en-sure monitoring

IP 0001/19

STERLING CHEMICAL MALTA LTD, HAL FAR

APPLICATION FOR VARIATION AND RENEWAL OF IPPC PERMIT

VOLUME 3: ADDENDUM 2 TO LAND AND GROUNDWATER RISK ASSESSMENT

Version 2: June 2019

Report Reference:

En-Sure Ltd, 2019. Sterling Chemical Malta Ltd, Hal Far. Application for Variation and Renewal of IPPC Permit: Volume 3: Addendum 2 to Land and Groundwater Risk Assessment (Version: 2). San Gwann, June 2019; vi + 31 pp.

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Quality Assurance

Sterling Chemical Malta Ltd, Hal Far
Application for Variation and Renewal of IPPC Permit: Volume 3
June 2019

Report for: Sterling Chemical Malta Ltd

Revision Schedule

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

File ref: N:_Active Projects\Environmental Permitting\ES_STG004 - Sterling Malta 2a\IPPC application\Response - June 2019\Vol 3 - Land & groundwater risk assessment.docx

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ADDENDUM 2 TO LAND AND GROUNDWATER RISK ASSESSMENT

Introduction

1. En-Sure Ltd was commissioned by Sterling Chemical Malta Ltd, herein referred to as 'the Operator', to prepare an application for variation of the Integrated Pollution Prevention and Control (IPPC) permit for the Sterling Chemical Malta Ltd facility.

2. The facility comprises a factory for the manufacture of Active Pharmaceutical Ingredients (APIs). The site is located at HF 50 and HF 51, Ħal Far Industrial Estate (as shown in **Figure 1**).

3. The proposed variations comprise an extension of the facility (as also shown in **Figure 1**, to include the adjacent HF 53 block); the extension is herein referred to as the 'Scheme'. The Scheme will include:

    - An R&D pilot plant (line 7 of the new production block in HF 53), and associated utilities;
    - Laboratories and other associated activities (including a maintenance workshop); and
    - Changing rooms, toilets, offices and underground parking.

4. A Land and Groundwater Risk Assessment[1] had been prepared for the facility in 2015, to cover the activities permitted at that time; that report is herein referred to as the 'original' risk assessment. An Addendum (Addendum 1)[2] to the original risk assessment was also prepared in August 2018, covering variations proposed at that time (including a micronisation facility, new reactors and cold rooms, a new temporary waste storage area, and a new LPG tank), which have since been approved.

5. The current Addendum (Addendum 2) covers the variations currently being applied for, and uses the same methodology as in the original risk assessment.

[1] En-Sure Ltd, 2015. *Sterling Chemical Malta Ltd, Ħal Far: Land and Groundwater Risk Assessment* (Version 1). San Ġwann, December 2015; iv + 41 pp. + 3 Appendices.
[2] En-Sure Ltd, 2018. Sterling Chemical Malta Ltd, Ħal Far. Application for Variation of IPPC Permit: Volume 3: Addendum 1 to Land and Groundwater Risk Assessment (Version: 2). San Gwann, August 2018; vi + 28 pp. + 1 Appendix.

Figure 1: Site location

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Location of Scheme site

Legend

Existing site boundary

Proposed site extension

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IPPC application

Map by: en-sure monitoring

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

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Description of the Site and the Surroundings

Location

6. The site (existing facility plus Scheme) covers an area of approximately 10,188 m^2 and is located in the Hal Far Industrial Estate, as shown in **Figure 1**.

History

7. The history of the Scheme site and its surroundings has been obtained through a review of available documentation.

8. The 1915 survey sheet for the area shows the Scheme site and its surroundings as unused garigue and agricultural land.

9. The former Hal Far airfield, which operated between the 1920s and the 1970s, was located just north of the Scheme site; this is confirmed in historical maps and aerial photos (**Figure 2** and **Figure 3** – the red arrow indicates the approximate site location). The airfield was heavily bombed during World War II.

Figure 2: 1953 map of Hal Far airfield[3]

[3] *RAF Hal Far (HMS Falcon)* www.ronaldv.nl/abandoned/airfields/MT/malta.html#halfar. The approximate location of the Scheme site is marked with an arrow.

Figure 3: 1960 aerial photo[4]

[4] *RAF Hal Far (HMS Falcon)* www.ronaldv.nl/abandoned/airfields/MT/malta.html#halfar. The approximate location of the Scheme site is marked with an arrow.

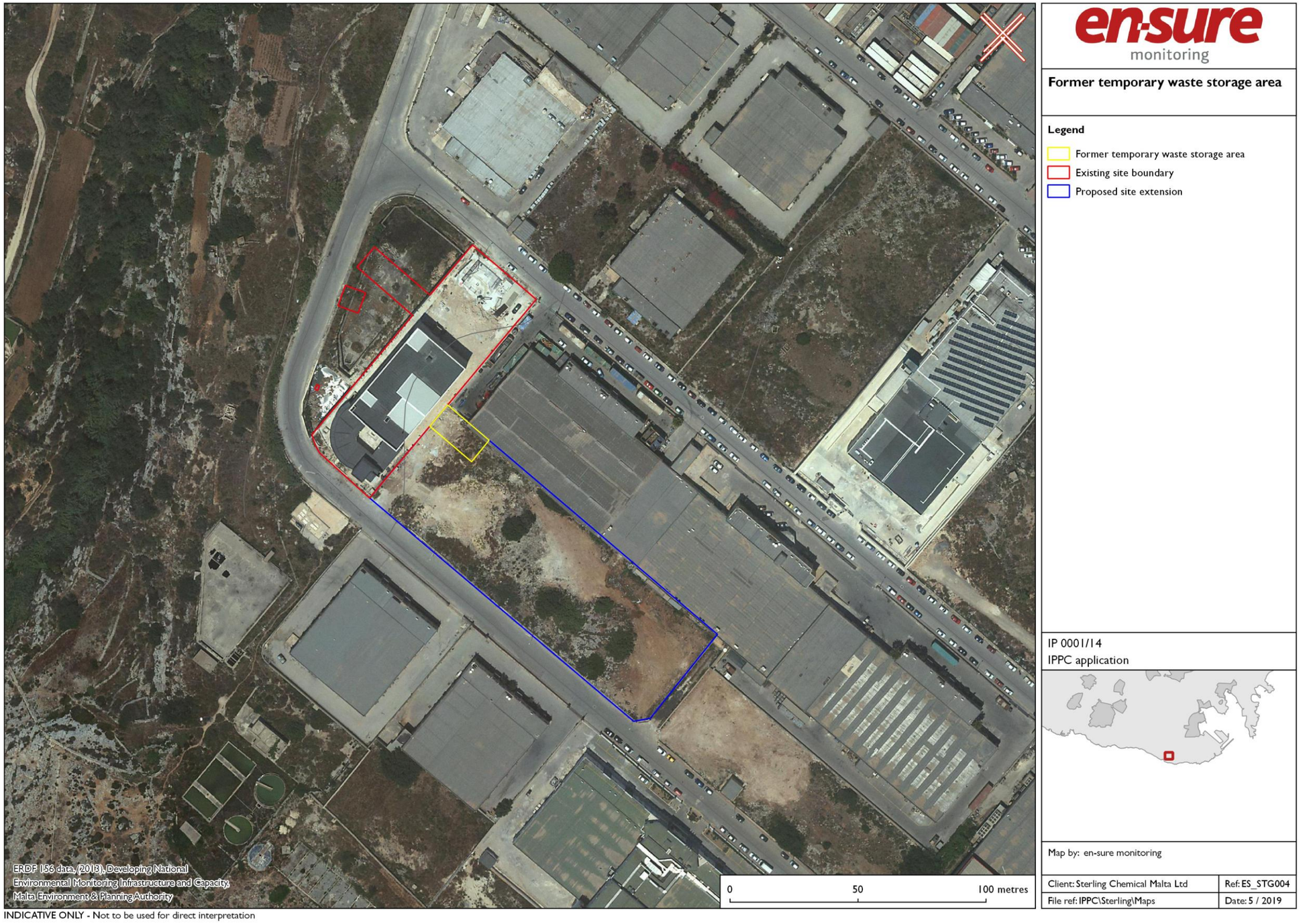
10. Aerial photos[5] from 1998 to 2016 indicate that the HF 53 block was unused and covered in vegetation. In 2017, some construction residues were reported by the Operator (**Figure 4**). The HF 53 block is currently under construction.

Figure 4: HF 53 site in 2017

11. Additionally, in 2017 a small part of the HF 53 site (at the northwestern corner of the HF 53 block, as shown in **Figure 5**) was used by the Operator as a temporary waste storage area for storage of liquid hazardous waste (of the same types that are currently produced) prior to removal off-site. The flooring in this area was composed of impermeable concrete; prefabricated containment was also used for storage of liquid hazardous waste. The Operator indicates that the maximum volume stored at any time was 6,000 L, and has confirmed that no spills occurred in this area. Waste storage activities here started around 2017 (the exact date is not documented) and ceased in January 2018; construction of an industrial building started in October / November 2017. During construction, excavated rock from the HF 53 site itself was compacted and used for backfilling.

[5] Planning Authority *Geoserver* http://geoserver.pa.org.mt/publicgeoserver.

Figure 5: Location of former temporary waste storage area



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Surrounding Land Uses

12. A land use survey was carried out in November 2015 and updated again in October 2018, covering approximately 250 m around the Scheme site. The land uses have been mapped in **Figure 7**.

13. The predominant land uses in the surrounding area are industrial (**Figure 6**), predominantly manufacturing activities (including pharmaceutical production, detergent manufacture, production of climate control systems, and printing presses) and storage / warehousing.

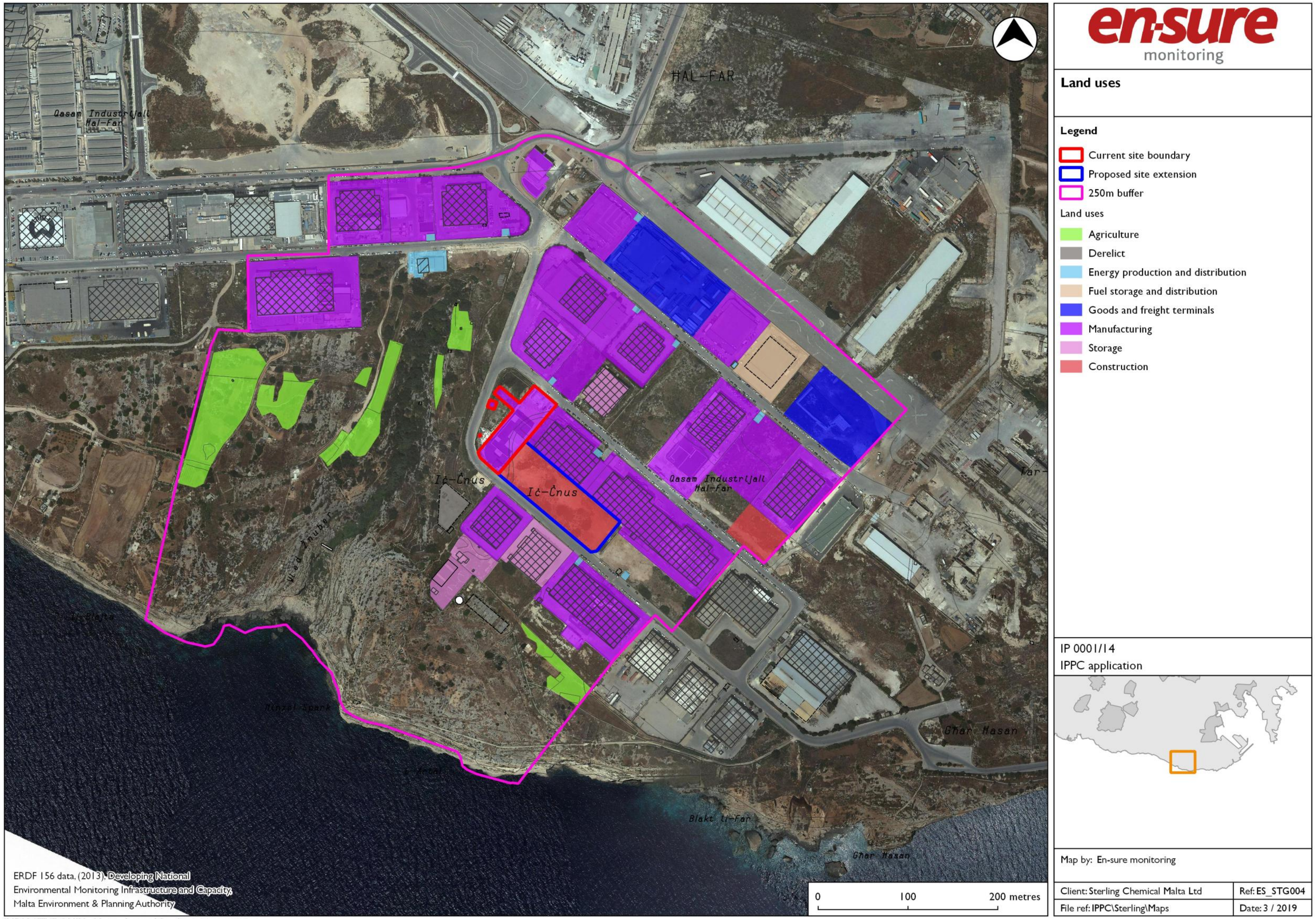
Figure 6: Industrial uses

14. There are a number of electricity substations servicing the area, and a transformer plant operated by Enemalta.

15. Some cultivated agricultural land is found along both sides of the Wied Żnuber valley, located to the west of the Scheme site.

16. There are no residential properties within 250 m of the Scheme site.

Figure 7: Land uses



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Description of the Variations

17. As mentioned, the proposed variations comprise a lateral extension to the existing plant, to include an R&D pilot plant and other associated activities.

18. A detailed description of these variations is included in **Volume 2** of the IPPC application, notably in Sections C1.3 and C2.2. An overview of the pilot plant layout is shown in **Figure 9**.

19. The following subsections summarise the aspects of these proposals that are relevant to the contamination of land and groundwater, and the associated mitigation. The changing rooms, toilets, offices, and parking are not considered relevant to the assessment of land and groundwater contamination, and will therefore not be considered further.

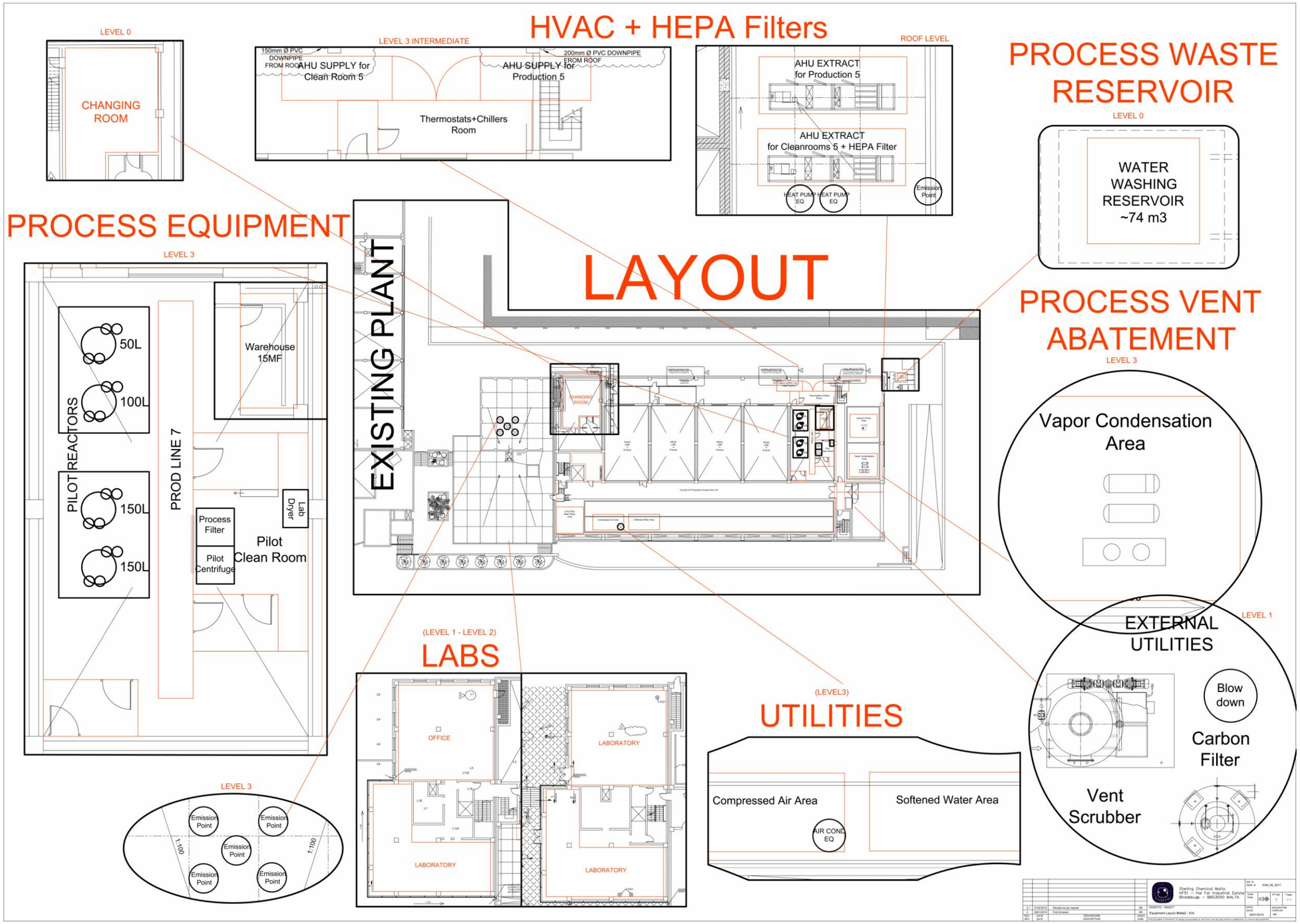
R&D pilot plant

20. The pilot plant (line 7) will include four small-scale reactors and other equipment, used for R&D scale-up of novel drugs for the company. The manufacturing processes will be similar to that already authorised and operational. There will be no changes to the types of raw materials used, or the types of products and waste generated as a result of this new production line.

21. Emissions to air from the reactors will be treated in a new scrubber (after treatment in two heat exchangers and a carbon filter); this treatment process is the same as for the existing production line. Local extraction leading to the scrubber is used when any containers are opened; an example is shown in **Figure 8**. Emissions from the clean room in the pilot plant will be treated using a HEPA filter.

Figure 8: Local extraction system

Figure 9: Overview of pilot plant



22. Solvent from the heat exchangers will be collected into container/s (drums or similar) located in an external utilities area (Level 1, HF 53 block). As this area is located outdoors, the containers will be stored on prefabricated containment.

23. Waste from the Scheme will largely be handled as per the existing arrangements. However, spilt effluent and wash water from floor washing will drain through gutters (made of steel) located around the internal perimeter, to a new 74 m^3 'water washing reservoir' at the northeastern corner of the HF 53 block.

24. Additionally, all the ground floor level (level 1) in the new HF 53 block (including indoor areas) will be underlain by an impermeable concrete layer. The pilot plant will have an epoxy resin coating on the floor; the clean room and finished product warehouse will have vinyl flooring.

25. The reservoir will be made of concrete and lined with HDPE to ensure impermeability; testing for impermeability will be carried out as required by the IPPC permit.

26. Effluent collected in the new 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.

27. A spill kit will also be included in the production line.

Laboratories

28. The new laboratories will be used for testing related to the pilot plant, and eventually for the rest of the new production lines in the HF 53 block. As with the existing laboratories at the facility, small quantities of chemicals / solvents will be consumed and associated waste generated.

29. Emissions from the laboratory fume hoods will be treated in a carbon filter before being released at roof level, and HEPA filters will be installed on the balance enclosure where weighing of powders is carried out.

30. Laboratory floors will be tiled with acid-resistant tiles and acid-resistant grout. Effluent from the sinks and floor drains in the new laboratories will drain to the new 'water washing reservoir', at times after receipt in a smaller 'water spillage reservoir' (which will also be concreted and lined with HDPE, and tested at intervals).

31. The laboratories will also have access to spill kits.

Maintenance Workshop

32. A maintenance workshop will also be operational on level 1. There will be minimal storage of liquid hazardous substances, however, any storage of liquid

hazardous substances in this area (such as cleaning agents) will be carried out in prefabricated cabinets with underlying containment.

Fire Prevention and Response

33. The existing 600 m^3 reservoir on the HF 51 block will now be reserved exclusively for firefighting of the entire site (including the existing site). This is kept full at all times, and a level meter with alarm is installed for this purpose. This volume is able to provide up to 150 minutes of firefighting water.

34. In the HF 53 block, an automatic fire detection system will be in place. This will include smoke detectors fitted with an acoustic alarm and beacon, as well as break glass manual call points. The firefighting system in the HF 53 block will include a sprinkler and wet mains system, connected to the existing fire pump, as well as fire cabinets containing fire extinguishers and a fire blanket. However, in the areas where hazardous substances are used no water is proposed.

35. It is expected that the dry chemical fire extinguishers (which are proposed for the new pilot plant and clean room) would be retained within the area generated, since they do not flow easily. Portable fire extinguishers will be used in the external utilities area; this will be collected in the prefabricated containment.

Relevant Hazardous Substances and Waste

36. The main contaminant types associated with the proposed variations, and their potential relevance to land / groundwater contamination are presented in **Table 1**.

Table 1: Contaminants and relevance to land / groundwater contamination

Proposed variation	Contaminant types	Relevance	Justification
New pilot plant	Raw materials (including organic solvents), products (APIs), hazardous waste	Relevant	Hazardous substances / waste in liquid form or solution; washwater from cleaning of production vessels would also be contaminated with these substances; without mitigation, gaseous / airborne particulate emissions may also be released and eventually contaminate land
New laboratories	Various chemicals used for testing	Not relevant	Stored and handled in very small-scale quantities (1 to 2.5 L bottles each).
	Products (APIs) undergoing testing	Not relevant	Handled in very small quantities.
Maintenance workshop	Cleaning agents and similar substances	Not relevant	Handled / stored in small quantities.

Risk Assessment

Overview

37. The risk assessment methodology is based in the identification and evaluation of source-pathway-receptor linkages, as described in the original risk assessment.

38. **Table 2** summarises potential sources of pollution associated with the proposed variations, and the respective pathway to the relevant receptors. The generation of used extinguishant in the event of a fire has also been considered.

39. **Table 2** also includes 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 in the Scheme.

Table 2: Pollution pathway identification and mitigation measures

Source	Pathway	Receptor	Mitigation measures	
			Construction mitigation measures	Operational mitigation measures
Spill from new production line (API products, hazardous raw materials / waste, wash water)	Direct contamination; permeable strata above water table[6]	• Land • Groundwater	• Underlying impermeable concrete layer, with epoxy resin / vinyl 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[7] • Certification of containment systems as required by IPPC permit • Spill kits, and staff training
Spill in new external utilities area	Direct contamination; permeable strata above water table; rainwater runoff	• Land • Groundwater	• 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
Spill during emptying of water washing reservoir	Direct contamination; permeable strata above water table; rainwater runoff	• Land • Groundwater	• 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

[6] A pathway only exists if the current mitigation measures fail.
[7] IBCs are intermediate bulk containers, typically having a volume of 1 m^3.

Source	Pathway	Receptor	Mitigation measures	
			Construction mitigation measures	Operational mitigation measures
Emissions to air from new pilot plant (APIs, VOCs, reaction by-products)	Air dispersion (prevailing wind direction) ; Wet precipitation	Land Groundwater	-	• 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
Emissions to air from new pilot plant clean room	Air dispersion (prevailing wind direction) Wet precipitation	Land Groundwater	-	• Abatement with HEPA filter • Emissions monitoring as required by IPPC permit • Differential pressure device to monitor filter condition • Replacement of filters as per maintenance schedule
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	• Rainwater reservoir with 600 m^3 of water (150 minutes) dedicated to firefighting; level meter with alarm	• Emergency fire procedures • Automatic fire detection system, sprinkler and wet mains system, fire extinguishers and fire blankets installed in HF 53 block • No water is proposed as an extinguishant in the areas where hazardous substances are used (dry chemical fire extinguishers will be used in the production lines and clean rooms) • Training of personnel in fire prevention and basic fire fighting • Contaminated used extinguishant (from portable extinguishers) from external utilities area contained in prefabricated containment

Identification of Potential Releases

40. Relevant releases could occur from accidental spillages of the various substances used and produced at the Scheme, including samples, raw materials, intermediates, products (APIs), solvents, and hazardous waste (especially liquid waste contaminated with organic solvents).

41. Releases could also occur from contaminated wash water, notably that generated from the production area during cleaning of equipment and floors.

42. Air emissions containing APIs, volatile organic compounds (VOCs) and / or reaction by-products will also be generated from the new pilot plant and clean room. However, mitigation measures will be in place to reduce air emissions, as described in **Table 2**.

43. Used extinguishant will also be generated in the event of a fire at the Scheme, which may become contaminated with hazardous substances.

Identification of Migration Pathways

44. 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.

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.

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.

45. However, a number of mitigation measures will be in place on site to prevent the migration of contaminants towards land and groundwater, as described earlier, and in **Table 2**.

Identification of Potential Receptors

46. 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 shown in **Figure 10**. At the Scheme site, the exposed rock formation is Lower Coralline Limestone.

47. Contaminants could also reach the groundwater in the unmitigated scenario. The mean sea level aquifer is the principal hydrogeological feature in the area (**Figure 11**). 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 55 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.

48. The site is located outside the Groundwater Safeguard Zone, and there are no private or public groundwater boreholes located within 400 m of the site.[8]

49. The facility 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 contains the following plant species: *Arundo donax*, *Crataegus monogyna*, *Erica multiflora*, *Ceratonia siliqua*, and *Opuntia ficus-indica*.

50. 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 12**. The garrigue in these areas is also designated as an AEI. The cliffs making up this part of the SPA / SAC are home to protected seabird breeding colonies, including 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.

[8] George Cassar (Malta Resources Authority), email dated 9th November 2015.

Figure 10: Geology of the Scheme site and its surroundings

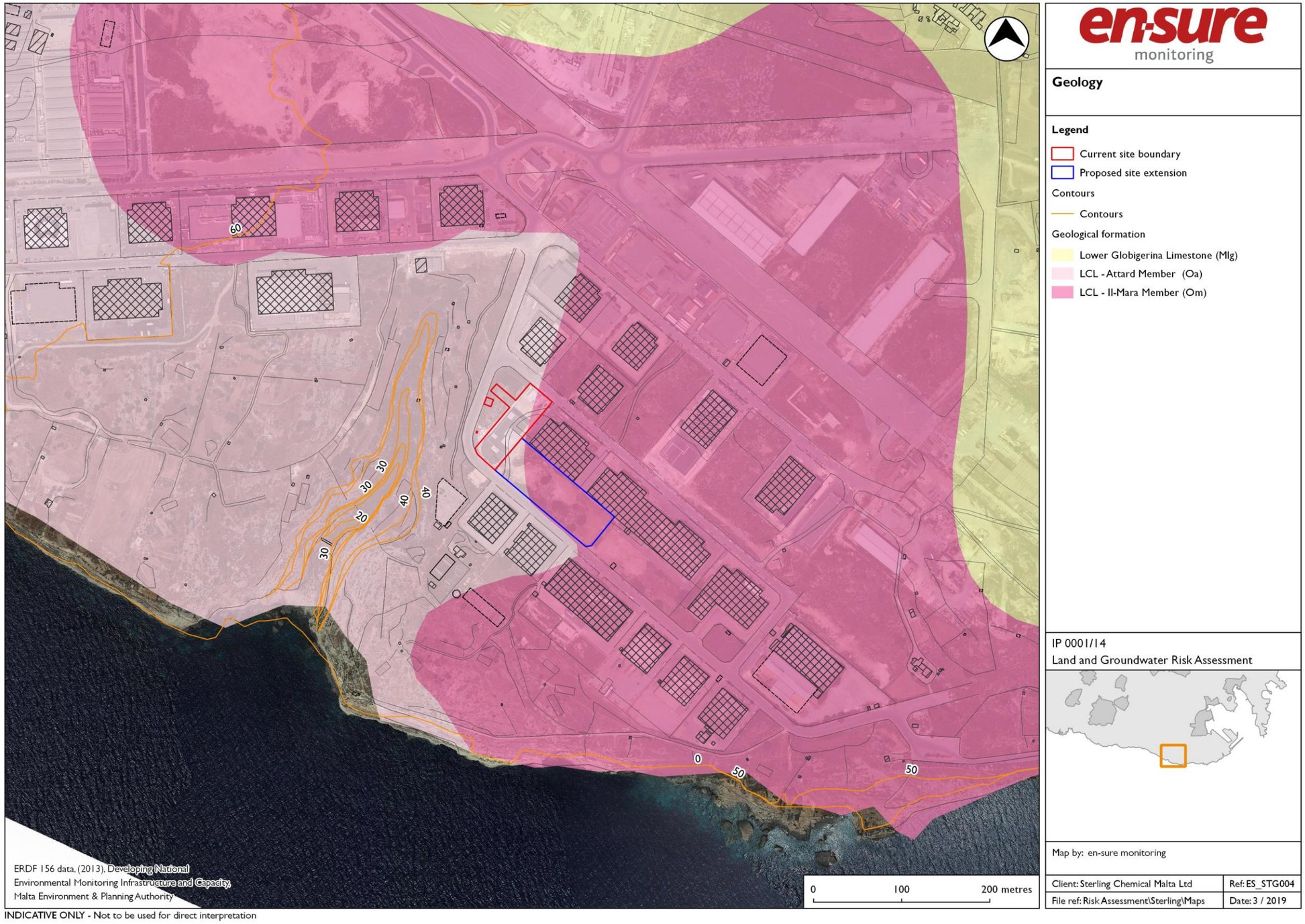


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Figure 11: Hydrology of the Scheme site and its surroundings

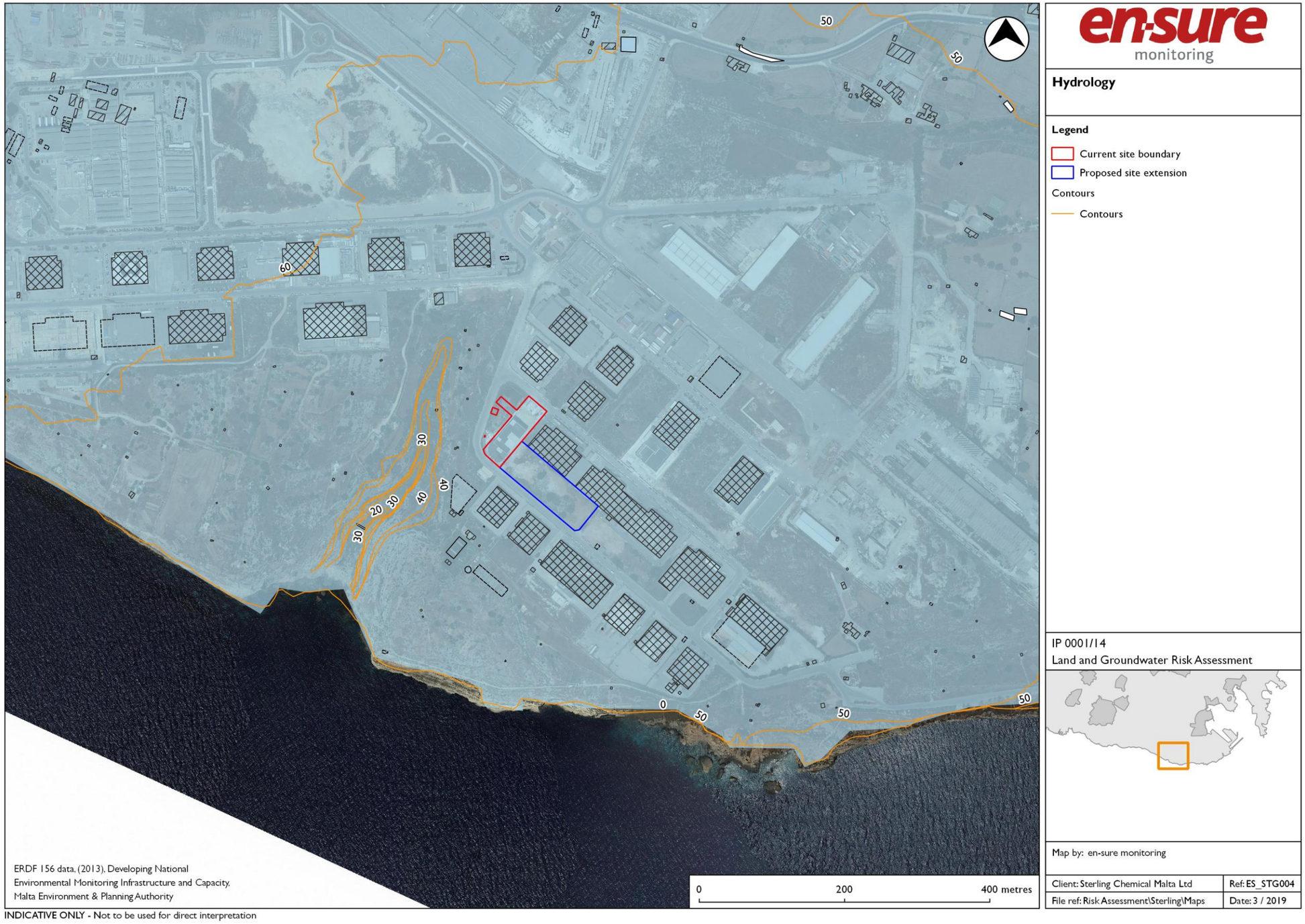

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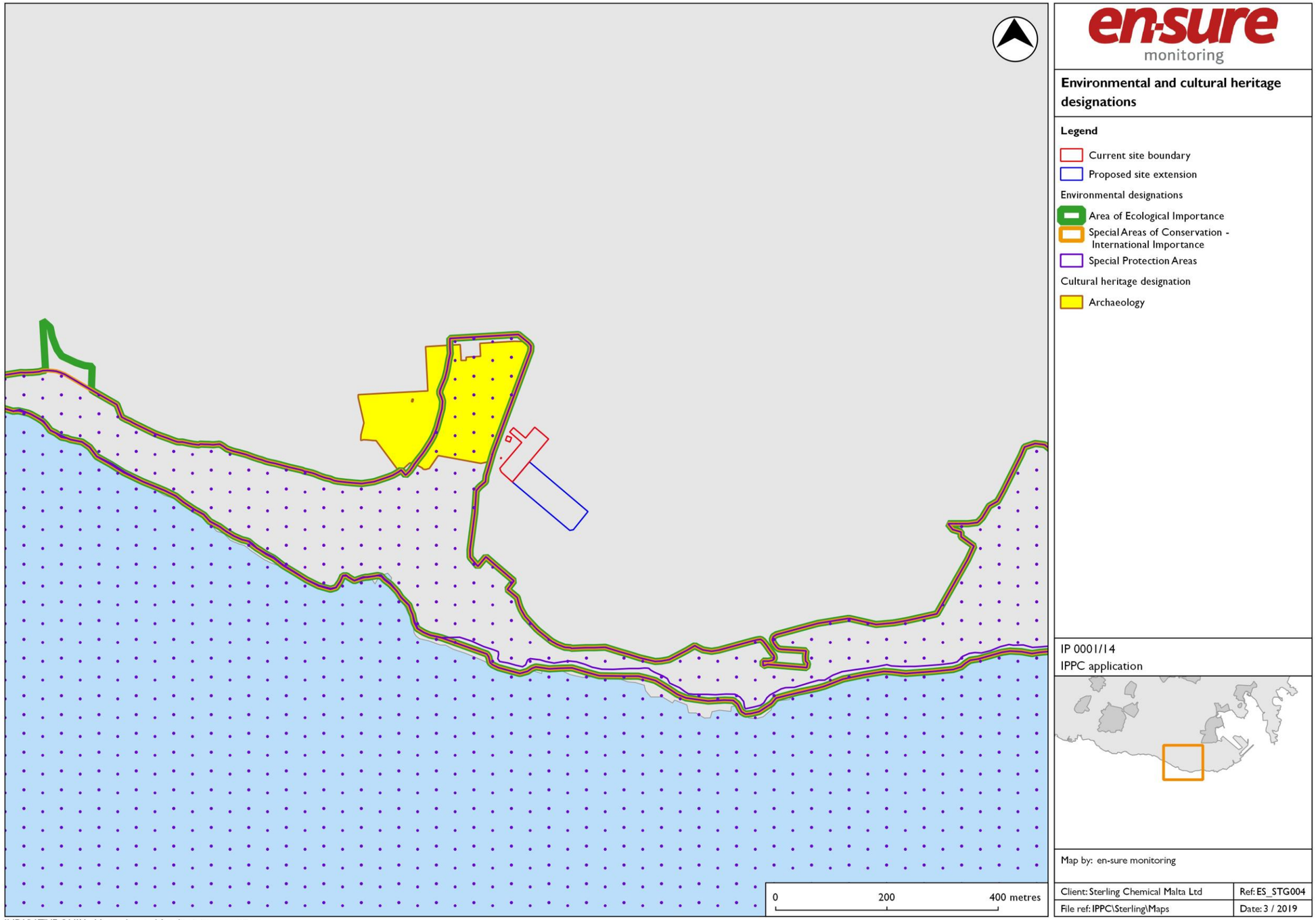
Figure 12: Environmental designations



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Risk Evaluation

51. The risks to land and groundwater have been assessed using the evaluation criteria described in the original risk assessment. 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

52. **Table 4** presents the risk levels for each source without the implementation of any mitigation measures.

Table 3: Risk levels (without mitigation)

Source	Environmental consequences	Likelihood of consequence	Resultant risk level
Spill in new pilot plant	Minor	Likely	Moderate
Spill in new external utilities area	Minor	Likely	Moderate
Spill during emptying of water washing reservoir	Minor	Likely	Moderate
Emissions to air from new pilot plant	Minor	Almost certain	Moderate
Emissions to air from new clean room	Minor	Almost certain	Moderate
Release of used contaminated extinguishant	Minor	Occasional	Moderate

53. The likelihood of an accidental spill in the new pilot plant, external utilities area, and during emptying of the water washing reservoir has been classified as likely without precautions. However, such spills are likely to be small, and therefore have minor environmental consequences.

54. In the scenario without mitigation, emissions to air will routinely be generated in the pilot plant and clean room and released to the surroundings, although there will be some dispersal before these emissions reach the land. Given the small scale of the Scheme, the environmental consequences have been classed as minor.

55. It is considered that runoff of used extinguishant from the Scheme could result in minor environmental consequences if the used extinguishant is contaminated with hazardous substances / waste from the Scheme and if it spreads beyond the site. Without mitigation, taking into account the flammability and quantity of the substances to be stored (not only at the Scheme but also at the rest of the facility), it is considered that a fire may occur occasionally.

With Mitigation

56. **Table 4** presents risk levels for each source with the implementation of the proposed mitigation measures.

Table 4: Risk levels (with mitigation)

Source	Environmental consequence	Likelihood of consequence	Resultant risk level
Spill in new pilot plant	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
Emissions to air from new pilot plant	Insignificant	Almost certain	Low
Emissions to air from new clean room	Insignificant	Almost certain	Low
Release of used contaminated extinguishant	Insignificant	Unlikely	Very low

59. Since the new pilot plant will include concreted containment, which will be periodically certified for impermeability, the pollutant linkage in case of a spill in this area is removed.

57. With prefabricated bunding, the pollutant linkage from the external utilities area is also removed; therefore a spill in this area would not present an environmental risk.

58. 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 will be 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.

59. Emissions to air from the new pilot plant and clean room 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 these scenarios has still been classified as almost certain.

60. Considering the measures that will be in place to prevent a fire, the generation of used extinguishant can be classified as unlikely. Given that only dry chemical fire extinguishers will be used in the areas where hazardous substances are used, the used extinguishant would be retained within the area generated (since such materials do not flow easily). Therefore the environmental consequences would be insignificant.

Conclusion and Recommendations

61. As a result of the mitigation measures envisaged to be implemented, notably containment and abatement systems, risks to land and groundwater from the

Scheme have been reduced to very low, and low, with no pollutant linkage identified in two scenarios.

62. As a result, baseline land and groundwater monitoring is not considered necessary, provided that the identified mitigation measures are implemented.

63. It is also recommended that a monitoring programme be set up to ensure that the mitigation measures are implemented and functioning effectively.

64. Finally, it is recommended that the risk assessment be reviewed in future if new categories of relevant hazardous substances / waste are proposed to be used or produced in significant quantities, if monitoring reveals that the effectiveness of the mitigation measures is reduced, or if additional activities are proposed that could present a risk of contamination of land or groundwater.