Case Officer Report

Subject:	IP 0001/23 – Application for the renewal and variation of IP 0004/21 to include two additional emissions points, relocate raw materials to QC lab, discharge RO reject to sewer, and change the use and layout of the 22-MR warehouse submitted by Sterling Chemicals Malta Ltd.
Date:	9th May 2024
To:	ERA Board
From:	Regulatory Affairs Directorate

1. Background

This report has been prepared for the determination of an application IP 0001/23 which is a renewal and variation of the current IPPC permit (IP 0004/21) submitted by Mr Roberto Tumbiolo obo Sterling Chemical Malta Ltd. In this regard, the application was received on 6th June 2023.

This application for a renewal and variation includes the following changes:

- The introduction of two additional emission to air points, namely from the micronisation plant and fire safety cabinets for the storage of raw materials, both located in the HF 51 block;
- Authorisation to relocate a small amount of raw materials from the raw materials warehouse to the QC laboratory;
- The inclusion of reverse osmosis (RO) reject as a source of effluent being discharged to sewer; and
- Changes to the use and layout of the waste warehouse hereinafter referred to as the 22-MR Warehouse.

2. Case Officer Report

2.1. Proposal

This operator is authorised to carry out operations and associated operations specified in the table below. Changes in permitted operations related to the current variation application include the addition of a reverse osmosis and three emergency generators. There are no changes to main operations covered by the current IPPC permit.

Operation	Description of Specified Operation	Limits of Specified Operation
Production by chemical or biological processing of pharmaceutical products including intermediates.	Synthesis of active pharmaceutical ingredients (APIs). Research & Development 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 preparation of radioactive APIs.
Associated operations of utilities.	Two (2) water purification plants.	From receipt of water to delivery of utility. Does not include the discharge of foul water generated from high potency line into sewage network.
	Sixteen (16) reactors.	As described in consolidated IPPC applications.
	Two (2) LPG boilers to produce steam/hot water.	From receipt of fuel to delivery of utility.
	Cooling tower.	From intake of water, to treatment and final discharge.
	Air handling units.	From the intake of outside air to filtration prior to extraction from the facility.
	One (1) reverse osmosis.	From receipt of water, to treatment and discharge to sewer.
Associated operations of waste management.	Handling and storage of waste generated from installation prior to dispatch offsite.	From generation of waste to dispatch for disposal or recovery (including recycling) offsite at permitted facilities. Includes separation of solvent mixture from industrial processes for recovery and reuse where possible, and storage of rejected products.

Emissions and Mitigation.

Emission Point Reference	Source	Mitigation
EM1	Production Area	HEPA Filter (HF4 - HF6), Carbon Filter, Heat Exchanger, Scrubber
	Weighing Room	
	Finished Goods area (clean room)	
	Microniser	
EM2	HVAC (General ventilation and air-conditioning) – H51 block	Fabric filter
EM3A	HVAC Production Line 2 clean rooms	HEPA filter (HF1)
EM3B	HVAC Production Line 1 clean rooms	HEPA filter (HF2)
EM3C	Micronisation plant clean rooms	HEPA filter (HF3)
EM4A	Laboratories	Fume Hood Extraction vent
EM4B	Laboratories	Fume Hood Extraction vent
EM4C	QC lab fume hoods	Carbon filter
EM4D	QC lab fume hoods	Carbon filter
EM4E	QC lab fume hoods	Carbon filter
EM5	Boiler	Boiler stack
EM6	Boiler	Boiler stack
EM7	Cooling Tower	Cooling tower stack
EM8A	AMS (Quality Control) lab fume hoods	Carbon filter
EM8B	AMS (Quality Control) lab fume hoods	Carbon filter
EM8C	AMS (Quality Control) lab fume hoods	Carbon filter
EM8D	AMS (Quality Control) lab cabinet and localised hoods	Carbon filter
EM10A	R&D laboratory	Fume Hood Extraction vent
EM10B	R&D lab fume hoods	Carbon filter
EM10C	R&D lab fume hoods	Carbon filter
EM10D	R&D lab fume hoods	Carbon filter
EM11	Micronisation laboratory	Fume Hood Extraction vent
EM12	Cold Rooms	Vent
EM13A	Production area	Heat Exchanger, Carbon Filter, Scrubber
EM13B	Production area	Scrubber backup fan
EM14	General ventilation	HVAC
EM15	HVAC Production Line 7 Clean rooms	HEPA filter (HF7)
EM16	Laboratory	Fume Hood Extraction vent
EM17	Laboratory	Fume Hood Extraction vent
EM18	Laboratory	Fume Hood Extraction vent
EM19	Laboratory	Fume Hood Extraction vent
EM20	Laboratory	Fume Hood Extraction vent

EM22	22-MR Warehouse	None
EM23	Microniser (Nitrogen Outlet)	HEPA filters (HF4 - HF6)
EM24	Ventilation System of Fire Safety Cabinet	Carbon filter
EM25	Emergency Diesel-Fuelled Fire pump	None

From the above list of emission points, EM 23 and EM24 are the new emission points being proposed. Location of emission points is available in Annex II.

Emission Limits to Air and Monitoring

Emission Point Reference	**Parameter**	**Limit**	**Frequency**
EM1 EM13A-B	Total VOC	20 mg C/Nm^3	Annually
	CO (Carbon Monoxide)	N/A	
	HCl (Gaseous Chloride)	7.5 mg/Nm^3	
	HF (Gaseous Fluoride)	<1 mg/Nm^3	
	Total Particulate Matter (Dust)	<1 mg/Nm^3	
	NH_3 (Ammonia)	10 mg/Nm^3	Every 6 months
	SO_2 (Sulphur Dioxide)	<150 mg/Nm^3	
	Toluene	<1 mg/Nm^3	
	Dichloromethane	<1 mg/Nm^3	
	Dimethylformamide	2 mg/Nm^3	
	Tetrahydrofuran	10 mg/Nm^3	
	Methyl Isobutyl	10 mg/Nm^3	
EM3A-C EM15	Total Particulate Matter (Dust)	<1 mg/Nm^3	Annually
EM4A-E EM8A-D EM10A-D EM11	Total VOC	20 mg C/Nm^3	Every 4 years[i]
	Total Particulate Matter (Dust)	<1 mg/Nm^3	
EM23	Total Particulate Matter (Dust)	<1 mg/Nm^3	

2.2. Supporting documents recommended for approval

2.2.1. Document: IP 0001/23 – Permit document
2.2.2. Drawing Numbers: IP 0001/23/DOC1 – Site layout Plan
2.2.3. Document: IP 0001/23/DOC2 – Emissions to Air Monitoring Method Statement
2.2.4. Document: IP 0001/23/DOC3 – Decommissioning and cessation plan

2.3. Applicable Law/ Policy

The proposal is to comply with:

- Environment Protection Act (CAP. 549)

[i] Monitoring frequency is subject to compliance with emission limit value, otherwise monitoring shall be carried out annually.

- Industrial Emissions (Framework) Regulations (S.L.549,76)
- Industrial Emissions (Integrated Pollution Prevention And Control) Regulations (S.L.549.77)
- Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (S.L.549.79)
- BREF Documents:
    - Best available techniques (BAT) specified for Manufacture of Organic Fine Chemicals (August 2006);
    - Best available techniques (BAT) specified for Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector (May 2016)
    - Best available techniques (BAT) specified for Common Waste Gas Management and Treatment Systems in the Chemical Sector (December 2022)

2.4. Site Description and Constraints

Sterling Chemical Malta Ltd. is located within an industrial area in Ħal Far, Birżebbuġa (as per Annex I).

2.5. Site History

The following permitting history is noted on site:

Number	Title	Status
IP 0001/14/A	New Application	Granted 13th August 2015
IP 0001/14/B	Variation	Granted 5th April 2019
IP 0001/19	Renewal and Variation	Granted 29th November 2019
IP 0004/21	Variation	Granted 22nd September 2021
PA 4236/08	Factory at Ħal 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.	Granted 22nd April 2010 *(Minor amendment to extend the canopy over the outdoor chemical/ waste store which was approved.)*
PA 3033/12	Installation of LPG bulk storage in a facility/factory already covered by permit PA 4236/08.	Granted 14th June 2013
PA 3638/18	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	Granted 7th March 2019
PA 8089/19	To sanction changes from approved permits PA 4236/08, DN 1094/18, DN 0624/16, including the increase in overall height; to change use approved in DN 1094/18 from general manufacturing (Class 5B) to production of Active	Granted 12th November 2020

	Pharmaceutical Ingredients (API); to replace parking layout approved in PA 3638/18 with waste containment area and including changes to landscaping; changes to boundary wall and access gates and extension of external warehouses.	
DN 0624/16	Extension to factory	Granted 14th September 2016
DN 0023/17	Extension to external area and carpark	Granted 25th January 2017
DN 0810/17	Construction of Factory	Granted 9th October 2017
DN 1094/18	Construction of factory	Granted 12th November 2018
DN 0259/20	Construction of external stores and security room, and alterations to boundary wall and site entrance.	Granted 13th April 2020

2.6. Consultations

2.6.1. Intra-ERA Feedback

The **Environmental Assessment Unit** stated that the proposed interventions were not significant from an environmental perspective, however it is noted that an additional IPPC variation application is required in order to address additional interventions proposed through PA 4688/23 that are currently not reflected in IP 0001/23.

Since the initial variation proposal included the installation of 3 standby generators, the **Air Quality & Water Unit (Noise Team)** had initially inquired whether said generators would be considered in the upcoming noise monitoring study, however this is no longer relevant since the installation of these generators are no longer part of this proposal.

The **Compliance and Enforcement Unit** noted that all AERs were submitted and all previous IP items were addressed. During inspections the site was found to be largely compliant, with the exception of inadequate bunding for storage of liquid waste. The issue is being followed by through the compliance process.

2.6.2. External Consultees Feedback

The **Malta Resources Authority** stated that there were no comments since the amendments covered by this variation do not fall within their remit.

Since the initial variation proposal included the installation of 3 standby generators, the **Regulatory for Energy & Water Services** had initially informed the applicant of the procedure to be followed, however this is no longer relevant since the installation of these generators are no longer part of this proposal.

The **Water Services Corporation** stated that there is no objection, provided that the IPPC permit covers annual renewal of the public sewer discharge permit, that all discharges to sewer are permitted, and that any changes to discharge sources are reported to them. Such requirements have been included in the proposed permit.

The **Civil Protection Department** had no further comments after it was clarified by the applicant that there were no proposed changes to the current fire safety measures.

The **Environmental Health Directorate** and the **Planning Authority** had no objections with the renewal and proposed variations.

The **Environment & Water Authority** encouraged the applicant to consider the installation of a solar photovoltaic system on the available warehouse roof space.

No feedback was provided by **The Malta Competition & Consumer Affairs Authority**, and the **Occupational Health & Safety Authority**.

2.7. Representations from Public

2.7.1. Public Consultation Dates: 9th September to 23rd September 2023
2.7.2. Responses Received: None

2.8. Discussion

Sterling Chemical Malta Ltd is a pharmaceutical company that produces Active Pharmaceutical Ingredients (APIs). APIs with antineoplastic/ cytotoxic, anti-inflammatory, contraceptive properties, amongst others are also produced on site. S.L.549.77 requires that installations carrying out activities as listed in section 4.5 of Schedule 1 to apply and obtain an IPPC permit prior to operations. In the case of this facility, operations consist of the "production of basic pharmaceutical products including intermediates".

The site has been covered by an IPPC permit since 2015 with various renewals and variations being approved throughout the years.

The application is in line with the Best Available Techniques specified in the BREF for Manufacture of Organic Fine Chemicals and those specified in the BREF for the common waste water and waste gas treatment/management systems in the chemical sector.

The BREF for Common Waste Gas Management and Treatment Systems in the Chemical Sector is still under review by both the Authority and the applicant. In line with Regulation 15(4), the implementation date for these BAT conclusions is of four years from its publication i.e. by end of 2026. To the extent possible, the proposed permit for IP 0001/23 has been drafted to incorporate the requirements of these BAT conclusions, however an improvement programme for its submission is being proposed. Should any further conditions based on this assessment be required to be incorporated, the Directorate will include these either as part of any variation applications (should this be submitted prior to the implementation deadline) or amend the permit to include such requirements.

The Regulatory consultation was carried out between 30th August and 30th September 2023 and no objections to the variation application were received.

A site visit was carried out on Tuesday 30th April 2024, where the site was found to be compliant with permit conditions. An additional emission point was noted to be associated with the fire pumps' room, for which the applicant was asked to update the application accordingly and thus a good working order certificate is being required by the permit as an Improvement program item and subsequently every five years.

The amendments to the permit being recommended include:

1. The amendment of the permitted emission points to air (to include the proposed additional emission points in this variation application);

2. The amendment to the emissions air monitoring programme to include monitoring from the new emission points, and monitoring of parameters to reflect the current APIs being produced at the facility;
3. Standardisation of certain conditions
4. Updating the Improvement Programme Items to include further assessment of the BAT conclusions specified in BREF for Common Waste Gas Management and Treatment Systems in the Chemical Sector
5. Updating of site layout plans to include new emission points.

2.9. Financial Matters

Application Fee	€7,500 (Renewal) + €1,500 (Variation) = €9,000 (Paid)
Financial Guarantee	€22,000 (previously €25,350)
Annual Fee	Annual fee amounting to 5% of the original application fee together with inspections fees at €200 per inspection have been paid. The annual fee is calculated at 5% rather than 10% in view that the installation is covered by a certified Environment Management System.

3. Recommendation:

The Regulatory Affairs Directorate recommends the GRANTING of this Renewal and Variation Permit for a period of ten (10) years; i.e. until 17th May 2034, subject to the following conditions as post decision requirements:

(a) Submission of bank guarantee of €22,000

The proposed permit conditions include:

(a) Standard conditions applicable to this sector:

- Prior to the production of any new Active Pharmaceutical Ingredient other than those approved by the Authority, the Permit Holder shall notify the Authority 3 months prior to the start of production and submit the following documentation[ii]:
    a. An updated Waste Gas Inventory as per BAT-Conclusion No. 2 of WGC (2022)[iii] to include the additional emissions envisaged;
    b. An updated Emissions to Air Monitoring Programme Method Statement, if necessary;
    c. Safety Data Sheets for the raw materials, intermediates and final product;
    d. An emission diagram detailing the production process and associated mitigation measures for the identified emissions; and
    e. A mass flow calculation in the case of the use of solvents carrying the hazard statements indicated in Conditions 2.2.19 and 2.2.23.

- Prior to restarting the production of Active Pharmaceutical Ingredients already approved by the Authority, the Permit Holder shall submit the following documentation:
    a. An updated Waste Gas Inventory to include the additional emissions envisaged;
    b. An updated Emissions to Air Monitoring Programme Method Statement, if necessary.

- Further to Conditions 1.6.1 and 1.6.2, emission monitoring is to be determined depending on the API production carried out at the Permitted Installation, and the respective emissions, as outlined in the waste gas inventory. When a change in API production leads to additional emissions not listed in Table 2.2.4, the Permit Holder is to apply for a Variation not later than 6 months prior to the start of production.
- Emission monitoring is to be carried out using the standards indicated in **Approved Document IP 0001/23/DOC2**. At least 3 readings shall be obtained during each measurement exercise. The Authority may request further additional tests should this be necessary.

[ii] Stipulated in 'Commission Implementing Decision (EU) 2022/2427 for common waste gas management & treatment systems in the chemical sector'.

(b) Site-specific condition:

- The Permit Holder shall carry out continuous monitoring of emissions to air for the emission points EM1 and EM13A-B only if the stacks to which abatement equipment is connected, emit a mass flow equal to or greater than 2 kg C/hr of total organic carbon. Should emissions be less than 2 kg C/hr of total organic carbon, the Permit Holder shall carry out periodic measurements as listed in Table 2.2.4.

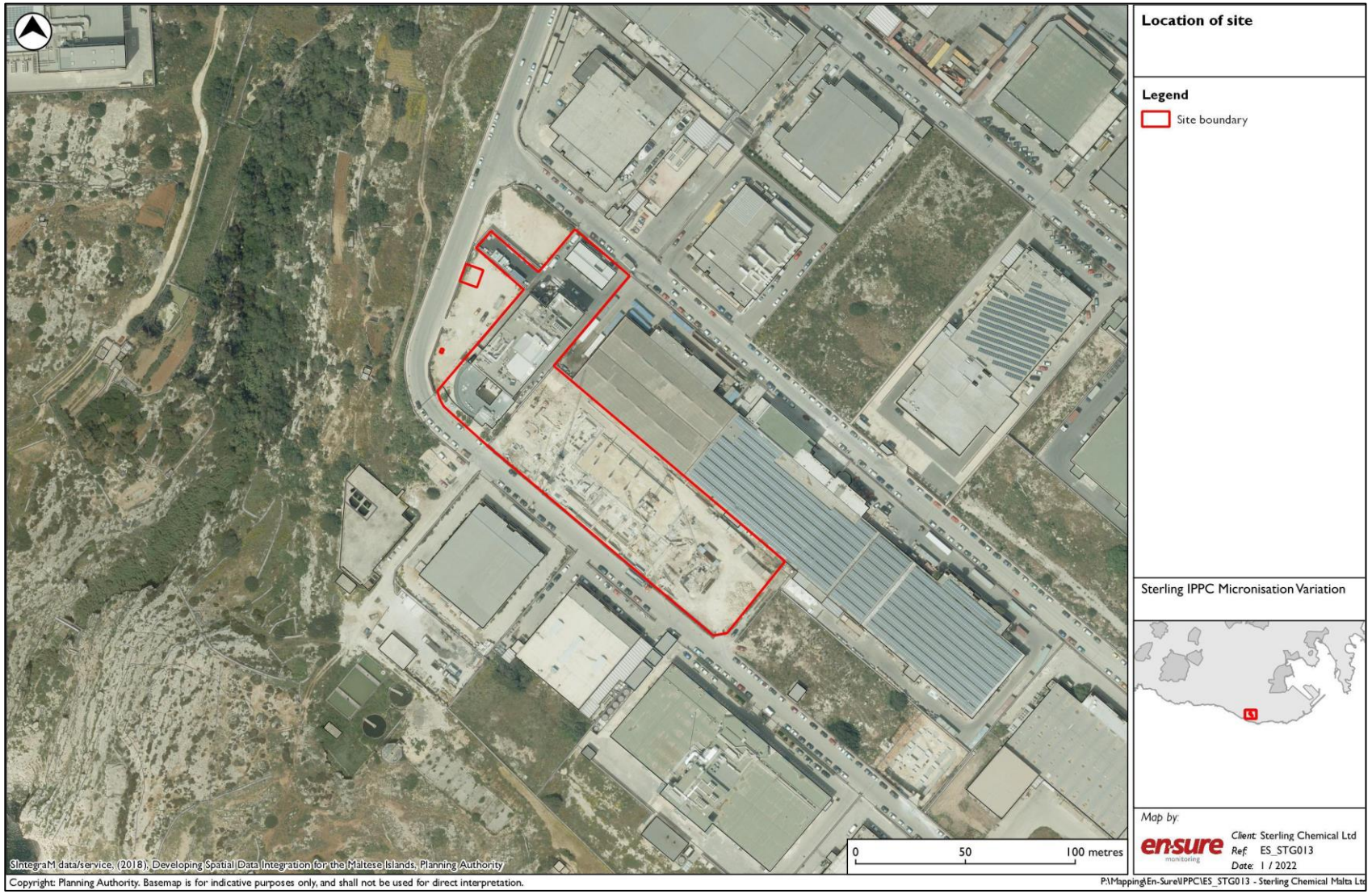
(c) Improvement programme items:

Reference	**Requirement**	**Deadline**
21	Submission of Best Available Techniques (BAT) comparison, under Directive 2010/75/EU of the European Parliament and the Council on industrial emissions, for common waste gas management & treatment systems in the chemical sector, in accordance with Condition 7.1.4.	Within four (4) months from the granting of the permit.
22	Good working order certificate for diesel fire pump (EM25) in accordance with Condition 2.2.16.	Within four (4) months from the granting of the permit.

This report to the ERA Board has been prepared, reviewed and endorsed by:

Case Officer:	**Reviewed & endorsed by:**
Signature:	Signature:
Date: 9th May 2024	Date: 9th May 2024

Annex I – Site Plan



Annex II – Emission Points