

Environment and Resources Authority Report



1. Application details:

1.1	Applicable Policy	Environment Protection Act (CAP. 549) S.L. 549.76 Industrial Emissions (Framework) Regulations, S.L 549.76 S.L. 549.77 Industrial Emissions (Integrated Pollution Prevention and Control) Regulations
1.2	Press dates	21 st April 2018
1.3	Application type	Renewal of IPPC Permit
1.4	Applicant	Mr. Antonio Sommei o.b.o Amino Chemicals Ltd.
1.5	Date of receipt of application	12 th January 2017
1.6	Approved documents	Application document is available on the website of the Environment & Resources Authority on the following link: https://era.org.mt/en/Pages/Amino-Chemicals-Ltd.aspx
1.7	Proposal	To operate an installation for the operation of an installation carrying out the following activity: <i>Activity 4.5 in Schedule 1 of the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L. 549.77) (“the Industrial Emissions (IPPC) Regulations”), to the extent authorised by the Permit, i.e.</i> “Production on an industrial scale by chemical or biological processing of pharmaceutical products including intermediates”.
1.8	Location	Amino Chemicals Ltd. MRA050X Marsa Industrial Estate, Marsa, MRS 3000

2. Background

2.1	Policy Context	Environment Protection Act (CAP. 549) <i>S.L. 549.77 requires installations carrying out activities as listed in section 4.5 of Schedule 1 to apply and obtain an IPPC permit prior to operations.</i> <i>In the case of this facility, operations consist of the “production of basic</i>
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		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.		
2.2	Justification for Application	<i>Application for the renewal of the IPPC permit IP 0003/06.</i>		
2.3	Permit History	Detail	Date	Comment
		<i>Application IP 0003/06</i>	<i>Received 21 November 2003</i>	<i>Not ‘Duly Made’</i>
		<i>Response to request for information</i>	<i>Request dated 02 December 2005</i>	<i>Response dated 20 December 2005 and February 2006</i>
		<i>Response to request for information</i>	<i>Request dated 25 August 2006</i> <i>‘Duly Made’ 25 August 2006 for existing installation only.</i>	<i>Response received 05 January 2007 and 15 January 2007.</i> <i>Information on extension received</i>
		<i>Response to request for information</i>	<i>Request dated 03 August 2007</i> <i>03 August 2007 MRA 050 (extension) not ‘Duly Made’</i>	<i>Response received 05 November 2007.</i> <i>Further information regarding extension was received</i>
		<i>Response to request for information</i>	<i>Request dated 03 September 2008 ‘Duly Made’ for both MRA 061 and MRA 050.</i> <i>Request for consolidated version for commencement of public notice.</i>	<i>Response received 29 May 2009 and 25 June 2009</i>
		<i>Public consultation</i>	<i>Commenced on 10 August 2009</i>	<i>Concluded on 10 September 2009</i>
		<i>Permit A determined</i>	<i>1st October 2009</i>	
		<i>Permit A issued</i>	<i>30 November 2009</i>	
		<i>Request for variation</i>	<i>Received 12 April 2010</i>	<i>Changes related to the submission date of the Environmental Management System.</i>
		<i>Permit B determined</i>	<i>24 June 2010</i>	
<i>Request for variation</i>	<i>6 December 2011</i>	<i>Changes related to approved permit in view of approval of PA 04782/09.</i>		

		<i>Public Consultation</i>	<i>Commenced on 5 March 2012</i>	<i>Concluded on 5 April 2012</i>
		<i>Permit C determined</i>	<i>26 July 2012</i>	
		<i>Permit C issued</i>	<i>27 February 2013</i>	
		<i>Request for variation</i>	<i>9 December 2013</i>	<i>Changes related to minor variations to the A50 site</i>
		<i>Public Consultation</i>	<i>Commenced on Friday 4 July 2014.</i>	<i>Concluded on Friday 18 July 2014.</i>
		<i>Permit D Determined</i>	<i>28 August 2014</i>	
		<i>Permit D issued</i>	<i>30 September 2014</i>	
		<i>Request for variation</i>	<i>30 April 2014</i>	<i>Installation of 1 ventilation system consisting of 1 air handling unit, 2 extractor fans, air ducts, control instrumentation and connection to existing utilities (power, steam)</i>
		<i>Public Consultation</i>	<i>Commenced on Friday 26 September 2014</i>	<i>Concluded on Sunday 26 October 2014</i>
		<i>Permit E Determined</i>	<i>26 March 2015</i>	
		<i>Permit issued</i>	<i>8 June 2015</i>	<i>Permit Expired 27 February 2017</i>
		<i>Request for renewal</i>	<i>12 January 2017</i>	
		<i>Permit Extended</i>	<i>27 January 2017</i>	<i>From 27 February 2017 to 27 June 2017</i>
			<i>30 June 2017</i>	<i>From 27 June 2017 to 27 December 2017</i>
			<i>5 December 2017</i>	<i>From 27 December 2017 to 27 April 2018</i>
		<i>Application duly made</i>	<i>21 February 2018</i>	
		<i>Public Consultation</i>	<i>Between 22 February till 8 March 2018</i>	
2.4	Compliance History	<p>In terms of compliance checks</p> <p>In terms of compliance assessment since the last issue of the permit two inspections have been carried out.</p> <p>During the 21 August 2015 the following non-compliances were noted:</p> <ol style="list-style-type: none"> 1. Non-compliance was noted with respect to the outside storage of IBCs pending disposal off-site. IBCs were found exposed to the elements in the outside courtyard in the ex-A50 site. Amino was requested to ensure that any liquids waste stored within the A50 warehouse are suitably banded. A proposal was submitted to ERA for the connection of the site 		

		<p>to the current site-drainage; however the proposal was later dismissed by the Applicant in view of future alternative plans for the warehouse. No waste storage was noted in this outside yard in subsequent inspections.</p> <p>2. No existing connection of the boiler room to the interceptor. However the necessary containment measures have since been implemented.</p> <p>During the 27 February 2017 inspection no non-compliances were observed during the time of inspection.</p> <p>In terms of annual reporting</p> <p>AERs have been submitted consistently throughout the years.</p> <p>In terms of incidents on site</p> <p>Since the issue of the last permit no incidents occurred on site.</p>
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2.5	Planning History	<p>PA Application</p>	<p>Details</p>	<p>Status</p>
		<p>PA 05423/06</p>	<p>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.</p>	<p>This application has been approved by the EPC/MEPA Board on 12 December 2010.</p>
		<p>PA 1051/07</p>	<p>Proposed rectification unit as to IP 0003/06.</p>	<p>This application has been approved by the EPC/MEPA Board on 15 November 2007</p>
		<p>PA 1876/08</p>	<p>Amendments to PA 1051/07 [rectification plant] addition of storage tank</p>	<p>Application has been withdrawn by the Planning Directorate</p>
		<p>PA 04551/09</p>	<p>Proposed addition sand alterations (internal & external) to existing office block.</p>	<p>This application has been approved by the EPC/MEPA Board on 14 December 2010.</p>
		<p>PA 04782/09</p>	<p>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.</p>	<p>This application has been approved by the EPC/MEPA Board on 7 December 2010.</p>
		<p>PA 1119/12</p>	<p>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</p>	<p>This application has been approved by the EPC/MEPA Board on 2 November 2012</p>

			<i>facilities.</i>	
		DN 00693/14	<i>To place air handling unit on roof - This application was submitted to address development considerations required for this variation.</i>	<i>This application has been approved by the EPC/MEPA Board on 23 May 2014</i>
		DN 1818/15	<i>To install PV Panels at roof level.</i>	<i>This application has been approved by the on 22 October 2017</i>
		DN 267/17	<i>Proposed additions and alterations to an existing MIP Estate Unit (Services in rear area).</i>	<i>This application has been approved on 31 May 2017</i>

3. Non Technical Summary of Activities

3.1	Proposed activities	Activity listed in Schedule 1 of the Industrial Emissions (IPPC) Regulations / Associated Activity	Description of specified activity	Limits of specified activity
		<i>Section 4.5: Production by chemical of biological processing of pharmaceutical products including intermediates.</i>	<i>Synthesis of active pharmaceutical ingredients (APIs).</i>	<i>From receipt of raw materials and associated chemicals to dispatch of finished product (including packaging and storage).</i> <i>Does not include the preparation of any radioactive APIs or use of cytotoxic/cytostatic materials.</i>
		<i>Associated activity of utilities</i>	<i>Reverse osmosis plant and deionisation plant.</i> <i>Two diesel boilers to produce steam and hot water.</i> <i>Two emergency electricity generators for provision of electricity in case of power failure.</i> <i>Operation of Nitrogen Generation Plant</i> <i>Operation of a air</i>	<i>From receipt of water to delivery of utility.</i> <i>From receipt of fuel to delivery of utility.</i> <i>From receipt of fuel to delivery of utility.</i> <i>From filtering of fresh air to delivery of nitrogen into production and finishing departments.</i> <i>From the intake of</i>

			<i>handling unit associated to fans for air returns from the Main Production Plant and Small Production Plant</i>	<i>outside air to filtration prior to extraction from the facility</i>
		<i>Associated activity of storage, treatment and disposal/recycling of waste materials</i>	<i>Handling, storage, treatment and disposal/recovery of wastes from installation.</i>	<i>From generation of waste to disposal or recycling onsite or offsite. Includes solvent mixture recovery and re-use where possible, storage of rejected products.</i>
		<i>Associated activity of maintenance</i>	<i>Maintenance and repairs which may be carried out in the repair shop in the installation</i>	<i>From maintenance/repair activity to appropriate recovery/disposal of any wastes created.</i>
3.2	Applicable BREFs	<p><i>Best available techniques (BAT) specified in the BREF for Manufacture of Organic Fine Chemicals (published August 2006).</i></p> <p><i>Best available techniques (BAT) specified in the BREF for emissions from storage (published July 2006);</i></p> <p><i>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)</i></p>		
3.3	Proposed emissions and mitigation	<i>There are no new emission sources as part of this renewal.</i>		

3. Assessment against Regulation 15(3) of S.L.549.77

4.1	Criteria for assessing the applicant's suitability	<p><i>In May 2016, the Best available techniques (BAT) specified in the BREF for the common waste water and waste gas treatment/ management systems in the chemical sector were adopted. In view of the fact that since the latest issue of IP003/06, the European Commission has published Commission Implementing Decision 2016/902 which describes the best available techniques (BAT) for setting permit conditions of installation covered by Chapter II of the IED (2010/75/EU) the operator was requested to carry out a comparison with the below mentioned BAT conclusions. IPPC installations are obliged to use BAT in their operations, article 14(3) of the IED has made the BAT conclusions mandatory. Moreover, existing installations are required to be compliant within four years from the publication of the Commission Implementing Decision.</i></p> <ol style="list-style-type: none"> <i>1. BAT 1 Environmental Management System</i> <i>2. BAT 2 Inventory of waste water and waste gas streams</i> <i>3. BAT 3 Monitoring of key process parameters</i> <i>4. BAT 4 Monitoring of emissions to water</i> <i>5. BAT 5 Monitoring of diffuse VOC emissions</i>
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5. Consultations

5.1	Internal	<i>Air & Waste; Air Quality Team</i>
		No feedback provided.
		<i>Air & Waste; Waste Management Team</i>
		<p><u>On application</u></p> <p>No comments.</p> <p><u>On permit</u></p> <p>Minor amendments to waste section and permit updated accordingly.</p>
		<i>Air & Waste; Noise Team</i>
		<p><u>On application</u></p> <p>From a Noise perspective, please find comments below:</p> <ol style="list-style-type: none"> 1. It should be highlighted to the applicant that any future noise studies need to be carried out according to the standard BS4142:2014 which replaced the standard BS4142 : 1997. 2. In the current 2015 Noise emissions report, noise levels need to be calculated using correct reference time intervals. According to the standard BS4142:1997, this should be: <ol style="list-style-type: none"> a. 1 hr during the day (07:00 - 23:00) b. 5 min during the night (23:00 – 07:00)

		<p><u>On permit</u></p> <p>Minor amendments to the noise section and permit updated accordingly.</p> <hr/> <p><i>Biodiversity & Water Unit</i></p> <p><u>On application</u></p> <p>No feedback provided.</p> <p><u>On permit</u></p> <p>We have no comments noting that there will be no discharges to surface waters.</p> <hr/> <p><i>Compliance & Enforcement Unit</i></p> <p>Minor amendments/recommendations, permit has been updated accordingly.</p> <hr/> <p><i>Environmental Assessment Unit</i></p> <p>No further comments on application.</p> <hr/> <p><i>Permitting Unit; Waste Permitting</i></p> <p>No feedback provided.</p> <hr/> <p><i>Permitting Unit; Nature Permitting</i></p> <p>No feedback provided.</p>
5.2	<p>External</p> <p>(in terms of regulation 19(2) of S.L. 549.77)</p>	<hr/> <p><i>Civil Protection Department</i></p> <p><u>On application</u></p> <p>No feedback provided.</p> <p><u>On permit</u></p> <p>CPD carried out an inspection in which it was determined that the installation as adequate fire safety. Due to distance from the fire hydrant system requested the installation of a rising main from the reservoir</p> <hr/> <p><i>Malta Competition and Consumer Affairs Authority</i></p> <p>No feedback provided.</p> <hr/> <p><i>Malta Resources Authority</i></p> <p><u>On application</u></p> <p>The MRA has no comment on this application in so far as the groundwater functions under its immediate remit.</p> <p><u>On permit</u></p>

		No feedback provided
Occupational Health and Safety Authority		
<p><u>On application</u></p> <p>From an OHS point of view the applicant</p> <p>The applicant shall abide by all relevant OHS legislation and in particular: Appoint a Project Supervisor for the Design Stage and a Project Supervisor for the Construction Stage and any such appointment shall be terminated, changed or renewed as necessary. The same person may be appointed to act as project supervisor for both the design and construction stage, if that person is competent to undertake the duties involved and</p> <p>Keep a health and safety file prepared by the Project Supervisor for the Design Stage.</p> <p>When the construction works related to this application are scheduled to last longer than thirty working days and on which more than twenty workers are occupied simultaneously, or on which the volume of work is scheduled to exceed five hundred person-days, the Project Supervisor for the Design Stage shall communicate a prior notice to the Occupational Health and Safety Authority (OHSA) at least four calendar weeks before work starts.</p> <p>The Project Supervisor for the Design Stage shall draw up a health and safety plan which sets out the occupational health and safety rules applicable to the construction activities concerned, outlining the measures to ensure cooperation between different contractors and shall also include specific measures concerning occupational risks that may be present at this site.</p> <p>2. If the development concerns a current or intended work place (as defined under Act XXVII of 2000), including a 'change of use', in addition to the above conditions, the applicant shall obtain an Architect's declaration that the necessary requirements arising out of LN 44 of 2002 have been included in the plans /drawings.</p> <p>In the case of sanctioning of works in a work place (as defined under Act XXVII of 2000), the applicant shall obtain an Architect's declaration that the building / development already carried out conforms to the requirements of LN 44 of 2002.</p> <p>All work equipment conforms to the requirements of the Work Equipment (Minimum Safety and Health Requirements) Regulations, L.N. 293/2016.</p> <p><u>On permit</u></p> <p>No feedback provided</p>		
Planning Authority		
No feedback provided.		
REWS		
<p><u>On application</u></p> <p>Request for the Operator to obtain a Secondary Fuel Storage authorization as</p>		

		<p>per S.L. 545.22 from REWS.</p> <p><u>On permit</u></p> <p>As part of the consultation of the permit REWS informed ERA that the Operator had applied for such an authorization. In view of this, REWS has no further comments.</p>
		<p>Environmental Health Directorate</p> <p><u>On application</u></p> <p>Comments/recommendations regarding this renewal. This is due the fact that there are no relevant changes</p> <p><u>On permit</u></p> <p>No feedback provided</p>
		<p>Water Services Corporation</p> <p><u>On application</u></p> <p>No further comments.</p> <p><u>On permit</u></p> <p>No feedback provided</p>
5.3	Operator	<p>Consultation on the draft permit conditions was carried out with the applicant prior to being presented to ERA Board. The applicant accepted the conditions, as being proposed. A consultation was also carried out in relation to the adoption of the BREF on the common waste water and waste gas treatment / management systems in the chemical sector.</p>

6. Public consultation

6.1	Public consultation	<i>22nd February 2018 to 8th March 2018</i>
6.2	Response	<i>One response was received from the public.</i>

7. Conditions

7.1	Conditions general	<p>Permitted Activities</p> <p><i>Conditions include which activities are permitted and any associated activities linked to operations.</i></p> <p>Overarching Management Condition</p> <p><i>Conditions in this section refer to Environment Management systems present on</i></p>
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		<p>site</p> <p>Operational Changes</p> <p>Conditions in this section refer to additional clearances required in case of :</p> <ul style="list-style-type: none">a. variations which could lead to significant impact on human health or the environment;b. any change in the nature or functioning or an extension of an installation where the change or extension in itself reaches the capacity thresholds set out in Schedule 1 of the Industrial Emissions (IPPC) Regulations;c. variations covered by the Environmental Impact Assessment Regulations;d. aspects of the operations specifically prohibited by this permit;e. changes to emission limit values;f. changes to fees;g. renewal of the validity of this permit <p>General Considerations</p> <p>Conditions include provisions regarding saving third party rights and duty of care of the environment</p> <p>General Site Operations, Infrastructure and Security</p> <p>Includes conditions regarding site identification board, site security and general cleanliness and upkeep of the site.</p> <p>Operational Conditions</p> <p>The Permitted Installation shall, subject to the conditions of this Permit, be managed, controlled and operated using the techniques and in the manner described in the original IPPC application and in the subsequent applications for renewal and variation, or as otherwise agreed in writing by the Authority</p> <p>Approval procedure for new production processes</p> <p>Prior to the production of any new Active Pharmaceutical Ingredients other than those approved by the Authority, the Operator is notify the Authority 6 months prior to the start of production and submit the necessary documentation.</p> <p>Improvement Programme</p> <p>Sets out the improvements to the plant and its operations with specific deadlines as described in Section 7.2 below. All IP items proposed in the previous permit have been fulfilled with the exception of the implementation of a baseline report and the associated submission of an outline site closure plan. New IP items have been added.</p> <p>Emissions to Air</p>
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Point sources have been identified and emission limit values set for various parameters:

Emission point reference	Source
PS1A	Scrubber AB 201
PS1B	Scrubber AB 202
PS 1C	Scrubber AB 203
PS 2A	Boiler 1
PS 2B	Boiler 2
PS 3	HVAC
PS 5A	Emergency generator - Production
PS 5B	Emergency generator - Office
PS 6	Air Return Production Plant
PS 7	Air Return Small Production Plant
PS 8A	Glove Box Fume Hood
PS 8B	R&D Fume Hoods
PS 8C	Lab Fume Hoods
PS 9A	Diesel Fire Pump
PS 9B	Diesel Fire Pump
PS 10A	Cooling Tower
PS10B	Cooling Tower CTW3
PS 10C	Cooling Tower GF 4
PS 10D	Cooling Tower GF 5

Conditions related to monitoring and where necessary abatement measures to abate emissions have been included. Conditions have been updated to reflect the requirements of Medium Combustion Plants Directive.

Cooling tower Registration

Conditions have been included so as to ensure control of the growth of micro-organisms including Legionella and with chemical or other agents to minimise scale formation, corrosion and fouling.

Discharges to sewers

Conditions have been included so as to ensure compliance with the sewer discharge permit issued by the WSC.

Discharges to groundwater

Conditions have been included to prohibit any discharges to groundwater

Fugitive emissions of substances to air

Conditions have been included in relation to the application of BAT so as to prevent or where that is not practicable to reduce fugitive emissions of substances to air from the Permitted Installation, with particular reference to specific areas.

Fugitive emissions of substances to water and sewer

Conditions have been included in relation to the application of BAT so as to prevent or where that is not practicable to reduce fugitive emissions of

	<p><i>substances to water (including to groundwater) and sewer from the Permitted Installation with particular reference to specific areas of the installation.</i></p> <p>Odour</p> <p><i>Conditions have been included in relation to the application of BAT so as to prevent or where that is not practicable to reduce odorous emissions from the Permitted Installation, in particular by:</i></p> <ul style="list-style-type: none"><i>a. limiting the use of odorous materials;</i><i>b. restricting odorous activities;</i><i>c. controlling the storage conditions of odorous materials;</i><i>d. controlling processing parameters to minimise the generation of odour;</i><i>e. optimising the performance of abatement systems;</i><i>f. timely monitoring, inspection and maintenance;</i><i>g. employing, where appropriate, an approved odour management plan</i> <p>Emissions to Land</p> <p><i>No emission from the Permitted Installation shall be made to land.</i></p> <p>Noise and Vibration</p> <p><i>Conditions have been included in relation to the application of BAT so as to prevent or where that is not practicable to reduce emissions of noise and vibration from the Permitted Installation</i></p> <p>Management of the facility</p> <p><i>Conditions have been included to address training of staff, maintenance of plant and equipment, incidents and complaints, and issues pertaining to the Technically competent person</i></p> <p>Solvents</p> <p><i>An inventory of solvent usage shall be maintained on site.</i></p> <p><i>Substances or preparations that are used in the installation and which, because of their content of VOCs are classified as carcinogens, mutagens or toxic to reproduction and are assigned or need to carry the hazard statements H340, H350, H350i, H360D or H360F, or the risk phrases R45, R46, R49, R60, or R61, shall be replaced as far as possible and as soon as possible. Details of the substances that shall be used as replacements and timeframes for substitution shall be submitted to the Competent Authority for approval prior to substitution</i></p> <p>Storage</p> <p><i>Conditions have been included to ensure the proper storage of raw materials, chemicals, fuels and wastes.</i></p> <p>Waste</p> <p><i>All wastes generated by the facility shall be disposed of through licensed contractors and shipped either abroad or treated/disposed in local facilities permitted by ERA to accept such waste.</i></p> <p>Energy Efficiency</p>
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	<p><i>As part of the Annual Environmental Report, the Operator has been requested to produce a report on the energy consumed at the Permitted Installation over the previous calendar year</i></p> <p>Accident prevention and control</p> <p><i>In the case of an accident, the Operator is being required to follow the Emergency Plan, as approved by the Civil Protection Department.</i></p> <p>Monitoring</p> <p><i>The Operator is required to maintain and implement an emissions monitoring programme which ensures that emissions are monitored as specified in this Permit, and the results of such monitoring shall be assessed. The programme shall ensure that monitoring is carried out under an appropriate range of operating conditions, and that measurements for the determination of concentrations of substances specified in this Permit shall be carried out representatively.</i></p> <p>Closure and Decommissioning</p> <p><i>In the event of cessation of business activity on the site, all wastes (including machinery, tanks, equipment) and hazardous materials (including chemicals) must be removed from the site such that any pollution risk is avoided and the site is returned to a satisfactory state. The Operator shall notify the Authority at least three months prior to taking actions, and shall submit a Site Closure plan to the Authority for approval. The Authority's approval is required prior to the commencement of the decommissioning works.</i></p> <p><i>When deemed necessary the Authority may require the permit holder to take such additional measures, as it considers necessary with respect to after care obligations in relation, but not limited to remedial action, rehabilitation and monitoring of the site.</i></p> <p><i>A finalised version of the Site Closure Plan shall be submitted to the Authority for approval not later than 10 days after the Authority is notified of the intention to decommission the site.</i></p> <p><i>The approved Site Closure Plan shall be implemented within 12 months of final cessation or decommissioning of the Permitted activities or part thereof or according to a timeframe as may be agreed with the Authority.</i></p> <p>Management of the facility</p> <p><i>Conditions have been included to address training of staff, maintenance of plant and equipment, incidents and complaints, and issues pertaining to the Technically Competent Person.</i></p> <p>Records, Reporting and Notification</p> <p><i>The operator is required to maintain records on several aspects of the permit and have these available for inspection by the Authority should the need arise.</i></p> <p><i>An Annual environment report has been included in the permit where the operator shall submit monitoring results and waste transfers for the previous calendar year.</i></p>
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		<p>A notification system has also been set up so as to ensure that any exceedances from ELVs, incidents on site or fugitive emissions are reported within a specific timeframe and through a set process.</p>		
7.2	Improvement programme	<p>The following items remain pending as part of the improvement programme within this variation.</p> <p>To note that Requirements 12 & 17 refer to the requirements present in IP 0003/06/D; requirements 23 to 29 are new.</p>		
		Reference	Requirement	Date
		12	Submission of a baseline report in line with "communication from Commission - European Commission Guidance concerning baseline reports under Article 22(2) of Directive 2010/75/EU on industrial emissions (2014/C 136/03)" pursuant to Regulations 9(3) and 16(2) of the Industrial Emissions (IPPC) Regulations.	Submission by 31 August 2018.
		17	Submission of an outline site closure plan.	By 31 May 2019
		23	Implementation of the fugitive emission minimisation within the centrifuge rooms ID 250	By 31 May 2018
		24	Submission of a P&ID diagram for the R&D and laboratory fumehoods	By 31 May 2018
		25	Submission of the monitoring proposal for a one-time air emission monitoring exercise from the fume hood exhaust vents.	By 30 June 2018
		26	Implementation of the approved proposal for the solid API charging into the reactors.	By 31 July 2018
		27	Submission of an updated fire safety report and implementation of requirements identified in the CPD inspection report dated 1 st April 2018.	By 31 October 2018
		28	Acquisition of authorisation for the operation of Secondary Storage Facilities of petroleum (under S.L. 545.22).	By 31 December 2018
		29	Notification of completion of the roofing on the boiler house and the adjacent fuel storage house [ex-A61 site].	By 31 December 2018

8. Financial matters

8.1	Financial guarantee	<i>Prior to issue of this permit, the applicant is to submit a financial guarantee of €33,750 to secure the obligations under this permit.</i>
8.2	Annual Fee	Prior to issue of the permit, the applicant shall pay ERA the sum of € 4,900 to cover the annual contributions for 2016 - 2018 (€1,500 per year) and inspections carried out in 2015-2017 (2 inspections at €200 each).
8.3	Other Fees	Future remittances will consist of the fixed annual amount of €1,500 and a variable addition reflecting ERA's cost for inspections. The latter variable component depends on the actual number of site inspections, which is determined by the performance of the operator. The total annual contribution has to be paid before the anniversary of the date of issue of this permit. Variations in ERA's inspection expenditure will be reflected in the following year's contribution.

9. Recommendation

IP 00003/06/F is being recommended for renewal for a period of 4 years, subject to the conditions indicated in section 7.

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

Case Officer: Gabriella Grima
Environment Protection Officer

Endorsed by: Anthony Aquilina
Unit Manager

Signature:

Signature:

Date:

Date:

ERA Board Decision: