

1. Application details:

1.1	Applicable Policy	Environment Protection Act (CAP. 549) S.L. 549.76 Industrial Emissions (Framework) Regulations S.L. 549.77 Industrial Emissions (Integrated Pollution Prevention and Control) Regulations
1.2	Press dates	<i>31 August 2019</i>
1.3	Application type	<i>Variation and Renewal of IPPC Permit</i>
1.4	Applicant	<i>Sterling Chemical (Malta) Ltd.</i>
1.5	Date of receipt of application	<i>25th March 2019</i>
1.6	Approved documents	<p>1. Application document is available on the website of the Environment & Resources Authority on the following link: https://era.org.mt/en/Pages/Sterling-Chemical-Plant-Ltd-IP-001_14.aspx</p> <p>2. <i>Permit document and post decision requirements letter 23 November 2018</i></p>
1.7	Proposal	<p>To vary the current permit allowing the operation an installation for the operation of an installation carrying out the following activity:</p> <p><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></p> <p>"Production on an industrial scale by chemical or biological processing of pharmaceutical products including intermediates".</p> <p>The proposed variation includes the following:</p> <p>The proposed variations comprise:</p> <ul style="list-style-type: none"> • 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 parking.
1.8	Location	<p><i>Sterling Chemical Malta Ltd.</i> <i>HF50 & HF51 & HF53</i> <i>Hal Far Industrial Estate</i> <i>Birzebbuga</i></p>

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2. Background

2.1	Policy Context	<p><i>Environment Protection Act (CAP. 549)</i></p> <p><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></p> <p><i>In the case of this facility, operations consist of the “production of basic pharmaceutical products including intermediates”.</i></p> <p><i>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.</i></p>		
2.2	Justification for Application	Application for the renewal and variation of IPPC permit IP 0001/14/B.		
2.3	Permit History	Detail	Date	Comment
		Application IP 0001/14	Received 28 May 2014	Not ‘Duly Made’
		Request for further information and Response	Request dated 17 February 2015	Response dated 18 March 2015
		Internal Consultation and Consultation with statutory consultees.	Commenced on 17 February 2015	Concluded on 19 March 2015
		Request for further information and Response	Request dated 15 April 2015	Response dated 28 May 2015
		Request for further information and Response	Application regarded as ‘Duly Made’ on 6 th June 2015 and 12 June 2015. Request for consolidated version for commencement of public consultation	Consolidated application submitted on 18 June 2015
		Public consultation	Commenced on 19 June 2015	Concluded on 19 July 2015
		Permit Determined	30 July 2015	
		Permit Issued	11 August 2015	
		Request for Variation IP0001/14/B	11 October 2017	
		Regulatory consultation	6 th April 2018 to 4 th May 2018	
		Application considered duly made	1 October 2018	

		<i>Public Consultation</i>	<i>5th October 2018 to 19th October 2018</i>	
		<i>Permit IP0001/14/B determined</i>	<i>23 November 2019</i>	
		<i>Permit IP0001/14/B issued</i>	<i>5 April 2019</i>	
		<i>Application for Variation and Renewal IP0001/19</i>	<i>25th March 2019</i>	
		<i>Regulatory consultation</i>	<i>12th April 2019 till 26th April 2019 and 19th June 2019 and 26th June 2019</i>	
		<i>Application duly made</i>	<i>28th June 2019</i>	
		<i>Public Consultation</i>	<i>6th July 2019 till 20th July 2019</i>	
2.5	Compliance History	<p><i>In terms of compliance checks</i></p> <ul style="list-style-type: none"> • Compliance inspection 5.4.18 • Compliance inspection 24.10.18 • Pre-determination site visit/ compliance inspection 29.7.19 <p>No significant environmental issues were noted, however an unpermitted waste storage area was noted in 2018. This was included in the previous variation application which was determined on 23.11.18.</p> <p>In terms of the operations as per application IP0001/19, the new facility is in the final stages of constructions. A familiarisation visit was performed on the site on the 29th July 2019. The following observations were made:</p> <ul style="list-style-type: none"> • Pilot reactors (Line 7); 4 reactors were noted to be in place, the associated ancillary equipment/ infrastructure was being assembled • Driers and centrifuges to be assembled • HVAC and HEPA filters; being assembled • Utilities area; scrubber and blowdown tank; in place • Vapour condensation area is still to be assembled • Compressed air area is still to be assembled • Water softening equipment is still to be assembled • Clean rooms are still to be finalized • Wash water reservoir (74m³); due to water ingress, the Operator notified ERA that the volume will need to be recalculated. Reservoir is still to be certified • The laboratory wash water reservoir, has been constructed yet certification is still pending. • Maintenance workshop is still be finalized • Laboratories and the rest of block A;; still in construction phase. Operator stated that that section will be commissioned in October 2019. <p>A second pre-operational inspection will need to be scheduled following commissioning to verify progress on the above.</p> <p><i>In terms of annual reporting</i></p> <p>AERs have been submitted consistently throughout the years. There were no particular issues in terms of reporting for both installations.</p> <p><i>In terms of incidents on site</i></p>		

		<p>Since the issue of the last permit no incidents occurred on site.</p> <p><i>In terms of complaints</i></p> <p>CED have received complaints in December 2018 mainly from BEAG alleging discharges of contaminated liquid from culverts along site onto road and eventually underlying valley. Complaints were backed with two articles on two different newspapers. These have been confirmed to be rain water culverts.</p>		
2.4	Planning History	<i>PA application</i>	<i>Details</i>	<i>Status</i>
		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
		DNO 624/16	Extension to factory	Granted 14 September 2016
		DNO 23/17	Extension to external area and carpark	Granted 25 January 2017
		DNO 617/17	Extension to offices	Granted July 2017
		DNO 810/17	Construction of Factory	Granted 9 October 2017
		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 March 2019
		DNO1094/18	Construction of factory	Granted 12 November 2018

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
		Section 4.5:	Synthesis of active pharmaceutical ingredients (APIs).	From receipt of raw materials and associated chemicals to dispatch of finished

		<i>Production by chemical of biological processing of pharmaceutical products including intermediates.</i>		<i>product (including packaging and storage).</i> <i>Includes manufacture of high potency cytotoxic/cytostatic drugs.</i> <i>Does not include the preparation of any radioactive APIs-</i>
		<i>Associated activity of utilities</i>	<i>Water purification plant.</i> <i>Operation of 16 reactors</i> <i>Operation of two LPG boilers</i> <i>Operation of a cooling tower</i> <i>Operation of a air handling units</i>	<i>From receipt of water to delivery of utility.</i> <i>As described in the consolidated IPPC application submitted on 2 October 2018</i> <i>From receipt of fuel to delivery of utility.</i> <i>From intake of water, to treatment and final discharge.</i> <i>From the intake of outside air to filtration prior to extraction from the facility</i>
		<i>Associated activity of waste management</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.</i> <i>Includes separation of solvent mixture from industrial process for recovery and re-use where possible, storage of rejected products.</i>
3.2	Applicable BREFs	<i>Best available techniques (BAT) specified in the BREF for Manufacture of Organic Fine Chemicals (published August 2006);</i> <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>		
3.3	Proposed emissions	Emissions to the Air The proposal includes the addition of eight new air emission points.		

and mitigation				
	Source	Main emission types	Abatement	Emission point
	Pilot plant reactors VOC, NOx, particulates	VOC, NOx, particulates	Two heat exchangers in series, carbon filter and scrubber	EM 13 (scrubber)
	Blowdown tank (emergency)	VOC, NOx, particulates	Scrubber	EM 13
	Local extraction in HF 53 production block, used when opening reactors / containers	VOC, NOx, particulates	Scrubber	EM 13
	HVAC system for line 7	Emission of air coming from HVAC system (air conditioning and general ventilation)	Not applicable – exhaust through air grilles with fabric filter	E M14
	HVAC system for clean room line 7	Particulates	HEPA filter	EM15
	HF 53 laboratory fume hoods	Solvents / chemicals / powders (small quantities)	Fume extractor hoods: carbon filter Balance enclosure for weighing powders: HEPA H13 filter	EM16 – EM20
	Emissions to the sewer			
	Only sanitary waste will be discharged to sewer from the Scheme, from the changing rooms and toilets in the HF 53 block. A new connection point to the main sewer line is proposed, therefore the facility will now have two connection points to the main sewer. The existing operations are already covered by a Sewer Discharge Permit (DMU 6745). Since the new connection will only discharge domestic effluent, the Water Services Corporation only requires a variation application for the Sewer Discharge Permit in 2020.			
Emissions to the surface and groundwater				
There are no emission sources as part of this variation.				
A Land and Groundwater Risk Assessment had been prepared for the facility in 2015, to cover the activities permitted at the time, with an Addendum prepared in 2018 to cover proposed new activities that have since been permitted. 2.16. An Addendum to that Assessment, covering the proposed variations addressed by the IPPC application, is included as part of the current IPPC application. This Risk Assessment concludes that the risks to land and groundwater from the proposal range from none (where there is no pollutant linkage) to low and very low.				
Emissions to land				

		<p>An emission to land from the overflow of the rainwater reservoir at the HF 53 site which includes brine reject from the water softener plant. The requirement for a proposal for alternative disposal options has been requested as part of the improvement programme.</p> <p>As stated above, the Risk Assessment concludes that the risks to land and groundwater from the proposal range from none (where there is no pollutant linkage) to low and very low.</p>
		<p>Noise and vibration</p> <p>Noise-generating activities from the proposal are likely to be similar to those already existing at Sterling Chemical, however, on a smaller scale since the proposal is a pilot/ R&D plant. Since the noise generated is from equipment similar to that already installed at the facility, and the site is located in an industrial area surrounded by existing industrial uses (and some distance away from sensitive receptors), impacts on noise sensitive receptors are not expected. Additionally, several of the equipment will be located indoors. Nevertheless, the IPPC permit already requires noise monitoring to be carried out periodically, and the next monitoring session is required once the microniser is commissioned. It is therefore suggested that noise monitoring for the pilot plant would be synchronised with that for the microniser, to enable an assessment of noise impacts from both plants.</p>
		<p>Waste Management</p> <p>The total waste quantities generated annually will increase only slightly as a result of the proposal, since this is a pilot plant/ R&D. Waste will largely continue to be stored on site as per the existing arrangements. All waste on site will continue to be transferred to licensed facilities using authorised waste carriers, and records will continue to be maintained and reported to ERA as per current practice.</p>

4. Assessment against Regulation 6 and 15 of S.L.549.77

4.1	Criteria for assessing the applicant's suitability	<p>Applicable BREF documents for the installation include;</p> <ul style="list-style-type: none"> • BREF for the manufacture of organic fine chemical • BREF for the common waste water and waste gas treatment/ management systems in the chemical sector <p>A BAT comparison exercise has been carried against both the above mentioned BREFs. Certain aspects and measures required by the BAT conclusions are included as improvement programme items.</p>
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5. Consultations

5.1	Internal	<p>Ambient Quality & Waste Unit; Air Quality Team</p> <p><u>On application</u></p> <p>No feedback was provided.</p> <p><u>On permit</u></p>
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		No feedback was provided.
		<i>Ambient Quality & Waste Unit; Waste Management Team</i>
		<p><u>On application</u></p> <p>With regards to this application, the waste team has no comments.</p> <p><u>On permit</u></p> <p>Two minor amendments were requested and permit amended accordingly;</p> <ol style="list-style-type: none"> 1. Page 22, Point 2.5.4 – re-ordered to be in line with the Waste Hierarchy. 2. Page 23, Point 2.5.11 – amended the title of S.L.549.43 to be the full title of the regulations.
		<i>Ambient Quality & Waste Unit; Noise Team</i>
		<p><u>On application</u></p> <p>As already suggested in the replies to the Environmental Assessment Unit on the EIA report consultation, when carrying out the noise monitoring study, reference to impact on the closest NSRs – residents at tal-papa in Birzebbugia (as indicated by the consultants themselves in the EIA report) is to be included.</p> <p><u>On permit</u></p> <p>No further comments from AQW's end on the revised permit.</p>
		<i>Biodiversity & Water Unit</i>
		<p><u>On application</u></p> <p>BWU has no comments from a surface water perspective.</p> <p><u>On permit</u></p> <p>No feedback was provided.</p>
		<i>Compliance & Enforcement Unit</i>
		<p><u>On application</u></p> <p>With regards, to the proposed monitoring committee, CED does not see the necessity of setting up of a monitoring committee for this site. The burden of imposing such committees on ourselves as an Authority without significant or persistent compliance or operational issues to require it is not sustainable.</p> <p>[It is to be noted that the request made by the local council, was made in the EIA consultation process and not as part of this IPPC application IP0001/19</p> <p><u>On permit</u></p> <p>Amendments were requested on certain conditions.</p>

		Environmental Assessment Unit
		<p><u>On application</u></p> <p>No comments.</p> <p><u>On EIA update</u></p> <p>EIA Public Hearing was carried on the 5th August 2019.</p>
		Permitting Unit; E-PRTR Permitting
		<p><u>On permit</u></p> <p>Minor amendments were requested on conditions relating to E-PRTR.</p>
5.2	External	
		Civil Protection Department
		<p><u>On application</u></p> <p>CPD made reference to a site visit held on Thursday 10 May. Overall the company has a very strong approach towards fire safety. The following requirement was made by CPD:</p> <p><i>“I also suggested that a fire plan is made outside the premises but behind the company security gate, and a list of MSDS’s of chemicals they handle in the reception or a memory stick in the fire plan in case the HAZMAT team needs it. I was also informed that a competent person is always on site for professional advice required by the CPD.”</i></p> <p>ERA is still awaiting confirmation from the Operator on the implementation of this measure.</p> <p><u>On permit</u></p> <p>The Civil Protection Department made a number of recommendations;</p> <p>1) CPD stated that they will be carrying out an inspection in Winter. 2) CPD requested that in the notifications section, a requirement is to be included such that if the fire hydrant system is down for maintenance and/or breakdown the department should be informed with and what measures are in place until the system is back on standby.</p> <p>The following condition is being proposed for inclusion, to which the CPD are in agreement with;</p> <p>5.6 <i>The Permit Holder is to notify the Civil Protection Department in the event that the fire hydrant system is not operational. The notification shall also include other measures which will be put in place until the fire hydrant system is rendered operational.</i>∞</p>
		Malta Competition and Consumer Affairs Authority
		<p><u>On application</u></p> <p>No feedback provided.</p>

		<p><u>On permit</u></p> <p>No feedback provided.</p>
		<p><i>Malta Resources Authority</i></p>
		<p><u>On application</u></p> <p>Please note that MRA has no comments on this application. However, please note that with the coming into force of the Act No. XXV of 2015 establishing the Regulator for Energy and Water Services, the Water Policy Framework Regulations and the Protection of Groundwater against Pollution and Deterioration Regulations have been excluded from the remit of Malta Resources Authority and as such the MRA has no authority to take a position on matters regulated by these regulations or indeed any other matter that does not fall within its remit.</p> <p><u>On permit</u></p> <p>No feedback provided.</p>
		<p><i>Occupational Health and Safety Authority</i></p>
		<p><u>On application</u></p> <p>With reference to the IPPC application renewal IP 0001/19, OHSa finds no objection to its approval by ERA, provided that the employer abides with Act XXVII of 2000 and all relevant OHS regulations.</p> <p><u>On permit</u></p> <p>Slight amendment requested on condition relating to the <i>Occupational Health and Safety Authority Act</i>, (Chapter 424).</p>
		<p><i>Planning Authority</i></p>
		<p>Following the assessment of the attached drawings in connection with IPPC application renewal and variation IP0001/19 Sterling Chemical Malta Ltd, the following discrepancies from the Planning Authority's approved drawings were noted::</p> <p>Level 0</p> <ul style="list-style-type: none"> • Parking space reduced from 39 parking spaces to 36. • Rain water reservoir with the volume of 1477 m³ changed into a store. • Construction of pump room adjacent to the emergency exit. • Service corridor extended further than that approved. • Construction of goods lift and extension to switch room. <p>Level 1</p> <ul style="list-style-type: none"> • Change of use from offices / stores to laboratories. • Construction of goods lift and stores. • Shifting of emergency exit staircase. <p>Level 2</p>

	<ul style="list-style-type: none"> • Roofing over part of double height space. • Change of use from canteen to laboratory. • Construction of goods lift. <p>Level 3</p> <ul style="list-style-type: none"> • Construction of offices. • Construction of goods lift. • Addition of an intermediate level. <p>General Note:</p> <p>The above changes may result in general changes on façade and increase in height. Such deviations may only be ascertained once façade details as built are submitted.</p> <p>The Operator replied that the differences in the drawings are largely due to the constraints of the DNO procedure, and will be rectified once the PA application is submitted. The volume of the reservoir will be 74 m³.</p> <p>The above feedback was relayed to the Planning Authority, to which the response was;</p> <p>There are no further comments to make and agree with the action to be taken by applicant.</p> <p><u>On permit</u></p> <p>No feedback provided.</p>
	<p>REWS</p> <p><u>On application</u></p> <p>Vol 1 document mentions that primarily fuel is used by the boilers while a generator is used for back up power. Vol 2 document mentions that diesel is used for heating.</p> <p>Even though it is stated that tanks will be stored within a bunded area and /or double skinned, the Regulator would like to inform the Environment and Resources Authority that Sterling Chemical Malta Ltd. should register any fuel storage with the Regulator for Energy and Water Services (REWS). Different application forms exist, depending on the type, use and quantities of fuel stored. Any queries on the application forms should be sent to enquiry@rews.org.mt.</p> <p>Clarification on the text on pages 87, 191, 239 of Vol 1 document: “Diesel-operated generators (diesel is not flammable)” Same goes to the Maltese text on page 103.</p> <p>It is to be noted that the above text is not correct due to the following reason: From 1st June 2015, the classification of diesel (EN 590) and similar fuel oils changed to flammable liquids under the CLP Regulation Classification, Labelling and Packaging (EU) regulation 1272/2008. It follows therefore, as of 1st June 2015, the upper flashpoint for flammable liquid increased from 55°C to 60°C, and, as a result, diesel, along with other similar fuel oils, are now classified as a flammable liquid.</p> <p>It should be noted, that the abovementioned comments refer to the generators proposed as part of Phase 2 (and referred to in the EIA Update Report); these generators are outside the scope of the current IPPC variation application and will be covered in a later variation application.</p>

		<p><u>On permit</u></p> <p>REWS has no further feedback on the revised permit.</p>
		<p><i>Environmental Health Directorate</i></p>
		<p><u>On application</u></p> <p>The proposed changes consist of an R&D pilot plant (line 7 of the new production block in HF 53), and associated utilities, laboratories and other associated activities and changing rooms, toilets, offices and parking.</p> <ol style="list-style-type: none"> 1. With these variations the Directorate has no objection 2. All mitigation measures regarding air and noise pollution are to be implemented during the operation phase by applicant to mitigate any significant adverse health effects and nuisances on sensitive receptors in the Area of Influence and the general public. The possible health effects of any residual impacts that cannot be mitigated and the overall cumulative impacts should also be taken into consideration. 3. As at present one cooling tower is already registered with the Health Authority with registration number 01901. 4. The Legionella Risk Assessment manual needs to be updated to included new changing rooms and toilet facilities. 5. Moreover, any other unpredicted impacts and nuisances which may arise from this operation and that may have a significant adverse effect on public health are to be immediately addressed by the applicant and the necessary mitigation measures taken; <p>Complaints lodged by the public regarding any adverse impacts/nuisances should be immediately addressed by the applicant. All complaints lodged and actions taken are to be recorded and such records are to be readily available to the Competent Authorities when requested.</p> <p><u>On permit</u></p> <p>No further comments.</p>
		<p><i>Water Services Corporation</i></p>
		<p><u>On application</u></p> <p>If the nature of the waste water discharged to sewer by Sterling Chemicals Malta Ltd. were to change from the current discharge of domestic sewage only (whether due to the extension of the factory or change in operations), they are to apply for a modification of their public sewer discharge permit at the DPU.</p> <p><u>On permit</u></p> <p>No objection from Discharge Permitting Unit's end.</p>

5.3	Operator	<p>Consultation on the draft permit conditions was carried out with the operator prior to being presented to the ERA Board. The operator requested clarifications on certain conditions and submitted timeframes for implementation of the improvement programme items.</p> <p>Following discussions with ERA, certain comments were taken on board and others amended accordingly. The operator accepted certain conditions which were proposed. ERA is awaiting feedback on other conditions which were forwarded to the operator.</p> <p>The authority is yet to notify the Operator on the revised financial guarantee and the annual fees.</p> <p>Moreover, the Operator has verbally requested that should the determination date be set on 23 September 2019, due to the time sensitive nature of the projects at Sterling Chemical Ltd., it is being requested that if the application is approved favourably, operations can initiate immediately without having to wait to have the permit "in hand".</p>
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6. Public consultation

6.1	Public consultation	6 th July 2019 till the 20 th July 2019
6.2	Response	One representation was submitted from the public.

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 site.</i></p> <p>Operational Changes</p> <p><i>Conditions in this section refer to additional clearances required in case of:</i></p> <ul style="list-style-type: none"> <i>i. variations which could lead to significant impact on human health or the environment;</i> <i>ii. 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;</i> <i>iii. variations covered by the Environmental Impact Assessment Regulations;</i> <i>iv. aspects of the operations specifically prohibited by this permit;</i> <i>v. changes to emission limit values;</i> <i>vi. changes to fees;</i> <i>vii. renewal of the validity of this permit</i>
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	<p><i>Instead of applying six months prior to the expiry of the permit, it is being proposed that this is revised to nine months.</i></p> <p>General Conditions</p> <p><i>Conditions include provisions regarding saving third party rights and duty of care of the environment</i></p> <p>General Site Operations, Infrastructure and Security</p> <p><i>Includes conditions regarding site identification board, site security and general cleanliness and upkeep of the site</i></p> <p>Pre-operational conditions</p> <p><i>The operation of the R&D in the HF53 shall not commence until such time that the following are submitted;</i></p> <ul style="list-style-type: none"> <i>i. Certification of the wash water reservoirs in the HF53 site to the satisfaction of the Authority, as per improvement programme no.17 in table 1.4.1</i> <i>ii. Certification of the scrubber capacity as per improvement programme no.18 in table 1.4.1</i> <i>iii. Certification that the HVAC and HEPA filtration systems have been installed and tested</i> <p><i>The operation of the laboratories in the HF53 shall not commence until such time that the;</i></p> <ul style="list-style-type: none"> <i>i. Certification of the laboratory wash water reservoir referred to in condition 1.7.1 i, is submitted and approved by the Authority</i> <i>ii. Submission of notification of commissioning as per improvement programme item no.19 in table 1.4.</i> <p>Operational Conditions</p> <p><i>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</i></p> <p>Approval procedure for new production processes</p> <p><i>Prior to the production of any new Active Pharmaceutical Ingredients other than those approved by the Authority, the Operator is notify the Authority 1 months prior to the start of production and submit the necessary documentation.</i></p> <p>Improvement Programme</p> <p><i>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</i></p>
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exception of the implementation of a baseline report and the associated submission of an outline site closure plan. New IP items have been added.

Emissions to Air

Point sources have been identified and emission limit values set for various parameters.

Point sources are :

<i>Emission point reference</i>	<i>Source</i>	<i>Location of emission point</i>
EM1	Production area	<i>Scrubber</i>
	Weighing Room	
	Finished Goods area	
	Microniser	
EM4A	Laboratories	Fume Hood Extraction vent
EM4B	Laboratories	Fume Hood Extraction vent
EM5	Boiler	Boiler stack
EM6	Boiler	Boiler stack
EM7	Cooling Tower	<i>Cooling Tower Stack</i>
EM10	Micronization laboratory	Fume Hood Extraction vent
EM11	Micronization laboratory	Fume Hood Extraction vent
EM12	Cold Room	Vent
EM13A	Pilot Plant reactors, local extraction in HF53 , blowdown tank	Scrubber
EM13B	Pilot Plant reactors, local extraction in HF53 , blowdown tank	Scrubber backup fan
EM14	Emission of air coming from HVAC system and general ventilation	Air grilles
EM15	HVAC	HEPA filter
EM16	Laboratory	Fume Hood
EM17	Laboratory	Fume Hood
EM 18	Laboratory	Fume Hood
EM 19	Laboratory	Fume Hood
EM20	Laboratory	Fume Hood

Emission Limit values are:

Emission point reference	Parameter	Limit
EM1,EM13	VOC as carbon	20 mgC/Nm ³

EM1,EM13	Total-Particulate Matter	<1 mg/ Nm ³
	Oxides of Nitrogen	50 µg/ m ³
	Ammonia	10 mg/ Nm ³
	HCL	7.5 mg/ Nm ³
<p>Cooling tower Registration</p> <p>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</p>		
<p>Discharges to sewers</p> <p>Conditions have been included so as to ensure compliance with the sewer discharge permit issued by the WSC.</p>		
<p>Discharges to groundwater</p> <p>Conditions have been included to prohibit any discharges to groundwater.</p>		
<p>Fugitive emissions of substances to air</p> <p>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.</p>		
<p>Fugitive emissions of substances to water and sewer</p> <p>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 water (including to groundwater) and sewer from the Permitted Installation with particular reference to specific areas of the installation. Brine reject shall only be disposed of as waste, unless agreed otherwise by the Authority.</p>		
<p>Odour</p> <p>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:</p> <ul style="list-style-type: none"> iii. limiting the use of odorous materials; iv. restricting odorous activities; v. controlling the storage conditions of odorous materials; vi. controlling processing parameters to minimise the generation of odour; vii. optimising the performance of abatement systems; viii. timely monitoring, inspection and maintenance; ix. employing, where appropriate, an approved odour management plan 		
<p>Emissions to Land</p> <p>No emission from the Permitted Installation shall be made to land.</p>		
<p>Noise and Vibration</p> <p>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.</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>Storage</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><i>Conditions have been included to ensure the proper storage of raw materials, chemicals, fuels and wastes.</i></p> <p>Waste</p> <p><i>Conditions have been included to ensure the proper classification of waste and disposal utilising carriers and brokers permitted by ERA and at facilities which are permitted to accept wastes.</i></p> <p>Energy Efficiency</p> <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>Notifications</p> <p><i>A notification system has also been set up so as to ensure that any exceedances from ELVs, incidents on site or fugitive emissions, particularly due to planned maintenance are reported within a specific timeframe and through a set process.</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>
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		<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> <p><i>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.</i></p>
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7.2	Improvement programme	<p><i>The following items have been included as items in the improvement programme:</i></p> <table border="1"> <thead> <tr> <th colspan="3">Table 1.4.1: Improvement programme</th></tr> <tr> <th>Reference</th><th>Requirement</th><th>Date</th></tr> </thead> <tbody> <tr> <td>2</td><td>Obtaining ISO 14001 accreditation and implementation of the corresponding Environmental Management System.</td><td>By 31 December 2019</td></tr> <tr> <td rowspan="2">6</td><td>Notification of the installation of the LPG storage and submission of certification from an independent fire safety consultant that all firefighting measures are in place.</td><td> A) Notification of installation: within one week of installation B) Certification: Within 1 month of installation C) REWS license within 1 month of installation </td></tr> <tr> <td>Notification of the decommissioning of the LPG storage in use as described in the original application</td><td>Within one week from removal from site.</td></tr> <tr> <td rowspan="2">10</td><td>Submission of a noise monitoring plan in line with Schedule 5 shall be carried out once the microniser and ancillary equipment in HF53 are commissioned.</td><td>By 31 December 2019</td></tr> <tr> <td>Implementation of a noise monitoring exercise and submission of the report.</td><td>Within 3 months of approval of the method statement by ERA</td></tr> <tr> <td rowspan="2">12</td><td>Submission of the monitoring proposal for a one-time air emission monitoring exercise from A) the fume hood exhaust vents (EM4, EM 10, EM11)</td><td>By 31 December 2019</td></tr> <tr> <td>B) the fume hood exhaust vents (EM16, EM17, EM18, EM19 & EM20)</td><td>3 months after commissioning</td></tr> <tr> <td>13</td><td>Update of the emergency plan to reflect the updated permitted activities.</td><td>By 31 December 2019</td></tr> <tr> <td rowspan="2">14</td><td>Identification of waste gas pollutants and implementation of a waste gas stream inventory in line with the requirements of BAT 2 and BAT 16 of the CID 2016/902 [Establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU for common waste water and waste gas treatment /management systems in the chemical sector.</td><td>By 31 December 2019</td></tr> <tr> <td>Submission of a monitoring proposal to reflect established best available techniques.</td><td>30 June of 2020</td></tr> </tbody> </table>	Table 1.4.1: Improvement programme			Reference	Requirement	Date	2	Obtaining ISO 14001 accreditation and implementation of the corresponding Environmental Management System.	By 31 December 2019	6	Notification of the installation of the LPG storage and submission of certification from an independent fire safety consultant that all firefighting measures are in place.	A) Notification of installation: within one week of installation B) Certification: Within 1 month of installation C) REWS license within 1 month of installation	Notification of the decommissioning of the LPG storage in use as described in the original application	Within one week from removal from site.	10	Submission of a noise monitoring plan in line with Schedule 5 shall be carried out once the microniser and ancillary equipment in HF53 are commissioned.	By 31 December 2019	Implementation of a noise monitoring exercise and submission of the report.	Within 3 months of approval of the method statement by ERA	12	Submission of the monitoring proposal for a one-time air emission monitoring exercise from A) the fume hood exhaust vents (EM4, EM 10, EM11)	By 31 December 2019	B) the fume hood exhaust vents (EM16, EM17, EM18, EM19 & EM20)	3 months after commissioning	13	Update of the emergency plan to reflect the updated permitted activities.	By 31 December 2019	14	Identification of waste gas pollutants and implementation of a waste gas stream inventory in line with the requirements of BAT 2 and BAT 16 of the CID 2016/902 [Establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU for common waste water and waste gas treatment /management systems in the chemical sector.	By 31 December 2019	Submission of a monitoring proposal to reflect established best available techniques.	30 June of 2020
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		15	Notification of regularization with the Planning Authority.	Within one month of decision by the Planning Authority
		16	Certification of impermeability of wash water reservoirs in the HF53 site	Within four weeks of issue of the permit
		17	Submission of scrubber capacity certification	Before commissioning of the R&D line
		18	Notification of commissioning of the laboratories in the HF53 site,	Within one week from commissioning.
		19	A Legionella Risk assessment manual is to be provided to the satisfaction of the Environmental Health directorate [∞]	By 31 December 2019
<p>* Requirement 2 refers to a requirement which featured in IP0001/14/A, requirements 5 till 14 featured in IP0001/14/B. 15 onwards are new additions. IP item 12 has been updated to reflect further requirements.</p>				

8. Financial matters

8.1	Financial guarantee	Prior to issue of this permit, the applicant is to update the financial guarantee of €23,400 to the value of €53,600 to secure the obligations under this permit.
8.2	Annual Fee	Prior to issue of the permit, the applicant shall pay ERA the sum of €1,700 to cover the annual contribution for 2020 (€1,500 per year) and the inspection fee covering 1 inspection carried out in 2019 (one inspection 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.
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9. Recommendation

Recommend for GRANTING, subject to the conditions indicated in section 8 for a period of period of 4 years.

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

Case Officer: Gabriella Grima
Environment Protection Officer

Endorsed by: Nathalie Ellul
Team Manager

Signature:

Signature:

Date:

Date:

ERA Board Decision: