



Case Officer Report

Subject: IP 0005/21 - Application for the renewal and variation of IP 0003/06/F in relation to the relocation of the nitrogen generation plant, the relocation of an emergency diesel generator and associated stack, and the cessation of part of the activities in the A50 warehouse submitted by Mr. Antonio Sommei obo Amino Chemicals Ltd.

Date: 26th April 2022

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 and renewal (IP 0005/21) to the current IPPC permit (IP 0003/06/F) submitted by Mr. Antonio Sommei obo Amino Chemicals Ltd. In this regard, the application was received on the 15th March 2021 and a consolidated application was submitted on 9th March 2022.

This application for a variation includes the following changes:

- Updating of the site layout plans including locations of emissions to air due to the:
 - Relocation of an emergency diesel generator and associated stack previously installed in a warehouse and now moved to the electric room as indicated in the layout plans (in the MRA050X (building B)).
 - Updating of the site plan due to the cessation of part of the activities carried out by Amino Chemicals Ltd. in the MRA050X (building B) warehouse, in view that a sister company shall occupy most of this area for other activities will be subject to a separate application.
 - Relocation of the nitrogen generation plant from within the warehouse of the MRA050X (building B) to an alternative area close to the warehouse.

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.	Synthesis of active pharmaceutical ingredients (APIs).	From receipt of raw materials and associated chemicals to dispatch of finished product (including packaging and storage). Does not include the preparation of any radioactive APIs or use of cytotoxic/cytostatic materials.
Associated activity of utilities	Reverse osmosis plant and deionization plant. Two diesel boilers with a rated thermal input of 1.4 MW and 1.55 MW respectively to produce steam and hot water. Two emergency electricity generators for provision of electricity in case of power failure Operation of Nitrogen Generation Plant Operation of air handling unit associated with fans for air returns from the Main Production Plant and Small Production Plant Operation of three cooling towers	From receipt of water to delivery of utility. Disposal of trade effluent in sewer network From receipt of fuel to delivery of utility. From receipt of fuel to delivery of utility. From filtering of fresh air to delivery of nitrogen into production and finishing departments. From the intake of outside air to filtration prior to extraction from the facility From the intake of water, to treatment and final discharge

Associated activity of storage, treatment and disposal/recycling of waste materials	Handling, storage, treatment and disposal/recovery of waste generated from installation	From generation of waste to disposal or recycling onsite or offsite. Includes solvent recovery for re-use where possible, and storage of rejected products. Process for recovery and re-use where possible, storage of rejected products.
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Proposed Emissions and Mitigation

Emission points to air		
Emission point reference	Source	Location of emission point
PS 1A	Scrubber AB 201	Scrubber stack
PS 1B	Scrubber AB 202	Scrubber stack
PS 1C	Scrubber AB 203	Scrubber stack
PS 2A	1.4 MWth Boiler 1	Boiler stack
PS 2B	1.55 MWth Boiler 2	Boiler stack
PS 3	HVAC	HVAC exhaust
PS 5A	Emergency generator - Production	Generator stack
PS 5B	Emergency generator - Office	Generator stack
PS 6	Air Return Production Plant	Extractor
PS 7	Air Return Small Production Plant	Extractor
PS 8A	Diesel Fire Pump	Engine Stack
PS 8B	Diesel Fire Pump	Engine Stack
PS 9A	Cooling Tower	Cooling Tower Stack
PS 9B	Cooling Tower CTW3	Cooling Tower Stack
PS 9C	Cooling Tower GF 4	Cooling Tower Stack
PS 10A	Glove Box Fume Hood	Glove Box stack
PS 10B	R&D Fume Hoods	Fume Hood stack
PS 10C	Lab Fume Hoods	Fume Hood stack

Emission limits to air and monitoring from Combustion plants		
Emission point reference	Parameter	Limit
PS1A, PS1B, PS1C	VOC as carbon	150 mgC/Nm ³
	NH ₃	10mg/m ³
	HCl	7.5 mg/Nm ³
PS2A, PS2B	Carbon Monoxide	-
PS2A, PS2B	Oxides of Nitrogen	200mg/m ³

The monitoring programme through this renewal and variation application remains unchanged from the current permit, as described in the Table above. From the above emission points, the relocated emission point is PS5B – Emergency generator (Office).

2.2 Supporting documents recommended for approval

- Documents: IP 0005/21
- Documents: IP 0005/21/DOC1
- Documents: IP 0005/21/DOC2
- Documents: IP 0005/21/DOC3

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.549.79 - Activity 7 (Manufacturing of Pharmaceutical products) in Schedule I of the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations, 2013.
- 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

Amino Chemicals Ltd. is located within an industrial area in the Marsa Industrial Estate.

2.5 Site History

The following permitting history is noted on site:

Number	Title	Status
<i>IP 0003/06/A</i>	<i>New Application</i>	<i>Granted on 30th November 2009</i>
<i>IP 0003/06/B</i>	<i>Variation application</i>	<i>Granted on 25th June 2010</i>
<i>IP 0003/06/C</i>	<i>Variation application</i>	<i>Granted on 27th February 2013</i>
<i>IP 0003/06/D</i>	<i>Variation application</i>	<i>Granted on 30th September 2014</i>
<i>IP 0003/06/E</i>	<i>Variation application</i>	<i>Granted on 8th June 2015</i>

Permit Extension IP 0003/06/E	Permit extended from 27 th February to 27 th June 2017	Granted on 27 th January 2017
	Permit extended from 27 th June to 27 th December 2017	Granted on 30 th June 2017
	Permit extended from 27 th December 2017 to 27 th April 2018	Granted on 5 th December 2017
IP 0003/06/F	Renewal application	Granted on 10 th July 2018
PA 05423/06	To demolish existing office block, construct proposed office block, effect additions to existing factory A 50 to convert it to storage to existing Amino Factory A 61.	Granted on 12 th December 2010
PA 1051/07	Proposed rectification unit as to IP 0003/06.	Granted on 15 th November 2007
PA 1876/08	Amendments to PA 1051/07 [rectification plant] addition of storage tank	Withdrawn
PA 04551/09	Proposed addition sand alterations (internal & external) to existing office block.	Granted on 14 th December 2010
PA 04782/09	Proposed additions and alterations to approved PA 5423/06. To include underground storage tanks to be relocated above ground and link between Marsa A50 factory and Marsa A61 factory.	Granted on 7 th December 2010
PA 1119/12	Additions and alterations to PA 5423/06 and PA 4551/09: to demolish existing office building and re-construct offices on two levels and basement parking spaces and ancillary facilities.	Granted on 2 nd November 2012
DN 00693/14	To place air handling unit on roof - This application was submitted to address development considerations required for this variation.	Granted on 23 rd May 2014
DN 1818/15	To install PV Panels at roof level.	Granted on 22 nd October 2017
DN 267/17	Proposed additions and alterations to an existing MIP Estate Unit (Services in rear area).	Granted on 31 st May 2017
DN 1042/20	Proposed Internal and external additions and alterations within an existing MIP Industrial Unit to create a plant for the	Granted on 16 th October 2020

	<i>manufacturing of medical cannabis products</i>	
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2.6 Consultations

i. Intra-ERA Feedback

Since Amino Chemicals Ltd. are producers of packaging in terms of SL 549.43, the standard condition related to renewal of their registration with ERA as a producer of packaging waste was requested and included in the proposed permit.

There were no comments from an environmental assessment and waste management perspective.

In view that the proposed changes do not impact discharges to sea there were no comments from a biodiversity and water point of view. In terms of air quality, the proposed variations are minimal, with no changes to air emissions.

Regarding noise, any upcoming noise monitoring should take into account any potential noise impacts in view of the relocation of the generator and nitrogen plant. Following this request, Amino Chemicals Ltd. submitted a noise assessment report, which satisfied all of the requirements.

The **Compliance & Enforcement Directorate** had no comments on the variation application and reported that all AERs including the respective certifications were submitted regularly and in a timely manner. With respect to the improvement programme (IP) items, CED reported that all IP items were addressed apart from IP 27 – Submission of an updated fire safety report and implementation of requirements identified in the CPD inspection report dated 1st April 2018. CED had reservations as to whether the permit should be issued prior to completion of this improvement programme item.

With respect to the reporting of fugitive emissions, for all reporting years, the fugitive emissions were noted to be below the threshold of 15% of the solvent input. However, some exceedances were reported for the point source emissions to air emerging from the scrubber. The following exceedances were reported:

- Year 2019 & 2020 - PS1B: Halogenated VOCs where the mass flow of sum of compounds > 100g/h
- Year 2020 - PS1A: VOCs where mass flow of sum of compounds > 10g/h

Following these exceedances Amino Chemicals' corrective action involved the replacement and cleaning of the scrubber solution.

ii. Feedback from External consultees

The **Environmental Health Directorate (EHD)** had no objection to the variation and confirmed that the variation application does not involve any changes to the amount of registered cooling towers.

The Occupational Health and Safety Authority also did not have any objection to the variation application.

The Regulator for Energy and Water Services requested an assessment to be carried out in relation to the relocation of the electrical generator to certify that this generator has been installed to a safe place away from any hazards and that it is operating in line with the latest fuel codes of practice. Amino Chemicals Ltd. have followed up on this request and have submitted the assessment report issued by REWS to ERA.

The Water Services Corporation, The Energy and Water Agency, The Malta Competition and Consumer Affairs Authority, Malta Resources Authority and the Planning Authority, and, did not provide any feedback with respect to the variation application.

The Civil Protection Department provided a fire safety inspection report as part of their feedback. It was noted that the industrial area is not protected by a fire hydrant ring main, and therefore Amino Chemicals have their own private fire hydrant ring main. The issue with this fire hydrant ring main is that the couplings are of an Italian standard and do not match those used by the CPD. Hence, in case of emergency the CPD would not be able to hook to the installation's system. CPD noted that some changes such as the inlet breeching have been made and also reported that Amino has a positive approach towards fire safety with proper personnel training in place. Furthermore the solvent handling areas are protected by fixed firefighting systems. The prevailing issue remains the incompatibility of the fire hydrant ring main coupling, however during the inspection, Amino Chemicals assured the CPD that the design shall be changed to suit the recommendations and technical drawing was communicated to ERA on the 11th April 2022.

2.7 Representations from public

- i. **Public consultation dates:** 16th March to 30th March 2022
- ii. **Responses received:** None

2.8 Discussion

Amino Chemicals Ltd. has been permitted through an IPPC permit since 2010. The current permit was granted on 10th July 2018. A request for variation of the current permit was submitted on 15th March 2021 and a consolidated application was submitted on 9th March 2022. In view that the current permit expires on 10th July 2022, the applicant was also requested to submit a request for renewal of the permit. The application was received on 27th January 2022.

The variation entails the relocation of the emergency generator and the nitrogen production plant from their current location in the warehouse (MRA050X) to other areas within the same facility, in view the main warehouse area will be used by a sister company of Amino Chemicals Ltd. for other activities which will be permitted separately. This warehouse was currently being utilised by Amino Chemicals for storage of used packaging materials and waste product.

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 22nd April and the 6th May 2021 and no objections to the variation application were received. A public consultation was held between the 16th March and 30th March 2022 and no representations from the public were received.

A site visit was conducted on the 19th November 2021. During the site visit, ERA officers observed the relocated generator and associated stack and noted that its new location as well as the locations of all other emission points were in line with the site layout plans submitted as part of the application. Furthermore, all fuel storage tanks were appropriately contained within bunds and no evidence of any spills were observed. Updated plans marking the locations of waste storage areas and fuel tanks were requested and following the site visit these were submitted by the applicant.

With respect to the updated site boundary, ERA officers were informed that third party employees would have access to the area located just outside the third party building (adjacent to the nitrogen generation plant, within the Amino Chemicals Ltd. site boundary). Furthermore, delivery of goods belonging to the third party would have to pass through part of Amino Chemicals Ltd. In this regard a condition has been included which requires the operator to supervise such areas when these are being used by third parties.

Regarding the lack of submission of the updated fire report, Amino Chemicals Ltd. have committed towards providing the report and making the recommended changes by the CPD by the 31st May 2022. Furthermore, during a fire safety inspection carried out by the CPD, it was noted that Amino Chemicals had a positive approach towards fire safety and training. In view of this, the EPU is proposing to include these requirements as an improvement programme item, as listed below.

The amendments to the permit being recommended include:

1. The exclusion of the part of the MRA050X (building B) warehouse from the site plan since activities within the warehouse are no longer carried out by Amino Chemicals Ltd.
2. The revision of the site layout plans to reflect the relocation of the nitrogen generation plant, the relocation of the emergency diesel generator.
3. The standardization of certain conditions,
4. Updating of the Improvement programme items.
5. The inclusion of waste storage locations in the approved site layout plans.
6. Removal of specific requirement to monitor for total particulate matter from the boilers since this is not required by S.L. 549.122, albeit the Authority reserves the right to request for any additional monitoring not being specified in this permit.

The operator had no feedback to the proposed permit conditions and agreed with the proposed bank guarantee. Additionally the operator informed the Authority that cooling tower (GF5) is non-operational and is set to be decommissioned along with its associated stack and chiller. A replacement chiller is to be installed however, this chiller's mode of operation does not require a cooling tower and hence emission point PS9D shall no longer exist.

2.9 Financial Matters

Application Fee	€9,250 (includes renewal of two MCP registrations) PAID
Financial guarantee	€20,850 (currently the financial guarantee amounts to €33,750)
Annual Fee	Annual fees covering the period 2019-2022 including inspection fees amounting to €6,200 PAID. Future remittances amounting to €1,500 per year and an additional €200 for each inspection carried out.

3. Environment Officer Recommendation:

- The Environment and Resources Directorate recommends the GRANTING of this Renewal and variation for a period of ten (10) years, subject to the following conditions as post decision requirements:

1. Submission of a bank guarantee of € 20,850

The proposed permit conditions include:

- Standard conditions applicable to this sector;
- Site-specific conditions requested by the Environmental Health Directorate concerning the cooling towers
- Instances where third parties are provided access to common areas shall be supervised at all times by the operator or his representatives.
- Improvement programme items:

Reference	Requirement	Deadline
27. ∞	Implementation of the requirements identified in the CPD inspection report dated 21 st May 2021 as certified by a fire expert.∞	31 st June 2022

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: 26th April 2022	Date: 26th April 2022
Endorsed by: Nathalie Ellul	
Team Manager (Permitting)	
Signature:	
Date: 26 th April 2022	