

## Form IPPC Part C: Application for a Variation



For ERA use only  
Application reference:

Use this part of the form if you are applying to vary the conditions or any other provision contained in your permit.

Please read carefully Appendix I attached with this application.

### C1 About the installation

Please fill in the installation table below with details of all the activities and operators at the whole installation, even if you are applying for a permit in respect of only part of the installation.

In **Column 1: Activities in “the stationary technical unit”**, please describe all activities listed in Annex I to the Industrial Emissions Directive that are proposed to be carried out.

For **Directly associated activities**, please identify any directly associated activities proposed to be carried out on the same site which:

- have a technical connection with the activities in the stationary technical unit; and
- could have an effect on pollution.

These could include, for example, boilers, generators, water purification systems, scrubbers and other air purification systems.

In **Column 2: Schedule 1 references**, write the category the installation falls under in Schedule 1 of the Industrial Emissions (IPPC) Regulations (S.L. 549.77) e.g. 1.1, 5.3(b)(i).

In **Column 3: Operator**, write the name of the operator for each activity (if you are the operator yourself, write “Applicant”).

In **Column 4: Variations**, indicate how the proposed changes would affect the activities.

#### C1.1 Installation details

COLUMN 1 Permitted activities in the “stationary technical unit”	COLUMN 2 Schedule 1 references	COLUMN 3 Operator	COLUMN 4 Proposed variations
As per current permit – no change	As per current permit – no change	Applicant	See Annex C-1

#### Directly associated activities

Quality Control	n/a	Combino Pharm (Malta) Ltd.	n/a

#### C1.2 Non-technical description

Please provide a non-technical description of the proposed changes.

Document reference number:

Annex C-1

## C1 About the installation *continued*

### C1.3 The proposed variations

Please provide a summary of the variations which you are applying for.

This should include:

- a description of the change in operation requiring the variation;
- an indication of the variations to the conditions of the permit that you wish to apply for.

Document reference number for the summary:

Annex C-1

### C1.4 Site maps and reports

Are you proposing any change in operation that would result in additional land being included within the site of the installation?

Yes ☐ No ☒

If yes, please provide:

#### C1.4.1

A site report, describing the condition of the site of that part of the installation in respect of which you are applying for a variation, and, in particular, identifying any substance in, on or under the land which may constitute a pollution risk. A baseline report assessing the state of the groundwater and land may also be required by the Authority.

Document reference number for the report:

Annex C-2

#### C1.4.2

A suitable map (or maps) showing the location of the site of the installation, and the area for which a variation of the IPPC permit is being applied for. The outline of the site and the area requiring the variation should be clearly marked in colour, and the surroundings of the site should be included in the map.

Document reference number for map(s):

Annex C-15

#### C1.4.3

Suitable block plans, properly labelled, showing any changes to the location and nature of the various activities being proposed on that site.

Document reference number for plans:

Annex C-15

*All maps and plans submitted shall be to scale, using a scale rule. Soft copies of plans should be submitted in .pdf format only.*

## C2 Your proposed techniques

### C2.1 Environmental Management System

Provide details of any changes to environmental management techniques resulting from your proposals.

Document reference number:

Annex C-1 and Annex C-3

### C2.2 Proposed activities

**C2.2.1** Describe any proposed changes to the installation activities.

Document reference number:

Annex C-1

**C2.2.2** Describe the proposed techniques and measures to prevent and reduce waste and emissions of substances and heat (including during periods of start-up or shut-down, momentary stoppage, leak or malfunction) as a result of your proposals.

Document reference number:

n/a

**C2.2.3** Submit a flow diagram summarising the proposed installation activities and indicating the changes.

Document reference number:

n/a

**C2.2.4** Include a comparison of the proposed changes to the activities with relevant BAT conclusions published by the European Commission, where these have been published.<sup>1</sup>

Document reference number:

Annex C-11

**C2.2.5** Include an outline of the main alternatives considered to the proposed changes to the technology, techniques and measures.

Document reference number

n/a

<sup>1</sup> Available from <http://eippcb.jrc.es/reference/> and/or <http://ec.europa.eu/environment/air/pollutants/stationary/ied/implementation.htm>

## C2 Your proposed techniques *continued*

### C2.3 Raw materials

Identify any changes to the raw and auxiliary materials, and any other substances (including fuels) proposed to be used as a result of your proposals.

If any changes are proposed, give details of quantities proposed to be used annually and submit respective MSDS sheets.

In addition, identify the storage location of these materials on a site layout plan and give details on:

- Maximum storage capacity;
- Containment measures (including bunding capacity, where applicable);
- Protective measures (including security).

Document reference number:

Annex C-4

### C2.4 Ozone depleting substances and fluorinated greenhouse gases

Identify any changes to the equipment using ozone depleting substances and fluorinated greenhouse gases, with a fluid charge of 3 kg or more.

For each such equipment, identify the type of equipment (hermetically-sealed systems, fixed systems or mobile systems), its use (firefighting, refrigeration/air-conditioning or high-voltage switchgear), charge (in kg) and the type of substance (e.g. R22, R407c, R134a).

Document reference number:

n/a

### C2.5 Maintenance

Describe any changes to the maintenance programme for the installation.

Document reference number:

n/a

### C2.6 Energy

**C2.6.1:** Describe any changes to the annual energy consumption, highlighting the main energy-consuming equipment, and generation by source and end-use (including information on energy generated on site, if applicable).

Document reference number: [Annex C-5](#)

**C2.6.2:** Describe any changes to the proposed basic measures for improvement of energy efficiency.

Document reference number:

Annex C-5

### C2.7 Water

Provide a breakdown of any changes to the proposed annual water consumption by source and end-use.

Document reference number:

Annex C-5

### C2.8 Risk assessment

Describe any changes to the documented system used to identify, assess and minimise the environmental risks and hazards of accidents and their consequences.

Include any changes to emergency plans in case of fire, actions to be taken in case of failure of abatement equipment and other environmentally relevant incidents (e.g. spillages, gas leakage).

Document reference number:

Annex C-6a and Annex C-6b (confidential)

### C2.9 Training

Please indicate whether any changes to the staff training programme will be required. Please submit the name of the technically competent person on site who will be responsible for such training.

Document reference number:

n/a

### C2.10 Cessation

Describe any changes to the outline decommissioning plan describing the draft proposed measures upon definitive cessation of activities, to avoid any pollution risk and return the site of the installation to a satisfactory state (including relevant measures for the design and construction of the installation).

This plan shall include a draft waste management strategy, and a qualitative assessment of the potential for contamination of land and groundwater pollution which might

## C2 Your proposed techniques *continued*

arise from the historical and current processes carried out at the installation.

Document reference number:

n/a

### C2.11 Multi-operator installations

Where you are not the only operator of the installation, describe any change to the techniques and measures (including those to be undertaken jointly by yourself and other operators) for ensuring satisfactory operation of the whole installation resulting from your proposals.

Document reference number:

Annexes C-12a, C-12b, C-13, C-14

## C3 Your proposed emissions

### C3.1 Waste<sup>2</sup>

**C3.1.1:** Characterise (using the European Waste Catalogue code, in accordance with LN 184 of 2011 as amended<sup>3</sup>) and quantify any changes to each waste stream from the installation.

Document reference number:

n/a

**C3.1.2:** Describe any changes to the proposed measures for waste management, storage and handling. If any are identified, also indicate the storage location of wastes on a site layout plan and give details on:

- Maximum storage capacity;
- Containment measures (including bunding capacity, where applicable);
- Protective measures (including security).

Document reference number:

n/a

**C3.1.3:** Describe how each waste stream identified in C3.1.1 is prepared for re use, recycled, recovered or disposed of. If you propose any disposal, explain why recovery is technically and economically impossible and describe the measures planned to avoid or reduce any impact on the environment.

<sup>2</sup> For installations carrying out waste management activities (activities listed in "Section 5: Waste management" of Annex I of the Industrial Emissions Directive), please use this section to document both incoming and outgoing waste.

<sup>3</sup> <http://www.mepa.org.mt/file.aspx?f=6289>.

## C3 Your proposed emissions *continued*

For these wastes, give details on authorised disposal/recovery facilities proposed to be used for each waste. If any on-site recovery of waste is proposed, provide details.

For each of these wastes, give details on off-site transportation, including registered waste carriers/brokers to be used.

Document reference number:

n/a

### C3.2 Emissions to Groundwater

Could there be changes to groundwater discharges from the installation?

Yes ☐ No ☒

If yes, explain how the requirements of the Protection of Groundwater against Pollution and Deterioration Regulations (S.L.549.53) have been addressed, and submit a map showing the proposed location of such emissions

Document reference number:

n/a

### C3.3 Emissions to Sewer

**C3.3.1:** Is a new sewer connection envisaged as a result of your proposal?

Yes ☐ No ☒

If yes, please submit a block plan of the site, showing the proposed layout of sewer connections and any other drains (colour-coded), as well as the proposed discharge point(s).

Document reference number:

n/a

**C3.3.2:** If a new sewer connection is envisaged, does the installation have a Sewer Discharge Permit?

Yes ☐ No ☐ n/a ☒

Please submit a copy of the permit or of the submitted application if the permit has not yet been issued.

Document reference number:

n/a

### C3 Your proposed emissions *continued*

**C3.3.3:** Could the proposal involve the release of any Schedule A or Schedule B substance into the sewers, or changes to releases?

Yes ☐ No ☒

If yes, explain how the requirements of Sewage Discharge Control Regulations (S.L.545.08) have been addressed.

Document reference number:

n/a

**C3.3.4:** Are new or changes to cesspit/s being proposed?

Yes ☐ No ☒

If yes, please provide certification by an independent, warranted engineer showing that each cesspit is in line with the requirements of Schedule 1 Activity 43 of LN 106 of 2007 (as may be amended).

Document reference number:

n/a

#### C3.4 Emissions to the Sea

Identify if the proposal may result in changes to direct discharges to coastal (up to 1 nautical mile from the coast line) or territorial waters.

Yes ☐ No ☒

If any changes are identified, explain how the requirements of the Pollution caused by Certain Dangerous Substances discharged into the Aquatic Environment Regulations (S.L.549.10) and the Water Policy Framework Regulations (S.L.549.100) have been addressed.

Include details of the source, any treatment proposed prior to discharge, composition and maximum volumes (in m<sup>3</sup>/day) discharged.

Document reference number:

n/a

In addition, please submit a block plan of the site, showing the proposed discharge point to the sea. Indicate the geo-referenced coordinates for discharge to sea.

Document reference number:

n/a

#### C3.5 Rainwater

Describe any changes to how rainwater is handled on site. If any changes are proposed,

attach a site drainage map indicating rainwater capture and harvesting/discharge.

Document reference number:

n/a

#### C3.6 Emissions to Air

Identify if there may be any changes in emissions of substances to air.

Yes ☐ No ☒

If any are identified, submit details of each emission point, the nature and the proposed quantities of substances emitted from each point and treatment/abatement measures. A block plan of the site showing each emission point should be submitted.

For each new boiler/generator, submit the following details: rated thermal input, energy output, date of manufacture, stack height, fuel type and annual fuel consumption.

Document reference number:

n/a

#### C3.7 Odour emissions

Identify if there may be changes in emissions of odour.

Yes ☐ No ☒

If any are identified, submit details of the main sources of odour, and the proposed techniques and measures for control of odour.

Document reference number:

n/a

#### C3.8 Emissions to Land

Identify if there may be any changes in emissions of substances to land.

Yes ☐ No ☒

If any are identified, submit details of the nature and the proposed quantities of substances emitted to land, as well as a map showing the proposed location of such emissions.

Document reference number:

n/a

### C3 Your proposed emissions *continued*

#### C3.9 Noise

Describe:

**C3.9.1:** The main sources of noise and vibration (including infrequent sources) of the new proposal;

**C3.9.2:** The proposed techniques and measures for control of noise;

**C3.9.3:** The nearest noise sensitive locations and distance away from the site (a site map may be submitted for this purpose); and

**C3.9.4:** Relevant environmental noise measurement surveys which have been undertaken (monitoring shall be according to the latest revisions of ISO1996 and the rating of industrial noise affecting residential areas shall be according to BS 4142; monitoring shall be carried out exclusively using type 1 sound level meter).

Document reference number:

n/a

#### C3.10 Monitoring

Describe the proposed measures for monitoring emissions arising from the proposal, including any environmental monitoring. The following must be specified:

**C3.10.1:** The location of each proposed monitoring point (plotted on a suitably-labelled block plan of the site);

**C3.10.2:** The substances (in each environmental medium) which are proposed to be monitored;

**C3.10.3:** The frequency with which monitoring is proposed to take place;

**C3.10.4:** The proposed measurement methodology, which should be a standard methodology, such as EN or ISO standard, or equivalent;

**C3.10.5:** The proposed procedure for evaluation of the results.

Document reference number:

n/a

#### C3.11 Emissions & waste summary

By means of a mass flow diagram, summarise the emissions and waste described in sections C3.1, C3.2, C3.3, C3.4, C3.6, and C3.8 of this application.

Document reference number:

n/a

### C4 Impact on the environment

#### C4.1 Environmental effects

Provide an assessment of the potential significant environmental effects (including transboundary effects) of the foreseeable emissions from the proposal.

Document reference number:

n/a

#### C4.2 Effects on other sites

Provide an assessment of whether the proposal is likely to have a significant effect on another site in Malta and, if it is, provide an assessment of the implications of the installation for that site.

Document reference number:

n/a

### C5 Environmental statements

#### C5.1 Environmental statement

Has this proposal required an EIA Report under the Environmental Impact Assessment Regulations (S.L. 549.46)?

Yes ☐ No ☒

If yes, please supply a copy of the environmental statement submitted and details of any decision made.

Document reference number:

n/a

## C6 Statutory consultees

We will use the information in this section to identify who we must consult about your proposals.

### C6.1 Local council

In which area is the installation located? If premises are on a boundary please give the names of all the relevant authorities.

Hal Far (B'Bugia Local Council)

### C6.2 Other sites

Are there any other sites which may be affected by emissions from the proposal? (Refer also to your answer to C4.2).

Yes ☐ No ☒

If yes, please give the names of the sites:

n/a

### C6.3 Port Authority

Could the installation involve the release of any substance into a harbour managed by a port authority?

Yes ☐ No ☒

If yes, please name the port authority:

n/a

## C7 Planning status

### C7.1 Planning status

Which of the following applies to the proposed installation activities?

We cannot issue a permit unless one of the following applies. Please tick the applicable answer and submit a copy of the relevant documents.

☒ You have planning permission.

Document reference number:

Annex C-7

☐ You have a certificate of lawful existing use or development.

Document reference number:

☐ Planning permission is not required - please say why and enclose written confirmation from the Planning Directorate at MEPA.

Document reference number:

☐ If you have submitted an application for planning permission which has not yet been determined, please provide a copy of the application.

Document reference number:



## C8 Technically competent person

### Technically competent person

We need to make sure that whoever holds the permit is a 'technically competent person'. This includes consideration of relevant offences, technical competence and financial provision.

#### C8.1 Technically competent management

Are any changes to the technically competent management of the activities proposed?

Yes ☒ No ☐

If yes, please give details for each person and provide the written evidence requested.

Responsible person 1:

Full Name: Selina Zerafa  
Position: EPHS Manager  
Date of employment: 21/01/2020  
Mobile number: /

Document reference number for copies of CV, relevant qualifications and recent police conduct certificate:

[Annex C-8 , Annex C-9 \(confidential\)](#)

Responsible person 2:

Full Name:  
Position:  
Date of employment:  
Mobile number:

Document reference number for copies of CV, relevant qualifications and recent police conduct certificate:

Responsible person 3:

Full Name:  
Position:  
Date of employment:  
Mobile number:

Document reference number for copies of CV, relevant qualifications and recent police conduct certificate:

#### C8.2 Management of other installations

Is any of the technically competent management already providing the technically competent management at other IPPC installations or at sites licensed under the Environmental and Development Planning Act 2010?

Yes ☒ No ☐

## C8 Technically competent person *cont.*

If yes, please use a separate sheet to give details of these people. For each person we need to know the:

- site/installation name and address;
- licence/permit reference number.

Document reference number for this information:

[n/a](#)

## C9 Expenditure plan

### C9.1 Expenditure plan

Please provide a plan of the estimated expenditure for each phase of the following specified activities arising from your proposal.

The plan should include the likely costs of:

- monitoring (emission/discharge and ambient monitoring);
- clearing the installation (including drainage systems) of all wastes;
- remedial action in the event of the failure of pollution control systems.

*We recognise that this plan may need to be revised before the issue of the final permit.*

Document reference number for expenditure plan:

[Annex C-10](#)

## C10 What to do next

Please read Appendix I, then prepare and sign a covering letter to attach to your application form.



## Appendix I

### Data Protection Clause

In terms of the Data Protection Act (Chapter 440 of the Laws of Malta), we will process any personal and/ or sensitive data supplied on/ in this submission or subsequently supplied by yourself, whether orally or in writing, for all or any of the following purposes:

1. The proper processing of your submission;
2. internal management, research and statistics;
3. the protection and promotion of our legitimate interests and the proper conduct of our obligations arising under any law or statutory instrument; and
4. to make public the necessary information as specified in the relevant law and/or instrument.

Relevant data will be disclosed or shared as appropriate with all our employees and with other third parties if pertinent to any of the purposes listed above.

You have the right to require that we provide you with access to your **personal data** as well as the right to rectify, or, in appropriate circumstances, erase/edit any inaccurate, incomplete or immaterial personal data which is being processed. However, you are required to inform us immediately of any alterations relating to your personal data which we are processing.

By sending your submission, you confirm that you are giving your explicit consent, in terms of the Data Protection Act, on behalf of yourself and all the other persons specified in this submission for the Authority to process your respective personal information as outlined above and you confirm that you have brought this Data Protection notice to the attention of these other persons and obtained their respective consents.

We undertake to implement appropriate measures and safeguards for the purpose of protecting the confidentiality, integrity and availability of all personal data processed.

---