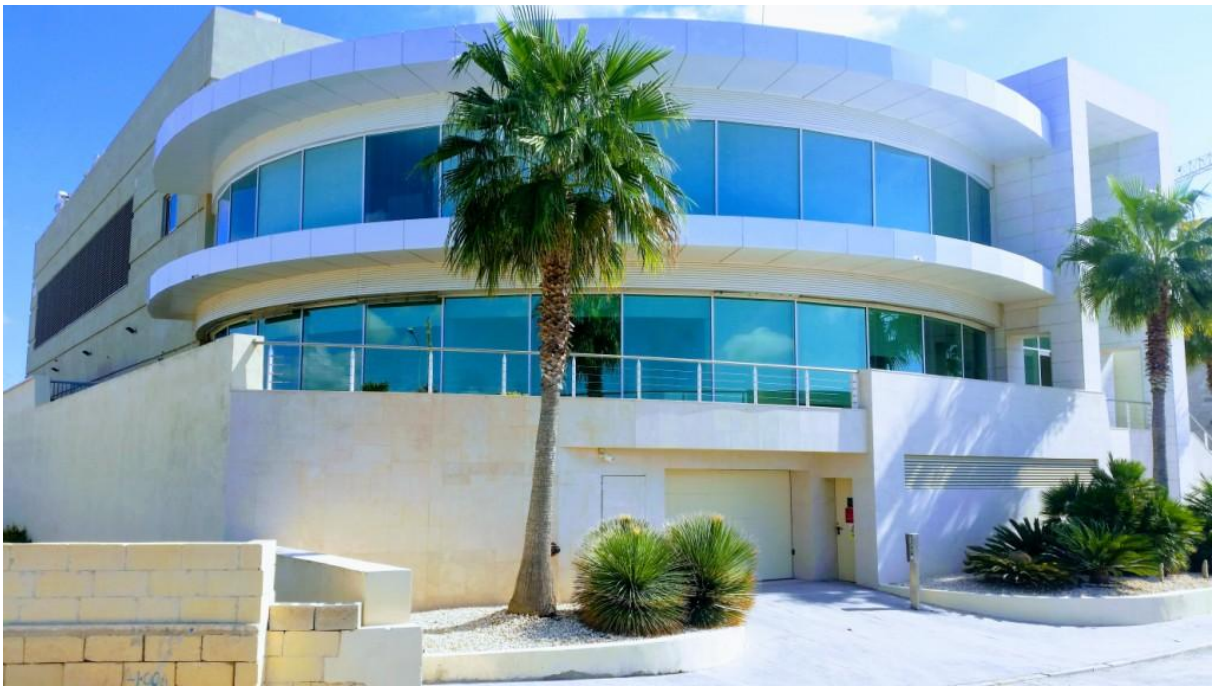
IP 0001/19

STERLING CHEMICAL MALTA LTD, HAL FAR

APPLICATION FOR VARIATION AND RENEWAL OF IPPC PERMIT
VOLUME 1: IPPC APPLICATION FORMS



Version 2: June 2019

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Quality Assurance

Sterling Chemical Malta Ltd, Hal Far
Application for Variation and Renewal of IPPC Permit: Volume 1
June 2019

Report for: Sterling Chemical Malta Ltd

Revision Schedule

Rev	Date	Details	Prepared by	Reviewed by	Approved by
00	Mar. 2019	Submission to client	**Rachel Decelis** Senior Consultant	**Rachel Xuereb** Director	**Adrian Mallia** Managing Director
01	Jun. 2019	Consolidated application	**Rachel Decelis** Senior Consultant	**Rachel Xuereb** Director	**Adrian Mallia** Managing Director

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FORM A

Form IPPC Part A – application for a permit, variation, transfer or surrender
For Environment & Resources Authority Use Only

Data received	Fee received: Yes No	Amount received	Name assigned to installation
	☐ ☐		

Application for a permit, variation, transfer or surrender

Integrated Pollution Prevention and Control (IPPC)

Industrial Emissions (IPPC) Regulations 2013

Introduction to Part A

When to use this form

Use this form if you are sending an application to the ERA under the Industrial Emissions (IPPC) Regulations, 2013.

The form is to be used for applications made in respect of both 'installations' and 'mobile plant' (and in the rest of the form, the term 'installation' also covers 'mobile plant' where appropriate).

Before you start to fill in this form

There may be two or more operators in a single installation. Each operator will need a permit, each obtained by a separate application. Your applications will principally relate to the part of the installation under your control, but will also need to include some information on the rest of the installation. This will help us to assess the operation of the whole installation. The term "installation", when used in this application form (and elsewhere) may refer to either the whole or part of the installation, depending on the nature of the information we are seeking to obtain.

Which parts of the form to fill in

The form is in five parts but we usually only send you the parts you need to fill in. Everyone has to fill in Part A, and prepare and sign a covering letter at the end of their application.
The other parts you need to fill in depends on the type of application you are making:

- To apply for a new permit – fill in Parts A and B;
- To vary an existing permit – fill in Parts A and C;
- To transfer all or part of an existing permit to

someone else – fill in Parts A and D. This should be a joint application by the transferor and the transferee;

- To surrender all or part of an existing permit – fill in Parts A and E.

Other documents we need to see

There are a number of other documents you will need to send us with your application. Each time a request for documents is made in the application form you will need to record a document reference number for the document or documents that you are submitting in the box provided on the form for this purpose.

Please also mark the document(s) clearly with this reference number and either the application reference number if you know it or your existing permit number. If you do not have either of these, please use the name of the installation.

If you know your Application Reference Number, please enter it into the box below:

IP 0001/19

Using continuation sheets

In the case of questions required to be answered on the application form itself, please use a continuation sheet if you need extra space; but please indicate clearly on the form that you have done so by stating a document reference number for that continuation sheet. Please also mark the continuation sheet itself clearly with the information referred to above.

Copies

Please submit 1 hard copy and 1 soft copy of the application form and all supporting information.
A soft copy of the application form must also be submitted to the consultees identified in Regulation 19(2) of Legal Notice 10 of 2013. A signed delivery note must be enclosed with the application to ERA.

If you need help and advice

We have made the application form as straightforward as possible, but please get in touch with us on tel: 2292 3500 or email: ippc@era.org.mt if you need any advice on how to set out the information we need.

A1 About your application

A1.1 What type of application are you making?

- ❑ new permit
- ☑ variation of an existing permit
- ❑ transfer of an existing permit
- ❑ surrender of an existing permit

A1.2 Name of the installation

Sterling Chemical Malta Ltd

Please tell us if this name is:

- ☑ already agreed with the ERA; or
- ❑ one that you are proposing.

A1.3 Please give the address of the site of the installation, and a map or plan showing the site of the installation and the location of the installation on the site

Street Address	HF50, HF 51, HF53	
	Hal Far Industrial Estate	
Locality	Birżebbuġa	Post Code BBG3000

A site plan is included in **Appendix 1**.

A1.4 Give details of any existing permit(s) for the installation.

Please give details of any applicable waste management licences, planning permits, environmental permits or sewer discharge permits. Include permit number(s), type(s) and date(s) of issue, and submit copies.

- IPPC permit: IP 0001/14/B (November 2018)
- Relevant development permits:
  - PA 04236/08 (issued April 2010)
  - PA 03033/12 (June 2013)
  - DN 0624/16 (September 2016)
  - DN 23/17 (January 2017)
  - DN 617/17 (July 2017)
  - DN 810/17 (October 2017)
  - PA 3638/18 (March 2019)
  - DN 1094/18 (November 2018)
- Sewer discharge permit from WSC (DMU 6745), renewed in 2019
- LPG secondary storage permit issued by REWS, licence no. LPG-00110-SS (SS110), last renewed in May 2018.

Copies of the above permits and applications, and correspondence with WSC, are included in **Appendix 2.**

A2 Authorised contacts

It will help us to have someone who we can contact directly with any questions about your application. The person you name should have the authority to act on your behalf.

A2.1 Who can we contact about your application?

This could be an agent rather than the operator.

Name

Marco Garilli

Position

HSE Manager

Address

Street Address	HF 51	
	Hal Far Industrial Estate	
Locality	Birżebbuġa	Post Code BBG3000

Phone Number +356 20908700

Fax Number +356 20908799

Email address
mgarilli@sterlingchemicalmalta.com

A2.2 Operational contact

If different to the above, please identify the person we should contact to discuss operational matters on an ongoing basis.

Name

Position

Address

Street Address		
Locality		Post Code

Phone Number

Fax Number

Email address

A3 About the operator

Please provide the information requested below about the 'operator', which means:

• for applications for a new permit – the person who it is proposed will have control over the installation in accordance with the permit (if granted),

• for applications for a variation, transfer or surrender – the person who currently has control over the installation in accordance with the permit.

If you are applying for a transfer, we will ask for more information relating to the proposed new operator (transferee) in Part D.

Legal status of operator

A3.1 Is the operator an individual, a group of individuals, a partnership or a company/corporate body?

- ❑ Individual (sole trader) or group of individuals: go to question A3.2.
- ❑ Partnership: go to question A3.3.
- ☑ Company or corporate body: go to question A3.5.

Individual applicants

A3.2 Please give us the following details.

Where more than one person is applying (other than as a partnership) we need details of each person.

Continue on separate sheets if necessary.

Full Name

ID Card/Passport No.

Trading/business name (if any)

Business address

Street Address		
Locality		Post Code

Phone Number

Fax Number

Email address

Now go to question A4, What to do next.

Applications from partnerships

A3.3 Who is applying?

We can only issue permits to named individuals, not to a partnership name. We therefore need details of each person in the partnership.

Continue on separate sheets if necessary.

Person

Full Name

ID Card/Passport No.

Principal place of business

Street Address		
Locality		Post Code

Contact Numbers

Phone Number

Fax Number

Email address

Person

Full Name

ID Card/Passport No.

Principal place of business

Street Address		
Locality		Post Code

Contact Numbers

Phone Number
Fax Number
Email address

Person

Full Name

ID Card/Passport No.

Principal place of business

Street Address		
Locality		Post Code

Contact Numbers

Phone Number
Fax Number
Email address

A3.4 Please give us the following details about the partnership.

Name of partnership (if there is one)

Principal place of business

Street Address		
Locality		Post Code

Contact Numbers

Phone Number
Fax Number
Email address

Now go to question A4, What to do next.

Companies or other corporate applicants

A3.5 Please gives us the following details.

Full name of company or corporate body.

Sterling Chemical Malta Ltd

Trading/business name (if different)

Registered office address

Street Address	HF 51 Hal Far Industrial Estate	
Locality	Birżebbuġa	Post Code BBG3000

Company registration number

C32508

Date of formation of company

9th February 2006

• For applications from companies, please provide a copy of the certificate of incorporation or registration and any certificates of subsequent name changes.

Document reference number

Appendix 3

• For applications from other corporate bodies, please provide evidence of status.

Document reference number

A3.6 Is the operator a subsidiary of a holding company?

No ☐

Yes ☑ **name of ultimate holding company**

S.N.I.F.F. ITALIA S.P.A.

Registered office address

Street Address	Via della Carboneria 30/32	
	Corciano (PG)	
Locality	Italy	Post Code 06073

Principal office address (if different)

Street Address		
Locality		Post Code

Company registration number

PG 112595

A4 What to do next

Now you need to fill in the other Parts of this form available online.

If you are applying for

- ❑ • A new permit – fill in IPPC Form Part B;
- ☑ • A variation – fill in IPPC Form Part C;
- ❑ • A transfer – submit a letter to the Authority
- ❑ • A surrender – fill in IPPC Form Part E.

FORM C

Form IPPC Part C: Application for a Variation

For ERA use only
Application reference:

Use this part of the form if you are applying to vary the conditions or any other provision contained in your permit.
Please read carefully Appendix I attached with this application.

C1 About the installation

Please fill in the installation table below with details of all the activities and operators at the whole installation, even if you are applying for a permit in respect of only part of the installation.

In **Column 1: Activities in "the stationary technical unit"**, please describe all activities listed in Annex I to the Industrial Emissions Directive that are proposed to be carried out.

For **Directly associated activities**, please identify any directly associated activities proposed to be carried out on the same site which:

- have a technical connection with the activities in the stationary technical unit; and
- could have an effect on pollution.

These could include, for example, boilers, generators, water purification systems, scrubbers and other air purification systems.

In **Column 2: Schedule 1 references**, write the category the installation falls under in Schedule 1 of the Industrial Emissions (IPPC) Regulations (LN 10/13), e.g. 1.1, 5.3(b)(i).

In **Column 3: Operator**, write the name of the operator for each activity (if you are the operator yourself, write "Applicant").

In **Column 4: Variations,** indicate how the proposed changes would affect the activities.

C1.1 Installation details

COLUMN 1 Permitted activities in the "stationary technical unit"	COLUMN 2 Schedule 1 references	COLUMN 3 Operator	COLUMN 4 Proposed variations
Synthesis of APIs	4.5	Applicant	Extension of site to include new R&D / pilot plant
Directly associated activities			
Associated activity of utilities: 1. Water purification plant. 2. Operation of 12 reactors 3. Two LPG boilers to produce steam and hot water 4. Operation of a cooling tower 5. Operation of air handling units	-	Applicant	1. Water softener will be added to water purification plant capabilities 2. Addition of pilot plant – 4 reactors 3. No changes 4. No changes 5. Addition of air handling units for pilot plant, addition of new scrubber

Associated activity of storage, treatment and disposal/recycling of waste materials: • Handling, storage, treatment and disposal/recovery of wastes from installation	-	Applicant	No changes to waste types. A small increase in waste quantities is expected as a result of the pilot plant. Most waste types will be handled as per the existing arrangements, however, certain liquid waste will be collected in a new water washing reservoir.

C1.2 Non-technical description

Please provide a non-technical description of the proposed changes.

Document reference number:

Volume 2: Chapter 2

C1 About the installation *continued*

C1.3 The proposed variations

Please provide a summary of the variations which you are applying for.

This should include:

- a description of the change in operation requiring the variation;
- an indication of the variations to the conditions of the permit that you wish to apply for.

Document reference number for the summary:

Volume 2: Chapter 2

C1.4 Site maps and reports

Are you proposing any change in operation that would result in additional land being included within the site of the installation?

Yes ☑ No ☐

If yes, please provide:

C.1.4.1

A site report, describing the condition of the site of that part of the installation in respect of which you are applying for a variation, and, in particular, identifying any substance in, on or under the land which may constitute a pollution risk. A baseline report assessing the state of the groundwater and land may also be required by the Authority.

Document reference number for the report:

Volume 2: Chapter 2; Volume 3: Addendum 2 to Land & Groundwater Risk Assessment

C1.4.2

A suitable map (or maps) showing the location of the site of the installation, and the area for which a variation of the IPPC permit is being applied for. The outline of the site and the area requiring the variation should be clearly marked in colour, and the surroundings of the site should be included in the map.

Document reference number for map(s):

Appendix 1

C1.4.3

Suitable block plans, properly labelled, showing any changes to the location and nature of the various activities being proposed on that site.

Document reference number for plans:

Volume 3: Addendum 2 to land & groundwater risk assessment

All maps and plans submitted shall be to scale, using a scale rule. Soft copies of plans should be submitted in .pdf format only.

C2 Your proposed techniques

C2.1 Environmental Management System

Provide details of any changes to environmental management techniques resulting from your proposals.

Document reference number:

Volume 2: Chapter 3

C2.2 Proposed activities

C2.2.1 Describe any proposed changes to the installation activities.

Document reference number:

Volume 2: Chapter 3

C2.2.2 Describe the proposed techniques and measures to prevent and reduce waste and emissions of substances and heat (including during periods of start-up or shut-down, momentary stoppage, leak or malfunction) as a result of your proposals.

Document reference number:

Volume 2: Chapter 3

C2.2.3 Submit a flow diagram summarising the proposed installation activities and indicating the changes.

Document reference number:

Volume 2: Chapter 3

C2.2.4 Include a comparison of the proposed changes to the activities with relevant BAT conclusions published by the European Commission, where these have been published.[1]

Document reference number:

Volume 2: Chapter 3

C2.2.5 Include an outline of the main alternatives considered to the proposed changes to the technology, techniques and measures.

Document reference number:

Volume 2: Chapter 3

[1] Available from http://eippcb.jrc.es/reference/ and/or http://ec.europa.eu/environment/air/pollutants/stationary/ied/implementation.htm

C2 Your proposed techniques *continued*

C2.3 Raw materials
Identify any changes to the raw and auxiliary materials, and any other substances (including fuels) proposed to be used as a result of your proposals.

If any changes are proposed, give details of quantities proposed to be used annually and submit respective MSDS sheets.

In addition, identify the storage location of these materials on a site layout plan and give details on:

- Maximum storage capacity;
- Containment measures (including bunding capacity, where applicable);
- Protective measures (including security).

Document reference number:

Volume 2: Chapter 3

C2.4 Ozone depleting substances and fluorinated greenhouse gases
Identify any changes to the equipment using ozone depleting substances and fluorinated greenhouse gases, with a fluid charge of 3 kg or more.

For each such equipment, identify the type of equipment (hermetically-sealed systems, fixed systems or mobile systems), its use (firefighting, refrigeration/air-conditioning or high-voltage switchgear), charge (in kg) and the type of substance (e.g. R22, R407c, R134a).

Document reference number:

Volume 2: Chapter 3

C2.5 Maintenance
Describe any changes to the maintenance programme for the installation.

Document reference number:

Volume 2: Chapter 3

C2.6 Energy
C2.6.1: Describe any changes to the annual energy consumption, highlighting the main energy-consuming equipment, and generation by source and end-use (including information on energy generated on site, if applicable).

C2.6.2: Describe any changes to the proposed basic measures for improvement of energy efficiency.

Document reference number:

Volume 2: Chapter 3

C2.7 Water
Provide a breakdown of any changes to the proposed annual water consumption by source and end-use.

Document reference number:

Volume 2: Chapter 3

C2.8 Risk assessment
Describe any changes to the documented system used to identify, assess and minimise the environmental risks and hazards of accidents and their consequences.

Include any changes to emergency plans in case of fire, actions to be taken in case of failure of abatement equipment and other environmentally relevant incidents (e.g. spillages, gas leakage).

Document reference number:

Volume 2: Chapter 3

C2.9 Training
Please indicate whether any changes to the staff training programme will be required. Please submit the name of the technically competent person on site who will be responsible for such training.

Document reference number:

Volume 2: Chapter 3

C2.10 Cessation
Describe any changes to the outline decommissioning plan describing the draft proposed measures upon definitive cessation of activities, to avoid any pollution risk and return the site of the installation to a satisfactory state (including relevant measures for the design and construction of the installation).

This plan shall include a draft waste management strategy, and a qualitative assessment of the potential for contamination of land and groundwater pollution which might arise from the historical and current processes carried out at the installation.

C2 Your proposed techniques *continued*

Document reference number:

Volume 2: Chapter 3

C2.11 Multi-operator installations

Where you are not the only operator of the installation, describe any change to the techniques and measures (including those to be undertaken jointly by yourself and other operators) for ensuring satisfactory operation of the whole installation resulting from your proposals.

Document reference number:

Not applicable.

C3 Your proposed emissions

C3.1 Waste[2]

C3.1.1: Characterise (using the European Waste Catalogue code, in accordance with LN 184 of 2011 as amended[3]) and quantify any changes to each waste stream from the installation.

Document reference number:

Volume 2: Chapter 4

C3.1.2: Describe any changes to the proposed measures for waste management, storage and handling. If any are identified, also indicate the storage location of wastes on a site layout plan and give details on:

- Maximum storage capacity;
- Containment measures (including bunding capacity, where applicable);
- Protective measures (including security).

Document reference number:

Volume 2: Chapter 4

C3.1.3: Describe how each waste stream identified in C3.1.1 is prepared for re use, recycled, recovered or disposed of. If you propose any disposal, explain why recovery is technically and economically impossible and describe the measures planned to avoid or reduce any impact on the environment.

[2] For installations carrying out waste management activities (activities listed in "Section 5: Waste management" of Annex I of the Industrial Emissions Directive), please use this section to document both incoming and outgoing waste.
[3] http://www.mepa.org.mt/file.aspx?f=6289.

C3 Your proposed emissions *continued*

For these wastes, give details on authorised disposal/recovery facilities proposed to be used for each waste. If any on-site recovery of waste is proposed, provide details.

For each of these wastes, give details on off-site transportation, including registered waste carriers/brokers to be used.

Document reference number:

Volume 2: Chapter 4

C3.2 Emissions to Groundwater

Could there be changes to groundwater discharges from the installation?
Yes ☐ No ☑

If yes, explain how the requirements of the Protection of Groundwater against Pollution and Deterioration Regulations (LN 108 of 2009) have been addressed, and submit a map showing the proposed location of such emissions.

Document reference number:

C3.3 Emissions to Sewer

C3.3.1: Is a new sewer connection envisaged as a result of your proposal?
Yes ☑ No ☐

If yes, please submit a block plan of the site, showing the proposed layout of sewer connections and any other drains (colour-coded), as well as the proposed discharge point(s).

Document reference number:

Volume 2: Chapter 4

C3.3.2: If a new sewer connection is envisaged, does the installation have a Sewer Discharge Permit?
Yes ☑ No ☐

Please submit a copy of the permit, or of the submitted application if the permit has not yet been issued.

Document reference number:

Volume 2: Chapter 4, Appendix 2

C3.3.3: Could the proposal involve the release of any Schedule A or Schedule B substance into the sewers, or changes to releases?
Yes ☐ No ☑

If yes, explain how the requirements of LN 139 of 2002 have been addressed.

Document reference number:

C3.3.4: Are new or changes to cesspit/s being proposed?
Yes ☑ No ☐

If yes, please provide certification by an independent, warranted engineer showing that each cesspit is in line with the requirements of Schedule 1 Activity 43 of LN 106 of 2007 (as may be amended).

Document reference number:

Volume 2: Chapter 4, Appendix 2

C3.4 Emissions to the Sea
Identify if the proposal may result in changes to direct discharges to coastal (up to 1 nautical mile from the coast line) or territorial waters.
Yes ☐ No ☑

If any changes are identified, explain how the requirements of the Discharge of Dangerous Substances Regulations (LN 213 of 2001) and the Water Policy Framework Regulations (LN 194 of 2004 as amended by LN 24 of 2011) have been addressed.

Include details of the source, any treatment proposed prior to discharge, composition and maximum volumes (in m^3/day) discharged.

Document reference number:

In addition, please submit a block plan of the site, showing the proposed discharge point to the sea. Indicate the geo-referenced coordinates for discharge to sea.

Document reference number:

C3.5 Rainwater
Describe any changes to how rainwater is handled on site. If any changes are proposed, attach a site drainage map indicating rainwater capture and harvesting/discharge.

Document reference number:

Volume 2: Chapter 4

C3.6 Emissions to Air
Identify if there may be any changes in emissions of substances to air.
Yes ☑ No ☐

If any are identified, submit details of each emission point, the nature and the proposed quantities of substances emitted from each point and treatment/abatement measures. A block plan of the site showing each emission point should be submitted.

For each new boiler/generator, submit the following details: rated thermal input, energy output, date of manufacture, stack height, fuel type and annual fuel consumption.

Document reference number:

Volume 2: Chapter 4

C3.7 Odour emissions
Identify if there may be changes in emissions of odour.
Yes ☐ No ☑

If any are identified, submit details of the main sources of odour, and the proposed techniques and measures for control of odour.

Document reference number:

C3.8 Emissions to Land
Identify if there may be any changes in emissions of substances to land.
Yes ☐ No ☑

If any are identified, submit details of the nature and the proposed quantities of substances emitted to land, as well as a map showing the proposed location of such emissions.

Document reference number:

C3 Your proposed emissions *continued*

C3.9 Noise
Describe:
C3.9.1: The main sources of noise and vibration (including infrequent sources) of the new proposal;
C3.9.2: The proposed techniques and measures for control of noise;
C3.9.3: The nearest noise sensitive locations and distance away from the site (a site map may be submitted for this purpose); and
C3.9.4: Relevant environmental noise measurement surveys which have been undertaken (monitoring shall be according to the latest revisions of ISO1996 and the rating of industrial noise affecting residential areas shall be according to BS 4142; monitoring shall be carried out exclusively using type 1 sound level meter).

Document reference number:

Volume 2: Chapter 4

C3.10 Monitoring
Describe the proposed measures for monitoring emissions arising from the proposal, including any environmental monitoring. The following must be specified:
C3.10.1: The location of each proposed monitoring point (plotted on a suitably-labelled block plan of the site);
C3.10.2: The substances (in each environmental medium) which are proposed to be monitored;
C3.10.3: The frequency with which monitoring is proposed to take place;
C3.10.4: The proposed measurement methodology, which should be a standard methodology, such as EN or ISO standard, or equivalent;
C3.10.5: The proposed procedure for evaluation of the results.

Document reference number:

Volume 2: Chapter 4

C3.11 Emissions & waste summary
By means of a mass flow diagram, summarise the emissions and waste described in sections C3.1, C3.2, C3.3, C3.4, C3.6, and C3.8 of this application.

Document reference number:

Volume 2: Chapter 3 (section C2.2)

C4 Impact on the environment

C4.1 Environmental effects
Provide an assessment of the potential significant environmental effects (including transboundary effects) of the foreseeable emissions from the proposal.

Document reference number:

Volume 2: Chapter 5

C4.2 Effects on other sites
Provide an assessment of whether the proposal is likely to have a significant effect on another site in Malta and, if it is, provide an assessment of the implications of the installation for that site.

Document reference number:

Volume 2: Chapter 5

C5 Environmental statements

C5.1 Environmental statement
Has this proposal required an environmental statement (EIS or EPS) under LN 204 of 2001 on the assessment of the effects of certain public and private projects on the environment?

Yes ☑ No ☐

If yes, please supply a copy of the environmental statement submitted and details of any decision made.

Document reference number:

Appendix 4

C6 Statutory consultees

We will use the information in this section to identify who we must consult about your proposals.

C6.1 Local council
In which area is the installation located? If premises are on a boundary please give the names of all the relevant authorities.

Birżebbuġa

C6.2 Other sites
Are there any other sites which may be affected by emissions from the proposal? (Refer also to your answer to C4.2).

Yes ☐ No ☑

If yes, please give the names of the sites:

C6.3 Port Authority
Could the installation involve the release of any substance into a harbour managed by a port authority?

Yes ☐ No ☑

If yes, please name the port authority:

C7 Planning status

C7.1 Planning status
Which of the following applies to the proposed installation activities?

We cannot issue a permit unless one of the following applies. Please tick the applicable answer and submit a copy of the relevant documents.

☑ You have planning permission.

Document reference number:

Appendix 2

☐ You have a certificate of lawful existing use or development.

Document reference number:

☐ Planning permission is not required - please say why and enclose written confirmation from the Planning Directorate at MEPA.

Document reference number:

☐ If you have submitted an application for planning permission which has not yet been determined, please provide a copy of the application.

Document reference number:

C8 Technically competent person

Technically competent person
We need to make sure that whoever holds the permit is a 'technically competent person'. This includes consideration of relevant offences, technical competence and financial provision.

C8.1 Technically competent management
Are any changes to the technically competent management of the activities proposed?
Yes ☑ No ☐

If yes, please give details for each person and provide the written evidence requested.

Responsible person 1:

Full Name: Position: Date of employment: Mobile number:

Document reference number for copies of CV, relevant qualifications and recent police conduct certificate:

Appendix 5

Responsible person 2:

Full Name: Position: Date of employment: Mobile number:

Document reference number for copies of CV, relevant qualifications and recent police conduct certificate:

Responsible person 3:

Full Name: Position: Date of employment: Mobile number:

Document reference number for copies of CV, relevant qualifications and recent police conduct certificate:

C8.2 Management of other installations
Is any of the technically competent management already providing the technically competent management at other IPPC installations or at sites licensed under the Environmental and Development Planning Act 2010?

C8 Technically competent person *cont.*

Yes ☐ No ☑

If yes, please use a separate sheet to give details of these people. For each person we need to know the:
- site/installation name and address;
- licence/permit reference number.

Document reference number for this information:

C9 Expenditure plan

C9.1 Expenditure plan
Please provide a plan of the estimated expenditure for each phase of the following specified activities arising from your proposal.

The plan should include the likely costs of:
- monitoring (emission/discharge and ambient monitoring);
- clearing the installation (including drainage systems) of all wastes;
- remedial action in the event of the failure of pollution control systems.

We recognise that this plan may need to be revised before the issue of the final permit.

Document reference number for expenditure plan:

Appendix 6

C10 What to do next

Please read Appendix I, then prepare and sign a covering letter to attach to your application form.

Appendix I
Data Protection Clause

In terms of the Data Protection Act (Chapter 440 of the Laws of Malta), we will process any personal and/ or sensitive data supplied on/ in this submission or subsequently supplied by yourself, whether orally or in writing, for all or any of the following purposes:

1. The proper processing of your submission;
2. internal management, research and statistics;
3. the protection and promotion of our legitimate interests and the proper conduct of our obligations arising under any law or statutory instrument; and
4. to make public the necessary information as specified in the relevant law and/or instrument.

Relevant data will be disclosed or shared as appropriate with all our employees and with other third parties if pertinent to any of the purposes listed above.

You have the right to require that we provide you with access to your **personal data** as well as the right to rectify, or, in appropriate circumstances, erase/edit any inaccurate, incomplete or immaterial personal data which is being processed. However, you are required to inform us immediately of any alterations relating to your personal data which we are processing.

By sending your submission, you confirm that you are giving your explicit consent, in terms of the Data Protection Act, on behalf of yourself and all the other persons specified in this submission for the Authority to process your respective personal information as outlined above and you confirm that you have brought this Data Protection notice to the attention of these other persons and obtained their respective consents.

We undertake to implement appropriate measures and safeguards for the purpose of protecting the confidentiality, integrity and availability of all personal data processed.

Appendix 1: Site plan

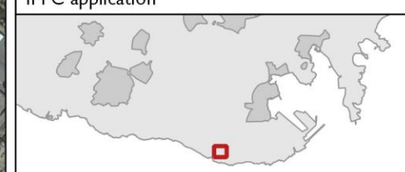
INDICATIVE ONLY - Not to be used for direct interpretation

Location of Scheme site

Legend

- Existing site boundary
- Proposed site extension

IP 0001/14
IPPC application



Map by: en-sure monitoring

Client: Sterling Chemical Malta Ltd	Ref: ES_STG004
File ref: IPPC\Sterling\Maps	Date: 3 / 2019

Appendix 2: Existing permits, and correspondence with WSC

ERA
Environment & Resources Authority

Permit with introductory note

Environment Protection Act (CAP. 549)
Industrial Emissions (Framework) Regulations (S.L. 549.76).
Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L. 549.77).

Sterling Chemical Malta Ltd.
HF 50 & HF 51,
Hal Far Industrial Estate,
Birzebbuga
BBG 3000

Permit number
IP 0001/14/B

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Introductory note

The following Permit is issued under Regulation 7 of the Industrial Emissions (Framework) Regulations, S.L.549.76 to operate an installation carrying 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.

> **"Installations carrying out an industrial scale the production by chemical or biological processing of pharmaceutical products including intermediates".**

Aspects of the operation of the installation which are not specifically regulated by conditions in the Permit may also be subject to the condition implied by Regulation 8 of the Industrial Emissions (IPPC) Regulations, which require the Operator to use the best available techniques for preventing or, where that is not practicable, reducing emissions from the installation.

Conditions marked with a "∞" shall be construed as conditions which are to be enforced by the Authority responsible for such an issue.

Techniques include both the technology used and the way in which the installation is designed, built, maintained, managed, operated and decommissioned.

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 BAT is.

A non-technical description of the installation is given in the original application dated 28 May 2014 and supported by the application for renewal and variation dated 11 October 2017, but the main activity of the installation is as follows:

- **Production of basic pharmaceutical products (Active Pharmaceutical Ingredients – APIs).**

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

Other IPPC Permits relating to this installation		
Operator	**Permit Number**	**Date of Issue**
Not applicable		

Superseded Licences/Authorisations/Consents relating to this installation		
Holder	**Reference Number**	**Date of Issue**
Sterling Chemical (Malta) Ltd.	*IP0001/14/A*	13 August 2015

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. Although certain information may be withheld from the public where it is commercially confidential or contrary to national security, this clause has not been applied to this application and the relevant documentation and permit.

Variations to the Permit

This Permit may be varied 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.

Surrender of the Permit

Before this Permit can be wholly or partially surrendered, an Application to surrender the Permit has to be made to the Competent Authority by the Operator. For the application to be successful, the Operator must be able to demonstrate to the Competent Authority that there is no pollution and public health risk and that no further steps are required to return the site to a satisfactory state. The Permit Holder shall retain all responsibility for management and activities within the site until the Authority officially approves the permit surrender in writing.

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 IPPC permit. The transfer of the permit will not relieve any of the operators from their environmental obligations and liabilities.

Status Log

Detail	Date	Comment
Application IP 0001/04	*Received* 28 May 2014	Not 'Duly Made'
Request for further information and Response	*Request dated* 17 February 2015	*Response dated* 18 March 2015
Internal Consultation and Consultation with statutory consultees.	*Commenced on 17 February 2015*	*Concluded on 19 March 2015*
Request for further information and Response	*Request dated 15 April 2015*	*Response dated 28 May 2015*
Request for further information and Response	*Application regarded as* 'Duly Made' on 6th June 2015 and 12 June 2015. Request for consolidated version for commencement of public consultation	*Consolidated application submitted on 18 June 2015*
Public consultation	*Commenced on* 19 June 2015	*Concluded on* 19 July 2015
Permit determined	30 July 2015	
Permit issued	13 August 2015	Permit expires 13 August 2019
Application IP 0001/04/B	11 October 2017	

Regulatory consultation	6 April till 4 May 2018	
Application considered duly made	2 October 2018	
Public consultation	Commenced on 5 October 2018	Concluded on 19 October 2018
Permit Determined	23 November 2018	
Permit Issued	5 April 2019	Permit expires: 13 August 2019

End of Introductory Note

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Permit

Permit number
IP 0001/14/B

[Approved Documents:

IP0001/14/B/DOC1]

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:

Sterling Chemical (Malta) Ltd. (hereinafter "the Operator")
Of / Whose Registered Office (or principal place of business) is at:

HF 50 & HF 51, Hal Far Industrial Estate, Birzebbuga, BBG 3000
(Company registration number: **C3250B/6**)

to operate an installation at:

HF 50 & HF 51, Hal Far Industrial Estate, Birzebbuga, BBG 3000

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

This permit is valid until 13 August 2019. An application for renewal of this permit is to be submitted at least six months prior to expiry of this permit.

Environment and Resources Authority **APPROVAL** Board No. 68 Held on 23/11/2018 Chairman Secretary	Date Issued: 5.4.2019

Conditions

1.1 General

These permit conditions shall be read in conjunction with the original IPPC Application received on 18th June 2015, and the application for variation received on 1st October 2018, as subsequently clarified and recorded in the status log above, and the post-decision requirements issued on 23 November 2018 which forms an integral part of these permit 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
Section 4.5: Production by chemical of biological processing of pharmaceutical products including intermediates.	Synthesis of active pharmaceutical ingredients (APIs).	From receipt of raw materials and associated chemicals to dispatch of finished product (including packaging and storage). Includes manufacture of high potency cytotoxic/cytostatic drugs. Does not include the preparation of any radioactive APIs
Associated activity of utilities	Water purification plant.	From receipt of water to delivery of utility. This does not include the discharge of any foul water generated from the high potency line into the sewerage network.
	Operation of 12 reactors	As described in the consolidated IPPC application submitted on 2 October 2018
	Operation of two LPG boilers to produce steam and hot water.	From receipt of fuel to delivery of utility.
	Operation of a cooling tower	From intake of water, to treatment and final discharge.

	Operation of air handling units	From the intake of outside air to filtration prior to extraction from the facility
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. Includes separation of solvent mixture from industrial process for recovery and re-use where possible, storage of rejected products.

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 3A to this Permit.

1.2.2 A site notice shall be clearly identified by a site identification board, which shall be replaced as soon as it is damaged or the information is no longer readable from a distance. The site identification board should be located at the site entrance and should contain the following information:

i. The company name and address
ii. 24 hour emergency mobile number

1.2.3 Site security systems shall be implemented at all times during the subsistence of this Permit, the objective of which shall be to prevent access which is not authorised either by the Permit Holder or under legal powers of entry. These shall be installed, operated and maintained, and shall be fully documented and recorded.

1.3 Overarching Management Condition

1.3.1 Following completion and approval of the Environment Management System (EMS), the operator shall endeavour to implement and maintain the EMS and allocate resources that are sufficient to achieve compliance with the limits and conditions of this Permit.

1.3.2 The Operator shall submit (including as part of the EMS) the following reports annually as part of the Annual Environmental Report of the site, according to the timeframe specified in Condition 4.2:

i. Environmental Policy containing the installation's environmental objectives and targets;
ii. Environmental Management Programme report (for the reporting year);
iii. Environmental Management Programme proposal (for the following year);

1.3.3 The Permitted Installation shall, subject to the conditions of this Permit, be managed, controlled and operated as described in the application and subsequent responses to requests for information submitted as per the Status Log above, or as otherwise previously agreed in writing by the Authority.

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
5	Notification once microniser is commissioned.	Within one week from commissioning.
6	Notification of the installation of the LPG storage and submission of certification from an independent fire safety consultant that all firefighting measures are in place.	A) Notification of installation: within one week of installation B) Certification: Within 1 month of installation
	Notification of the decommissioning of the LPG storage in use as described in the original application	Within one week from removal from site.
7	Notification of the construction and certification of the integrity and impermeability of the sump in the temporary waste area.	A) Notification Within 5 days of completion of works B) Certification within one month of installation
8	Implementation of the mitigation measures identified in the Pollution pathway identification and mitigation measures tables included as part of land and groundwater risk assessment report (report version 2 dated August 2018). And inclusion of such in the procedures established as part of the Environmental Management System [EMS]. A) Safety detectors for the cold rooms will be in place.	A) By 30 April 2019
9	Registration with ERA as a producer of packaging as required by the Packaging and Packaging Waste Regulations (S.L. 549.43.)	Within two weeks of issue of the permit
10	Submission of a noise monitoring plan in line with Schedule 5 shall be carried out once the microniser is commissioned.	By 31 December 2019
	Implementation of a noise monitoring exercise and submission of the report.	Within 3 months of approval of the method statement by ERA
11	Submission of an updated BAT Organic Fine Chemicals assessment [BREF document for the Manufacture of Organic Fine Chemicals, August 2006].	By 31 August 2019
2	Obtaining ISO 14001 accreditation and implementation of the corresponding Environmental Management System.	By 31 December 2019

12	Submission of the monitoring proposal for a one-time air emission monitoring exercise from the fume hood exhaust vents (EM4, EM 10 & EM11)	By 31 December 2019
13	Update of the emergency plan to reflect the updated permitted activities.	By 31 December 2019
14	Identification of waste gas pollutants and implementation of a waste gas stream inventory in line with the requirements of BAT 2 and BAT 16 of the CID 2016/902 [Establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU for common waste water and waste gas treatment /management systems in the chemical sector.	By 31 December 2019
	Submission of a monitoring proposal to reflect established best available techniques.	30 June of 2020
	Submission of a monitoring to reflect established best available techniques.	As agreed with the Authority

* Requirement 2 refer to a requirement which featured in IP0001/04/A, requirements 5 onwards are new additions.

1.5 Operational Changes

1.5.1 The Operator shall seek the Authority's written agreement prior to any operational changes as defined by S.L 549.77 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 public health from the Permitted Installation; any relevant supporting assessments and drawings; and the proposed implementation date. Operational changes shall include but not be limited to:

a) Installation of new reactors, centrifuges, driers and other equipment;
b) Inclusion of new production lines or process areas

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 Protection 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 emission limit values;
f) changes to fees;
g) renewal of the validity of this permit.

1.6 Approval procedure for new production processes

1.6.1 Prior to the production of any new Active Pharmaceutical Ingredient other than those approved by the Authority, the Operator shall notify the Authority 1 month prior to the start of production and submit the following documentation:

i. Safety Data Sheets for the raw materials, intermediates and final product.
ii. An Emission Diagram detailing the production process and associated mitigation measures for the identified emissions.
iii. A mass flow calculation in the case of the use of solvents carrying the hazard statements indicated in conditions 2.2.1.18 and 2.2.1.19.

1.7 Pre-Operational Conditions

1.7.1 There are no pre-operational conditions.

1.8 Off-site Conditions

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

1.9 General Conditions

1.9.1 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, the Occupational Health and Safety Authority, Transport Malta, the Regulator for Energy and Water Services (REWS) and the Environmental Health Directorate.

1.9.2 This permit is granted saving third party rights. The Operator is not excused from obtaining any other permission required by law.

1.9.3 The validity of this permit is until 13 August 2019. The Permit Holder is able to renew the permit upon application with the Authority expressing his/her intention at least six months prior to the expiry of the permit. The permit will be considered renewed once the official renewed permit is issued by the Authority.

1.9.4 The permit is issued against a Bank Guarantee of €23,400 which shall be renewed annually. This guarantee will have to be maintained throughout the validity of the permit. Following renewal and/or variations to this permit, the Authority may require amendments to the Bank Guarantee.

1.9.5 The Bank Guarantee shall remain in place for the duration of validity of this permit and shall only be released upon confirmation of full compliance with the permit conditions by the Authority.

1.9.6 The Authority may take part or all of the bank guarantee if the Permit Holder fails to take the necessary action, or fails to fulfil his legal obligations under the Act or its subsidiary legislation thereof, in cases of non-compliance with these permit conditions, or in cases where environmental integrity is threatened. This bank guarantee is without prejudice to any environmental liabilities incurred by the Permit Holder through failure to adhere with permit conditions or any other works/activity carried out on site. Should the Authority forfeit the Bank Guarantee either in part or in full, the permit holder shall ensure that this is replenished without undue delay, in any case not exceeding 2 months from the date of forfeiture.

1.9.8 In cases where the bank guarantee does not cover the expenses incurred by the Authority to take any remedial action on the Permit Holder's behalf, the Permit Holder is to financially reimburse the Authority of all the expenses incurred within.

1.9.9 A copy of this permit shall be available at all times at the site office, including any variation notices of amendments to it.

1.9.10 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. Training records shall be maintained in line with Condition 2.11.3.

1.9.11 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.

1.9.12 All plant, equipment and technical means used in operating the Permitted Installation shall be maintained in a good operating condition and maintenance records of the above shall be kept by the operator in line with Section 2.3 of this Permit.

1.9.13 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.

1.9.14 All persons have a duty of care to protect the environment. The Operator shall become familiar with his legal obligations and good environmental practice.

1.9.15 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.

1.9.16 Without prejudice to condition 1.9.15, the Authority may take any action deemed necessary including but not limited to the suspension of any activity/operation until investigations are concluded.

1.9.17 The site shall be maintained in a tidy condition, free from litter and waste (whether arising from own activities or external sources.

1.9.18 The site must be well secured at all times.

1.9.19 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.

1.9.20 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 or audits carried out by the Authority may be made at the Permit Holder's financial expense.

1.9.21 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. The Operator shall also provide all the necessary assistance to enable the Authority to take samples if necessary.

1.9.22 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.

1.9.23 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.

1.9.24 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 prejudcide to the emergency plan for the installation and Health and Safety.

1.9.25 The Operator shall undertake all necessary measures and precautions to prevent spillage of raw materials, intermediates, products, waste and any other materials.

2 Operating Conditions

2.1 In-Process Controls

2.1.1 The Permitted Installation shall, subject to the conditions of this Permit, be operated using the techniques and in the manner described in the IPPC application, or as otherwise agreed in writing by the Authority in accordance with conditions 1.5.1 and 1.5.2 of this Permit.

2.2 Emissions

2.2.1 Emissions to Air (excluding Odour, Noise or Vibration) from Specified Points

2.2.1.1 All processes which generate significant levels of airborne contaminants (such as dusts, toxic gases, odorous chemicals) shall have effective local collection and shall discharge (after treatment where necessary) through a stack or vent located and/or designed in such a way as to avoid local environmentally detrimental effects.

2.2.1.2 Emissions to air shall only arise from the emission points specified in Table 2.2.1, as per Schedule 3B.

Table 2.2.1 : Emission points to air

Emission point reference	Source	Location of emission point
EM1	Production area	Scrubber stack
	Weighing Room	
	Finished Goods area (clean room)	
	Microniser	
EM4	Laboratories	Fume Hood Extraction vent
EM5	Boiler	Boiler stack

EM6	Boiler	Boiler stack
EM7	Cooling Tower	Cooling tower stack
EM10	Micronization laboratory	Fume Hood Extraction vent
EM11	Micronization laboratory	Fume Hood Extraction vent
EM12	Cold Rooms	Vent

2.2.1.3 The limits for emissions to air for the parameters and emission points set out in Table 2.2.2 shall not be exceeded.

Table 2.2.2 : Emission limits to air and monitoring

Emission point reference	Parameter	Limit	
EM1	VOC as carbon	20	mgC/Nm^3
EM1	Total Particulate Matter	<1	mg/ Nm^3
EM1	Ammonia	10	mg/m^3
EM1	HCl	7.5	mg/m^3
EM1	HBr	<1	mg/m^3

API Handling

2.2.1.4 There shall be no storage or handling of APIs in dry powder form in the storage areas unless storage is carried out in double polyethylene bags, closed with seals and re-packaged in polyethylene UN approved Drums. These shall only be handled and stored outside of such storage arrangements in the enclosed process rooms having dedicated extraction and room filtration as per condition 2.2.1.5.

2.2.1.5 Emissions to air from all areas where active pharmaceutical ingredients in dry powder form are handled (including weighed, processed, compacted and dried) shall be exhausted through abatement equipment having at least 99.9% efficiency.

2.2.1.6 The operational effectiveness of filters (such as HEPA filters) for the control of particulate emissions of pharmaceutical raw materials intermediates and products shall be monitored by means of a pressure differential recorder or equally effective means. Such recorders shall be visible and audible to operators working on the equipment such that an out of range incident can be easily and immediately identified.

2.2.1.7 When filters are found to have reached the pressure alert limit indicated by filter manufacturer, these shall be immediately replaced as per approved Standard Operating Procedure and where applicable, damaged filters shall be treated as hazardous waste as per S.L.549.63. Records of filter changes should be kept in line with Section 3 of the Permit.

2.2.1.8 Further to condition 2.2.1.6, the operator shall carry out and document HEPA filter integrity monitoring for exhaust filters indicated in Schedule 3C, on a weekly basis in line with the approved Standard Operating Procedure. The results of the monitoring shall be submitted on a quarterly basis to the Authority and the Birzebbuga local council electronically. Such results shall also be submitted as part of the Annual Environmental Report, in the format specified in Schedule 2.

2.2.1.9 HEPA Filter efficiency certification for exhaust filters is to be submitted on an annual basis as part of the Annual Environmental Report, in the format specified in Schedule 2.

Combustion Plants

2.2.1.10 Industrial combustion plants (e.g. boilers, generators, etc.) shall be compliant with the provisions of S.L.549.50, Ambient Air Quality Regulations and S.L.549.122 Limitation of Emissions of Certain Pollutants into the air from Medium Combustion Plant Regulations.

2.2.1.11 Only LPG shall be utilised as a source of fuel for the boilers and other combustion plants on site. The co-incineration of any material or additional fuel including engine or other waste oil is strictly prohibited. Any change in fuel type shall require the notification and approval of the Authority prior to commencement of its utilisation.

2.2.1.12 The operator shall keep the periods of start-up and shut-down of the combustion plant as short as possible.

2.2.1.13 The operator shall submit certification for the boilers (EM5 & EM6) referred to in table 2.2.1, by an independent warranted engineer showing that the boilers are in good working condition every four years. The certifications shall be submitted as part of the Annual Environmental Report (AER).

2.2.1.14 Should the Operator intend to install equipment which could lead to additional emissions to air (e.g. boiler, etc.), a variation of this Permit must be secured prior to installation and operation of this equipment.

Emissions from Scrubber

2.2.1.15 Regarding emissions of VOCs from organic solvents, the installation shall comply with either of the following emission limits:

i A total emission limit value of 15% of the solvent input, or

ii. The emission limit value for waste gases as defined in table 2.2.2 for point source EM1 and a fugitive emission value of 15% of the solvent input.

2.2.1.16 Compliance with the total emission limit value or with the fugitive emission value is to be demonstrated in accordance with the guidance provided in Schedule IV of the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (S.L. 549.79) and as may be subsequently amended, and, the VOC Reporting Template in Schedule 4. The calculations shall take account of all organic solvents used within the installation, including raw materials used in the process and solvent used for cleaning the equipment.

2.2.1.17 Compliance with the waste gas emission limit value in Table 2.2.2 shall be demonstrated through a monitoring exercise carried out in accordance with Regulations 7 and 8 of the industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (S.L. 549.79).

2.2.1.18 Discharges-of VOCs which are assigned or need to carry the hazard statements H340, H350, H350i, H360D or H360F (or the risk phrases R45, R46, R49, R60, or R61), where the mass flow of the sum of the compounds causing the risk labelling (H340, H350, H350i, H360D or H360F) is greater or equal to 10 g/hour, an emission limit value of 2 mg/Nm^3 shall be complied with. The emission limit value refers to the mass sum of the individual compounds causing the risk labelling and these limits relate to dry gas and volume flows without dilution. Where the Operator has not used such substances during a particular year, he shall notify the Authority as part

of the Annual Environmental Report, and such monitoring shall not be required during that year.

2.2.1.19 Without prejudice to the emission limit for total VOC as carbon specified in Table 2.2.2, discharges from the scrubber of halogenated VOCs which are assigned or need to carry the hazard statements H341 or H351 (or the risk phrases R40 or R68), and where the mass flow of the sum of the compounds causing the labelling is greater than or equal to 100 g/hour, shall comply with an emission limit value of 20 mg/Nm^3. The emission limit value refers to the mass sum of the individual compounds and these limits relate to dry gas and volume flows without dilution. Where the operator has not used such substances during a particular year, he shall notify the Authority as part of the Annual Environmental Report, and such monitoring shall not be required during that year.

2.2.1.20 The Operator shall monitor the parameters listed in Table 2.2.2 and in Conditions 2.2.1.15 – 2.2.1.16 annually provided that the limits detected are within the emission limit values specified in Table 2.2.2 and Conditions 2.2.1.15 – 2.2.1.16. Otherwise, monitoring shall be carried out at six-monthly intervals. Monitoring from the scrubber shall be carried out during production, while monitoring from the boiler shall be carried out during its operation. Measurements for the parameters shall be carried out according to Regulations 7 and 8 of the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (549.79).

Monitoring Provisions and Emergency considerations

2.2.1.21 Sampling and analysis of polluting substances and measurements of process parameters shall be based on methods enabling reliable, representative and comparable results. Methods complying with harmonised EN standards shall be presumed to satisfy this requirement.

2.2.1.22 The operator shall keep a record of and process all monitoring results in such a way as to enable the verification of compliance with the emission limit values set out in Tables 2.2.2.

2.2.1.23 In the event of, malfunction or breakdown leading to abnormal emissions, the Operator must:

i Investigate immediately and undertake corrective action to ensure compliance is restored without undue delay.

ii Adjust the process or activity to minimise those emissions.

iii Record the events and actions taken.

iv In the event of non-compliance causing immediate danger to human health, operation of the activity must be suspended and the Competent Authority informed within 24 hours.

2.2.1.24 Further to condition 2.2.1.23, the operator shall, at the written request of ERA and within 10 working days, identify the specific cause of the of the abnormal emission and examine means for its elimination or minimisation including:

i Relocating / redesigning the stack(s) or vent(s) to a point where nuisance is minimised

ii Replacement of fuel

iii Preventative measures such as replacement of process materials (e.g. odorous solvents) by substances which are less detrimental to the environment

iv Improved storage of materials

2.2.1.25 All abatement equipment and ducting shall be cleaned and maintained on a regular basis (as per manufacturer specifications and approved SOPs) in line with Section 2.3 of the Permit.

Fugitive emissions of substances to air

2.2.1.26 The Operator shall use BAT so as to prevent or were not practicable to reduce fugitive emissions of substances to air from the Permitted Installation, in particular from the:

- process areas
- storage areas, including solvent storage, raw materials storage and waste storage
- buildings
- pipes, valves and other transfer systems
- open surfaces

provided always that the techniques used by the Operator shall be no less effective than those described in the Application, where relevant and approved by the Authority prior to their implementation.

2.2.2 Cooling Tower Registration ∞

2.2.2.1 Any new cooling tower on site shall be registered with the Environmental Health Directorate, within a timeframe agreed with the Environmental Health Directorate.

2.2.2.2 The installation shall comply with the conditions set by the Environmental Health Directorate and with the provisions of the Control of Legionella Regulations, (S.L.465.03).

2.2.2.3 The Permit Holder and Operator shall abide to the following Minimum Disinfection and water monitoring conditions for cooling towers.

a) Water of the cooling tower should be continuously treated with one or more biocides to effectively control the growth of micro-organisms including Legionella and with chemical or other agents to minimise scale formation, corrosion and fouling.

b) A chlorine-compatible bio-dispersant is added to the recirculating water of the cooling tower system and, that the system is then disinfected, cleaned and re-disinfected;

i immediately prior to initial start-up following commissioning, or any shut down period of greater than one month;

ii at intervals not exceeding 6 months;

c) At least every 6 months a sample of the recirculating water of the cooling tower system shall be tested for *Legionella* and at least every month for heterotrophic colony count, at a laboratory accredited for such tests (or other laboratory providing the equivalent performance and reliability). The results of such tests shall be submitted as part of the Annual Environmental Report of the installation in the format specified therein (Table S2.4.3).

2.2.3 Discharges to surface water

2.2.3.1 There shall be no discharges to surface water.

2.2.4 Discharges to the sewer ∞

2.2.4.1 The Operator shall ensure the Sewer Discharge Permit from the Water Services Corporation (WSC) is obtained and updated every year and shall supply all the information requested by the WSC and take all the necessary actions as instructed by the WSC and/or the Authority. The operator shall forward to the Authority a copy of any Sewer Discharge Permit issued by the Water Services Corporation within 10 days of its issue. No emissions of trade effluent to sewer shall be discharged from this premises unless the entity asks for and obtains a modification of the existing Public Sewer Discharge Permit from the Water Services Corporation.

2.2.4.2 The Operator shall follow the conditions of the Sewer Discharge Permit, as may be updated from time to time by the Water Services Corporation and the provisions of the Sewer Discharge Control Regulations (S.L.545.08).

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

2.2.4.4 Rainwater shall not be discharged into the sewer. Foul sewer drains must be strictly segregated from storm water drains.

2.2.4.5 Emissions shall only arise from the emission point specified in Table 2.2.3, as described in the IPPC application and shall only constitute emissions from sanitary facilities.

2.2.4.6 Emissions of trade effluent to sewer shall only arise from the emission point specified in Table 2.2.3, and Schedule 3B:

Table 2.2.3: Emission point to sewer

Emission point reference	Source	Location of emission point
EM9	Sewer discharge connection	Sewer discharge point

2.2.4.7 The operator shall monitor emissions to the sewer as may be directed by the Water Services Corporation from time to time. The Operator shall inform the Authority of any changes to the Sewer Discharge Permit of the installation or changes made by the Water Services Corporation to monitoring requirements or frequency of monitoring.

2.2.4.8 All process and storage areas must be appropriately contained. Any accidental release of substances shall be duly reported to the Waster Services Corporation and effluents treated/contained 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.

2.2.5 Discharges to groundwater∞

2.2.5.1 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 (S.L.549.63).

2.2.5.2 Further to conditions 2.2.5.1 the operator shall not allow any discharges to groundwater.

2.2.5.3 The operations of 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.

2.2.6 Fugitive emissions of substances to water and sewer

2.2.6.1 The operations of the installation shall not hinder the achievement of good chemical and quantitative status of surface waters as prescribed under the Water Policy Framework Regulations, S.L.549.100.

2.2.6.2 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

2.2.6.3 Catchment pits and bunds on site must be tested and certified to be leak-proof by an independent, warranted civil engineer or engineer before any renewal of this IPPC permit. Such certification shall be also submitted as part of the AER by end of March after the end of each year when testing has occurred.

2.2.6.4 All rainwater runoff from the temporary waste management area shall be diverted to the sump which is fitted with a lockable valve. This valve shall remain locked in the closed position at all times other than when clean rainwater is discharged and shall be carried out under supervision. In the case of spillages, the collected material shall be discarded as hazardous waste.

2.2.7 Emission to Land

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

2.2.7.2 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.

2.2.8 Odour

2.2.8.1 The Operator shall use BAT so as to prevent or where that is not practicable to reduce odorous emissions from the Permitted Installation, in particular by:

- limiting the use of odorous materials;
- restricting odorous activities;
- controlling the storage conditions of odorous materials;
- controlling processing parameters to minimise the generation of odour;
- optimising the performance of abatement systems;
- timely monitoring, inspection and maintenance;
- employing, where appropriate, an approved odour management plan

provided always that the techniques used by the Operator shall be no less effective than those described in the Application, and where relevant approved by the Authority prior to their implementation.

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

2.2.8.3 In case of complaints regarding odours which upon investigations are verified, the Authority may require the Operator to submit an odour management plan, which would include recommendations for abatement of the odour and timeframes for implementation.

2.2.9 Noise

2.2.9.1 The Operator shall use BAT so as to prevent or where that is not practicable to reduce emissions of noise and vibration from the Permitted Installation, in particular by:

i Equipment maintenance, e.g. circulating pumps, extraction fans, compressors.

Ii Use and maintenance of appropriate attenuation, ex. silencers, barriers, enclosures

iii Appropriate timing and location of noisy activities and vehicle movements

iv Periodic checking of noise emissions, either qualitatively or quantitatively; and

v Maintenance of building fabric

Provided always that the techniques used by the Operator shall be no less effective than those described in the Application, where relevant and approved by the Authority prior to their implementation.

2.2.9.2 Emergency generators/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.

2.2.9.3 The level of noise emitted from the installation at all operational times shall not exceed the background noise level by 5dB.

Noise Monitoring

2.2.9.4 Noise monitoring is to be carried out every 5 years to ensure that the above limits are not exceeded. Noise monitoring shall also be carried out upon commissioning of any new equipment which in the opinion of the Authority has the potential to significantly increase noise emissions from the installation. The locations shall be chosen and the measurements and assessment made according to BS 4142:2014.

2.2.9.5 Without prejudice to the requirements stipulated in Table 1.4.1, the next noise monitoring exercise shall be carried out by not later than 31 December 2020 or as agreed with the Authority.

2.2.9.6 Following the execution of the noise monitoring exercise outlined in condition 2.2.9.5, the operator shall implement any suggested corrective actions which may arise from the results of such a report within a timeframe agreed upon with the Authority.

2.2.9.7 As part of the AER, records of noise monitoring of the previous year shall be submitted to the Competent Authority by not later than end of March after the end of

each reporting year, in the format specified in Schedule 2 of this permit. A detailed report shall also accompany such results.

2.3 Maintenance

2.3.1 All plant and equipment used in operating the Permitted Installation shall be maintained in good operating condition.

2.3.2 The Operator shall maintain a record of plant and equipment covered by condition 2.3.1, and for such plant and equipment:

i. a written or electronic maintenance programme; and
ii. records of its maintenance.

2.3.3 The Permit Holder shall maintain appropriate access to standby and/or spares of HEPA Filters to ensure the operation of the abatement system.

2.4 Solvents

2.4.1 A monthly inventory of solvent usage shall be maintained on site.

2.4.2 This permit does not authorise the use of substances and preparations which because of their content of volatile organic compounds, are classified as carcinogens, mutagens, or toxic to reproduction, and are assigned or need to carry the hazard statements H340, H341, H350, H350i, H351, H360D or H360F (or the risk phrases R40, R45, R46, R49, R60, R61 or R68) other than those included in the submitted IPPC Application.

2.4.3 The Operator shall submit to the Competent Authority, a plan for the replacement, as far as reasonably practicable for the process & relevant installation, of substances or preparations that are used in the installation and which, because of their content of VOCs are classified as carcinogens, mutagens or toxic to reproduction and are assigned or need to carry the hazard statements H340, H350, H350i, H360D or H360F or the risk phrases R45, R46, R49, R60, or R61, shall be replaced by less harmful substances / preparations.. Details of the substances that shall be used as replacements and timeframes for substitution shall be submitted to the Competent Authority for approval prior to substitution. A reduction programme shall be submitted to the Competent Authority on an annual basis together with the submission of the Annual Environmental Report.

2.4.4 The operator shall and examine options to replace substances or preparations listed in condition 2.4.2, a report of which shall be submitted to the Authority annually, together with the AER.

2.4.5 The operator shall, annually as part of the Annual Environmental Reports submit an updated list of the raw materials and generated waste streams being produced.

2.5 Waste

Waste storage and handling

2.5.1 The Operator shall use BAT in the design, maintenance and operation of all facilities for the storage and handling of waste on site such that there are no releases to water or land during normal operation and that emissions to air and risk of accidental release to water or land are minimised.

2.5.2 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).

2.5.3 The Operator shall be committed to reduce waste generation where possible.

2.5.4 Waste produced at the Permitted Installation shall be recycled, reused or recovered unless technically and/or economically unfeasible.

2.5.5 All wastes shall be stored within a designated and controlled storage area(s) prior to ultimate disposal. Wastes to be recycled shall be stored in a designated container or area and shall not be mixed with other wastes.

2.5.6 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.

2.5.7 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 waste, substances or materials.

2.5.8 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.

2.5.9 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.

2.5.10 Packaging and containers which came into contact with hazardous substances shall be regarded as hazardous waste and shall be disposed of in an appropriate manner.

2.5.11 Operator shall register with ERA as a producer of packaging and provide the required information, as well as achieve the targets as set out in S.L.549.43, the Packaging and Packaging Waste Regulations. Documentation as evidence of such should be maintained for a period of 3 years and be made available, upon request by ERA.

2.5.12 On-site disposal of wastes by any means including burning, disposal to drain or surface water, burying or deposition on land is prohibited. This excludes treated waste water discharged into sewer in line with the Sewer Discharge Permit.

2.5.13 No storage of waste, equipment or materials is permitted on property outside the site premises.

2.5.14 All storage of materials or waste shall take place only in locations where thorough clean-up and site reinstatement can be readily undertaken.

2.5.15 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.

2.5.16 No storage of waste destined for recovery is permitted for a period exceeding 3 years.

2.5.17 No storage of waste destined for disposal is permitted for a period exceeding 12 months.

2.5.18 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

2.5.19 In the case of waste that is sent for treatment or recovery to another facility locally or abroad, the audit trail shall cover all waste from the point of generation or collection to the end recovery or disposal facility.

2.5.20 Prior to initiating any waste export procedure, the operator shall check with the Competent Authority in the country of export, to ensure that the correct export code/s according to the relevant Annexes of Regulation No 1013/2006 on shipments of waste are being applied.

2.5.21 Without prejudice to condition 2.5.4, the 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 as implemented through S.L. 549.65;

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.

2.5.22 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.

2.5.23 Transport of hazardous waste within the Maltese Islands shall be accompanied by the necessary waste transfer permits issued by the Authority. Applications for such permits are made through the hazardous waste consignment permit procedure available from the Authority's Offices.

2.5.24 Permit Holder 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. Waste receipts should be made available upon request.

2.5.25 Conditions related to the transport of chemicals and hazardous wastes on land are included in section 2.9.

Records

2.5.26 Disposal and/or recovery certificates shall be kept on record and made available for inspection for a period of at least 5 years from date of their issue.

2.5.27 As part of the AER, the operator shall submit the name of each carrier used in the transport of the substances specified in Conditions 2.5.21 and 2.5.22, in the format specified in Schedule 2, by end of March after the end of each reporting year.

2.5.28 As part of the Annual Environmental Report for the installation, the Operator shall produce a report on the off-site transfers of waste and wastes recycled/ recovered at the Permitted Installation over the previous calendar year, providing the information listed in Schedule 2.

2.5.29 Without prejudice to Condition 2.5.4, disposal of wastes including rejects, expired products, and other wastes are to be managed in accordance with the legal obligations of the Waste Regulations (S.L. 549.63). Off-site disposal or recovery of wastes may only take place at a facility licensed for that purpose.

2.6 Energy Efficiency

2.6.1 As part of the Annual Environmental Report, the Operator shall produce a report on the energy consumed at the Permitted Installation over the previous calendar year, by the end of March of each year, providing the information listed in Schedule 2.

2.6.2 The Operator shall maintain and operate the Permitted Installation so as to secure energy efficiency, in particular by:

i. ensuring that the appropriate operating and maintenance systems are in place;
ii. ensuring that all the plant is adequately insulated to minimise energy loss or gain;
iii. ensuring that the type of lighting used is energy-efficient;
iv. ensuring that all appropriate containment methods (e.g. seals) are employed and maintained to minimise energy loss;
v. maintaining and implementing an energy efficiency plan which identifies energy-saving techniques that are applicable to the activities and their associated environmental benefit, and prioritises them.

2.7 Monitoring

2.7.1 The Operator shall maintain and implement an emissions monitoring programme which ensures that emissions are monitored as specified in this Permit, and the results of such monitoring shall be assessed. The programme shall ensure that monitoring is carried out under an appropriate range of operating conditions, and that measurements for the determination of concentrations of substances specified in this Permit shall be carried out representatively.

2.7.2 Sampling and analysis of all pollutants, as well as reference measurement methods to calibrate automated, continuous measurement systems shall be carried out as specified by the appropriate CEN standards. If CEN standards are not available, ISO standards, national or international standards, which will ensure the provision of data of an equivalent scientific quality, as agreed in writing with the Authority, shall apply. In addition, VOC emissions shall be measured and assessed according to Regulation 8(2) of the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations.

2.7.3 Monitoring equipment, techniques, personnel and organisations employed for the monitoring requirements in condition 2.7.1 of this Permit shall be from a certified or accredited laboratory or laboratory in the process of accreditation, as confirmed by the National Accreditation Body (NAB-Malta). As part of the Annual Environmental Report, the operator shall provide evidence of certification or accreditation of laboratories used.

2.7.4 The Operator shall maintain records of all monitoring taken or carried out (this includes records of the taking and analysis of samples, instrument measurements (periodic and continual), calibrations, examinations, tests and surveys) and any assessment or evaluation made on the basis of such data, for at least a period of 5 years. Such records may be requested at any time by the Authority.

2.7.5 The Operator shall provide ERA with monitoring reports as indicated in Section 4 of this permit.

2.8 Storage

2.8.1 All bulk fuel and chemical storage tanks, shall be provided with an adequately designed bund system with an impermeable base and walls. The capacity of the bund shall be a minimum of 110% of the largest tank within the bund or 25% of the total capacity of all the tanks within the bund. All filling and off-take points shall be located within the bund.

2.8.2 Containers for bulk storage of chemicals shall be properly designed, located, labelled, bunded and maintained so as to prevent accidental spillage. Incompatible chemicals shall not be stored within the same bund.

2.8.3 The construction of fuel tanks shall comply with relevant REWS standards.

2.8.4 Drums and containers of solvents, oils or any other chemicals 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.

2.8.5 Chemicals of different properties shall be stored and handled as specified in respective SDS sheets. Such sheets shall be made available and accessible to personnel responsible for the management of the storage areas and for inspection by the Competent Authority.

2.8.6 Bulk storage tanks for chemicals and associated bunding and pipe work shall be visually inspected at least once a month. Such records should be kept and made available to the Authority upon request.

2.8.7 Drainage systems (including catchment pits, bunds) shall be designed, constructed, inspected, validated and maintained; and shall be fully documented and recorded to be fit for purpose while meeting the following construction quality assurance standards. All areas are to:

i. Be fully impermeable;
ii. Be kept free from cracks which could increase permeability;
iii. Be leak-proof and resistant to physical and chemical stresses to which they may be subjected;
iv. Be laid to fall towards the drainage system to prevent pond formation.

Such systems shall be certified by an independent, warranted civil engineer or engineer as being leak-proof and resistant to physical and chemical stresses to which they may be subjected. Such testing and certification shall be carried out in the year prior to any renewal of this IPPC permit. The certification shall be submitted as part of the AER in the format specified in Schedule 2. This is without prejudice to the Authority requesting such testing and certification should there be reason to believe that the interceptor may not be in good working order.

2.9 Transport ∞

2.9.1 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.

2.10 Ozone Depleting Substances and Fluorinated Greenhouse Gases∞

2.10.1 All installation, maintenance and servicing of equipment containing Fluorinated Greenhouse Gases shall abide by the requirements of Regulation (EU) No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No. 842/06, Commission Regulation (EC) Nos 1516/07, 304/08, 306/08 and S.L.427.94, Fluorinated Greenhouse Gases (implementing) Regulations.

2.10.2 The use of HCFCs in the maintenance and servicing, in particular refilling, or products and equipment whose function relies on such substances shall be prohibited.

2.10.3 Maintenance and servicing of equipment containing ozone depleting substances and fluorinated greenhouse gases shall be carried out in accordance with the legal provisions of Regulation (EU) No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No. 842/2006 and its implementing acts and Regulation (EC) No. 1005/2009 on substances that deplete the Ozone Layer. All maintenance and servicing shall be reported in the AER as per template in Schedule 2.

2.10.4 For all equipment installed on site utilising Ozone Depleting Substances or Fluorinated Greenhouse Gases, information pertaining to installation, maintenance and servicing shall be provided as prescribed in Schedule 2. When any equipment is replaced by new equipment, The Authority shall be notified in this regard and details provided on the new equipment installed.

2.10.5 Upon decommissioning of all equipment containing foam and insulation panels containing substances falling within the scope of EC Regulation No. 1005/09 on substances that deplete the Ozone Layer & S.L. 549.58 on substances that deplete the ozone Layer, together with Regulation (EU) No. 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No.842/2006, or containing foam and insulation panels utilising such substances the waste gas should be treated as hazardous waste and any foam containing components need to be disposed of at specialised facilities where possible ODS/F gas can be extracted prior to disposal.

2.10.6 No new equipment or components containing substances falling within the scope of EC Regulation No. 1005/2009 on Substances that Deplete the Ozone Layer & S.L. 549.58 on Substances that Deplete the Ozone Layer, shall be installed within the site.

2.10.7 Where required, leak detection systems as per the legal provisions of Regulation (EU) No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No. 842/2006 shall be installed and well maintained.

∞ Applicable to Fluorinated Greenhouse Gases

2.11 Management and Technically Competent Person

Training

2.11.1 The Permitted Installation shall be supervised and controlled by staff who are suitably trained and fully conversant with the requirements of this Permit.

2.11.2 All staff shall be fully conversant with those aspects of the Permit conditions which are relevant to their duties and shall be provided with adequate professional

technical development and training and written operating instructions to enable them to effectively carry out their duties.

2.11.3 The Operator shall maintain a record of the skills and training requirements for all staff whose tasks in relation to the Permitted Installation may have an impact on the environment and on public health and shall keep records of all relevant training.

Attendance of Technically Competent Person(s)

2.11.4 The Technically Competent Person (TCP) is responsible for the implementation of all the obligations stipulated in this permit, must supervise the rest of the staff on site and shall be the operator's technical focal point for the implementation of the conditions of this permit.

2.11.5 Attendance of the technically competent person(s) at the Site shall be recorded on arrival and departure.

2.11.6 For the whole operational hours permitted for the Site under this Permit, the Technically Competent Person/s or their delegate/s shall be physically in attendance at the Site. The Technically Competent Person/s or their delegate/s has to be permanently present on site during the manufacture of APIs. The permit holder is to provide details as to how he intends to provide this coverage in order to take into account unavoidable absences due to continuous operation, vacation or sick leave.

2.11.7 Where the Site has been notified to the Authority as being either non-operational or closed, the Technically Competent Person shall be capable of attending the Site within one hour.

Changes in Technically Competent Persons

2.11.8 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.

2.11.9 In the event of the death, dismissal, resignation, leave, or of extended sick 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.

Incidents and Complaints

2.11.10 The Operator shall maintain and implement written procedures for:

i Taking prompt remedial action, investigating and reporting to the Competent Authority actual or potential non-compliance with operating procedures or emission limits and if such events occur.

ii Investigating incidents, (including any malfunction, breakdown or failure of plant, equipment or techniques, down time, any short-term and long-term remedial measures and near-misses) and prompt implementation of appropriate actions; and

iii Ensuring that detailed records are made of all such actions and investigations.

2.11.10 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.

2.11.11 As part of the Annual Environmental Report of the Permitted Installation, the Operator shall provide the information specified in Schedule 2 by not later than end of March after the end of each reporting year.

2.12 Accident prevention and control

2.12.1 In the case of an accident, the Operator shall follow the Emergency Plan submitted as part of the IPPC application, as may be updated from time to time

2.12.2 The plan shall be updated whenever necessary and the updated version sent by the Permit Holder to the Civil Protection Department for their perusal/clearance. ∞

2.12.3 The plan shall be reviewed at least every 2 years or as soon as practicable after an accident, whichever is the earlier, and the Authority notified of the results of the review within 2 months of its completion.

2.12.4 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 to the satisfaction of the Occupational Health and Safety Authority. ∞

2.12.5 The Operator shall have sufficient employees trained to deal with any emergency that may arise, e.g. fire-fighting, spills and first aid.

2.12.6 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.

2.12.7 The Operator is to make available Health and Safety documentation freely available.

2.12.8 Spillages of chemicals or other hazardous material shall receive immediate attention to prevent escape to drain, surface water or land. Spilled material shall be disposed of in an appropriate manner. Kits for the collection of liquid and powder spills shall be available on site at strategic locations.

2.12.9 In the case of an accident (including fire, chemical spills, etc.), the Operator shall follow the Emergency Response Plan or the standard operating procedures related to spill response (whichever may be applicable) and, in the case that such accident could cause environmental damage, the Operator shall notify the Authority within 24 hours.

2.12.10 Small leaks or spills shall be cleared up immediately by the application of absorbent materials. All sand and other material shall be disposed of as approved by the responsible authority.

2.12.11 The operator shall have in storage an adequate supply of suitable absorbent material to absorb any spillage.

2.12.12 The Operator is to carry out monitoring of the head space of the wash water reservoir for potential fire hazards. The monitoring results shall be submitted as part of the AER in the format specified in Schedule 2.

2.13 Closure and Decommissioning

2.13.1 The Operator shall endeavour to carry out a full review of the *Site Closure Plan* at least every 4 years and shall include all the following information.

2.13.1.1 A draft waste management plan which shall include:

i. The identification and characterisation of sources and types of wastes;
ii. Criteria for segregation of wastes;
iii. Proposed treatment, conditioning, transport, storage and disposal/ recovery methods;
iv. Potential reuse/recycling of such wastes
v. Details on decommissioning and disposal of equipment

2.13.1.2 A list of materials which will not be disposed of but transferred to third parties for re-use including any unprocessed raw materials and finished products.

2.13.1.3 A qualitative assessment of the potential for contamination of land and groundwater pollution which might arise from the historical and current processes carried out at the installation.

2.13.2 The Operator shall maintain and operate the Permitted Installation so as to prevent or minimise any pollution and public health risk, including the generation of waste, on closure and decommissioning in particular by: -

i. Attention to the design of new plant or equipment;

ii. The maintenance of a record of any events which have, or might have, impacted on the condition of the site along with any further investigation or remediation work carried out; and

iii. The maintenance of the preliminary site closure plan to demonstrate that the installation can be decommissioned avoiding any pollution and public health risk and returning the site of operation to a satisfactory state.

2.13.3 The Operator shall notify the Authority immediately upon a decision being taken to decommission all or part of the site, or planned cessation for a period greater than 6 months, of all or part of the permitted activities. The Authority may impose further requirements in the case of planned cessation for a period greater than 6 months.

2.13.4 In the event of cessation of operations on the site, all wastes, equipment and hazardous materials (including fuels and chemicals) must be removed from the site such that any pollution risk is avoided and the site is returned to a satisfactory state. The Operator shall notify the Authority immediately upon a decision being taken to cease business activity. In the case of full decommissioning, applicant shall submit a decommissioning plan in accordance with the terms of reference provided by the Authority for approval by the relevant Authorities. The obligations arising from the permit shall subsist until the Authority confirms in writing that the implementation of the decommissioning plan has been implemented to its satisfaction.

2.13.5 A finalised version of the *Site Closure Plan* shall be submitted to the Authority for approval not later than 10 days after the Authority is notified of the intention to decommission the site.

2.13.6 The approved Decommissioning Plan shall be implemented within 12 months of final cessation of the Permitted activities or part thereof or according to a timeframe as may be agreed with the Authority.

2.13.7 When deemed necessary, the authority may require the permit holder to take such additional measures as it considers necessary with respect to after care obligations in relation, but not limited to the remedial action, rehabilitation, and monitoring of the site.

3 Records

3.1 The Operator shall ensure that all records required to be made by this Permit and any other records made by it in relation to the operation of the Permitted Installation shall:-

3.1.1 be made available for inspection by the Authority upon request;

3.1.2 be supplied to the Authority on demand and without charge and in the format requested;

3.1.3 be legible

3.1.4 indicate any amendments which have been made and shall include the original record wherever possible; and

3.1.5 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.

3.2 A daily operations log should be kept on site in which the following information shall be recorded on a daily basis:

3.2.1 Any incidents that took place on site such as mechanical faults in the machinery or equipment used on site, any spills, fires, etc and the remedial action taken.

3.2.2 Any maintenance and inspections carried out on machinery and equipment.

3.2.3 Any defects or damage to the Site Security System.

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.

3.3 The Operator shall maintain a record of the skills and training requirements for all staff whose tasks in relation to the Permitted Installation may have an impact on the environment and shall keep records of all relevant training.

4 Reporting

4.1 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.

4.2 The Operator shall submit to the Authority an Annual Environmental Report (AER) of the previous year to the Competent Authority by the end of March of each year. The AER shall contain all the information listed in Schedule 2 of this Permit. The AER shall be forwarded to the Authority in electronic format.

4.3 The European Pollutant Release and Transfer Register (E-PRTR) report for the installation shall be submitted as part of the Annual Environment Report, by end of March of each year, or as required by Legislation. All quantities shall be reported, even when these do not exceed the thresholds mentioned in EC Regulation 166/2006. The format used for reporting shall be that established by Legislation, notably S.L. 549.47.

4.4 The Operator shall, within 6 months of receipt of written notice from the Authority, submit to the Authority a report assessing whether all appropriate preventive measures continue to be taken against pollution, in particular through the application of the best available techniques, at the installation. The report shall consider any relevant published technical guidance current at the time of the notice which is either supplied with or referred to in the notice, and shall assess the costs and benefits of applying techniques described in that guidance, or otherwise identified by the Operator, that may provide environmental improvement.

5 Notifications

5.1 The Operator shall notify the Authority without delay of:-

5.1.1 the detection of an emission of any substance which exceeds any limit or criterion in this Permit specified in relation to the substance;

5.1.2 the detection of any fugitive emission which has caused, is causing or may cause exceedances of the emission limit values stipulated in the permit;

5.1.3 the detection of any malfunction, breakdown or failure of plant or techniques which has caused, is causing or has the potential to cause exceedances of the emission limit values stipulated in the permit; and

5.1.4 any accident which has caused, is causing or has the potential to cause significant pollution and/or public health risk.

5.2 The Operator shall submit written confirmation to the Authority of any notification under condition 5.1, by sending:

5.2.1 the information listed in Schedule 1 to this Permit within 24 hours of such notification; and

5.2.2 the information listed in Table S2.5.1 of Schedule 2 and such information shall be in accordance with that Schedule as part of the AER.

5.3 The Operator shall give written notification as soon as practicable prior to any of the following:-

5.3.1 permanent cessation of the operation of part or all of the Permitted Installation;

5.3.2 cessation of operation of part or all of the Permitted Installation for a period likely to exceed 1 year; and

5.3.3 resumption of the operation of part or all of the Permitted Installation after a cessation notified under condition 5.3.2

5.4 The Operator shall notify the Authority, as soon as practicable, of any information concerning the state of the site which affects or updates that provided to the Authority as part of the Site Report submitted with the application for this Permit.

5.5 The Operator shall notify the following matters to the Authority in writing within 10 working days of their occurrence: -

5.5.1 Where the Operator is a registered company:-

5.5.1.1 Any change in the Operator's trading name, registered name or registered office address;

5.5.1.2 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

5.5.1.3 Any steps taken with a view to the Operator going into administration, entering into a company voluntary arrangement or being wound up.

5.5.2 Where the Operator is a corporate body other than a registered company: -

5.5.2.1 Any change in the Operator's name or address; and

5.5.2.2 Any steps taken with a view to the dissolution of the Operator.

5.5.3 In any other case: -

5.5.3.1 The death of any of the named Operators (where the Operator consists of more than one named individual);

5.5.3.2 Any change in the Operator's name(s) or address(es);

5.5.3.3 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

6 Interpretation

6.1 In this Permit, the following expressions shall have the following meanings:-

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

"mg.Nm^{-3}" or *"mg/Nm^3"* means milligramme per normal metre cubed.

"Land" means the upper layer of the earth's crust and shall include all the various components of the lithosphere to the rock-water and rock-air boundary, where the topmost 200 cm which is made up of inorganic and organic components and which serves as a habitat for micro- and macroorganisms is defined as soil.

"AER" means the Annual Environmental Report.

"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 the Environment Protection Act 2016 to exercise any of the powers specified therein.

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

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

"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."

"VOC Solvents Regulations" means the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (S.L.549.79, as may be amended from time to time).

VOC" means Volatile Organic Compound as defined by the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (S.L. 549.77)

"Year" or *"reporting year"* means calendar year ending 31 December.

The Regulations" means the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L. 549.77) and any 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.

"BREF" means the latest version of the BAT reference document published by the European Commission.

"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 under conditions 2.2.1 - 2.2.6 of this Permit.

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.

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.

"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" means *"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.

"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 Malta 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 Site" means the land, structures, plant and equipment to which this Permit relates;

6.2 Where a minimum limit is set for pH, reference to exceeding the limit shall mean that the parameter shall not be less than that limit.

6.3 Unless otherwise stated, any references in this Permit to concentrations of substances in emissions into air means:-

6.3.1 in relation to gases from combustion processes, all emission limit values are defined at a temperature of 273.15K, a pressure of 101.3 kPa after correction for the water vapour content of the waste gases and at a standardised O_2 for 6% medium combustion plants using solid fuels, 3% for medium combustion plants, other than engines and gas turbines, using liquid and gaseous fuels and 15% for gas turbines.

6.3.2 in relation to gases from non-combustion sources, the concentration at a temperature of 273K and at a pressure of 101.3 kPa, with no correction for water vapour content.

6.4 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.

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 and 5.2 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 to human health 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[1]	
I.D. Card No./Passport No.	
Post	
Signature	
Date	

[1] Authorised to sign on behalf of Operator

Schedule 2
Annual Environmental Report

Important note
By this submission, you confirm that you give your explicit consent for the entire contents of this Annual Environment Report to be made available on the Authority's public website.

S2.1 Introduction

IPPC Permit Number	
Reporting Year	
Name and location of Site	
Brief description of activities at the site	

S2.2 Environment Management System & Reporting

Please attach a supporting document with the following:

	Tick (✓)
1. Environmental Policy containing the installation's environmental objectives and targets;	
2. Environmental Management Programme report (for the reporting year);	
3. Environmental Management Programme proposal (for the following year);	
4. European Pollutant Release and Transfer Register Report (as per Condition 4.3)[i].	

S2.3 Process Data

S2.3.1 Annual Summary

	Units	Previous reporting year[ii]	Current reporting year
Quantity of product	Tonnes		
Total Annual Energy Consumption (from electricity and other sources)	MWh		
Electricity from renewable energy sources	MWh		
Energy consumption per unit product	MWh/tonne of product		
Annual water consumption	m^3		
Water consumption per unit product	m^3/tonne of product		
Annual quantity of waste produced	Tonnes		
Waste produced per unit product	tonne waste/ tonne product		

S2.3.2 Fuel consumption

	Units	Sulphur Content [iii]	Consumption	
			Previous Year	Current Year
LPG	m^3			

[i] The format used for reporting shall be that published in the Government Gazette (http://www.doi.gov.mt/EN/gazetteonline/2007/07/gazts/GG%2013.7.pdf)
[ii] "Previous reporting year" is not applicable for the first reporting year (2015)
[iii] Specify units (e.g. as percentage, or mg/kg)

S2.3.3 List of Raw Materials

Raw Material	Risk phrase	Annual Quantity Used (kg)

S2.3.4 Data on ozone depleting substances and fluorinated greenhouse gases

Table 1: Registration of equipment

Equipment code	Type of equipment	Use	Charge (kg) /CO_2 (eq)	Type of substance
EQ 1				
EQ 2				
EQ 3				

Table 2: Maintenance Schedule[i]

Data Submitted for each scheduled inspection[ii]	Equipment Code							
	EQ 1	EQ 2	EQ 3	EQ 4	EQ 5	EQ 6	EQ 7	Continue as required
Date of inspection								
All amounts of leakages detected (in Kg/CO_2 equiv[iii])								
Actions taken to eliminate such leakages								
Quantity and nature of the substances involved								
Serial number of the personnel involved								
Quantities added[iv] and/or recovered (in Kg/ CO_2 equiv).								

[i] (a) for equipment that contains fluorinated greenhouse gases in quantities of 5 tonnes of CO_2 equivalent or more, but of less than 50 tonnes of CO_2 equivalent: at least every 12 months; or where a leakage detection system is installed, at least every 24 months; (b) for equipment that contains fluorinated greenhouse gases in quantities of 50 tonnes of CO_2 equivalent or more, but of less than 500 tonnes of CO_2 equivalent: at least every six months or, where a leakage detection system is installed, at least every 12 months; (c)for equipment that contains fluorinated greenhouse gases in quantities of 500 tonnes of CO_2 equivalent or more: at least every three months or, where a leakage detection system is installed, at least every six months.

[ii] Table to be repeated for every scheduled inspection as per 'footnote 1' above

[iii] Carbon Dioxide equivalent – use annex 1 for calculation

[iv] The quantities of added fluorinated greenhouse gases are from recycled or reclaimed stocks, please include the name and address of the recycling or reclamation facility and, where applicable, the certificate number

S2.4 Monitoring Data

S2.4.1 Emissions to air

Parameter	Emission point reference	Limit Value	Standard methodology used	Total annual number of exceedances [i]		Concentration (Annual Average)			Total Annual Load		
				Previous year	Present year	Unit	Previous year	Present year	Unit	Previous year	Present year
VOC as Carbon	EM1	20 mgC /Nm^3				mgC/m^3			kg		
VOCs: R45, R46, R49, R60 or R61 (H340, H350, H350i, H360D, or H360F) where mass flow of sum of compounds ≥ 10 g/h[ii]	EM1	2 mg/Nm^3		[iii]		mgC/m^3			kg		
Halogenated VOCs: R40 or R68 (H341 or H351) where mass flow of sum of compounds ≥ 100 g/h[iv]	EM1	20 mgC/Nm3		[v]		mgC/Nm^3			kg		
NH_3	EM1	10mg/m^3				mg/m^3			kg		
HBR	EM1	1 mg/m^3				mg/m^3			kg		
HCl	EM1	7.5 mg/Nm^3				mg/m^3			kg		
Total Particulate Matter	EM1	<1 mg/ m^3				mg/m^3			Kg		

Name of laboratory where tests in this section have been carried out	
Is this laboratory accredited (certified) for the above tests?	Yes ☐ No ☐

[i] If the total number of exceedances exceeds 0, the value of each of these exceedances (for the reporting year) must be submitted in a separate report, together with action taken to regularise the situation. Where only one measurement was required to be made during the year, the total annual number of exceedances is taken to be zero if the measurement indicates compliance with the limit value.

[ii] Where mass flow is <10g/h, appropriate calculations are required to confirm this.

[iii] For those VOCs only, do any of the hourly averages exceed the emission limit value by more than a factor of 1.5? Only such values are considered as exceedances.

[iv] Where mass flow is <100g/h, appropriate calculations are required to confirm this.

Additional documentation to be submitted:

	Tick (✓)
Accreditation certificate(s) of laboratory	
Calculations showing mass flow of VOCs with risk phrases H340, H350, H350i, H360D, or H360F (R45, R46, R49, R60, or R61) where mass flow of sum of compounds < 10 g/h	
Calculations showing mass flow of halogenated VOCs with risk phrases H341 or H351 (R40 or R68) where mass flow of sum of compounds < 100 g/h	

S2.4.2 HEPA Filter Integrity Monitoring[i]

Date of Inspection		Differential Pressure						
		HF1	HF2	HF3	HF4	HF5	HF6	Continued as required
Week 1								
Week 2								
Week 3								
Week 4								
Continued as required								

Additional documentation to be submitted:

Efficiency certification	Tick (✓)
HF1	
HF2	
HF3	
HF4	
HF5	
HF6	

S2.4.3 Cooling tower monitoring

Parameter	Timeframe	Standard methodology used	Result	
			Previous year [i]	Present year
Heterotrophic colony count	1st month			
	2nd month			
	3rd month			
	4th month			
	5th month			
	6th month			
	7th month			
	8th month			
	9th month			
	10th month			
	11th month			
	12th month			
Legionella	1st six months			
	2nd six months			

Name of laboratory where tests in this section have been carried out	
Is this laboratory accredited (certified) for the above tests?	Yes ☐ No ☐

Additional documentation to be submitted:

	Tick (✓)
Accreditation certificate(s) of laboratory	

[i] "Previous year" is not applicable for the first reporting year (2015).

S2.4.4 Noise monitoring[1]

Year when noise monitoring was last carried out	
Testing due in (year)	

Additional documentation to be submitted if test was carried out during previous reporting year:

	Tick (✓)
Noise monitoring report according to BS 4142:2014	

[1] Noise monitoring shall be carried out according to BS 4142:2014, all the series of ISO1996 and any other standard methodology stipulated by the Authority.

S2.4.5 Off-site transfers of waste

Date of transfer	EWC Code[i]	Description of waste	Quantity of waste (in kg)	Treatment applied before transfer	Mode of transport	Names of agent & transporter of waste (GBR Number)	Ultimate destination (address) of waste	Consignment note number [ii]	Name of person responsible for ultimate disposal/recovery	Disposal/ Recovery	Details of Recovery (if applicable)

[i] European Waste Catalogue Code (Reference: Commission Decision 2000/532/EC: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014D0955&from=EN)

[ii] For hazardous waste only. If waste is not hazardous, please write "N/A".

S2.4.6 On-site recycling/recovery of wastes

EWC Code	Description of Waste	Amount Recycled or recovered (in kg)	Recycling or Recovery

S2.4.7 Testing of catchment pits and bunds

	Number on site	Date of last test	Testing due on (date)
Catchment pits			
Bunds			
Others: (specify)			

Additional documentation to be submitted if test was carried out during previous reporting year:

	Tick (✓)
Certification by warranted engineer	

S2.4.8 Testing of the wash water reservoir

Test Date	% Lower Explosive Limit	% O_2

S2.5 Incidents and Complaints

S2.5.1 Non-Compliance Incidents during Reporting Year

Date of incident	Brief description of Incident	Cause	Corrective action

Total number of non-compliance incidents for previous year:[i]	
Total number of non-compliance incidents for current reporting year:	

S2.5.2 Complaints made by the public

Date of Complaint	Description of complaint	Actions taken

Total number of complaints for previous year: [i]	
Total number of complaints for current reporting year:	

[i] "Previous year" data is not required in the first reporting year (2015).

S2.6 Transport

Name of registered waste carrier used during reporting year	Waste type(s) transported

S2.7 Submission of Certifications and Documentation

Please attach any supporting documentation with the following:

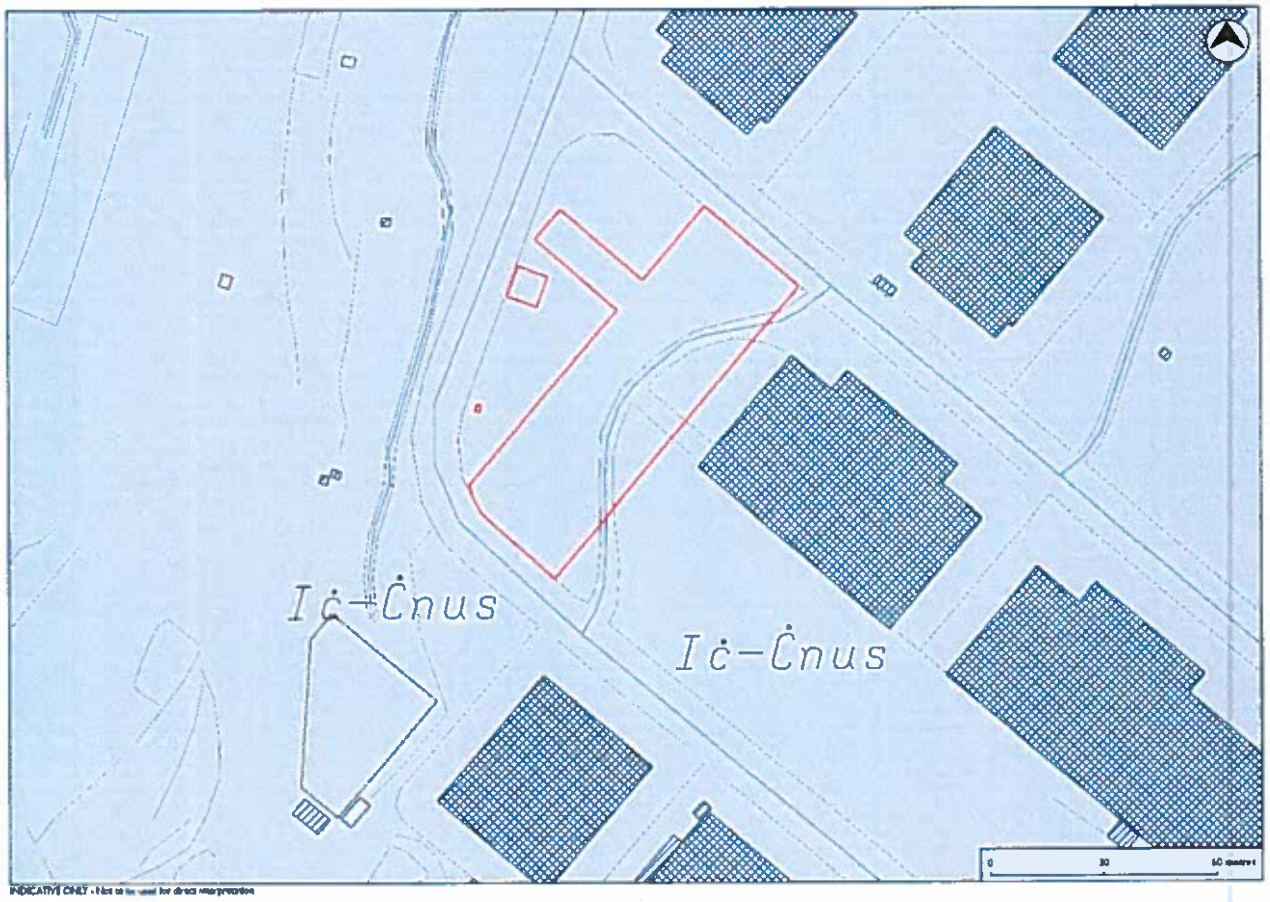
Reference in Permit	
1.4	Improvement Programme Items as per Table 1.4
2.2.1	Certification that the boilers (EM5 & EM6) are in good working condition
2.2.1.8	Further to condition 2.2.1.6, the operator shall carry out and document HEPA filter integrity monitoring for exhaust filters indicated in Schedule 3C, on a weekly basis in line with the approved Standard Operating Procedure. The results of the monitoring shall be submitted on a quarterly basis to the Authority and the Birzebbuga local council electronically. Such results shall also be submitted as part of the Annual Environmental Report, in the format specified in Schedule 2.
2.2.1.9	HEPA Filter efficiency certification for exhaust filters is to be submitted on an annual basis as part of the Annual Environmental Report, in the format specified in Schedule 2.
2.2.1.16	Calculations showing the mass flow of VOCs with the hazard statements H340, H350, H350i, H360D or H360F (or risk phrases R45, R46, R49, R60 or R61), where the mass flow of the sum of the compounds < 10g/h.
2.2.1.17	Calculations showing the mass flow of VOCs with the hazard statements H341 or H351 (or the risk phrases R40 or R68) where the mass flow of the sum of the compounds < 100 g/h.
2.2.9.4 & 2.2.9.5	Without prejudice to the requirements stipulated in Table 1.4.1, the next noise monitoring exercise shall be carried out by not later than 31 December 2020 or as agreed with the Authority.
2.8.7 & 2.2.6.3	Catchment pits and bunds on site must be tested and certified to be leak-proof by an independent, warranted civil engineer or engineer before any renewal of this IPPC permit.
2.4.3	The Operator shall submit to the Competent Authority, within one year of issue of this permit, a plan for the replacement, as far as reasonably practicable for the process & relevant installation, of substances or preparations that are used in the installation and which, because of their content of VOCs are classified as carcinogens, mutagens or toxic to reproduction and are assigned or need to carry the hazard statements H340, H350, H350i, H360D or H360F or the risk phrases R45, R46, R49, R60, or R61, shall be replaced by less harmful substances / preparations.. Details of the substances that shall be used as replacements and timeframes for substitution shall be submitted to the Competent Authority for approval prior to substitution.
2.12.12	The Operator is to carry out monitoring of the head space of the wash water reservoir for potential fire hazards. The monitoring results shall be submitted as part of the AER in the format specified in Schedule 2.

Applicant's declaration

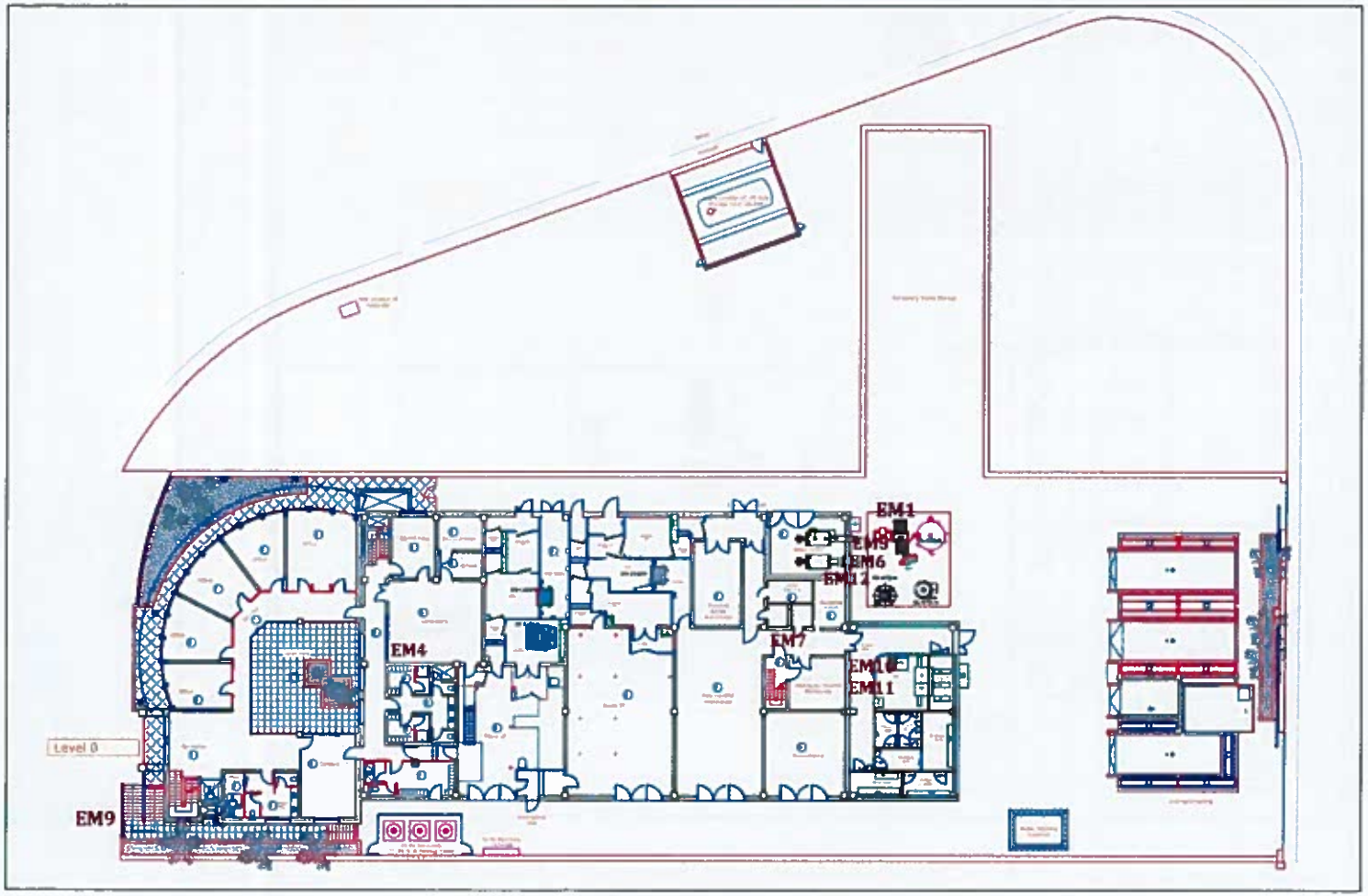
I declare that, to the best of my knowledge, all the above information is correct and substantiated.

.....	.....	.....
Name *(in block letters)*	**ID Card Number**	**on behalf of / in my own name** *(in block letters)*
.....		.....
Signature		**Date**

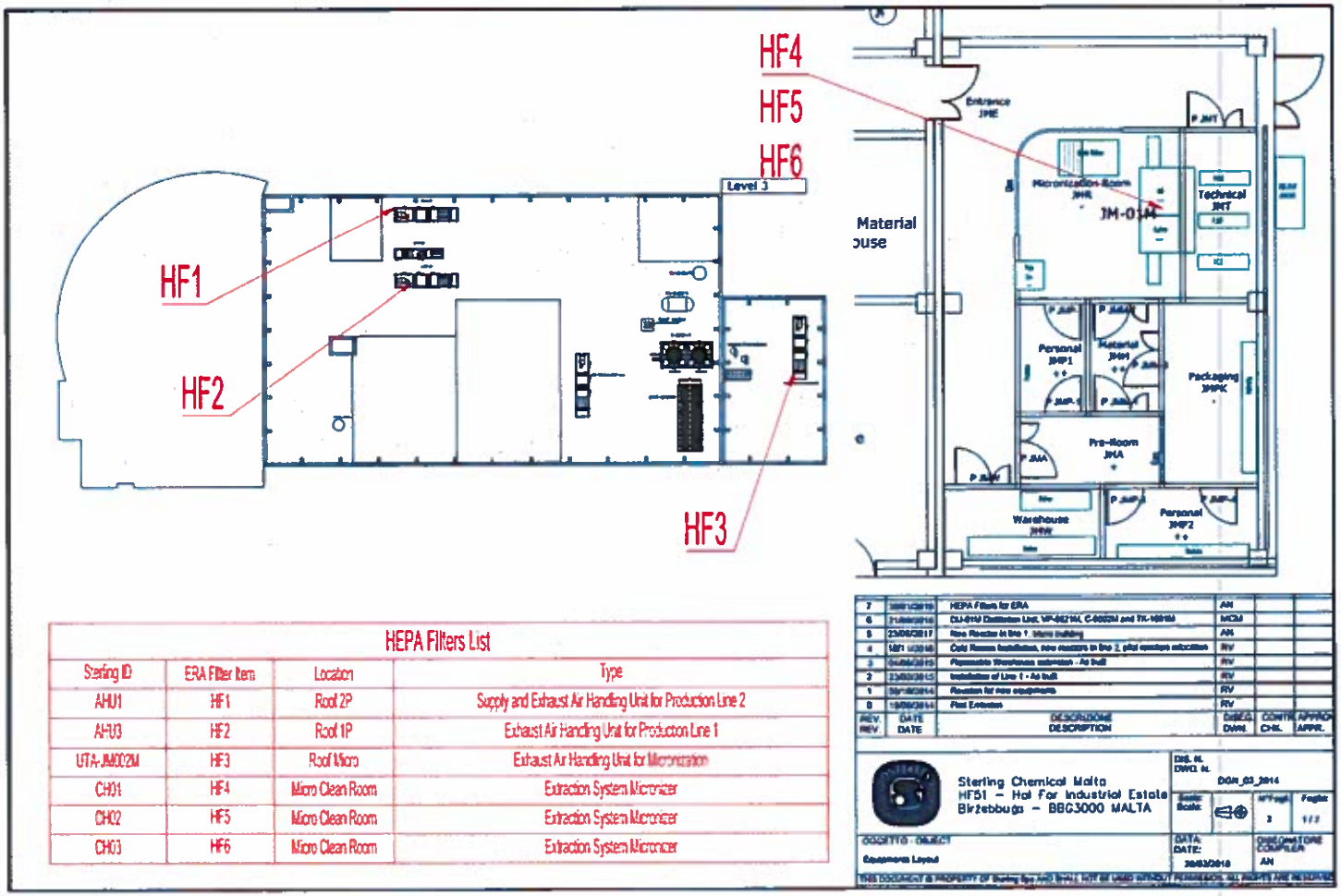
Schedule 3A
Site Plan



Schedule 3B
Effluent and Air Emission Points



Schedule 3C
Location of exhaust HEPA Filters installed on site



HEPA Filters List			
Sterling ID	ERA Filter Item	Location	Type
AHU1	HF1	Roof 2P	Supply and Exhaust Air Handling Unit for Production Line 2
AHU3	HF2	Roof 1P	Exhaust Air Handling Unit for Production Line 1
UTA-JM002M	HF3	Roof Micro	Exhaust Air Handling Unit for Micronization
CH01	HF4	Micro Clean Room	Extraction System Micronizer
CH02	HF5	Micro Clean Room	Extraction System Micronizer
CH03	HF6	Micro Clean Room	Extraction System Micronizer

Schedule 4
VOC Report

Kindly fill in the questionnaire with the information requested below. This information is being requested for the reporting period detailed below, in accordance with the installation's IPPC permit.	
Permit Number	**IP 0001/14/B**
Installation	**Sterling Chemical Malta Ltd.**
Activity	**Manufacturing of Pharmaceutical Products**
Reporting Period	Day Month Year – Day Month Year

Solvents VOC emissions calculation is based on the guidance provided in the Solvent Management Plan in Schedule IV of S.L.549.79)

1	**Solvent Input and Consumption calculation**			
a	New Solvent Input = The quantity of organic solvents or their quantity in mixtures purchased which are used as input into the process in the time frame over which the mass balance is being calculated	**I**		**Kg VOC**
2	**Fugitive Emissions calculation**			
	Fugitive Emissions (F) is determined by subtraction of other measured emissions (i.e. **F = I - O1 - O5 - O6**):			
a	Quantity of organic solvents in Waste gases (annual load) *Information / calculation to be submitted as part of ER – Section 1.5 Table 2.*	**O1**		**Kg VOC**
b	Quantity of organic solvents and/or organic compounds lost due to chemical or physical reactions (including those that are destroyed by incineration or other waste gas or waste water treatments, or captured, as long as they are not counted under O6, O7 or O8).	**O5**		**Kg VOC**
c	Quantity of organic solvents contained in disposed waste *Only solvents in waste that was produced and disposed of during the reporting period should be included as O6.* *VOC content in waste needs to be verified by sampling and analysis in an accredited lab and copy of test result to be submitted together with this report*[1].	**O6**		**Kg VOC**
d	Sum of above Emissions (Total output of organic solvents) *(cells 2a+2b+2c)*	**ΣO = O1+O5+O6**		**Kg VOC**
e	Fugitive Emissions = Input – (Total output of organic solvents) *(cells 1a – 2d)*	**F = I - ΣO**		**Kg VOC**

[1] In case waste load (and type) can be considered to be constant, a one-time sampling and analysis would be sufficient.

f	Fugitive Emissions as a % of Total Solvent Input *(cells 2e / 1a) x 100*	= F / I X 100	_____	%
g	Quantity of waste containing solvents that was present on site at the end of the reporting period pending disposal	/	_____	Kg
If the fugitive emission value in row 2h has exceeded the Emission Limit Value as stipulated in Condition 2.1.1.12 of IP 0001/14/B, you are requested to provide further information on: ▪ Timeframe during which the emission Limit value and/or the fugitive emission value was exceeded; ▪ Reasons identified for non-compliance; ▪ Corrective actions taken; ▪ Emissions performance following the corrective actions This information is to be submitted as a signed and dated document together with this report, referenced in the appropriate field on the right.			**Attached Document** _____ *(Name or Number reference)*	
3	During the reporting period, did the installation make use of substances or preparations which, because of their content of VOCs classified as carcinogens, mutagens or toxic to reproduction, are assigned or need to carry the risk phrases R45, R46, R49, R60, and/or R61 (or the hazard statements H340, H350, H350i, H360D or H360F)? **If YES, please submit the documentation required in accordance with permit condition 2.1.1.15 of IP 0001/14/B.**		**Yes / No**	
4	During the reporting period, did the installation make use of halogenated VOCs which are assigned or need to carry the risk phrases R40 or R68 (or the hazard statements H341 and H351)? **If YES, please submit the documentation required in accordance with permit condition 2.1.1.16 of IP 0001/14/B.**		**Yes / No**	

Applicant's declaration

I declare that, to the best of my knowledge, all the above information is correct and substantiated.

.....	.....	.....
Name *(in block letters)*	**ID Card Number**	**on behalf of / in my own name** *(in block letters)*
.....		.....
Signature		**Date**

Schedule 5
Terms of Reference for Noise Monitoring

1. Introduction

The noise monitoring shall be carried out by the Operator. A consultant that is either an accredited Acoustic expert or qualified professional Engineer and is approved by ERA according to the following criteria shall be commissioned who will propose a monitoring procedure for measuring noise levels within and around the installation as described in section 2 below.

The person(s) undertaking the "on field monitoring" shall be in possession of a certification for the collection of data.

The noise monitoring survey and impact study report shall be compiled and reviewed by a person who is in possession of a:

(a) Bachelors degree in Acoustics, or

(b) Bachelors degree in Physics, Architecture, Civil Engineering or Engineering, Environmental Health, Environmental Science/Management, Occupational Health and Safety, or a related degree to the satisfaction of ERA **and** an MQF Level 7 specialisation degree in Acoustics, **or**

(c) Bachelors degree in Physics, Architecture, Civil Engineering or Engineering, Environmental Health, Environmental Science/Management, Occupational Health and Safety, or a related degree to the satisfaction of ERA **and** in addition the consultant must be at least an associate member of the Institute of Acoustics or equivalent grade of Membership of a professional body for those working in acoustics and noise in any one of the EU member states or any other reputable professional body to the satisfaction of ERA.

Copies of such qualifications and certification shall be submitted to ERA prior to the monitoring proposal.

The consultant, in collaboration with ERA, shall seek advice from the Local Council during the selection of the sensitive receptors.

2. Content of monitoring study

The monitoring study should address the following issues:

1. A description of the installation – this shall include a description of all processes carried out on site and related equipment and infrastructures.

2. A description of the surrounding areas – this shall include identification of the types of activities, whether residential or commercial, roads and other amenities. These shall be location-specific taking into account their location with respect to the site.

3. Identification of the main sources of noise and vibration – this shall include all processes on site, including aspects such as transport noise on site, plant equipment, mechanical operations, etc (amongst others) and their times of operation.

4. Identification of the closest noise sensitive receptors – this shall be carried out after assessing the noise levels in the plant's perimeter and in the other locations identified in point 2 above under normal operating conditions of the plant. The various monitoring points shall be identified with a unique code and an analyses of the ambient noise to which each monitoring point is subjected to.

5. Environmental Noise Survey – this shall include details of the standards used for measurements, equipment used including calibration details and certificates, resultant measurement data, assessment methods and complaints significance scale. The survey is to be carried out according to the latest revisions of ISO1996 and the rating of industrial noise affecting residential areas shall be according to BS4142:2014. The survey should include perimeter noise levels, baseline noise survey of sensitive receptor sites, noise impact on site sensitive receipts including day and night background levels. The data compiled for both day and night is a typical representation of the current situation at all receptor points and the measurement time interval is sufficient enough to obtain representative value of a typical background when the specific noise source will be operating.

6. The monitoring shall be performed exclusively using a calibrated type 1 sound level meter conforming to BS 6698/IEC 61672 Class 1. The use of type 2 sound level meters or less is not considered acceptable and will not be considered. The sound level meter, calibrator and microphone must hold a valid current calibration certificate from an accredited laboratory (ex. UKAS)

7. Prior to the initial data collection and at the end of the monitoring day, all acoustic instrumentation system such as the sound level meters are calibrated, and checked immediately before and after each series of monitoring readings. Results must be within ±1.0dB, otherwise discarded and read again.

Impact assessment of noise events on noise sensitive receptor site – this shall include an assessment according to the guidelines BS 4142:2014, ISO1996 and ISO9613 or any other standard and any other standard methodology stipulated by the Authority. A summary of the data obtained after the survey has been carried out in relation to the noise sensitive receptors identified above shall be submitted.

8. Conclusions and Mitigation measures – this shall include a summary report of findings from the noise monitoring survey including the impact assessment of noise events on noise receptors sites and any remedial action and/or mitigation measures to be implemented by the operator in order to reduce impacts resulting from the site of operation.

9. As a basis for the collection of background data, monitoring shall be carried out during a period when there are no operations at the facility. If this is not possible, operations are to be temporarily suppressed during readings. If this is still not possible, a measurement at an alternative location where the residual sound is comparable to the assessment location(s) with justifications shall be provided.

10. Monitoring shall consider seasonal variations including but not limited to the occurrence of the fireworks and any other similar typical seasonal predominant noise sources. The recommended time periods over a twenty-four hour period are categorized in terms of daytime, from 0700-2300 hrs ($L_{Aeq,[16hrs]}$) and night-time period from 2300 – 0700 hrs ($L_{Aeq[8hrs]}$).

END OF PERMIT

Table 3: Pollution pathway identification and mitigation measures

Source	Pathway	Receptor	Mitigation measures	Notes
Spillage of APIs / hazardous waste from micronisation area	Permeable strata above water table[7]	Land Groundwater	• Concrete flooring overlain by an impermeable vinyl / resin layer (including skirting) • Several rooms and a corridor separate the micronisation plant and the outdoor area	The impermeable vinyl / resin flooring has been installed.
Contaminated solvent / wash water from cleaning of equipment / floors in micronisation area	Permeable strata above water table[7]	Land Groundwater	As above, plus: • Not more than 100 L of cleaning solvents present in the micronisation room at any time • Solvent / used wash water collected for disposal as hazardous waste after use	As above.
Spill of samples / raw materials / intermediates / products in cold rooms	Permeable strata above water table[7]	Land Groundwater	• Concrete flooring overlain by an impermeable vinyl layer; floor slopes inwards • Spill kit	These measures are all in place.
Potentially contaminated wash water from cleaning of cold room floors	Permeable strata above water table[7]	Land Groundwater	As above, plus: • Used wash water is collected using absorbent pads, which are disposed of as hazardous waste	This measure is already in place.
Emissions of APIs to air from the micronisation facility	Air dispersion (prevailing wind direction); Wet precipitation	Land Groundwater	• Emissions are treated using a HEPA filter (H13), followed by carbon filter and scrubber • Full implementation of maintenance programme	These measures are now in place.

[7] A pathway only exists if the mitigation measures fail.

Source	Pathway	Receptor	Mitigation measures	Notes
Emissions of samples / raw materials / intermediates / API products to air from the cold rooms	Air dispersion (prevailing wind direction); Wet precipitation	Land Groundwater	• No exposure of materials to atmosphere under normal conditions • Most substances in powder form, in packages under 10 kg; liquid chemical (triflic anhydride) in up to 40 kg drums • Spill kit	The Scheme will also install safety detectors, which in case of formation of vapours that can cause a fire, will activate the forced expulsion of air from the cold rooms to the external environment.
Spill of hazardous waste from new temporary waste storage area	Permeable strata above water table[7]	Land Groundwater	• Storage of most liquid hazardous waste on prefabricated containment systems • Ground made of concrete overlain by tarmac • Sump to be installed and drain pipe to be fitted with a locked valve; only discharges of clean rainwater will be allowed, and under supervision • Spill kit	The spill kit is already in place, the locked valve will be in place by mid-November 2018, and the sump will be in place by end December 2018. The Operator intends to replace this area with a new external and fully contained built flammable warehouse in 2019; this will be covered in a separate IPPC application.

Source	Pathway	Receptor	Mitigation measures	Notes
Used firefighting water (potentially generated in case of a fire in the new temporary waste management area), contaminated with hazardous waste	Permeable strata above water table[7]	Land Groundwater	*Measures to reduce the probability / severity of a fire in the new* *temporary waste management area:* • Well ventilated area • Regular removal of waste • Existing fire response procedures will apply to the new areas • Portable foam fire extinguishers and water hose reel • 600 m_3 firefighting reservoir always kept full (level meter with alarm) *Measures to prevent uncontrolled discharge of contaminated firefighting water:* • Storage of most liquid hazardous waste on prefabricated containment systems • Ground made of concrete overlain by tarmac • Sump to be installed and drain pipe to be fitted with a locked valve; only discharges of clean rainwater will be allowed, and under supervision	Most of these measures are already in place; the locked valve will be in place by mid-November 2018, and the sump will be in place by end December 2018. The Operator intends to replace this area with a new external and fully contained built flammable warehouse in 2019; this will be covered in a separate IPPC application.

Copy of Original Decision Notice

Mr. Gorg Cilia
obo MIP Ltd
UB8 San Gwann Industrial Estate
San Gwann

Date: 15 Oct 2010
Our Ref: PA/04236/08

Application Number:	PA/04236/08
Application Type:	Full development permission
Date Received:	29 August 2008
Approved Documents:	PA4236/08/1C/55A/55B/55C/55D/55E/55F/29C/29D/29F/29I. Accessibility Audit report PA 4236/08/61A Fire Safety and Ventilation Report PA 4236/08/69
Location:	Factory HF 51, Qasam Industrijali, Hal Far
Proposal:	Factory at Hal Far for Sterling Chemicals Ltd. This excludes the installation of a plant and operation as an API for manufacturing which is subject to a separate permit.

Development Planning Act, 1992
Full Development Permission

The Malta Environment & Planning Authority hereby grants development permission in accordance with the application and plans described above, subject to the following conditions:

1 a) This permit is being issued exclusively for the construction of the factory premises and for the use of the site for research and development and administration only. The manufacturing of commercial quantities of APIs is not allowed, unless a separate development permit and IPPC permit has been obtained from the MEPA.

b) The development permit is strictly without prejudice to any additional requirements (e.g. ancillary infrastructure & modifications to the approved development) as may be required in connection with the operational permit. Depending on the nature of the requirements in question, a new or amended development permit application may also be required.

c) Any modifications to the approved development shall not be exempted from any EIA, IPPC permit or other legal requirement.

d) A list of all chemicals used including quantities kept on premises together with production quantities shall be made available for inspection at any time upon request of MEPA.

e) No discharge point for any type of effluent to land, storm drains or sea is allowed, unless specifically approved under a permit issued by MEPA.

MALTA ENVIRONMENT & PLANNING AUTHORITY
L-AWTORITA' TA' MALTA DWAR L-AMBJENT U L-IPPJANAR

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http://www.mepa.org.mt • email: enquiries@mepa.org.mt

f) Foul sewer drains must be strictly segregated from storm water drains.

g) All discharges to the foul sewer, including process effluents and wash waters (e.g. Contaminated with industrial detergents etc.), shall comply with the requirements of a license issued by the Water Services Corporation. Any grease trap or sedimentation tank or other equipment specified by the WSC shall be adequately sized.

h) All operations concerning the management of waste during the construction phase are subject to the legal provisions of Legal Notice 337 Waste Management (Permit and Control) Regulations of 2001 and Legal Notice 106 Waste Management (Activity Registration) Regulations, 2007. Wastes are to be separated according to the different waste streams as per EWC codes and disposed of in facilities permitted to receive such waste as per provisions of Legal Notice 337 Waste Management (Permit and Control) Regulations of 2001.

i) Inert waste material resulting from excavations or from demolition may be reused as fill material or shall be deposited at facilities permitted by MEPA and in accordance with the legal provisions laid down in LN 337 Waste Management (Permit and Control) Regulations of 2001 and LN 106 Waste Management (Activity Registration) Regulations, 2007.

2 Prior to the issuing of this development permit the applicant shall submit a financial planning contribution of €4,467 which will be used in the EIPP Partnership Programme.

3 The following conditions are imposed by the Department of Environmental Health:

(a) All building and sanitary laws and regulations are complied with;

(b) Toilet rooms and anterooms are to be naturally or mechanically ventilated;

(c) Rainwater from reservoir may be used for the flushing of WCs but is not be used for personal hygiene;

(d) Floors are to be of an impervious material, and easy to clean and precautions are to be taken in the event of spillages of chemicals;

(e) Chemicals are to be kept segregated and in a bonded area;

(f) Water washing reservoirs are to be of an impervious material and of adequate size.;

(g) Any generated noxious fumes, gases, dusts, powders etc are to be controlled by means of an adequate ventilation system and are not to be discharged into the atmosphere.

(h) All necessary measures are to be taken to prevent the causing of nuisance to neighboring properties (factories) and their personnel by means of fumes, gases, dust, steam odour, noise and vibrations both during the construction phase and afterwards.

(i) If cooling towers are constructed, applicant is to abide by Legal Notice 5 of 2006 –

Control of Legionella Regulations and LN6 of 2006 - Registration of Cooling Towers and Evaporative Condensers.

The applicant shall consult Department of Environmental Health during the construction phase of the development hereby approved, to ensure that the development is carried out in conformity with the conditions imposed by the Department of Environmental Health.

4 The following conditions are imposed by the Malta Resources Authority:

a) There should be no direct or indirect discharges of effluents into the environment or groundwater in particular. These effluents will include all substances which have a deleterious effect on the physical and chemical composition of groundwater, and compounds liable to cause the formation of such substances in groundwater such as to render it unfit for human consumption; and

b) All necessary permits relating to discharge to the government sewers should be obtained from the Water Services Corporation.

c) The MRA reserves the right to inspect the premises as and when required; and take any action in case of any infringement of these conditions.

The applicant shall consult Malta Resources Authority during the construction phase of the development hereby approved, to ensure that the development is carried out in conformity with the conditions imposed by the Malta Resources Authority.

5 Landscaping of the site shall be implemented in its entirety within the first planting season following completion of the development hereby approved, in accordance with the details submitted with the application unless the prior approval in writing of the Malta Environment & Planning Authority has been obtained to depart from these details. No compliance certificate (partial or full) shall be issued on part, or the whole, of the development hereby approved prior to the implementation of the landscaping scheme in its entirety.

6 The development shall be constructed in conformity with the provisions set out in the accessibility audit report (approved document PA4236/08/61A).

7 There shall be no service pipes, cables or wires visible on the front elevation or on any other elevations of the building which are visible from the street.

8 Air conditioning units shall not be located on the facades of the building which are visible from a public space. Any such units located at roof level shall be set back from the facade by at least 1 metre.

9 a) This development permission is valid for a period of FIVE YEARS from the date of this notice but will cease to be valid if the development is not completed by the end of this five year period.

b) It should be noted that a third party may have the right of appeal against this

permission. Any development which is carried out when such an appeal has been made, or until the time limit for the submission of such an appeal has expired, is undertaken at the risk that this permission may be revoked by the Planning Appeals Board or quashed by the Court of Appeal.

c) This development permission does not remove or replace the need to obtain the consent of the land/building owner to this development before it is carried out. Furthermore, it does not imply that consent will necessarily be forthcoming nor does it bind the land/building owner to agree to this development. Where the land/building is owned or administered by the Government of Malta a specific clearance and agreement must be obtained for this development from the Land and/or Estate Management Departments.

d) All works shall be carried out strictly in accordance with the approved plans and the conditions of this permission. Where a matter is not specified on the plans then the conditions of this permission and of Development Control Policy and Design Guidance shall take precedence and modify the plans accordingly.

e) All building works shall be erected in accordance with the official alignment and proposed/existing finished road levels as set out on site by the Malta Environment & Planning Authority's Land Surveyor. The Setting Out Request Notice must be returned to the Land Survey Unit of the Malta Environment & Planning Authority when the setting out of the alignment and levels is required.

f) Before any part of the development hereby permitted commences, the enclosed green copy of the Development Permit shall be displayed on the site. This must be mounted on a notice board, suitably protected from the weather and located not more than 2 metres above ground level at a point on the site boundary where it is clearly visible and can be easily read from the street. The copy of the permit must be maintained in a good condition and it shall remain displayed on the site until the works are complete.

g) The enclosed Commencement Notice shall be returned to the Malta Environment & Planning Authority so that it is received at least five days prior to the commencement of the development hereby permitted.

h) Copies of all approved plans and elevations shall be available for inspection on site by Malta Environment & Planning Authority staff at all reasonable times.

i) Where the street bordering the site is unopened, it shall be opened up prior to the commencement of the building operations hereby permitted.

j) The Enforcement Unit of the Malta Environment & Planning Authority shall be notified prior to the commencement of the following stages of the development : construction of the foundations; roofing over the last basement level; roofing over the first level above ground level.

k) The height of the building shall not exceed the height as indicated on the approved drawings PA4236/08/55E

l) A water cistern with a volume in cubic metres of 60% of the total roof area (in square metres) of the building(s) shall be constructed to store rainwater run-off from the built-up area of the development. This cistern shall be completed and available for use prior to the development hereby permitted being first brought into use.

m) The development hereby permitted shall not be brought into use until the Final Compliance (Completion) Certificate, certifying that the development has been carried out in full accordance with the plans approved by this permission and with the other conditions imposed in this permission, has been issued by the Malta Environment & Planning Authority.

n) Apertures and balconies shall not be constructed of gold, silver or bronze aluminium.

o) The facade of the building shall be constructed in local stone, except where other materials, finishes and colours are indicated on the approved plans and drawings.

p) Where applicable hoarding should be erected in accordance with Schedule 2 of the Environmental Management Construction Site Regulations, LN 295 of 2007

q) The permit is issued on condition that, where applicable, any excavation shall be subject to the requirements of the Civil Code regarding neighbouring tenements.

r) Any soil on the site shall not be built over but shall be collected for reuse. A permit from the Director of Agriculture is required to remove the soil from the site. All soil shall be deposited at the place indicated by the Director of Agriculture; and authorisation by the Environment Protection Directorate shall also be required prior to any deposition on open or undeveloped land unless located within officially approved development zones. Contaminated soils (if any) are to be managed/disposed of in accordance with the legal provisions laid down in Legal Notice 337 Waste Management (Permit and Control), Regulations, 2001 and L.N. 168 Waste Management (Landfill) Regulations, 2002 and its amendments.

s) Where applicable, the development, hereby permitted, shall be carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, LN 295 of 2007.

t) This permission relates only to the additions and alterations specifically indicated on the approved drawings. This permission does not sanction any illegal development that may exist on the site.

Should the site fall within areas designated as HOS and property originating from the Housing Authority, this permit does not exonerate the applicant from obtaining the necessary clearances from the same Authority.

This permit is granted saving third party rights. The applicant is not excused from obtaining any other permission required by law. The applicant should contact the following regarding the location and provision of services prior to commencing development:- Enemalta, Water Services Corporation and Cable Network Operators.

Sylvana De Bono
Board Secretary
MEPA

[PADCNCopy]

PA/04236/08 Print Date: 15/10/2010

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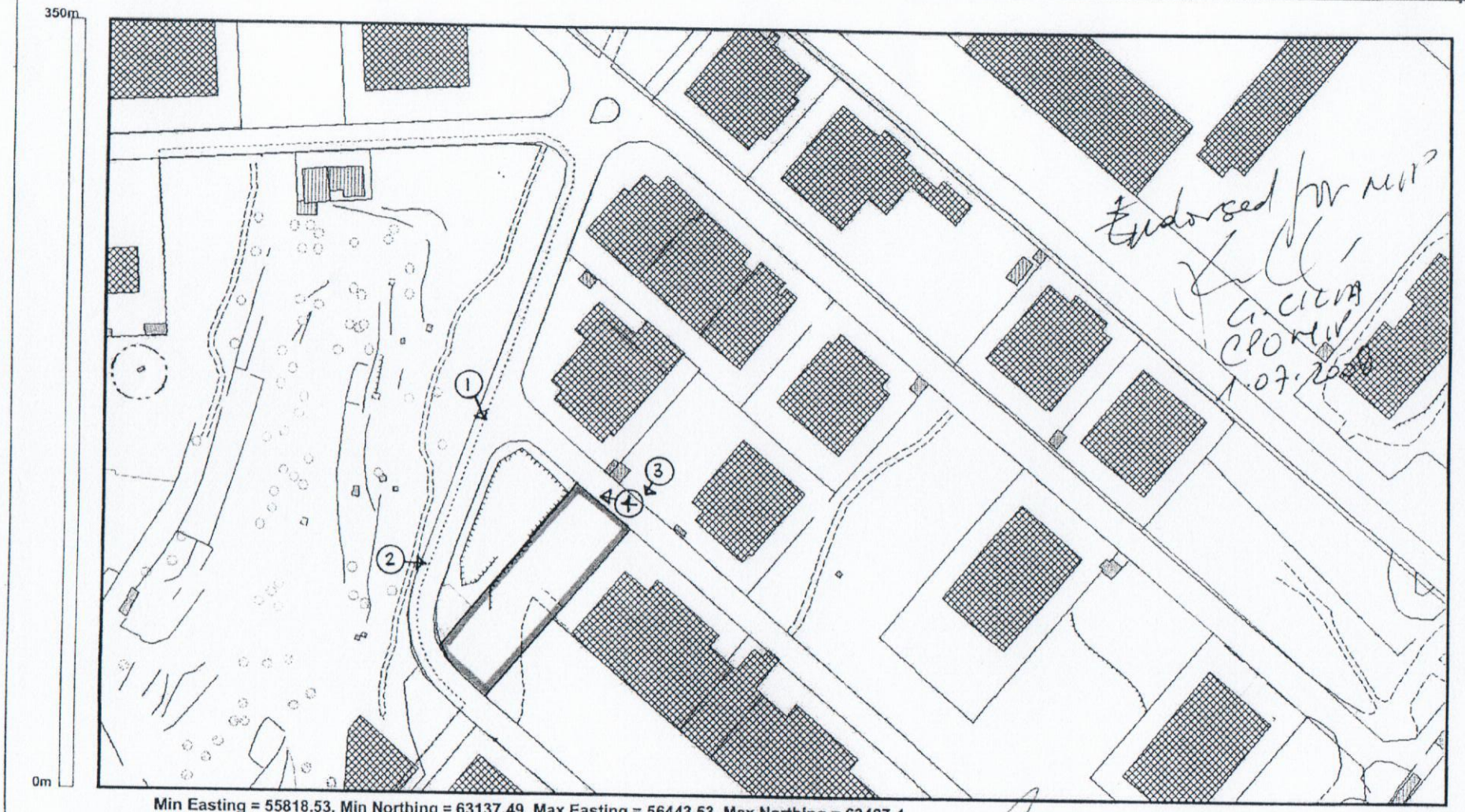

MEPA

www.mepa.org.mt
St. Francis Ravelin
Floriana
PO Box 200, Valletta. Malta
Tel: +356 240976 Fax: +356 224846

Site Plan, Scale 1:2500

Malta Environment & Planning Authority

APPROVAL

Printed on: Saturday, December 06, 2008

Not to be used for interpretation or scaling of scheme alignments

Board No. PA120-09/10 held on 22/4/2010

Chairman _____ Secretary _____

Plan No: PA 4236/08/1c

741865

Copy of Original Decision Notice

Date:26 June 2013
Our Ref: PA/03033/12

Mr. Simone Ferlin
Sterling Chemicals Malta Ltd.
C/O 44
Triq San Frangisk
Sliema SLM 2069

Application Number:	PA/03033/12
Application Type:	Full development permission
Date Received:	17 October 2012
Approved Documents:	Site Plan - PA3033/12/1A Part existing and proposed Plan - PA3033/12/36a Part existing and proposed Elevation - PA3033/12/36b Civil Protection Directorate Conditions - PA3033/12/35
Location:	Factory HF 51, Qasam Industrijali, Hal Far, Birzebbugia, Malta
Proposal:	Installation of LPG bulk storage in a facility/factory already covered by permit PA/04236/08.

Environment and Development Planning Act, 2010
Full Development Permission

The Malta Environment & Planning Authority hereby grants development permission in accordance with the application and documents described above, subject to the following conditions:

1 Environmental Conditions:

a. Removal and re-use of soil, and management of waste generated by site preparation, excavation and construction operations:

(i) Any soil on the site shall not be built over but shall be collected for re-use in accordance with the Fertile Soil (Preservation) Act, 1973. A permit from the Director of Agriculture may be required to this effect.

(ii) The deposition and reuse of any soil removed from the site shall be approved in advance by MEPA's Environment Protection Directorate if it would involve deposition or re-use in any site which is located Outside Development Zones or within a scheduled or otherwise legally protected site.

(iii) Contaminated soils are to be managed and disposed of in accordance with the legal provisions laid down in Legal Notice 184 of 2011 [The Waste Management Regulations of 2011] as amended by Legal Notice 441 of 2011 and L.N. 168 of 2002 [Waste Management (Landfill) Regulations of 2002] and its amendments. (d) Inert waste material resulting from demolition may be reused as fill material within the site (as long as this is in

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line with the approved plans and other conditions of this permit), or shall be deposited at facilities permitted by MEPA and in accordance with the legal provisions laid down in Legal Notice 184 of 2011 [The Waste Management Regulations of 2011] as amended by Legal Notice 441 of 2011 and Legal Notice 106 of 2007 [Waste Management (Activity Registration) Regulations of 2007].

(iv) All operations concerning the management of waste are subject to the legal provisions of Legal Notice 184 of 2011 [The Waste Management Regulations 2011] as amended by Legal Notice 441 of 2011 and Legal Notice 106 of 2007 [Waste Management (Activity Registration) Regulations of 2007].

b. All operations concerning the management of waste are subject to the legal provisions of Legal Notice 184 of 2011 [The Waste Management Regulations of 2011] as amended by Legal Notice 441 of 2011 and Legal Notice 106 of 2007 [Waste Management (Activity Registration) Regulations, 2007].

c. Inert waste material/rock resulting from excavations or from demolition may be reused as fill material on site or shall be deposited at facilities permitted by MEPA and in accordance with the legal provisions laid down in Legal Notice 184 of 2011 [The Waste Management Regulations of 2011] as amended by Legal Notice 441 of 2011 and Legal Notice 106 of 2007 [Waste Management (Activity Registration) Regulations, 2007].

2 a) This development permission is valid for a period of FIVE YEARS from the date of publication of the decision in the press but will cease to be valid if the development is not completed by the end of this validity period.

b) This permission relates only to the development as specifically indicated on the approved drawings. This permission does not sanction any other illegal development that may exist on the site.

c) Copies of all approved drawings and documents shall be available for inspection on site by MEPA staff at all reasonable times. All works shall be carried out strictly in accordance with the approved drawings, documents and conditions of this permission. Where a matter is not specified, then the conditions of this permission and of Development Control Policy and Design Guidance shall take precedence and shall modify the drawings and documents accordingly.

d) Where applicable, all building works shall be erected in accordance with the official alignment and official/existing finished road levels as set out on site by MEPA's Land Surveyor. The Setting Out Request Notice must be submitted to the Land Survey Unit of MEPA when the setting out of the alignment and levels is required.

e) Where an officially schemed street, within the development zone, bordering the site is unopened or unformed, it shall be opened up and brought up to its proper, approved and official formation levels prior to the commencement of any development hereby being permitted.

f) Before any part of the development hereby permitted commences, the enclosed green copy of this development permission shall be displayed on the site. This must be mounted on a notice board, suitably protected from the weather and located not more than 2 metres above ground level at a point on the site boundary where it is clearly visible and can be easily read from the street. The copy of the permission must be maintained in a good condition and it shall remain displayed on the site until the works are complete.

g) The enclosed Commencement Notice shall be returned to MEPA so that it is received at least five days prior to the commencement of any works hereby permitted.

h) Where applicable, the development hereby permitted shall be carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, Legal Notice 295 of 2007 (or subsequent amendments). Any hoarding shall be erected in accordance with Schedule 2 of the same Regulations.

i) The height of the development shall not exceed the permitted number of floors and the height in metres as indicated on the approved drawings.

j) There shall be no service pipes, cables or wires visible on the front elevation or on any other elevations of the building which are visible from the street or public space.

3 The conditions imposed and enforced by the Civil Protection Department are at document PA3033/12/35. The architect/applicant are required to contact the Civil Protection Department, throughout all the construction phases of the development hereby approved, to ensure that the development is carried out in conformity with the conditions imposed by the Civil Protection Department].

Where the approved drawings and/or documents are dimensioned, then the declared dimensions shall prevail over the actual size as depicted on the approved drawings and/or documents.

Developers are advised to check the invert level to the sewer main with the Water Services Corporation as they would have to make their own arrangements where a gravity service connection is not possible. In these cases, the architect has to indicate the solutions envisaged and to indicate on the plan what needs to be carried out and obtain approval from WSC. Developers are further reminded that connection of storm water into main sewers is not allowed.

A third party may have the right of appeal against this permission. Any action taken on this permission when such an appeal has been made, or until the time limit for the submission of such an appeal has expired, is undertaken at the risk that this permission may be revoked by the Environment and Planning Review Tribunal or quashed by the Court of Appeal.

If the declaration of ownership, as contained in the application form, is determined as incorrect by a Court of Law, then the said Court of Law can declare this development permission as null and void. This development permission does not remove or replace the need to obtain the consent of the land/building owner to this development before it is carried out. Furthermore, it does not imply that consent will necessarily be forthcoming nor does it bind the land/building owner to agree to this development. Where the land/building is owned or administered by the Government of Malta a specific clearance and agreement must be obtained for this development from the Land and/or Estate Management Departments.

This development permission is granted saving third party rights. This permission does not exonerate the applicant from obtaining any other necessary permission, license, clearance or approval required from any Government department, local council, agency or authority (including MEPA), as required by any law or regulation.

This development permit does not authorise any storage of substances listed in Occupational Health and Safety Authority Act (Cap. 424) - Control of Major Accident Hazards Regulations, 2003, as amended, in quantities that would render this site an establishment within scope of these regulations.

The storage and handling of said substances may require a new or amended development permission in line with current policies and regulations.

For any non-residential uses hereby being approved, prior to commencement of any works on site or any eventual permitted change of use, the applicant shall be required to contact the Environment Protection Directorate (within MEPA) to obtain any necessary operational permit or registration. This requirement does not apply to Class 4, 5, 7 and 8 uses as listed in the Development Planning (Use Classes) Order (1994), or its subsequent amendments.

This decision is being published on 6 July 2013.

David Cassar
f/Head EPC Secretariat
Environment and Planning Commission

[PADCNCopy]

PLANNING AUTHORITY

Perit Wallace Farrugia
No. 44, Apartment 3
St. Francis Street

Sliema SLM 2069

Date : 16 September 2016
Your Ref : 165/15

Dear Sir/Madam,

Notification Number:	DN 00624/16
Proposal:	Extension to factory.
Location:	Factory HF 51, Qasam Industrijali, Birzebbugia, Malta

Permitted Development by the Development Notification Order, 2007.

We refer to your notification of intent to undertake the above mentioned works, validated on 7 April 2016.

In accordance with the Development Notification Order, 2007, the development as endorsed on the attached drawings and site plan **DN0624/16/1B/5B/5C/5D/5E/5F/5G/5H doc. 5A (KNPD Accessibility Audit Report),**
doc. 5i (Civil Protection Dept. Report) and doc. 5J (Fire Safety & Ventilation Report) is permitted under the following class:

16(i) The construction, re-development, alteration or extension of an industrial unit.

This clearance is granted in relation to the proposed development **ONLY** as indicated in conventional colours on plans and **does not** cover any other development whether shown or not shown on plans, **does not** cover any CTB concession and **does not** sanction any illegal development which may exist on site, even if shown on plans.

This written notification is limited to the development as shown on the submitted plans and is issued without prejudice to sub-article 55(7) of the Development Planning Act, 2016.

This written notification is valid for a period of 12 Months from 14 September 2016 to 14 September 2017, but is rendered null in the event that the development is subsequently modified, extended or relocated in a manner which would result in the limitations set out in the Development Notification Order being exceeded.

The written notification is granted saving third party rights. This notification does not exonerate the applicant from obtaining any other necessary permission, license, clearance or approval required from any Government department, local council, agency or authority, as required by any law or regulation, including an environmental permit from the Planning Authority for the operation of the permitted development.

A Commencement Notice is to be submitted to the Planning Authority, by the *perit* on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, **if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised** - Article 72(4) of the Development Planning Act (2016).

Where applicable, the development, hereby notified, shall be carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, LN 295 of 2007.

If the declaration of ownership, as contained in the application form, is determined as incorrect by an Administrative Tribunal or by a Court of Law, then the said notification and its effects shall be considered as null and void.

Yours sincerely,

Vincent Cassar
Chairman
Planning Board

PLANNING AUTHORITY

Perit Wallace Farrugia
No. 44, Apartment 3
St. Francis Street

Sliema SLM 2069

Date : 25 January 2017
Your Ref : 128/16

Dear Sir/Madam,

Notification Number:	DN 00023/17
Proposal:	Extension to external area and carpark.
Location:	Sterling Chemicals Ltd., Factory HF50, Qasam Industrijali, Birzebbugia, Malta

Permitted Development by the Development Notification Order, 2016.

We refer to your notification of intent to undertake the above mentioned works, validated on 17 January 2017.

In accordance with the Development Notification Order, 2016, the development as endorsed on the attached drawings and site plan **DN00023/17/1A/1B/1C doc. 1D (CRPD Accessibility Audit Report)**
is permitted under the following class:

16(i) The construction, re-development, alteration or extension of an industrial unit.

This clearance is granted in relation to the proposed development **ONLY** as indicated in conventional colours on plans and **does not** cover any other development whether shown or not shown on plans, **does not** cover any CTB concession and **does not** sanction any illegal development which may exist on site, even if shown on plans.

This written notification is limited to the development as shown on the submitted plans and is issued without prejudice to sub-article 55(7) of the Development Planning Act, 2016.

This written notification is valid for a period of 12 Months from 25 January 2017 to 25 January 2018, but is rendered null in the event that the development is subsequently modified, extended or relocated in a manner which would result in the limitations set out in the Development Notification Order being exceeded.

The written notification is granted saving third party rights. This notification does not exonerate the applicant from obtaining any other necessary permission, license, clearance or approval required from any Government department, local council, agency or authority, as required by any law or regulation, including an environmental permit from the Planning Authority for the operation of the permitted development.

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A Commencement Notice is to be submitted to the Planning Authority, by the *perit* on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, **if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised** - Article 72(4) of the Development Planning Act (2016).

Where applicable, the development, hereby notified, shall be carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, LN 295 of 2007.

If the declaration of ownership, as contained in the application form, is determined as incorrect by an Administrative Tribunal or by a Court of Law, then the said notification and its effects shall be considered as null and void.

Yours sincerely,

Vincent Cassar
Chairman
Planning Board

174/16
Comm
Artn.

PLANNING AUTHORITY

Perit Wallace Farrugia
No. 44, Apartment 3
St. Francis Street

Sliema SLM 2069

Date : 18 July 2017
Your Ref : 174/16

Dear Sir/Madam,

Notification Number:	DN 00617/17
Proposal:	Extension to offices.
Location:	Sterling Chemicals Ltd., Factory HF51, Qasam Industrijali, Birzebbugia, Malta

Permitted Development by the Development Notification Order, 2016.

We refer to your notification of intent to undertake the above mentioned works, validated on 13 July 2017.

In accordance with the Development Notification Order, 2016, the development as endorsed on the attached drawings and site plan **DN617/1A/1C/1E doc. 1F (Fire Safety & Ventilation Report) doc.1G (Civil Protection Dept Report) doc. 1H (CRPD Accessibility Audit Report)** is permitted under the following class:

16(i) The construction, re-development, alteration or extension of an industrial unit.

This clearance is granted in relation to the proposed development **ONLY** as indicated in conventional colours on plans and does **Not** cover any other works or sanction any illegal development which may exist on site, even if shown on plans.

This written notification is limited to the development as shown on the submitted plans and is issued without prejudice to sub-article 55(7) of the Development Planning Act, 2016.

This written notification is valid for a period of for a period of 12 Months from 18 July 2017 to 18 July 2018, but is rendered null in the event that the development is subsequently modified, extended or relocated in a manner which would result in the limitations set out in the Development Notification Order being exceeded.

The written notification is granted saving third party rights. This notification does not exonerate the applicant from obtaining any other necessary permission, license, clearance or approval required from any Government department, local council, agency or authority, as required by any law or regulation, including an environmental permit from the Planning Authority for the operation of the permitted development.

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A Commencement Notice is to be submitted to the Planning Authority, by the *perit* on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, **if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised** - Article 72(4) of the Development Planning Act (2016).

Where applicable, the development, hereby notified, shall be carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, LN 295 of 2007.

If the declaration of ownership, as contained in the application form, is determined as incorrect by an Administrative Tribunal or by a Court of Law, then the said notification and its effects shall be considered as null and void.

Yours sincerely,

Vincent Cassar
Chairman
Planning Board

Malta Industrial Parks Ltd. Attn: Damian Whitehead
Malta Industrial Parks
Guardamangia Hill

Pieta MEC0001

Date : 9 October 2017
Our Ref: DN 00810/17

Dear Sir/Madam,

Notification Number:	DN 00810/17
Proposal:	Construction of factory.
Location:	HF53, Qasam Industrijali, Birzebbugia, Malta

Development Planning Act, 2016
Development Notification Order, 2016.

We refer to your notification of intent to undertake the above mentioned works, validated on 11 September 2017.

In accordance with the Development Notification Order, 2016, the development as endorsed on the attached drawings and site plan **DN810/17/1A/1C/1D/E/1F/1G/1H/1I/1J/ 6A(CRPD Clearance),1M(Civil Protection),1L(Environment & Resources Authority),1N(Fire Safety & Ventilation Report)**
is permitted under the following class:

16(i) The construction, re-development, alteration or extension of an industrial unit.

This clearance is granted in relation to the proposed development **ONLY** as indicated in conventional colours on plans and does **Not** cover any other works or sanction any illegal development which may exist on site, even if shown on plans.

This written notification is limited to the development as shown on the submitted plans and is issued without prejudice to sub-article 55(7) of the Development Planning Act, 2016.

This written notification is valid from 09 October 2017 to 09 October 2018, but is rendered null in the event that the development is subsequently modified, extended or relocated in a manner which would result in the limitations set out in the Development Notification Order being exceeded.

The written notification is granted saving third party rights. This notification does not exonerate the applicant from obtaining any other necessary permission, license, clearance or approval required from any Government department, local council, agency or authority, as required by any law or regulation, including an environmental permit from the Planning Authority for the operation of the permitted development.

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A Commencement Notice is to be submitted to the Planning Authority, by the *perit* on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, **if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised** - Article 72(4) of the Development Planning Act (2016).

Where applicable, the development, hereby notified, shall be carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, LN 295 of 2007.

If the declaration of ownership, as contained in the application form, is determined as incorrect by an Administrative Tribunal or by a Court of Law, then the said notification and its effects shall be considered as null and void.

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Important Notice

In view of the provisions of Article 72(4) of the Development Planning Act (2016), a Commencement Notice is to be submitted to the Planning Authority, by the perit on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised.

-DocDNDcnApplicant-

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Sterling Chemicals Malta Attn: Mr Roberto Tumbiolo

Date: 7 March 2019
Our Ref: PA/03638/18

Application Number:	PA/03638/18
Application Type:	Full development permission
Date Received:	23 March 2018
Approved Documents:	PA 3638/18/10B/73B/73C/73D/81B *Supporting Documents:* PA 3638/18/42A (WSC conditions); PA 3638/18/48A (EHD conditions); PA 3638/18/50A (CRPD conditions); PA 3638/18/53A (SCH conditions); PA 3638/18/66B (Engineer's Report); PA 3638/18/81C (REWS Clearance).
Location:	HF 50, HF 51, HF 53, Hal-Far Industrial Estate, Hal Far, Birzebbuga, Malta
Proposal:	Removal of existing LPG storage approved in PA/03033/12, and installation of new 25,000 Litre LPG storage tank, including all required ancillary equipment and pipework, minor amendments to parking area layout and construction of new boundary wall.

Development Planning Act, 2016
Full Development Permission

The Planning Authority hereby grants development permission in accordance with the application and documents described above, subject to the following conditions:

1 a) This development permission is valid for a period of FIVE YEARS from the date of publication of the decision in the press but will cease to be valid if the development is not completed by the end of this validity period.

b) This permission relates only to the development as specifically indicated on the approved drawings. This permission does not sanction any other illegal development that may exist on the site.

c) A Commencement Notice is to be submitted to the Planning Authority, by the perit on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall

invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, **if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised** - Article 72(4) of the Development Planning Act (2016).

d) Copies of all approved drawings and documents shall be available for inspection on site by Planning Authority officers at all reasonable times.

e) The development shall be carried out in complete accordance with the approved drawings, documents and conditions of this permission. Where a matter is not specified, then the conditions of this permission and of Development Control Design Policy, Guidance and Standards 2015 shall apply.

f) Before any part of the development hereby permitted commences, the enclosed green copy of this development permission shall be displayed on the site. This must be mounted on a notice board, suitably protected from the weather and located not more than 2 metres above ground level at a point on the site boundary where it is clearly visible and can be easily read from the street. The copy of the permission must be maintained in a good condition and it shall remain displayed on the site until the works are completed.

g) All building works shall be erected in accordance with the official alignment and official/existing finished road levels as set out on site by the Planning Authority's Land Surveyor. The Setting Out Request Notice must be submitted to the Land Survey Unit of the Planning Authority when the setting out of the alignment and levels is required.

h) It is the responsibility of the permit holder to ensure that development is carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, Legal Notice 295 of 2007 (or subsequent amendments). Any hoarding shall be erected in accordance with Schedule 2 of the same Regulations.

i) No steps, ramps or street furniture are to be constructed on or encroached onto the public pavement or road.

j) Any doors and windows, the lower edge of which is less than 2m above road level, and any gates shall not open outwards onto a public pavement or road.

k) There shall be no service pipes, cables or wires visible on the front elevation or on any other elevations of the building which are visible from the street or public space.

l) Any parking spaces shall only be used for the parking of private cars and shall be kept available at all times for this purpose.

2 The development hereby permitted shall be subject to Final Compliance (Completion) Certification, verifying that the development has been carried out in full accordance with the approved drawings, documents and conditions imposed in this development permission, except where such conditions are enforced by other entities. Prior to the issue

of any compliance certificate on any part of this development, the applicant shall submit to Planning Authority, in relation to that part of the building:

(i) Certification from a qualified engineer confirming that the development fully satisfies the requirements specified in supporting document PA 3638/18/66B

3 The conditions imposed and enforced by the Environmental Health Directorate are at supporting document PA/3638/18/48A. The architect / applicant is required to contact the Environmental Health Directorate, throughout the implementation of the development hereby approved, to ensure conformity with the imposed conditions. A copy of the relative correspondence issued by the Environmental Health Directorate shall be submitted to the Planning Authority accordingly.

4 The conditions imposed and enforced by the Commission for the Rights of Persons with Disability are at supporting document PA/3638/18/50A. The architect / applicant is required to contact the Commission for the Rights of Persons with Disability, throughout the implementation of the development hereby approved, to ensure conformity with the imposed conditions. A copy of the relative correspondence issued by the Commission for the Rights of Persons with Disability shall be submitted to the Planning Authority accordingly.

5 The conditions imposed and enforced by the Superintendence for Cultural Heritage are at supporting document PA/3638/18/53A. The architect / applicant is required to contact the Superintendence for Cultural Heritage, throughout the implementation of the development hereby approved, to ensure conformity with the imposed conditions. A copy of the relative correspondence issued by the Superintendence for Cultural Heritage shall be submitted to the Planning Authority accordingly.

6 The conditions imposed and enforced by the Regulator for Energy and Water Services (REWS) are at supporting document PA/3638/18/81C. The architect / applicant is required to contact the Regulator for Energy and Water Services, throughout the implementation of the development hereby approved, to ensure conformity with the imposed conditions. A copy of the relative correspondence issued by the Regulator for Energy and Water Services shall be submitted to the Planning Authority accordingly.

7 The operational changes to the site approved by the development permit shall not commence until such time that the variation / renewal of the Environmental Registration / Environmental Permit is issued by ERA.

8 **Conditions imposed and enforced by other entities**

A. Where construction activity is involved:

(a) the applicant shall:

(i) Appoint a Project Supervisor for the Design Stage and a Project Supervisor for the Construction Stage and any such appointment shall be terminated, changed or renewed as necessary. The same person may be appointed to act as project supervisor

for both the design and construction stage, if that person is competent to undertake the duties involved and

(ii) Keep a health and safety file prepared by the Project Supervisor for the Design Stage.

(b) When the construction works related to this application are scheduled to last longer than thirty working days and on which more than twenty workers are occupied simultaneously, or on which the volume of work is scheduled to exceed five hundred person-days, the project supervisor **shall communicate a prior notice to the Occupational Health and Safety Authority (OHSA) at least four calendar weeks before commencement of works**.

(c) The Project Supervisor for the Design Stage shall **draw up a health and safety plan** which sets out the occupational health and safety rules applicable to the construction activities concerned, outlining the measures to ensure cooperation between different contractors and shall also include specific measures concerning occupational risks that may be present at this site.

B. Where the development concerns a place of work:

The applicant shall:
(i) obtain a Perit's declaration that the necessary requirements arising out of LN 44 of 2002 have been included in the plans and drawings; and

(ii) obtain a Perit's declaration that the building conforms to the requirements of LN 44 of 2002.

C. The development is to strictly adhere to the 'Design Guidelines on fire safety for buildings in Malta' to ensure that all Fire Safety measures and provisions are addressed as indicated in the Design Guidelines on Fire Safety for Buildings in Malta, published by the DCID in 2004, (or other relevant standard, provided it is approved by the Civil Protection Department), Policies, and the Laws and Regulations of Malta.

D. In the event of an accidental discovery in the course of approved works, any cultural heritage feature discovered should not be damaged or disturbed and the Superintendence is to be immediately informed of such discovery. Any cultural heritage features discovered are to be investigated, evaluated and protected in line with the Cultural Heritage Act 2002 (CAP 445). The discovery of cultural heritage features may require the amendment of approved plans.

In terms of Article 72(3) of the Development Planning Act, 2016, the execution and validity of this permission is automatically temporarily **suspended** and no works as approved by the said development permission may commence before the lapse of the time period established in Article 13 of the Environment and Planning Review Tribunal Act and subsequently will remain so suspended if the Tribunal so decides in accordance with the Environment and Planning Review Tribunal Act.

Where the approved drawings and/or documents are dimensioned, then the declared dimensions shall prevail over the actual size as depicted on the approved drawings and/or documents.

Developers are advised to check the invert level to the sewer main with the Water Services Corporation as they would have to make their own arrangements where a gravity service connection is not possible. In these cases, the architect has to indicate the solutions envisaged and to indicate on the plan what needs to be carried out and obtain approval from WSC. Developers are further reminded that connection of storm water into main sewers is not allowed.

If the declaration of ownership, as contained in the application form, is determined as incorrect by a Court of Law, then the said Court of Law can declare this development permission as null and void. This development permission does not remove or replace the need to obtain the consent of the land/building owner to this development before it is carried out. Furthermore, it does not imply that consent will necessarily be forthcoming nor does it bind the land/building owner to agree to this development. Where the land/building is owned or administered by the Government of Malta a specific clearance and agreement must be obtained for this development from the Land and/or Estate Management Departments.

This development permission is granted saving third party rights. This permission does not exonerate the applicant from obtaining any other necessary permission, license, clearance or approval required from any Government department, local council, agency or authority, as required by any law or regulation.

This development permit does not authorise any storage of substances listed in Occupational Health and Safety Authority Act (Cap. 424) - Control of Major Accident Hazards Regulations, 2003, as amended, in quantities that would render this site an establishment within scope of these regulations. The storage and handling of said substances may require a new or amended development permission in line with current policies and regulations.

For any non-residential uses hereby being approved, prior to commencement of any works on site or any eventual permitted change of use, the applicant shall be required to contact the Environment and Resources Authority to obtain any necessary operational permit or registration. This requirement does not apply to Class 2B, 2C, 4A and 4B uses as listed in the Development Planning (Use Classes) Order 2014, or its subsequent amendments.

This decision is being published on 20 March 2019.

Marthese Debono
Secretary Planning Commission
Within Development Scheme

Notes to Applicant and Perit

Right for reconsideration

Where applicable, you have a right to submit a request for reconsideration to the Authority in terms of regulation 14 of Legal Notice 162 of 2016.

Right for appeal

You have a right to submit an appeal, against the decision, to the Environment and Planning Review Tribunal in terms of Article 13 of the Environment and Planning Review Tribunal Act, 2016.

Time limits

Requests for reconsideration or appeals must be made within 30 days from the publication of the decision notification in the local press as required by regulation 14(1) of Legal Notice 162 of 2016.

Fees to submit a request for reconsideration or appeal

In either case, there is a fee to be paid which should accompany the request for reconsideration or the appeal. The fees are as follows:

For reconsideration - 3% of the Development Permit Fee paid in respect of the original application, subject to a minimum of €69.88.

For appeal - 5% of DPF (Development Permit Fee) paid in respect of the original application, subject to a minimum of €150 + €50 administrative fee (LN 112 of 2016).

Submission of request for reconsideration or appeal

With regards to requests for reconsideration, Form PA 4/16 must be used for submission. All fields of the Form must be filled in as appropriate. Requests for reconsideration can only be submitted electronically.

With regards to appeals, as required by Article 13 of the Environment and Planning Review Tribunal Act, 2016, the submission must include the detailed grounds for appeal and the requests being made by the appellant. Appeals must be submitted physically at the offices of the Environment and Planning Review Tribunal, St. Francis Ditch, Floriana.

Important Notice

In view of the provisions of Article 72(4) of the Development Planning Act (2016), a Commencement Notice is to be submitted to the Planning Authority, by the perit on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised.

-PADCN-

Sterling Chemicals Malta Attn: Roberto Tumbiolo

Date : 12 November 2018
Our Ref: DN 01094/18

Dear Sir/Madam,

Notification Number:	DN 01094/18
Proposal:	Construction of factory
Location:	HF53, Qasam Industrijali Hal-Far, Birzebbugia, Malta

Development Planning Act, 2016
Development Notification Order, 2016.

We refer to your notification of intent to undertake the above mentioned works, validated on 16 October 2018.

In accordance with the Development Notification Order, 2016, the development as endorsed on the attached drawings and site plan **DN001094/18/1A/5A/5B/5C/5D/5F/G/5H/5I/5J**

DO NOT PRINT - For ease of reference only:-
doc.1L (CPD)
doc.1M (Fire Safety and Ventilation Report)
doc.1N (CRPD clearance letter)
doc. 7B (Malta Industrial Parks clearance letter)
is permitted under the following class:

16(i) The construction, re-development, alteration or extension of an industrial unit.

This clearance is granted in relation to the proposed development **ONLY** as indicated on plans in conventional colors and does **Not** cover any other works or sanction any illegal development which may exist on site, even if shown on plans.
written notification is limited to the development as shown on the submitted plans and is issued without prejudice to sub-article 55(7) of the Development Planning Act, 2016.

This written notification is valid from 12 November 2018 to 12 November 2019, but is rendered null in the event that the development is subsequently modified, extended or relocated in a manner which would result in the limitations set out in the Development Notification Order being exceeded.

The written notification is granted saving third party rights. This notification does not exonerate the applicant from obtaining any other necessary permission, license, clearance or approval required from any Government department, local council, agency or authority, as required by any law or -

regulation, including an environmental permit from the Planning Authority for the operation of the permitted development.

A Commencement Notice is to be submitted to the Planning Authority, by the *perit* on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, **if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised** - Article 72(4) of the Development Planning Act (2016).

Where applicable, the development, hereby notified, shall be carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, LN 295 of 2007.

If the declaration of ownership, as contained in the application form, is determined as incorrect by an Administrative Tribunal or by a Court of Law, then the said notification and its effects shall be considered as null and void.

Perit Vincent Cassar
Chairman Planning Baord

c.c.: Perit Wallace Farrugia

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Important Notice

In view of the provisions of Article 72(4) of the Development Planning Act (2016), a Commencement Notice is to be submitted to the Planning Authority, by the perit on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised.

-DocDNDcnApplicant-

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water
services corporation

19th February 2019

MR. ROBERTO TUMBIOLO
Sterling Chemical Malta Ltd.
HF 51, Hal Far Industrial Estate,
Birzebbugia, BBG 3000

Dear Mr. Tumbiolo,

Re: Issue of Public Sewer Discharge Permit

With reference to the above, please find enclosed the Public Sewer Discharge Permit for the above mentioned premises.

Permit is valid for one year.

We kindly appreciate that for next year's renewal, you call at our offices one month prior to the expiry date.

If you have any queries, please do not hesitate to inform us.

Kind regards,

Mr. Trevor Chircop Bray
Managing Professional – Discharge Permitting
Discharge Permit Unit

Water Services Corporation
Triq Ħal Qormi, Ħal Luqa, LQA 9043, Malta

(+356) 2244 5566
customercare@wsc.com.mt

wsc.com.mt

water
services corporation

PUBLIC SEWER DISCHARGE PERMIT

SUBJECT

Sterling Chemical Malta Ltd.
HF 51, Hal Far Industrial Estate,
Birzebbugia, BBG 3000

OUR REFERENCE: DMU 6745 **ACTIVITY: FACTORY**

YOUR REFERENCE:

To whom it may concern

Applicant, **Mr. Roberto Tumbiolo** has submitted an application to discharge trade effluent into the Public Sewer in terms of L.N. 139 of 2002 as amended by L.N. 378 of 2005.

This application has been accepted and the necessary permit is hereby being issued to the applicant. The issued permit relates only to the discharge of domestic sewage. No discharge of trade effluent in the sewer system is permitted. **Permit is valid for one (1) year from date of issue.**

Mr. Trevor Chircop Bray
Managing Professional – Discharge Permitting
Discharge Permit Unit

19 February 2019

Conditions printed overleaf

Water Services Corporation
Triq Ħal Qormi, Ħal Luqa, LQA 9043, Malta

(+356) 2244 5566
customercare@wsc.com.mt

wsc.com.mt

Conditions for Permit

The Water Services Corporation would have no objection to this application provided that L.N. 139 of 2002 as amended by L.N. 378 of 2005 is adhered, in particular (but without prejudice to all other sections of the regulation):

1. Applicant shall not discharge any prohibited effluent (directly or indirectly) into the public sewerage system.
2. Applicant shall not discharge (directly or indirectly) into the public sewer any effluent containing material which alone, or in combination with the contents of the sewer, is likely:
   - To damage the sewage system, including pipe work, sumps and equipment, or block, cause overflows or in any other way interfere with the free flow of the contents of the sewer.
   - To constitute a health hazard to sewer maintenance personnel by emission of flammable, explosive, toxic, irritating or asphyxiating gases or vapours. Such material includes; volatile organic compounds (including solvents) and substances rich in sulphur and sulphur containing compounds.
   - To interfere with treatment and recovery of liquid and solid waste. Such material includes: substances that create a high oxygen demand, non-biodegradable organic matter, surfactants, salts and biocides, nitrification inhibitors, heavy metals, boron and other substances which render the recovered material unfit for re-use.
   - To bring about adverse aesthetic or other objectionable effects on the marine ecosystem upon discharge into the marine environment; floating material, settable solids which smoother benthic marine life, substances which are toxic to marine life.
3. The discharge of any substance, including such substance as is listed in Schedule B to these regulations, shall be restricted according to the provisions of regulation 5. Guideline maximum discharge concentration values for selected substances are shown in Schedule C to these regulations.
4. Applicant is to indicate suitable effluent inspection and sampling points, which points must be to the satisfaction of Managing Professional – Discharge Permitting, Water Services Corporation.
5. Applicant is to record related discharge parameters and records are to be made available to the, Managing Professional – Discharge Permitting, Water Services Corporation.
6. Maximum component discharge concentrations shall not be reached by dilution of effluent by tap water, ground water, storm water or sewage.

Applicant has **one (1) year** to present sound scientific evidence, to the satisfaction of the Managing Professional – Discharge Permitting that they are adhering to L.N. 139 of 2002 as amended by L.N. 378 of 2005.

The above-mentioned conditions are without prejudice to all other sections laid down in L.N. 139 of 2002 as amended by L.N. 378 of 2005.

Failure to comply with the above mentioned conditions or any other article in L.N. 139 of 2002 as amended by L.N. 378 of 2005 shall nullify such permit.

Rachel Decelis

From: Matthew Vella [Matthew.Vella@wsc.com.mt]
Sent: 22 March 2019 09:12
To: Marco Garilli
Cc: anicolella@sterlingchemicalmalta.com; Trevor Giles Chircop Bray; Anthony Gili; WSC DPU; Andrea Caneponi; Rachel Decelis
Subject: RE: DMU 6745 - Sterling Chemicals Birzebbugia

Dear Marco,

Noted.

The permit has been compiled and you should receive it shortly by post.

Thanks and kind regards,

water services corporation

Matthew John Vella BSc. (Hons) MSc.
Senior Professional | Discharge Permit Unit

E matthew.vella@wsc.com.mt
T +356 2244 3129

Water Services Corporation
Qormi Road, Luqa, LQA 9043
Malta, Europe.

wsc.com.m

From: Marco Garilli <mgarilli@sterlingchemicalmalta.com>
Sent: Thursday, March 21, 2019 5:05 PM
To: Matthew Vella <Matthew.Vella@wsc.com.mt>
Cc: anicolella@sterlingchemicalmalta.com; Trevor Giles Chircop Bray <TrevorGiles.ChircopBray@wsc.com.mt>; Anthony Gili <Anthony.Gili@wsc.com.mt>; WSC DPU <WSC.DPU@wsc.com.mt>; Andrea Caneponi <acaneponi@sterlingchemicalmalta.com>; Rachel Decelis <racheld@ensure.com.mt>
Subject: Re: DMU 6745 - Sterling Chemicals Birzebbugia

Dear Matthew,
Yes, ONLY domestic sewage will be discharged to WSC sewer, and that all industrial waste will be collected and disposed of as hazardous waste, as per current procedure.
Regards.

HORMONE & STEROID SPECIALISTS STERLING

Marco Garilli
HSE Manager
T: **+356 20908746** | Mob: **+356 99101171**
E: mgarilli@SterlingChemicalMalta.com

STERLING CHEMICAL MALTA Ltd. HF51, Hal-Far Industrial Estate Birzebbugia BBG3000
VAT Number MT 16941304

Il giorno gio 21 mar 2019 alle ore 13:55 Matthew Vella <Matthew.Vella@wsc.com.mt> ha scritto:

> Dear Marco,

The application for this year can be left as is, i.e. for HF51. Then the application for next year should cover HF 50, 51 and 53.

Can you kindly confirm that after all the upgrades have been made, ONLY domestic sewage will be discharged to WSC sewer, and that all industrial waste will be collected and disposed of as hazardous waste, as per current procedure?

Thanks and kind regards,

water services corporation

Matthew John Vella BSc. (Hons) MSc.
Senior Professional | Discharge Permit Unit

E matthew.vella@wsc.com.mt
T +356 2244 3129

Water Services Corporation
Qormi Road, Luqa, LQA 9043
Malta, Europe.

wsc.com.

Just to confirm, after all the upgrades have been made, it will still be that ONLY domestic

From: Marco Garilli <mgarilli@sterlingchemicalmalta.com>
Sent: Thursday, March 21, 2019 1:19 PM
To: Matthew Vella <Matthew.Vella@wsc.com.mt>
Cc: anicolella@sterlingchemicalmalta.com; Trevor Giles Chircop Bray <TrevorGiles.ChircopBray@wsc.com.mt>; Anthony Gili <Anthony.Gili@wsc.com.mt>; WSC DPU <WSC.DPU@wsc.com.mt>; Andrea Caneponi <acaneponi@sterlingchemicalmalta.com>
Subject: Re: DMU 6745 - Sterling Chemicals Birzebbugia

Dear Matthew,

as requested I send the draw layouts with the internal drains proposed as updates.

Regarding the latter, I ask if I should send you another application form which includes all 3 areas HF 50 - HF 51 - HF 53.

Thanks in advance.

Regards.

Marco Garilli
HSE Manager
T: **+356 20908746** | Mob: **+356 99101171**
E: mgarilli@SterlingChemicalMalta.com

STERLING CHEMICAL MALTA Ltd. HF51, Hal-Far Industrial Estate Birzebbugia BBG3000
VAT Number MT 16941304

Il giorno mer 13 mar 2019 alle ore 07:37 Matthew Vella <Matthew.Vella@wsc.com.mt> ha scritto:

Dear Marco,

I need the current internal drains layout – if there were any changes from Drawing No. 38-06-612 dated 13/06/12.

I would also need the internal drains layout of the proposed upgrades.

Thanks and kind regards,

Matthew John Vella BSc. (Hons)
MSc.
Senior Professional | Discharge Permit Unit

E matthew.vella@wsc.com.mt
T +356 2244 3129

Water Services Corporation
Qormi Road, Luqa, LQA 9043
Malta, Europe.

wsc.com

REGULATOR FOR ENERGY & WATER SERVICES

Reference No. SS/110

27th March 2017

Simone Ferlin
Sterling Chemical Malta Ltd, HF 51,
Hal Far Industrial Estate
B'Bugia

LPG SECONDARY STORAGE AUTHORISATION 2017

Dear Sir/Madam,

In accordance with the Liquefied Petroleum Gas Market Regulations S.L.545.20, please be advised that your LPG Secondary Storage Authorisation for year 2017 is due for renewal. Please note that payment for the year 2016 is still pending.

You are therefore kindly requested to send a cheque to the amount of **€100** drawn in favour of the Regulator for Energy and Water Services (REWS) together with the following documents prepared by a REWS competent person (list attached):

- Periodic Inspection Report
- Written Scheme

Your renewal authorisation fee together with the above requested documents should reach the Regulator by not later than 28th April 2017.

Please note that failure to submit payment and all of the above documents will result in the Regulator not being in a position to renew the LPG Secondary Storage Authorisation for year 2017.

Yours sincerely,

Ing. Marjohn Abela
Chief Executive Officer

Millennia • 2nd Floor • Aldo Moro Road • Marsa • MRS 9065 • Malta
Tel: +356 21220619 • Fax: +356 22955200 • E-mail: enquiry@rews.org.mt • www.rews.org.mt
Office Opening Hours: 8.30a.m. – 3.30p.m. Mon - Fri

PAY 8% CASH

REGULATOR FOR ENERGY & WATER SERVICES

Mr Simone Ferlin (on behalf of: Sterling Chemical Malta Ltd)
HF51
Hal Far Industrial Estate
B`Bugia

Receipt No.: R-041270

Date: 25/04/2017

Received from Mr Simone Ferlin (on behalf of: Sterling Chemical Malta Ltd), ID No.: AS 5424464 / VAT No:MT16941304 , the sum of € 100 Cash, being payment of License No. LPG-00110-SS (SS110) for LPG Secondary Storage licence.

Please retain this receipt as the LPG Secondary Storage Licence for year 2016 & 2017.

Additional Notes: Payment of License Fee 2016 & 2017

Receiving Officer
For Regulator for Energy & Water Services

Millennia • 2nd Floor • Aldo Moro Road • Marsa • MRS 9065 • Malta
Tel: +356 21220619 • Fax: +356 22955200 • E-mail: enquiry@rews.org.mt • www.rews.org.mt

Appendix 3: Company registration certificate

Registrar of Companies

MALTA

Our Ref: C 32508

8th May 2017

TO WHOM IT MAY CONCERN

This is to certify that Sterling Chemical Malta Limited of HF51, Hal-Far Industrial Estate, Birzebbugia BBG3000, Malta was registered under the Laws of Malta on the 20th November 2003 and is still so registered.

According to our records the present shareholders of the company are:

Name	Number of Shares
S.N.I.F.F. Italia SPA (Company Reg. No. 112595)	3,499 Ordinary Shares of EUR 0.8393 each
Osiris Trust Limited (Company Reg. No. C 36502)	1 Ordinary Share of EUR 0.8393

The present directors of the company are:

Simone Ferlin (Italian Passport No. 009477W)
Alessandro Bianchi (Italian I.D. Card No. AT8871126)
Roberto Tumbiolo (Italian Passport No. AA4260020)

The present secretary of the company is:

Alessandro Bianchi (Italian I.D. Card No. AT8871126)

This information is provided on the basis of the documents registered in respect of the company.

Natalie Farrugia

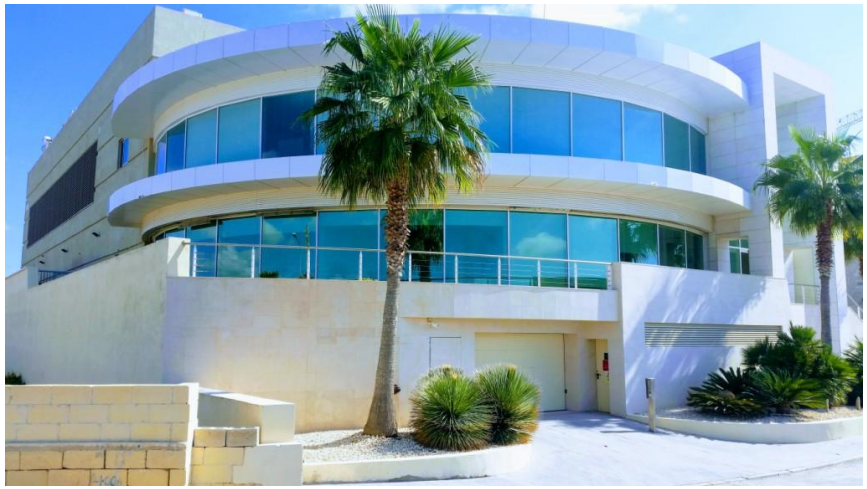
f/Registrar of Companies

Appendix 4: Environmental Impact Assessment update report

EXTENSION TO STERLING CHEMICAL LTD

ENVIRONMENTAL IMPACT ASSESSMENT UPDATE REPORT

NON-TECHNICAL SUMMARY



Version 1: March 2019

Report Reference:

Adi Associates Environmental Consultants Ltd, 2019. Extension to Sterling Chemical Ltd, Ħal Far. Environmental Impact Assessment Update – Non-technical Summary. San Gwann, March 2019; ii + 13 pp.

PLEASE CONSIDER YOUR ENVIRONMENTAL RESPONSIBILITIES BEFORE COPYING THIS REPORT

This report is printed on green paper sourced from sustainable wood forests

Quality Assurance

Extension to Sterling Chemical Malta Ltd, Ħal Far
Environmental Impact Assessment Update Report

Report for: **Sterling Chemical Malta Ltd**

Revision Schedule

Rev	Date	Details	Written by:	Checked by:	Approved by:
00	Mar 2019	Submission to client	**Rachel Xuereb** Director	**Rachel Decelis** Senior Consultant	**Adrian Mallia** Managing Director

File ref: G:_Active Projects\EIA\SCL001 - Sterling Chemical EIA Update\EPS\NTS English_new version.doc

Kappara Business Centre
113 Triq Birkirkara
San Gwann SGN 4197
MALTA

Tel. / Fax: 21378172 - 77

Email: info@adi-associates.com
Web: www.adi-associates.com

INTRODUCTION

1. This Environmental Impact Assessment (EIA) Update Report was commissioned by Sterling Chemical Malta Ltd to support a proposal to extend their existing operation in Hal Far.

2. Although a planning application for the extension of the Sterling Chemical Malta has not yet been submitted, a Project Description Statement (PDS) for the development was submitted in October 2017 and the Environment and Resources Authority (ERA) determined that the development required an Environmental Impact Statement Update (EIS Update) in accordance with the *Environmental Impact Assessment Regulations, 2007* (S.L.549.46). Hereafter in this EIA, the proposed development is referred to as 'the Scheme'. A detailed description of the Scheme is provided in **Chapter 2** of the EIA Update Report.

Purpose of the EIA Update Report

3. The purpose of this EIA Update Report is to present the findings of the EIA. EIA is the process of systematically assessing the likely significant environmental impacts of development proposals. EIA also ensures that the significance of these impacts, and the scope for reducing them, is clearly understood by the public, and by ERA and the Planning Authority (PA) before a decision is made on whether or not the development should be approved.

Background to the Scheme

4. The current factory of Sterling Chemical Malta (Factory HF51) was permitted under PA/04236/08. An Environmental Impact Statement was prepared for an additional floor to the existing management area, an extension of the production area, and the installation of a manufacturing plant for the production of active pharmaceutical ingredients (APIs), and the installation of storage tanks for liquid petroleum gas (LPG).

5. Additionally development permit application PA/03033/12 was approved in June 2013 for the installation of an LPG bulk storage facility. Subsequently, for various extensions, including in sites adjacent to the originally permitted factory, a number of Development Notification Orders (DNOs) were issued as follows:

   - For HF51: DN/00624/16 & DN/00617/17;
   - HF50: DN/00023/17; and
   - HF53: DN/00810/17 & DN/01094/18.

6. Under the approved DNOs, the Applicant is authorised to build the extension and only operate a research and development (R&D) line. A Full Development Permit application will be submitted to the Planning Authority (PA) in order for Sterling Chemical Malta to be able to operate industrially from the proposed extensions to the current factory.

7. The current premises of Sterling Chemical Malta Ltd also have an Integrated Pollution Prevention and Control (IPPC) permit (IP 0001/14/B). It is understood that this permit will be updated to take into account the Scheme.

Terms of Reference

8. Since this is an EIA Update, no Terms of Reference have been provided by ERA. Reference is therefore made to the Terms of Reference that had been issued for the EIS for an *installation of manufacturing plant and obtaining an operations permit for the production of active pharmaceutical ingredients (API) and the installation of LPG storage tanks in a facility/factory already covered by permit PA/04236/08 at Factory HF 51, Qasam Industrijali, Ħal Far, Birżebbuġa*[1].

EIA Approach

9. The 2014 Environmental Impact Statement was used for the baseline studies of ecology and the geo-environment because it was considered that a new baseline survey did not need to be carried out since the data prepared for the EIS is still valid.

10. An assessment of the Scheme's impact on the features present on / within the Scheme site and the relevant Area of Influence (A of I) was undertaken, and any potential environmental benefits of the Scheme were identified.

Significance of Impacts

11. The following criteria were used in the EIA to assess the significance of an impact:

- type of impact (adverse / beneficial);
- extent and magnitude of impact;
- direct or indirect impact;
- duration of impact (short term / long term; permanent / temporary);
- comparison with legal requirements, policies and standards;
- sensitivity of receptor (residential dwellings, hotel, recreational areas, etc.);
- probability of impact occurring (certain, likely, uncertain, unlikely, remote);
- reversibility of impact;
- scope for mitigation / enhancement (very good, good, none); and

[1] ERSLI Consultants, 2014, Environmental Impact Statement *for an installation of manufacturing plant and obtaining an operations permit for the production of active pharmaceutical ingredients (API) and the installation of LPG storage tanks in a facility/factory already covered by permit PA/04236/08 at Factory HF 51, Qasam Industrijali, Ħal Far, Birżebbuġa.*

- residual impacts.

12. Using these criteria, the significance of the negative impacts arising from the Scheme was categorised, as follows:

    - **not significant**, where the impact is environmentally acceptable;
    - **minor significance**, where the impact is manageable;
    - **moderate significance** (where applicable), where the impact may be manageable in certain circumstances, although is likely to require implementation of suitable mitigation measures; and
    - **major significance**, where the impact is environmentally damaging and requires redesign or mitigation measures to minimise it.

13. The EIA Update Report includes an assessment of the significance of predicted impacts and, following the implementation of any proposed mitigation measures, the significance of any residual impacts. A summary of the identified significant impacts is included in **Chapter 5** of the EIA Update Report. The recommended mitigation measures, and residual impacts, are described in respect of each topic area, at the end of the relevant chapter (see **Chapters 3** and **4** of the EIA report) as well as in **Chapter 5**.

Uncertainty

14. The EIA process is designed to enable good decision-making based on the best possible information about the environmental implications of a proposed development. However, there will always be some uncertainty as to the exact scale and nature of the environmental impacts. This arises through shortcomings in information, doubts, or lack of certainty on the likelihood that an incidence will occur, and/or due to the limitations of the prediction process itself. Where uncertainties have arisen, and where they remain, this is clearly stated in the EIA Update Report.

Consultation

15. Consultation with the Birżebbuġa Local Council was undertaken during the preparation of this EIA Update. The purpose of this consultation was to identify the issues that the Council considered important for the locality, and to inform the EIA.

16. The issues identified by the Local Council can be summarised as follows:

    - Proper waste management should be carried out especially with regards to hazardous waste;
    - Potential emissions to air;
    - Noise emissions especially for the residents of Tal-Papa;

- Proper containment of wastewater;
- Potential accidents that could happen; and
- Proper contingency planning.

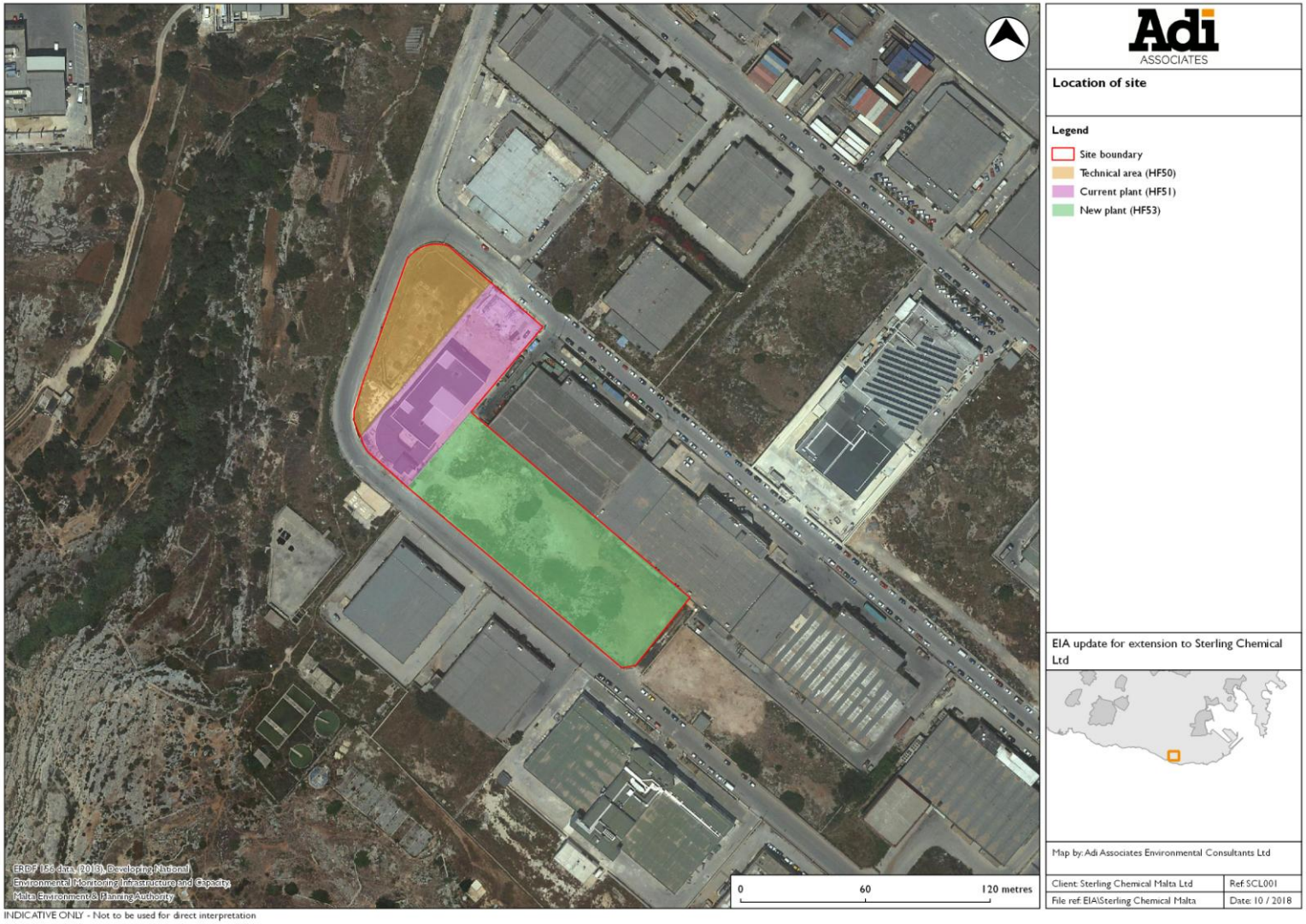
17. The Local Council also requested that once the IPPC permit is issued there would be a monitoring committee set up including Local Council representatives and the Applicant to discuss emerging operational issues. This is already done for the Malta Freeport Terminals operation and according to the Local Council this system works well.

Assessment of Alternatives

18. As explained by the Applicant, Sterling Chemical Malta needs to expand the current production capacity following the strong API demand by the international market. The Applicant advises that the expansion cannot be achieved in a different site from the current operation as this would result in duplicating operating units and human resources. In addition Hal Far is in close proximity to the port and an area where a number of chemical-pharmaceutical activities are located. The zero option would also result in the transfer of capital to other countries. Furthermore as the building of the Scheme production area is already permitted under DN/00810/17 and DN/01094/18, the zero option entails not operating a pharmaceutical company within this location, resulting in a vacant building or one that is operated for other manufacturing purposes.

3.32. Production processes and technologies are evaluated at the design phase, and optimised to improve performance and reduce environmental impacts, for instance by increasing production yields, lowering energy and water consumption, reducing production time and space required, while also respecting product quality requirements.

Figure 1: Location of the Scheme



DESCRIPTION OF SCHEME

19. The Scheme will affect two areas that are next to the current production site and that Sterling Chemical Malta has taken over from Malta Industrial Parks Ltd (MIP). The site to the west of the current production plant (HF50) is intended to provide facilities to support the production areas, whereas the eastern block (HF53) will involve the additional production facility (see **Figure 2**).

20. The DNO permit issued for the construction of HF53 allows for the facility to be used for Research and Development (R&D); it does not allow for the industrialization process. Therefore phase 1 of the project comprises research activities to develop innovative synthetic processes for the preparation of novel APIs for the Company. This activity has already started in the current laboratories and preliminary data on first products is already available.

21. Once the planning permit is issued, the Scheme operation is expected to start in 2020. Phase 2 envisages the operation of production lines, a raw materials warehouse, extension to the external flammable warehouse and technical area, bulk waste storage facilities, maintenance workshop, three laboratories, and new offices and underground car park.

Western Area

22. This area will consist of:

- External Flammable Goods Warehouse;
- LPG Tank Area; and
- Bulk Waste Storage Area.

23. The **External Flammable Goods Warehouse** is a covered external storage area where both raw materials and flammable waste resulting from the production processes will be stored. The existing external flammable warehouse in the HF51 block will be extended slightly eastwards, and westwards to the HF50 block. The extension will consist of new covered sheds, similar in construction to the ones already in place. The storage area is open-air but sheltered by a steel roof to protect the waste from the elements. The storage areas on each side are underlain by a concrete bund linked to a small sump, while the central area (used for loading / unloading) is also concreted, and laid to fall towards a floor drain at the centre of each shed; this floor drain leads to an underground sump just outside each warehouse.

24. The **fractioning area** consists of a room where raw materials are weighed according to production requirements; fractioning is done before start of production. In this area, weighing of solids and fractioning (decanting into smaller containers) of raw materials and solvents takes place.

25. The **Bulk Waste Storage Area** is located in front of the flammable waste and raw material storage area and

adjacent to the current facility (Malta 1). The design caters for a facility on two levels namely:

- Filling of storage tanks at the production level +99.95 m (Level 01); and
- Filling of the ISO tanks at level +97.30 m with a level access to the road (Level 0).

26. A total of 9 x 10,000 litre tanks and 1 x 15,000 l tank will be installed at Level 0 as stockage tanks for liquid hazardous waste before it is transferred by pumps into the respective ISO-tank for eventual export. The tanks will be of the vertical single-skin fixed roof type.

27. The tanks will be located within reinforced concrete bunds with a bunded volume of 110% the size of the containment tank. The tanks will be covered with inert, clay-like material.

28. The lower level at level +97.30 m of the storage area (Level 0) will comprise:

- Space for the parking of 4 ISO tanks on site. This area will be covered and protected from rainfall. The ISO tank parking spaces that will be interconnected with a yard for manoeuvrability, which will be linked to the road through a 10.5 m wide gate;
- A bunded area dedicated for the operation of pumps; and
- An indoor storage area for plant and equipment.

29. The waste area will also include a waste water reservoir and a wash water reservoir, with a capacity of 15,000 L each.

30. Three generators will also be included on Level 0, for use in case of mains supply failure.

31. On Level 0, space will also be provided for the inclusion of several covered waste skips, for storage of non-hazardous separated waste (e.g. recyclables, organic, and municipal waste) arising from non-production activities on site.

32. **LPG Tank area**: currently at the eastern border of the production area there are 3 LPG vertical tanks, each with a capacity of 2,250 litres. There is a pending planning application (PA/03638/18) to replace these tanks with a bulk storage tank in the western part of the site**.** A 25,000 litre LPG tank will be installed to replace these three LPG tanks; this will service the Scheme's two existing steam generators and a future additional steam generator.

Eastern Area

33. The eastern part of the Scheme (HF53) comprises a four storey building for additional API production. This part of the Scheme has an area of approximately 4,500 m^2. This plant will be connected to the existing Sterling facility by a level 0 service corridor in the parking area. The new

building will comprise:

- Production Unit (synthesis with reactors, filters, centrifuges and auxiliary systems);
- Clean Room Unit (drying, grinding and packaging);
- Service Unit (steam generator, vacuum, water, compressed air);
- Auxiliary Unit (technologies and measures for the environment, health and safety protection such as carbon filter, scrubber, wash water reservoir, fire water reservoir); and
- Underground parking.

34. The manufacturing process in the extension will be similar to the one currently carried out at Sterling Chemical - the synthesis of active pharmaceutical ingredients (APIs), including steroids, anti-inflammatory drugs, hormones (contraceptives) and anti-cancer drugs. These pharmaceuticals are typically considered to be high-potency APIs. The list of APIs produced changes from time to time as a result of research and development activities.

35. The production capabilities of Sterling Chemical Malta will be increased through the addition of four new production lines and one R&D line in the new HF53 site.

Access, Traffic and Parking

36. Currently there is a car park at Level 0 with an entrance from beneath the existing reception area. Another car park at Level 0 is planned to the east of the Scheme (HF53). This car park has a capacity of 36 vehicles and will be dedicated to employees. Staff can access the lobby of the Scheme through stairs and / or a lift connected to the parking area.

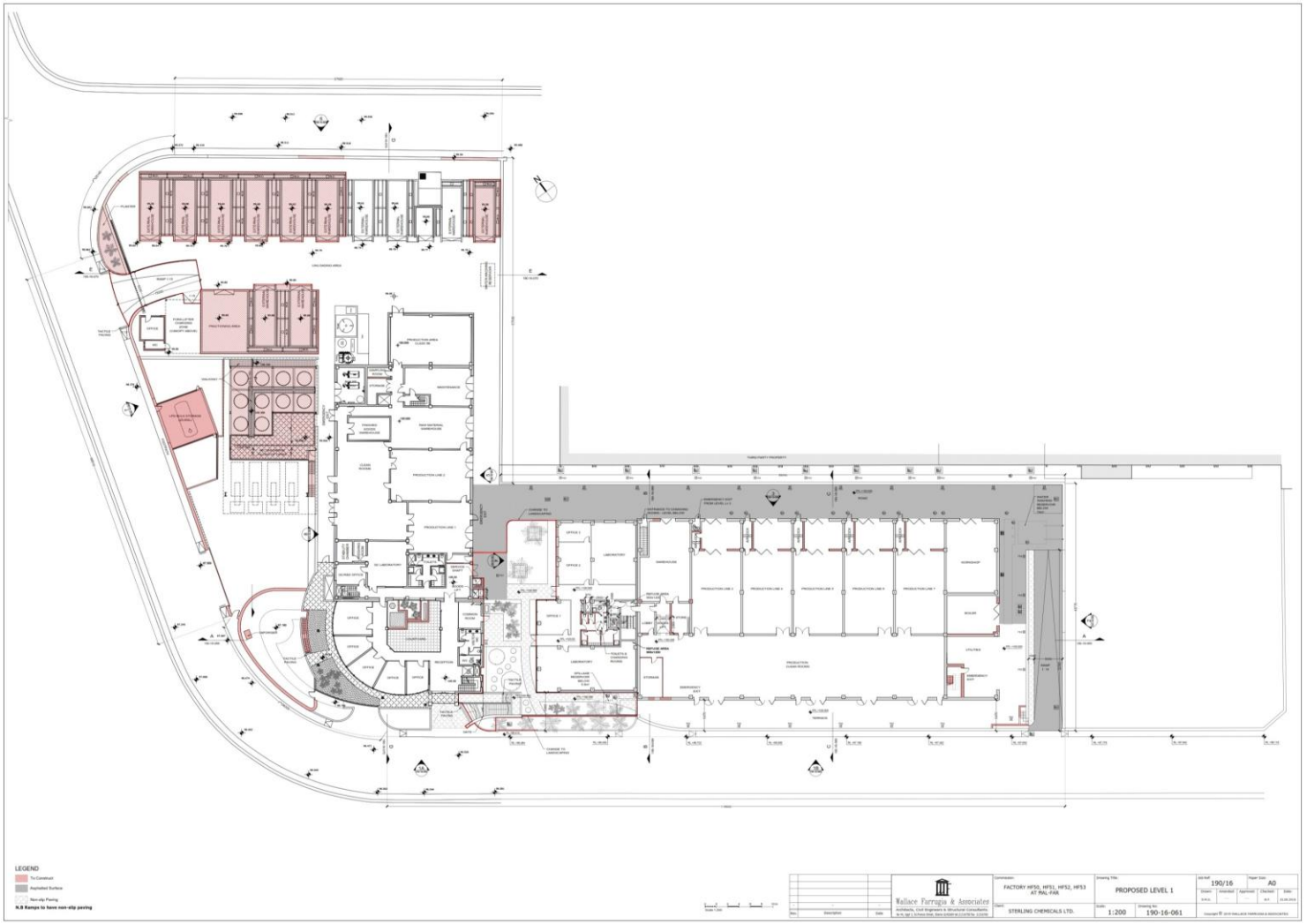
37. Access for heavy goods vehicles including delivery vehicles for raw materials and collection of waste is via a dedicated access along the northern side. The access is not public and will be secured by means of two gates.

38. Since the Scheme will be connected to the existing Sterling Chemical Malta operation, access for staff and guests will be from the main entrance on the southern side of the Scheme. The existing lobby will also serve as the access / reception area for the Scheme.

Services

39. Malta Industrial Parks Ltd (MIP) – the owners of the Industrial Estate - confirmed to the Applicant that the Ħal Far Industrial Area is serviced with all the required utilities including a sewerage system, electricity and water supply systems. All these services are located underground and have the capacity to absorb the demand of the Scheme.

Figure 2: Proposed Level 1 of the Scheme



Scheme Construction

40. Since the buildings envisaged to host the Scheme have already been built, as such there is no extensive construction period; HF53 will need to be connected to the existing HF51. The external warehouses are likely to be constructed as general purpose warehouses through the DNO procedure so there is minimal construction on the site of HF50 in the eventual full development planning application.

Scheme Operation

41. Sterling Chemical currently employs 90 staff. Since the production processes will not all be launched simultaneously but in phases, it is envisaged that the first phase would employ an additional 10 persons and the second phase would employ an additional 30 persons. It is estimated that the total staff complement would be 130. The Scheme will operate from Monday to Friday for 24 hours each day (in 3 shifts).

42. Although the waste types generated by the Scheme are the same as those already generated by the current Sterling Chemical operations, the waste quantities generated annually will increase. It is noted that the types and quantities of waste generated are variable, as they are highly dependent on production activities.

43. Emissions from the new reactors in the new production lines will be routed to a new scrubber. As with the existing reactors, each reactor will be connected to a heat exchanger to condense organic vapours; the entire reactor line is also connected to a second, larger heat exchanger, following which vapours are treated in a carbon filter and the scrubber.

44. Three new emission points covering general ventilation from the existing and new production lines and raw materials warehouses are also being introduced.

45. The Scheme also includes one new steam generator, three new emergency electricity generators, and two new cooling towers.

SIGNIFICANT ENVIRONMENTAL IMPACTS AND MITIGATION

46. The predicted impacts of the Scheme were assessed on a topic area basis. The potential impacts identified during the assessment related to the geo-environment and ecology are described below.

Geo-Environment

47. The impact of the operation of the Scheme on hydrogeological resources is considered to be insignificant due to the extensive mitigation measures inbuilt into the Scheme.

Ecology

48. The impact on the flora and fauna outside the Scheme site

is considered to be minor to not significant in terms of noise and light pollution and impacts from spills and leakages. The potential impact in case of a large fire is considered minor to major due to the potential release of used contaminated extinguishant.

Mitigation

49. Where appropriate, mitigation measures have been recommended and these are described at the end of **Chapters 3** and **4** of the EIA Update Report. It would be appropriate for, and it is recommended that, these mitigation measures be taken account of in the conditions of any eventual development permit.

50. Various mitigation measures have been in-built in the construction of the Scheme including:

- Underlying impermeable concrete layer, with epoxy resin coating on the floor in new production area and new raw materials warehouse;
- Gutters in new production area and new raw materials warehouse leading to a 74 m^3 concreted wash water reservoir;
- Underlying impermeable concrete layer, with acid-resistant tiles and acid-resistant grout in the laboratories;
- Spills from the laboratories collected in floor drains and diverted to the 66 m^3 water washing reservoir;
- Gutters bounding designated transfer area leading to water washing reservoir;
- The external flammable goods warehouses are covered and underlain with concrete bunds and the central area is concreted, laid to fall to a central floor drain leading to an underground sump with closed valve;
- In the waste storage area, bulk tanks are inside a reinforced concrete bund, overflowing to reservoir;
- The bulk tank, transfer area and ISO tank area are covered to prevent rainwater ingress;
- ISO tank area, transfer area and store flooring are concreted, laid to fall to reservoir;
- Diesel in stored in double skin tanks with a capacity <1,000 L each and stored on concrete;
- LPG tank placement and design conforms to Maltese and UK Codes of Practice and is certified according to Pressure Equipment Regulations;
- LPG tank is located below ground, protected from mechanical damage and has fire walls on two sides;
- Natural ventilation of bulk LPG tank, external

flammable warehouse and bulk waste tanks (to avoid build-up of gas);

- Diesel-operated generators (diesel is not flammable); and
- Rainwater reservoir with 600 m^3 of water (150 minutes) dedicated to fire-fighting; level meter with alarm.

51. Other mitigation measures relating to the operation of the Scheme include:

- Effluent from production / washing of production equipment is collected in IBCs[2];
- Certification of containment systems as required by IPPC permit;
- Spill kits and staff training;
- Raw materials typically stored in drums or IBCs, not larger than 1 m^3 each;
- No storage, transfers under staff supervision;
- Laboratory waste that is generated in relatively larger quantities collected in containers for disposal;
- Storage of waste solvent on prefabricated containment;
- Regular removal of waste;
- Waste transferred to licensed waste carriers having appropriate containment, and under supervision of Scheme staff;
- Level gauges and high level alarms on tanks in waste storage area;
- Waste transfers under supervision;
- Waste transfers logged to ensure no losses during transfers;
- Certification of containment systems as required by IPPC permit;
- Spill kits for minor spills, and staff training;
- Emissions from reactors treated in heat exchangers, carbon filter and scrubber;
- Blowdown tanks to contain emissions in case of emergency; emissions from blowdown tanks routed to scrubber;
- Local extraction used if containers are opened; emissions directed to scrubber;

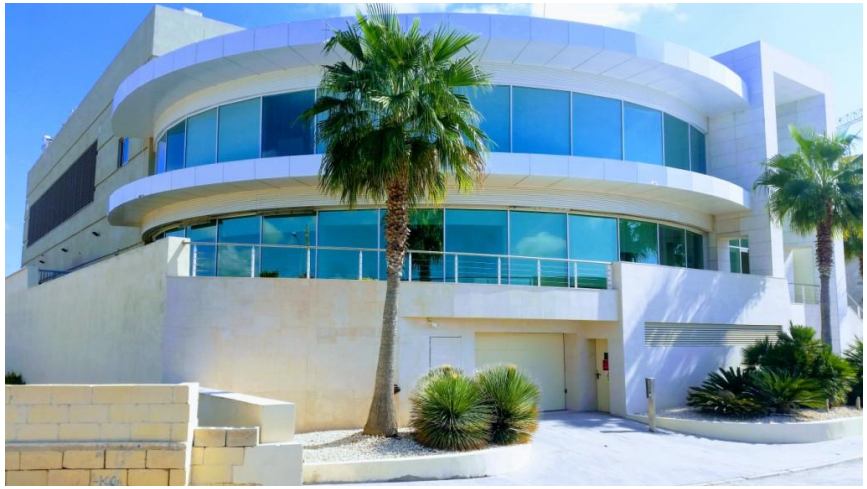
[2] IBCs are intermediate bulk containers, typically having a volume of 1 m^3.

- Emissions monitoring as required by IPPC permit; and
- Maintenance of abatement systems.

ESTENSJONI TA' STERLING CHEMICAL LTD

STUDJU TAL-IMPATT AMBJENTALI
RAPPORT AĠĠORNAT

SUNT MHUX TEKNIKU



Verżjoni 1: Marzu 2019

Referenza tar-Rapport:

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Rapport għal: **Sterling Chemical Malta Ltd**

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INTRODUZZJONI

1 Dan ir-Rapport Aġġornat tal-iStudju tal-Impatt Ambjentali (SIA) ntlabna nagħmluh minn Sterling Chemical Malta Ltd b'appoġġ għall-proposta tagħhom li jestendu l-operazzjoni li għandhom bħalissa f'Ħal Far.

2 Għalkemm għadha ma ġietx ippreżentata applikazzjoni ta' ippjanar għall-estensjoni ta' Sterling Chemical Malta, Dikjarazzjoni Deskrittiva tal-Proġett (DDP) għall-iżvilupp kienet sottomessa f'Ottubru 2017 u l-Awtorità tal-Ambjent u r-Riżorsi (ERA) ddeċidiet li l-iżvilupp kien jeħtieġ Aġġornament tad-Dikjarazzjoni dwar l-Impatt Ambjentali (Aġġornament DIA) skont ir-*Regolamenti dwar l-iStudju tal-Impatt Ambjentali, 2007* (S.L.549.46). Minn hawn 'il quddiem f'dan l-iSIA, l-iżvilupp propost qed jissejjaħ 'l-iSkema'. Deskrizzjoni ddettaljata tal-iSkema tinsab f'**Kapitlu 2** tar-Rapport Aġġornat tal-iSIA.

Skop tar-Rapport Aġġornat tal-iSIA

3 L-iskop ta' dan ir-Rapport Aġġornat tal-iSIA huwa li jkunu ppreżentati r-riżultati tal-iSIA. SIA huwa l-proċess li bih l-impatti ambjentali importanti li probabbli joħorġu mill-proposti ta' żvilupp ikunu studjati b'mod sistematiku. SIA jiżgura wkoll li s-sinjifikat ta' dawn l-impatti, u x'possibbiltà hemm li jitnaqqsu, jinftehmu b'mod ċar kemm mill-pubbliku u kemm mill-ERA u l-Awtorita tal-Ippjanar (PA) qabel ma tittieħed deċiżjoni dwar jekk l-iżvilupp għandux jiġi approvat jew le.

Sfond tal-iSkema

4 Il-fabbrika li Sterling Chemical Malta għandhom bħalissa (Fabbrika HF51) kienet ingħatat permess taħt PA/04236/08. Kienet tħejjiet Dikjarazzjoni dwar l-Impatt Ambjentali għal żieda ta' sular fil-management area eżistenti, estensjoni tal-area tal-produzzjoni, u l-installazzjoni ta' impjant tal-manifattura għall-produzzjoni ta' ingredjenti farmaċewtiċi attivi (IFA/APIs), u l-installazzjoni ta' tankijiet għall-ħażna ta' liquid petroleum gas (LPG).

5 Barra minn hekk, l-applikazzjoni għal permess ta' żvilupp PA/03033/12 kienet ġiet approvata f'Ġunju 2013 għall-installazzjoni ta' faċilità ta' ħażna bil-kwantità (bulk storage facility) ta' LPG. Sussegwentement, għal diversi estensjonijiet, inkluż f'siti maġenb il-fabbrika permessa fil-bidu, inħarġu għadd ta' Development Notification Orders (DNOs) kif ġej:

- Għal HF51: DN/00624/16 & DN/00617/17;
- HF50: DN/00023/17; u
- HF53: DN/00810/17 & DN/01094/18.

6 Taħt id-DNOs approvati, l-Applikant huwa awtorizzat jibni l-estensjoni u jħaddem biss linja ta' riċerka u żvilupp (R&Ż(research and development (R&D) line). Applikazzjoni għal Permess Sħiħ ta' Żvilupp sa tiġi

sottomessa lill-Awtorità tal-Ippjanar (PA) biex Sterling Chemical Malta tkun tista' topera industrijalment mill-estensjonijiet proposti għall-fabbrika preżenti.

7 Il-bini li Sterling Chemical Malta Ltd tokkupa bħalissa għandu wkoll Integrated Pollution Prevention and Control (IPPC) permit (IP 0001/14/B). Huwa mifhum li dan il-permess ikun aġġornat biex jieħu in konsiderazzjoni l-iSkema.

Termini ta' Referenza

8 Billi dan huwa Aġġornament ta' SIA, ma ngħatawx Termini ta' Referenza mill-ERA. Qed nirreferu għalhekk għat-Termini ta' Referenza li kienu nħarġu għad-DIA għal *installazzjoni ta' impjant ta' manifattura u l-kisba ta' permess operazzjonali biex issir produzzjoni ta' ingredjenti farmaċewtiċi attivi (IFA/API) u l-installazzjoni ta' tankijiet għall-ħażna ta' LPG ġo faċilita/fabbrika diġà koperta mill-permess PA/04236/08 fil-Fabbrika HF 51, Qasam Industrijali, Ħal Far, Birżebbuġa*[1].

Kif sar l-iSIA

9 Id-Dikjarazzjoni dwar l-Impatt Ambjentali li saret fl-2014 intużat għall-istħarriġ bażiku tal-ekoloġija u l-ġeo-ambjent għaliex intqies li ma kienx hemm bżonn li jsir stħarriġ bażiku ġdid minħabba li d-data mħejjija għad-DIA għadha valida.

10 Sar studju ddettaljat tal-impatt li l-Iskema jkollha fuq il-karatteristiċi preżenti fis-Sit tal-iSkema u l-Area ta' Influwenza (A ta' I) rilevanti, u ġie identifikat kull benifiċċju ambjentali possibbli tal-Iskema.

Importanza tal-Impatti

11 Il-kriterji li ntużaw fl-iSIA biex jiġi studjat kemm huwa importanti impatt huma dawn:

- tip tal-impatt (ħażin/benefiku);
- firxa u kobor tal-impatt;
- impatt dirett jew indirett;
- kemm idum jinħass l-impatt (żmien qasir/ fit-tul; permanenti / temporanju);
- tqabbil ma' dak li jitolbu l-liġi, il-policies u l-istandards;
- kemm hu sensittiv dak li jintlaqat minnu (djar, lukanda, inħawi ta' rikreazzjoni, eċċ.);
- probabbiltà li l-impatt iseħħ (ċert, aktarx, inċert, aktarx le, remota);
- kemm hu reversibbli l-impatt;
- kemm hemm possibbiltà ta' mitigazzjoni/titjib

[1] ERSLI Consultants, 2014, Environmental Impact Statement *for an installation of manufacturing plant and obtaining an operations permit for the production of active pharmaceutical ingredients (API) and the installation of LPG storage tanks in a facility/factory already covered by permit PA/04236/08 at Factory HF 51, Qasam Industrijali, Ħal Far, Birżebbuġa.*

(tajba ħafna, tajba, xejn); u

- impatti residwi.

12 Meta ntużaw dawn il-kriterji, l-importanza tal-impatti negattivi li jirriżultaw mill-iSkema tqiegħdet f'kategoriji kif ġej:

- **mhux importanti**, fejn l-impatt huwa ambjentalment aċċettabbli;
- **importanza żgħira**, fejn l-impatt jista' jkun ikkontrollat;
- **importanza moderata** (fejn applikabbli), fejn l-impatt jista' jkun ikkontrollat f'ċerti ċirkustanzi, għalkemm aktarx ikun jeħtieġ l-implimentazzjoni ta' miżuri ta' mitigazzjoni; u
- **importanza kbira**, fejn l-impatt jagħmel ħsara lill-ambjent u jeħtieġ disinn mill-ġdid jew miżuri mitigatorji biex jitnaqqas kemm jista' jkun.

13 Ir-Rapport Aġġornat dwar l-iSIA jinkludi studju tal-importanza tal-impatti mbassrin u, wara l-implimentazzjoni ta' miżuri mitigatorji proposti, tal-importanza ta' xi impatti residwi. Ġabra fil-qosor tal-impatti importanti identifikati tinsab f'**Kapitlu 5** tar-Rapport Aġġornat dwar l-iSIA. Il-miżuri ta' mitigazzjoni rrakkomandati, u l-impatti residwi, huma deskritti, għal kull qasam ta' suġġett, fl-aħħar tal-kapitlu rilevanti (ara **Kapitli 3** u **4** tar-Rapport dwar l-iSIA) kif ukoll f'**Kapitlu 5**.

Inċertezza

14 Il-proċess tal-iSIA huwa mfassal b'mod li jagħmilha possibbli li jittieħdu deċiżjonijiet tajbin ibbażati fuq l-aħjar informazzjoni possibbli dwar l-implikazzjonijiet ambjentali ta' żvilupp propost. Madankollu, dejjem ikun hemm xi inċertezza dwar il-kobor u n-natura eżatta tal-impatti ambjentali. Dan jiġi minn nuqqasijiet fl-informazzjoni, dubji, jew nuqqas ta' ċertezza fuq kemm hemm probabbiltà li ħaġa tiġri, u/jew minħabba l-limitazzjonijiet tal-proċess tat-tbassir innifsu. Fejn qamu inċertezzi, u fejn baqgħu, jintqal b'mod ċar fir-Rapport Aġġornat dwar l-iSIA.

Konsultazzjoni

15 Saret konsultazzjoni mal-Kunsill Lokali ta' Birżebbuġa waqt it-tħejjija ta' dan l-Aġġornament tal-iSIA. L-iskop ta' din il-konsultazzjoni kien li jkunu identifikati l-punti li l-Kunsill kien jikkonsidra importanti għal-lokalità, u biex l-iSIA jkun mibni fuq informazzjoni tajba.

16 Il-punti li tqajmu mill-Kunsill Lokali jistgħu jinġabru kif ġej:

- Irid ikun hemm immaniġġjar xieraq tal-iskart speċjalment fejn jidħol skart perikoluż;
- Possibbiltà ta' emissjonijiet fl-arja;
- Ħsejjes, speċjalment għar-residenti fl-inħawi Tal-Papa;

- Kontroll xieraq tal-ilma maħmuġ;
- Possibbiltà li jiġru xi inċidenti; u
- Ippjanar xieraq għall-kontinġenzi.

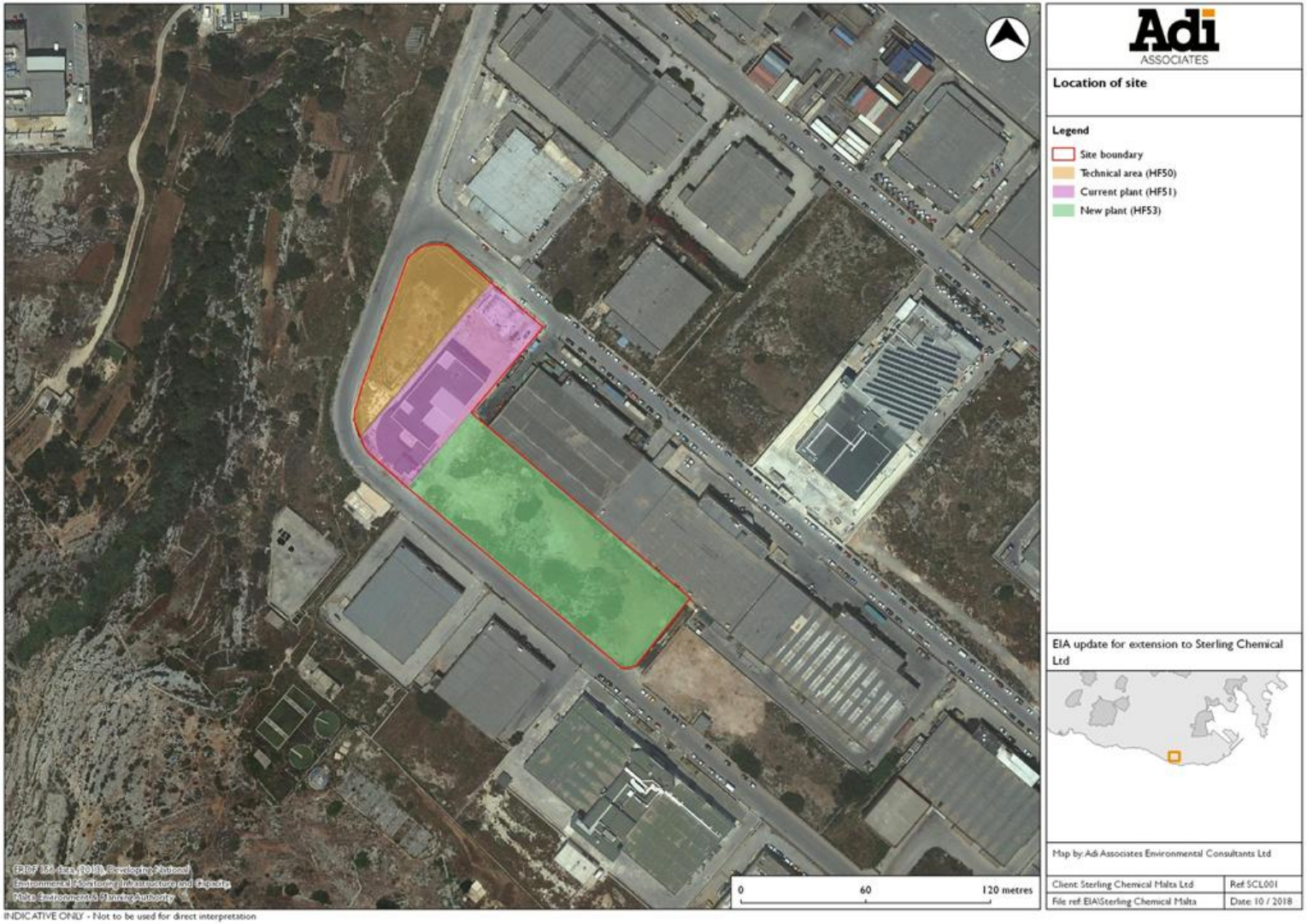
17 Il-Kunsill Lokali talab ukoll li, ladarba jinħareġ il-permess IPPC, jinħatar kumitat ta' monitoraġġ li jkun jinkludi rappreżentanti tal-Kunsill Lokali u l-Applikant biex jiddiskuti problemi operazzjonali li jinqalgħu. Dan qed isir diġà għat-tħaddim tat-Terminali tal-Port Ħieles u skond il-Kunsill Lokali din is-sistema taħdem tajjeb.

Studju tal-Alternattivi

18 Kif spjega l-Applikant, Sterling Chemical Malta għandha bżonn tkabbar il-produzjoni preżenti wara domanda qawwija għal IFA/API mis-suq internazzjonali. L-Applikant jinforma li l-espansjoni ma tistax isseħħ f'sit differenti minn dak tal-operazzjoni preżenti għax dan jirriżulta fid-duplikazzjoni tal-unitajiet operattivi u riżorsi umani. Barra minn hekk, Ħal Far qiegħed qrib ħafna tal-port u ta' area fejn jinsabu numru ta' attivitajiet kimiko-farmaċewtiċi. L-opzjoni zero twassal ukoll għal trasferiment ta' kapital lejn pajjiżi oħrajn. Barra minn dan, billi l-bini tal-area ta' produzzjoni tal-iSkema huwa diġà permess taħt DN/00810/17 u DN/01094/18, l-opzjoni zero tkun tfisser li ma toperax kumpanija farmaċewtika f'dan il-post, b'riżultat li jitħalla bini battal jew wieħed imħaddem għal skopijiet oħra ta' manifattura.

3.32. Il-proċessi u t-teknoloġiji tal-produzzjoni jiġu evalwati fil-fażi tad-disinn, u ottimizzati biex titjieb il-prestazzjoni u jitnaqqsu l-impatti ambjentali, ngħidu aħna billi jitkabbar ir-rendiment tal-produzzjoni, jitbaxxa l-konsum ta' ilma u enerġija, jitnaqqsu l-ħin u l-ispazju meħtieġa għall-produzzjoni, waqt li jibqgħu irrispettati r-rekwiżiti tal-kwalità tal-prodott.

Fig. 1: Post tal-iSkema



DESKRIZZJONI TAL-ISKEMA

19 L-iSkema tolqot żewġ areas (meded ta' art) li jinsabu maġenb is-sit tal-produzzjoni eżistenti u li Sterling Chemical Malta ħadet mingħand Malta Industrial Parks Ltd (MIP). Is-sit fin-naħa tal-Punent tal-impjant ta' produzzjoni preżenti (HF50) huwa intenzjonat biex jipprovdi faċilitajiet li jissapportjaw iż-żoni tal-produzzjoni, waqt li l-blokk tal-Lvant (HF53) jinvolvi l-faċilità ta' produzzjoni addizzjonali (ara **Fig. 2**).

20 Il-permess DNO maħruġ għall-bini ta' HF53 jippermetti l-użu tal-faċilità għal Riċerka u Żvilupp (R&Ż)/(R&D); ma jippermettix il-proċess ta' industrijalizzazzjoni. Għalhekk fażi 1 tal-proġett tiġbor fiha attivitajiet ta' riċerka biex jiġu żviluppati proċessi sintetiċi innovattivi għat-tħejjija ta' IFA/API ġodda għall-Kumpanija. Din l-attività diġà nbdiet fil-laboratorji li hemm bħalissa u data preliminari fuq l-ewwel prodotti hija diġà disponibbli.

21 Ladarba joħroġ il-permess tal-ippjanar, it-tħaddim tal-iSkema mistenni jibda fl-2020. Fażi 2 taħseb għall-operazzjoni ta' linji ta' produzzjoni, maħżen għall-materja prima, estensjoni għall-maħżen estern għal materjal li jaqbad malajr u area teknika, faċiltajiet fejn jinħażen skart bil-kwantità, ħanut għal xogħol ta' manutenzjoni, tliet laboratorji, u uffiċċji ġodda u parkeġġ taħt l-art.

Area tal-Punent

22 Din l-area tkun tikkonsisti fi:

- Maħżen Estern għal Prodotti li Jaqbdu;
- Area għal Tank tal-LPG; u
- Area għall-Ħażna ta' Skart bil-Kwantità.

23 Il-**Maħżen Estern għal Prodotti li Jaqbdu** hija medda ta' ħażna esterna mgħottija fejn jinħażnu kemm materja prima, kif ukoll skart li jista' jaqbad li jirriżulta mill-proċessi tal-produzzjoni. Il-maħżen għal materjal li jaqbad li hemm bħalissa fil-blokk HF51 ikun estiż daqsxejn lejn il-Lvant, u lejn il-Punent sal-blokk HF50. L-estensjoni tkun tikkonsisti f'barrakki ġodda mgħottijin, ta' kostruzzjoni simili għal ta' dawk li hemm diġà. L-area tal-ħażna qiegħda għall-beraħ, iżda mkenna b'saqaf tal-azzar biex l-iskart ikun protett mill-elementi. L-areas tal-ħażna fuq kull ġenb għandhom taħthom ilqugħ tal-konkrit konness ma' tank żgħir, waqt li l-area ċentrali (użata għat-tagħbija u l-ħatt) hija wkoll miksija bil-konkrit, u mxaqilba lejn kanal fl-art f'nofs kull barrakka; dan il-kanal fl-art jagħti għal tank taħt l-art sewwasew barra kull maħżen.

24 L-**area ta' frazzjonament** tikkonsisti f'kamra fejn il-materja prima tintiżen skont ir-rekwiżiti tal-produzzjoni; il-frazzjonament isir qabel tibda l-produzzjoni. F'din l-area jsir l-użin tas-solidi u l-frazzjonament (tferrigħ f'kontenituri iżgħar) tal-materja prima u s-solventi.

25 L-**Area għall-Ħażna ta' Skart bil-Kwantità** tinsab faċċata tal-area tal-ħażna tal-iskart u materja prima li jaqbdu u maġenb il-faċilità li hemm bħalissa (Malta 1).

Id-disinn jaħseb għal faċilità fuq żewġ livelli, jiġifieri:

- Mili tat-tankijiet tal-ħażna fil-livell tal-produzzjoni +99.95 m (Livell 01); u
- Mili tat-tankijiet ISO fil-livell +97.30 m b'aċċess mal-livell tat-triq (Livell 0).

26 Total ta' 9 tankijiet x 10,000 litru u tank 1 x 15,000 l ikunu installati f'Livell 0 bħala tankijiet tal-ħażna għal skart perikoluż likwidu qabel ma jiġi ttrasferit bil-pompi għal ġot-tank ISO rispettiv sakemm ikun esportat. It-tankijiet ikunu tat-tip vertikali b'qoxra waħda u saqaf fiss.

27 It-tankijiet jitqiegħdu ġo lqugħ tal-konkrit rinfurzat b'volum ta' iżolament ta' 110% tad-daqs tat-tank ta' ġo fih. It-tankijiet ikunu mgħottijin b'materjal inert li jixbah it-tafal.

28 Il-livell iżjed baxx fil-livell +97.30 m tal-area tal-ħażna (Livell 0) jkun fih:

- Spazju għall-parkeġġ ta' 4 tankijiet ISO fis-sit. Din iż-żona tkun mgħottija u protetta mix-xita. L-ispazji ta' parkeġġ għat-tankijiet ISO li jkunu interkonnessi ma' bitħa fejn dawn jistgħu jimmanuvraw, ikunu konnessi mat-triq permezz ta' xatba wiesgħa 10.5 m;
- Żona bi lqugħ ta' iżolament apposta għat-tħaddim tal-pompi; u
- Area ta' ħażna interna għal impjant u tagħmir.

29 Iż-żona tal-iskart tkun tinkludi wkoll ġibjun għall-ilma maħmuġ u ġibjun għall-ilma tat-tindif, li jesgħu 15,000 litru kull wieħed.

30 Tliet ġeneraturi jkunu inklużi wkoll f'Livell 0, biex jintużaw f'każ li tinqata' l-provvista tal-mains.

31 F'Livell 0, jiġi pprovdut ukoll spazju fejn jitqiegħdu għadd ta' skips mgħottijin għall-iskart, għall-ħażna ta' skart isseparat mhux ta' periklu (p.eż. Skart riċiklabbli, organiku, u muniċipali) li jirriżulta minn attivitajiet fis-sit mhux marbuta mal-produzzjoni.

32 **Area tat-Tank għal-LPG**: bħalissa mal-konfini tal-Lvant taż-żona tal-produzzjoni hemm 3 tankijiet vertikali tal-LPG, kull wieħed jesa' 2,250 litru. Hemm applikazzjoni ta' ippjanar pendenti (PA/03638/18) biex dawn it-tankijiet jinbidlu ma' tank għal ħażna bil-kwantità fil-parti tal-Punent tas-sit**.** Jiġi installat tank tal-LPG ta' 25,000 litru li jieħu post dawn it-tliet tankijiet tal-LPG; dan jaqdi ż-żewġ ġeneraturi tal-fwar eżistenti tal-iSkema u ġeneratur tal-fwar ieħor li jiżdied fil-futur.

Area tal-Lvant

33 Il-parti tal-Lvant tal-iSkema (HF53) fiha bini ta' erba' sulari għall-produzzjoni addizzjonali ta' IFA/API. Din il-parti tal-iSkema fiha medda ta' madwar 4,500 m^2. Dan l-impjant jiġi konness mal-faċilità eżistenti ta' Sterling b'kuritur ta' servizz f'livell 0 fiż-żona tal-

parkeġġ. Il-bini l-ġdid ikun fih:

- Unitá tal-Produzzjoni (sinteżi bir-reatturi, filtri, ċentrifugi u sistemi awżiljari);
- Unità Clean Room (tnixxif, tħin u ppakkjar);
- Unità tas-Servizz (ġeneratur tal-fwar, vacuum, ilma, arja kompressa);
- Unità Awżiljari (teknoloġiji u miżuri għall-ambjent, protezzjoni tas-saħħa u sigurtà bħal filter tal-karbonju, scrubber, ġibjun/tank għall-ilma tat-tindif, ġibjun/tank għall-ilma għat-tifi tan-nar); u
- Parkeġġ taħt l-art.

34 Il-proċess tal-manifattura fl-estensjoni jkun bħal dak li jsir bħalissa fi Sterling Chemical – is-sinteżi ta' ingredjenti farmaċewtiċi attivi (IFA/API), inklużi sterojdi, mediċinali anti-infjammatorji, ormoni (kontraċettivi) u mediċinali kontra l-kanċer. Dawn il-farmaċewtiċi huma tipikament ikkonsidrati IFA/API ta' qawwa għolja. Il-lista ta' IFA/API prodotti tinbidel minn żmien għal ieħor bħala riżultat tal-attivitajiet ta' riċerka u żvilupp.

35 Il-kapaċitajiet produttivi ta' Sterling Chemical Malta joktru bis-saħħa taż-żieda ta' erba' linji ġodda ta' produzzjoni u linja oħra ta' R&Ż/R&D fis-sit il-ġdid HF53.

Aċċess, Traffiku u Parkeġġ

36 Bħalissa hemm parkeġġ għall-karozzi f'Livell 0 b'daħla minn taħt ir-reception area eżistenti. Hemm ippjanat parkeġġ ieħor f'Livell 0 in-naħa tal-Lvant tal-iSkema (HF53). Dan il-parkeġġ jesa' 36 vettura u jkun apposta għall-impjegati. Il-ħaddiema jkunu jistgħu jaslu fil-lobby tal-iSkema permezz ta' taraġ u/jew lift konnessi mal-area tal-parkeġġ.

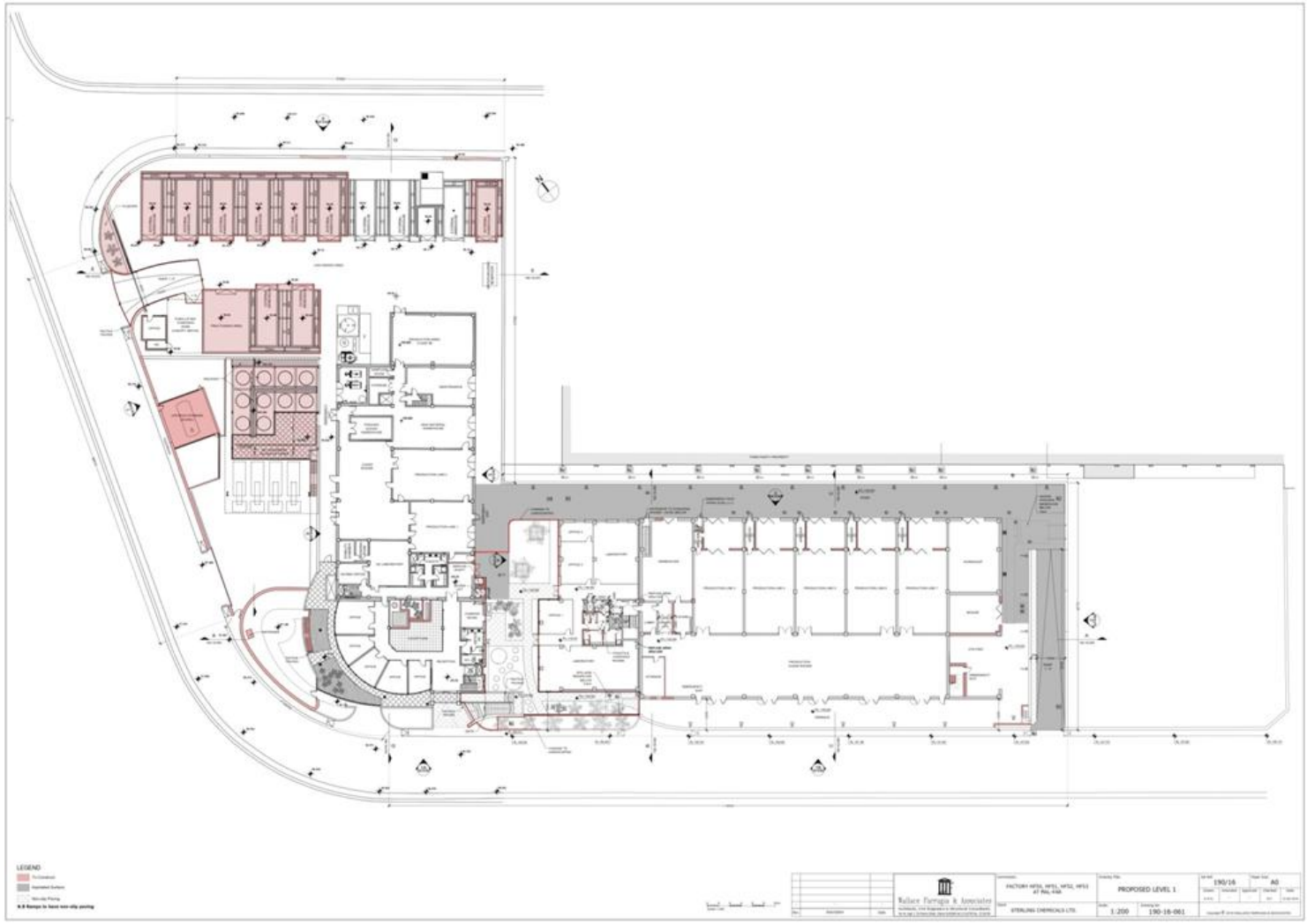
37 Aċċess għall-vetturi kbar inklużi dawk għat-tqassim tal-merkanzija għall-materja prima u l-ġbir tal-iskart isir minn aċċess apposta għalihom matul in-naħa tat-Tramuntana. L-aċċess mhux pubbliku u s-sigurtà tiegħu tkun protetta permezz ta' żewġ xatbiet.

38 Billi l-iSkema tkun konnessa mal-operazzjoni eżistenti ta' Sterling Chemical Malta, l-aċċess għall-ħaddiema u mistednin ikun mid-daħla prinċipali fin-naħa tan-Nofsinhar tal-iSkema. Il-lobby eżistenti sservi wkoll bħala aċċess/reception area għall-iSkema .

Servizzi

39 Malta Industrial Parks Ltd (MIP) – sid taż-Żona Industrijali – ikkonfermat lill-Applikant li ż-Żona Industrijali ta' Ħal Far għandha pprovduti s-servizzi kollha meħtieġa, inklużi sistema tad-drenaġġ u sistema ta' provvista ta' dawl u ilma. Dawn is-servizzi huma kollha taħt l-art u għandhom il-kapaċità li jassorbu d-domanda tal-iSkema.

Fig. 2: Livell 1 tal-iSkema kif propost



Kostruzzjoni tal-iSkema

40 Billi l-bini li sa jilqa' fih l-iSkema diġà nbena, fil-fatt mhux sa jkun hemm perjodu estensiv ta' kostruzzjoni; HF53 tkun trid tiġi konnessa mal-eżistenti HF51. L-imħażen esterni aktarx jinbnew bħala mħażen għal użu ġenerali permezz tal-proċedura DNO u b'hekk ikun hemm kostruzzjoni minima fuq is-sit ta' HF50 jekk ikun hemm applikazzjoni għal żvilupp sħiħ.

Tħaddim tal-iSkema

41 Sterling Chemical bħalissa timpjega 90 ħaddiem. Billi l-proċessi tal-produzzjoni ma jinbdewx kollha fl-istess ħin imma f'fażijiet, huwa meqjus li fl-ewwel fażi jkunu impjegati 10 persuni oħra u fit-tieni fażi jiżdiedu 30 persuna oħra. Huwa stmat li l-għadd totali ta' ħaddiema jkun 130. L-iSkema topera mit-Tnejn sal-Ġimgħa għal 24 siegħa kuljum (fi 3 xiftijiet).

42 Għalkemm it-tipi ta' skart li toħloq l-iSkema huma l-istess bħal dawk li diġà jirriżultaw mill-operazzjonijiet preżenti ta' Sterling Chemical, il-kwantitajiet ta' skart iġġenerati fis-sena jikbru. Ta' min jinnota li t-tipi u l-kwantitajiet ta' skart li jinħoloq ivarjaw, billi jiddependu ħafna mill-attivitajiet tal-produzzjoni.

43 Emissjonijiet mir-reatturi l-ġodda fil-linji ta' produzzjoni l-ġodda jiġu indirizzati lejn scrubber ġdid. Bħalma jsir fil-każ tar-reatturi eżistenti, kull reattur ikun mqabbda ma' heat exchanger biex fwar organiċi jkunu kkondensati; il-linja sħiħa ta' reatturi hija wkoll mqabbda ma' heat exchanger ieħor akbar, u wara l-fwar jiġu trattati ġo filtru tal-karbonju u l-iscrubber.

44 Sa jkunu introdotti wkoll tliet punti ta' emissjoni ġodda li jkopru l-ventilazzjoni ġenerali mil-linji ta' produzzjoni eżistenti u dawk ġodda u mħażen għall-materja prima.

45 L-iSkema tinkludi wkoll ġeneratur tal-fwar ġdid, tliet ġeneraturi ġodda tal-elettriċità għall-emerġenzi, u żewġ torrijiet tat-tkessiħ (cooling towers) ġodda.

IMPATTI AMBJENTALI IMPORTANTI U MITIGAZZJONI

46 L-impatti mbassrin tal-iSkema kienu studjati qasam qasam. L-impatti potenzjali identifikati waqt l-istudju kellhom x'jaqsmu mal-ġeo-ambjent u l-ekoloġija u huma deskritti hawn taħt.

Ġeo-Ambjent

47 L-impatt tal-operazzjoni tal-iSkema fuq riżorsi idroġeoloġiċi huwa meqjus insinjifikanti minħabba l-miżuri mitigatorji estensivi li hemm mibnijin fl-iSkema.

Ekoloġija

48 L-impatt fuq il-flora u l-fawna 'l barra mis-sit tal-iSkema jitqies bejn żgħir u mhux sinjifikanti fejn jidħlu ħsejjes u tniġġis mid-dawl u impatti minn materjal li jixxerred jew joqtor. L-impatt potenzjali f'każ ta' nirien kbar jitqies bejn żgħir u kbir minħabba l-possibbiltà li joħroġ materjal imniġġes ma' dak li jkun intuża għat-tifi tan-nar.

Mitigazzjoni

49 Fejn huwa xieraq, kienu rrakkomandati miżuri ta' mitigazzjoni u dawn huma deskritti fl-aħħar tal-**Kapitli 3** u **4** tar-Rapport Aġġornat tal-iSIA. Ikun xieraq, u huwa rrakkomandat, li jingħata kas ta' dawn il-miżuri ta' mitigazzjoni fil-kundizzjonijiet ta' kull permess ta' żvilupp li jista' joħroġ.

50 Diversi miżuri ta' mitigazzjoni inbnew fil-kostruzzjoni tal-iSkema inklużi:

- Saff tal-konkrit impermeabbli fil-qiegħ, b'kisja ta' reżina epossidika (epoxy resin) mal-art fiż-żona tal-produzzjoni l-ġdida u maħżen ġdid għall-materja prima;
- Kanali (Gutters) fiż-żona tal-produzzjoni l-ġdida u l-maħżen tal-materja prima li jagħtu għal ġibjun ta' 74 m^3 miksi bil-konkrit u li jiġbor fih ilma tal-ħasil;
- Saff ta' konkrit impermeabbli fil-qiegħ, b'madum u ħalib tat-tikħil reżistenti għall-aċidu fil-laboratorji;
- Tixrid mil-laboratorji jinġabar f'kanali fl-art u jiġi indirizzat lejn il-ġibjun ta' 74 m^3 li jiġbor fih ilma tal-ħasil;
- Kanali mad-dawra taż-żona ta' trasferiment li jagħtu għall-ġibjun tal-ilma tal-ħasil;
- L-imħażen esterni għal prodotti li jaqbdu huma mgħottijin u għandhom taħthom ilqugħ tal-konkrit u l-area ċentrali hija miksija bil-konkrit, imxaqilba lejn kanal f'nofs l-art li jagħti għal tank taħt l-art b' valv magħluq;
- Fiż-żona fejn jinħażen l-iskart, tankijiet kbar qegħdin ġo lqugħ ta' konkrit rinfurzat, li jfur għal ġol-ġibjun;
- Iż-żoni tat-tankijiet kbar, tat-trasferiment u tat-tankijiet ISO huma mgħottijin biex ma jitħalliex jidħol ilma tax-xita;
- Iż-żona tat-tankijiet ISO, iż-żona tat-trasferiment u l-qiegħa tal-imħażen huma miksijin bil-konkrit, u mxaqilbin lejn il-ġibjun;
- Id-diesel jinħażen f'tankijiet b'żewġ qoxriet li jesgħu <1,000 L l-wieħed u jinħażen fuq il-konkrit;
- It-tqegħid u d-disinn tat-tank tal-LPG jaqbel mal-Kodiċi ta' Prattika ta' Malta u tar-Renju Unit u huwa ċċertifikat skont ir-Regolamenti tat-Tagħmir ta' Pressjoni (Pressure Equipment Regulations);
- It-tank tal-LPG qiegħed taħt l-art, protett minn ħsara mekkanika u b'ħitan jifilħu għan-nar fuq żewġ naħiet;
- Ventilazzjoni naturali tat-tank il-kbir tal-LPG, tal-maħżen estern tal-materjal li jaqbad u t-tankijiet il-kbar tal-iskart (biex ma jinġemax il-gass);
- Ġeneraturi mħaddmin bid-diesel (id-diesel ma

jaqbadx); u

- Ġibjun tal-ilma tax-xita b'600 m^3 ta' ilma (150 minuta) apposta għat-tifi tan-nar; arloġġ tal-livell bl-allarm.

51 Miżuri oħrajn ta' mitigazzjoni marbuta mal-operazzjoni tal-iSkema jinkludu:

- Likwidu li joħroġ mill-produzzjoni/ħasil tat-tagħmir tal-produzzjoni jinġabar f'IBCs[2];
- Ċertifikazzjoni tas-sistemi ta' konteniment kif mitlub mill-permess IPPC;
- Kits għat-tixrid u taħriġ tal-impjegati;
- Materja prima tkun tipikament maħżuna f'tankijiet jew IBCs, kull wieħed mhux ikbar minn 1 m^3;
- Ebda ħażna, trasferimenti taħt superviżjoni mill-impjegati;
- Skart tal-laboratorju li jkun iġġenerat fi kwantitajiiet relattivament akbar jinġabar f'kontenituri biex jintrema;
- Ħażna ta' solvent skartat fuq materjal prefabbrikat ta' konteniment;
- Tneħħija regolari ta' skart;
- Skart trasferit għand trasportaturi liċenzjati għall-ġarr tal-iskart li għandhom konteniment xieraq, u taħt is-superviżjoni ta' staff tal-iSkema;
- Kejl tal-livell u allarm ta' livell għoli mat-tankijiet fiż-żona tal-ħażna tal-iskart;
- Trasferiment tal-iskart taħt superviżjoni;
- Trasferiment ta' skart illoggjat biex jiżgura li ma jkunx hemm telf waqt it-trasferimenti;
- Ċertifikazzjoni tas-sistemi ta' konteniment kif mitlub mill-permess IPPC;
- Kits tat-tixrid għal tixrid żgħir, u taħriġ tal-ħaddiema;
- Emissjonijiet mir-reatturi trattati f'heat exchangers, filtru tal-karbonju u scrubber;
- Blowdown tanks biex irażżnu l-emissjonijiet f'każ ta' emerġenza; emissjonijiet mill-blowdown tanks indirizzati lejn l-iscrubber;
- Tintuża estrazzjoni lokali jekk jinfetħu l-kontenituri; l-emissjonijiet indirizzati lejn l-iscrubber;
- Monitoraġġ tal-emissjonijiet kif mitlub mill-permess IPPC; u
- Manutenzjoni tas-sistemi tat-tbaxxija (abatement systems).

.

[2] IBCs huma intermediate bulk containers, b'volum tipiku ta' 1 m^3.

EXTENSION TO STERLING CHEMICAL LTD

ENVIRONMENTAL IMPACT ASSESSMENT UPDATE

Version 1: March 2019

Report Reference:

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Quality Assurance

Extension to Sterling Chemical Ltd in Ħal Far
Environmental Impact Assessment Update
March 2019

Report for: **Sterling Chemical Malta Ltd**

Revision Schedule

Rev	Date	Details	Written by:	Checked by:	Approved by:
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CONSULTANTS' DECLARATION

Adi Associates Environmental Consultants Ltd, Malta, prepared this Environmental Impact Assessment Report.

The *Environmental Impact Assessment Regulations, 2017* (S.L. 549.46), Section 17(3) requires that each of the Consultants declares that they have no conflict of interest that may affect any aspect covered by the Regulations.

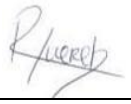
We declare that Adi Associates Environmental Consultants Ltd has no conflict of interest in the proposed development.

Adi Associates Environmental Consultants Ltd has coordinated this EIA and has provided technical input to specific parts of the EIA Update Report as identified in the previous page.

Adi Associates Environmental Consultants Ltd takes responsibility for statements and conclusions contained in the parts of the report prepared directly by its staff. However, statements made and conclusions drawn by the independent sub-consultants who prepared the baseline studies reproduced in the Technical Appendices and which informed the Environmental Impact Assessment Update Report remain the responsibility of the individual sub-consultants.

Adrian Mallia
Managing Director, Adi Associates

The undersigned consultants and contributors hereby declare that they carried out the study or part thereof as identified on page v, that they have no personal or financial interest in the proposed development, and that they are not in any way associated with any individual, company, association or grouping that has any direct or indirect personal, professional or financial interest in the proposed development.

Rachel Xuereb	
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1. INTRODUCTION

1.1. This Environmental Impact Assessment (EIA) Update describes a proposal for the extension to the existing Sterling Chemical Factory in Ħal Far (see **Figure 1.1**).

1.2. The project is proposed by Sterling Chemical Ltd, hereinafter referred to as 'the Applicant'; the project is hereinafter referred to as 'the Scheme'.

BACKGROUND TO THE SCHEME

1.3. The current factory of Sterling Chemical (Factory HF51) was permitted under PA/04236/08. An Environmental Impact Statement was prepared for an additional floor to the existing management area, an extension of the production area, and the installation of a manufacturing plant for the production of active pharmaceutical ingredients (APIs), and the installation of storage tanks for liquid petroleum gas (LPG).

1.4. Additionally, PA/03033/12 was approved in June 2013 for the installation of an LPG bulk storage facility. There is a pending planning application PA/03638/18 for the *removal of existing LPG storage approved in PA/03033/12, and installation of new 25,000 Litre LPG storage tank, including all required ancillary equipment and pipework, minor amendments to parking area layout and construction of new boundary wall*.

1.5. For various extensions, including in sites adjacent to the permitted factory a number of Development Notification Orders (DNOs) were issued as follows:

- For HF51: DN/00624/16 & DN/00617/17;
- HF50: DN/00023/17; and
- HF53: DN/00810/17 & DN/01094/18.

1.6. Under these DNOs, the Applicant is authorised to build the extension but not to operate from it. A Full Development Permit application will be submitted to the Planning Authority (PA) in order for Sterling Chemical to be able to operate from the proposed extensions to the current factory.

1.7. The current premises of Sterling Chemical Malta Ltd also have an Integrated Pollution Prevention and Control (IPPC) permit (IP 0001/14/A and IP 0001/14/B). It is understood that this permit will be updated to take into account the Scheme.

1.8. Although a planning application for the extension of the Sterling Chemical has not yet been submitted a Project Description Statement (PDS) for the development was submitted in October 2017 and the Environment and Resources Authority (ERA) determined that the development required an Environmental Impact Statement

Update (EIS Update) in accordance the *Environmental Impact Assessment Regulations, 2007* (Legal Notice 114 of 2007 as amended, S.L.549.46)[1]. ERA stated:

> *Without prejudice to the final recommendation and decision on this proposal, you are hereby being requested to update the EIA carried out in relation to proposal assessed through EA 00057/12. The EIA Update shall include all the necessary updates for the studies undertaken in the certified EIS of 2014.*

PURPOSE OF THE EIA UPDATE

1.9. The purpose of this EIA Update is to present the findings of the EIA. EIA is the process of systematically assessing the likely significant environmental impacts of development proposals. EIA also ensures that the significance of these impacts, and the scope for reducing them, is clearly understood by both the public and by ERA and the PA, before a decision is made on whether or not the development should be approved.

STRUCTURE OF THE EIA UPDATE

1.10. Following this introduction, the EIA Update is structured as follows:

- **Chapter 2**: Description of Site and Scheme
- **Chapter 3**: Geo-Environment
- **Chapter 4**: Ecology
- **Chapter 5**: Key Impacts, Cumulative Effects and Summary of Mitigation

1.11. The Environmental Risk Assessment is presented as **Volume 2** of the EIA Update.

1.12. The EIA Update includes a Non-Technical Summary in Maltese and English.

PRESENTATION OF THE EIA UPDATE

1.13. The EIA Update is divided into three main parts. Following this chapter, Part 1 comprises **Chapter 2**, which describes the Scheme and its surroundings.

1.14. Part 2 comprises **Chapter 3** and **Chapter 4,** which describe the potential environmental impacts of the Scheme in relation to geo-environment and ecology. Each of these chapters is structured as follows:

- Introduction: identifying the key issues and how the chapter relates to the ToR;

[1] It is noted that the 2007 Regulations have since been revised. The new *Environmental Impact Assessment*

- Assessment methodology: summarising the methods used in undertaking the baseline survey and the assessment;
- Existing conditions: a summary of the existing baseline situation and trends irrespective of the Scheme; and
- Assessment of impacts associated with the Scheme, identifying:
    - Potential impacts: a summary of the potential impacts of the Scheme;
    - Prediction and significance of impacts: a prediction of the likely impacts of the Scheme against the baseline situation and an assessment of the significance of the impacts;
    - Mitigation measures: a summary of potential mitigation / enhancement measures, to offset any identified adverse impacts;
    - Residual impacts: a clear statement of those impacts that still have an impact following mitigation, indicating the significance of the residual impact; and
    - Summary: a summary table of the impacts.

1.15. Part 3 comprises **Chapter 5**, which addresses the cumulative effects of the Scheme, and summarises the impacts and proposed mitigation measures.

METHODOLOGY

1.16. The current guidance on the EIA process is contained in the *Environmental Impact Assessment (EIA) Regulations, 2017* (Legal Notice 412 of 2017**,** S.L. 549.46). As mentioned, the Environment and Resources Authority (ERA) has directed that an Environmental Impact Assessment (EIA) Update be prepared for Scheme.

1.17. Based on the Terms of Reference issued for the EIA for the construction of Sterling Chemical (PA 04236/08), it was considered that the following sections of the EIA would be updated:

- Description of the Scheme due to the proposed additions to the approved development;
- Geo-environment due to the potential impacts on the hydrogeology from the operation of the Scheme;
- Ecology due to the potential impacts from the operation of the Scheme; and
- Environmental Risk Assessment due to the intensification of the use on the Site.

1.18. In agreement with ERA the Cultural Heritage Study was scoped out because, as explained above and in **Chapter 2**, the Scheme buildings have already been built and the nearest cultural heritage feature is across the road from the Site and would not

be affected by the operation of the Scheme.

EIA Approach

1.19. Good practice necessitates that EIA be treated as an iterative process, rather than a one-off, post-design environmental appraisal. In this way, the findings from the EIA can be fed into the design process, resulting in a more environmentally sensitive project. This approach was adopted for this EIA.

1.20. Baseline surveys for the specialist EIA topics were undertaken by the Consultants based on the Area of Influence (A of I) agreed with ERA for each topic area. A detailed assessment of the Scheme's impact on the features present within the A of I was undertaken, and any potential environmental benefits of the Scheme were identified.

Significance of Impacts

1.21. Assessment of the significance of impacts arising from a development is a key stage in the EIA process. This judgement is critical in informing the decision-making process. However, defining significance can be difficult. In general terms, environmental significance involves assessing the amount of change to the environment perceived to be acceptable to the community (Sippe, 1999).

1.22. The following criteria were used in this EIA to assess the significance of an impact:

- Type of impact (adverse / beneficial);
- Extent and magnitude of impact;
- Direct or indirect impact;
- Duration of impact (short term / long term; permanent / temporary);
- Comparison with legal requirements, policies and standards;
- Sensitivity of receptor (residential dwellings, hotels, recreational areas, etc.);
- Probability of impact occurring (certain, likely, uncertain, unlikely, remote);
- Reversibility of impact;
- Scope for mitigation / enhancement (very good, good, none); and
- Residual impacts.

1.23. Using these criteria, the significance of the impacts arising from the Scheme was categorised in the EPS, as follows:

- **Not significant**;

- **Minor significance**;
- **Moderate significance** (as relevant); and
- **Major significance**.

1.24. Definitions of the meaning of the 'significance categories' above in relation to each topic area are included in the topic area chapters (see **Chapter 3** and **Chapter 4** of the EIA Update Report). However, in general terms, if an impact is 'not significant', it is considered to be environmentally acceptable; an impact of 'minor significance' refers to an impact that is considered to be manageable; an impact of 'moderate significance' refers to an impact that may be manageable in certain circumstances, although is likely to require implementation of suitable mitigation measures; and an impact of 'major significance' refers to an impact that is considered to be environmentally damaging such as to require that the Scheme be redesigned, or that mitigation measures be put in place to minimise the impact.

1.25. The EIA Update includes an assessment of the significance of predicted impacts and, following the implementation of any proposed mitigation measures, the significance of any residual impacts. A summary of the identified significant impacts is included in **Chapter 5**. The recommended mitigation measures, and the residual impacts, are described in respect of each topic area, at the end of the relevant chapter (see **Chapter 3** and **Chapter 4**).

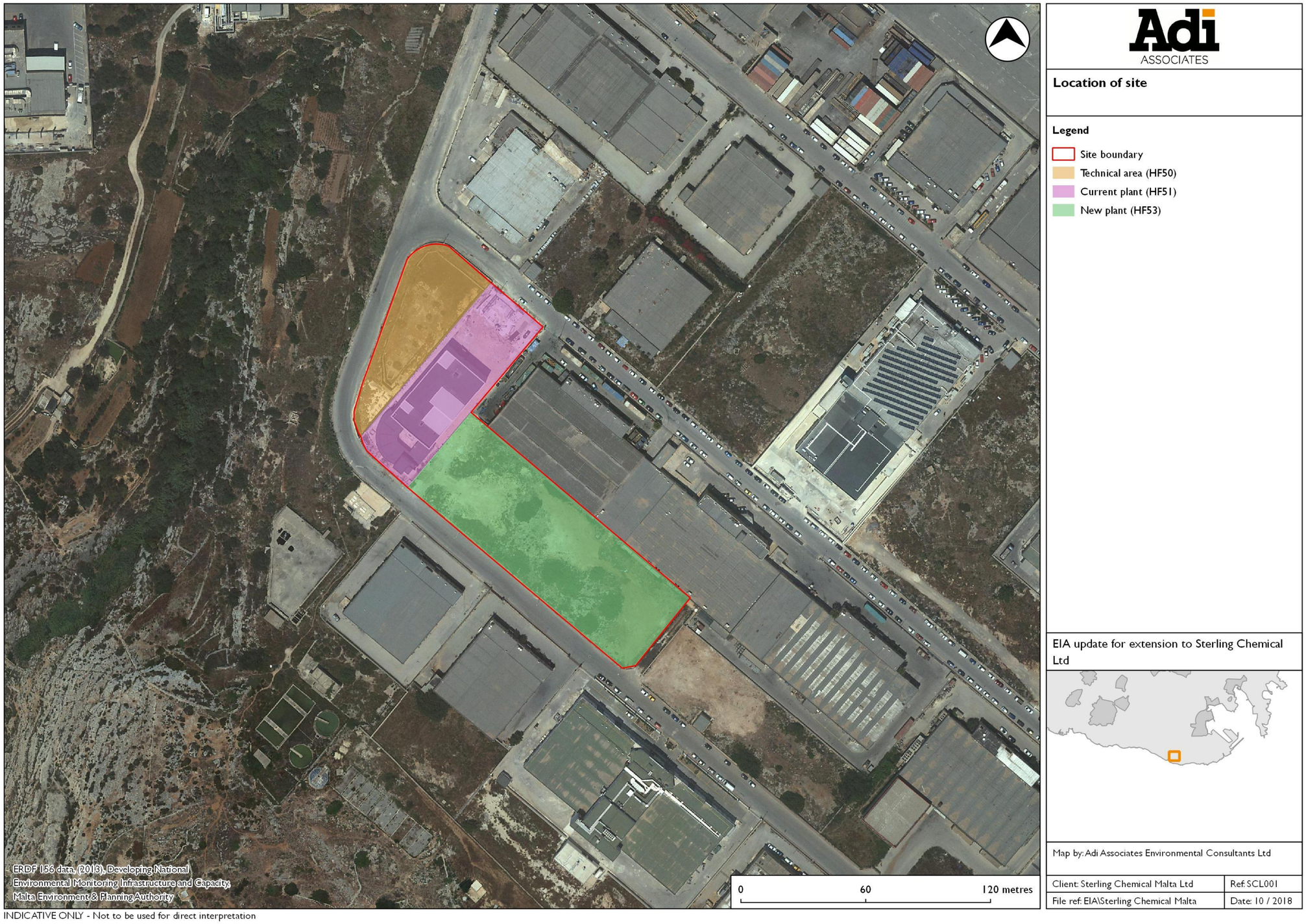
UNCERTAINTY

1.26. The EIA process is designed to enable good decision-making based on the best possible information about the environmental implications of a development. There will always be some uncertainty in predicting potential impacts, as to the exact nature and scale of the impacts. This arises through shortcomings in information, doubts, or lack of certainty on the likelihood that an incidence would occur, and / or due to the limitations of the prediction process itself. Where uncertainties have arisen, and where they remain, this is clearly stated in the EIA Update.

CONSULTATION

1.27. There has been consultation with ERA throughout the EIA process. Additionally, there was consultation with Birżebbuġa Local Council. The purpose of this consultation was to identify the issues the Council considered important in respect of the locality, and to inform the EIA. The Council was invited to meet with the Consultants. The feedback from this consultation is described in **Chapter 2** of the EIA Update.

Figure 1.1: Location of the Scheme Site



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2. DESCRIPTION OF SCHEME AND SITE

INTRODUCTION

2.1. This chapter describes the Scheme and the Scheme Site and the surroundings.

OBJECTIVES OF THE SCHEME

2.2. As described by the Applicant, the main objective of the Scheme is to consolidate further Sterling Chemical's production in Malta by expanding the production capabilities of the Scheme.

CONSULTATION

2.3. As mentioned in **Chapter 1**, there was consultation with the Birżebbuġa Local Council during the preparation of this EIA Update. The purpose of this consultation was to identify the issues that the Council considered important for the locality, and to inform the EIA.

2.4. The issues identified by the Local Council can be summarised as follows:

- Proper waste management should be carried out especially with regards to hazardous waste;
- Potential emissions to air;
- Noise emissions especially for the residents of Tal-Papa;
- Proper containment of wastewater;
- Potential accidents that could happen; and
- Proper contingency planning.

2.5. The Local Council also requested that once the IPPC permit is issued there would be a monitoring committee set up including Local Council representatives and the Applicant to discuss emerging operational issues. This is already done for the Malta Freeport Terminals operation and according to the Local Council this system works well.

ALTERNATIVES

2.6. As explained by the Applicant, Sterling Chemical Malta needs to expand the current production capacity Scheme following the strong API demand by the international market. The Applicant advises that the expansion cannot be achieved in a different site from the current operation as this would result in duplicating operating units and human resources. In addition Ħal Far is in close proximity to the port and an area where a number of chemical-pharmaceutical activities are located. The zero option

would result in the transfer of capital to other countries. Furthermore, as the building of the Scheme production area is already permitted under DN/00810/17 and DN/01094/18, the zero option entails not operating a pharmaceutical company within this location, resulting in a vacant building or one that is operated for other manufacturing purposes.

3.32. Production processes and technologies are evaluated at the design phase, and optimised to improve performance and reduce environmental impacts, for instance by increasing production yields, lowering energy and water consumption, reducing production time and space required, while also respecting product quality requirements.

3.33. Examples of the alternative technologies considered and the rationale for selecting a particular technology, including environmental considerations, are presented in **Table 2.1**.

Table 2.1: Alternative technologies considered

Function	Selected solution	Alternative considered	Rationale
Centrifugation	Horizontal peeler centrifuge	Vertical peeler centrifuge	The horizontal peeler centrifuge is more powerful, and results in uniform solid product size distribution, and is also more easily cleaned thoroughly. Its high discharge speed reduces the time taken to accelerate and brake; thus reducing power consumption and wear and tear.
Drying	Static tray dryer	Conical screw vacuum dryer	The static dryer is more energy-efficient and drying is more uniform.
Cleaning reactors	Spray-ball system	Manual injection	The spray-ball system reduces operator exposure and the amount of cleaning solvent used, and removes the risk of fugitive VOC emissions.

3.34. The placement of equipment has also considered environmental impacts and where possible equipment (such as pumps, chillers, and compressors) is being placed inside a building (rather than in an external area or on the roof) to reduce visual and noise impacts, and improve energy efficiency and lifetime of the machinery.

SITE DESCRIPTION

2.7. The Scheme site is located within the Ħal Far Industrial Area.

2.8. The Scheme site has an area of approximately 12,290 m^2. The Scheme site comprises the current premises of Sterling Chemical, including both the administration building as well as the production area. The Scheme site also includes a number of extensions that have been permitted under various Development Notification Orders (DNOs) and Planning Applications and that were being built at the time of writing the EIA Update (see below).

2.9. **Figure 2.2** shows various images of the Scheme site as it is currently. **Figure 2.3** shows the existing site together with any approved or pending DNOs and planning

applications. As shown in **Figure 2.3** the following permits have been issued:

- PA/04236/08 – Construction of factory HF51 – the main Sterling Chemical building and minor amendment to this PA for the construction of warehousing to the north of the existing Sterling Chemical building;
- PA/03033/12 – Installation of LPG Bulk Storage (HF50);
- DN/0023/17 – Extension to the external area and car park to the west of the existing Sterling Chemical building (HF50);
- DN/00617/17 – Extension to offices;
- DN/00624/16 – Extension to HF51 Factory – extension of the production facility to the north of the main Sterling Chemical building; and
- DN/00810/17 and DN/01094/18 – Construction of factory HF53 to the southeast of the existing Sterling Chemical building;

2.10. In addition, there is a pending planning application for the relocation of the LPG storage, amendments to the car park, and construction of the boundary wall (PA/03638/18).

2.11. The site of HF53 (the eastern part of the Scheme) is currently being constructed as per Development Notification Order. The site northwest of the current installation is currently used as a temporary waste storage area. The waste storage area houses existing waste streams already produced by the Scheme, primarily liquid hazardous wastes. Much of the waste is stored on prefabricated containment systems; in addition the ground in this area is laid to fall towards a sump leading to a pipe with a locked valve, opened only to discharge clean rainwater.

Surrounding Uses

2.12. A land use survey was carried out on 6th November 2015 and updated again in October 2018, covering approximately 250 m around the Scheme site. The land uses have been mapped in **Figure 2.4**.

2.13. The predominant land uses in the surrounding area are industrial, predominantly manufacturing activities (including pharmaceutical production, detergent manufacture, production of climate control systems, and printing presses) and storage / warehousing (see **Figure 2.1**).

2.14. There are a number of electricity substations servicing the area, and a transformer plant operated by Enemalta.

2.15. Some cultivated agricultural land is found along both sides of the Wied Żnuber valley, located to the west of the Scheme site.

2.16. There are no residential properties within 250 m of the Scheme site.

Natural and Cultural Designations

2.17. As shown in **Figure 2.5** the Scheme site is adjacent to the coastal cliffs that are designated as an Area of Ecological Importance (AEI), Special Area of Conservation of International Importance under GN112/2007 (Rdumijiet ta' Malta – Rdumijiet tan-Nofsinhar), and a Special Protection Area (Rdumijiet ta' Malta – Wied Moqbol sal-Ponta ta' Bengħisa).

2.18. The area to the west of the Scheme site is designated for archaeology as the area is protected under Government Notice 1082/2009 because of the presence of a Grade 1 protected Wied Żnuber Dolmen (Class A) and the surrounding Buffer Zone.

Figure 2.1: Industrial uses

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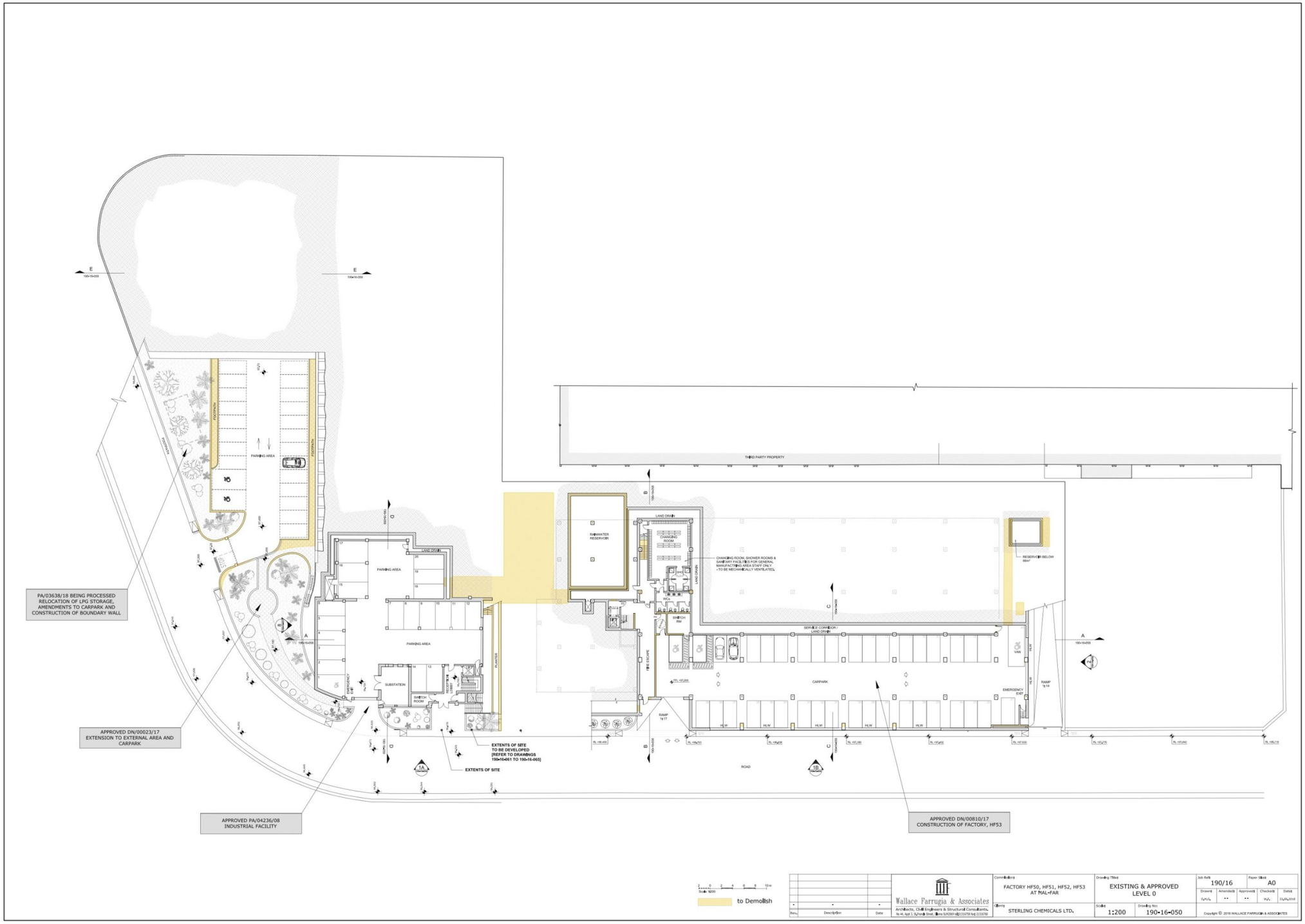
Figure 2.2: Images showing the Scheme Site currently

<table>
<tr><td>  </td><td> 
</td><td>  </td></tr>
<tr><td>Existing Sterling Chemical Factory (HF51)</td><td colspan="2">Ongoing works to construct adjacent unit at Sterling Chemical (HF53)</td></tr>
<tr><td>  </td><td>  </td><td>  </td></tr>
<tr><td>Existing site to the northwest of Sterling Chemical main building (HF50)</td><td colspan="2">Temporary waste storage area</td></tr>
</table>

Figure 2.3: Existing plans showing approved and pending planning applications



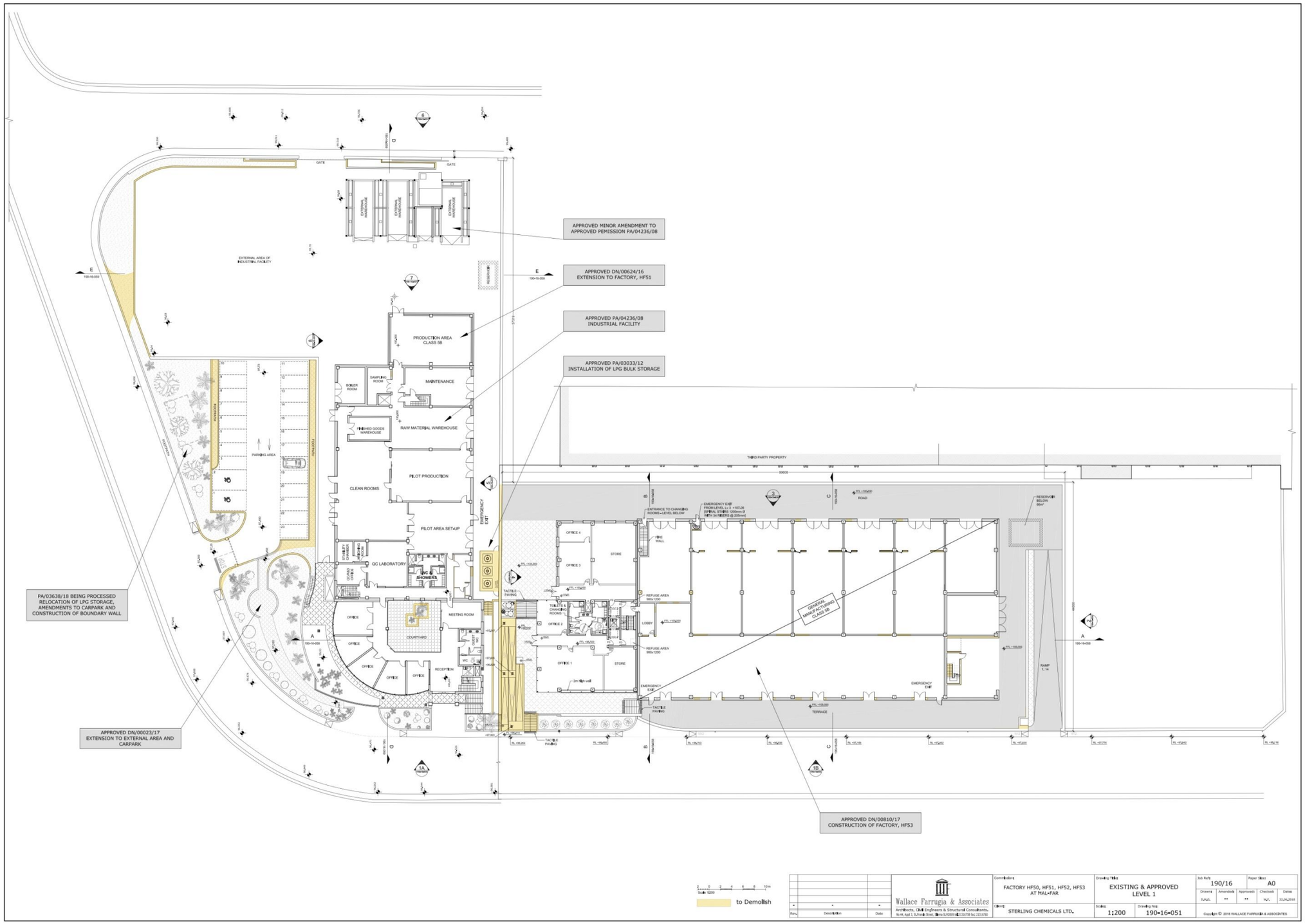

APPROVED MINOR AMENDMENT TO APPROVED PEMISSION PA/04236/08
APPROVED DN/00624/16 EXTENSION TO FACTORY, HF51
APPROVED PA/04236/08 INDUSTRIAL FACILITY
APPROVED PA/03033/12 INSTALLATION OF LPG BULK STORAGE
PA/03638/18 BEING PROCESSED RELOCATION OF LPG STORAGE, AMENDMENTS TO CARPARK AND CONSTRUCTION OF BOUNDARY WALL
APPROVED DN/00023/17 EXTENSION TO EXTERNAL AREA AND CARPARK
APPROVED DN/00810/17 CONSTRUCTION OF FACTORY, HF53
EXTERNAL AREA OF INDUSTRIAL FACILITY
PRODUCTION AREA CLASS 0B
BOILER ROOM
SAMPLING ROOM
MAINTENANCE
FINISHED GOODS WAREHOUSE
RAW MATERIAL WAREHOUSE
CLEAN ROOMS
PILOT PRODUCTION
PILOT AREA SET-UP
QC LABORATORY
OFFICE
COURTYARD
MEETING ROOM
RECEPTION
PARKING AREA
THIRD PARTY PROPERTY
ROAD
GENERAL MANUFACTURING CLASS 2B
TERRACE
RAMP 1; 14
to Demolish
Wallace Farrugia & Associates
Architects, Civil Engineers & Structural Consultants
FACTORY HF50, HF51, HF52, HF53 AT MAL-FAR
STERLING CHEMICALS LTD.
EXISTING & APPROVED LEVEL 1
1:200
190-16-051
190/16
A0

Figure 2.4: Land uses

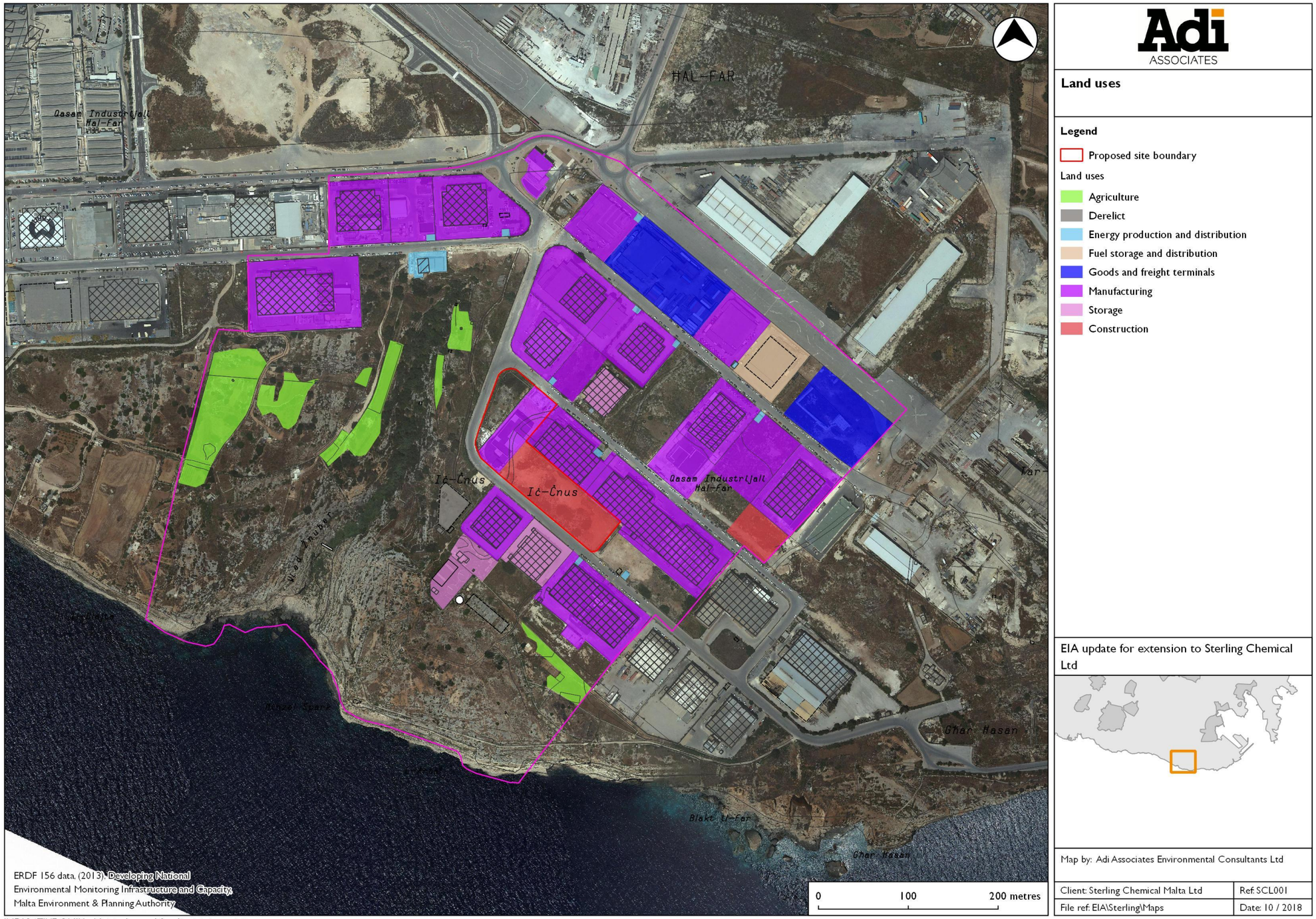


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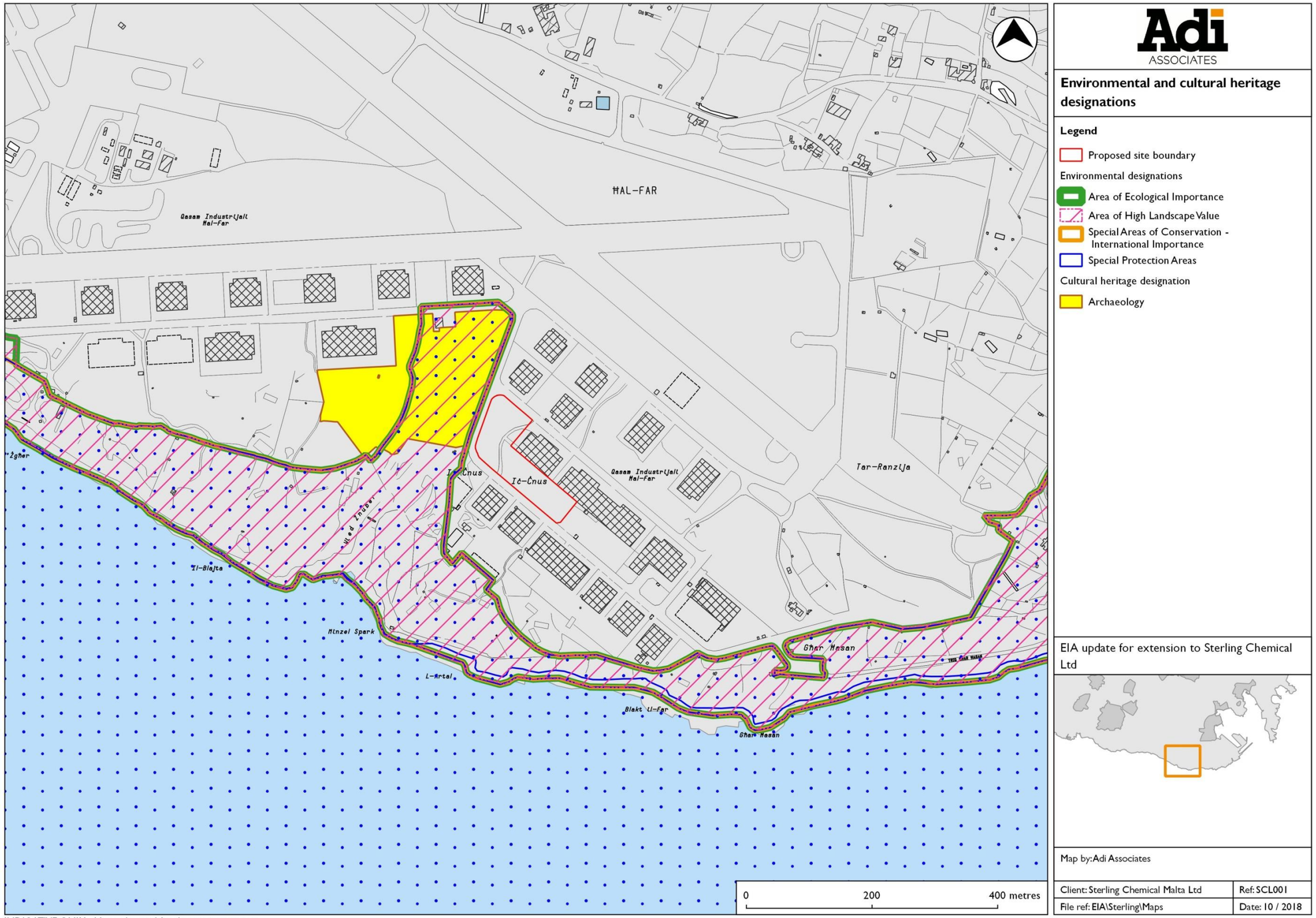
Figure 2.5: Natural and cultural designations around the Site



Adi ASSOCIATES

Environmental and cultural heritage designations

Legend

Proposed site boundary

Environmental designations

Area of Ecological Importance

Area of High Landscape Value

Special Areas of Conservation - International Importance

Special Protection Areas

Cultural heritage designation

Archaeology

EIA update for extension to Sterling Chemical Ltd

Map by: Adi Associates

Client: Sterling Chemical Malta Ltd	Ref: SCL001
File ref: EIA\Sterling\Maps	Date: 10 / 2018

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SCHEME DESCRIPTION

2.19. The Scheme will affect two areas that are located next to the current production site and that Sterling Chemical Malta has taken over from Malta Industrial Parks (MIP). The site to the west of the current production plant is intended to provide facilities to support the production areas, whereas the eastern block will involve the additional production facility.

2.20. The DNO permit issued for the construction of HF53 allows for the facility to be used for Research and Development (R&D); it does not allow for the industrialization process. Therefore phase 1 of the project comprises research activities to develop innovative synthetic processes for the preparation of novel APIs for the Company. This activity has already started in the current laboratories and preliminary data on first products is already available. It is anticipated that in Quarters 3 and 4 of 2019 the R&D scale-up activity will be initiated in HF53 using 4 small (R&D) scale reactors (50 litres to 150 litres capacity). This phase comprises installation of the pilot plant (line 7) as well as utilities (Levels 1 and 3), changing rooms, toilets, offices (at levels 0 and 1) and laboratories (Levels 1 and 2) and a kitchen at Level 2.

2.21. This R&D line 7 will prepare 1 to 2 kg of product in order to perform stability studies, generate data for pharmaceutical documentation (drug master file) and to present a complete technical package to potential future customers.

2.22. Once the planning permit is issued, the Scheme operation is expected to start in 2020. Phase 2 envisages the operation of production lines, a raw materials warehouse, external flammable warehouse and technical area, maintenance workshop, three laboratories, new offices and car park area.

Western Area

2.23. This area will consist of:

- External Flammable Goods Warehouse;
- LPG Tank Area; and
- Bulk Waste Storage Area.

2.24. The **External Flammable Goods Warehouse** is a covered external storage area where both raw materials and flammable waste resulting from the production processes will be stored. The existing external flammable warehouse in the HF51 block will be extended slightly eastwards, and westwards to the HF50 block. The extension will consist of new covered sheds, similar in construction to the ones already in place (**Figure 2.6**). The storage area is open-air but sheltered by a steel roof to protect the waste from the elements. The storage areas on each side are underlain by a concrete bund linked to a small sump, while the central area (used for loading / unloading) is also concreted, and laid to fall towards a floor drain at the centre of each shed; this floor drain leads to an underground sump just outside each

warehouse. The sump will contain lockable valves, which are normally kept closed. In case of a spill, the contents of the sump are pumped out and discarded as hazardous waste. The valves can only be opened by a responsible person, and will only be opened to release clean rainwater if there is no contamination.

2.25. The fractioning area consists of a room where raw materials are weighed according to production requirements; fractioning is done before start of production. In this area weighing of solids and fractioning (decanting into smaller containers) of raw materials and solvents takes place; there is no waste stored in this area and no storage of raw material so the maximum volume held at any one time is of one container such as an IBC (1m^3). The transfer of liquids from one tank to another container would be carried out within a closed circuit in order to prevent the release of VOCs to the atmosphere. This circuit involves membrane pumps (pneumatic pump) with nitrogen and closed circuit connected to process vent which go to carbon / scrubbers. Emissions will only be limited to the time required for the opening or closing of the tanks/drums being filled. The floor is laid to fall towards the floor drain, going towards a sump with a lockable valve.

Figure 2.6: Existing external warehouse for flammable materials

2.26. The **Bulk Waste Storage Area** is located in front of the flammable waste and raw material storage area and adjacent to the current facility (Malta 1). This area has been designed by PTMatic Ltd, the entity responsible for waste management on behalf of Sterling Chemical. The design caters for a facility on two levels, namely:

- Loading of storage tanks at the production level +99.95 (Level 01); and
- Loading of the ISO tanks at level +97.30 with a level access to the road (Level 0).

2.27. As shown in **Figure 2.7**, a total of 9 x 10,000 litre tanks and 1 x 15,000 l tank will be installed at Level 0 as stockage tanks for liquid hazardous waste before it is transferred by pumps into the respective ISO-tank for eventual export. It is envisaged that the waste types to be stored in each tank will be as shown in **Table 2.2**. The tanks will be of the vertical single-skin fixed roof type.

Table 2.2: Waste types

Tanks	EWC code	Description
2 x 10,000 L	16 10 01*	Aqueous liquid wastes containing hazardous substances
2 x 10,000 L	07 07 04*	Other organic solvents, washing liquids and mother liquors
2 x 10,000 L	07 07 03*	Dichloromethane
1 x 10,000 L 1 x 15,000 L	07 07 04*	Acetone
2 x 10,000 L	07 07 04*	Ethanol

2.28. The tanks will be located within reinforced concrete bunds with a bunded volume of 110% the size of the containment tank. The tanks will be covered with inert, clay-like material. The tank farm and the loading area at Level +99.95m (Level 1) will be protected from rainfall by means of a lightweight roof with open sides for ventilation purposes. Waste is transported to the loading area at Level 1 in IBC tanks on palletisers and/or forklift. Waste is then pumped from a designated area into the stockage tanks referred to above.

2.29. Waste transfers will be logged. The bulk tanks will include level gauges, and the levels before and after filling cross-checked against the waste transfer logs to ensure that there are no losses; the level gauges will also help ensure the tanks are not overfilled. High-level alarms will also be installed on the tanks to ensure they are not overfilled.

2.30. The lower level at level +97.30m of the storage area (Level 0) will comprise:

- Space for the parking of 4 ISO tanks on site. This area will be covered and protected from rainfall. The ISO tank parking spaces that will be interconnected with a yard for manoeuvrability, which will be linked to the road through a 10.5 m wide gate;
- A bunded area dedicated to the operation of pumps; and
- An indoor storage area for plant and equipment.

2.31. The waste area will also include a waste water reservoir and a wash water reservoir, with a capacity of 15,000 L each. All the pump areas and loading areas including the ISO-tank loading area at Level +97.30m and the IBC unloading area at +99.95m will be bunded and drained to the underground wash water recovery tank. This tank will be purposely reserved and piped to collect any spillage and wash water from the operations undertaken.

2.32. These underground reservoirs will be constructed in reinforced concrete and suitably lined. The reservoirs will be linked through a controlled overflow in case additional storage capacity is required in the event of an extraordinary occurrence. Generally, the waste water recovery sump will be utilized to recover any solvent in case of rupture of a solvent tank but will be otherwise empty.

2.33. All activity zones and bunded areas will be protected from rainfall. Clean rain water falling onto the covered roof and non-bunded, non technical and non-contaminated areas, will also be directed towards the road. Rainwater in the planter area surrounding the LPG tank will be soaked away.

2.34. Three generators will also be included on Level 0, for use in case of mains supply failure.

2.35. On Level 0, space will also be provided for the inclusion of several covered waste skips, for storage of non-hazardous separated waste (e.g. recyclables, organic, and municipal waste) arising from non-production activities on site.

2.36. **LPG Tank area**: currently at the eastern border of the production area there are 3 LPG vertical tanks, each with a capacity of 2,250 litres. There is a pending planning application (PA/03638/18) to replace these tanks with a bulk storage tank in the western part of the site as shown in **Figure 2.8**. A 25,000 litre LPG tank will be installed to replace these three LPG tanks; this will service the Scheme's two existing steam generators and a future additional steam generator.

2.37. The LPG tank and pipeline have been designed and sited to conform to Maltese and UK Codes of Practice, and the tank will be certified according to the Pressure Equipment Regulations, SL 427.29. The tank will have fire walls on two sides, and meet the requirements for safety distances on the other two sides. The LPG tank is surrounded by walls on each side to reduce the risk of accidental collision. The LPG tank and vaporiser are also located in a well-ventilated area to ensure no build-up of gas.

2.38. Additionally, the boiler rooms are fitted with gas sensors to detect leakage. Activation of the gas sensors will activate quick-closing valves in the boiler rooms, shutting down the release of gas; the valves can also be activated manually. A quick-closing valve will be installed at the vaporiser outlet. Isolating valves will also be installed on the steam generators and outside the boiler rooms.

Eastern Area

2.39. The eastern part of the Scheme (HF53) comprises a four storey building for

additional API production. This part of the Scheme has an area of approximately 4,500 m^2. This plant will be connected to the existing Sterling facility by a level 0 service corridor in the parking area. The new building will comprise:

- Production Unit (synthesis with reactor, filter, centrifuges and auxiliary systems);
- Clean Room Unit (drying, grinding and packaging);
- Service Unit (steam generator, vacuum, water, compressed air);
- Auxiliary Unit (technologies and measures for the environment, health and safety protection such as carbon filter, scrubber, wash water reservoir, fire water reservoir); and
- Underground parking.

2.40. The manufacturing process in the extension will be similar to the one currently carried out at Sterling Chemical - the synthesis of active pharmaceutical ingredients (APIs), including steroids, anti-inflammatory drugs, hormones (contraceptives) and anti-cancer drugs. These pharmaceuticals are typically considered to be high-potency APIs. The list of APIs produced changes from time to time as a result of research and development activities.

2.41. The production capabilities of Sterling Chemical will be increased through the addition of four new production lines and one R&D line in the new HF53 site. The production lines will be commissioned in two phases, as explained previously. However, the processes and abatement systems in all production lines will be similar.

2.42. The new production facilities will follow processes similar to those already authorised and operational in the HF51 site. The equipment installed in these areas will also be similar to the existing ones, and include batch reactors, dryers, centrifuges, distillers, pilot units, and so on. A maximum of 30 full-height reactors will be installed in total, with capacities ranging from 5 L to 12,500 L (typically 2,500 L), depending on the needs of the Scheme. These are described hereunder.

2.43. The new production plant is divided in two areas:

- Production lines; and
- Clean room area.

2.44. Clean rooms handle the finishing of the product (e.g. driers). In this area powders are handled, and also solvents to clean equipment; the floor is covered in vinyl.

2.45. In the Production lines area there are reactors, filters, and centrifuges of varying dimensions and characteristics that will be used depending on the chemical synthesis provided in the production programme. The reactors are likely to have a capacity varying from 1,000 litres to 10,000 litres. In this area there are a number of mobile filters of variable capacity type that are positioned below the reactors in order to

connect them to a fixed line and to separate the liquid mass from the solid.

2.46. The finished product comes out wet from the production lines, where it is dried in static dryers. The active ingredient is dried up to the point that it almost ready for the packaging (the final part of the process is cleaning and the de-lumping by the warehouse).

2.47. The production cycle begins with the preparation of the raw material in the warehouse (as described below). Once the necessary checks are carried out, the raw materials are brought by the production operators to the reactors and near the loading lines. Solid state raw materials are loaded by opening the top hatch of the reactor found on the upper floor (mezzanine in each line). The fluid load takes place from the bottom of the reactor by an unmovable line and by pumping from the tank. The loading system is a closed circuit one and the vapours that could develop are diverted to the abatement systems (vapour condenser, scrubber, and activated carbon filter).

2.48. The operations that are carried out in the reactor vary depending on the final product required; however, the initial activity typically involves the mixing and homogenization of the mass and chemical transformation by setting the reaction chamber conditions (temperature, humidity, reaction rate, pressure) and by addition of other substances. During the synthesis, at the end of the transformation, it may also be necessary to transfer the product from reactor to reactor; for example, in the case of liquid / liquid separations and to extract the mother liquors from the reagent mass.

2.49. A further separation between reaction products occurs through the heating of the mixture and resultant distillation. The products present in the mixture have different boiling points that are reached in the cylindrical shaped distillation column characterised by a temperature gradient.

2.50. Once the transformation is complete, the next step is filtration or centrifugation. In the case of filtration, all the filters are wheeled, so they are positioned near the bottom valve of the reactor and connected by a flexible hose. This operation is carried out in a closed circuit. The filter retains the solid in the upper basket and lets the liquid flow. At the end of the operation, the filter cover is opened and the solid is removed by inserting it into polyethylene bags and then into aluminium drums. These are tagged and brought to the warehouse for the process control analysis to verify the "purity" of the intermediate or the quality of the finished product.

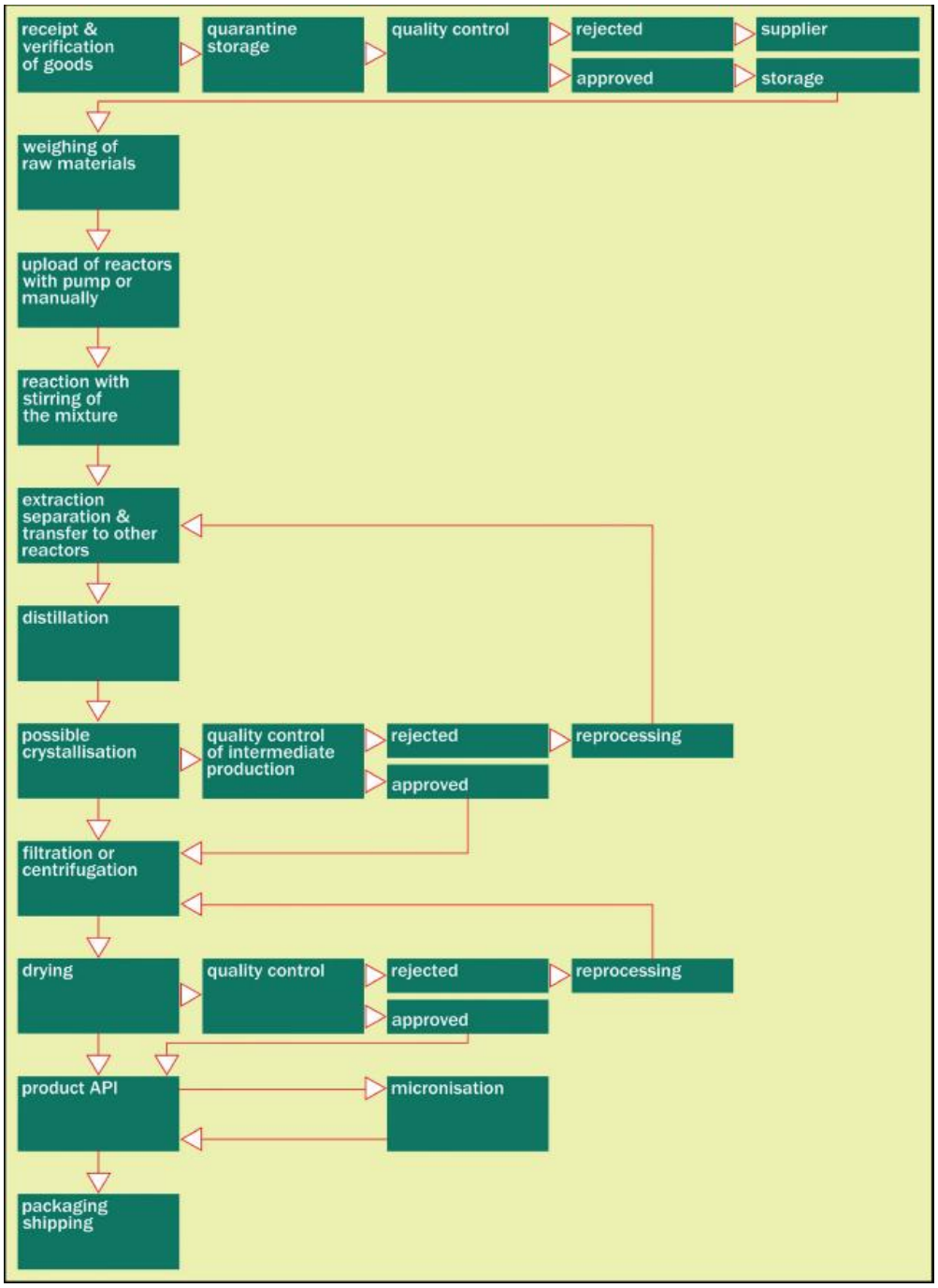
2.51. In case of centrifugation (a different liquid / solid separation operation), the reactor that hosts the mass is connected to the fixed line of the centrifuge located in the finishing area. The spin speed is set electronically and the solid remains in the basket while the liquid is conveyed into collection tanks and then, beyond a certain level of overflow, into an IBC to be discarded. Once the centrifugation is complete, the hatch is opened and the product is manually discharged. The latter goes into bags, then in labelled drums and to the finished products warehouse.

2.52. Following release from the control laboratories, the product becomes the starting point for the next synthesis step (in case of intermediates); or, in the case of a finished product, it is brought to the drying rooms, loaded on the shelves and inserted into the dryer. After the drying process, in the case of a finished product, it can either be stored in the designated room awaiting sale, or, in the case of a product already sold, the required quantity is weighed and brought to the packaging room. From here it is led to the main warehouse where the outer packaging is labelled and the product packed.

2.53. **Figure 2.7** summarises the production processes occurring at the Scheme.

2.54. An indicative list of raw materials used in the production of APIs, as well as the APIs produced / planned to be produced by the Scheme is included in below. This list is quite extensive, to cover the possibility of production of a range of products. It may also need to be updated from time to time as a result of refinement of existing processes, and the production of new categories of APIs (subject to prior ERA authorisation as required). In this case, however, the existing storage arrangements described in this EIA are expected to be retained.

Figure 2.7: API production flow diagram



2.55. Plant cleaning is a delicate operation due to the type of product that Sterling Chemical produces and the materials that are used in cleaning. The cleaning phase involves two aspects:

- Plant cleaning, a process which varies according to the materials that would have been used and the time of execution; and
- Cleaning validation, which involves the certification of the quality of the work.

2.56. Plant cleaning is specific process that utilizes different materials. Generally the reactors are cleaned using a solvent. In order to prevent emissions into the working environment during solvent suction operations, localised and general air extraction are activated. Each reactor is equipped with two suction hoods, one located in the cargo area and the other in the unloading area. The system captures the polluting agent (liquid, solid, or steam) directly at the point where it is produced providing adequate protection for the operator. The operations involve initially cleaning the dripper balloons of the reactor with potable water which is then discharged through the bottom valve into portable tanks. Following this, the solvent is loaded and the exhaust valves opened and the content poured in the dripper balloon for washing the drip line. The mass is stirred by heating through the use of hot water in the jacket that surrounds the reactor. The mass is then cooled down to ambient temperature and the contents of the reactor and collecting balloons discharged into portable cisterns that host the non-chlorinated organic solvents and sent for disposal as hazardous waste. The cleaning operation is repeated.

2.57. The filter and centrifuge are cleaned by transferring the mass used in the last line reactor / crystallizer to the filter or to the centrifuge inerted with nitrogen. The mass of the solvent is then centrifuged and loaded into portable tanks and assigned the corresponding EWC code (070703 and 070704*). The filter and centrifuge is cleaned using lint-free cloth wipes impregnated with solvent used to clean the production line and discarded as hazardous waste.

2.58. Cleaning activities are carried out for both tools used in the reclamation, such as shells, tubes, liquid samples, and anything else that would have been used. Validation would involve the collection of buffers or samples of the rinse liquid after reclamation, for each type of tool in use for three consecutive batches of production.

2.59. As for the plant, validation refers to checking the effectiveness of cleaning carried out in three consecutive batches of production. The maximum limit of acceptable residual would be calculated based on the daily therapeutic dose, as the active pharmaceutical products have a very low toxicity but a very high activity. All reclamation operations must be carried out within one week from the end of the use of the equipment and tools and would be valid for one month. After this time, and before using such equipment, it would be necessary to repeat the clean-up operation corresponding to the last work performed. The water required for the cleaning operations would be sourced from the mains water supply network (treated using a water softening system on site).

2.60. The proposed facility also includes three laboratories at Level 1. Small-scale quantities of chemicals are stored in the laboratories (in 1 to 2.5 litre bottles). Three offices are located near the laboratories in the central part of the Scheme.

2.61. Adjacent to the laboratory is a warehouse (double height) with a loading / unloading area. The warehouse is divided into four different storage functions for the storage of raw materials, finished product, sampling / weighing room; and packing room. In the raw materials warehouse the raw materials are positioned on platforms depending on their use in the production process – heavier goods are placed at the bottom while goods to be analyzed by the Quality Control Laboratory must be placed in a "quarantine area" and then, once approved, transferred to the "approved area". Rejected goods are transferred to a dedicated area. The raw materials product storage holds drums / containers of solid product on pallets stored in shelves at up to six levels. The finished product storage holds drums / containers of finished solid product on pallets stored in shelves also up to six levels. Sampling / weighing is also performed in this warehouse. In the weighing room raw materials useful for the production, quality control laboratory and for research and development are weighed and dispatched. The area is kept at room temperature, to avoid hot temperatures affecting the product. The packaging room found in the warehouse is for secondary packaging such that the product does not come in direct contact with the packaging material.

2.62. A boiler room and external utility area where scrubbers and charcoal filters are installed for the control of emissions to the atmosphere are also proposed to the east of the HF53 building adjacent to the production area. There are also two collection tanks, one for washing waters or any spilled liquids inside the production area (on plans labelled as water washing reservoir) with a capacity of 74 m^3; the other for rainwater collection with a capacity of 1,032 m^3. This reservoir will be used for irrigation whereas the existing reservoir in HF51 will also be used for fire fighting. There is a third smaller collection tank serving the laboratories, called "spillage reservoir" with a capacity of 5.5 m^3; the latter is located just below the laboratories and overflows to the water washing reservoir. The same building also hosts a staff canteen and parking at level 0 with access via a ramp from the main road.

2.63. In terms of flooring in the production area (HF53), this will be similar to the current production area. All indoor areas will be concreted. In the production areas the floors are made of epoxy resin with stainless steel gutters draining to the wash water reservoir. The storage areas and warehouse floors are made of power-floated concrete with surface hardener whereas the laboratories have floors covered in tiles that are acid resistant and with acid resistant grout. The utilities area is concreted and all roads are overlain with tarmac.

2.64. The utilities area is in the open and comprises the following:

- A new scrubber;
- Blow down tanks – maximum 5 (one for each line);
- Reverse Osmosis plant for the boiler (on level 3) and a water softener; and
- Two new cooling towers that will be installed in different phases of the operation. These will be on the roof of the production clean room.

2.65. In the boiler room, two new boilers are proposed, although they will be commissioned gradually. Boiler exhaust will be at the side of the utilities room.

2.66. **Figure 2.8** to **Figure 2.12** show the floor plan layout at each level and **Figure 2.13** shows the sections.

Figure 2.8: Proposed Level 0

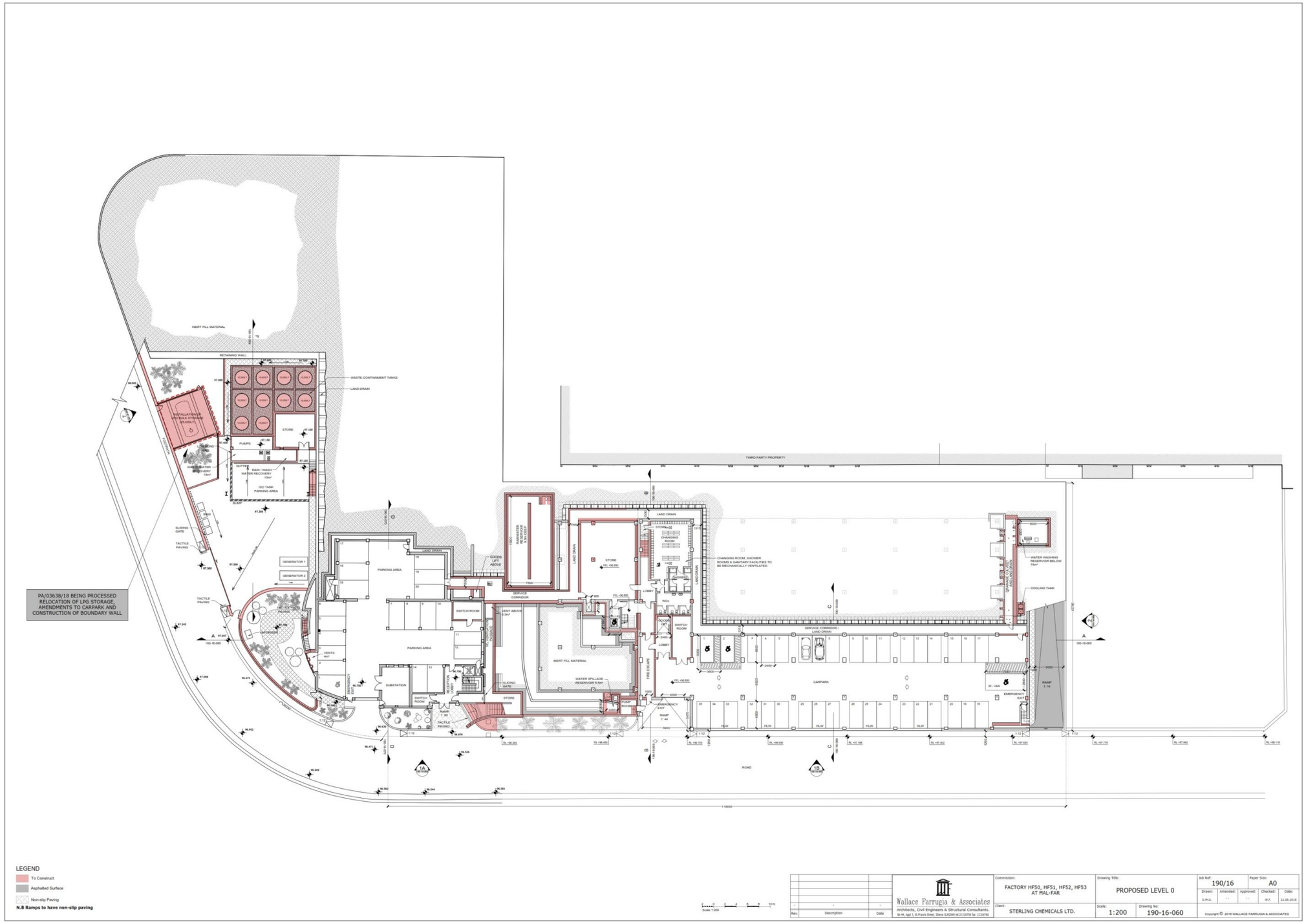


Figure 2.9: Proposed Level 1

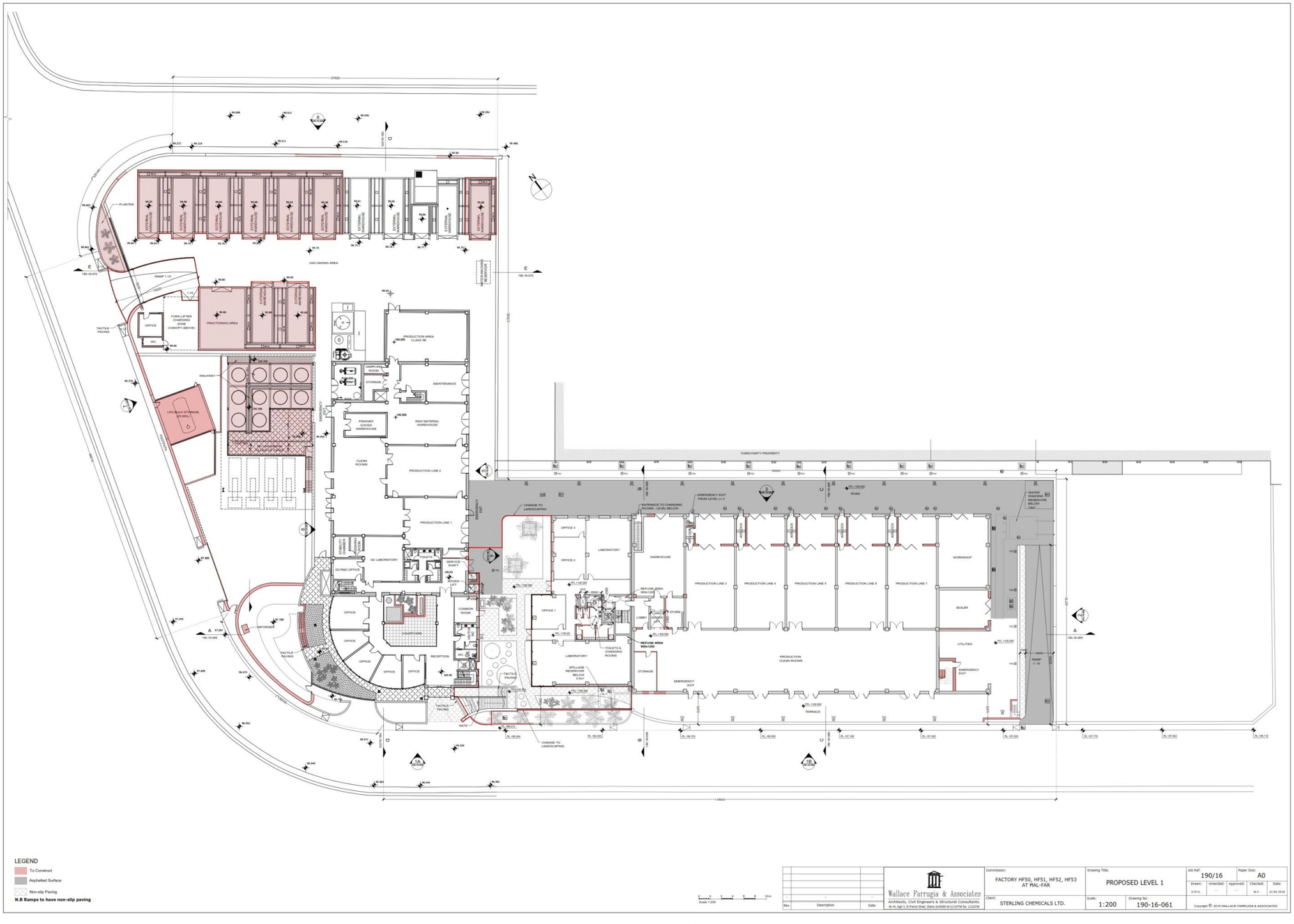
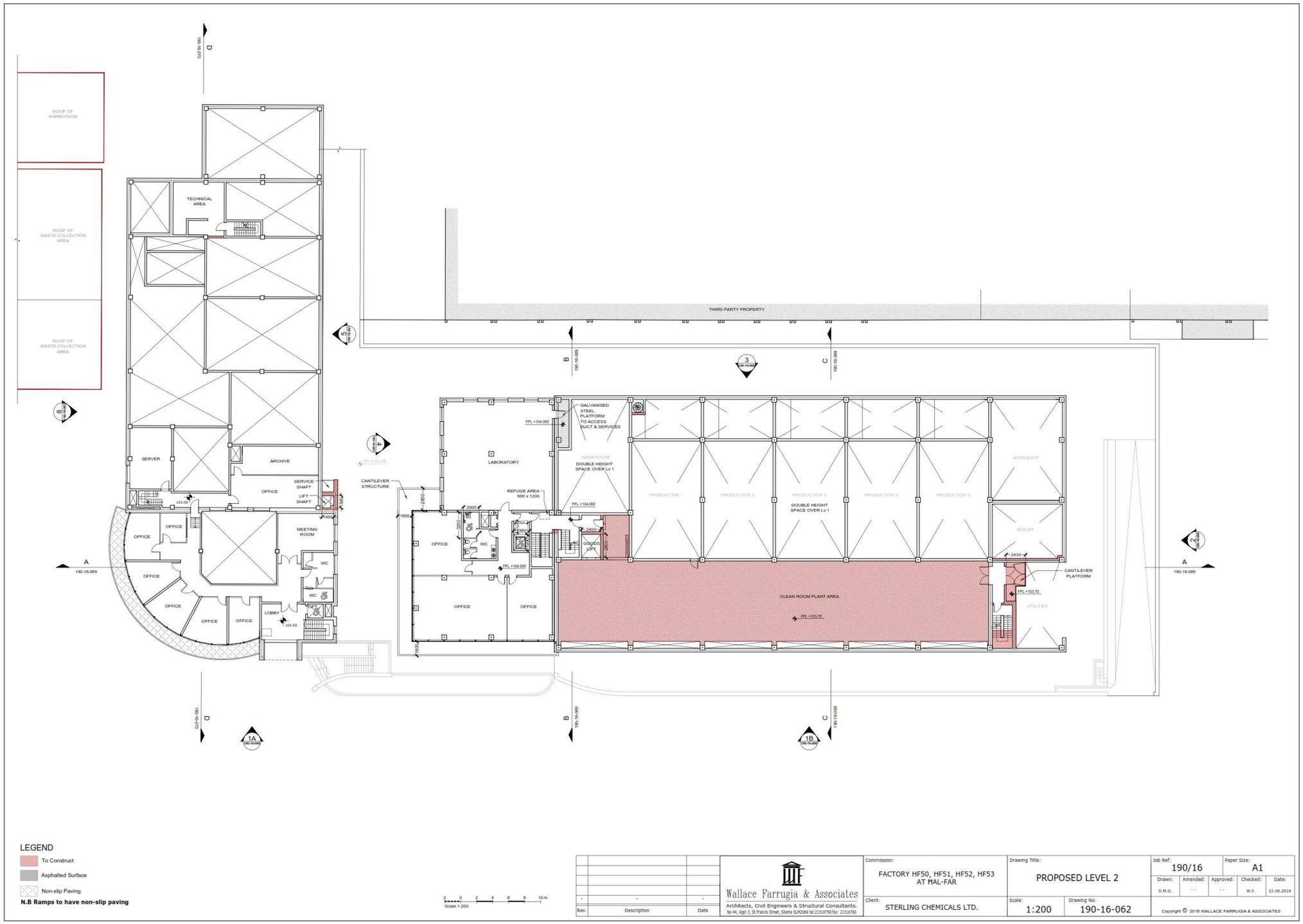


Figure 2.10: Proposed Level 2



LEGEND

- To Construct
- Asphalted Surface
- Non-slip Paving

N.B Ramps to have non-slip paving

Scale 1:200

Rev.	Description	Date
-	-	-

Wallace Farrugia & Associates
Architects, Civil Engineers & Structural Consultants.
No 44, Appt 3, St.Francis Street, Sliema SLM2069 tel:21316758 fax: 21316760

Commission:	FACTORY HF50, HF51, HF52, HF53 AT HAL-FAR
Client:	STERLING CHEMICALS LTD.
Drawing Title:	PROPOSED LEVEL 2
Scale:	1:200
Drawing No:	190-16-062
Job Ref:	190/16
Paper Size:	A1
Drawn:	D.M.G.
Amended:	--
Approved:	--
Checked:	W.F.
Date:	22.06.2018

Figure 2.11: Proposed Level 3

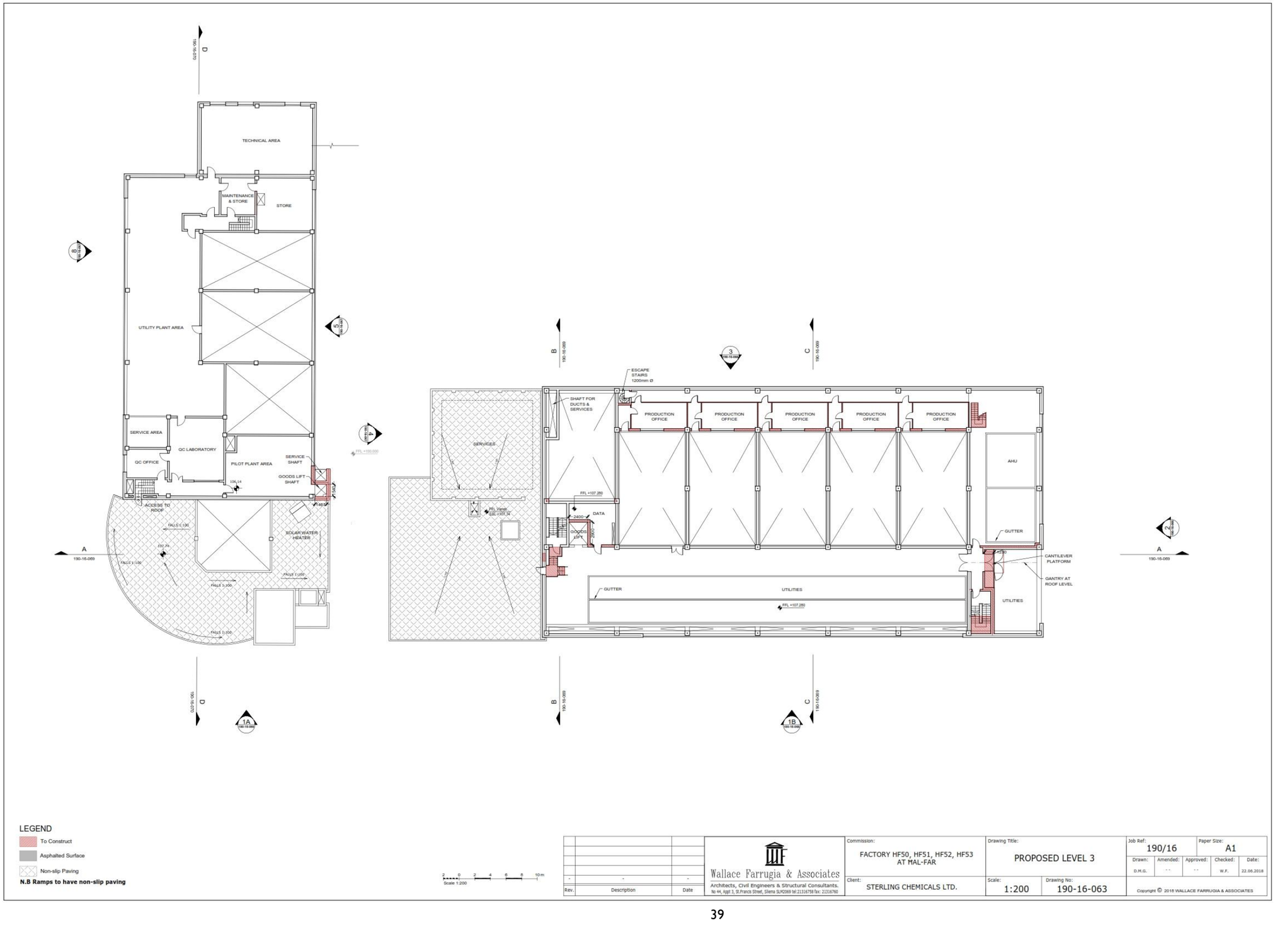


Figure 2.12: Proposed Level 3 (intermediate level)

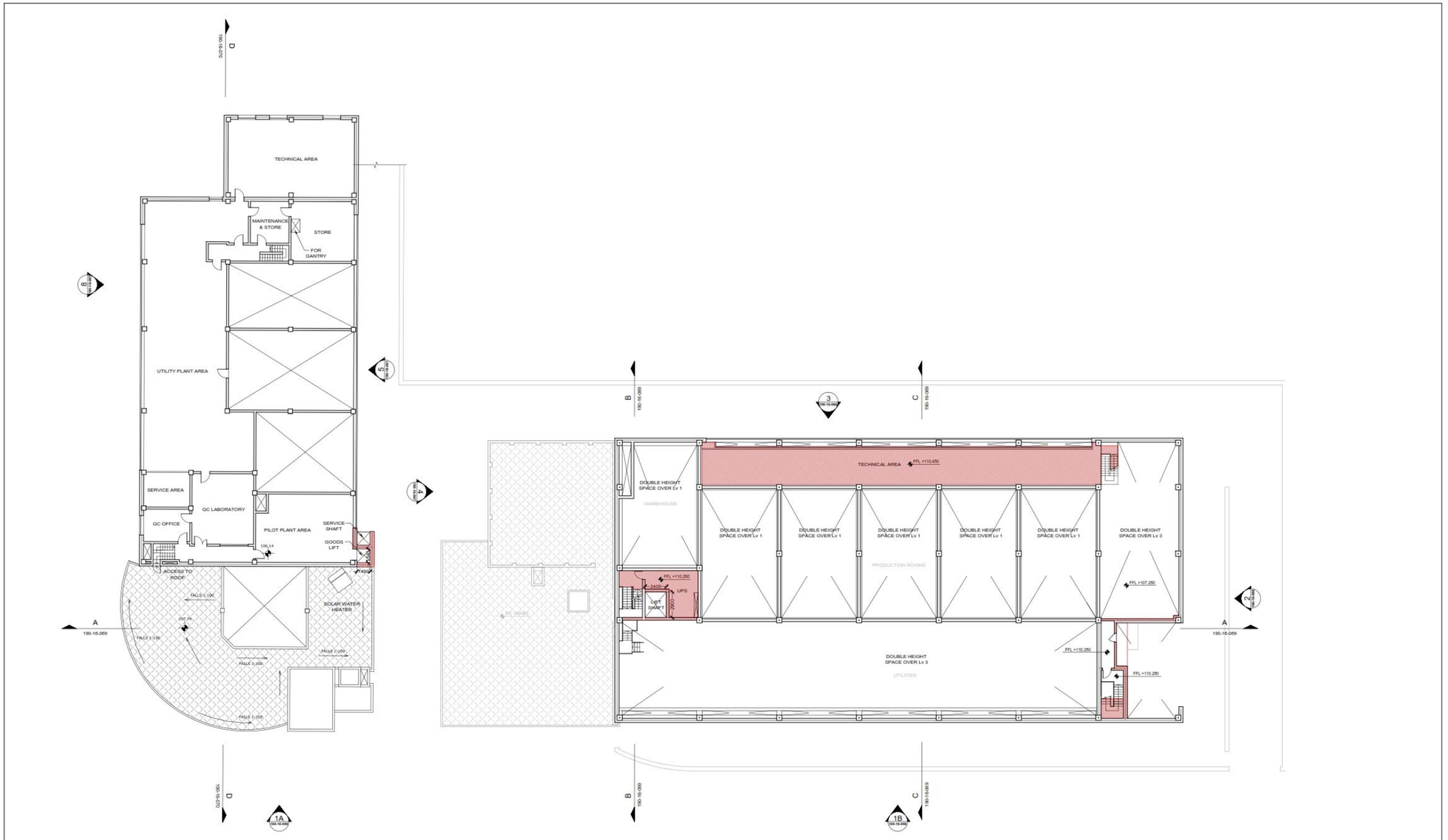
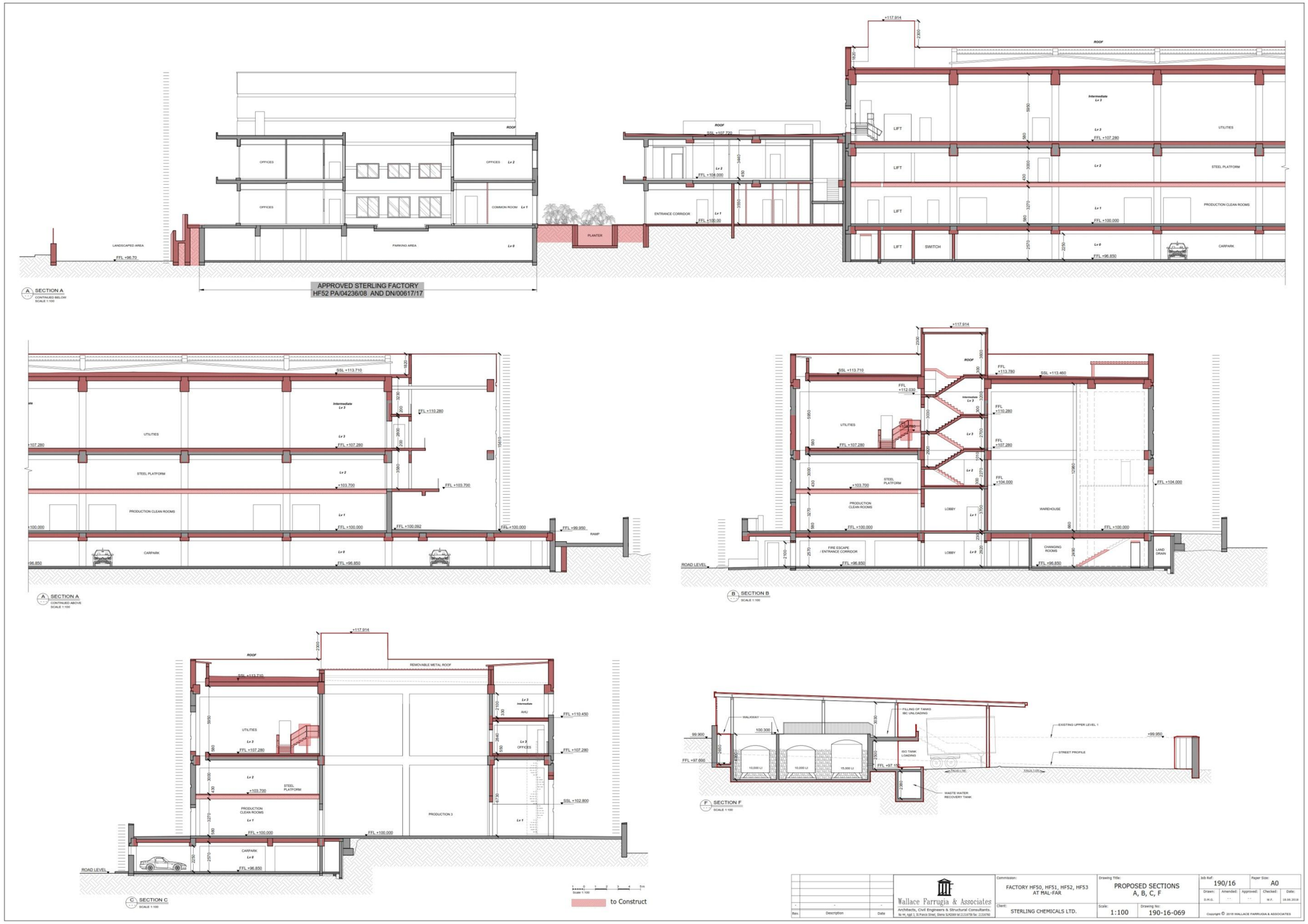
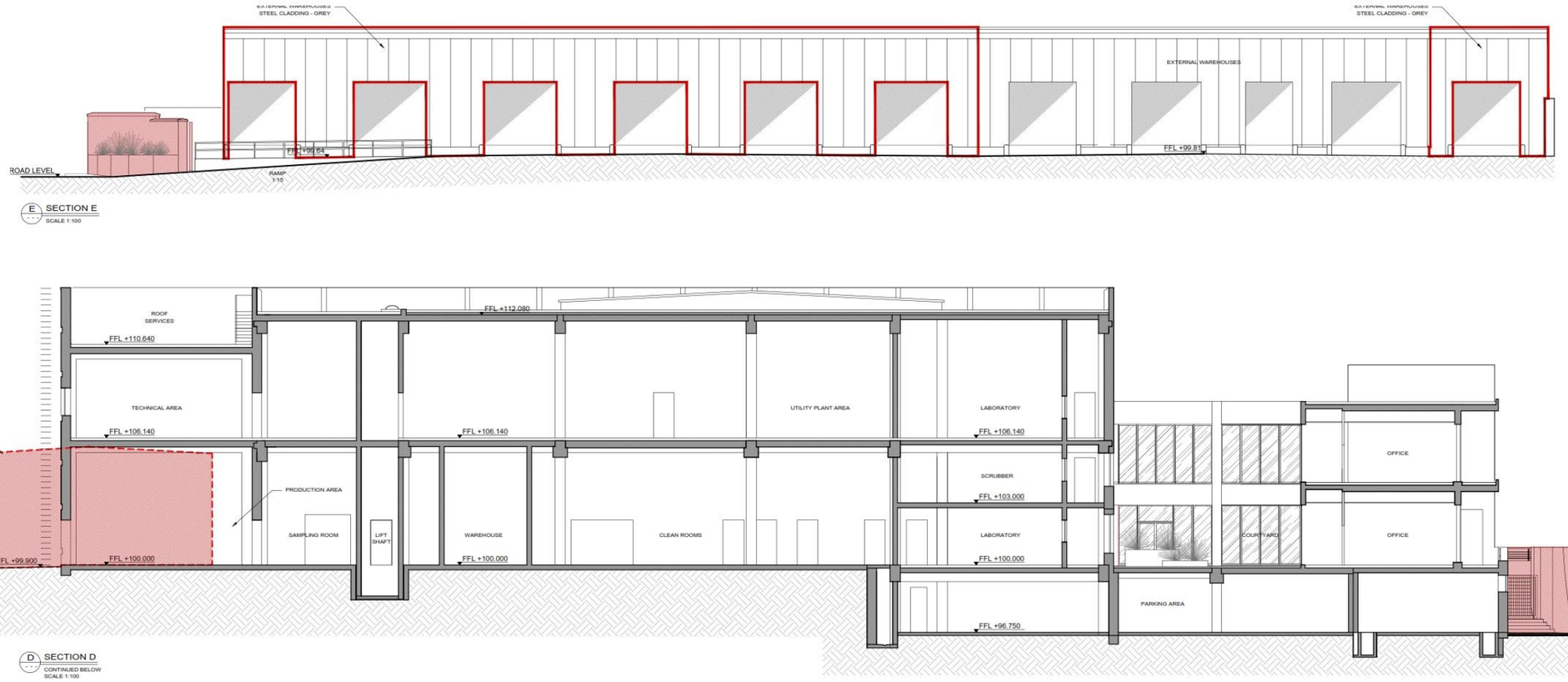


Figure 2.13: Proposed sections




EXTERNAL WAREHOUSES
STEEL CLADDING - GREY
EXTERNAL WAREHOUSES
STEEL CLADDING - GREY
EXTERNAL WAREHOUSES
FFL +99.64
FFL +99.81
ROAD LEVEL
RAMP
1:10
E SECTION E
SCALE 1:100
ROOF SERVICES
FFL +110.640
FFL +112.080
TECHNICAL AREA
FFL +106.140
UTILITY PLANT AREA
LABORATORY
FFL +106.140
FFL +106.140
OFFICE
SCRUBBER
FFL +103.000
PRODUCTION AREA
SAMPLING ROOM
LIFT SHAFT
WAREHOUSE
CLEAN ROOMS
LABORATORY
COURTYARD
OFFICE
FFL +99.900
FFL +100.000
FFL +100.000
FFL +100.000
PARKING AREA
FFL +96.750
D SECTION D
CONTINUED BELOW
SCALE 1:100
ROOF SERVICES
FFL +110.640
TECHNICAL AREA
FFL +106.140
EXTERNAL WAREHOUSES
EXTERNAL WAREHOUSES
STEEL CLADDING - GREY
PRODUCTION AREA
SAMPLING ROOM
ROAD LEVEL
FFL +99.900
FFL +100.000
D SECTION D
CONTINUED ABOVE
SCALE 1:100
to Construct
1 0 1 2 3 4 5 m
Scale: 1:100
Rev. Drawn Description Date
Wallace Farrugia & Associates
Architects, Civil Engineers & Structural Consultants.
No 44, Appt 3, St.Francis Street, Sliema SLM2069 tel:21316758 fax: 21316760
Commission:
FACTORY HF50, HF51, HF52, HF53
AT MAL-FAR
Client:
STERLING CHEMICALS LTD.
Drawing Title:
PROPOSED SECTIONS
D, E
Scale: 1:100
Drawing No: 190-16-070
Job Ref: 190/16
Paper Size: A1
Drawn: D.M.G.
Amended: -
Approved: -
Checked: W.F.
Date: 18.06.2018
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ACCESS, TRAFFIC AND PARKING

2.67. Currently there is a car park at Level 0 with an entrance from beneath the existing reception area. Another car park at Level 0 is planned to the east of the Scheme (HF53). This car park has a capacity of 36 vehicles and will be dedicated to employees. Staff can access the lobby of the Scheme through stairs and / or a lift connected to the parking area.

2.68. Access for heavy goods vehicles including delivery vehicles for raw materials and collection of waste is via a dedicated access along the northern side. The access is not public and will be secured by means of two gates.

2.69. Since the Scheme will be connected to the existing Sterling Chemical operation, access for staff and guests will be from the main entrance on the southern side of the Scheme. The existing lobby will also serve as the access / reception area for the Scheme.

SERVICES

2.70. Malta Industrial Parks Ltd (the owners of the industrial estate) have confirmed to the Applicant that the Ħal Far Industrial Area is serviced with all the required utilities including a sewerage system, electricity and water supply systems. All these services are located underground and have the capacity to absorb the demand of the Scheme.

Electricity Supply

2.71. The main sources of energy supply to the Scheme are:

- Thermal energy obtained by burning natural gas in the boiler that supplies heat to the Scheme; and
- Electricity from the main power supply.

2.72. It is estimated that Phase 1 (R&D) would consume an additional 815 MWh per annum and Phase 2 an additional 4,075 MWh and 380 m^3 of LPG.

Water Supply

2.73. The Scheme has two main sources of supply, namely: harvested rainwater which is collected in underground reservoirs tanks and used for irrigation and fire-fighting, and mains water supplied by the Water Services Corporation.

2.74. The Scheme's total annual water consumption is estimated at 1,350 m^3 in Phase 1 and 10,800 m^3 in Phase 2.

2.75. All mains water used for production and cleaning is passed through the water softener; sanitary water is not softened. A new reverse osmosis plant will be installed to supply water to the boiler. The reject water and brine from the softening system and RO go to the rainwater reservoir, and then to the street (overflow). It is

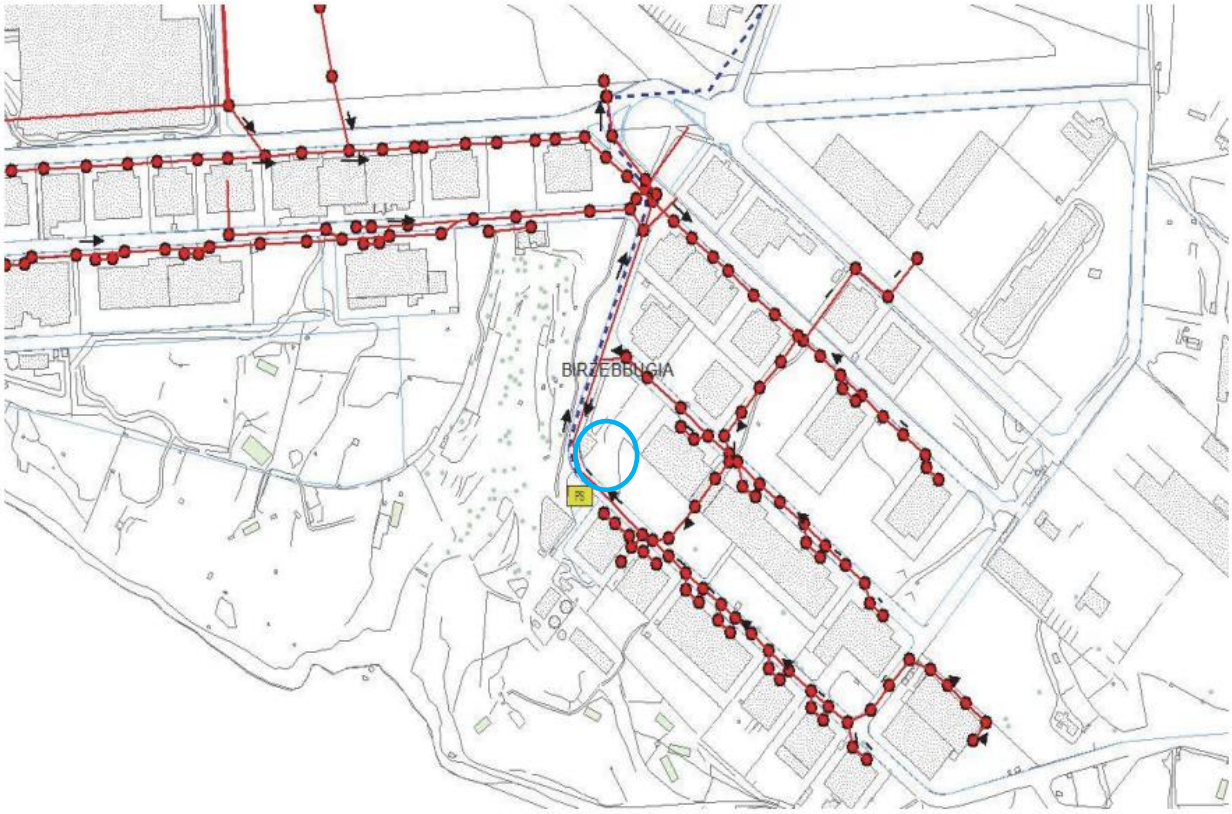
estimated that the RO will only be used when boiler water needs changing and the estimated (discontinuous) discharge is less than 100 L per week.

Drainage

2.76. The Drainage Pumping Station in the vicinity of the Scheme is highlighted in yellow in **Figure 2.14**. The pumping station is connected to the main grid by means of a rising main that is shown in dark blue. Only domestic sewage (from the canteen, toilets, and showers) will be disposed of through this system.

2.77. All black and grey water is separated from the process and rainwater systems, and is connected to the WSC sewage network. As shown below the pumping station links to the main sewerage system through a pressure main.

Figure 2.14: Sewerage system in the vicinity of the Scheme



2.78. The water used for cleaning equipment or cleaning of laboratory equipment and plant (except the piping and reactor) is considered to be contaminated and will therefore will be managed as hazardous waste (EWC code 16 10 01*). This contaminated washing water originates from the production department (lines and finishing unit), the laboratories, and the temporary storage of indoor wastes.

2.79. The laboratories wash their own equipment in sinks that are connected to the 'water washing reservoir' (in one of the laboratories, after receipt in a smaller 'water spillage reservoir', which overflows to this larger reservoir). This effluent is made up of 80% water, 15% acetone and a small amount from traces of other pollutants. Hazardous waste, if generated in larger quantities (e.g. waste solution for analysis) will be collected in cans, then poured into larger containers and disposed of as hazardous waste. The floor drains are also connected to the water washing reservoir.

2.80. The washing water from all the production areas collects to gutters fitted along the walls. Since the ground is laid to fall towards the gutters any wash water is collected and conveyed to the water washing reservoir.

2.81. The wash water management system is similar to the one currently operated by Sterling Chemical in HF51. The wash water is collected in mobile tanks (IBCs of capacity 1 m^3); water from floor washing and any spills are collected in gutters around the internal perimeter, which drain to the 74 m^3 'water washing reservoir'.

Stormwater

2.82. As mentioned, the Scheme has a reservoir with capacity of 1,032 m^3 for the collection of clean rainwater from the roofs. The water will be used as second class water and for irrigation. The rainwater overflow is connected to the road.

2.83. No rainwater is collected from Area A (HF50) given the small area; rainwater from the LPG area is allowed to seep through the backfilled area beneath the site.

2.84. The drainage of the Scheme is shown in **Figures 2.15** and **2.16**.

Figure 2.15: Drainage Layout at Level 0

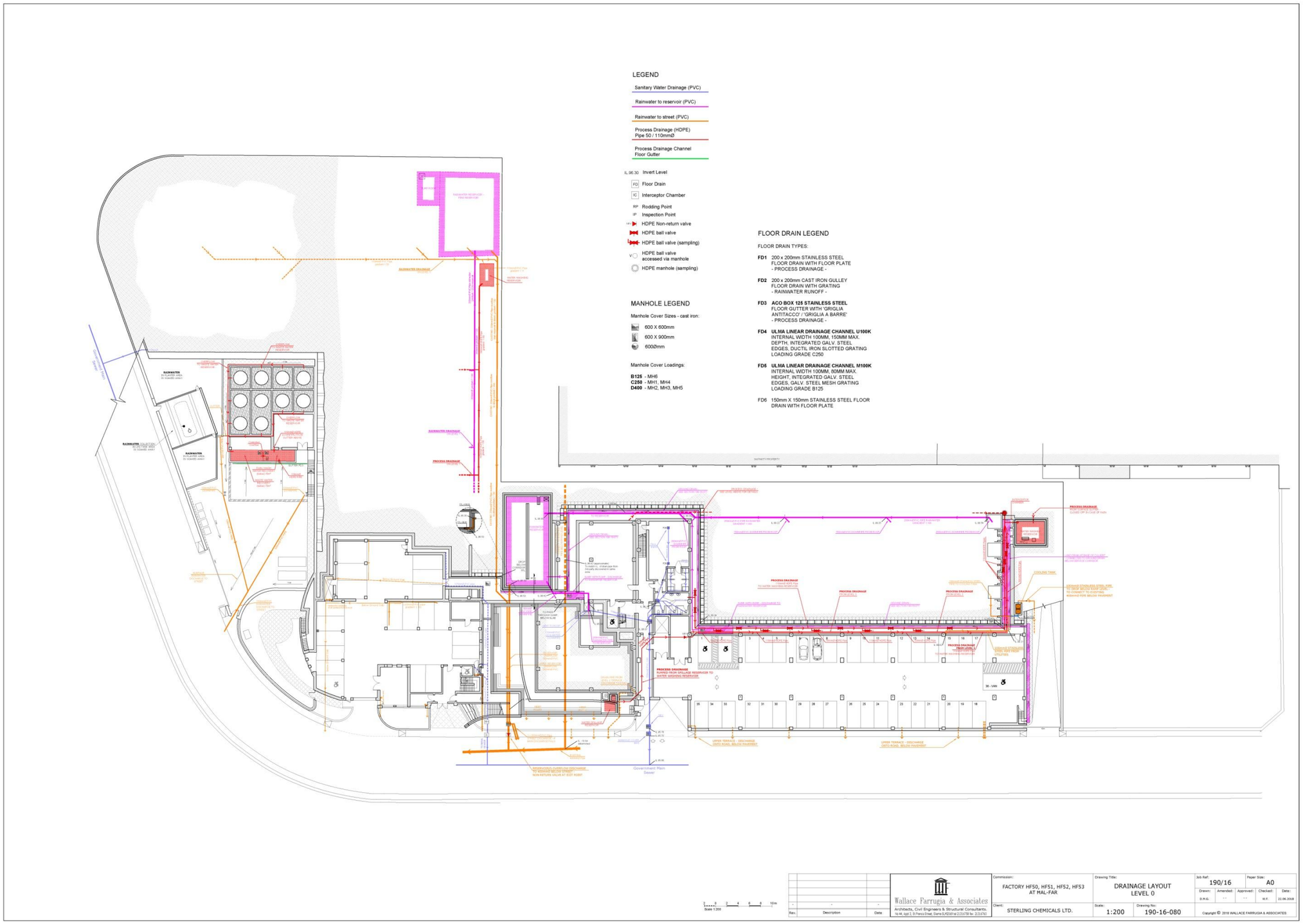
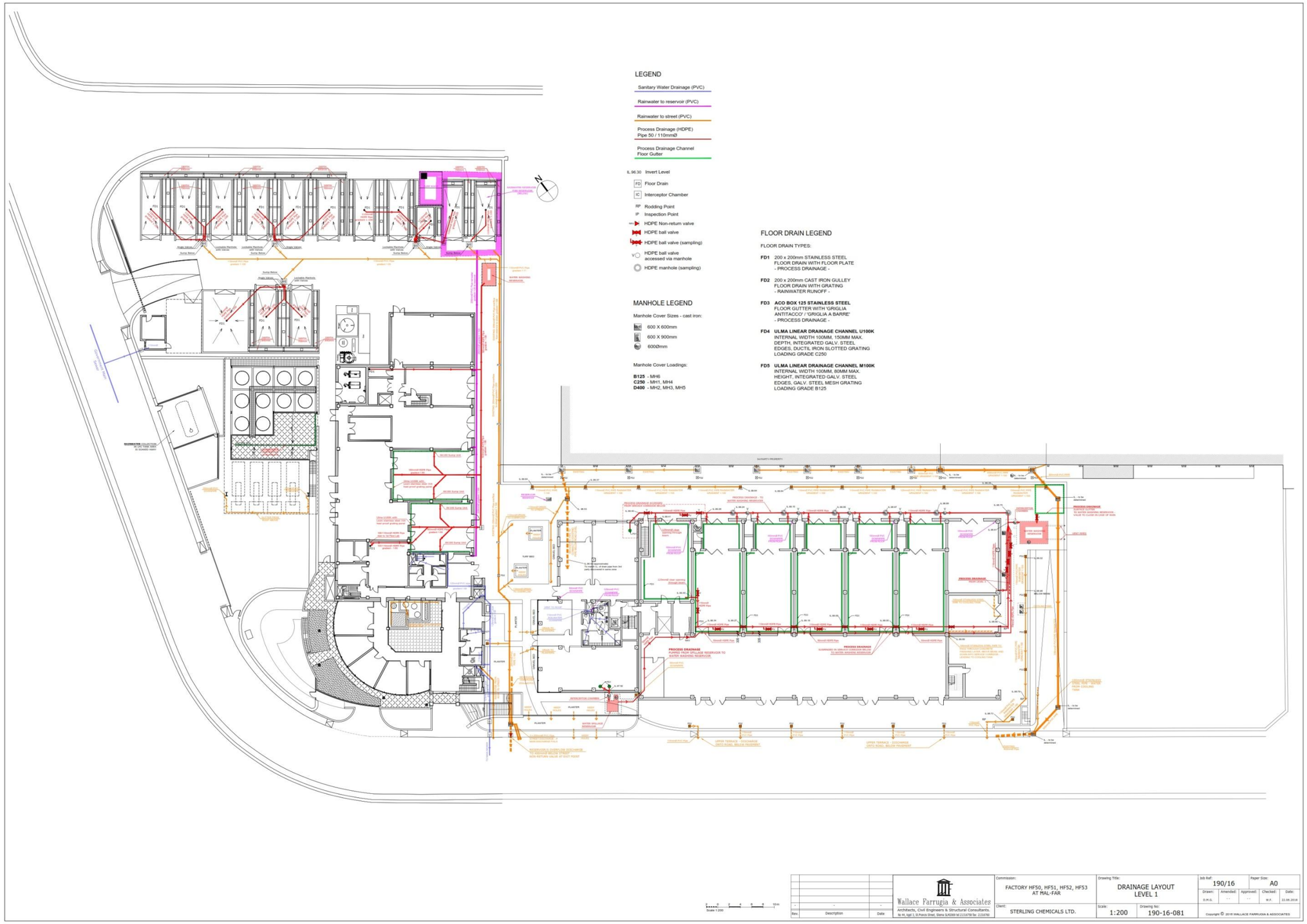


Figure 2.16: Drainage Layout at Level 1



SCHEME CONSTRUCTION

2.85. Since the buildings envisaged to host the Scheme have already been built, as such there is no construction period. HF53 is currently being built up to 14 metres; following the development permit the height will be raised to 17 metres and HF53 connected to the existing HF51. The external warehouses are likely to be constructed as general purpose warehouses through the DNO procedure so there is minimal construction on the site of HF50 in the eventual full development planning application.

SCHEME OPERATION

Employment and Occupancy

2.86. Sterling Chemical currently employs 90 staff. Since the production processes will not all be launched simultaneously but in phases, it is envisaged that the first phase would employ an additional 10 persons and the second phase would employ an additional 30 persons. It is estimated that the total staff complement would be 130. The Scheme will operate from Monday to Friday for 24 hours each day (in 3 shifts).

2.87. The raw materials currently in use in the largest quantities are presented in **Table 2.3**. The principal raw materials are organic compounds, especially solvents, with some being halogenated. The same types of raw materials will continue to be used as part of the Scheme.

Table 2.3: Key raw materials currently in use

1-Butanol	Triflic anhydride	Methanesulfonyl chloride
2-Butanone	Dichloromethane	Methanol
3-Pentanone	N,N-dimethyacetamide	Hexane
Ethyl acetate	N,N-dimethylformamide	Propionyl chloride
Acetone	1,4-dioxane	Methyl tertiary butyl ether
Acetonitrile (anhydrous)	Heptane	Tert-butyldimethylsilyl chloride
Glacial acetic acid	Ethanol	Tetrahydrofuran
Acetic acid solution (80%)	Petroleum ether	Thionyl chloride
1-propanol	Diethyl ether	Toluene
Acetic anhydride	Isopropyl acetate	

Operational Waste

2.88. Although the waste types generated by the Scheme are the same as those already generated by current operations at Sterling Chemical, the waste quantities generated annually will increase; the estimated quantities generated as a result of the Scheme are presented in **Table 2.4**. It is noted that the types and quantities of waste generated are variable, as they are highly dependent on production activities.

Table 2.4: Estimated waste quantities

EWC code	Description	Estimated annual quantity generated (tonnes)		
		Current	Including Phase 1 and 2	Including Phase 3
07 07 01*	Aqueous washing liquids and mother liquors	377	250	180
16 10 01*	Aqueous liquid wastes containing hazardous substances	150	300	500
07 07 03*	Organic halogenated solvents, washing liquids, and mother liquors	130	200	300
07 07 04*	Other organic solvents, washing liquids, and mother liquors	290	400	700
06 01 02*	Hydrochloric acid	0.1	0.2	0.3
06 01 06*	Other acids	0.5	1	2
07 07 10*	Other filter cakes and spent absorbents	15	30	70
08 03 17*	Waste printing toner containing hazardous substances	0.02	0.02	0.04
15 01 10*	Packaging containing residues of or contaminated by hazardous substances	20	40	80
15 02 02*	Absorbents, filter materials (including HEPA filters), wiping cloths, protective clothing contaminated by dangerous substances	6	12	20
16 02 11*	Discarded equipment containing chlorofluorocarbons, HCFC, HFC	0.2	0.4	0.8
16 02 13*	Discarded equipment containing hazardous components other than those mentioned in 16 02 09 to 16 02 12	0.3	0.6	1
16 03 05*	Organic wastes containing hazardous substances	0.002	0.004	0.008
16 05 08*	Discarded organic chemicals consisting of or containing hazardous substances	1	2	3
16 05 06*	Laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals	0.2	0.5	1
16 08 07*	Spent catalysts contaminated with hazardous substances	0.02	0.04	0.08
16 06 02*	Ni-Cd batteries	5	-	-
13 02 05*	Mineral-based non-chlorinated engine, gear and lubricating oils	0.09	-	-
13 01 11*	Synthetic hydraulic oils	0.02	0.04	0.1
15 01 02	Plastic packaging	6	10	20
15 01 01	Paper and cardboard packaging	3	6	10
15 01 04	Metallic packaging	-	1	3
15 01 07	Glass packaging	-	2	5

EWC code	Description	Estimated annual quantity generated (tonnes)		
		Current	Including Phase 1 and 2	Including Phase 3
15 01 06	Mixed packaging	-	1	2
15 01 03	Wooden packaging	5	10	15
20 01 38	Wood other than that mentioned in 20 01 37	6	12	20
20 01 39	Plastics	-	1	2
20 01 08	Biodegradable kitchen and canteen waste	5	15	30
20 01 02	Glass	1	2	4
20 03 01	Mixed municipal waste	20	30	50

Emissions

Emissions to Air

2.89. Emissions from the new reactors in the new production lines will be routed to a new scrubber. As with the existing reactors, each reactor will be connected to a heat exchanger to condense organic vapours; the entire reactor line is also connected to a second, larger heat exchanger, following which vapours are treated in a carbon filter and the scrubber.

2.90. The sizing of the scrubber is currently at design phase; however, it will be designed to handle the flow from all phases of the extension.

2.91. In case of an emergency condition in the reactors, blowdown tanks will be in place as a safety measure (as with the current production lines). Blowdown tanks enable safe and quick emptying of reactors, which is important to prevent harm to persons, equipment, and also the environment if an abnormal situation requiring quick release of pressure in the reactors occurs. The blowdown tanks will be located in the Utilities area (Level 1, HF53). Emissions from the blowdown tanks are then routed to the scrubber.

2.92. Three new emission points covering general ventilation from the existing and new production lines and raw materials warehouses are also being introduced. Exhaust air from these areas is released through air grilles having a basic fabric filter. It is noted that no handling of powder is carried out in these areas, and if any containers are opened (e.g. reactors or IBCs), local extraction is used which is directed to the existing or new scrubber.

2.93. Emissions from the new clean rooms in the HF53 block will be treated using HEPA H13 filters having a filtration efficiency greater than 99.95%. It is noted that a differential pressure device is installed before and after each HEPA filter in order to monitor the operation of the filter; the filters will also be included in the Scheme's maintenance programme and replaced as per the maintenance schedule.

2.94. Exhaust air from the new cold room (labelled as 'Storage' in the HF53 Level 1 drawing) will vent directly to the atmosphere. It is noted that only storage activities are carried out in this area, and there is no exposure of substances to the atmosphere (and therefore no releases of dangerous substances to air) under normal conditions.

2.95. The new laboratories will include fume hoods, emissions from which will be treated through a carbon filter prior to release at roof level. Additionally, a HEPA H13 filter will also be installed on the suction hoods (balance enclosure) where weighing of powders is carried out; the treated air will exhaust inside the same laboratory.

2.96. The Scheme also includes two new boilers, two new emergency electricity generators, and two new cooling towers.

2.97. With respect to the new boilers, one new boiler will be installed in Phase 2, which

will work at approximately 40% capacity in Phase 2 and at full capacity in Phase 3.

2.98. It is noted that the generators are required in order to ensure continuity and control of operations in case of mains electricity supply failure, and will be used minimally. Two generators will be installed as part of Phase 2, to provide electricity for the existing plant plus Phase 2 of the proposed extension. A third generator will be installed as part of Phase 3 (in the same area).

2.99. Additionally, the bulk waste storage tanks will be connected to the existing scrubber (EM1), with the tanks used for storage of dichloromethane (DCM) waste being connected to the carbon filter before reaching the scrubber.

2.100. The new emission points to air are summarised in **Table 2.5**.

Table 2.5: Scheme emission points to air

Source	Main emission types	Abatement
Bulk waste storage tanks (HF50)	VOC	Scrubber (Emissions from tanks used for storage of dichloromethane will be treated in carbon filter first)
HVAC system for production lines 1 and 2, raw materials warehouse, maintenance workshop	Emission of air coming from HVAC system (air conditioning and general ventilation)	Not applicable – exhaust through air grilles with fabric filter
Reactors (HF53)	VOC, NO_x, particulates	Two heat exchangers in series, carbon filter and scrubber
HVAC system for HF53 warehouse (raw materials), production lines 3 and 4	Emission of air coming from HVAC system (air conditioning and general ventilation)	Not applicable – exhaust through air grilles with fabric filter
HVAC system for production lines 5, 6, and 7	Emission of air coming from HVAC system (air conditioning and general ventilation)	Not applicable – exhaust through air grilles with fabric filter
HVAC system for clean rooms line 3	Particulates	HEPA filter
HVAC system for clean rooms line 4	Particulates	HEPA filter
HVAC system for clean rooms line 5	Particulates	HEPA filter
HVAC system for clean rooms line 6	Particulates	HEPA filter
HVAC system for clean rooms line 7	Particulates	HEPA filter
Local extraction in HF53 production block, used when opening reactors / containers, located in: • indoor weighing areas (in raw materials warehouse); • sampling room (inside raw material warehouse); • finished goods store (in production clean room area); and • the clean rooms.	VOC, NO_x, particulates	Scrubber
HF53 cold room	Finished products (small quantities)	None (vents directly to atmosphere)

Source	Main emission types	Abatement
HF53 laboratory fume hoods	Solvents / chemicals / powders (small quantities)	Fume extractor hoods: carbon filter Balance enclosure for weighing powders: HEPA H13 filter
HF53 Laboratory fume hoods	Solvents / chemicals / powders (small quantities)	Fume extractor hoods: carbon filter Balance enclosure for weighing powders: HEPA H13 filter
HF53 laboratory fume hoods	Solvents / chemicals / powders (small quantities)	Fume extractor hoods: carbon filter Balance enclosure for weighing powders: HEPA H13 filter
Boiler (Phase 2 and 3)	Combustion by-products	Use of LPG as fuel, regular maintenance
New cooling tower (Phase 2)	Waste heat	Treatment of circulating cooling water (including dosing with biocides)
New cooling tower (Phase 3)	Waste heat	Treatment of circulating cooling water (including dosing with biocides)
Emergency electricity generator 1 (for existing plant + Phase 2)	Combustion by-products	Use of diesel EN 590 as fuel, regular maintenance, used only in case of mains supply failure
Emergency electricity generator 2 (for existing plant + Phase 2)	Combustion by-products	Use of diesel EN 590 as fuel, regular maintenance, used only in case of mains supply failure
Emergency electricity generator 3 (Phase 3)	Combustion by-products	Use of diesel EN 590 as fuel, regular maintenance, used only in case of mains supply failure

Greenhouse Gases

2.101. The Scheme (both phases) plus the current development envisages an estimated annual electricity consumption of approximately 5,705,000 kWh (5,705 MWh), and around 9,000 tonnes of fuel consumption, primarily for the operation of the boilers (and to a much lesser extent, the emergency electricity generators).

2.102. **Table 2.6** illustrates the CO_2 emissions expected to be generated from the operation of the Scheme and the current operation of Sterling Chemical.

Table 2.6: CO_2 Emissions from Scheme and the approved development during Operation

Source	Current consumption	Current annual CO_2 emissions	Consumption of the current installation plus the Scheme	Future annual CO_2 emissions
Electricity	1,630 MWh	1,255 tonnes	5,705 MWh	4,393 tonnes
LPG combustion (boilers)	190 m^3	286 tonnes	570 m^3	859 tonnes
Diesel combustion (generators)	0 L	0 tonnes	<1,500 L	<4 tonnes
Total CO_2 emissions (tonnes)	**Current:**	**1,541 tonnes**	**Current plus Scheme:**	**5,252 tonnes**

Noise Emissions

2.103. It is not expected that the Scheme will generate significant sources of vibration, heat or radiation. Construction noise impacts have been scoped out of this impact assessment because the building housing HF53 has already been built and the warehouses in the western area (HF50) are likely to be permitted through the DNO procedure.

2.104. Noise generating activities from the Scheme are likely to be similar to those already existing at Sterling Chemical Malta. The equipment likely to generate noise from the Scheme includes that listed in **Table 2.7**.

Table 2.7: Noise-generating equipment

Location	Equipment	Notes
Clean room plant area (Level 2)	Air handling units for clean rooms	The air handling units are likely to generate noise
Clean room plant area (Level 2)	Skid for thermal regulation of the reactors	This is a small pump that is used around two days per week
Technical area (Level 3 intermediate)	Air handling unit	The air handling units are likely to generate noise
Utilities area (Level 3)	Pumps	Pumps are likely to generate noise
Utilities area (Level 3)	Chiller water tanks	Chiller water tanks are likely to generate noise

2.105. Since the Scheme is expected to generate noise that is similar to that generated by the existing operation, operational noise levels are likely to be similar too. In 2015[2], the following noise levels were measured.

[2] Acousti-Cal Consultancy, 2015, Sterling Chemical Malta Ltd.: Presentation of noise measurements for IPPC license.

Table 2.8: Measuring noise levels from current facility

Location	Day measurement (background – plant inoperative) (LAeq)	Day measurement (plant operative) (LAeq)	Night measurement (background – plant inoperative) (LAeq)	Night measurement (plant operative) (LAeq)
Back road	50.5	61.6	49	52.7
Side Road (Opposite utility Plant)	59.4	66.1	58.6	67.1

3. GEO-ENVIRONMENT

INTRODUCTION

3.1. This chapter describes the geology, geomorphology and hydrology within the Scheme site and its surroundings. It also includes an assessment of the impacts and risks posed by the Scheme on the geo-environment. The key geo-environment issues arising from the Scheme are outlined below:

Key Issues:

- **Impacts on geo-environment from the operation of the Scheme**

Terms of Reference

3.2. Since this is an EIA Update, no Terms of Reference have been provided by ERA. Reference is therefore made to the Terms of Reference that had been issued for the EIS for an *installation of manufacturing plant and obtaining an operations permit for the production of active pharmaceutical ingredients (API) and the installation of LPG storage tanks in a facility/factory already covered by permit PA/04236/08 at Factory HF 51, Qasam Industrijali, Ħal Far, Birżebbuġa*[3].

ASSESSMENT METHODOLOGY

3.3. The assessment methodology for the geo-environment study is described below.

Standards and Policy Guidance

3.4. The principal sources of guidance for the impact assessment were the *Strategic Plan for the Environment and Development 2015*, the *Structure Plan for the Maltese Islands 1992*[4], the *Grand Harbour Local Plan 2006*, the *Minerals Subject Plan 2002,* and *The Earth Conservation Strategy 1991* (The British Nature Conservancy Council).

3.5. The European Union (EU) does not have any directive that protects the geo-environment *per se*; however Directive 92/43/EEC (Habitats Directive) seeks to

[3] ERSLI Consultants, 2014, Environmental Impact Statement *for an installation of manufacturing plant and obtaining an operations permit for the production of active pharmaceutical ingredients (API) and the installation of LPG storage tanks in a facility/factory already covered by permit PA/04236/08 at Factory HF 51, Qasam Industrijali, Ħal Far, Birżebbuġa.*

[4] The *Structure Plan for the Maltese Islands 1992* has been superseded by the *Strategic Plan for the Environment and Development 2015* (SPED); however, the SPED does not outline policy guidance relating to the geo-environment in the level of detail that it was outlined in the Structure Plan. In the absence of specific policy guidance, reference is still made to the relevant policies of the Structure Plan.

preserve and protect certain geology / geomorphologic features where these features constitute important habitats. This Directive has been transposed into national legislation (S.L. 549.44).

3.6. Conservation profiles are intended to prevent future potential damage to sites. Since no earth conservation model exists for the Maltese Islands, it has been suggested in past studies (for example, Debono & Scerri, 1996[5] and Mallia *et al.*, 1999[6]) that until such a model is formulated, models used in other countries can be adopted for local use. The conservation model that has been used is that adopted by The Earth Conservation Strategy of the Nature Conservancy Council (UK).

Area of Influence

3.7. The Area of Influence (A of I) for the geo-environment was taken as that outlined in the EIS for an *installation of manufacturing plant and obtaining an operations permit for the production of active pharmaceutical ingredients (API) and the installation of LPG storage tanks in a facility/factory already covered by permit PA/04236/08 at Factory HF 51, Qasam Industrijali, Ħal Far, Birżebbuġa.* It was considered that a new baseline survey did not need to be carried out since the data prepared for the EIS is still valid.

[5] Debono, G. and Scerri, S., 1996. North Harbours Local Plan Geology Survey Report. Prepared by Malta University Services for the Planning Authority, Floriana, Malta; 72 pp. + 210 data cards + 15 figures + 20 plates.
[6] Mallia, A., Briguglio, M., Ellul, A.E., and Formosa, S., 1999. Population, Tourism, Land-Use and Non-Renewable Resources in the State of the Environment Report for Malta 1998, commissioned by the Environment Protection Department, Government of Malta, Malta Council for Science and Technology, Malta.

BASELINE: GEOLOGY

Stratigraphy

3.8. The five late-tertiary formations exposed on the Maltese Islands are:

- Upper Coralline Limestone (youngest);
- Greensand;
- Blue Clay;
- Globigerina Limestone; and
- Lower Coralline Limestone (oldest).

3.9. In addition to these formations, Quaternary continental deposits are also known to occur sporadically on the Maltese Islands. An unconformity and an erosional surface separate this unit from the underlying marine sedimentary succession.

3.10. As is shown in the geological map in **Figure 3.1**, the predominant exposed geological strata in area are the il-Mara and Attard members of the Lower Coralline Limestone Formation. The mouth of Wied Żnuber is characterised by the occurrence of the il-Magħlaq member of the same formation.

Lower Coralline Limestone Formation

3.11. The Lower Coralline Limestone Formation is the lowermost rock formation exposed on the Maltese Islands. It is extensively exposed at the site and along the eastern coastline. This rock formation is of particular hydrogeological importance as its pores and fissures host the mean sea level aquifer (MSLA) below the Site.

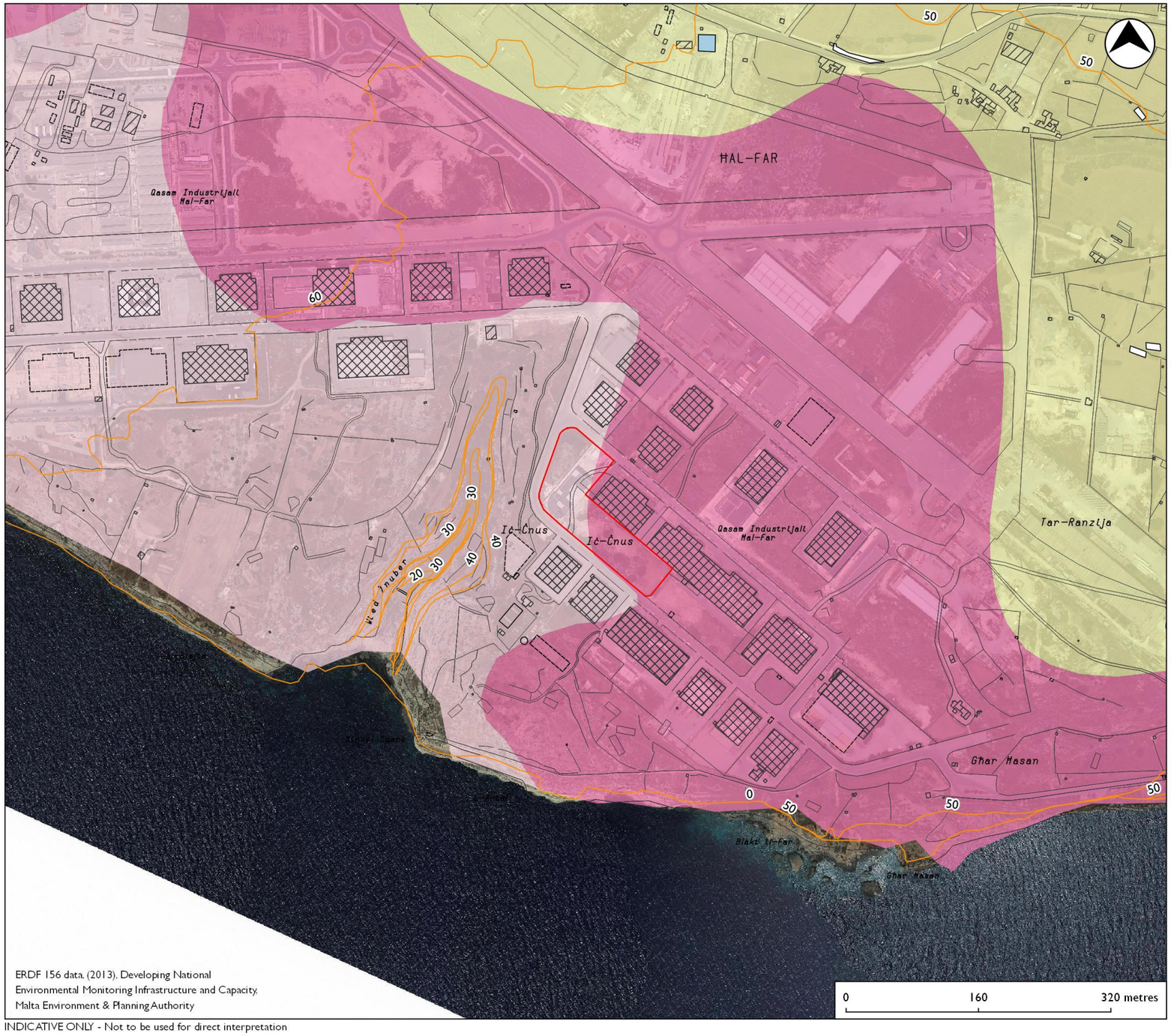
3.12. The formation is known to be over 140 m thick. Although the base of the formation is taken at sea level, it extends well below sea level. The contact with the overlying Globigerina Limestone Formation is sharp and is represented by a hard ground.

3.13. This rock formation has been subdivided into four members as follows (Pedley, 1978):

- Wied Magħlaq Member (oldest);
- Attard Member;
- Xlendi Member; and
- Il-Mara Member (youngest).

3.14. Of the four members listed above only the Il-Mara and Attard Members were found in the area.

Figure 3.1: Geological Map of the Scheme Site and its Surroundings



ERDF 156 data. (2013). Developing National Environmental Monitoring Infrastructure and Capacity. Malta Environment & Planning Authority

INDICATIVE ONLY - Not to be used for direct interpretation

Adi ASSOCIATES

Geology

Legend

- Proposed site boundary
- Contours

Geological formation

- Lower Globigerina Limestone (Mlg)
- LCL - Attard Member (Oa)
- LCL - Il-Mara Member (Om)

EIA update for extension to Sterling Chemical Ltd

Map by: Adi Associates Environmental Consultants Ltd

Client: Sterling Chemical Malta Ltd	Ref: SCL001
File ref: EIA\Sterling\Maps	Date: 10 / 2018

GEOMORPHOLOGY

3.15. According to the 2014 EIS, the geomorphologic units that surround the Site are the high coastline, the Ħal Far plain, Wied Żnuber, and a limestone pavement.

3.16. The most impressive geomorphologic feature in the area is the imposing sheer limestone cliffs that rise almost vertically to about 60 m above sea level. Their origin is closely related to the gentle dip of the Maltese Islands to the northeast and wave action at the toe of the cliff face, which undermines the rock face. The rock face fails along vertical shear planes giving rise to the sheer cliff.

3.17. The Ħal Far plain forms the disused airfield and appears to represent the bedding plane at the top of Il-Mara member which is marked by hard ground. This bedding plane is particularly resistant to weathering in contrast to the overlying beds of the Globigerina Limestone Formation, which have been eroded to expose the top of the Lower Coralline Limestone Il-Mara Member.

3.18. Wied Żnuber is a deep gorge which has a maximum depth of about 60 m. It is one of the few drainage systems that discharges on the southwest coastline. Its orientation appears to be primarily controlled by north-south orientated fractures. It is likely that the action of water on the limestone produced the deep gorge by solution during past climates. Probably presently it is a relict geomorphological feature.

3.19. Rocks of the il-Mara, Xlendi, Attard and Wied Magħlaq members (of the Lower Coralline Limestone Formation) are prone to solution producing a variety of solution features, which highly enhance the permeability of limestone. These range from shallow rock pools and narrow conduits to large solution features such as caverns. One such cavern now modified by anthropogenic activities is present on the western slopes of the Wied Żnuber valley. A much larger solution cavern is the well-known Ħasan's cave (Għar Ħasan), which is perched in the cliff face circa 500 m southeast of the Site. Rock pools, conduits and open joints are best seen on the limestone pavement that lines the flanks of the Wied Żnuber gorge. Lower Coralline Limestone is composed of a pure limestone and for this reason residual clays in the form of terra rossa soil are scarce. The limestone is therefore bare and is exposed as a limestone pavement locally known as 'Xagħra'. Rock permeability is further enhanced by the widening of fractures and bedding planes by chemical solution. Fractures frequently channel percolating rainwater, and in the process widen the open fracture by the solution.

HYDROLOGY AND HYDROGEOLOGY

3.20. According to the 2014 EIS, there is no perched aquifer beneath the site as there is no impermeable rock layer such as the Blue Clay Formation, in the rock sequence beneath the Site. As there is no other impermeable rock formation present in the lithologic succession, the only aquifer beneath the site is the mean sea level aquifer (MSLA), which lies some 60 m below the surface. This also represents the

hydrogeological feature closest to the site.

3.21. The sea level aquifer is lens shaped reaching some 3 m high above sea level at the centre of the island of Malta and thins out to zero thickness at the coastline. Given that the site is only about 320 m away from the coastline, the aquifer would be thinly developed or non-existent beneath the site.

3.22. The watercourse of this valley system has its origin at the Ħal Far Industrial Zone. It flows through the old runway and Wied Żnuber and discharges into the sea. A true watercourse is only developed in Wied Żnuber. The 2014 EIS noted that presently this valley is considered a relict geomorphological feature generated in past climates during the Pleistocene. No water flows through the valley system except run-off water generated during heavy downpours. Such run-off ceases soon after the rain has stopped.

3.23. The site lies within the Wied Żnuber catchment, which covers an area of circa 1.78 km^2. The rock mass in Wied Żnuber in particular, has high fissure permeability. Fissures frequency seen can be as close as 1m and even less.

3.24. The nearest WSC borehole which taps the MSLA is located circa 1,000 m away from the Site.

Figure 3.2: Hydrology of the Scheme site and its surroundings

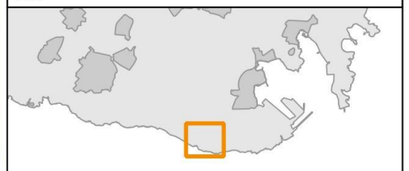
INDICATIVE ONLY - Not to be used for direct interpretation

Hydrology

Legend

- Proposed site boundary
- Malta main mean sea level aquifer
- Contours

EIA update for extension to Sterling Chemical Ltd



Map by: Adi Associates Environmental Consultants Ltd

Client: Sterling Chemical Malta Ltd	Ref: SCL001
File ref: EIA\Sterling\Maps	Date: 10 / 2018

ASSESSMENT OF IMPACTS

Impact Significance

3.25. The following criteria were used to assess the significance of the negative impacts of the Scheme on the geo-environment:

- **Not significant**:
    - Little or no change to the geological, geomorphological and hydrogeological regime.
- **Minor significance**:
    - Changes to the geological, geomorphological and hydrogeological regime that may affect neighbouring properties but which may be offset by mitigation measures.
- **Major significance**:
    - Changes to the geological, geomorphological and hydrogeological regime that may affect neighbouring properties and which may not be offset by mitigation measures (if negative) or may be enhanced by mitigation measures (if positive).

Prediction and Significance of Impacts

Potential impacts

3.26. The potential impacts associated with the Scheme are those mainly related to its operation.

3.27. It is clarified that since the buildings hosting the Scheme have largely been built through the Development Notification Order process, construction impacts are scoped out of the assessment. Any construction interventions are likely to be minor in nature and are unlikely to significantly affect the geo-environment of the area.

3.28. The categories of impacts that may be experienced as a result of the activities undertaken on the Scheme site during operation (as described in **Chapter 2**) include:

- Risks to the hydrology of Wied Żnuber in the Area of Influence from spills / leakages.

3.29. The impacts that will affect the A of I as a result of the operation of the Scheme will depend on the mitigation measures adopted during the operation of the Scheme, including containment measures.

3.30. The following sections provide a more detailed assessment of these impacts as they relate to the operation of the Scheme.

Impacts from surface water discharge

3.31. The 2014 EIS had identified that the following activities from the Scheme could affect hydrological resources: emission of fine particulates, discharge of pollutants dissolved or suspended in water, increase in vehicular traffic, and generation and handling of hazardous waste with the principal receptor being Wied Żnuber. However, the EIS concluded that vehicular emissions would not be significant due to relatively low volumes of traffic and that emissions of fine particulates are mitigated through the installation of extensive air abatement systems as described in **Chapter 2**.

3.32. The Risk Assessment presented in **Volume 2** of this EIA Update Report concludes that since the new production lines, raw materials warehouse, laboratories, external flammable warehouse, fractioning area, and bulk waste storage area will include concreted containment, which will be periodically certified for impermeability, the pollutant linkage in case of a spill (large or small) in these areas is removed, rendering the impact not significant.

3.33. A spill in the new clean rooms or cold room would need to travel to the outdoor area and down one storey before it can start to contaminate the environment; given this distance, the small scale of activities / storage in these areas, and the presence of spill kits and trained staff, the impact of a spill would be insignificant.

3.34. With prefabricated bunding, the pollutant linkage from the maintenance area and external utilities area is also removed; therefore, a spill in this area would also be not significant.

3.35. A spill during emptying of water washing reservoir would only have environmental consequences if the lorry parks outside the designated area. However, given that the transfer activities are supervised, the environmental effects would still be insignificant as the transfer would be immediately stopped and the spill collected.

3.36. A diesel spill could only occur during transfer activities, since the tanks are double-skinned. Since transfers are supervised, the environmental effects would be insignificant as the transfer would be immediately stopped and the spill collected.

3.37. Based on the above the impact is therefore likely to be not significant.

MITIGATION

3.38. Various mitigation measures have been in-built in the construction of the Scheme, including:

- Underlying impermeable concrete layer, with epoxy resin coating on the floor in the new production area and the new raw material warehouse;
- Gutters in the new production area and the new raw material warehouse leading to a 74 m^3 concreted water washing reservoir;
- Underlying impermeable concrete layer, with acid-resistant tiles and acid-resistant

grout in the laboratories;

- Spills from the laboratories collected in floor drains go to a water spillage reservoir and then diverted to the 74 m^3 water washing reservoir;
- Gutters bounding designated transfer area leading to water washing reservoir;
- The external flammable warehouses are covered and underlain with concrete bunds, and the central area is concreted, laid to fall to a central floor drain leading to an underground sump with a closed valve;
- In the waste storage area, bulk tanks are inside a reinforced concrete bund, overflowing to reservoir;
- The bulk tank, transfer area, and ISO tank area are covered to prevent rainwater ingress;
- The ISO tank area, transfer area, and store flooring are concreted, laid to fall to reservoir; and
- Diesel is stored in double-skinned tanks with a capacity <1,000 L each and placed on concrete.

3.39. Measures to prevent fire, and therefore the generation of potentially contaminated extinguishant include:

- LPG tank placement and design conforms to Maltese and UK Codes of Practice and is certified according to Pressure Equipment Regulations;
- LPG tank is located below ground, protected from mechanical damage, and has fire walls on two sides;
- Natural ventilation of bulk LPG tank, external flammable warehouse, and bulk waste tanks (to avoid build-up of gas);
- Diesel-operated generators (diesel is not flammable); and
- Rainwater reservoir with 600 m^3 of water (150 minutes) dedicated to fire-fighting; level meter with alarm.

3.40. Other mitigation measures relating to the operation of the Scheme include:

- Effluent from production / washing of production equipment is collected in IBCs[7];
- Certification of containment systems as required by the IPPC permit;

[7] IBCs are intermediate bulk containers, typically having a volume of 1 m^3.

- Spill kits, and staff training on spill prevention and response;
- Raw materials typically stored in drums or IBCs not larger than 1 m^3 each;
- No storage in the new clean rooms, with transfers undertaken under staff supervision;
- Laboratory waste that is generated in relatively larger quantities is collected in containers for disposal;
- Storage of waste solvent in the new external utilities area is on prefabricated containment;
- Regular removal of waste;
- Waste transferred to licensed waste carriers having appropriate containment, and under supervision of Scheme staff;
- Level gauges and high level alarms on tanks in waste storage area;
- Waste transfers under supervision;
- Waste transfers logged to ensure no losses during transfers; and
- Certification of containment systems as required by IPPC permit.

RESIDUAL IMPACTS

3.41. Following implementation of mitigation measures, residual impacts are expected to be not significant.

Table 3.1: Summary of Impacts on the Geo-environment

Predicted Impact	Beneficial /Adverse	Nature, Scale and Type of Impact						Probability of Impact Occurring (Likely/ Unlikely/ Remote/ Uncertain)	Significance of Impact (Major/ Moderate/ Minor/Not Significant)	Proposed Mitigation Measures	Significance of Residual Impact (Major/ Moderate/ Minor/Not Significant)
		Constr'n /Oper'n	Extent of Impact (Nat/ Local /Site)	Direct/ Indirect	S'term/ L'term	Perm/ Temp	Revers/ Irrevers				
Impact on hydrogeology from spills	Adverse	Oper'n	Local	Direct	Long-term	Perm	Revers	Likely	Not Significant	In-built in the design - bunding, concrete flooring plus operational measures such as training, use of spill kits, and maintenance and testing and containment systems	Not Significant

4. TERRESTRIAL ECOLOGY

4.1. This chapter considers the likely environmental impacts on the habitats, fauna, and flora as a result of the Scheme. The potential key ecological issues are outlined below:

Key Issues

- **Disturbance to habitats and species as a result of the Scheme**

4.2. Since this is an EIA Update, no Terms of Reference have been provided by ERA. Reference is therefore made to the Terms of Reference that had been issued for the EIS for an *installation of manufacturing plant and obtaining an operations permit for the production of active pharmaceutical ingredients (API) and the installation of LPG storage tanks in a facility/factory already covered by permit PA/04236/08 at Factory HF 51, Qasam Industrijali, Ħal Far, Birżebbuġa*[8].

METHODOLOGY

Area of Influence

4.3. The Area of Influence (A of I) for potential impacts on the land and land uses likely to be affected by the Scheme has been defined to ensure that ecologically sensitive areas that may be impacted are included in the study. The A of I is shown in **Figure 4.1**.

4.4. This is the same A of I that was used in the 2014 EIS. This baseline study is still considered relevant and was not updated.

Objectives of the Assessment

4.5. The objectives of the terrestrial ecology assessment were to:

- Describe the biotic assemblages and communities present within the A of I, and to evaluate their importance;
- Identify, describe and analyse the relevant international / Maltese legislation and protocols, agreements, etc., as well as Government / ERA / Planning Authority (PA) policies;
- Identify the threats and opportunities posed by the Scheme in respect of the

[8] ERSLI Consultants, 2014, Environmental Impact Statement *for an installation of manufacturing plant and obtaining an operations permit for the production of active pharmaceutical ingredients (API) and the installation of LPG storage tanks in a facility/factory already covered by permit PA/04236/08 at Factory HF 51, Qasam Industrijali, Ħal Far, Birżebbuġa.*

findings;

- Predict the impacts of the Scheme on the ecological value of the A of I;
- Assess the significance of the impacts on the ecology of the A of I; and
- Describe the mitigation measures designed to minimise adverse impacts on ecology and enhance any beneficial impacts on the ecological features of the A of I.

Legislation, Policies and Guidance

International legislation

4.6. International legislation relevant to the ecology of the A of I is mainly that designed to protect specific habitat types / biotopes or individual species. Of particular relevance are:

- *Convention on the Conservation of European Wildlife and Natural Habitats* (the Bern Convention);
- *Convention on the Conservation of Migratory Species of Wild Animals* (the Bonn Convention);
- The European Union's Council Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds (the 'Wild Birds Directive'); and
- The European Union's Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (the 'Habitats Directive').

Local legislation

4.7. Local legislation relevant to the ecology of the A of I is mainly that designed to protect individual features, habitats, or species. Of particular relevance are:

- Act XXIX of 1973 (Fertile Soil (Preservation) Act, Cap 236) and the *Preservation of Fertile Soils Regulations*, S.L. 236.02;
- *Trees and Woodlands Protection Regulations* (S.L 549.123);
- *Conservation of Wild Birds Regulations, 2006* (S.L. 549.42); and
- *Flora, Fauna and Natural Habitats Protection Regulations, 2006* (S.L. 549.44) and its subsidiary Government Notice 112 of 2007.

Marsaxlokk Bay Local Plan 1995

4.8. The Marsaxlokk Bay Local Plan identifies the area adjacent to the Scheme site as an Ecologically Important Area (MBLP Ħal Far Inset Map, Figure 3).

Figure 4.1: Area of Influence as taken from the 2014 EIS

Guidelines

4.9. The most relevant policy guidance is the former MEPA's *Guidelines on Trees, Shrubs and Plants for Planting and Landscaping in the Maltese Islands*. This document provides detailed guidance on the types of plants that can be used for landscaping purposes in rural, urban, or agricultural situations. The guidance includes methods of planting and lists of species suitable for the different areas. The document has been updated through ERA's draft *National Code of Good Practice Landscaping, Forestation & Invasive Alien Species.*

Baseline Survey Methodology

4.10. The Ecology Baseline Survey is taken from the 2014 EIS as prepared by ERSLI Consultants. The references to the Trees and Woodlands Protection Regulations (S.L. 549.123) have been updated to refer to the 2018 regulations

4.11. The Ecology Study comprised:

- A habitats survey of the A of I indicated in **Figure 4.1**; and
- A vertebrate study (mainly focused on birds but also including the hedgehog, shrew, bats, the weasel, wood mouse, and painted frog) based on historical, published and unpublished data obtained from a number of sources.

ECOLOGY BASELINE SURVEY

4.12. According to the 2014 EIS, the Area of Influence has been subject to much anthropogenic influence, and traces of original vegetational communities persist in patches with limited accessibility. Much of the headwater regions and valley sides of Wied Żnuber have been exploited for agriculture and related land uses, with consequent modification of natural communities. A number of parcels of land in these zones were undergoing secondary ecological succession at the time of survey. A number of trees, some presumably representing deliberate introductions along agricultural margins, were also noted. The relatively undisturbed valley sides were generally colonised by shrub formations, broadly characteristic of maritime steppe/garrigue, and, more specifically, by elements of the Maltese Rdum Community. Derelict areas subject to large-amplitude disturbance were noted within the boundary of the Ħal Far Industrial Zone. Such areas were generally colonised by ruderal species.

Vegetation assemblages

4.13. The vegetation assemblages identified in the 2014 EIS are described below.

Valley bed

4.14. According to the 2014 EIS, much of the valley bed was colonised by cane formations composed of dense, monospecific beds of Great Reed (*Arundo donax*) interspersed

with relatively extensive patches of dense secondary maquis based on Carob (*Ceratonia siliqua*) [Trees & Woodlands: Schedule I, Part A, Table 2]. Tracts of the bed closer to the valley mouth were colonised by open scrub formations dominated by Maltese Salt-Tree (*Darniella melitensis*) [LN 311/2006: Regl.26; RDB: Endemic] and that were continuous with the rupestral assemblages colonising the vertical valley sides. A number of patches of Prickly Pear (*Opuntia ficus-indica*), presumably dispersed from adjacent agricultural areas, colonised parts of the bed.

4.15. The following species were recorded from this area: *Ceratonia siliqua* (Carob) and *Darniella melitensis* (Maltese Salt-Tree).

Valley sides (including rupestral habitats)

4.16. The sloping valley sides of Wied Żnuber were colonised by shrub formations, with different shrub species achieving local dominance in different patches. Gaps in habitat space, presumably opened through disturbance, were colonised by various ruderal species, mainly species dispersing from adjacent agricultural areas. Dominant shrubs included Mediterranean Heath (*Erica multiflora*) [LN 311/2006: III(b), VIII(b)] and White Hedge-Nettle (*Prasium majus*). Other shrubs recorded from these areas included Olive-leaved Germander (*Teucrium fruticans*), Egyptian St John's Wort (*Hypericum aegypticum*) [RDB: Rest (MED)], Maltese Salt-Tree (*Darniella melitensis*) [LN 311/2006: Regl.26; RDB: Endemic], Lentisk (*Pistacia lentiscus*) [Trees & Woodlands: Schedule 1, Part A Table 2], Mediterranean Thyme (*Thymbra capitata*) [LN311/2006: III(b); RDB: GN 85 (1932)], Common Hawthorn (*Crataegus monogyna*)[Tree and Woodlands: Schedule 1, Part A Table 2], and Eastern Phagnalon (*Phagnalon graecum subsp. ginzbergeri*) [RDB: Rest (MED)]. A patch dominated by Maltese Sea-Lavender (*Limonium melitense*) [LN 311/2006: III(b); RDB: Endemic] was also recorded from these areas.

4.17. On steeper slopes, immediately overlooking the sheer cliff faces, species recorded included Maltese Rock-Centaury (*Cheirolophus crassifolius*) [LN 311/2006: II(b), V(b); Habitats Directive: Annex II; RDB: Endemic, R, Rest (MI)], Golden Samphire (*Limbarda crithmoides*), Mediterranean Stonecrop (*Sedum sediforme*) and Cliff Carrot (*Daucus rupestris*) [RDB: Rest (MED+MI)].

4.18. Rocky areas not colonised by shrub formations were generally characterised by assemblages consistent with steppe communities, and comprised geophytic species including Branched Asphodel (*Asphodelus aestivus*), Crocus (*Romulea sp.)* and Field Gladiolus (*Gladiolus italicus*). Other species recorded from these open areas included Maltese Sea-Chamomile (*Anthemis urvilleana*) [LN 311/2006: X(b); RDB: Endemic], Clustered Carline Thistle (*Carlina involucrata*) [RDB: Rest (MED)], Pine Spurge (*Euphorbia pinea*), Wild Artichoke (*Cynara cardunculus*), Sweet Alison (*Lobularia maritima*), Sticky Fleabane (*Dittrichia viscosa*), Grey Birdsfoot Trefoil (*Lotus cytisoides*) and Crown Daisy (*Glebionis coronaria*). Larger phanerophytes, presumably originating through dispersal from adjacent agricultural areas, were also observed on various parts of the valley sides. These included Blue-Leaved Wattle (*Acacia cyanophylla*) [Trees & Woodlands: Schedule 2], Eucalyptus (*Eucalyptus camaldulensis*) [Trees &

Woodlands: Schedule 2], and Fig (*Ficus carica*).

4.19. The dominant shrub colonising sheer cliff faces, in terms of biomass and abundance, was Maltese Salt-Tree (*Darniella melitensis*) [LN 311/2006: Regl.26; RDB: Endemic]. Other species recorded from this part of the area included Golden Samphire (*Limbarda crithmoides*), Egyptian St John's Wort (*Hypericum aegypticum*) [RDB: Rest (MED)], Silvery Ragwort (*Jacobaea maritima subsp. sicula*) [LN 311/2006: Regl.26], Sea Squill (*Drimia maritima*) [LN 311/2006: VIII(b), X(b); RDB: Rest (MED)] and Maltese Cliff-Orache (*Atriplex lanfrancoi*) [LN 311/2006: II(b), V(b); Habitats Directive: Annex II; RDB: Endemic, R, Rest (MI)].

4.20. Karstic solution hollows, functioning as temporary freshwater rockpools, were noted on the valley sides. Pools characterised by a sufficiently long hydroperiod were colonised by Sanicle-leaved Water Crowfoot (*Ranunculus saniculifolius*). Species noted from these pools by Hili (2004), but not observed during the baseline survey, also included Southern Water-Starwort (*Callitriche truncata*) [RDB: R, Rest (MI)], Maltese Waterwort (*Elatine gussonei*) [LN 311/2006: I(b); RDB: R, Rest (MED+MI)].

4.21. A detailed multi-seasonal study of Wied Żnuber by Hili (2004) recorded a number of species from these areas that were not noted during the 2014 survey. These included Cage Thistle (*Atractylis cancellata*) [LN 311/2006: IV(b)RDB: RR, Rest (MED+MI)], Drooping broomrape (*Orobanche cernua*) [RDB: RR, Rest (MI)] and Maltese Toadflax *Linaria pseudolaxiflora* [LN 311/2006: II(b); RDB: R, Rest (MED+MI)], a Pelago-Maltese endemic restricted to the Maltese Islands, Lampedusa and Linosa.

Overcliff areas

4.22. According to the 2014 EIS, the karstified areas on the overcliff plateaux were colonised by a mosaic of assemblages representing remnant scrubland communities interspersed with extensive intercalations of vegetation consistent with steppe communities. The shrub matrix was, in places, dominated by Mediterranean heath (*Erica multiflora*) [LN 311/2006: III(b), VIII(b)] and also comprised Egyptian St John's Wort (*Hypericum aegypticum*) [RDB: Rest (MED)], Olive-Leaved Germander (*Teucrium fruticans*), Eastern Phagnalon (*Phagnalon graecum subsp. ginzbergeri*) [RDB: Rest (MED)], Mediterranean Thyme (*Thymbra capitata*) [LN311/2006: III(b); RDB: GN 85 (1932)], Golden Samphire (*Limbarda crithmoides*), Maltese Salt-Tree (*Darniella melitensis*) [LN 311/2006: Regl.26; RDB: Endemic], Maltese Fleabane (*Chiliadenus bocconei*) [LN 311/2006: X(b); RDB: Endemic], Wolfbane (*Periploca angustifolia*) [RDB: Rest (MED)], Maltese Sea-Lavender (*Limonium melitense*) [LN 311/2006:III(b); RDB: Endemic], and Maltese Savory (*Satureja microphylla*) [LN 311/2006: VIII(b); RDB: Rest (MED)]. Patches of habitat consistent with steppe communities were characterised by geophytes, including Sea Squill (*Drimia maritima*) [LN 311/2006: VIII(b), X(b); RDB: Rest (MED)], French Daffodil (*Narcissus tazetta*) [LN 311/2006: VIII(b)], Branched Asphodel (*Asphodelus aestivus*), and Crocus (*Romulea* sp.) and grasses including Bermuda Grass (*Hyparrhenia hirta*). A relatively very small number of orchids were noted at the time of the 2014 survey. These included Pyramidal Orchid (*Anacamptis pyramidalis*) [LN 311/2006: VIII(b)], Scented Bug Orchid (*Orchis coriophora subsp.*

fragrans) and Small-Flowered Tongue Orchid (*Serapias parviflora*).

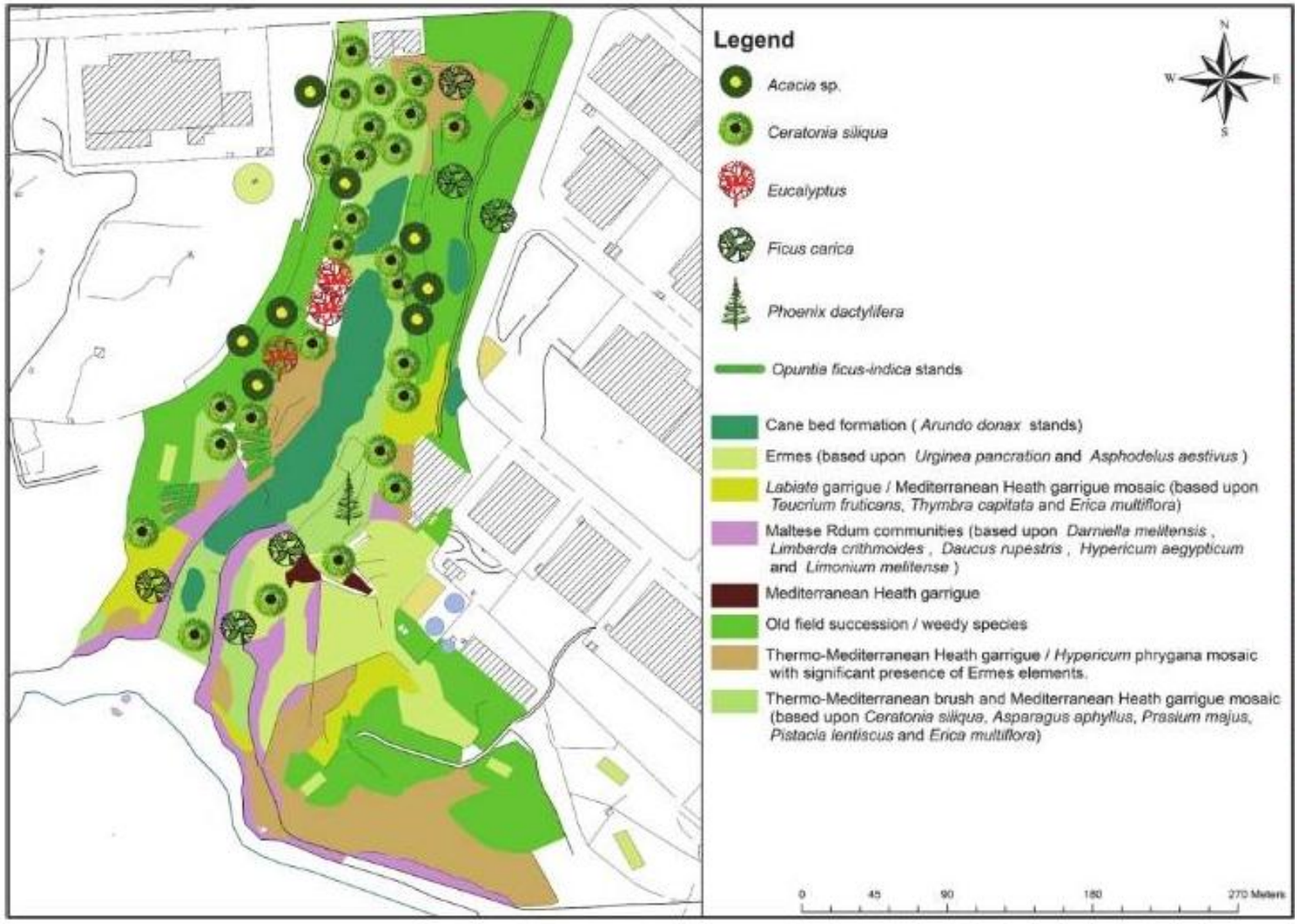
4.23. Other species recorded from these areas included Clustered Carline Thistle (*Carlina involucrata*) [RDB: Rest (MED)], Scarlet/Blue Pimpernel (*Anagallis arvensis*), Pine Spurge (*Euphorbia pinea*), Pygmy Cudweed (*Evax pygmaea*), Wall Valantia (*Valantia muralis*), Tree Mallow (*Malva dendropomorpha*) and Sulla (*Hedysarum coronarium*).

4.24. A shallow basin that was dry at the time of survey but that may function as a temporary freshwater pool was noted in these areas. The sediment within the basin was colonised by Pennyroyal (*Mentha pulegium*) and Sticky Fleabane (*Dittrichia viscosa*).

Disturbed Areas

4.25. According to the 2014 EIS, relatively extensive tracts of habitat that were subject to large-amplitude anthropogenic disruption in the past were colonised by an assemblage of opportunistic ruderal species superimposed on the remnants of the pre-disturbance valley-side communities that colonised these areas. Remnants of the original communities in these areas were represented by isolated shrubs including Maltese Salt-Tree (*Darniella melitensis*) [LN 311/2006: Regl.26; RDB: Endemic], Mediterranean Heath (*Erica multiflora*) [LN 311/2006: III(b), VIII(b)], Egyptian St John's Wort (*Hypericum aegypticum*) [RDB: Rest (MED)], Spiny Chicory (*Cichorium spinosum*), Blue Stonecrop (*Sedum caerulaeum*) [RDB: Rest(MED)], Sea Squill (*Drimia maritima*) [LN 311/2006: VIII(b), X(b); RDB: Rest (MED)] and Lentisk (*Pistacia lentiscus*) [Trees & Woodlands: Schedule 1, Part A Table 2]. Assemblages characteristic of secondary ecological succession were superimposed on the remnant shrub matrix. Such assemblages comprised perennial species indicative of a sustained period of post-disturbance ecological stability including Fennel (*Foeniculum vulgare*), Sticky Fleabane (*Dittrichia viscosa*), and Spiny Asparagus (*Asparagus aphyllus*). Other patches within these areas were colonised by species with shorter lifecycles and relatively rapid regeneration including Cape Sorrel (*Oxalis pes-caprae*), White Mignonette (*Reseda alba*), Crown Daisy (*Glebionis coronaria*), Borage (*Borgao officinalis*) and Milk Vetch (*Astragalus boeticus*).

Figure 4.2: Biotopes map showing general distribution of plant communities in the Area of Influence



Source: *ERSLI Consultants Ltd, 2014, Environmental Impact Statement installation of manufacturing plant and obtaining an operations permit for the production of active pharmaceutical ingredients (API) and the installation of LPG storage tanks in a facility/factory already covered by permit PA/04236/08 at Factory HF 51, Qasam Industrijali, Ħal Far, Birżebbuġa*

Fauna

4.26. The 2014 EIS Ecology Survey also included a vertebrate's survey in the area shown in **Figure 4.4**. This survey was not repeated in this Environmental Impact Assessment; however, a summary of the baseline information contained in the 2014 EIS is reproduced hereunder.

Birds

Resident and breeding species

4.27. According to the 2014 EIS, the seacliffs from Ħal-Far westwards towards Wied Moqbol harbour breeding colonies of two Birds Directive Annex I species, namely: Scopoli's Shearwater *Calonectris diomedea* and Yelkouan Shearwaters *Puffinus yelkouan*. Both species also breed along the cliffs inside Wied Żnuber. The Blue Rock Thrush Monticola *solitarius* is mainly confined to the sea-cliffs and a single pair is known to breed at Wied Żnuber. During the breeding season, coastal birds fly inland in search of food (reptiles, snails) on the remaining open grounds close to Wied Żnuber, Ħal Far and the area between Wied Żnuber and the eastern tip of the industrial zone.

4.28. The Short-toed Lark *Calandrella brachydactyla*, which is also an Annex I species, is a summer breeding visitor. It was formerly a common breeder in the Ħal Far area, but numbers have declined drastically since the 1980s. No breeding has been recorded in the Area of Influence since 2007.

4.29. The Cetti's Warbler *Cettia cetti* colonised the islands in the early 1970s with the first nests discovered in the Wied il-Luq-Girgenti area. In the following years the species' range began to expand and today it is also found breeding on Gozo. Breeding at Wied Żnuber has not been recorded but one to two males are present in the valley throughout the year.

4.30. The Zitting Cisticola *Cisticola juncidis* colonised the islands some 30 years ago and is present in the area in single numbers. The Sardinian Warbler *Sylvia melanocephala* breeds in all types of habitat from rural to urban areas while the Spectacled Warbler *Sylvia conspicillata,* which has also decreased in the last 20 years, is now mainly confined to the top of coastal cliffs. The Spanish Sparrow *Passer hispaniolensis* is by far the most ubiquitous, frequently seen in and around the industrial zone.

Passage migrants

4.31. Most of the migrant species, other than those birds that arrive during the night, head for the coast when they see land. They usually fly inland against the wind funnelling through valleys that run towards the coast. All of these valley mouths such as Wied Żnuber, are important for migrants, especially for those which have been brought down by adverse weather conditions. Large numbers of birds are usually seen when a period of adverse weather, such as head-winds, overcast or stormy weather, follow suddenly on a period of settled, fine weather and more

favourable winds. 'Coasting' by many migrant species occurs frequently during migration. Whilst weather conditions affect the numbers and diversity of migrants, there is always a consistent migration of birds passing through the islands both in spring and autumn.

4.32. Although valleys, rocky ridges and coastal areas seem to be most favoured by bird species of open country, on migration all species, even those which inhabit woodland and other types of habitats, are invariably recorded almost everywhere. The Maltese Islands are in such a unique situation that migrating birds may be noted to occur along the entire coast, even in developed areas.

Wintering birds

4.33. When the autumn movement of trans-Saharan migrants comes to an end, another set of European birds start arriving to spend the winter in the Mediterranean basin. Around 50 different species are regularly recorded in the Maltese Islands and many of them stay for the entire winter until they return to European breeding grounds in March.

4.34. Up to the late 1970s when the Ħal Far airfield was still run by the British Forces, several flocks of Lapwings, Golden Plovers, Skylarks and other species used to overwinter in the airfield. Since the 1980s no flocking birds were ever recorded overwintering in the area mainly due to direct (bird shooting) and indirect (urbanisation, leisure activities) interference.

4.35. Today, birds such as Skylarks and several species of Thrushes (e.g. Song Thrush and Blackbird), Chats (e.g. Robins and Black Redstarts) and passerine species regularly try to overwinter in the area of influence, but the larger species (Thrushes and Larks) are normally shot.

Breeding birds in the Area of influence

4.36. Scopoli's Shearwater *Calonectris diomedea* is a breeding visitor to the Maltese Islands. The first birds make landfall in the last ten days of February. The single egg is laid in a crevice, fissure, or under boulders and vegetation in the latter half of May. Incubation lasts 52 days and the chicks hatch in mid-July. By the end of October all the colonies are deserted. The estimated breeding population of this bird in the Maltese Islands has been estimated at less than 5,000 pairs. The cliffs from Wied ix-Xaqqa to Wied Moqbol were known to hold about 500 to 800 pairs but the current estimates are of 400 to 450 breeding pairs, which is half the population of 10 years ago.

4.37. As a result of increasing human pressure (direct persecution, noise and lights pollution on the cliffs) these birds are being pushed down the more inaccessible cliff sites. In the last 10 years several 'accessible' nest sites located on the top parts of the cliffs have been deserted. The 2014 EIS notes that every evening from March to October, streams of flying birds, coming from their feeding grounds, pass within 1-4 km offshore on their way to their breeding colonies. The distance from

land is conditioned by climatic factors, mainly the presence or absence of strong winds. At certain times of the year, especially during the incubation and the fledging period, the two species of shearwaters frequent specific areas for feeding and these areas lie primarily off the south-eastern coast of Malta at distances ranging from 12 to 500 km offshore.

4.38. The Yelkouan Shearwater *Puffinus yelkouan* is endemic to the central and eastern Mediterranean. The world population is estimated at 13,000-33,000 breeding pairs with Malta holding an estimated population of 1,680 to 1,990 pairs, that is, 10% of the global population. The population at Ħal Far from Wied ix-Xaqqa to Wied Moqbol has been estimated at 100 to 150 pairs. According to the 2014 EIS, counts in 2011 and 2013 showed a small decline in the number of breeding birds, with an estimated total of 95 to 100 pairs.

4.39. The Barn Swallow *Hirundo rustica* is a common spring and autumn passage migrant, sometimes occurring in treble figures. The 2014 EIS notes that single pairs have been known to breed almost annually in the last decade. Since 2008, single pairs have been recorded breeding at the extreme eastern end of the Area of Influence.

4.40. The Cetti's Warbler *Cettia cetti* is a fairly common, localised breeding resident. This species established itself in Malta in the late 1960s, before which it was a vagrant species. In the past 30 years, the spread of Cetti's Warbler in Malta has been steadily gaining foothold in many areas throughout the islands, including on Gozo. The 2014 EIS expert John J Borg has observed single males calling from Wied Żnuber since at least the early 1980s. In 2013 an empty nest was located in the lower part of the valley and a male was heard calling on numerous occasions.

4.41. The Zitting Cisticola *Cisticola juncidis* is Malta's smallest breeding bird. It is very common, widespread, and largely sedentary. The first breeding record was in 1973 when soon after it spread throughout the islands, arriving in Gozo two years later in 1975. Although present in most habitats, the breeding numbers in the Ħal-Far area have been gradually on the decline due to loss of habitat and increased human presence. It favours areas with tall grasses where it can construct its bottle-shaped nest as well as for roosting requirements.

4.42. The Spectacled Warbler *Sylvia conspicillata* is a frequent breeding resident, mainly confined to coastal areas particularly in the south and western side of Malta and Gozo. Its preferred habitat is dry open countryside, garrigue and low scrub. The species suffers a lot from predation by the Western Whip Snake *Hierophys viridiflavus*. According to the 2014 EIS, in 2012 and 2013 up to 4 pairs were recorded by Borg, while in previous years (pre-2000) breeding pairs were recorded in various areas away from the sea cliffs.

4.43. The Sardinian Warbler *Sylvia melanocephala* is a very common and widespread breeding resident. It inhabits a wide range of habitats including maquis, garrigue, woodland, farmland abandoned fields, as well as gardens and green areas in built up areas. The breeding season normally lasts from February to July.

Bats

4.44. According to the 2014 EIS, the Lesser Horseshoe Bat (*Rhinolophus hipposideros*) was only recorded once in the upper part of Wied Żnuber close to dense vegetation in September 2013.

4.45. The Maghrebian Bat (*Myotis punicus*) is found in numerous caves along the cliff face from Wied ix-Xaqqa to Wied Moqbol. Għar Ħasan was the most important roost site of these caves, followed by Għar in-Nagħaġ close to Bengħajsa. The roost inside Għar Ħasan was deserted in 2006 due to constant human disturbance. Single specimens were recorded hunting throughout much of the Area of Influence. A resident species is present in the area throughout the whole year.

4.46. The Soprano Pipistrelle (*Pipistrellus pygamaeus*) was the most frequently encountered of all the six species recorded in the area. Like all the other *Pipistrellus* species in the area, this bat roosts in narrow cracks and crevices along the cliff face. Single bats were seen flying up the cliffs and flying inland towards their feeding grounds. It was frequently seen flying along the lamp-lit streets and along paths. Single bats seasonally roost in narrow cracks and crevices in a number of factories and other buildings.

4.47. Although it frequents the same roosting and feeding habitats as *P. pygmaeus*, the presence of Kuhl's Pipistrelle (*Pipistrellus kuhli*) in the Area of Influence appears to be less numerous than *P. pygmaeus*.

4.48. Roosting Grey Long-eared Bats (*Plecotus austriascus*) have been found inside Għar Ħasan since 1987, with two to three individuals recorded throughout the year. Single bats have been heard (using a bat detector) coming up the cliffs as well as foraging in the lower and upper parts of Wied Żnuber where they hunt for insects among foliage.

Other fauna

4.49. The 2014 EIS describes a number of fauna that are found in the Area of Influence. The Weasel (*Mustela nivalis*) has been seen in the Area of Influence mostly in the late afternoon or early evening. The majority of sightings (circa 80%) are from the upper Wied Żnuber area. The rest were observed along the garrigue and cliffs area.

4.50. The Algerian Hedgehog (*Atelerix algirus*) has been recorded crossing the footpaths and dirt roads. Before the area was flooded with artificial lighting, it was more common. Most sightings (eight) were on the road leading from the old runway towards Għar Ħasan, between Wied Żnuber and the Scheme site.

4.51. Single specimens of the Pygmy White-toothed Shrew (*Suncus etruscus*) were originally recorded in Wied Żnuber in the past but none were seen from 2010 to 2012. Three freshly 'killed' specimen were found dead in March, June, and September 2013 on the dirt road leading from Għar Ħasan towards Wied Żnuber.

4.52. According to the 2014 EIS, the Wood Mouse (*Apodemus sylvaticus*) was regularly recorded in the Area of Influence, especially in Wied Żnuber and the immediate surroundings.

4.53. The Wild Rabbit (*Oryctolagus cuniculus*) is relatively common and in some years very common, especially along the cliff edges and around Wied Żnuber.

4.54. The Painted Frog (*Discoglossus discoglossus pictus*) is present in small numbers in and around water reservoirs. It is also present in rock pools during winter, and a small population is found in the lower parts of Wied Żnuber where overflowing water, including sewage, found its way down the valley and accumulated into a large pool close to the British fortification wall which runs across the valley.

4.55. The Moorish Gecko (*Tarentola mauretanica*), is present in and around rubble walls, inside buildings as well as inside caves, while the Turkish Gecko (*Hemidactylus turcicus*) is present near habitations and is commonly seen on factory walls and inside abandoned buildings.

4.56. The Chameleon (*Chamaeleo chamaeleon*) was recorded only on two occasions on trees in the upper parts of Wied Żnuber. This species was probably introduced in the area by humans or else has expanded its range as it is present in good numbers in the Għar Dalam and Birżebbuġa area.

4.57. According to the 2014 EIS the Maltese Wall Lizard (*Podarcis filfolensis*) is present in single figures throughout the whole Area of Influence. Recent observations have shown a decline in numbers. The causes for this decline are not known but may be attributed to a considerable increase in the number of rats in the whole area.

4.58. Single specimens of the Ocellated Skink (*Chalcides ocellatus*) were encountered in most areas especially near rubble walls.

4.59. The Western Whip Snake (*Hierophys viridiflavus*) is regularly seen during the spring and summer months. The upper Wied Żnuber appears to be preferred to the lower parts of the valley close to the sea, where it has never been recorded.

4.60. Only two adult specimens of the European Leopard Snake or Rat snake (*Zamenis situla*) have been recorded: one on the upper slopes of Wied Żnuber in May 2012 and another adult but considerably smaller in size about 30 metres south-west from the first one in July 2013.

Figure 4.3: Area of Influence for Vertebrates

DETERMINING IMPACT SIGNIFICANCE

1.26. In assessing the significance of the potential negative impacts arising from the Scheme, the following criteria have been used:

- **Not significant** (for example, no material change in habitat quality and / or extent);
- **Minor significance** (for example, small-scale loss / disturbance of habitat that is unlikely to affect the ecological integrity of the A of I); and
- **Major significance** (for example, large-scale loss / disturbance of habitat that is likely to affect the ecological integrity of the A of I).

1.27. The concept of 'material change' needs to be viewed in the context of the Scheme, as described in **Chapter 2**. For a change to be material, it must affect the ecological integrity of the habitats and the interactions of the species they support more than they would be affected by the continuation of the uses already extant in the area and to which the ecology is accommodated. This is best illustrated by reference to a specific impact, such as dust deposition. In many situations, although an area may already be affected by dust inundation from agriculture and excavations associated with urban development in the locality, the redevelopment of a particular site per se is not likely to materially affect the amount of entrained dust because construction activities have been more or less continuous over the years; as one site is developed another area is excavated. The site of dust generation moves, but the overall level of dust generating activities may not change substantially. For there to be a 'material change' in the effects of dust, there firstly needs to be a significant change in the level of dust generated, and secondly that change must be noticeable in its effects on the environment.

1.28. Changes that would qualify as a 'material change' would be a reduction in habitat size or other alteration that modifies the habitat to such an extent that the integrity of the habitat and / or ecological feature would be affected. Such changes would include fragmentation of habitats, isolation of populations, and chronic effects that may lead to long-term or permanent changes in the physico-chemical characteristics of the habitats and hence of the species they support.

4.61. It is clarified that since the buildings hosting the Scheme have largely been built through the Development Notification Order process, construction impacts are scoped out of the assessment. Any remaining construction interventions are likely to be minor in nature and are unlikely to significantly affect biodiversity in the area.

ASSESSMENT OF IMPACTS

Potential impacts

4.62. The potential impacts associated with the Scheme are those mainly related to its operation.

4.63. The categories of impacts that may be experienced as a result of the activities undertaken on the Scheme site during operation (as described in **Chapter 2**) include:

- Disturbance and/or damage to habitats and/or wildlife within and near the Scheme Site including from light and noise;
- Risks to the habitats and species in the Area of Influence from spills / leakages; and
- Risks to the habitats and species in the Area of Influence from emissions to the air.

4.64. The impacts that will affect the A of I as a result of the operation of the Scheme will depend on the mitigation measures adopted during the operation of the Scheme, including abatement measures, as well as the sensitivity of the habitats and species in the A of I.

4.65. The following sections provide a more detailed assessment of these impacts as they relate to the operation of the Scheme.

Prediction and Significance of Impacts

Disturbance to Habitats and Species Populations of Conservation Significance

4.66. As mentioned, the Scheme has already been largely built and very few construction interventions are left for the Scheme to become operational. Therefore disturbance from construction activities is likely to be minimal.

4.67. The Scheme is likely to increase traffic in the area. As stated in the 2014 EIS, spillages from traffic attracted by the Scheme are not expected to constitute a significant conservation concern for the vegetation communities in Wied Żnuber, as any fluid spillages would be likely to flow along the road. The impact is not considered significant.

4.68. In view that the area already has light sources, the habitats and species in the vicinity of the development are already affected by light trespass. Research provides evidence that noise and light pollution can have significant impacts on a number of animal taxa including, in particular, invertebrates[9]. Impacts include changes in foraging and reproductive behaviours, reduction in fitness, increased risk of predation and

[9] Research including: Davies, T.W., Bennie, J., Gaston, K.J. 2012. Street lighting changes the composition of invertebrate communities. Biology Letters; Morley, E.L., Jones, G., Radford, A. N. 2014. The importance of invertebrates when considering the impacts of anthropogenic noise. 281(1776). Proceedings of the Royal Society Biological Sciences; Bruce-White, C. & Shardlow, M. 2011. A Review of the Impact of Artificial Light on Invertebrates – Putting the Backbone into Invertebrate Conservation. Buglife – The Invertebrate Conservation Trust.

reduced reproductive success (Newport et al, 2014).[10] In the case of artificial light, such effects generally are a result of changes in orientation, disorientation, or misorientation, and attraction or repulsion from the altered light environment (Longcore & Rich, 2004).[11] Most animals are sensitive to light and almost all have some form of identifiable photo receptors. In addition, a number of mammals are nocturnal, in particular, bat species.

4.69. As described above, the area is known to host breeding colonies of seabirds as well as bats and other fauna. The area is already subjected to noise and light disturbance from existing industrial operations, including from the operation of Sterling Chemical Malta itself. Given that the new facility, which will operate 24 hours a day for 5 days a week, is located behind an existing industrial installation, the noise and light generated from the Scheme is not being newly introduced into the area. This, as well as the fact that there is an industrial installation across from the Scheme effectively screening the Scheme from the coastal cliffs, means that the disturbance to fauna is expected to be minor to not significant.

Risks to the habitats and species in the Area of Influence from spills / leakages

4.70. The main concern during operation is the potential for contamination of the habitats of interest in the area in the case of spillages or accidents at the site. **Volume 2** of this EIA Update Report provides a detailed environmental risk assessment.

4.71. Releases could occur from accidental spillages of the various substances used and produced on site, namely raw materials (such as solvents, reagents, acids, and bases), products (APIs, in powder form or in solution), hazardous waste (especially liquid waste contaminated with organic solvents), substances used for maintenance and other associated site activities, as well as diesel fuel.

4.72. Releases could also occur from contaminated washwater, notably that generated from the production area during cleaning of equipment and floors.

4.73. Used extinguishant will also be generated in the event of a fire, and, without mitigation this may become contaminated with raw materials (including solvents and fuel), products (APIs), and hazardous waste stored and handled on site.

4.74. The risk assessment assesses impacts from accident scenarios including fire/explosion, flooding and earthquake. It also identifies potential sources, pathways and receptors. The habitats of interest are identified as potential receptors in accidents where there could be leaks or spillages. In the absence of mitigation, the risk assessment identifies that the potential for spillages and releases is high and

[10] Newport, J., Shorthouse, D.J., Manning, A.D. The effects of light and noise from urban development on biodiversity: Implications for protected areas in Australia. Volume 3, Issue 3. Ecological Management & Restoration.

[11] Longcore, T., Rich, C. 2004. Ecological light pollution. 2(4). Front Ecol Environ.

extreme in some cases. With mitigation in place, the risk of such an event is classified as low to very low, with a moderate risk level in the case of a large fire where there could potentially be a release of used contaminated extinguishant.

4.75. From an impact assessment point of view, a spill in the area could result in a minor to major impact on habitats of conservation interest, in particular those found in the Wied Żnuber valley system and beyond. The full extent of the impact would depend on the degree of the spill and how quickly it would be cleaned up. However noting the findings of the risk assessment and the mitigation measures in place, it is likely that spills would not be on a major scale; therefore, the impact is considered to be of minor significance. In the case of a fire, if contained quickly, the extent of impact would be minor. In the case of a large fire the impact would be minor to major, depending on the extent of the impact and what species or habitats are affected.

Risks to the habitats and species in the Area of Influence from emissions to the air

4.76. Operation of the Scheme from various activities on site, including from the production lines, is expected to generate emissions containing APIs, volatile organic compounds (VOCs) and / or reaction by-products. The emissions will be transported by wind and, after deposition, by surface runoff following rainfall. Winds in the Maltese Islands are most likely to blow from the northwest or west suggesting that the predominant direction of travel of windborne particulate is away from the Wied Żnuber area.

4.77. According to the Risk Assessment presented in **Volume 2** of this EIA Update Report, emissions to air from the production lines, clean rooms, laboratories, fractioning area, and bulk waste storage area are not expected to have a significant impact on the environment, due to the abatement systems that will be in place. As described in detail in **Chapter 2** the extensive air abatement system includes scrubbers, HEPA filters, and carbon filters. The impact on the surrounding ecology from emissions from the Scheme is not expected to be significant.

MITIGATION

1.84. It is acknowledged that the operation of the Scheme will be subject to an IPPC permit (also noting that the current operation already has an IPPC permit). The operational issues discussed above including the required mitigation measures to control emissions will be controlled through that permit. Notwithstanding, the following mitigation measures are proposed in order to attempt to reduce the significance of impacts identified above:

- In the case where exterior lighting is allowed, it is important that it is kept to a minimum and that a building management system is in place to limit light spill. In particular, no lights should be shone onto the surrounding natural areas;
- Any proposed landscaping should be ecologically compatible with the adjacent natural habitats and in line with MEPA's 2002 Guidelines on Trees, Shrubs and

Plants for Planting and Landscaping the Maltese Islands as well as ERA's 2018 National Code of Good Practice – Landscaping, Forestation and Invasive Alien Species;

- All abatement (scrubbers and filters) and containment systems (bunds, impermeable flooring, and washing water reservoir) must be put in place before commencement of operations;
- When installing noise generating equipment such as air handling units, where possible install noise screening and direction away from the cliffs; and
- Operational waste management should be carried out diligently, to reduce the risk of escape of waste to the surrounding natural areas.

RESIDUAL IMPACTS

4.78. Assuming mitigation measures are appropriately implemented as listed above, the significance of residual impacts on ecology within the A of I are considered to be minor to not significant with the exception of a large fire where the impact from release of used extinguishant is minor to major.

Table 4.1: Summary of Ecological Impacts

Predicted impact	Beneficial /adverse	Nature, Scale and Type of Impact					Probability of Impact Occurring (likely/ unlikely/ remote/ uncertain)	Significance of Impact (major/ minor /not significant)	Proposed Mitigation Measures	Significance of Residual Impact (major/ minor/not significant)
		Extent of Impact (nat/local /site)	Direct/ indirect	S'term/ l'term	Perm/ temp	Revers/ irrevers				
Disturbance and/or damage to habitats and/or wildlife within and near the Scheme site including from light and noise	Adverse	Local	Direct & indirect	L term	Perm	Revers	Likely	Minor to not significant	Lighting plan with measures designed to reduce light pollution Screening of noise-generating activities	Minor to not significant
Risks to the habitats and species in the Area of Influence from spills / leakages	Adverse	Local	Direct & indirect	S term	Temp	Irrevers	Likely	Minor in case of spillages and minor to major in case of a large fire (release of used extinguishant)	Containment, impermeable concrete flooring	Minor in case of spillages and minor to major in case of a large fire (release of used extinguishant)
Risks to the habitats and species in the Area of Influence from emissions to the air	Adverse	Local	Direct & indirect	S term	Temp	Revers	Likely	Not significant	Abatement through scrubbers and/or filters	Not significant

5. SUMMARY OF KEY IMPACTS, INTERACTION BETWEEN IMPACTS AND MITIGATION

INTRODUCTION

5.1. The purpose of this chapter is to provide a summary of the key environmental impacts, their interaction and cumulative effects, and their mitigation. The chapter addresses the requirements to describe mitigation measures to prevent, eliminate, reduce or offset (as relevant) the identified significant adverse effects of the Scheme and to identify cumulative and residual impacts. The chapter concludes with a summary of the mitigation measures proposed in the Environmental Impact Assessment Update as well as a description of the required authorisations.

SUMMARY OF KEY IMPACTS

5.2. **Chapters 3** and **4** describe the predicted impacts of the Scheme in relation to geo-environment and ecology, in accordance with the environmental topic areas originally identified in the Terms of Reference for the construction of Sterling Chemical Malta.

5.3. For each predicted impact, an assessment has been made as to whether the impact is likely to be of major, moderate, minor significance, or of no significance; the criteria that were used to judge significance are described in each of the chapters. Predicted major and minor impacts have been identified and, in the case of negative impacts, there is a description of how these could be mitigated. All the impacts identified are summarised in **Table 5.1** at the end of this Chapter.

5.4. No major impacts have been identified on sensitive receptors in terms of geo-environment. Minor to major impacts have been identified for ecology as described hereunder. The impacts, relevant mitigation measures, and the residual impacts are discussed hereunder.

Geo-environment

5.5. The impact of the operation of the Scheme of hydrogeological resources is considered to be insignificant due to the extensive mitigation measures inbuilt into the Scheme.

Ecology

5.6. The impact on the flora and fauna outside the Scheme Site is considered to be minor to not significant in terms of noise and light pollution and impacts from spills and leakages. The potential impact in case of a large fire is considered minor to major due to the potential release of used contaminated extinguishant.

INTERACTION OF IMPACTS

5.7. The interaction of impacts with the current baseline is also described in **Chapters 3**

and **4**. The interactions are summarised in **Table 5.1** below. The interaction between impacts describes the potential cumulative or reactive nature of the various disturbances caused by the Scheme during construction and operation.

5.8. As described in **Chapter 2** the Scheme has largely been constructed through the DNO process, and therefore construction impacts are not relevant to this EIA Update Report. The operation of the Scheme is expected to be very similar to that currently in operation.

CUMULATIVE IMPACTS

5.9. Cumulative impacts are those that result from incremental changes caused by other past, present, or reasonably foreseeable actions together with the Scheme.

5.10. The various impacts identified in **Chapters 3** and **4** were assessed in the context of the existing baseline (encompassing the past and present context). With regards to air quality given that the same abatement systems will be used as the current Sterling Chemical Malta, no cumulative effects are expected. With regards to noise, the location of the utilities area, which is likely to generate most noise, is relatively far away from the current installation so cumulative effects are unlikely.

MITIGATION

5.11. This EIA Update Report reports on the findings of the EIA, in accordance with ERA requirements. Where appropriate, mitigation measures have been recommended and these have been agreed to by the Applicant; these are described at the end of each of **Chapters 3** and **4** and summarised in **Table 5.1**. It would be appropriate for, and it is recommended that, these mitigation measures be taken account of in the conditions of any eventual development permit.

REQUIRED AUTHORISATIONS

5.12. As mentioned, the operation of Sterling Chemical Malta is already subject to IPPC permit IP 0001/14/B. The operation of the Scheme will require a variation to the IPPC permit. Additionally the LPG storage will need to be licensed by the Regulator for Energy and Water Services (REWS). An update to the Sewer Discharge Permit, issued by the Water Services Corporation (WSC) will also be required.

Table 5.1: Summary of Impact Assessment

Predicted Impact	Beneficial / Adverse /Neutral	Nature, Scale and Type of Impact						Probability of Impact Occurring (Likely/ Unlikely/ Remote/ Uncertain)	Significance of Impact (Major/ Moderate/ Minor/Not Significant)	Proposed Mitigation Measures	Significance of Residual Impact (Major/ Moderate/ Minor/Not Significant)
		Constr'n /Oper'n	Extent of Impact (Nat/ Local /Site)	Direct/ Indirect	S'term / L'term	Perm/ Temp	Revers/ Irrevers				
Geo-environment											
Impact on hydrogeology from spills	Adverse	Oper'n	Local	Direct	L term	Perm	Revers	Likely	Not Significant	In-built in the design - bunding, concrete flooring plus operational measures such as training, use of spill kits, and maintenance of equipment and containment systems	Not Significant
Ecology											
Disturbance and/or damage to habitats and/or wildlife within and near the Scheme site including from light and noise	Adverse	Oper'n	Local	Direct & indirect	L term	Perm	Revers	Likely	Minor to not significant	Lighting plan with measures designed to reduce light pollution Screening of noise-generating activities	Minor to not significant

Predicted Impact	Beneficial / Adverse /Neutral	Nature, Scale and Type of Impact						Probability of Impact Occurring (Likely/ Unlikely/ Remote/ Uncertain)	Significance of Impact (Major/ Moderate/ Minor/Not Significant)	Proposed Mitigation Measures	Significance of Residual Impact (Major/ Moderate/ Minor/Not Significant)
		Constr'n /Oper'n	Extent of Impact (Nat/ Local /Site)	Direct/ Indirect	S'term / L'term	Perm/ Temp	Revers/ Irrevers				
Risks to the habitats and species in the Area of Influence from spills / leakages	Adverse		Local	Direct & indirect	S term	Temp	Irrevers	Likely	Minor in case of spillages and minor to major in case of a large fire (generation of used extinguishant)	Containment, impermeable concrete flooring	Minor in case of spillages and minor to major in case of a large fire (generation of used extinguishant)
Risks to the habitats and species in the Area of influence from emissions to the air	Adverse		Local	Direct & indirect	S term	Temp	Revers	Likely	Not significant	Abatement through scrubbers and filters	Not significant

EXTENSION TO STERLING CHEMICAL LTD

ENVIRONMENTAL IMPACT ASSESSMENT UPDATE

VOLUME 2: ENVIRONMENTAL RISK ASSESSMENT

Version 1: March 2019

Report Reference:

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Quality Assurance

Extension to Sterling Chemical Ltd in Ħal Far
Environmental Impact Assessment Update
March 2019

Report for: **Sterling Chemical Ltd**

Revision Schedule

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ENVIRONMENTAL RISK ASSESSMENT

INTRODUCTION

1. Volume 2 of the Environmental Impact Assessment Update Report (EIA Update) presents an environmental risk assessment for the Scheme.

Terms of Reference

2. Since this is an EIA Update, no Terms of Reference have been provided by ERA. Reference is therefore made to the Terms of Reference that had been issued for the Environmental Impact Statement (EIS) for an *installation of manufacturing plant and obtaining an operations permit for the production of active pharmaceutical ingredients (API) and the installation of LPG storage tanks in a facility/factory already covered by permit PA/04236/08 at Factory HF 51, Qasam Industrijali, Ħal Far, Birżebbuġa*[1].

ASSESSMENT METHODOLOGY

Scheme Phases

3. The Scheme will involve three major phases, as follows:

   - Construction;
   - Operation; and
   - Decommissioning.

4. As described in **Chapter 2** of the EIA Update, the construction phase is already underway, and almost complete. Additionally, it is not considered that this phase presents significant environmental risk, given that most construction materials handled are inert / non-hazardous in nature. Therefore it is considered that the environmental risk from this phase does not need to be further assessed.

5. Any decommissioning of the Scheme will also follow an approved Decommissioning Plan, which will be in accordance with international practice and the guidance applicable at the time of decommissioning. An outline Decommissioning Plan is already in place, as required by the Integrated Pollution Prevention and Control (IPPC) permit, and which will also apply to the Scheme. A final decommissioning plan will be submitted to ERA before the site is decommissioned. It would be premature to carry out an environmental risk assessment on the decommissioning phase at this

[1] ERSLI Consultants, 2014, Environmental Impact Statement *for an installation of manufacturing plant and obtaining an operations permit for the production of active pharmaceutical ingredients (API) and the installation of LPG storage tanks in a facility/factory already covered by permit PA/04236/08 at Factory HF 51, Qasam Industrijali, Ħal Far, Birżebbuġa.*

stage, since this can only be carried out at the time of the decommissioning. However, an environmental risk assessment can be carried out as part of the approval process of the full Decommissioning Plan, if required by the Planning Authority (PA) or ERA.

Objectives

6. This volume of the EIA Update Report therefore presents a detailed environmental risk assessment of the Scheme operations by:

- Describing and evaluating the risks to the environment associated with the Scheme, including risks arising due to the nature of the materials to be stored, handled and produced, and the risks associated with the activities to be undertaken on site; and
- Describing the measures which will be undertaken to mitigate such risks, and evaluating the residual risk levels.

Methodology

Source-Pathway-Receptor Linkage

7. An environmental risk occurs when there is a means by which a hazard can result in a deleterious impact on the surrounding environment, that is, receptors. The presence of a hazard alone does not constitute a risk. A risk is only present if there is a pathway which links the source (hazard) to the receptor. This is known as the source-pathway-receptor linkage.[2]

8. Environmental risk assessment is the process by which source-pathway-receptor linkages are identified and evaluated. If any of the three elements are absent then there is no complete linkage, and thus no unacceptable risk.

Risk Assessment Criteria

9. If a source-pathway-receptor linkage is found, the magnitude of a risk is a function of the consequences of pollution and the likelihood that such pollution will occur.

10. The risk criteria applied in this assessment is based on a matrix consistent with ISO 31010: *Risk management: Risk assessment techniques*.

11. **Table 1** presents the criteria used for assessing environmental consequences; **Table 2** presents the criteria used for assessing the likelihood of the event occurring. The overall risk level is then determined by combining the two factors, using the matrix in **Table 3**.

[2] Defra (2002) *Groundwater Protection Code: Petrol Stations and other Fuel Dispensing Facilities involving Underground Storage Tanks* http://www.adlib.ac.uk/resources/000/082/529/groundwater_petrol_code.pdf.

Table 1: Criteria for Assessing Environmental Consequences

Severity Level	Effects on Natural Environment
1: Insignificant	Limited damage to minimal area of low significance.
2: Minor	Minor effects on biological or physical environment. Minor short/medium-term damage to small area of limited significance.
3: Moderate	Moderate effects on biological or physical environment (e.g. air, water) but not affecting ecosystem function. Moderate short/medium-term widespread impacts (e.g. significant spills).
4: Major	Serious environmental effects with some impairment of ecosystem function. Relatively widespread medium-long term impacts.
5: Catastrophic	Very serious environmental effects with impairment of ecosystem function. Long term, widespread effects on significant environment (e.g. national park).

Table 2: Measure of Likelihood

Level	Descriptor	Description	Guideline Frequency
A	Almost certain	Consequence is expected to occur in most circumstances	Occurs more than once per month
B	Likely	Consequence will probably occur in most circumstances	Occurs once every 1 month - 1 year
C	Occasionally	Consequence should occur at some time	Occurs once every 1 year - 10 years
D	Unlikely	Consequence could occur at some time	Occurs once every 10 years - 100 years
E	Rare	Consequence may only occur in exceptional circumstances	Occurs less than once every 100 years

Table 3: Risk Matrix

Likelihood	Environmental Consequence					No Pollutant Linkage
	1: Insignificant	2: Minor	3: Moderate	4: Major	5: Catastrophic	
A: Almost Certain	Low	Moderate	Extreme	Extreme	Extreme	None
B: Likely	Low	Moderate	High	Extreme	Extreme	
C: Occasional	Very low	Moderate	High	High	Extreme	
D: Unlikely	Very low	Low	Moderate	High	High	
E: Rare	Very low	Low	Moderate	Moderate	High	

Overview

12. The Scheme will include manufacture, storage and processing of hazardous substances and waste which, without mitigation, could present a risk to the environment through underground, surface and airborne pollution.

13. **Table 4** summarises potential sources of pollution and the respective pathway to the relevant receptor. The table also describes the mitigation measures that will be adopted to mitigate such risks, distinguishing between fixed construction elements incorporated by the Scheme and operational / procedural mitigation measures. It is to be noted that all the mitigation measures in the table will be implemented as part of the Scheme, and several of these measures are in fact mandatory, in line with the requirements of the Environment and Resources Authority (ERA) and the Regulator for Energy and Water Services (REWS).

14. **Table 5** identifies source-pathway-receptor linkages for major accident scenarios of fire, flooding, and earthquakes.

Table 4: Pollution Pathway Identification and Mitigation Measures

Source	Pathway	Receptor	Mitigation Measures	
			Construction Mitigation Measures	Operational Mitigation Measures
Spill from new production lines (API products, hazardous raw materials / waste, wash water)	Direct contamination; permeable strata above water table	• Land • Groundwater • Wied Żnuber, leading to sea • Agricultural land • Cultural heritage features in valley • Cliffs and garrigue (SPA, SAC, AEI)	• Underlying impermeable concrete layer, with epoxy resin coating on the floor • Gutters leading to a 74 m^3 concreted water washing reservoir	• Alarm on reservoir (to ensure no overfilling) • Effluent from production / washing of production equipment is collected in IBCs[3] • Certification of containment systems as required by IPPC permit • Spill kits, and staff training
Spill from new raw material warehouse (e.g. solvents, reagents, acids, bases)	Direct contamination; permeable strata above water table	• Land • Groundwater • Wied Żnuber, leading to sea • Agricultural land • Cultural heritage features in valley • Cliffs and garrigue (SPA, SAC, AEI)	• Underlying impermeable concrete layer with surface hardener • Gutters leading to a 74 m^3 water washing reservoir	• Alarm on reservoir (to ensure no overfilling) • Certification of containment systems as required by IPPC permit • Raw materials typically stored in drums or IBCs, not larger than 1 m^3 each • Spill kit, and staff training

[3] IBCs are intermediate bulk containers, typically having a volume of 1 m^3.

Source	Pathway	Receptor	Mitigation Measures	
			Construction Mitigation Measures	Operational Mitigation Measures
Spill from new clean rooms	Direct contamination; permeable strata above water table	• Land • Groundwater • Wied Żnuber, leading to sea • Agricultural land • Cultural heritage features in valley • Cliffs and garrigue (SPA, SAC, AEI)	• Underlying impermeable concrete layer with vinyl coating • Clean rooms are on Level 1 (no direct contact with ground due to underlying car park)	• No storage, transfers under staff supervision • Spill kits[4], and staff training
Spill from new cold room	Direct contamination; permeable strata above water table	• Land • Groundwater • Wied Żnuber, leading to sea • Agricultural land • Cultural heritage features in valley • Cliffs and garrigue (SPA, SAC, AEI)	• Underlying impermeable concrete layer • Cold room at Level 1 (no direct contact with ground due to underlying car park)	• Spill kits[4], and staff training

[4] The nearest spill kits will be in the nearby production lines; spill kits cannot be stored in this area due to product quality requirements.

Source	Pathway	Receptor	Mitigation Measures	
			Construction Mitigation Measures	Operational Mitigation Measures
Spill from new laboratories	Direct contamination; permeable strata above water table	• Land • Groundwater • Wied Żnuber, leading to sea • Agricultural land • Cultural heritage features in valley • Cliffs and garrigue (SPA, SAC, AEI)	• Underlying impermeable concrete layer, with acid-resistant tiles and acid-resistant grout • Spills collected in floor drains and diverted to the 74 m^3 water washing reservoir	• Alarm on reservoir (to ensure no overfilling) • Certification of containment systems as required by IPPC permit • Laboratory waste generated in relatively larger quantities collected in containers for disposal • Spill kits, and staff training
Spill in maintenance workshop	Direct contamination; permeable strata above water table	• Land • Groundwater • Wied Żnuber, leading to sea • Agricultural land • Cultural heritage features in valley • Cliffs and garrigue (SPA, SAC, AEI)	• Underlying impermeable concrete layer	• Minimal liquid hazardous substances used • Any liquid hazardous substances stored in a cabinet with underlying containment
Spill in new external utilities area	Direct contamination; permeable strata above water table; rainwater runoff	• Land • Groundwater • Wied Żnuber, leading to sea • Agricultural land • Cultural heritage features in valley • Cliffs and garrigue (SPA, SAC, AEI)	• Underlying impermeable concrete layer • Utilities area at Level 1 (no direct contact with ground due to underlying car park)	• Storage of waste solvent on prefabricated containment

Source	Pathway	Receptor	Mitigation Measures	
			Construction Mitigation Measures	Operational Mitigation Measures
Spill during emptying of water washing reservoir	Direct contamination; permeable strata above water table; rainwater runoff	• Land • Groundwater • Wied Żnuber, leading to sea • Agricultural land • Cultural heritage features in valley • Cliffs and garrigue (SPA, SAC, AEI)	• Gutters bounding designated transfer area, leading to water washing reservoir	• Lorry to park in designated area only • Valve connecting area to reservoir opened during waste transfer
Spill from external flammable warehouse	Direct contamination; permeable strata above water table; rainwater runoff	• Land • Groundwater • Wied Żnuber, leading to sea • Agricultural land • Cultural heritage features in valley • Cliffs and garrigue (SPA, SAC, AEI)	• Covered sheds • Underlying concrete bunds beneath storage areas • Central area concreted, laid to fall to a central floor drain leading to an underground sump with closed valve	• Certification of containment systems as required by IPPC permit • Storage in designated areas only • Waste / raw materials typically stored in drums or IBCs, not larger than 1 m^3 each • Regular removal of waste • Waste transferred to licensed waste carriers having appropriate containment, and under supervision of Scheme staff • Spill kits, and staff training • Valve can only be opened by a responsible person, to release clean rainwater
Spill from new fractioning area	Direct contamination; permeable strata above water table; rainwater runoff	• Land • Groundwater • Wied Żnuber, leading to sea • Agricultural land • Cultural heritage features in valley • Cliffs and garrigue (SPA, SAC, AEI)	• Covered shed • Floor laid to fall towards a floor drain leading to an underground sump with closed valve	• Certification of containment systems as required by IPPC permit • No storage, only transfers and weighing • Valve can only be opened by a responsible person, to release clean rainwater • Spill kits, and staff training

Source	Pathway	Receptor	Mitigation Measures	
			Construction Mitigation Measures	Operational Mitigation Measures
Spill / leak in new bulk waste storage area (HF 50 block)	Direct contamination; permeable strata above water table	• Land • Groundwater • Wied Żnuber, leading to sea • Agricultural land • Cultural heritage features in valley • Cliffs and garrigue (SPA, SAC, AEI)	• Bulk tanks inside a reinforced concrete bund, overflowing to reservoir • Bulk tank, transfer area and ISO tank area covered to prevent rainwater ingress • ISO tank area, transfer area and store flooring concreted, laid to fall to reservoir	• Level gauges and high level alarms on tanks • Waste transfers under supervision • Waste transfers logged to ensure no losses during transfers • Certification of containment systems as required by IPPC permit • Spill kits for minor spills, and staff training
Diesel spill from generator day tanks	Direct contamination; permeable strata above water table; rainwater runoff	• Land • Groundwater • Wied Żnuber, leading to sea • Agricultural land • Cultural heritage features in valley • Cliffs and garrigue (SPA, SAC, AEI)	• Storage of diesel in double skin tanks • Capacity <1,000 L each • Underlying concrete • Protection from mechanical damage installed on generators' bases	• Spill kits, and staff training
Emissions to air from new production lines (APIs, VOCs, reaction by-products)	Air dispersion (prevailing wind direction)	Air sensitive receptors	-	• Emissions from reactors treated in heat exchangers, carbon filter and scrubber • Blowdown tanks to contain emissions in case of emergency; emissions from blowdown tanks routed to scrubber • Local extraction used if containers are opened, emissions directed to scrubber • Emissions monitoring as required by IPPC permit • Maintenance of abatement systems

Source	Pathway	Receptor	Mitigation Measures	
			Construction Mitigation Measures	Operational Mitigation Measures
Emissions to air from new clean rooms	Air dispersion (prevailing wind direction)	Air sensitive receptors	-	• Abatement with HEPA filters for areas where substances are handled • Emissions monitoring as required by IPPC permit • Differential pressure device to monitor filter condition • Replacement of filters as per maintenance schedule
Emissions of APIs to air from cold rooms / other storage areas for hazardous substances in HF 53 block	Air dispersion (prevailing wind direction)	Air sensitive receptors	-	• No exposure of products to atmosphere under normal conditions • Most substances in powder form, in packages under 20 kg • Spill kits, and staff training
Emissions to air from new laboratories	Air dispersion (prevailing wind direction)	Air sensitive receptors	-	• Small-scale handling of reagents and APIs • Emissions from fume hoods treated in carbon filters • HEPA filters for balance enclosures (used for weighing powders) • Replacement of filters as per maintenance schedule • Emissions monitoring as required by IPPC permit
Emissions to air from new fractioning area	Air dispersion (prevailing wind direction)	Air sensitive receptors	-	• Closed-cycle system for dispensing raw materials
Emissions to air from bulk new waste area (HF 50 block)	Air dispersion (prevailing wind direction)	Air sensitive receptors	-	• Bulk storage tanks connected to scrubber, dichloromethane tanks also connected to carbon filter • Closed-cycle system for waste transfers to ISO tanks

Source	Pathway	Receptor	Mitigation Measures	
			Construction Mitigation Measures	**Operational Mitigation Measures**
Release of used extinguishant (generated in case of a fire), contaminated with raw materials (including solvents), products (APIs) and / or hazardous waste	Direct contamination; permeable strata above water table; rainwater runoff	• Land • Groundwater • Wied Żnuber, leading to sea • Agricultural land • Cultural heritage features in valley • Cliffs and garrigue (SPA, SAC, AEI)	• Mitigation measures to reduce the likelihood / severity of a fire (and therefore the generation of used extinguishant) are listed in **Table 5** • Fate of contaminated used extinguishant: ○ New production lines, raw material warehouse, laboratories: Collected in 74 m^3 water washing reservoir ○ Clean rooms, cold rooms: Flows to outdoor area on Level 1 (discharges to road); only portable fire extinguishers installed in these areas ○ External flammable warehouse, fractioning area: Concreted bunds / sump ○ Bulk waste storage area: Concrete bund / reservoir in storage and activity areas	• Mitigation measures to reduce the likelihood / severity of a fire (and therefore the generation of used extinguishant) are listed in **Table 5** • Containment of contaminated used extinguishant: ○ In maintenance workshop, external utilities area: Prefabricated containment

Table 5: Pollution Pathway Identification and Mitigation Measures for Major Accident Scenarios

Scenario	Source	Pathway	Receptor	Mitigation Measures	
				Construction Mitigation Measures	Operational Mitigation Measures
Fire	Flammable materials, including solvents, waste and LPG	Conduction; convection; radiation; along the wind direction	• Surrounding land users • Wied Żnuber • Cultural heritage features in valley • Cliffs and garrigue (SPA, SAC, AEI)	***Fire prevention:*** • Covered external flammable warehouse and tanks in bulk waste storage area • LPG tank placement and design conform to Maltese and UK Codes of Practice • LPG tank certified according to Pressure Equipment Regulations • LPG tank located below ground, protected from mechanical damage • LPG tank has fire walls on two sides • Natural ventilation of bulk LPG tank, external flammable warehouse and bulk waste tanks (to avoid build-up of gas) • Diesel-operated generators (diesel is not flammable) ***Fire fighting:*** • Rainwater reservoir with 600 m^3 of water (150 minutes) dedicated to firefighting; level meter with alarm	***Fire prevention:*** • No smoking near external flammable warehouse, LPG tank and bulk waste storage area • Closed-cycle system for dispensing raw materials in fractioning area • Boiler rooms fitted with gas sensors, linked to quick-closing valves • Valves also installed on LPG vaporiser, on boilers and outside boiler rooms • Scrubber and closed-cycle system in bulk waste area (HF 50 block) • New bulk waste storage area will be defined as ATEX; pumps will be ATEX rated, earthing system for loading / unloading operations • Fire risk assessment by a competent fire expert will be carried out on the new bulk waste storage area (HF 50 block); recommended mitigation measures will be implemented ***Fire fighting:*** • Emergency fire procedures • Automatic fire detection system, sprinkler and wet mains system, fire extinguishers and fire blankets installed in HF 53 block • Fire detection and firefighting arrangements for bulk waste area (HF 50 block) will be defined by competent fire expert and implemented • Training of personnel in fire prevention and basic fire fighting

Scenario	Source	Pathway	Receptor	Mitigation Measures	
				Construction Mitigation Measures	**Operational Mitigation Measures**
Flooding	Contaminants from storage and handling of various dangerous substances / hazardous waste at the Scheme	Direct contamination; permeable strata above water table; rainwater runoff	• Land • Groundwater • Wied Żnuber • Agricultural land • Cultural heritage features in valley • Cliffs and garrigue (SPA, SAC, AEI)	***HF 53 block:*** • New production areas, raw material warehouse, clean rooms, etc. located indoors • Clean rainwater from roofs of HF 53 production lines and workshop collected in reservoir (overflows below street level, with street-level discharge as backup); rainwater from internal roads and terrace discharged below street level • Land drain in HF 53 block; rainwater discharged to rainwater reservoir ***HF 50 block:*** • Covered external flammable warehouse and fractioning area • Rainwater reaching external flammable warehouse roads discharged to road • Rainwater drainage for LPG tank area • Double-skin diesel tanks • Covered bulk tank, ISO tank and waste transfer areas; rainwater reaching roofs / clean external areas in the bulk waste storage area is discharged to road	• Valve connecting water washing reservoir emptying area to reservoir closed outside transfer activities • External flammable warehouse and fractioning area: Valve for rainwater drainage (opened by responsible person), drains to road • Storage of most dangerous substances / hazardous waste indoors or under cover

Scenario	Source	Pathway	Receptor	Mitigation Measures	
				Construction Mitigation Measures	Operational Mitigation Measures
Earthquake	Contaminants from storage and handling of various dangerous substances / hazardous waste at the Scheme	Direct contamination; permeable strata above water table; rainwater runoff	• Land • Groundwater • Wied Żnuber • Agricultural land • Cultural heritage features in valley • Cliffs and garrigue (SPA, SAC, AEI)	• Impermeable concrete layer underlying all indoor areas and utilities area in HF 53 block, external flammable warehouse and fractioning area, and bulk waste area in HF 50 block • Concreted water washing reservoir for HF 53 block • Concreted bunds in external flammable warehouse and bulk waste storage area	• Periodic certification of containment systems as required by IPPC permit

Identification of Potential Releases

15. Releases could occur from accidental spillages of the various substances used and produced on site, namely raw materials (such as solvents, reagents, acids and bases), products (APIs, in powder form or in solution), hazardous waste (especially liquid waste contaminated with organic solvents), substances used for maintenance and other associated site activities, as well as diesel fuel.

16. Releases could also occur from contaminated washwater, notably that generated from the production area during cleaning of equipment and floors.

17. Air emissions containing APIs, volatile organic compounds (VOCs) and / or reaction by-products will also be generated from various activities on site, including from the production lines. Mitigation measures will, however, be in place to reduce air emissions, as described in **Table 4**.

18. Used extinguishant will also be generated in the event of a fire, and, without mitigation this may become contaminated with raw materials (including solvents and fuel), products (APIs), and hazardous waste stored and handled on site.

Identification of Migration Pathways

Without Mitigation

19. In the absence of mitigation (such as containment), spills and leaks could contaminate the land directly, and could potentially also reach the groundwater through any permeable rock strata underlying the site, or through direct pathways such as fissures. As noted in **Chapter 3**, the groundwater at the Scheme site is expected to be found at a depth of around 60 m below the land surface, and the groundwater layer would be fairly thin (since the Scheme is very close to the coast). The same pathway would be followed in the event of flooding or an earthquake.

20. Certain spills could also contaminate rainwater reaching the site, resulting in potential on-site and off-site contamination of land (and eventually groundwater) through rainwater runoff. In the unmitigated scenario, used extinguishant could similarly contaminate land and groundwater.

21. Large spills could also flow downstream until they reach the Wied Żnuber valley, which discharges surface water at sea level.

22. The principal pathway for air emissions would be air dispersion, particularly in the prevailing wind direction; the prevailing wind locally is from the northwest.

23. In general, fire spreads by conduction (transfer through direct contact with flammable materials), convection (flow of liquid / gas from hot to cooler areas – mainly upwards until a ceiling is reached, where applicable), and radiation (via electromagnetic waves, until a flammable object is reached). Fire can also spread along the direction of the prevailing wind at the time.

With Mitigation

24. A number of mitigation measures will be in place on site to prevent the migration of contaminants towards receptors, as described below, and in **Table 4** and **Table 5**.

25. Indoor areas in the new HF 53 block will be underlain by an impermeable concrete layer. The new production lines will have an epoxy resin coating on the floor, while the warehouse for storage of raw materials will have power-floated concrete flooring with surface hardener. These rooms will have stainless steel gutters around the internal perimeter, draining to a 74 m^3 'water washing reservoir' at the northeastern corner of the HF 53 block. The gutters will collect any spilt effluent and wash water from floor washing. It is noted that wastewater generated from production or from washing of production equipment is not drained to this reservoir, but is pumped out into IBCs and discarded as hazardous waste.

26. Clean rooms and cold rooms will also have impermeable flooring, and be separated from the outdoor ground level by an intervening outdoor area as well as an entire storey.

27. Spills in the laboratories in HF 53 block will be collected in floor drains, and diverted to the above 74 m^3 'water washing reservoir' (in one of the laboratories, after receipt in a smaller 'water spillage reservoir', which overflows to this larger reservoir). Laboratory floors will be tiled with acid-resistant tiles and acid-resistant grout.

28. Effluent collected in the water washing reservoir will be discarded as hazardous waste, and an alarm will be in place to ensure no overfilling. Effluent from the reservoir will pumped out to lorry. During such transfers, the lorry will park in a designated area bounded with gutters to collect any spills during such transfers, which are diverted back to the reservoir. The valve connecting this zone to the reservoir will normally be kept closed, to avoid rainwater entering the reservoir, but will be opened during the filling process.

29. The maintenance workshop and external utilities area will also have concrete flooring, and prefabricated containment will be used for storage of hazardous substances and waste.

30. In the external flammable warehouse, any spills during storage will be collected in underlying concreted bunds having a containment capacity corresponding to 25% of the maximum volume stored therein. Spills in the central area of each warehouse, which is only used for transfer / handling (but not storage) of substances / waste, will drain on the concrete floor to a floor drain at the centre of each shed; this floor drain leads to an underground sump just outside each warehouse. The sump will contain lockable valves, which are normally kept closed. In case of a spill, the contents of the sump are pumped out and discarded as hazardous waste. The valves can only be opened by a responsible person, and will only be opened to release clean rainwater if there is no contamination.

31. Similarly, any spills during handling of materials in the fractioning area (HF 50 block) will drain on the concrete floor towards a floor drain, and be contained in a sump

with a lockable valve. The valve will be kept closed, and only opened by a responsible person to release clean rainwater.

32. In the new bulk waste storage area (HF 50 block), the bulk tanks will be located inside a reinforced concreted bund having a capacity of at least 110% of the tank volume within the bund. The bund will include an external membrane and an internal epoxy paint layer to ensure impermeability. The tanks will be covered by argillaceous[5] material, with a mesh at the top of the tank to prevent any escape. The bund will overflow to a 'waste water recovery' reservoir having a capacity of a capacity of 15,000 L, and therefore providing additional containment capacity if needed. This reservoir will be concreted and lined with an HDPE membrane on the inside and a bituminous membrane on the outside. Any effluent collected in this reservoir will be assumed to be contaminated and discarded as hazardous waste.

33. The waste water reservoir will also be connected with a valve leading to an adjacent 15,000 L 'rain / wash water recovery' reservoir; the valve will normally be kept closed, but can be opened in case extra spill capacity is needed.

34. In this zone, the floor in the ISO tank area, the transfer area and the store will be concreted, and will be laid to fall towards gutters that leads to the 'rain / wash water recovery' reservoir. This reservoir will also be concreted and lined with an HDPE membrane on the inside and a bituminous membrane on the outside. It is noted that all transfers will be supervised; therefore any spills would be detected well before the reservoir capacity is reached.

35. Diesel for the generators will only be stored in a day tank within each of the genset enclosures. The tanks will be double-skinned with at least 110% containment capacity.

36. Spill kits will also be installed in or close to the above areas, and staff will receive training on spill prevention and control.

37. Emissions to air will be mitigated through the use of abatement systems as described in **Table 4**.

79. Measures will also be in place to reduce the risk of a fire, as described in **Table 5**. With respect to the new bulk waste storage area, which envisages the storage of flammable waste in bulk, a fire risk assessment will be conducted by a competent fire expert, and the recommended mitigation measures will be implemented. The existing underground 600 m^3 reservoir will be dedicated for fire-fighting water purposes. Depending on where it is generated, used extinguishant will typically be contained, except in the case of the clean rooms and cold rooms, which will be discharged to road. However, no firefighting water will be generated in the clean rooms and cold rooms, since portable fire extinguishers will be used in these areas.

[5] A clayey material which floats in case of a spill.

Identification of Potential Receptors

38. In the scenario without mitigation, in the event of a spill or leak, the first receptor is the underlying land. The geology of the site and its immediate surroundings are as described in **Chapter 3**. At the Scheme site, the exposed rock formation is Lower Coralline Limestone.

39. Contaminants could also reach the groundwater in the unmitigated scenario. As described in **Chapter 3**, the mean sea level aquifer is the principal hydrogeological feature in the area. This aquifer is a lens-shaped water body reaching some 3 m above sea level in central Malta and thinning out to zero thickness at the coastline. Since the site is located close to the coast, the groundwater at the Scheme site is expected to be found at a depth of around 60 m below the land surface, and the groundwater layer would be fairly thin. As a result, even if the land becomes contaminated with a release from the Scheme and provided there are no direct routes to groundwater (such as fissures), significant attenuation of contaminants is expected, considering that there is a considerable depth of rock before the material is able to reach the groundwater.

40. The site is located outside the Groundwater Safeguard Zone, and there are no registered private or public groundwater boreholes located within 400 m of the site.[6]

41. The Scheme is also located around 12 m from the valley sides of Wied Żnuber, which discharges surface water at sea level. This valley includes a maquis habitat that is described in **Chapter 4** of the EIA Update Report.

42. The cliffs located along the coast just south / southeast of the site are designated as part of a Special Protected Area (SPA), a Natura2000 Special Area of Conservation (SAC) – Site of International Importance, and scheduled as an Area of Ecological Importance (AEI), as shown in **Figure 1**. The garrigue in these areas is also designated as an AEI. The cliffs making up this part of the SPA / SAC are home to a number of birds species including protected seabird breeding colonies, such as the Scopoli's and Yelkouan Shearwaters. The blue rock thrush (*il-merill*), which is a species of conservation importance, also frequents and breeds in the area.

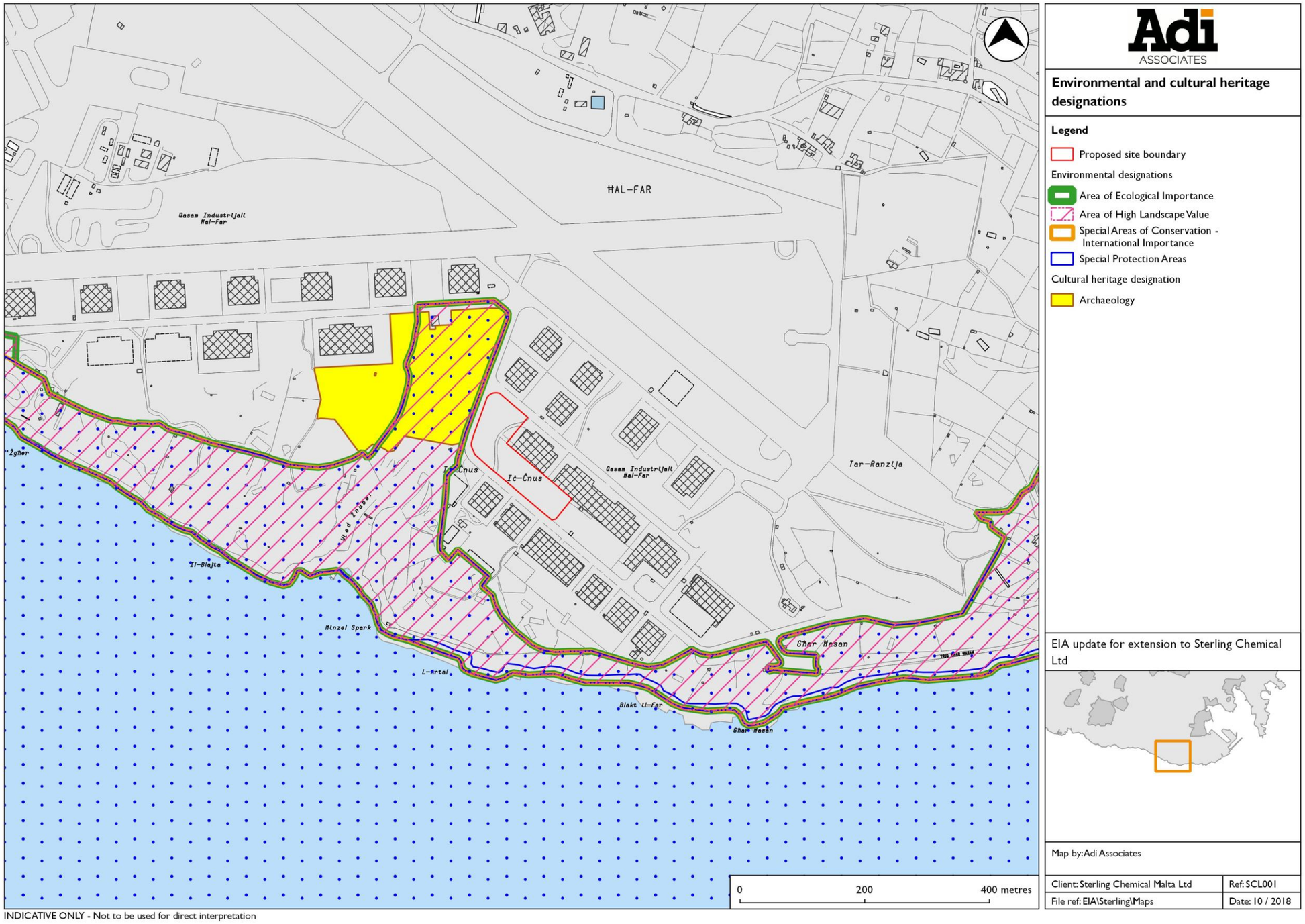
43. The Wied Żnuber valley also includes cultural heritage features, notably the Wied Żnuber Dolmen on the west of the valley side, which is scheduled as a Class A Site of Archaeological Importance; the area around the dolmen (shown in **Figure 1**) is scheduled as a buffer zone. The 2014 EIS also identified other features of cultural heritage importance in the valley, including a tomb and a British-period stop wall at the mouth of the valley. It is noted that all the identified cultural heritage features are separated from the Scheme site by a road.

44. Additionally, the predominant land use in the area around the Scheme Site, as described in **Chapter 2** of the EIA Update Report, is industrial (predominantly

[6] George Cassar (Malta Resources Authority), email dated 9th November 2015.

manufacturing). There is some cultivated agricultural land along the sides of the Wied Żnuber valley, whereas agricultural areas are sensitive to the effects of a spill or leak. There are no residential properties within 250 m of the Scheme site.

Figure 1: Environmental and cultural heritage designations



Adi ASSOCIATES

Environmental and cultural heritage designations

Legend

- Proposed site boundary

Environmental designations

- Area of Ecological Importance
- Area of High Landscape Value
- Special Areas of Conservation - International Importance
- Special Protection Areas

Cultural heritage designation

- Archaeology

EIA update for extension to Sterling Chemical Ltd

Map by: Adi Associates

Client: Sterling Chemical Malta Ltd	Ref: SCL001
File ref: EIA\Sterling\Maps	Date: 10 / 2018

INDICATIVE ONLY - Not to be used for direct interpretation

Risk Evaluation

45. The various risks on the environment have been assessed using the evaluation criteria described above (**Table 1** to **Table 3**). The risks associated with both the unmitigated and mitigated scenarios are evaluated. However, it should be noted that the Scheme envisages including all of the mitigation measures described.

Without Mitigation

46. **Table 6** presents risk levels for each source without the implementation of any mitigation measures.

Table 6: Risk Levels Without Mitigation

Source	Environmental Consequences	Likelihood of Consequence	Resultant Risk Level
Small spill in new production lines	Minor	Almost certain	Moderate
Large spill in new production lines	Major	Unlikely	High
Spill in new raw material warehouse	Minor	Likely	Moderate
Spill in new clean rooms	Minor	Likely	Moderate
Spill in new cold room	Minor	Likely	Moderate
Spill in new laboratories	Insignificant	Likely	Low
Spill in maintenance workshop	Minor	Occasional	Moderate
Spill in new external utilities area	Minor	Likely	Moderate
Spill during emptying of water washing reservoir	Minor	Likely	Moderate
Spill in external flammable warehouse	Minor	Likely	Moderate
Spill from new fractioning area	Minor	Likely	Moderate
Small spill in new bulk waste storage area (HF 50 block)	Minor	Almost certain	Moderate
Large leak in new bulk waste storage area (HF 50 block)	Major	Unlikely	High
Diesel spill from generator day tanks	Minor	Occasionally	Moderate
Emissions to air from new production lines	Moderate	Almost certain	Extreme
Emissions to air from new clean rooms	Minor	Almost certain	Moderate
Emissions to air from cold rooms / other storage areas for hazardous substances in HF 53 block – small release	Insignificant	Occasionally	Very low
Emissions to air from cold rooms / other storage areas for hazardous substances in HF 53 block – larger release	Minor	Unlikely	Low
Emissions to air from new laboratories	Insignificant	Almost certain	Low

Source	Environmental Consequences	Likelihood of Consequence	Resultant Risk Level
Emissions to air from new fractioning area	Insignificant	Almost certain	Low
Emissions to air from new bulk waste area (HF 50 block)	Moderate	Almost certain	Extreme
Release of used contaminated extinguishant	Moderate	Occasional	High
Fire	Major	Occasional	High
Contamination from flooding	Major	Unlikely	High
Spill resulting from an earthquake	Major	Unlikely	High

47. The likelihood of a small spill in the new production lines has been classified as almost certain because there are frequent transfers of relatively large quantities of materials; a large spill (such as due to rupture of a reactor) is, however, unlikely. The consequences of a small spill would be minor and likely confined to the area where the spill occurs, but a large spill can have major consequences due to the sensitivity of the surroundings (particularly the Scheme's proximity to the protected cliffs and garrigue), and the nature of materials handled in production activities.

48. Spills in the new raw material warehouse, clean rooms, cold rooms, external flammable warehouse, and the fractioning area would have minor environmental consequences, since in these areas materials are stored in small containers, typically not exceeding 1 m^3. However, the probability of an accidental spill is considered likely, without precautions. In the maintenance workshop, a spill would also have minor environmental consequences, but the frequency has been classified as occasional since there is minimal storage of liquid hazardous substances, and these are handled less frequently.

49. In the laboratories, reagents and APIs will be stored and handled in very small quantities therefore any spills are likely to have insignificant consequences, even without mitigation. However, small spills could occur regularly in laboratories, so the probability has been classified as likely.

50. Small spills are also likely to occur during emptying of the underground water washing reservoir, however, as they are likely to be small the environmental consequence has been classified as minor.

51. In the new bulk waste storage area (HF 50 block), the likelihood of a small spill has been classified as almost certain, because there will be frequent transfers of waste; a large spill would require an unusual event such as rupture of a tank, and has therefore been classified as unlikely. The consequences of a small spill would be minor and likely confined to the area where the spill occurs, but, without containment, a large spill could have major consequences due to the environmental sensitivity of the surroundings and the hazardous nature of the waste.

52. A diesel spill would have minor environmental consequences, as there will only be

small-scale storage on site; the likelihood has been classified as occasional as the diesel day tanks will not require filling very often (since the generators will only be used in case of mains electricity supply failure).

53. In the scenario without mitigation, emissions to air will routinely be generated in the production lines and bulk waste area, and released to the surroundings, although there will be some dispersal before these emissions reach sensitive receptors. Therefore the environmental consequences have been classed as moderate. Emissions to air will also routinely be generated from transfer activities in the clean rooms, laboratories, and fractioning area, although the quantities will be much smaller, therefore the environmental effects have been classified as insignificant to minor.

54. With regard to the cold rooms and other storage areas for hazardous substances in the HF 53 block, there is no exposure of materials to atmosphere under normal conditions; therefore emissions to air are not routinely generated. A small spill resulting in a release to air could occur occasionally (but result in insignificant environmental consequences), whereas a larger spill could occur less frequently (and lead to minor environmental consequences).

55. It is considered that runoff of used extinguishant could result in moderate environmental consequences, particularly if the used extinguishant is contaminated with hazardous substances / waste. Without mitigation, taking into account the flammability and quantity of the substances to be stored, it is considered that a fire may occur occasionally, and the direct environmental consequences of a fire could be major.

56. The probability of a severe flood causing contamination has been classified as unlikely following a review of Malta's Preliminary Flood Risk Assessment, [7] in which the area surrounding the Scheme site was not identified as being particularly susceptible to flash flooding. Without mitigation, the environmental consequences of a flood could be major, as contaminants could travel outside the site and contaminate the surrounding land (which includes agricultural land, protected cliffs and garrigue, and cultural heritage features), the underlying groundwater, the Wied Żnuber watercourse and eventually the sea.

57. While a severe earthquake is also considered unlikely, the environmental consequences could also be major in the unmitigated scenario.

[7] Malta Resources Authority (2013) *Preliminary Flood Risk Assessment* http://mra.org.mt/wp-content/uploads/2013/06/Preliminary-Flood-Risk-Assessment.pdf.

With Mitigation

58. **Table 7** presents risk levels for each source with the implementation of the proposed mitigation measures.

Table 7: Risk Levels With Mitigation

Source	Environmental Consequences	Likelihood of Consequence	Resultant Risk Level
Small spill in new production lines	No pollutant linkage		None
Large spill in new production lines	No pollutant linkage		None
Spill in new raw material warehouse	No pollutant linkage		None
Spill in new clean rooms	Insignificant	Occasional	Very low
Spill in new cold room	Insignificant	Occasional	Very low
Spill in new laboratories	No pollutant linkage		None
Spill in maintenance workshop	No pollutant linkage		None
Spill in new external utilities area	No pollutant linkage		None
Spill during emptying of water washing reservoir	Insignificant	Occasional	Very low
Spill in external flammable warehouse	No pollutant linkage		None
Spill from new fractioning area	No pollutant linkage		None
Small spill in new bulk waste storage area (HF 50 block)	No pollutant linkage		None
Large leak in new bulk waste storage area (HF 50 block)	No pollutant linkage		None
Diesel spill from generator day tanks	Insignificant	Occasional	Very low
Emissions to air from new production lines	Insignificant	Almost certain	Low
Emissions to air from new clean rooms	Insignificant	Almost certain	Low
Emissions to air from cold rooms / other storage areas for hazardous substances in HF 53 block – small release	Insignificant	Occasionally	Very low
Emissions to air from cold rooms / other storage areas for hazardous substances in HF 53 block – larger release	Minor	Unlikely	Low
Emissions to air from new laboratories	Insignificant	Almost certain	Low
Emissions to air from new fractioning area	Insignificant	Almost certain	Low
Emissions to air from new bulk waste area (HF 50 block)	Insignificant	Almost certain	Low
Release of used contaminated extinguishant – small fire	Minor	Unlikely	Low
Release of used contaminated extinguishant – large fire	Moderate	Unlikely	Moderate
Fire	Minor	Unlikely	Low

Source	Environmental Consequences	Likelihood of Consequence	Resultant Risk Level
Contamination from flooding	No pollutant linkage		None
Spill resulting from an earthquake	Minor	Unlikely	Low

59. Since the new production lines, raw materials warehouse, laboratories, external flammable warehouse, fractioning area, and bulk waste storage area will include concreted containment, which will be periodically certified for impermeability, the pollutant linkage in case of a spill (large or small) in these areas is removed.

60. A spill in the new clean rooms or cold room would need to travel to the outdoor area and down one storey before it can start to contaminate the environment; given this distance, the small scale of activities / storage in these areas and the presence of spill kits and trained staff, a spill would have insignificant environmental consequences. With care on spill prevention, the possibility of a spill in these areas is considered occasional.

61. With prefabricated bunding, the pollutant linkage from the maintenance area and external utilities area is also removed; therefore a spill in these areas would not present an environmental risk.

62. A spill during emptying of water washing reservoir would only have environmental consequences if the lorry parks outside the designated area. However, given that the transfer activities are supervised, the environmental effects would still be insignificant as the transfer would be immediately stopped and the spill collected. This scenario has been classified as occasional.

63. A diesel spill could only occur during transfer activities, since the tanks are double-skinned. Since transfers are supervised, the environmental effects would be insignificant as the transfer would be immediately stopped and the spill collected. This scenario has been classified as occasional.

64. Emissions to air from the production lines, clean rooms, laboratories, fractioning area, and bulk waste storage area are not expected to have a significant impact on the environment, due to the abatement systems that will be in place. Such emissions are routinely generated, and therefore the likelihood of this scenario has still been classified as almost certain.

65. The risk of emissions to air from the cold rooms and other storage areas for hazardous substances in HF 53 block is similar to the scenario without mitigation, since there is no exposure of materials to atmosphere under normal conditions.

66. Considering the measures that will be in place to prevent a fire, the generation of used firefighting water can be classified as unlikely. Given the containment systems that will be in place, used extinguishant will only be released to the surrounding environment if the containment capacity is exceeded (since there will be 600 m^3 of firefighting water available, whereas the bunds on site are smaller). It is noted,

however, that use of the entire firefighting reservoir capacity would correspond to up to 2.5 hours of firefighting, and this capacity would not be used entirely if the fire is put out quickly. Therefore the environmental consequences of used extinguishant release could range from minor in case of a small fire, to moderate in case of a large fire with a large release of used extinguishant.

67. Given the measures that will be in place to detect and tackle a fire as soon as possible, and thus reduce the risk of it spreading beyond the site, the environmental consequences of a fire have been classified as minor.

68. In view of the containment systems that will be in place at the Scheme, the possibility of flooding leading to release of hazardous substances to the environment has been removed.

69. The probability of a severe earthquake remains unlikely; however the environmental consequences are expected to be reduced to minor with mitigation measures in place, as it is unlikely that the impermeable concreted areas will fail entirely even in case of an earthquake.

70. In conclusion, as a result of the mitigation measures envisaged to be implemented, notably containment and abatement systems, environmental risks from the Scheme have been reduced to very low, low and moderate, with no pollutant linkage identified in various scenarios.

Appendix 5: Technically competent management

Mr Marco Garilli has left Sterling Chemical Malta Ltd. Mr Alessandro Bianchi (who is already an approved Technically Competent Person (TCP) for the facility) will be the facility's TCP until a second TCP is nominated.

Appendix 6: Expenditure plan

1. ERA's ToR in respect of expenditure are:

> *Please provide a plan of the estimated expenditure for each phase of the following specified activities arising from your proposal.*
>
> *The plan should include the likely costs of:*
>
> - *monitoring (emission/discharge and ambient monitoring);*
> - *clearing the installation (including drainage systems) of all wastes;*
> - *remedial action in the event of the failure of pollution control systems.*
>
> *We recognise that this plan may need to be revised before the issue of the final permit.*

2. A monitoring programme for emissions to air is included in section C3.10 of the IPPC application (**Volume 2**). The estimated cost is as shown in **Table 1**.

Table 1: Cost of emissions monitoring to air

Emission point reference	**Parameters**	**Estimated cost per monitoring session**
EM13 (scrubber)	VOC as carbon	€850
	Total particulate matter	
	Ammonia	
	HCl	
	HBr	
	VOCs having hazard statements H340, H350, H350i, H360D or H360F	€600
	Halogenated VOCs having hazard statements H341 or H351	
EM14 (HVAC system for line 7)	Total particulate matter	€500
	Total VOC	
HVAC system for clean room line 7	Total particulate matter	€250
EM16-EM20 (laboratory fume hoods)	Total VOC	€250

3. Monitoring of VOCs in the head-space of the new reservoirs will be carried out using in-house equipment.

4. Additionally, a noise monitoring study will be carried out once the Scheme is commissioned. The cost for this study is estimated at around €2,000.

5. Additionally, as described in section C3.1 of the IPPC application (**Volume 2**), since the proposed variations are similar to the existing processes, no new waste

types are envisaged. Therefore there are no new expenses associated with clearing the installation of all wastes. The cost of clearing all the waste on site including both the existing and proposed elements (and assuming that all waste storage areas and wastewater reservoirs are full) is estimated at €65,000 (including VAT).

6. The type of pollution control systems at the Scheme (including for abatement of air emissions, and containment systems), as well as the types of substances and waste to be handled will also largely remain the same. It is therefore considered that the types of emissions (and associated expenses) in the event of a failure of the pollution control systems will remain approximately the same as in the current scenario. It is difficult to quantify the cost of remedial action as this would depend on the type of incident, the severity, and the area / receptors affected. As an indication, the cost of cleaning up and disposing of a small spill on site (2 m^3) that is outside the contained areas is estimated at €2,000 (including VAT).