

## RESPONSE TO FEEDBACK ON IPPC APPLICATION

### Comments made by ERA

#### Form A

Section	Duly made?	ERA Comments 12 <sup>th</sup> June 2018	Sterling Chemical Malta Ltd replies 28 <sup>th</sup> August 2018	Duly made?	ERA Comments 1 October 2018
A1.1	✓	Noted	-		
A1.2	✓	Noted	-		
A1.3	✓	<p><u>Document: VOL 1 - Application Forms</u> <u>Appendix 1: Site plan</u></p> <p>Noted</p>	-	✓	<p><u>Document: VOL 1 - Application Forms</u> <u>Appendix 1: Site plan</u></p> <p>Has been amended to include Waste Management Area and LPG (as covered by PA 3638/18) as requested.</p>
A1.4	×	<p><u>Document: VOL 1 - Application Forms</u> <u>Appendix 2: Existing permits</u></p> <p>IPPC permit: IP 0001/14/A (August 2015) PA 04236/08 (issued April 2010) PA 03033/12 (June 2013) DN 0624/16 (September 2016) DN 617/17 (July 2017) LPG secondary storage permit issued by REWS, licence no. LPG-00110-SS (SS110), last renewed in April 2017. Sewer discharge permit from WSC (DMU 6745), last renewed in February 2017</p> <p>For Documents a-e Noted. However kindly include PA3638/18 in the list.</p> <p>For item h. Kindly clarify as to whether the authorisation for the LPG Secondary License for 2018 is in place. To also note that in view of the PA3638/18 an updated application will eventually be required.</p> <p>For item g. Sewer Discharge Permit, kindly submit a valid sewer discharge permit.</p>	<p>Included.</p> <p>Please refer to <b>Volume 1, Appendix 2</b>. An updated application to REWS will also be submitted in due course to cover the new LPG tank.</p> <p>Please refer to <b>Volume 1, Appendix 2</b>.</p>	✓	<p>Noted</p> <p>Noted. SCM to advise when PA3638/18 is determined.</p>

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A2.1	✓	Noted.	-		
A3.1	✓	Noted.	-		
A3.5	✓	<u>Document: VOL 1 - Application Forms</u> <u>Appendix 3: Company registration certificate</u> Noted.	-		
A3.6	✓	Noted.	-		

### Form C

Section	Duly made?	ERA Comments 12 <sup>th</sup> June 2018	Sterling Chemical Malta Ltd replies 28 <sup>th</sup> August 2018	Duly made?	ERA Comments 1 October 2018
C1.1	✓	Noted.	-		
C1.2	✓	<u>Document: VOL 2 - IPPC variation application</u> <u>Chapter 2: C1.2 Non-Technical Description</u> Noted.	-		
C1.3	×	<u>Document: VOL 2 - IPPC variation application</u> <u>Chapter 2: C1.3 The Proposed Variations</u>  In relation to point 2.12 stating that the construction of the micronization facility is covered by DN 0624/16. In an inspection carried out at the facility on 5 April 2018 it was noted that works were still ongoing. In this regard, and in view that the development permit expired on 14 September 2017. Kindly clarify whether the applicant is in possession of a valid development permit.  In relation to the permit conditions which are foreseen in view of this variation, kindly note that the number of emission points to air will need to be updated two include the two new emission points from the fume hoods.  In this regard, kindly note that an update to the Effluent and Air Emission Points (Schedule 3A of IP0001/14) is required.	Sterling Chemical advises that construction works were complete by this date, and only finishing works were underway.  Noted.  Please see <b>Attachment 1</b> .	✓	<u>Document: VOL 2 - IPPC variation application</u>  <u>Chapter 2: C1.3 The Proposed Variations</u>  Noted.  <u>Document Volume 2- IPPC variation application</u>  <u>Figure 4.9: Emissions points from the Scheme pg 65</u>  Updates have been noted.
C1.4	×	In relation to the approved site plan as per the approved permit IP0001/14/A, kindly note that during an inspection held on 5 April 2018, ERA officials noted a new area for storage of waste has been constructed and is in operation. This area is outside the	The IPPC application has been updated.  This development is covered by DN 23/17; a copy of the decision notice is included	✓	Noted.

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		permitted site boundary currently permitted. In view of this, an update to the application to address the inclusion of this area is to be submitted. Also, kindly provide the development permit number, which covered this extension.	in <b>Volume 1, Appendix 2.</b>		
C1.4.1	×	<p><u>Document: Volume 2: Chapter 2</u></p> <p>Kindly note that the Site Report will need to be updated to include the current extension, which is used for waste management.</p> <p><u>Document: Volume 3: Addendum 1 to Land &amp; Groundwater Risk Assessment</u></p> <ol style="list-style-type: none"> <li>1) Kindly update addendum to the land and groundwater risk assessment to include the recently constructed waste management area and the proposal for the introduction of the LPG storage tank.</li> <li>2) It is mentioned that the air from the microionizer will be filtered using H13 HEPA filters, and then routed to the scrubber, however the original risk assessment stated that emissions from all areas will be mitigated using three filters (HEPA, EU8 and EU3), carbon filter and scrubber. In this regard, kindly clarify the proposed rationale for the microionizer and whether all emissions points on site are treated as specified in the original risk assessment?</li> <li>3) Regarding the recertification of the reservoir kindly note that as per condition 2.2.6.4 of the current permit IP0001/14/A, such certification is to be carried out prior to the renewal.</li> <li>4) Regarding the leak detection system from the micro ionization process, kindly verify whether these are fitted with audible alarms.</li> <li>5) Reference is made to point 25, therefore should it be understood that an overflow from the wastewater reservoir this will be discharged to the sewer? In this regard can you kindly submit a cross-section of the reservoir.</li> </ol>	<p>This has been updated.</p> <ol style="list-style-type: none"> <li>1. Please refer to <b>Volume 3.</b></li> <li>2. Sterling Chemical clarifies that the following air abatement is currently applied at the Scheme; please also see the response to section C3.6 below: <ul style="list-style-type: none"> <li>• Each reactor is 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 scrubber (EM1);</li> <li>• Air from the production areas, indoor weighing areas, finished goods warehouse and clean rooms goes directly through the carbon filter and scrubber (EM1);</li> <li>• The sampling room (area 34) is also subject to local extraction before being connected to the carbon filter and scrubber (EM1); this also helps avoid fugitive emissions;</li> <li>• With regard to the laboratories (EM4), exhaust air is treated using a carbon filter or carbon + HEPA filter. It is noted that very small quantities of APIs and other chemicals are handled here.</li> </ul> <p>It is noted that the abatement system chosen in each instance reflects the nature of emissions. As a result, the conclusions of the original risk assessment are unchanged.</p> <p>With regard to the microniser, very fine particulate emissions and no solvents are generated by the microniser during operation. Solvents are only used during cleaning. It is clarified that the microniser will be connected to H13 HEPA filters, a carbon filter and the scrubber, which is appropriate abatement for these types of emissions.</p> </li> <li>3. Noted. Recertification will be carried out prior to renewal of the IPPC permit.</li> <li>4. There is no acoustic alarm, however, an operator is always present during the operation of the microniser.</li> <li>5. Confirmed. Please see <b>Attachment 2</b>; it is noted that this is an existing reservoir. Nevertheless Sterling Chemical has clarified that there is in fact no connection from the micronisation area to the sewer; <b>Volume 2</b> and <b>Volume 3</b> of the IPPC</li> </ol>	✓	<p><u>Document: Volume 2: Chapter 2</u></p> <p>Noted.</p> <p><u>Document: Volume 3: Addendum 1 to Land &amp; Groundwater Risk Assessment</u></p> <ol style="list-style-type: none"> <li>1. Noted.</li> <li>2. Noted</li> <li>3. Noted</li> <li>4. Noted, ERA will be discussing further the possible inclusion of further mitigation measures.</li> <li>5. <u>Attachment 2: Cross-section of the reservoir</u></li> </ol> <p>Noted, however kindly clarify as to whether there is a connection between the sewer and the wash water reservoir.</p> <ol style="list-style-type: none"> <li>6. <u>Attachment 3: Fire detection and fire fighting plan for micronization plant</u></li> </ol> <p>Noted. The Feedback/report from fire consultants will be required for onward forwarding to CPD.</p>

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		6) Kindly submit the 'fire detection and fire fighting plan' to ERA.	application have been updated.  6. Please see <b>Attachment 3</b> . This covers the micronisation facility; following a review by the fire consultants no such systems were considered necessary for the cold rooms, being cold and damp rooms (nevertheless, a fire extinguisher is already located right outside the corridor leading to the cold rooms). Firefighting measures for the new temporary waste storage area are as described in section C2.8; those for the new LPG tank will be defined by the fire consultants at a later stage.		
C1.4.2	×	Kindly submit amended maps in view of the inclusion of the waste management area.	Please refer to <b>Volume 3</b> .	✓	Noted
C1.4.3	×	<u>Document: Volume 3: Addendum 1 to Land &amp; Groundwater Risk Assessment</u>  Kindly note that block plans are to be updated to reflect also the introduction of the LPG storage tank as well as the recently constructed waste management area.	Please refer to <b>Volume 3</b> .	✓	<u>Document: Volume 3: Addendum 1 to Land &amp; Groundwater Risk Assessment August 2018</u>  Noted
C2.1	×	<u>Document: Volume 2: Chapter 3 C2.1 Environmental Management System</u>  1. Operator is to clarify whether in view that the deadline proposed for implementation of the EMS is 2019, whether it would be including the new operations and extension (for Site A & C)?  2. Regarding the documentation submitted, ERA has the following comments. a. Kindly note that that the Civil Protection Department number should read 112 as opposed to 911. b. Certain documents, are completely in Italian others partially. Kindly ensure that the documents are provided in clear comprehensible English. c. Kindly not that the in-text reference 'Risk assessment carcinogens and mutagens document rev.01' has not been submitted d. Certain documents will need to be updated to reflect the changes proposed in this variation. e. Kindly note that ERA has recently updated its waste permitting procedures, therefore the SOP titled 'Waste Management' will need to be updated. f. References made to MEPA are to be changed to ERA for those issues of environmental concern.  3. Regarding the query on the maximum allowable capacity for gas ammonia use and storage, kindly note that ERA finds no objection to the proposal. Nonetheless, a risk assessment evaluating the risks and the required control measures associated with the handling and storage of chemicals will be required. The risk assessment must be carried out by a competent person. Moreover, training and health surveillance with regards to the appropriate use of the substance must be ensured as per LN 227 of 2003. Kindly note that the indicative occupational exposure limit value for ammonia is TWA of 14 mg/m <sup>2</sup> [relevant communication attached Annex III].	1. The new areas will be included in the EMS once they are fully commissioned.  2. These comments concern EMS documents that were submitted as part of an earlier request for postponement of ISO 14001 certification, mainly to show the current state of implementation. All EMS documents are being reviewed as part of the ISO 14001 certification process, and these comments are being taken into account. A copy of the final updated documents can be submitted to ERA once certification is obtained, if required.  3. This query was related to a future project, and is unrelated to this application. These requirements will be met if and when this need arises.  4. This is in progress and targeted for 2019.	✓	<u>Document: Volume 2: Chapter 3 C2.1 Environmental Management System</u>  1. Noted improvement programme item in permit will be updated. 2. Noted. 3. Noted. 4. Noted.

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		4. In the original application it was also mentioned that the OHSAS 18001 certification would be obtained. Has this been achieved?			
C2.2 C2.2.1	×	<u>Document: Volume 2: Chapter 3</u>  Kindly include the LPG storage and the waste management area in this section.	This section has been updated.	✓	<u>Document: Volume 2: Chapter 3</u>  Noted.
C2.2.2	×	<u>Document: Volume 2: Chapter 3</u>  Kindly clarify what existing air emission mitigation measures are in place for the QC labs, in view that that from previous reports submitted by Sterling Chemical Malta indicate treatment through HEPA filters. On the other carbon filter are being proposed for the micro ionization laboratory.	The Applicant has clarified that the existing labs are fitted with either a carbon filter or carbon filter with HEPA filter before exhausting to the atmosphere. Please see also the response to C3.6 below. Similarly, carbon filters are being proposed for the micronisation laboratory's fume hoods, whereas in the suction hoods (balance enclosure) where weighing of powders is carried out, a HEPA H13 filter will be installed.	✓	<u>Document: Volume 2: Chapter 3</u>  Noted
C2.2.3	×	<u>Document: Volume 2: Chapter 3</u>  Noted.			
C2.2.4	×	Kindly note that a comparison exercise of current practices with the Commission Implementing Decision (EU) 2016/902 establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for common waste water and waste gas treatment/management systems in the chemical sector will be required <u>for the entire site</u> . It is pertinent to note that this is a horizontal BREF and applies also to the chemical sector.  Doc: Commission Implementing Decision 2016/902  <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L.2016.152.01.0023.01.ENG">http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L.2016.152.01.0023.01.ENG</a>  For your reference kindly note that the entire Doc Best Available Techniques (BAT) Reference Document for Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector is available in the following link.  <a href="http://eippcb.jrc.ec.europa.eu/reference/BREF/CWW_Bref_2016_published.pdf">http://eippcb.jrc.ec.europa.eu/reference/BREF/CWW_Bref_2016_published.pdf</a>  For ease of reference please find attached a template [Annex IV] to carry out the comparison exercise.	This is now included in <b>Volume 2, Chapter 3</b> .	✓	<u>Document: Volume 2: Annex 5: BAT assessment</u>  Further assessment and discussions with the Operator will be required.
C2.2.5	✓	<u>Document: Volume 2: Chapter 3</u>  Noted.			

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C2.3	×	<u>Document: Volume 2: Chapter 3: C2.3 Raw Materials</u>  Kindly update in view of proposed new LPG storage tank.	Section updated.	✓	<u>Document: Volume 2: Chapter 3: C2.3 Raw Materials</u>  Noted
C2.4	×	<u>Document: Volume 2: Chapter 3 C2.4 Ozone Depleting Substances and Fluorinated Greenhouse Gases</u>  Kindly indicate whether such equipment EQ 12 and EQ 13 has been registered with MCCA. Moreover, can you indicate whether the equipment is a hermetically-sealed system/ fixed systems etc.	This equipment will be registered with MCCA upon commissioning. The equipment is fixed, but not hermetically sealed.	✓	<u>Document: Volume 2: Chapter 3 C2.4 Ozone Depleting Substances and Fluorinated Greenhouse Gases</u>  Noted
C2.5	×	<u>Document: Volume 2: Chapter 3 C2.5 Maintenance</u>  Kindly submit maintenance plan (MN.SOP.001) once this is updated in view of the proposed changes.  Kindly include inspection schedule of ODS containing equipment.	This is now included in section C2.5.  The inspection schedule for refrigerant-containing equipment is now included as part of section C2.4.	✓	<u>Document: Volume 2: Chapter 3 C2.5 Maintenance</u>  Noted.
C2.6 C2.6.1 C2.6.2	✓	<u>Document: Volume 2: Chapter 3 C2.6 Energy</u>  Noted.	-		
C2.7	×	<u>Document: Volume 2: Chapter 3 C2.7 Water</u>  Kindly clarify whether any additional water will be consumed in view of the cooling water system for the new cold room.	This cooling water system is a closed-loop system, so there is no additional water consumption related to it.	✓	<u>Document: Volume 2: Chapter 3 C2.7 Water</u>  Noted
C2.8		<u>Document: Volume 2: Chapter 3 C2.8 Risk Assessment</u>  Kindly comments made on EMS above section C2.1.	Please see responses to section C2.1 above.	✓	<u>Document: Volume 2: Chapter 3 C2.8 Risk Assessment</u>  Noted
C2.9	✓	<u>Document: Volume 2: Chapter 3 C2.9 Training</u>  Noted, kindly see comments made on EMS.	Please see responses to section C2.1 above.	✓	<u>Document: Volume 2: Chapter 3 C2.9 Training</u>  Noted

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C2.10	✓	Noted	-		
C2.11	✓	Noted	-		
C3.1 C3.1.1 C3.1.2 C3.1.3	×	<u>Document: Volume 2: Chapter 4 Waste</u> Kindly submit the requested information in relation to the new waste management area.	Please refer to the updated section C3.1 in <b>Volume 2</b> .	✓	<u>Document: Volume 2: Chapter 4 Waste</u> Noted.
C3.2	✓	Noted.	-		
C3.3 C3.3.1 C3.3.2 C3.3.3 C3.3.4	✓	Noted.	-		
C3.4	✓	Noted.	-		
C3.5	×	<u>Document: Volume 2: Chapter 4 C3.5</u> Kindly provide updated rainwater drainage map to cater for the new waste management area.	Please refer to the updated section C3.5 in <b>Volume 2</b> .	✓	<u>Document: Volume 2: Chapter 4</u> Noted.
C3.6	×	<u>Document: Volume 2: Chapter 4 C3.6 Emissions to Air</u> Kindly note that the HEPA Filter installed in the micro-ionizer will need to be tested once installed.  Regarding point 4.13, in which it is mentioned that scrubber is oversized and can handle the increased flow arising from the new activities. Kindly provide confirmation showing that the operational flow of the scrubber can handle the increased the production volume.  Further to section C2.2.2, kindly provide an exhaustive list of all emissions points, specifying each abatement technology associated which each point.	Noted. The microniser is equipped with differential pressure probes to constantly measure the pressure before and after the filter; the maximum clogging pressure is listed on the datasheet of the filters.  Please refer section C3.6, which now includes a P&ID schematic for the scrubber. As shown in this section, the scrubber can handle a flow rate of up to 5,000 m <sup>3</sup> /h. As a worst case scenario, the micronisation area would vent 420 m <sup>3</sup> /h (20+300+20+40+40). The sum of all the vents is 4,778 m <sup>3</sup> /h if all vents are used simultaneously; this is highly improbable due to discontinuous processes being in place, but even if it were the case, the scrubber could handle this flow. In the case of future introduction of new vents which exceed the capacity of the scrubber, a new calculation accounting for contemporaneity of events will be carried out, or pressure monitoring of the working conditions will be carried out over a period of one month to verify the contemporaneity of events.  Sterling Chemical clarifies that the emission points to air and associated abatement is as follows; the location of these emission points is as shown in <b>Attachment 1</b> . As	✓	<u>Document: Volume 2: Chapter 4 C3.6 Emissions to Air</u> a) Noted. b) Noted. c) The updated emission table is noted, however ERA shall be reviewing whether further mitigations measures will be required, as especially in relation to potential emissions from cold room.

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			<p>mentioned, the abatement system chosen reflects the nature of emissions.</p> <table border="1"> <thead> <tr> <th>Source</th> <th>Main emission types</th> <th>Abatement</th> <th>Emission point</th> </tr> </thead> <tbody> <tr> <td>Reactors (existing and new)</td> <td>VOC, NO<sub>x</sub></td> <td>Two heat exchangers in series, carbon filters, scrubber</td> <td>EM1 (scrubber)</td> </tr> <tr> <td>Production areas, indoor weighing areas, finished goods warehouse and clean rooms</td> <td>Particulates</td> <td>Carbon filter, scrubber</td> <td>EM1 (scrubber)</td> </tr> <tr> <td>Sampling room (area 34)</td> <td>Particulates</td> <td>Local extraction, carbon filter, scrubber</td> <td>EM1 (scrubber)</td> </tr> <tr> <td>Existing laboratories</td> <td>Solvents / chemicals / powders (small quantities)</td> <td>Carbon filter, or carbon filter + HEPA filter (plus ventilation fan)</td> <td>EM4 (Laboratories)</td> </tr> <tr> <td>Steam generator</td> <td>Combustion by-products</td> <td>Use of LPG as fuel, regular maintenance</td> <td>EM5 (generator extractor)</td> </tr> <tr> <td>Steam generator</td> <td>Combustion by-products</td> <td>Use of LPG as fuel, regular maintenance</td> <td>EM6 (generator extractor)</td> </tr> <tr> <td>Cooling tower</td> <td>Waste heat</td> <td>Treatment of circulating cooling water (including dosing with biocides)</td> <td>EM7 (cooling tower stack)<sup>1</sup></td> </tr> <tr> <td>Microniser</td> <td>Particulates</td> <td>H13 HEPA filters, carbon filter, scrubber</td> <td>EM1 (scrubber)</td> </tr> <tr> <td>Micronisation laboratory - two fume hoods</td> <td>Solvents / chemicals / powders (small quantities)</td> <td> <ul style="list-style-type: none"> <li>Suction hood (balance enclosure) where weighing of powders is carried out: HEPA H13 filter</li> <li>Fume</li> </ul> </td> <td>EM10 EM11</td> </tr> </tbody> </table>	Source	Main emission types	Abatement	Emission point	Reactors (existing and new)	VOC, NO <sub>x</sub>	Two heat exchangers in series, carbon filters, scrubber	EM1 (scrubber)	Production areas, indoor weighing areas, finished goods warehouse and clean rooms	Particulates	Carbon filter, scrubber	EM1 (scrubber)	Sampling room (area 34)	Particulates	Local extraction, carbon filter, scrubber	EM1 (scrubber)	Existing laboratories	Solvents / chemicals / powders (small quantities)	Carbon filter, or carbon filter + HEPA filter (plus ventilation fan)	EM4 (Laboratories)	Steam generator	Combustion by-products	Use of LPG as fuel, regular maintenance	EM5 (generator extractor)	Steam generator	Combustion by-products	Use of LPG as fuel, regular maintenance	EM6 (generator extractor)	Cooling tower	Waste heat	Treatment of circulating cooling water (including dosing with biocides)	EM7 (cooling tower stack) <sup>1</sup>	Microniser	Particulates	H13 HEPA filters, carbon filter, scrubber	EM1 (scrubber)	Micronisation laboratory - two fume hoods	Solvents / chemicals / powders (small quantities)	<ul style="list-style-type: none"> <li>Suction hood (balance enclosure) where weighing of powders is carried out: HEPA H13 filter</li> <li>Fume</li> </ul>	EM10 EM11		
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Reactors (existing and new)	VOC, NO <sub>x</sub>	Two heat exchangers in series, carbon filters, scrubber	EM1 (scrubber)																																										
Production areas, indoor weighing areas, finished goods warehouse and clean rooms	Particulates	Carbon filter, scrubber	EM1 (scrubber)																																										
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Existing laboratories	Solvents / chemicals / powders (small quantities)	Carbon filter, or carbon filter + HEPA filter (plus ventilation fan)	EM4 (Laboratories)																																										
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Micronisation laboratory - two fume hoods	Solvents / chemicals / powders (small quantities)	<ul style="list-style-type: none"> <li>Suction hood (balance enclosure) where weighing of powders is carried out: HEPA H13 filter</li> <li>Fume</li> </ul>	EM10 EM11																																										

<sup>1</sup> There is only one cooling tower; hence EM8 can be removed from the permit.



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					extractor hoods: carbon filter			
			New cold rooms	Samples / raw materials / intermediates / products (small quantities)	None (vents directly to atmosphere)	EM12		
C3.7	✓	Noted	-					
C3.8	✓	Noted	-					
C3.9 C3.9.1 C3.9.2 C3.9.3 C3.9.4	×	<u>Document: Volume 2: C3.9 Noise</u>  Noted, in view of the condition 2.2.9.4 of IP0001/14/A, kindly note that noise monitoring will be required following commissioning of the micronization.	Noted. This section has been updated.				✓	<u>Document: Volume 2: C3.9 Noise</u>  Noted.
C3.10 C3.10.1 C3.10.2 C3.10.3 C3.10.4 C3.10.5	×	<u>Document: Volume 2: Chapter 4 C3.10 Monitoring</u>  In addition to the noise monitoring, kindly note that a monitoring proposal for a one-time air emission monitoring exercise from all fume hood exhaust vents will be required.	It is understood that this comment applies to emissions from the new micronisation fume hoods (EM10 and EM11), since emissions from the existing laboratory fume hoods are already monitored (from the scrubber at EM4). Monitoring from EM10 and EM11 will be undertaken as requested.				✓	<u>Document: Volume 2: Chapter 4 C3.10 Monitoring</u>  Noted.
C3.11	✓	<u>Document: Volume 2: Chapter 3 (section C2.2)</u>  Noted.	-					
C4.1	✓	<u>Document: Volume 2: Chapter 5</u>  Point 5.6 may require updating in view of any updates to the land and groundwater risk assessment which may be required as part of the new waste area.	The land and groundwater risk assessment has been updated ( <b>Volume 3</b> ) and point 5.6 has been retained.				✓	Noted.
C4.2	✓	<u>Document: Volume 2: Chapter 5</u>  Noted.	-					
C5.1	×	Noted, however kindly confirm that the proposed variations were already factored into the primary 2015 EIA.	It is noted that these variations were subject to the following development planning permits: <ul style="list-style-type: none"> <li>• Micronisation facility: DN 0624/16 (issued September 2016);</li> <li>• New offices and meeting rooms: DN 00617/17 (issued July 2017);</li> <li>• New temporary waste storage area: DN 23/17 (issued January 2017); and</li> <li>• New LPG tank: PA 3638/18 (application under review; note minute 45a from ERA dated 14<sup>th</sup> May 2018).</li> </ul> No EIA update was requested regarding the proposed variations during the above development planning processes. Additionally, it is noted that the EIA for the current facility states that the number and volume of reactors may vary (paragraph 4.3.2.11). Micronisation is also already referred to in the EIA as part of the finishing process.				✓	Noted.

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C6.2	✓	Noted.	-		
C6.3	✓	Noted.	-		
C7.1	×	<u>Document: Volume 1: Appendix 2</u>  Refer to A1.4	Please refer to the responses to section A1.4 above.	✓	Noted.
C8.1	×	<u>Document: VOL 1 - Application Forms</u> <u>Appendix 4: Technically competent management</u>  CV has been noted, however Operator is to confirm whether Mr. Marco Garilli is also to be included as another TCP or a delegate of Mr. Bianchi.	This is confirmed. Section C8.1 has been updated.	✓	<u>Document: VOL 1 - Application Forms</u>  <u>Appendix 4: Technically competent management</u>  Noted
C8.2	✓	Noted.	-		
C9.1	×	<u>Document 1:Volume 1 : Appendix 5</u>  Kindly update the expenditure plan if required in view of inclusion of air monitoring from the labs and noise monitoring due to the introduction of new equipment.	The expenditure plan has been updated.	✓	<u>Document 1:Volume 1 : Appendix 5</u>  Noted
C10	✓	Noted.	-		

**Feedback from Statutory Consultees**

**External Consultees**

Comment received from	Feedback	ERA reply and comment 14 <sup>th</sup> June 2018	Sterling Chemical (Malta) Ltd. reply 28 <sup>th</sup> August 2018	Further comment by external consultee	ERA reply and comment 1.10.18
Environmental Health Directorate	<p>1. With these variations the Directorate has no objection;</p> <p>2. Mitigation measures and monitoring programme to avoid / reduce any source of air pollution are to be put into practice, this include:</p> <p>a. The installation of the H13 HEPA filters routed through scrubber for micronization</p> <p>b. Two fume hoods fitted with carbon filters</p> <p>c. Emission from cold room to pass from scrubber</p> <p>3. Mitigation measures to prevent contamination of groundwater from spillage of samples, raw materials, solvent and APIs/ hazardous water form micronization area, wash water from cleaning of equipment, floor and clod room, are to be adopted, this consist of;</p> <p>Concrete flooring and overlain of impermeable vinyl/resin layer</p> <p>Gutters connected to wash watering reservoir.</p> <p>Cold room floor to slope inwards from door</p> <p>4. Mitigation measures and monitoring to reduce the risk of noise pollution are to be adopted; this includes the enclosing of micronization room and technical area in a concreted room.</p> <p>5. Mitigation measures stated to prevent the leakage of contaminated water from the washing water reservoir are to be implemented. It is highly recommended that said reservoir is kept under constant monitoring to avoid the risk of leakage that could pose a risk to the contamination of ground water or nearby valley.</p> <p>6. In the case that other wet cooling systems, apart from the R410-A, are to be used for the air cooling are to be registered with the Environmental Health Directorate</p> <p>7. A waste management system is to be implemented and hazardous waste is to be collected, transferred and disposed by licensed personal.</p> <p>8. The aim to obtain the ISO 14001:2015 certification is highly recommended.</p> <p>9. Safe and proper handling of raw materials on site should also be ensured. Adequate preventive measures are to be taken regarding the potential accidental spillage of hazardous fluids and chemicals which are also to be well managed and adequately stored</p>	<p>Noted, all points are addressed in the application or through ERAs review. Other requirements will be included a permit conditions. Operator is to note feedback received from EHD.</p>	<p>Noted.</p>	<p>Kindly note that comments related to our Directorate have been noted and we have no further comments to submit.</p>	<p>Noted.</p>

Comment received from	Feedback	ERA reply and comment 14 <sup>th</sup> June 2018	Sterling Chemical (Malta) Ltd. reply 28 <sup>th</sup> August 2018	Further comment by external consultee	ERA reply and comment 1.10.18
	<p>10. Reservoir-harvested rain water should not be used for human consumption and/or personal hygiene. Reservoir overflow should be directly discharged onto the street. Since the rain water reservoir will be used for fire-fighting it is suggested to be chlorine to prevent the spread of Legionella diseases from sprinkles.</p> <p>11. Moreover, any other unpredicted impacts and nuisances which may arise from this operation and that may have a significant adverse effect on public health are to be immediately addressed by the applicant and the necessary mitigation measures taken;</p> <p>12. Complaints lodged by the public regarding any adverse impacts/nuisances should be immediately addressed by the applicant. All complaints lodged and actions taken are to be recorded and such records are to be readily available to the Competent Authorities when requested.</p>				
Malta Competition and Consumer Affairs Authority	No feedback provided.		-	Please note that MCCA no longer registers equipment containing F-gases as per Legal notice 143 of 2018:  <a href="http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&amp;itemid=12826&amp;l=1">http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&amp;itemid=12826&amp;l=1</a>	Noted.
Malta Resources Authority	Please note that groundwater protection does not fall within the remit of the MRA. You may wish to note articles 50 and 51 in the Act XXV of 2015:  <a href="http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&amp;itemid=27004&amp;l=1">http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&amp;itemid=27004&amp;l=1</a>  We do not have any comments on matters within the Authority's remit.	No further comments.	-		
Planning Authority	No feedback provided.		-		
Regulatory for Energy and Water Services	The Regulator has no comments for the variation of IPPC permit of Sterling Chemical Malta Ltd forwarded by CD on the 4th April.  Just a point of clarification – on page 56 Clause 2.13.6 states “All fuels on site shall be stored in tanks which comply with relevant MRA standards”. MRA should read REWS.	Operator is to amend accordingly.	It is understood that ERA will update this permit condition.	REWS has no further comments	ERA will update permit condition.
Civil Protection	CPD made reference to a site visit held on Thursday 10 May 2018. Overall CPD determined that the company has a very strong approach towards fire safety.	Operator is to take note.	Noted; Sterling Chemical confirms that these measures have been implemented.		No further comments

Comment received from	Feedback	ERA reply and comment 14 <sup>th</sup> June 2018	Sterling Chemical (Malta) Ltd. reply 28 <sup>th</sup> August 2018	Further comment by external consultee	ERA reply and comment 1.10.18
Department	<p>Nonetheless the following improvisations were highlighted:</p> <p>An LPG sign needs to be installed. A sign is to be installed where industrial gases are in place. The inclusion of a fire plan in the location requested. The provision of a list of MSDS of chemicals handled on site is to be kept at reception.</p>				were received from CPD.
Water Services Corporation	<p>WSC have the following feedback:</p> <p>The new micronisation facility mentions the setting up of a new lab. Volume 3 article 12 states that small quantities of chemicals will be used and concurrent small quantities of waste will be produced. If these wastes are in liquid form, these shall not be discharged to sewer unless explicit permission is given by the WSC following review and testing. In the interim period, such wastes are to be disposed of as hazardous materials.</p> <p>The micronisation process will also produce waste waters as mentioned in Volume 2 article 3.21. Moreover, these waste waters will be stored in a water washing reservoir fitted with a level sensor indicating the level when 80% of the tank capacity is attained. This waste water shall not be discharged to sewer unless explicit permission is given by the WSC following review and testing. In the interim period, such wastes are to be disposed of as hazardous materials.</p> <p>Volume 2 section C2.7 article 3.52 states that further mains water purification capacity will be added. If this is done through the use of Reverse Osmosis, the discharge of water softener reject waters to sewer is not permitted and alternative solutions should be sought.</p>	Operator take note and provide reply.	<p>Liquid waste from the laboratory and micronisation process (including any spills) will be disposed of as hazardous waste, and not discharged to sewer.</p> <p>The Applicant has clarified that no further mains water purification capacity will be added, and as stated mains water consumption will only increase by around 25 m<sup>3</sup> annually. It is noted that mains water is currently purified using a water softener and no Reverse Osmosis plant is installed. The reject does not require treatment as it only contains minimal constituents; it therefore goes to the rain water reservoir, which is primarily reserved for firefighting.</p>		WSC has no further comments.
OHSA	<p>OHSA finds no objection to the approval of this permit provided that the applicant abides by all relevant OHS legislation and in particular:</p> <p>The employer carries or ensure that there is carried out, a suitable, sufficient and systematic assessment of all the occupational health and safety hazards which may be present at the place of work and the resultant risks involved concerning all aspects of the work activity. This risk assessment shall be reviewed and / or updated on a regular basis as per prevailing OHS regulations.</p>	Operator is to take note. These will be included as permit conditions.	Noted.		

Comment received from	Feedback	ERA reply and comment 14 <sup>th</sup> June 2018	Sterling Chemical (Malta) Ltd. reply 28 <sup>th</sup> August 2018	Further comment by external consultee	ERA reply and comment 1.10.18
	Subsequent to this assessment the employer shall take all necessary measures to prevent occupational risks to health and safety, and shall control those factors which are likely to give rise to accidents or which create a risk to occupational health and, or safety.				

### Internal Consultees

Comment received from	Feedback	ERA reply and comment 14 <sup>th</sup> June 2018	Sterling Chemical (Malta) Ltd. reply 28 <sup>th</sup> August 2018	Further comment by internal consultee	ERA reply and comment 1.10.18
Environmental Assessment Unit	We have no comments regarding the IPPC process. However, once the EIA Update is submitted, we will forward it for your info.	No further comments.	-		
Biodiversity & Water Unit	No feedback provided.		-	No comments from BWU.	
Air quality & Waste Unit  Air Quality Team	No feedback provided.		-		
Air quality & Waste Unit  Waste Management Team	With regards to this application the waste team has no comments.	No further comments.	Noted.	The Waste Team has no comments on the amended IPPC application	
Air quality & Waste Unit  Noise Team	From a Noise perspective, the applicant is to ensure that the noise abatement measure mentioned in Volume 2, Section C3.9, point 4.16 noting that the two noise generating sources [the micronization room and the associated technical area] will be enclosed in concrete is actually carried out.	Operator is to take note.	Noted.	Feedback has been noted and agreed to. However, I would like to point out two minor suggestions in the permit:  1. The noise monitoring is to be carried out in accordance to the recent standard BS4142:2014 and not 1997.  2. Prior to the initiation of the noise monitoring study, the operator is to submit a method statement including the methodology that will be used for the noise monitoring and for the assessment of impact. Together with a copy of the qualifications and CV of the consultant carrying out the noise study.	Permit will be updated to reflect requirements.

Comment received from	Feedback	ERA reply and comment 14 <sup>th</sup> June 2018	Sterling Chemical (Malta) Ltd. reply 28 <sup>th</sup> August 2018	Further comment by internal consultee	ERA reply and comment 1.10.18
Compliance & Enforcement	No feedback provided.		-		
Permitting Unit Waste Permitting	No feedback provided.		-		

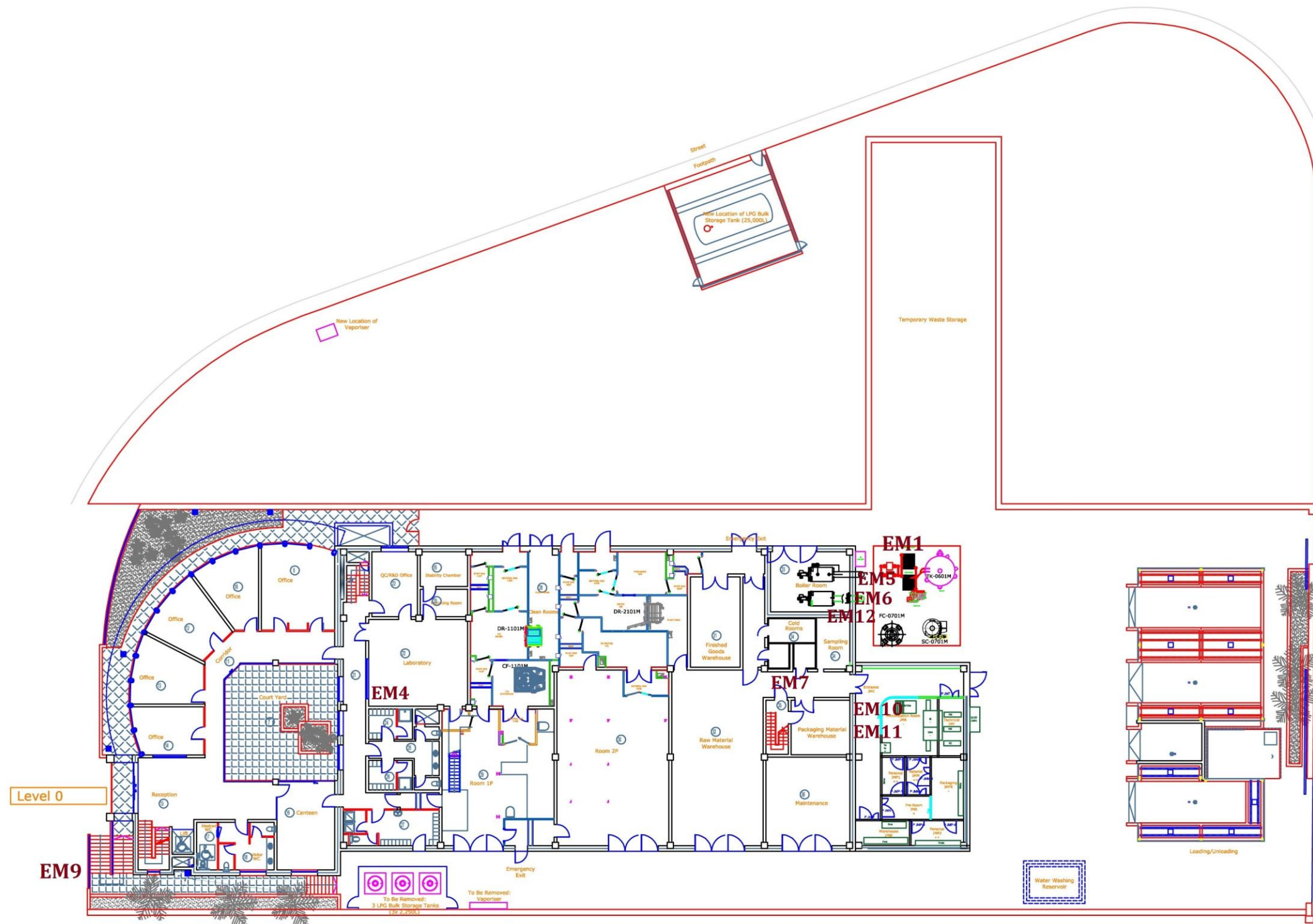






## **Attachment 1: Effluent and air emission points**



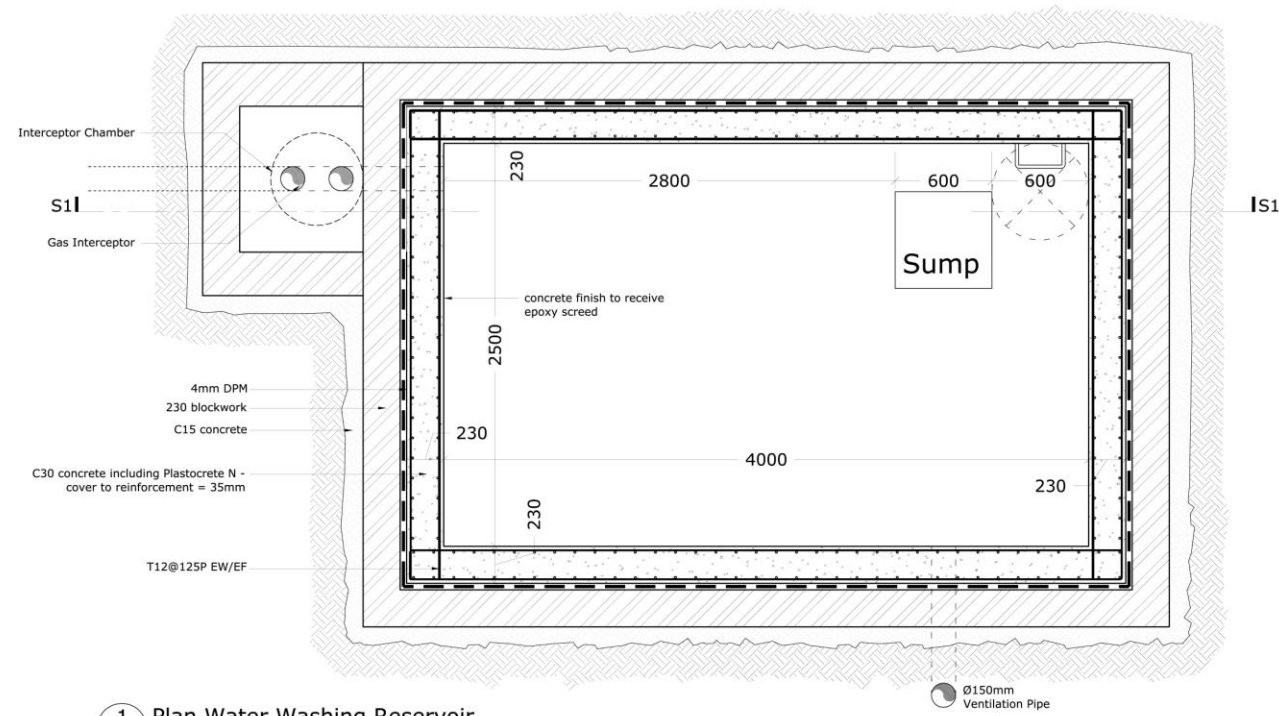




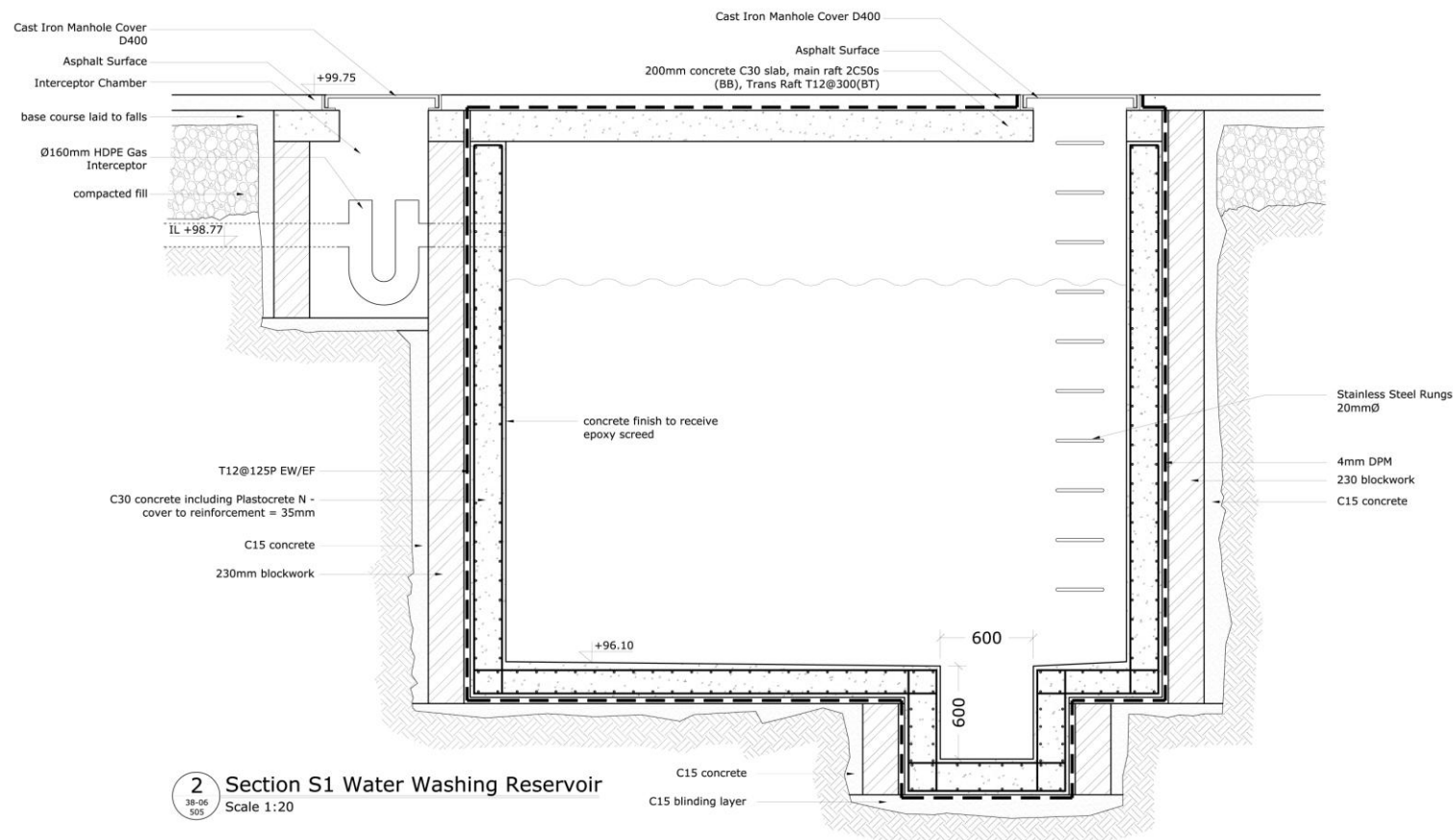
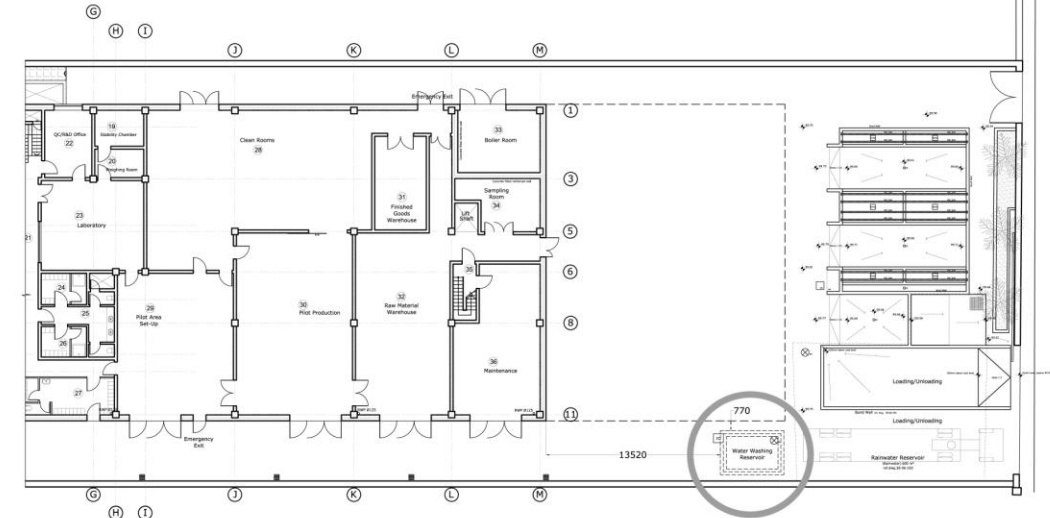


**Attachment 2: Cross-section of the reservoir**





**1** Plan Water Washing Reservoir  
Scale 1:20



**2** Section S1 Water Washing Reservoir  
Scale 1:20

Rev.	Description	Date
A	Revised Drawing	09-01-12

  
**Wallace Farrugia & Associates**  
 Architects, Civil Engineers & Structural Consultants.  
 No 44, Appt 3, St Francis Street, Sierra SLK2069 tel: 21316758 fax: 21316760

Commission:  
**Factory at Hal-Far Industrial Estate, Hal-Far**  
 Client:  
**STERLING SNIFF**  
 Drawing Title:  
**Water Washing Reservoir**  
 Scale: **1:20** Drawing No: **38-06-505A**  
 Job Ref: **38/06**

Drawn:	Amended:	Approved:	Checked:	Date:
W.F.				28-04-2009

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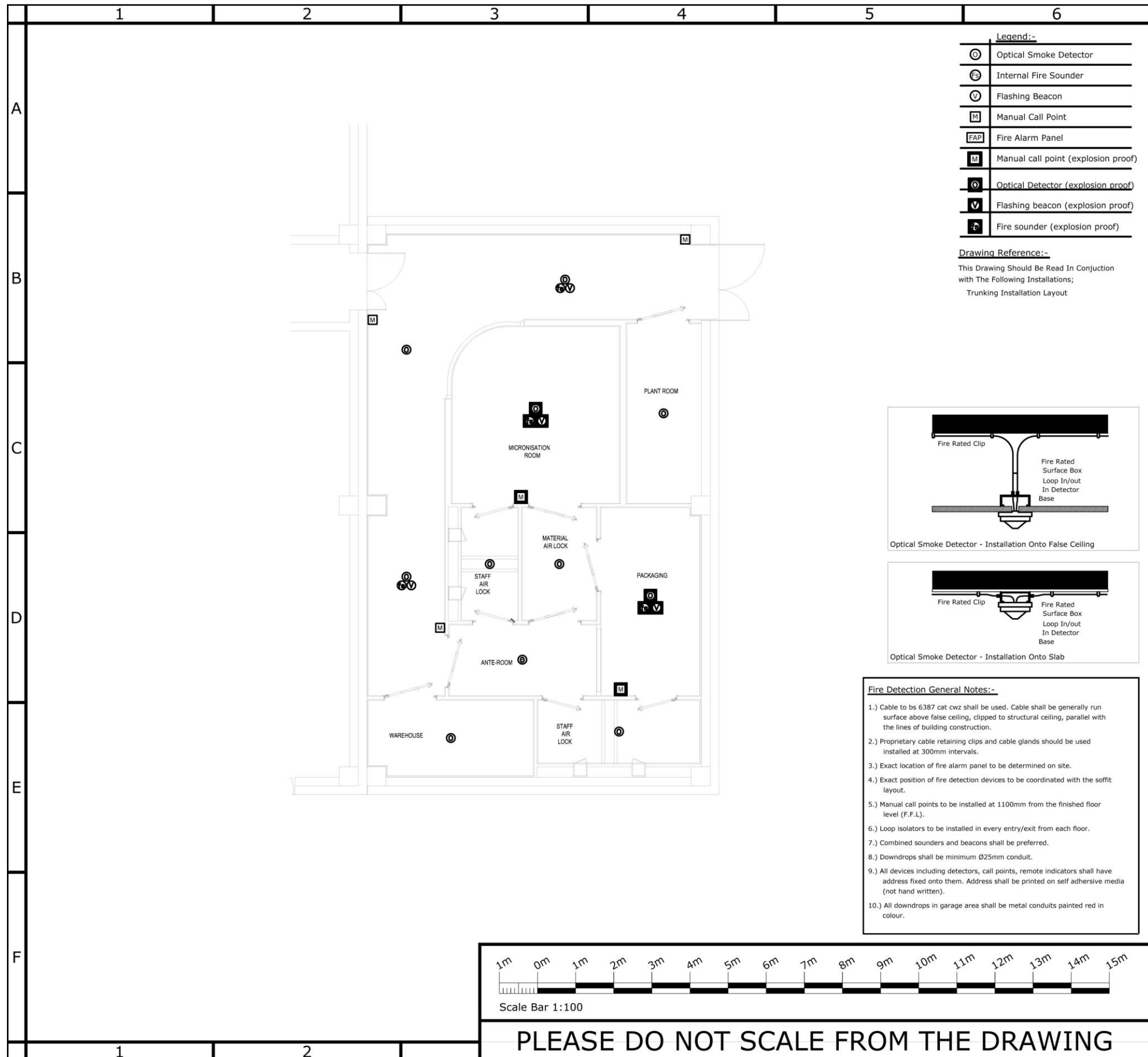






**Attachment 3: Fire detection and fire fighting plan for micronisation plant**





**General Notes and Legends**

-	-	-	-
-	-	-	-
-	-	-	-
No.	Date	By	Revision/Issue

**CAMILLERI & CUSCHIERI**  
Consulting Engineers  
Design Centre, Level 2, Triq it-Torri, Swatar, B'Kara, Malta  
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Job No.:	Drawing No.:	Revision No.:
17.041	STM.01.FD.01	00
Scale:	Paper Size:	Checked By:
1:100	A3	
Date:	Drawn By:	
11.09.17	<i>Antonella Basso</i>	

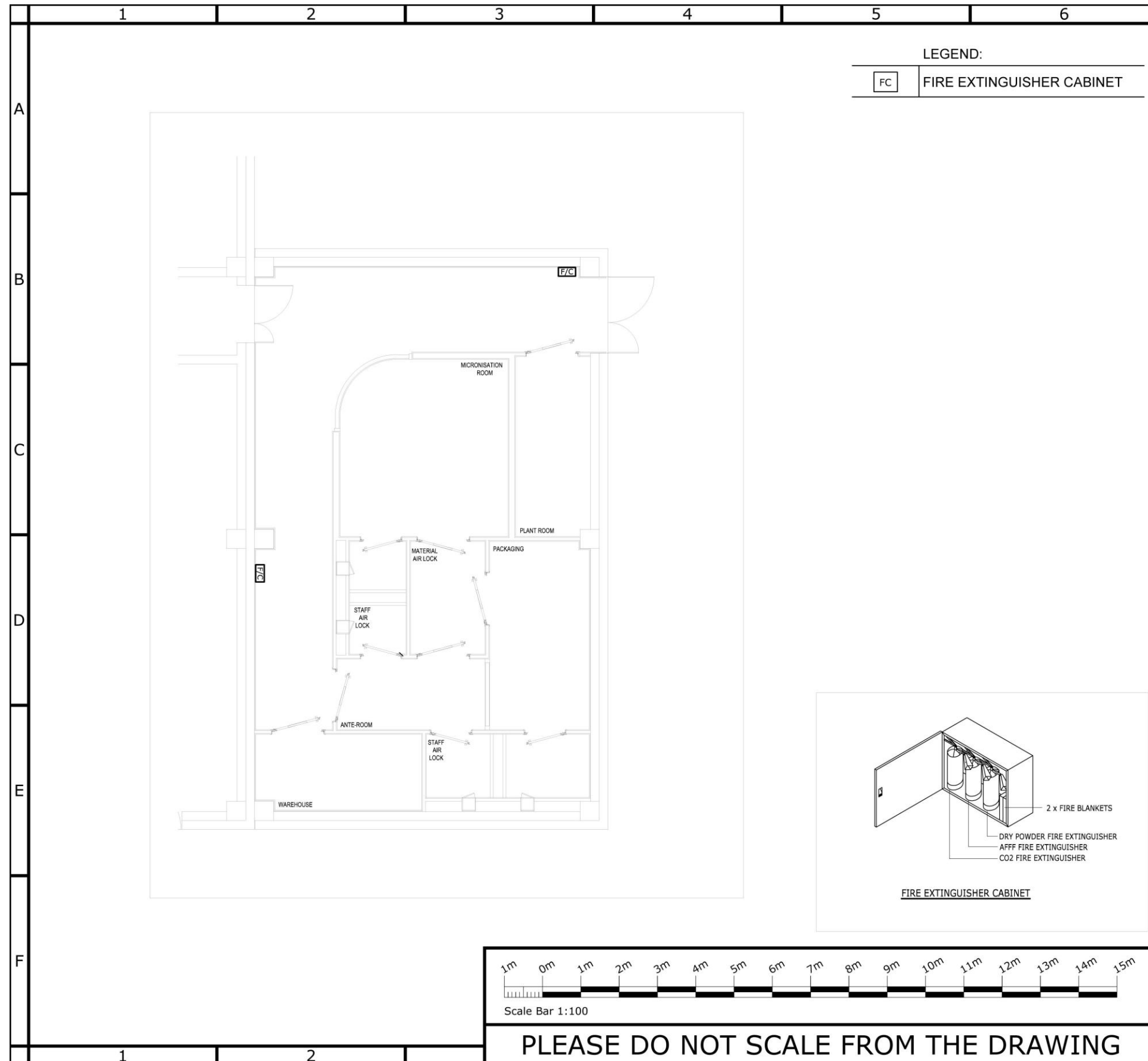
**Project Name & Address:**

**Sterling Ltd  
Micronisation**

Position: Ground Floor


Service: Fire Detection Installation Layout

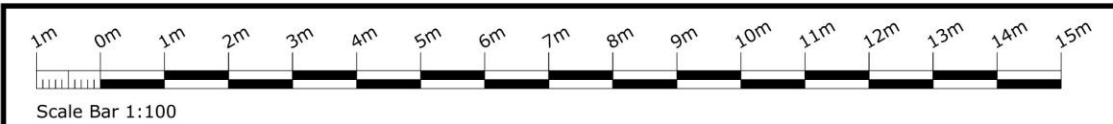




LEGEND:

FC	FIRE EXTINGUISHER CABINET
----	---------------------------

<b>General Notes and Legends</b>			
-	-	-	-
01	02.10.17	A.B	Revised Layout
No.	Date	By	Revision/Issue
 <b>CAMILLERI &amp; CUSCHIERI</b> Consulting Engineers Design Centre, Level 2, Triq it-Torri, Swatar, B'Kara, Malta Tel: +356 21 220431, +356 21 251797 Fax: +356 21 225747. Mobile: +356 9949 2960, +356 9945 5495 E-Mail: info@camilleriandcuschieri.com			
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Job No.:	Drawing No.:	Revision No.:	
17.041	STM.01.FF.01	01	
Scale:	Paper Size:	Checked By:	
1:100	A3		
Date:	Drawn By:		
11.09.17	<i>Aufyrella Busco</i>		
<b>Project Name &amp; Address:</b>  <div style="text-align: center; margin-top: 20px;"> <b>Sterling Ltd</b>  <b>Micronisation</b> </div>			
Position:			
Ground Floor			
Service:			
Fire Fighting Installation layout			



PLEASE DO NOT SCALE FROM THE DRAWING