



Case Officer Report

Subject: IP 0004/21 - Application for the variation of IP 0001/19 to include the operation of a waste storage warehouse, the inclusion of additional emission points to air and updating the emissions monitoring programme.

Date: 18th August 2021

To: ERA Board

From: Environment and Resources Directorate

Case Officer: Isaac Meekers

1. Background

This report has been prepared for the determination of an application for variation (IP 0004/21) to the current IPPC permit (IP 0001/19) submitted by Mr. Andrea Caneponi obo Sterling Chemical Malta Ltd. The variation application is related to the additional operation of a waste storage warehouse, the inclusion of additional emission points to air and the updating of the emissions monitoring programme. In this regard, the application was received on 26th February 2021 and a consolidated application was submitted on 3rd June 2021 and amended on the 17th July 2021.

This application for a variation includes the following changes:

- The operation of a warehouse in the HF53 block, to be used for waste storage
- The inclusion of additional emission points to air from production areas and laboratory fume hoods, located in the HF51 block, as well as the ventilation system for the new waste warehouse in the HF53 block,
- Updating of the air emissions monitoring programme to remove ammonia, since this is not used or produced in any of the production activities on site.

2. Case Officer Report

2.1 Proposal

The operator is authorized to carry out the activities and the associated activities specified in the table below. The variation application does not entail any changes to the already permitted activities.

| Activity | Description of specified activity | Limits of specified activity |
|---|--|--|
| Production by chemical or biological processing of pharmaceutical products including intermediates. | <p>Synthesis of active pharmaceutical ingredients (APIs).</p> <p>Research & Development of active pharmaceutical ingredients (APIs).</p> | <p>From receipt of raw materials and associated chemicals to dispatch of finished product (including packaging and storage).</p> <p>Includes manufacture of high potency cytotoxic/cytostatic drugs.</p> <p>Does not include the preparation of any radioactive APIs</p> |
| Associated activity of utilities | <p>Two water purification plants.</p> <p>Operation of 16 reactors</p> <p>Operation of two LPG boilers to produce steam and hot water.</p> <p>Operation of a cooling tower</p> <p>Operation of air handling units</p> | <p>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.</p> <p>As described in the consolidated IPPC applications.</p> <p>From receipt of fuel to delivery of utility.</p> <p>From intake of water, to treatment and final discharge.</p> <p>From the intake of outside air to filtration prior to extraction from the facility</p> |
| Associated activity of waste management | Handling and storage of waste generated from installation prior to dispatch offsite. | <p>From generation of waste to dispatch for disposal or recovery (including recycling) offsite.</p> <p>Includes separation of solvent mixture from industrial process for recovery and re-use where possible, storage of rejected products.</p> |

Proposed Emissions and Mitigation

| Emission point reference | Source | Location of emission point |
|--------------------------|---|----------------------------|
| EM1 | Production area | Scrubber stack |
| | 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 | Microniser lab fume hoods | Carbon filter |
| EM4D | Microniser lab fume hoods | Carbon filter |
| EM4E | Microniser 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 fume hoods | Carbon filter |
| EM10A | Micronization 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 | Micronization laboratory | Fume Hood Extraction vent |
| EM12 | Cold Rooms | Vent |
| EM13 A | Production area | Scrubber |
| EM13 B | Production area | Scrubber backup fan |
| EM14 | General ventilation | HVAC |
| EM15 | Clean rooms | HVAC- HEPA filter |
| 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 | Waste Warehouse | None |

| Emission limits to air and monitoring | | | |
|---------------------------------------|-----------|------------------------|-----------|
| Emission point reference | Parameter | Limit | Frequency |
| EM1, EM13 | | 20 mgC/Nm ³ | Annually |

| | | | | |
|--|----------------------------|-----|---------------------|--|
| EM4A, EM4B, EM4C, EM4D, EM4E, EM8A, EM8B, EM8C, EM8D, EM10A, EM10B, EM10C, EM10D, EM11 | VOC (Total Organic Carbon) | | | Every four years subject to condition 2.2.1.21 |
| EM1, EM13, EM3A, EM3B, EM3C | Total Particulate Matter | <1 | mg/ Nm ³ | Annually |
| EM4A, EM4B, EM4C, EM4D, EM4E, EM8A, EM8B, EM8C, EM8D, EM10A, EM10B, EM10C, EM10D, EM11 | | | | Once subject to condition 2.2.1.21 |
| EM1, EM13 | HCl | 7.5 | mg/m ³ | Annually |
| EM1, EM13 | HBr | <1 | mg/m ³ | Annually |

From the above the following new emission points are being proposed:

- EM2
- EM3A, EM3B, EM3C
- EM4C, EM4D, EM4E
- EM8A, EM8B, EM8C, EM8D
- EM10B, EM10C, EM10D
- EM22

2.2 Supporting documents recommended for approval

- Documents: IP 0004/21
- Documents: IP 0004/21/DOC1
- Documents: IP 0004/21/DOC2

2.3 Applicable law/ policy

The proposal is to comply with:

- Environment Protection Act (CAP. 549);
- 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”.
- S.L. 549.77 also requires installations carrying out the abovementioned activities to take all necessary actions aimed at the removal, control, containment and reduction of relevant hazardous substances, so that the site ceases to pose any significant risk to human health and the environment due to the contamination of soil and water as a result of the permitted activities.
- Activity 7 (Manufacturing of Pharmaceutical products) in Schedule I of the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations, 2013 (S.L.549.79).
- BREF documents:

- Best available techniques (BAT) specified in the BREF for Manufacture of Organic Fine Chemicals (published August 2006);
- Best available techniques (BAT) specified in the BREF for the common waste water and waste gas treatment/management systems in the chemical sector (published May 2016);

2.4 Site Description and Constraints

Sterling Chemical Malta Ltd. is located within an industrial area in Hal Far, Birzebbuga.

2.5 Site History

The following permitting history is noted on site:

| Number | Title | Status |
|--------------|--|---|
| IP 0001/19 | Renewal and Variation | Granted on 29 th November 2019 for a period of 4 years |
| IP 0001/14/B | Variation | Granted on 5 th April 2019 for a period of 4 years |
| IP 0001/14/A | New Application | Granted on 13 th August 2015 for a period of 4 years |
| PA 4236/08 | 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. | Granted on 22 nd April 2010 and subject to a minor amendment to extend the canopy over the outdoor chemical/waste store which was also approved. |
| PA 3033/12 | Installation of LPG bulk storage in a facility/factory already covered by permit PA/04236/08. | Granted on 14 th 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 7 th March 2019 |
| PA 8089/19 | To sanction changes from approved permits PA04236/08, DN/01094/18, DN00624/16, including the increase in overall height; to change use approved in DN/01094/18 from general manufacturing (Class 5B) to | Granted on 12 th November 2020 |

| | | |
|-------------------|--|---|
| | <i>production of Active Pharmaceutical Ingredients (API); to replace parking layout approved in PA03638/18 with waste containment area and including changes to landscaping; changes to boundary wall and access gates and extension of external warehouses.</i> | |
| <i>DN 624/16</i> | <i>Extension to factory</i> | <i>Granted 14th September 2016</i> |
| <i>DN 23/17</i> | <i>Extension to external area and carpark</i> | <i>Granted 25th January 2017</i> |
| <i>DN 810/17</i> | <i>Construction of Factory</i> | <i>Granted 9th October 2017</i> |
| <i>DN 1094/18</i> | <i>Construction of factory</i> | <i>Granted 12th November 2018</i> |
| <i>DN 0259/20</i> | <i>Construction of external stores and security room, and alterations to boundary wall and site entrance.</i> | <i>Granted on 13th April 2020</i> |

2.6 Consultations

i. Intra-ERA Feedback

Extended Producer Responsibility

Since Sterling Chemicals are producers of packaging in terms of SL 549.43. The inclusion of the following condition is therefore suggested:

“Permit Holder shall renew their registration with ERA as a producer of packaging and provide the required information as set out in Subsidiary Legislation 549.43, the Packaging and Packaging Waste Regulations unless putting less than 100kgs of packaging on the market annually. In case the Permit Holder opts to be self-compliant for back-end packaging, the targets as set out in Subsidiary Legislation 549.43, the Packaging and Packaging Waste Regulations, shall also be achieved. Documentation in relation to the Permit Holder’s obligations pertaining to S.L 549.43, the Packaging and Packaging Waste Regulations shall be maintained for a period of 5 years and be made available, upon request by ERA.”

The **Compliance & Enforcement Directorate** inspected the site in April 2021 and found the installation to be compliant with the permit conditions. Furthermore, no complaints have been received since the issuance of the permit. From the AERs submitted in 2015 to 2020 CED are in discussion with applicant in relation to one minor ELV exceedance for Halogenated VOCs from EM1 which was reported in 2020. Sterling Chemical Malta Ltd. declared to have replaced the old carbon filter in order to have better control of emissions, and stated that new sampling will be carried out and results will be sent as soon as representative conditions of production are in place.

Sterling Chemical Malta Ltd. also submitted Solvent VOC emissions (Schedule 4) in 2019 and 2020. The latest boiler certification was submitted in 2019 and HEPA filter differential data was submitted in 2020. With respect to HEPA Filter efficiency certification, CED noted that all certifications were submitted.

With respect to IP items, CED reported that all IP items in IP 0001/19 have been closed. IP However, Improvement Programme item 14 related to the submission of the inventory on waste gases as required by the BAT conclusion was not submitted within the required timeframe. For completeness sake, this item is being reproduced below:

A Compliance Order (OK0023/20) was issued due to the time-sensitive nature of this requirement. Following submissions, the inventory and monitoring was considered to be acceptable, the accrued fine settled and the Order closed.

The **Air Quality & Waste Unit; Noise Team** noted no specific issues in relation to the permit variation.

ii. **Feedback from External consultees**

The Environmental Health Directorate (EHD) did not have any objection to the variation and provided generic comments with respect to mitigation measures, air monitoring, pest control, legionella regulations, nuisances and complaints, which are reflected in the proposed permit. Sterling Chemical Malta Ltd. confirmed that there are no new water emission points and that the legionella plan remains unchanged and still valid.

The Regulator for Energy and Water Services had no comments in relation to the variation application, while the **Water Services Corporation** stated that they had no objection to the application.

The Malta Competition and Consumer Affairs Authority, Malta Resources Authority, Planning Authority, Civil Protection Department, and Occupational Health and Safety Authority did not provide any feedback with respect to the variation application.

iii. **Feedback from the Applicant**

The applicant requested minor clarifications and amendments to the permit and these were addressed accordingly. Furthermore, the applicant informed the ERA on a change to the permit holder name from Mr. Andrea Caneponi to Mr. Roberto Tumbiolo. Queries related to emissions to air monitoring were clarified and the respective permit condition requiring the annual monitoring of emissions from the scrubbers was reworded for clarity.

2.7 Representations from public

- i. **Public consultation dates:** 19th June to 3rd July 2021
- ii. **Responses received:** None

2.8 Discussion

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 Regulatory consultation was carried out between 1st April and 22nd April 2021 and no objections to the variation application were received. Following consultation with applicant, all required 6 HEPA filters certificates were submitted, thereby enabling the satisfaction of the pre-operational condition concerning the research and development in HF53.

A public consultation was carried out between 19th June and 3rd July 2021 and no representations from the public were received.

A site visit was conducted on the 25th June 2021. During the site visit, ERA officers noted that pilot-scale operations including R & D were underway within the HF53 facility. The proposed waste storage warehouse was observed. No waste was present within the warehouse and the area was contained with gutters and underlying pipework such that in case of any spills, the liquid shall be passed to the water washing reservoir. Spill kits and sprinklers were also installed within the proposed waste storage warehouse. The wash water reservoir was also observed as well as the functioning of the wash water reservoir of the alarm system. Furthermore, Sterling Chemical Ltd. explained how manual measurements of the reservoir would be taken on a daily basis to confirm the proper functioning of the automatic alarm system.

ERA officers also noted the locations of the proposed additional emission points. It was noted that EM22 (ventilation from the waste storage warehouse) is yet to be constructed, while EM8A-D were slightly misplaced in the site layout plans provided and therefore an amendment to the site layout plans was requested to match their exact locations and references for EM4C-EM4E. Following discussions with operator, it was determined that compliance with S.L. 549.79 shall be determined using the waste gases and fugitive emission limit values. Furthermore, the operator indicated that only one of EM13A or EM13B scrubber and extractor fans is operational at any point in time, any therefore monitoring can take place from that specific active point.

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 a number of the new emission points,
3. removing the requirement of ammonia monitoring since ammonia is not used for any of the production processes.
4. the standardization of certain conditions,
5. updating of the Improvement programme items to include submission of monitoring from the new emission points.
6. the inclusion of waste storage locations in the approved site layout plans.

2.9 Financial Matters

| | |
|----------------------------|---|
| Application Fee | €1,500 – paid |
| Financial guarantee | €25,350 Previously €53,600 |
| Annual Fee | Prior to issue of the permit, the applicant shall pay ERA the sum of €3,200 to cover the annual contribution for year 2021 and 2022: (€1,500 per year) and the inspection fee covering 1 inspection carried out to date since 2020 (rate of €200 per inspection). |

3. Environment Officer Recommendation:

- The Environment and Resources Directorate recommends the GRANTING of this Variation for a period up until the expiry of IP0001/19 i.e. until 29th November 2023, subject to the following conditions as post decision requirements:
 1. Submission of a bank guarantee of €25,350
 2. Annual fee of €3,200 covering year 2021, 2022 (€1,500 per year) and one inspection carried out to date (rated at €200 per inspection)

The proposed permit conditions include:

- Standard conditions applicable to this sector;
- Site-specific conditions;
 - Within the first year of commissioning of the laboratories generating the emissions listed above, the Permit Holder shall monitor the listed parameters as per defined frequency provided that the limits detected are within the applicable emission limit values. Otherwise, monitoring shall be carried out annually until compliance with the emission limit values is achieved for 2 years in a row. Measurements for VOC shall be carried out according to Regulations 7 and 8 of the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (549.79).
 - Only non-flammable waste shall be stored in the waste storage warehouse in the HF53 block. These shall consist of the waste streams described in the following table, in accordance to the European Waste Catalogue codes as published in Council Directive 2000/532/EC and as may be amended from time to time shall be stored on site.

| Waste Location Code | EWC Code | Description |
|---------------------|-----------|---|
| 10 | 06 01 06* | Other acids |
| | 07 07 01* | Aqueous washing liquids and mother liquors |
| | 07 07 03* | Organic halogenated solvents, washing liquids, and mother liquors – dichloromethane |
| | 16 10 01* | Aqueous liquid wastes containing hazardous substances |

- 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 other than those notified to the Authority
- Monitoring from EM13A or EM13B depending on which one is active at the time of monitoring
- Improvement programme items:

| Reference | Requirement | Deadline |
|-----------|--|------------------|
| 20 | Emissions to air monitoring in accordance with condition 2.2.1.21 for emission points: EM4A, EM4B, EM10A, EM11 | By December 2021 |

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| This report to the ERA Board has been prepared, reviewed and endorsed by: | |
| Case Officer: Isaac Meekers | Reviewed by: Simon Farrugia |
| Asst. Env. Protection Officer | Senior Env. Protection Officer |
| Signature: | Signature: |
| Date: 12 th August 2021 | Date: 12 th August 2021 |
| Endorsed by: Nathalie Ellul | |
| Team Manager (Permitting) | |
| Signature: | |
| Date: 12 th August 2021 | |