



Headquarters,  
Johnstown Castle Estate,  
County Wexford, Ireland

## GREENHOUSE GAS EMISSIONS PERMIT

**Permit Register Number:** IE-GHG194-10521-3

**Operator:** MSD International GmbH t/a MSD  
Ireland (Dunboyne Biologics)  
Piercetown  
Dunboyne  
Meath  
A86 HD21

**Installation Name:** MSD Ireland (Dunboyne Biologics)

**Site Name:** MSD Ireland (Dunboyne Biologics)

**Location:** Piercetown  
Dunboyne  
Meath  
A86 HD21

Ireland

## Introductory Note

***This introductory note does not form a part of the Greenhouse Gas Emissions Permit.***

This Greenhouse Gas Emissions Permit authorises the holder to undertake named activities resulting in emissions of Carbon Dioxide from the listed emission sources. It also contains requirements that must be met in respect of such emissions, including monitoring and reporting requirements. This Greenhouse Gas Emissions Permit places an obligation on the Operator to surrender allowances to the Agency equal to the annual reportable emissions of carbon dioxide equivalent from the installation in each calendar year, no later than four months after the end of each such year.

### Contact with Agency:

If you contact the Agency about this Greenhouse Gas Emissions Permit please quote the following reference: Greenhouse Gas Emissions Permit N<sup>o</sup> IE-GHG194-10521.

All correspondence in relation to this permit should be addressed to:

*Email:* help.ets@epa.ie

*By Post:* Climate Change Unit, Environmental Protection Agency  
P.O. Box 3000, Johnstown Castle Estate,  
Co. Wexford

### Updating of the permit:

This Greenhouse Gas Emissions Permit may be updated by the Agency, subject to compliance with Condition 2. The current Greenhouse Gas Emissions Permit will normally be available on the Agency's website at [www.epa.ie](http://www.epa.ie) and [ETSWAP](#).

### Surrender of the permit:

Before this Greenhouse Gas Emissions Permit can be wholly or partially surrendered, a written application must be made to the on-line ETS portal, and written permission received from, the Agency through [ETSWAP](#).

### Transfer of the permit or part of the permit:

Before this Greenhouse Gas Emissions Permit can be wholly or partially transferred to another Operator a joint written application to transfer this Greenhouse Gas Emissions Permit must be made (by both the existing and proposed Operators) to, and written permission received from, the Agency through the on-line ETS portal [ETSWAP](#).

**Licence held pursuant to the Environmental Protection Agency Act 1992, as amended.** (as of the date of this permit):

<b>IPC/IE Licence Register Number</b>
P1073-01



## Status Log

### Current Permit

Permit number	Date application received	Date Permit issued	Comment
IE-GHG194-10521-3	08 March 2021	26 March 2021	Transfer of the permit from Takeda Dunboyne Biologics Limited to MSD International GmbH t/a MSD Ireland (Dunboyne Biologics) to take effect from 01 January 2021.

### Previous Permits

Permit number	Change Type	Date application received	Date Permit issued	Comment
IE-GHG194-10521-1	GHG Permit Application	08 February 2019	23 July 2019	
IE-GHG194-10521-2	GHG Variation	27 September 2019	01 October 2019	Transfer of the permit to Takeda Dunboyne Biologics Limited from Shire Pharmaceuticals Ireland Limited.

### End of Introductory Note



## Glossary of Terms

For the purposes of this permit the terms listed in the left hand column shall have the meaning given in the right hand column below:

The Agency	Environmental Protection Agency.
Agreement	Agreement in writing.
Allowance	Permission to emit to the atmosphere one tonne of carbon dioxide equivalent during a specified period issued for the purposes of Directive 2003/87/EC by the Agency or by a designated national competent authority of a Member State of the European Union.
Annual Reportable Emissions	Reportable Emissions of carbon dioxide made in any calendar year commencing from 1 January 2005 or the year of commencement of the activity, whichever is the later.
A & V Regulation	Commission Regulation (EU) No 600/2012 of 21 June 2012 on the verification of greenhouse gas emission reports and tonne-kilometre reports and the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council and any amendments or revisions thereto.
Category A Installation	As defined in Article 19.2 (a) of the M&R Regulation.
Category B Installation	As defined in Article 19.2 (b) of the M&R Regulation.
Category C Installation	As defined in Article 19.2 (c) of the M&R Regulation.
The Directive	Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC.
Emissions	The release of greenhouse gases into the atmosphere from sources in an installation.
EPA	Environmental Protection Agency.
Fall-Back Methodology	As defined in Article 22 of the M&R Regulation.
GHG	Greenhouse gas.
GHG Permit	Greenhouse gas emissions permit.
Greenhouse Gas	Any of the gases in Schedule 2 of the Regulations.
IPC/IE	Integrated Pollution Control/Industrial Emissions.
Installation	Any stationary technical unit where one or more activities listed in Schedule 1 to the Regulations are carried out. Also any other directly associated activities which have a technical connection with the activities carried out on that site and which could have an effect on emissions and pollution. References to an installation include references to part of an installation.

Installation with low emissions	As defined in Article 47 of the M&R Regulation.
Major Source Streams	As defined in Article 19.3 (c) of the M&R Regulation.
M&R Regulation	Commission Regulation (EU) No 601/2012 of 21 June 2012 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC of the European Parliament and of the Council and any amendments or revisions thereto.
Mis-statement	An omission, misrepresentation or error in the Operators reported data, not considering the uncertainty permissible pursuant to Article 12(1)(a) of Regulation (EU) no 601/2012.
N/A	Not applicable.
Monitoring Plan	The Plan submitted and approved in accordance with Condition 3.1 of this permit and attached at Appendix 1.
Non-conformity	Any act or omission by the Operator, either intentional or unintentional, that is contrary to the greenhouse gas emissions permit and the requirements of the Monitoring Plan.
The National Administrator	The person so designated in accordance with the requirements of any Regulations adopted as provided for under Article 19.3 of Directive 2003/87/EC.
The Operator (for the purposes of this permit)	MSD International GmbH t/a MSD Ireland (Dunboyne Biologics)
“operator”	Any person who operates or controls an installation or to whom decisive economic power over the functioning of the installation has been delegated.
Person	Any natural or legal person.
Reportable emissions	The total releases to the atmosphere of carbon dioxide (expressed in tonnes of carbon dioxide equivalent) from the emission sources specified in Table 2 and arising from the Schedule 1 activities which are specified in Table 1.
The Regulations	European Communities (Greenhouse Gas Emissions Trading) Regulations 2012 (S.I. No 490 of 2012) and any amendments or revisions thereto.
The Verifier	A legal person or another legal entity carrying out verification activities pursuant to Regulation (EU) No 600/2012 and accredited by a national accreditation body pursuant to Regulation (EC) No 765/2008 and Regulation (EU) No 600/2012 or a natural person otherwise authorised, without prejudice to Article 5(2) of Regulation (EC) No 765/2008, at the time a verification report is issued.
The Registry	The Registry as provided for under Article 19 of Directive 2003/87/EC.



Schedule 1

Schedule 1 to the Regulations.



## Reasons for the Decision

The Agency is satisfied, on the basis of the information available, that subject to compliance with the conditions of this permit, the Operator is capable of monitoring and reporting emissions in accordance with the requirements of the Regulations.

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## Activities Permitted

Pursuant to the Regulations the Agency transfers this Greenhouse Gas Emissions Permit, subject to any subsequent revisions, corrections or modifications it deems appropriate, to:

### The Operator:

MSD International GmbH t/a MSD Ireland (Dunboyne Biologics)  
Piercetown  
Dunboyne  
Meath  
A86 HD21

Company Registration Number: 909434

from

### The Former Operator:

Takeda Dunboyne Biologics Limited  
Block 2 Miesian Plaza  
50 - 58 Baggot Street Lower  
Dublin 2

D02 Y754

to carry out the following

### Categories of activity:

Annex 1 Activity
Combustion of fuels in installations with a total rated thermal input exceeding 20 MW (except in installations for the incineration of hazardous or municipal waste)

at the following installation(s):

MSD Ireland (Dunboyne Biologics) **Installation number:** 213140

located at

Piercetown  
Dunboyne  
Meath  
A86 HD21  
Ireland

subject to the five conditions contained herein, with the reasons therefor and associated tables attached thereto.

In accordance with Joint Declaration made to the Agency on 02 March 2021, *MSD International GmbH t/a MSD Ireland (Dunboyne Biologics)* is deemed to have assumed and accepted all liabilities, requirements and obligations provided for in or arising under the permit, regardless of how and in respect of what period, including the period 2019-2021, prior to the transfer of the permit, that may arise.

# Conditions

## Condition 1. The Permitted Installation

- 1.1 This permit is being granted in substitution for the previous GHG permit granted to the Operator as listed in the Status Log of this GHG permit.
- 1.2 The Operator is authorised to undertake the activities and/or the directly associated activities specified in Table 1 below resulting in the emission of carbon dioxide:

**Table 1 - Activities which are listed in Schedule 1 of the Regulations and other directly associated activities carried out on the site:**

Installation No.: 213140

Activity Description
Combustion of fuels in installations with a total rated thermal input exceeding 20 MW (except in installations for the incineration of hazardous or municipal waste)
Directly Associated Activity Description
N/A

- 1.3 Carbon dioxide from Schedule 1 activities shall be emitted to atmosphere only from the emission sources as listed in Table 2 below:

**Table 2 Emission Sources and Capacities:**

Emission Source Reference	Emission Source Description	Capacity	Capacity Units
S1	Steam Boiler	4.11	MW
S2	Steam Boiler	4.11	MW
S3	Steam Boiler	4.11	MW
S4	Diesel Generator	4.5	MW
S5	Diesel Generator	4.5	MW
S6	Fire Pump	0.49	MW
S7	Canteen Burner 1	0.02	MW

Emission Source Reference	Emission Source Description	Capacity	Capacity Units
S8	Canteen Burner 2	0.03	MW
S9	Canteen Burner 3	0.02	MW
S10	Canteen Burner 4	0.06	MW

- 1.4 The activity shall be controlled, operated and maintained so that emissions of carbon dioxide shall take place only as set out in this GHG Emissions Permit. The permit does not control emissions of gases other than carbon dioxide. All agreed plans, programmes and methodologies required to be carried out under the terms of this permit, become part of this permit.
- 1.5 This GHG Permit is for the purposes of GHG emissions permitting under the European Communities (Greenhouse Gas Emissions Trading) Regulations 2012 and any amendments to the same only and nothing in this permit shall be construed as negating the Operator’s statutory obligations or requirements under any other enactments or regulations unless specifically amended by the Regulations.
- 1.6 Any reference in this permit to ‘installation’ shall mean the installation as described in the Greenhouse Gas Emissions Permit application and any amendments approved by the Agency.

*Reason: To describe the installation and clarify the scope of this permit.*

## Condition 2. Notification

- 2.1 No alteration to, or reconstruction in respect of, the activity or any part thereof which would, or is likely to, result in a change in:
  - 2.1.1 the nature or functioning of the installation;
  - 2.1.2 the capacity of the installation as detailed in this permit;
  - 2.1.3 the fuels used at the installation;
  - 2.1.4 the range of activities to be carried out at the installation
 that may require updating of the GHG permit shall be carried out or commenced without prior notice to and without the prior written agreement of the Agency.
- 2.2 The Operator shall notify the Agency in writing of the cessation of all or part of any activity listed in Table 1 of this permit no later than one month from the date of cessation or by 31 December of the year of cessation, whichever is sooner.
- 2.3 The Operator shall apply for an update of this GHG Permit where there is a change to the Operator name and/or registered address of the Operator, within seven days of the change.
- 2.4 For installations or parts of installations which have not come into operation when the application for this permit was made the Operator shall notify the Agency of the date of commencement of the activity within seven days of commencement.

- 2.5 The Operator shall notify the Agency in writing within three days of becoming aware of any factors which may prevent compliance with the conditions of this permit.
- 2.6 The Operator shall submit to the Agency by 21 January of each year a declaration of operability. The declaration submitted shall be in the format required by the Agency.
- 2.7 All notifications required under Condition 2 above shall be made to the address given in the Explanatory Note included with this permit.
- 2.8 The Operator shall submit to the Agency by 31 December of each year all relevant information about any planned or effective changes to the capacity, activity level and operation of an installation. The information submitted shall be in the format required by the Agency.

*Reason: To provide for the notification of updated information on the activity.*

### **Condition 3. Monitoring and Reporting**

- 3.1 The Operator shall monitor and record greenhouse gas emissions on site in accordance with the M&R Regulation and the approved Monitoring Plan attached at Appendix 1 to this GHG permit and in compliance with any other guidance approved by the Agency for the purposes of implementing the Directive and/or the Regulations.
- 3.2 The Operator shall modify the monitoring plan in any of the following situations:
  - 3.2.1 new emissions occur due to new activities carried out or due to the use of new fuels or materials not yet contained in the monitoring plan;
  - 3.2.2 the change of availability of data, due to the use of new measurement instrument types, sampling methods or analysis methods, or for other reasons, leads to higher accuracy in the determination of emissions;
  - 3.2.3 data resulting from the previously applied monitoring methodology has been found incorrect;
  - 3.2.4 changing the monitoring plan improves the accuracy of the reported data, unless this is technically not feasible or incurs unreasonable costs;
  - 3.2.5 the monitoring plan is not in conformity with the requirements of the M&R Regulation and the Agency requests a change;
  - 3.2.6 it is necessary to respond to the suggestions for improvement of the monitoring plan contained in the verification report.

The Operator shall notify any proposals for modification of the monitoring plan to the Agency without undue delay. Any significant modifications of the monitoring plan, as defined in Article 15 of the M&R Regulation, shall be subject to approval by the Agency. Where approved these changes shall be implemented within a timeframe agreed by the Agency.

- 3.3 Temporary changes to the monitoring methodology:
  - 3.3.1 Where it is for technical reasons temporarily not feasible to apply the tier in the monitoring plan for the activity data or each calculation factor of a fuel or material stream as approved by the Agency, the Operator shall apply the highest achievable tier until the conditions for application of the tier approved in the monitoring plan have been restored. The Operator shall take all necessary measures to allow the prompt restoration of the tier in the approved monitoring plan. The Operator shall notify the temporary change to the monitoring methodology without undue delay to the Agency specifying:
    - (i) The reasons for the deviation from the tier;

- (ii) in detail, the interim monitoring methodology applied by the Operator to determine the emissions until the conditions for the application of the tier in the monitoring plan have been restored;
  - (iii) the measures the Operator is taking to restore the conditions for the application of the tier in the approved monitoring plan;
  - (iv) the anticipated point in time when application of the approved tier will be resumed.
- 3.3.2 A record of all non-compliances with the approved monitoring plan shall be maintained on-site and shall be available on-site for inspection by authorised persons of the Agency and/or by the Verifier at all reasonable times.
- 3.4 The Operator shall appoint a Verifier to ensure that, before their submission, the reports required by Condition 3.5 below are verified in accordance with the criteria set out in Schedule 5 of the Regulations, the A&V Regulation and any more detailed requirements of the Agency.
- 3.5 The written report of the verified annual reportable emissions and the verification report in respect of each calendar year shall be submitted to the Agency by the Operator no later than 31 March of the following year. The reports shall be in the format required by the Agency and meet the criteria set out in the M&R and A&V Regulations.
- 3.6 The Operator shall enter the verified annual reportable emissions figure for the preceding year into the Registry no later than 31 March of the following year. This figure shall be electronically approved by the Verifier in the registry no later than 31 March of each year.
- 3.7 Where an Operator is applying the Fall-Back methodology, the Operator shall assess and quantify each year the uncertainties of all parameters used for the determination of the annual emissions in accordance with the ISO Guide to the Expression of Uncertainty in Measurement or another equivalent internationally accepted standard and include the verified results in the written report of the verified annual reportable emissions to be submitted to the Agency by 31 March each year.
- 3.8 An Operator shall submit to the Agency for approval a report containing the information detailed in (i) or (ii) below, where appropriate, by the following deadlines:
  - (a) for a category A installation, by 30 June every four years;
  - (b) for a category B installation, by 30 June every two years;
  - (c) for a category C installation, by 30 June every year.
  - (i) Where the Operator does not apply at least the tiers required pursuant to the first subparagraph of Article 26(1) and to Article 41(1) of the M&R Regulation, the Operator shall provide a justification as to why it is technically not feasible or would incur unreasonable costs to apply the required tiers. Where evidence is found that measures needed for reaching those tiers have become technically feasible and do not incur unreasonable costs, the Operator shall notify the Agency of appropriate modifications to the monitoring plan and submit proposals for implementing appropriate measures and its timing.
  - (ii) Where the Operator applies a fall-back monitoring methodology, the Operator shall provide a justification as to why it is technically not feasible or would incur unreasonable costs to apply at least tier 1 for one or more major or minor source streams. Where evidence is found that measures needed for reaching at least tier 1 for those source streams have become technically feasible and do not incur unreasonable costs, the Operator shall notify the Agency of appropriate modifications to the monitoring plan, submit proposals and a timeframe for implementing appropriate measures.
- 3.9 Where the verification report states outstanding non conformities, misstatements or recommendations for improvements the Operator shall submit a report to the Agency for approval

by 30 June of the year in which the verification report is issued. This requirement does not apply to the Operator of an installation with low emissions where the verification report contains recommendations for improvements only. The report shall describe how and when the Operator has rectified or plans to rectify the non-conformities identified and to implement recommended improvements. Where recommended improvements would not lead to an improvement of the monitoring methodology this must be justified by the Operator. Where the recommended improvements would incur unreasonable costs the Operator shall provide evidence of the unreasonable nature of the costs. The Operator shall implement the improvements specified by the Agency in response to the report submitted in accordance with this Condition in accordance with a timeframe set by the Agency.

- 3.10 The Operator shall make available to the Verifier and to the Agency any information and data relating to emissions of carbon dioxide which are required in order to verify the reports referred to in Condition 3.5 above or as required by the Agency to facilitate it in establishing benchmarks and/or best practice guidance.
- 3.11 Provision shall also be made for the transfer of environmental information, in relation to this permit, to the Agency's computer system, as may be requested by the Agency.
- 3.12 The Operator shall retain all information as specified in the M&R Regulation for a period of at least 10 years after the submission of the relevant annual report. This shall include all annual emissions reports submitted by the Former Operator(s) in respect of the installation.
- 3.13 A record of independent confirmation of capacities listed in this permit shall be available on-site for inspection by authorised persons of the Agency at all reasonable times.
- 3.14 The Operator shall keep records of all modifications of the monitoring plan. The records shall include the information specified in Article 16.3 of the M&R Regulation.
- 3.15 The Operator shall ensure that members of the public can view a copy of this permit and any reports submitted to the Agency in accordance with this permit at all reasonable times. This requirement shall be integrated with the requirements of any public information programme approved by the Agency in relation to any other permit or licence held by the Operator for the site.
- 3.16 Any discrepancies with regard to reports submitted by the Former Operator(s) in respect of this installation become the liability of the Operator.

*Reason: To provide for monitoring and reporting in accordance with the Regulations.*

## **Condition 4. Allowances**

- 4.1 Surrender of Allowances
- 4.1.1 The Operator shall, by 30 April in each year, surrender to the Agency, or other appropriate body specified by the Agency, allowances equal to the annual reportable emissions in the preceding calendar year.
- 4.1.2 The number of allowances to be surrendered shall be the annual reportable emissions for the preceding calendar year plus such allowances as may be necessary to cover any earlier calendar year in respect of which allowances remain outstanding and due, including any liabilities arising from the period before the permit was transferred. This includes allowances to cover the amount of any annual reportable emissions in respect of which allowances were not surrendered in accordance with Condition 4.1.1 in the previous year, and the amount of any reportable emissions which were discovered during the previous year to have been unreported in reports submitted under Condition 3 in that or in earlier years.



- 4.1.3 In relation to activities or parts of activities which have ceased to take place and have been notified to the Agency in accordance with Condition 2.2 above, the Operator shall surrender to the Agency allowances equal to the annual reportable emissions from such activities in the preceding calendar year or part thereof, together with such allowances as may be necessary to cover any earlier calendar year in respect of which allowances remain outstanding and due as described in Condition 4.1.2 above.
- 4.1.4 The Operator may, from 2008 onwards, subject to the provisions of the Regulations and the relevant National Allocation Plan for that compliance year, surrender emission reduction units (ERUs) and certified emission reduction units (CERs) in place of allowances.
- 4.2 The holding, transfer, surrender and cancellation of allowances shall be in accordance with the requirements of any Regulations adopted as provided for under Article 19.3 of Directive 2003/87/EC, any amendment or revision to the same and any guidance issued by the Agency or the National Administrator.
- 4.3 The Operator shall provide the National Administrator with all the necessary information for the opening of an Operator holding account for the installation described in Condition 1 of this permit within twenty working days of the issue of this permit, unless such an account is already open.

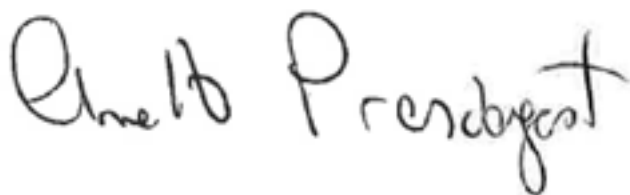
*Reason: To provide for the surrendering, holding, transfer and cancellation of allowances in respect of reported emissions.*

## Condition 5. Penalties

5.1 Any Operator who fails to comply with Condition 4.1 above shall be subject to the provisions of the Regulations, including, but not limited to the payment of penalties.

*Reason: To provide for the payment of excess emissions penalties as required under the Regulations.*

Signed by the Authorised Person on this the 26 March 2021:



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Ms. Annette Prendergast  
Inspector/ Authorised Person

# Appendix 1 to Greenhouse Gas Emissions Permit Number IE-GHG194-10521

## Monitoring Plan

### 1. Guidelines & Conditions

1. Directive 2003/87/EC as amended by Directive 2009/29/EC (hereinafter "the (revised) EU ETS Directive") requires operators of installations which are included in the European Greenhouse Gas Emission Trading Scheme (the EU ETS) to hold a valid GHG emission permit issued by the relevant Competent Authority and to monitor and report their emissions and have the reports verified by an independent and accredited verifier.

The Directive can be downloaded from:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2003L0087:20090625:EN:PDF>

2. The Monitoring and Reporting Regulation (Commission Regulation (EU) No 601/2012) (hereinafter the "MRR") defines further requirements for monitoring and reporting.

The MRR can be downloaded from:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:181:0030:0104:EN:PDF>

Article 12 of the MRR sets out specific requirements for the content and submission of the monitoring plan and its updates. Article 12 outlines the importance of the Monitoring plan as follows:

*The monitoring plan shall consist of a detailed complete and transparent documentation of the monitoring methodology of a specific installation [or aircraft operator] and shall contain at least the elements laid down in Annex I.*

Furthermore Article 74(1) states:

*Member States may require the operator and aircraft operator to use electronic templates or specific file formats for submission of monitoring plans and changes to the monitoring plan as well as for submission of annual emissions reports tonne-kilometre data reports verification reports and improvement reports. Those templates or file format specifications established by the Member States shall at least contain the information contained in electronic templates or file format specifications published by the Commission*

3. All Commission guidance documents on the Monitoring and Reporting Regulation will be published at the link below as they become available:

[http://ec.europa.eu/clima/policies/ets/monitoring/index\\_en.htm](http://ec.europa.eu/clima/policies/ets/monitoring/index_en.htm)

#### (a) Information sources:

##### EU Websites:

EU-Legislation: <http://eur-lex.europa.eu/en/index.htm>

EU ETS general: [http://ec.europa.eu/clima/policies/ets/index\\_en.htm](http://ec.europa.eu/clima/policies/ets/index_en.htm)

Monitoring and Reporting in the EU ETS: [http://ec.europa.eu/clima/policies/ets/monitoring/index\\_en.htm](http://ec.europa.eu/clima/policies/ets/monitoring/index_en.htm)

**Environmental Protection Agency Website:**

<http://www.epa.ie>

**Environmental Protection Agency Contact:**

[GHGpermit@epa.ie](mailto:GHGpermit@epa.ie)

## 2. Application Details

The Installation Name, Site Name and the address of the site of the installation are detailed below. The Site Name and address can be updated from the Organisation Details Page on the ETSWAP website. The Installation Name can only be updated by your Competent Authority.

**Installation name** MSD Ireland (Dunboyne Biologics)

**Site name** MSD Ireland (Dunboyne Biologics)

**Address** Piercetown  
Dunboyne  
Meath  
A86 HD21  
Ireland

**Grid reference of site main entrance** National Grid Reference 301541E 245097N

**Licence held pursuant to the Environmental Protection Agency Act 1992, as amended.** Yes

IPC/IE Licence Register Number	Licence holder	Competent body
P1073-01	MSD International GmbH t/a MSD Ireland (Dunboyne Biologics)	Environmental Protection Agency

Has the regulated activity commenced at the Installation? Yes

Date of Regulated Activity commencement 29 April 2020

This information is only required to identify the first relevant reporting year of an installation. If the installation was in operation from the beginning of 2008 and held a Greenhouse Gas Emissions Permit from this point, 1 January 2008 will be used where the actual date of commencement is not readily known.

### 3. About the Operator

The information about the "Operator" is listed below. The "Operator" is defined as the person who it is proposed will have control over the relevant Regulated Activities in the installation in respect of which this application is being made.

#### (b) Operator Details

The name of the operator and where applicable the company registration number are detailed below. These details can only be updated by the Environmental Protection Agency.

<b>Operator name</b>	MSD International GmbH t/a MSD Ireland (Dunboyne Biologics)
<b>Company Registration Number</b>	909434

#### Operator Legal status

The legal status of the operator is:	Company / Corporate Body
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**(c) Company / Corporate Body**

Is the trading / business name different to the operator name? No

**Registered office address**

Address Line 1	Piercetown
Address Line 2	N/A
City/Town	Dunboyne
County	Meath
Postcode	A86 HD21

**Principal office address**

Is the principal office address different to the registered office address? No

**Holding company**

Does the company belong to a holding company? Yes

Holding company name MSD International GmbH

**Holding company address**

Address Line 1	Weyrstrasse 20
Address Line 2	6000 Lucerne 6
City/Town	Switzerland
County	N/A
Postcode	N/A
Company registration number	CHE-115.587.106

Is the holding company principal address different to the holding company address? No

**(d) Operator Authority**

Does the operator named above have the authority and ability to:

- 
- |   |     |
|---|-----|
| a. manage site operations through having day-to-day control of plant operation including the manner and rate of operation                   | Yes |
| b. ensure that permit conditions are effectively complied with  | Yes |
| c. control monitor and report specified emissions   | Yes |
| d. be responsible for trading in Allowances so that at the end of a reporting period allowances can be balanced against reported emissions. | Yes |

#### 4. Service Contact

##### e. Service Contact

Address	MSD Ireland (Dunboyne Biologics) Piercetown Dunboyne Meath A86 HD21 Ireland
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#### 5. Installation Activities

##### f. Installation Description

Below is a description of the installation and its activities, a brief outline description of the site and the installation and the location of the installation on the site. The description also includes a non-technical summary of the activities carried out at the installation briefly describing each activity performed and the technical units used within each activity.

The Installation is a multiproduct Biopharmaceutical facility in Piercetown, County Meath. The facility has been designed to accommodate production of existing rare disease products, specifically the manufacture of drug substances for enzyme replacement and antibody-based therapies.

It is anticipated that the initial phase of the development will provide for commercial production of two products, one of which utilizes a cell culture-based fed-batch bioreactor production process (both upstream and downstream processing) and a second which is limited to drug substance processing only (downstream processing only).

Upstream processing will include inoculation, cell expansion, and harvest/depth filtration operated in fed-batch mode. This includes both open and closed processing. The Upstream area will be located on the first floor of the Manufacturing Building.

The facility has also been designed to accommodate many downstream products from various mammalian cell lines and product concentrations. The purification processes for each will differ slightly but are designed to utilise their physiochemical properties through the use of a variety methods of separation in the purification of proteins from impurities such as host cell derived proteins. Overall each process will vary due to the deferring nature of the compounds and their target molecules. Regardless of these differences, all of the steps have similar unit operations that are separated into pre-viral and post-viral operations.

The Production and Central Utilities Building (CUB) house the upstream and downstream production areas as well as a number of key utilities. These utilities include 3 no. natural gas fired boilers required to produce plant steam for use as a heating medium for the Water for Injection (WFI) stills (stills heating WFI to sanitizing temperature), for the clean steam generator, the humidification steam generator, the parts washers, for the decontamination autoclaves, or for hot water sanitization of equipment.

The boilers operate 24/7 with 2 continuous and 1 duty standby. The main emissions include combustion products from the ignition of natural gas. Each boiler has a stack height of 27.3m above ground level which is sufficient to ensure minimal impact on the ambient air quality in the vicinity of the site. A platform for EPA sampling and associated power points have been provided as per EPA guidance on sampling, and these emission points will be controlled and monitored in accordance with the IE licence.

There are 4 no. natural gas burners (S7-S10) located at the canteen within the LAC building.

Electrical energy is used to power the facility and is supplied from an ESB Substation Building on the site. 2 no. diesel generators are available to supply emergency power to critical and essential manufacturing and utility equipment and systems. Both generators have a 12m exhaust stack.

Firewater for the site is supplied from the Fire Water pumphouse and a 1,537m<sup>3</sup> water tank located to the south of the Warehouse. The Fire Water System is pressurized by two fire pumps; one electric main pump and one diesel back-up pump. The generators and the fire pump have been listed as potential air emissions in the IE licence application and will be tested periodically, approximately 4-6 hours every 3 months. The facility will operate a Building Automation System (BAS) automation system for control, monitoring, data collection and alarm/reporting of the HVAC air handling systems and Mechanical utility systems site wide. This includes the Fuel Oil and Natural Gas utility systems. The BAS is capable of being configured to categorize alarm levels. The alarm levels will allow for alarm optimization by differentiating alert alarms from action alarms. The alarm levels will also facilitate alarm masking and alarm shelving to avoid nuisance alarms and alarm floods. BAS alarms will be displayed and acknowledged on the BAS workstations.

**g. Annex 1 Activities**

The table below lists the technical details for each Annex 1 activity carried out at the installation.

Note that 'capacity' in this context means:

- Rated thermal input (for combustion installations) which is defined as the rate at which fuel can be burned at the maximum continuous rating of the installation multiplied by the calorific value of the fuel and expressed as megawatts thermal.
- Production capacity for those specified Annex I activities for which production capacity determines ETS eligibility.

Annex 1 Activity	Total Capacity	Capacity units	Specified Emissions
Combustion of fuels in installations with a total rated thermal input exceeding 20	21.95	MW	Carbon Dioxide



Annex 1 Activity	Total Capacity	Capacity units	Specified Emissions
MW (except in installations for the incineration of hazardous or municipal waste)			

**h. Site Diagram**

The table below lists attachments (if available) that provide a simple diagram showing emissions sources source streams sampling points and metering/measurement equipment.

Attachment	Description
GHG Permit drawing.pdf	Site Layout with Emission Points
Diesel gen specifications.pdf	Diesel gen specifications
Diesel tank level guage.pdf	Diesel tank level guage
Boiler specifications.pdf	Boiler specifications
Honeywell Elster SM_RI_X datasheet.pdf	Turbine Gas Meter
Firewater pump data sheet.pdf	Firewater pump data sheet

**i. Estimated Annual Emissions**

Detail of the estimated annual emission of CO<sub>2</sub> equivalent. This information enables categorisation of the installation in accordance with Article 19 of the MRR and is based on the average verified annual emissions of the previous trading period data OR if this data is not available or is inappropriate a conservative estimate of annual average emissions including transferred CO<sub>2</sub> excluding CO<sub>2</sub> from biomass.

Estimated Annual Emissions (tonnes CO<sub>2(e)</sub>) 22245.2

Justification for the use of a conservative estimate of CO<sub>2</sub> emissions. New installation - not currently operational.

Conservative estimate made using fuel use per hour at 100% load for max no. of anticipated hours per year.

Diesel generators and Fire pumps: Assumed 6 hours every 3 months for testing (per unit). Diesel supply at 100% load used to calculate the total tonnage of fuel used. Emissions calculated using the formula: Annual CO<sub>2</sub> = Total diesel usage (tonnes) x EF x NCVt x OxF

Natural Gas boilers: Assumes each unit is operating 8766 hours per year. Natural gas supply at 100% load used to calculate total volume of gas used (in Nm<sup>3</sup>). Emissions calculated using the formula: Annual CO<sub>2</sub> = Total gas usage (Nm<sup>3</sup>) x EF x NCV x OxF

Installation Category: A

## 6. Emissions Details

### j. About your emissions

Annex I of the Monitoring and Reporting Regulations (MRR) requires that monitoring plans include a description of "the installation" and activities to be carried out and monitored including a list of emission sources and source streams. The information provided in this template relates to the Annex I activity(ies) comprised in the installation in question and should relate to a single installation. It includes any activities carried out by the operator and does not include related activities carried out by other operators.

### k. Emission Sources

The table below lists all the emission sources at the installation, which may include directly associated activities/excluded activities.

Emission Source Reference	Emission Source Description
S1	Steam Boiler
S2	Steam Boiler
S3	Steam Boiler
S4	Diesel Generator
S5	Diesel Generator
S6	Fire Pump
S7	Canteen Burner 1
S8	Canteen Burner 2
S9	Canteen Burner 3
S10	Canteen Burner 4

The table below lists the emission sources which are linked to the Regulated Activities at the installation.

Emission Source Reference	Emission Source Description
S1	Steam Boiler
S2	Steam Boiler
S3	Steam Boiler
S4	Diesel Generator
S5	Diesel Generator
S6	Fire Pump

Emission Source Reference	Emission Source Description
S7	Canteen Burner 1
S8	Canteen Burner 2
S9	Canteen Burner 3
S10	Canteen Burner 4

#### I. Emission Points

The table below lists all the emission points at the installation, which may include directly associated activities/excluded activities.

Emission Point Reference	Emission Point Description
EP1	Stack 1 (Steam boiler)
EP2	Stack 2 (Steam boiler)
EP3	Stack 3 (Steam boiler)
EP4	Stack 4 (Diesel Generator)
EP5	Stack 5 (Diesel Generator)
EP6	Stack 6 (Fire Pump)
EP7	Canteen Burner 1
EP8	Canteen Burner 2
EP9	Canteen Burner 3
EP10	Canteen Burner 4

#### m. Source Streams (fuels and/or materials)

The table below lists the source streams which are used in Schedule 1 Activities at the installation.

Source Stream Reference	Source Stream Type	Source Stream Description
F1(GO)	Combustion: Commercial standard fuels	Gas/Diesel Oil
F2 (NG)	Combustion: Other gaseous & liquid fuels	Natural Gas

#### n. Emissions Summary

The table below provides a summary of the emission source and source stream details in the installation.

Source streams ( Fuel / Material )	Emission Source Refs.	Emission Point Refs.	Annex 1 Activity
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Source streams ( Fuel / Material )	Emission Source Refs.	Emission Point Refs.	Annex 1 Activity
F1(GO)	S4,S5,S6	EP4,EP5,EP6	Combustion of fuels in installations with a total rated thermal input exceeding 20 MW (except in installations for the incineration of hazardous or municipal waste)
F2 (NG)	S1,S2,S3,S7,S8,S9,S10	EP1,EP2,EP3,EP7,EP8,EP9,E P10	Combustion of fuels in installations with a total rated thermal input exceeding 20 MW (except in installations for the incineration of hazardous or municipal waste)

**o. Excluded Activities**

Certain activities that result in greenhouse gas emissions may be excluded under the EU ETS Directive for example truly mobile sources such as vehicle emissions.

Do you have any excluded activities which need to be identified in your monitoring plan? No

**7. Low Emissions Eligibility**

**p. Low Emissions Eligibility**

The operator may submit a simplified monitoring plan for an installation where no nitrous oxide activities are carried out and it can be demonstrated that:

(a) the average verified annual emissions of the installation during the previous trading period was less than 25 000 tonnes CO<sub>2(e)</sub> per year or;

(b) where this data is not available or inappropriate a conservative estimate shows that emissions for the next 5 years will be less than 25 000 tonnes CO<sub>2(e)</sub> per year.

Note: the above data shall include transferred CO<sub>2</sub> but exclude CO<sub>2</sub> stemming from biomass.

Does the installation satisfy the criteria for installations with low emissions (as defined by Article 47 of the MRR)? Yes

If the installation is an installation with low emissions as defined above there are a number of special provisions which may be applied to provide a simplified monitoring plan. These provisions are set out in Article 47 of the MRR.

## 8. Monitoring Approaches

### q. Monitoring Approaches

Emissions may be determined using either a calculation based methodology ("calculation") or measurement based methodology ("measurement") except where the use of a specific methodology is mandatory according to the provisions of the MRR. [MRR Article 21].

Note: the operator may subject to competent authority approval combine measurement and calculation for different sources. The operator is required to ensure and demonstrate that neither gaps nor double counting of reportable emissions occurs.

Please specify whether or not you propose to apply the following monitoring approaches. Select all monitoring approaches that are applicable to you. The consecutive sections will become mandatory based on the selected approaches.

Calculation	Yes
Measurement	No
Fall-back approach	No
Monitoring of N <sub>2</sub> O	No
Monitoring of PFC	No
Monitoring of transferred / inherent CO <sub>2</sub>	No

## 9. Calculation

### r. Approach Description

The calculation approach including formulae used to determine annual CO<sub>2</sub> emissions:

#### CALCULATION OF ANNUAL DIESEL FUEL USAGE

The methodology used to calculate annual fuel consumption will be based on monitoring data for consumption (tonnes/hour) of the generators. Fuel consumption will be continuously monitored using level gauges on each of the 2 no. 5,000 litre sub-base double skinned tanks. for the generators and on the smaller 450L double skinned tank for the fire pump which plug the information into an automated system to keep account of the fuel usage on the site. Manual checks including annual stock levels and semi-annual checks of all flow meters and systems to check the accuracy of the readings in the automated system will be carried out. Once operational the Utilities Engineer, or their delegate, will ensure that the level gauges on the diesel tanks are checked at the beginning and end of each year to quantify the starting and closing stock levels. Delivery dockets and invoices will also will used as a cross check to determine annual fuel consumption. Meters on the diesel tanks will be calibrated and certified annually.

#### CALCULATION OF ANNUAL NATURAL GAS USAGE

Natural gas is supplied directly to the boilers on a continuous basis from mains supply. A supplier owned and operated meter will measure natural gas usage onsite. This will be used to calculate the monthly gas usage for invoicing purposes. The Operator will use the invoices to determine the annual fuel usage.

#### CALCULATION OF ANNUAL CO<sub>2</sub> EMISSIONS FROM DIESEL FIRED GENERATORS

CO<sub>2</sub> Emissions (tonnes per year) = Fuel Consumed (tonnes per year) x Emission Factor (tCO<sub>2</sub>/TJ) x NCV(TJ/kt)/1000 x Oxidation Factor.

- Annual diesel consumption (in tonnes) is converted from litres using representative density factor of 0.86.
- The Emission Factor and NCV are both taken from the EPA guidance for the monitoring year.
- As the unit for NCV is TJ/kt, this value is divided by 1000 to give NCV in tonnes.
- The oxidation factor applied is 1.0 in accordance with Commission Implementing Regulation No. 2018/2066 as amended by Commission Implementing Regulation (EU) 2020/2085.

#### CALCULATION OF ANNUAL CO<sub>2</sub> EMISSIONS FROM NATURAL GAS FIRED BOILERS

CO<sub>2</sub> Emissions (tonnes per year) = Fuel Consumed (Nm<sup>3</sup>/year) x Emission Factor (tCO<sub>2</sub>/TJ) x NCV(TJ/Nm<sup>3</sup>) x Oxidation Factor.

- The Emission Factor is taken from the EPA guidance for the monitoring year.
- NCV for natural gas will be calculated from monthly gas bills using the formula provided in the EPA guidance. Once operational, natural gas calculations will be made using monthly invoices and gas supply meter readings. Gross consumption of natural gas (kWh) is converted from gross to net caloric value using the most recent conversion factor provided by the EPA. This is then converted to TJ by multiplying by 3.6 x 10<sup>-6</sup>. The calculation of TJ per Nm<sup>3</sup> is done using the standardised natural gas volume.
- As there are no existing gas bills for the installation the average NCV for Natural Gas installations in Dublin (37 MJ/Nm<sup>3</sup>) as reported in the AEM Reports for 2016 was used for the initial calculation. Fuel consumption (m<sup>3</sup>/hr) is taken from the boiler specifications (at 100% load) assuming total run time of 8766 hours per year (i.e. 24/7).
- The oxidation factor applied is 1.0 in accordance with Commission Implementing Regulation No. 2018/2066 as amended by Commission Implementing Regulation (EU) 2020/2085.

### s. Measurement Devices

Below is a description of the specification and location of the measurement systems used for each source stream where emissions are determined by calculation

Also a description of all measurement devices including sub-meters and meters used to deduct non-Annex I activities to be used for each source and source stream.

Source Stream Refs.	Emission Source Refs.	Measurement Device Ref.	Type of Measurement Device	Measurement Range	Metering Range Units	Specified Uncertainty (+/- %)	Location
F1(GO)	S4,S5,S6	Diesel Fuel Tanks	Level gauge	Variable	Litres	5	Emergency Generator Compound and Pump House
F2 (NG)	S1,S2,S3,S7,S8,S9,S10	Bord Gais meter	Turbine meter	Variable	Nm3/hr	2	GAS REDUCING STATION

Source Stream Refs.	Measurement Device Ref.	Determination Method	Instrument Under Control Of	Conditions Of Article 29(1) Satisfied	Invoices Used To Determine Amount Of Fuel Or Material	Trade Partner And Operator Independent
F1(GO)	Diesel Fuel Tanks	Continual	Operator	N/A	N/A	N/A
F2 (NG)	Bord Gais meter	Continual	Trade partner	Yes	Yes	Yes

### t. Applied Tiers

The table below identifies the tiers applied against the relevant input data for each source stream and confirms whether a standard (MRR Article 24) or mass balance (MRR Article 25) approach is applied.

(i) The highest tiers as defined in Annex II of the MRR should be used by Category B and C installations to determine the activity data and each calculation factor (except the oxidation factor and conversion factor) for each major source stream. Category A installations should apply as a minimum the tiers listed in Annex V.

(ii) Operators may apply a tier one level lower than those referred to in sub paragraph (i) above for Category C installations and up to two levels lower for Category A and B installations with a minimum of tier 1 if the operator can demonstrate to the satisfaction of the competent authority that this is not technically feasible or would lead to unreasonable cost to apply the higher tier. The justification for not applying the higher tier should be recorded when completing the tier table.

(iii) The competent authority may allow an operator to apply even lower tiers than those referred to in the sub paragraph (ii) with a minimum of tier 1 for a transition period of up to three years if the operator can demonstrate to the satisfaction of the competent authority that this is not technically feasible or would lead to unreasonable cost to apply the higher tier and provides an improvement plan detailing how and by when at least the tier referred to in sub paragraph (ii) will be achieved. The improvement plan should be referenced in subsequent table and provided to the competent authority at the time of submission of this plan.

(iv) For minor source streams operators shall apply the highest tier which is technically feasible and will not lead to unreasonable costs with a minimum of tier 1 for activity data and each calculation factor. For de-minimis source streams operators may use conservative estimations rather than tiers unless a defined tier can be achieved without additional effort (MRR Article 26(2)).

(v) Installations with low emissions as identified in section 6(d) may apply as a minimum tier 1 for determining activity data and calculation factors for all source streams unless higher accuracy is achievable without additional effort.

\* Note 1: For commercial standard fuels the minimum tiers listed in Annex V of the MRR may be applied for all activities in all installations.

\* Note 2: If you are intending to apply a fall-back approach please complete the table below and select "n/a" for the tiers to be applied for each source stream where a fall-back approach is used. Section 10 "Fall-back" must also be completed for these source streams.

\* Note 3: For biomass or mixed fuels the emission factor is the preliminary emission factor as defined in Definition 35 Article 3 of the MRR.

Source Stream Refs.	Emission Source Refs.	Measurement Device Refs.	Overall Metering Uncertainty (less than +/- %)	Applied Monitoring Approach	Activity Data Tier Applied	Net Calorific Value Tier Applied	Emission Factor Tier Applied	Carbon Content Tier Applied	Oxidation Factor Tier Applied	Conversion Factor Tier Applied	Biomass Fraction Tier Applied	Estimated Emissions tCO <sub>2(e)</sub>	% of Total Estimated Emissions	Source Category	Highest Tiers Applied	Justification for not applying the highest tiers	Improvement Plan Reference (where applicable)
F1(GO)	S4,S5,S6	Diesel Fuel Tanks	<5.0%	Standard	2	2a	2a	N/A	1	N/A	N/A	60.37	0.27	Major	Yes	n/a	n/a



Source Stream Refs.	Emission Source Refs.	Measurement Device Refs.	Overall Metering Uncertainty (less than +/- %)	Applied Monitoring Approach	Activity Data Tier Applied	Net Calorific Value Tier Applied	Emission Factor Tier Applied	Carbon Content Tier Applied	Oxidation Factor Tier Applied	Conversion Factor Tier Applied	Biomass Fraction Tier Applied	Estimated Emissions tCO <sub>2(e)</sub>	% of Total Estimated Emissions	Source Category	Highest Tiers Applied	Justification for not applying the highest tiers	Improvement Plan Reference (where applicable)
F2 (NG)	S1,S2,S3,S7,S8,S9,S10	Bord Gais meter	<2.5%	Standard	2	2b	2a	N/A	1	N/A	N/A	22436	99.73	Major	Yes	n/a	n/a

Total Estimated Emissions for Calculation (tonnes CO<sub>2(e)</sub>)

22496.37

**u. Applied tiers**

Applied tiers for each source stream

Source Stream Ref.	Emission Source Refs.	Activity Data Tier Applied	Net Calorific Value Tier Applied	Emission Factor Tier Applied	Carbon Content Tier Applied	Oxidation Factor Tier Applied	Conversion Factor Tier Applied	Biomass Fraction Tier Applied
F1(GO)	S4,S5,S6	2	2a	2a	N/A	1	N/A	N/A
F2 (NG)	S1,S2,S3,S7,S8,S9,S10	2	2b	2a	N/A	1	N/A	N/A

**v. Justification for Applied tiers**

Justifications for the applied tiers for each major source stream where highest tiers are not currently achieved.

<b>Source Stream Ref.</b>	<b>Emission Source Refs.</b>	<b>Justification for the applied tier</b>	<b>Improvement Plan Reference (where applicable)</b>
N/A	N/A	N/A	N/A

## 10. Calculation Factors

### w. Default Values

The table below lists, for each parameter, where default values are to be used for calculation factors.

Source Stream Refs.	Emission Source Refs.	Parameter	Reference Source	Default Value applied (where appropriate)
F1(GO)	S4,S5,S6	NCV	National GHG Inventory	n/a
F1(GO)	S4,S5,S6	EF	National GHG Inventory	n/a
F1(GO)	S4,S5,S6	OxF	Commission Implementing Regulation No. 2018/2066 as amended by Commission Implementing Regulation (EU) 2020/2085; MRR	1
F2 (NG)	S1,S2,S3,S7,S8,S9,S10	NCV	Gas Bills	n/a
F2 (NG)	S1,S2,S3,S7,S8,S9,S10	EF	National GHG Inventory	n/a
F2 (NG)	S1,S2,S3,S7,S8,S9,S10	OxF	Commission Implementing Regulation No. 2018/2066 as amended by Commission Implementing Regulation (EU) 2020/2085; MRR	1

### Sampling and Analysis

Do you undertake sampling and analysis of any of the parameters used in the calculation of your CO<sub>2</sub> emissions?  No

## 11. Management

### x. Monitoring and Reporting Responsibilities

Responsibilities for monitoring and reporting emissions from the installation are listed below:

Relevant job titles/posts and provide a succinct summary of their role relevant to monitoring and reporting are listed below.

Job Title / Post	Responsibilities
Site Lead	The Site Lead is responsible for the overall operation of the site including compliance with the GHG Regulations and the requirements of the GHG permit. The Site Lead is responsible for ensuring that sufficient systems and controls are in place to ensure compliance can be met and that any non-compliance is adequately addressed.
EHS lead	The EHS Lead reports to the Site Lead and is responsible for directing, co-ordinating and leading all EHS functions at the site including compliance with the GHG Regulations and the requirements of the GHG permit. The EHS lead will be responsible for verifying source data, making annual calculations, managing planned and unplanned changes in the operation, and submitting the data to the EPA in accordance with the GHG permit. The EHS lead is also responsible for ensuring the data and calculations are independently checked by an ISO 14065 accredited Verification Body. The EHS Lead is supported by a team of EHS Specialists.
Plant Engineering Operations Lead	The Plant Engineering Operations Lead, or their delegate is responsible for leading and managing utilities on the site. As such, the Plant Engineering Operations Lead, or their delegate will be responsible for ensuring accurate collection of data on fuel consumption including allocation of staff to undertake annual monitoring of level gauges and proper record keeping of deliveries and invoices.
Maintenance Lead	The Maintenance Lead is responsible for leading and managing the maintenance activities onsite. The Maintenance Lead will therefore be responsible for ensuring the level gauges and flow meters are calibrated annually.
Automation Lead	The Automation Lead is also responsible for ensuring the BAS is operating at all times and is recording diesel and natural gas use data.
Utilities Engineer	The Utilities Engineer shall ensure that automated monthly generator emissions data is maintained to show planned and unplanned generator runs with the emissions based on the run-time and load being delivered by the generators. The Utilities Engineer shall

Job Title / Post	Responsibilities
	ensure that the information system used to monitor and store GHG data is regularly tested and the data backed up. The Utilities Engineer will ensure potential improvements and optimization, of the quantification and monitoring systems will be assessed annually.
Facilities Lead	The Facilities Lead, or their delegate, is responsible for ensuring that fuel delivery invoices and gas bills are cross checked with actual consumption rates and oil stock levels to ensure accuracy of data collection. The Facilities Lead, or their delegate, is responsible for identifying measurement differences between current and previous years as stored by the automated system.

Attachment	Description
N/A	N/A

**y. Assignment of Responsibilities**

Details of the procedure used for managing the assignment of responsibilities for monitoring and reporting within the installation and for managing the competencies of responsible personnel in accordance with Article 58(3)(c) of the MRR:

This procedure identifies how the monitoring and reporting responsibilities for the roles identified above are assigned and how training and reviews are undertaken.

Title of procedure	Operating Procedure for Management of Fuel Usage and ETS Emissions
Reference for procedure	TBC
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	<p>The Utilities Engineer, or their delegate is responsible for delegating onsite operational work including the collection of fuel oil and natural gas consumption data and fuel deliveries and invoices. All staff involved in this work will be suitably trained engineers or technicians.</p> <p>The Maintenance Lead is responsible for ensuring that the level gauges and flow meters are calibrated in accordance with plant ICA’s (flow meters for gas generators to be managed by Bord Gais).</p> <p>The Automation Lead is also responsible for setting up the appropriate checks and allocating staff to maintain the BAS.</p> <p>The EHS Lead is responsible for ensuring the site is compliant with the requirements of its GHG permit at all times. The EHS Lead will provide guidance to other onsite personnel to ensure accurate data collection.</p> <p>Competence will be managed through education, training, and regular appraisal of the team. All staff will be trained in site operating procedures which include environmental compliance. Annual performance reviews will ensure the competence of all employees is assessed.</p>
Post or department responsible for the procedure and for any data generated	Site Lead
Location where records are kept	Building Automation System (BAS) and internal IT system
Name of IT system used	N/A
List of EN or other standards applied	N/A

**z. Monitoring Plan Appropriateness**

Details of the procedure used for regular evaluation of the monitoring plan's appropriateness covering in particular any potential measures for the improvement of the monitoring methodology:

Title of procedure	Operating Procedure for Management of Fuel Usage and ETS Emissions
Reference for procedure	TBC
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	<p>The EHS Lead, or their delegate, is responsible for checking the data from all emissions sources and source streams and ensuring completeness, recording, and reporting relevant changes in nature and functioning of the installation, and assessing compliance with the thresholds for the applied tiers of each source stream and emission source. More specifically, the EHS Lead or their delegate will ensure that the facility complies with the MRR by ensuring available updates are regularly reviewed. The EHS Lead or their delegate, will also be responsible for assessing potential means of improvement to the monitoring methodology.</p> <p>The Site Lead will be responsible for the selection and application of new processes and tools for the collection, review and reporting of GHG information. Any proposed changes will be submitted by the EHS Lead, or their delegate, to the EPA for approval prior to implementation. The Site Lead, or their delegate, will also assess the effect of changes to other related systems.</p> <p>The information systems used to monitor and store GHG data will be regularly tested and the data backed up which will be managed by the Utilities Engineer, or their delegate. Potential improvements and optimisation of the quantification and monitoring systems will be assessed by the Maintenance Lead in conjunction with the Utilities Engineer, or their delegate.</p>
Post or department responsible for the procedure and for any data generated	Site Lead and EHS Lead
Location where records are kept	Building Automation System (BAS) and internal IT system
Name of IT system used	N/A
List of EN or other standards applied	N/A

**aa. Data Flow Activities**

Details of the procedures used to manage data flow activities in accordance with Article 57 of the MRR:

Title of procedure	Operating Procedure for Management of Fuel Usage and
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<p>Reference for procedure          Diagram reference          Brief description of procedure. The description should cover the essential parameters and operations performed</p>	<p>ETS Emissions          TBC          N/A          This procedure identifies the primary data sources and provides detail on the steps to be taken from primary data collection through to the calculation of annual emissions. The procedure includes;</p> <ul style="list-style-type: none"> <li>- details of automated and manual processes including any manual verification of data.</li> <li>- details of the relevant technologies and software used.</li> <li>- details on the recording and storing of data.</li> <li>- details of formulas used in calculating the emissions.</li> </ul>
<p>Post or department responsible for the procedure and for any data generated           Location where records are kept          Name of IT system used          List of EN or other standards applied          List of primary data sources</p>	<p>Site Lead supported by Plant Engineering Operations Lead and Facilities Lead (data collection) and EHS Lead (emissions calculations)          Building Automation System (BAS) and internal IT system          N/A          N/A          Data from metered fuel oil deliveries as displayed on delivery dockets and invoices           Data from level gauges on fuel tanks           Data from onsite natural gas use meters (monitored by the BAS)           Data from metered gas bills</p>
<p>Description of the relevant processing steps for each specific data flow activity.           Identify each step in the data flow and include the formulas and data used to determine emissions from the primary data. Include details of any relevant electronic data processing and storage systems and other inputs (including manual inputs) and confirm how outputs of data flow activities are recorded</p>	<p>Emission and oxidation factors as issued and updated by the EPA          Source Stream F1 (Diesel Fuel Oil)           Fuel is measured using bulk tank level indicators (level gauges) on each of the fuel tanks with high/low alerts and low fuel alarms. These are tracked using an automated stock level/usage system with records kept on the BAS. inputted into the system.           The delivery of diesel is subject to onsite supervision by a qualified site employee or contractor with the readings from level gauges on the fuel tanks recorded before and after fuelling. Records from each fuel delivery including delivery dockets and invoices are retained and are used to cross check the fuel tank data. A manual check sheet is completed and retained onsite for each delivery in</p>

accordance with relevant legislation.

Verification of data will also be undertaken periodically to ensure automated data is being accurately recorded. Errors identified will be reported to the Engineering Lead for action. The data collected is used to calculate monthly emissions data to show planned (and unplanned) generator runs with the emissions based on the run time and the load being delivered by the generators.

The Facilities Lead or their delegate will also be responsible for ensuring that fuel delivery invoices are cross checked with actual consumption rates and oil stock levels to ensure accuracy of data collection.

CO2 emissions will be calculated by using the activity data, and the NCV, EF and OxF taken from the EPA Document "Country Specific Net Calorific Values and CO2 Emission Factors for use in the Annual Installation Emissions Report".

Generator tanks will be inspected annually to verify the operation of the level gauges.

#### Source Stream F2 (Natural Gas)

Natural Gas supply will be metered onsite at the Bord Gais turbine meter. This meter will be under the control of Bord Gais and will be in place for the purposes of gas billing.

The site will also record natural gas usage via the BAS. As with Source Stream F1, the automated natural gas usage data will be compared with the gas bills to ensure accuracy of data collection. The data collected will be used to calculate monthly emissions data for the gas generators.

Verification of data will also be undertaken periodically to ensure automated data is being accurately recorded. Errors identified will be reported to the Site Lead for immediate action.

#### CALCULATION OF ANNUAL CO2 EMISSIONS FROM NATURAL GAS FIRED BOILERS

CO2 Emissions (tonnes per year) = Fuel Consumed (Nm<sup>3</sup>/year) x Emission Factor (tCO<sub>2</sub>/TJ) x NCV(TJ/Nm<sup>3</sup>) x Oxidation Factor.

- The Emission Factor is taken from the EPA guidance for the monitoring year.

- NCV for natural gas will be calculated from monthly gas

bills using the formula provided in the EPA guidance.

Submit relevant documents to record data flow activities

Attachment	Description
N/A	N/A

**bb. Assessing and Controlling Risks**

Details of the procedures used to assess inherent risks and control risks in accordance with Article 58 of the MRR:

Title of procedure	Operating Procedure for Management of Fuel Usage and ETS Emissions
Reference for procedure	TBC
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	<p>An assessment of the potential risks was undertaken as part of the design of the installation. From this, the Inherent Risk is classified as moderate as steam boilers and generator sets are in common usage. The Control Risk, or the risk of a material error in the recording of data or a misstatement relating to the GHG emissions, is low as the recording systems are fully automated and regularly verified by onsite personnel. Instruments will also be independently calibrated, and data collected will be independently verified by an accredited Verifier.</p> <p>The Site Lead is responsible for ensuring that control risks associated with the GHG emissions are adequately identified. The Plant Engineering Operations Lead is also responsible for ensuring all inherent and control risks relating to the operation of the steam boilers and generators and the collection of data are addressed.</p>
Post or department responsible for the procedure and for any data generated	Site Lead supported by Plant Engineering Operations Lead and Facilities Lead
Location where records are kept	Building Automation System (BAS) and internal IT system
Name of IT system used	N/A
List of EN or other standards applied	N/A

**cc. Quality Assurance of Metering / Measuring Equipment**

Details of the procedures used to ensure quality assurance of measuring equipment in accordance with Article 58 and 59 of the MRR.

Title of procedure	Operating Procedure for Management of Fuel Usage and ETS Emissions
Reference for procedure	TBC
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	The bulk fuel tank level indicators (level gauges) will be independently calibrated by an accredited contractor in accordance with the manufacturers recommendations. The Facilities Lead, or delegated staff member, will review the calibration records to ensure they are thorough and accurate. Fuel delivery tankers are fitted with meters which are also subject to calibration in accordance with the relevant standards. Records for the calibration of these meters will be obtained from the supplier and reviewed by the Maintenance Lead delegated staff member. The Maintenance Lead is also responsible for ensuring that the gas meters are appropriately maintained and calibrated by the trade partner.
Post or department responsible for the procedure and for any data generated	Facilities Lead and Maintenance Lead
Location where records are kept	Building Automation System (BAS) and internal IT system
Name of IT system used	N/A
List of EN or other standards applied	N/A

**dd. Quality Assurance of Information Technology used for Data Flow Activities**

Details of the procedures used to ensure quality assurance of information technology used for data flow activities in accordance with Article 58 and 60 of the MRR:

Title of procedure	Operating Procedure for Management of Fuel Usage and ETS Emissions
Reference for procedure	TBC
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	This section of the procedure outlines the quality assurance measures to be implemented for the specific information technology involved in the collection and storage of data. As the gas oil stock/usage and natural gas usage information is automatically recorded and stored on the BAS, controls will be in place to ensure this data is secured and backed up. Access to the BAS data will be personalised with individual logins and encrypted/unique passwords providing complete information security. All data will be backed up on the company server. Software will be regularly tested by IT personnel.
Post or department responsible for the procedure and for any data generated	Automation Lead

Location where records are kept	Building Automation System (BAS) and internal IT system
Name of IT system used	N/A
List of EN or other standards applied	N/A

**ee. Review and Validation of Data**

Details of the procedures used to ensure regular internal reviews and validation of data in accordance with Articles 58 and 62 of the MRR.

Title of procedure	Operating Procedure for Management of Fuel Usage and ETS Emissions
Reference for procedure	TBC
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Review of all fuel use data will be undertaken by the Facilities Lead, or their delegate, at least annually. The Facilities Lead, or their delegate, will be responsible for identifying measurement differences between current and previous years as stored by the automated system. Verification of data will also be undertaken periodically to ensure automated data is being accurately recorded. Errors identified will be reported to the Plant Engineering Operations Lead for immediate action. The Facilities Lead or their delegate will also be responsible for ensuring that fuel delivery invoices and gas bills are cross checked with actual consumption rates and oil stock levels to ensure accuracy of data collection.
Post or department responsible for the procedure and for any data generated	Facilities Lead and Plant Engineering Operations Lead
Location where records are kept	Building Automation System (BAS) and internal IT system
Name of IT system used	N/A
List of EN or other standards applied	N/A

**ff. Corrections and Corrective Actions**

Details of the procedures used to handle corrections and corrective actions in accordance with Articles 58 and 63 of the MRR:

Title of procedure	Operating Procedure for Management of Fuel Usage and ETS Emissions
Reference for procedure	TBC
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	The EHS Lead is responsible for compliance with the EPA approved monitoring plan and GHG permit. The EHS Lead will be responsible for checking the automated emissions data and notifying the EPA of any non-compliant data and any factor which may prevent compliance with the conditions of the permit within three days of becoming

aware of these factors. All non-compliances will be recorded onsite by the EHS Lead and records shall be made available for inspection by the EPA or by the independent verifier at all reasonable times. The EHS Lead will be responsible for investigating all non-compliances to determine the cause of the non-compliance and to determine the appropriate corrective action.

The EHS Lead, or their delegate, will also undertake an assessment of the effectiveness of the existing preventative measures and the required changes. All procedures affected by the corrective actions will also be amended. Where, for technical reasons only, the monitoring tier for the activity data, emissions factors, oxidation factors or conversion factors as approved in the monitoring plan is temporarily not feasible then the highest achievable tier will be applied to the monitoring data until it is possible to restore monitoring to the approved tier. Any such changes will be reported by the EHS Lead, or their delegate, to the EPA without undue delay with clarification over the reasons for the deviation, a description of the interim monitoring methodology, the measures being undertaken to restore monitoring to the approved tier, and the anticipated time frame for resuming approved monitoring.

Post or department responsible for the procedure and for any data generated	Site Lead and EHS Lead
Location where records are kept	Building Automation System (BAS) and internal IT system
Name of IT system used	N/A
List of EN or other standards applied	N/A

**gg. Control of Outsourced Activities**

Details of the procedures used to control outsourced processes in accordance with Articles 59 and 64 of the MRR.

Title of procedure	Operating Procedure for Management of Fuel Usage and ETS Emissions
Reference for procedure	TBC
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	This procedure covers the management of all outsourced work in relation to the GHG licence and related operations. This includes the management of accredited technicians employed for annual calibration of level gauges, management of contract with the trade partner for the natural gas generators, and external auditors employed to independently verify GHG data. This is primarily controlled through Service Level Agreements which define the controls by which the contractor is obliged to comply. The

Plant Engineering Operations Lead, Facilities Lead and the Maintenance Lead will be responsible for the standing-up and management of contracts with third-party service providers as applicable.

In addition to this, only verification bodies who are ISO 14065 accredited and accredited in accordance with the AVR Regulation and are on an Accredited Body list of approved vendors shall be used. For the verification of delivery dockets from fuel delivery trucks, calibration records will be requested which must have been completed by an accredited vendor.

Post or department responsible for the procedure and for any data generated	Plant Engineering Operations Lead, Facilities Lead, and Maintenance Lead
Location where records are kept	Building Automation System (BAS) and internal IT system
Name of IT system used	N/A
List of EN or other standards applied	N/A

**hh. Record Keeping and Documentation**

Details of the procedures used to manage record keeping and documentation:

Title of procedure	Operating Procedure for Management of Fuel Usage and ETS Emissions
Reference for procedure	TBC
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	All automated and / or manually entered primary data shall be retained and maintained onsite in accordance with Shire’s information management procedures. Documentation to be kept includes all primary data collected, documentation on the selection of the monitoring methodology, any updates to the monitoring plan, any non-compliances or temporal variations to the monitoring plan, all written procedures including those outlined in this monitoring plan, the site risk assessment, details of all calibration and external auditing, and any improvement reports, monthly reports, annual reports and any other related documentation whether in paper, electronic or other format. In accordance with Article 66 of the MRR, data and information stipulated in IX of relevance to the installation shall be stored onsite for 10 years and be made readily available upon request of the EPA or the independent verifier.
Post or department responsible for the procedure and for any data generated	Site Lead
Location where records are kept	Building Automation System (BAS) and internal IT system
Name of IT system used	N/A
List of EN or other standards applied	N/A

**ii. Risk Assessment**

The results of a risk assessment that demonstrates that the control activities and procedures are commensurate with the risks identified:

Attachment	Description
N/A	N/A

**jj. Environmental Management System**

Does your organisation have a documented Environmental Management System? Yes

Is the Environmental Management System certified by an accredited organisation? No

**12. Changes in Operation****kk. Changes in Operation**

Article 24(1) of Commission Decision 2011/278/EC requires that Member States must ensure that all relevant information about any planned or effective changes to the capacity activity level and operation of an installation is submitted by the operator to the competent authority by 31 December each year. Article 12(3) of the MRR further provides that Member States may require information to be included in the monitoring plan of an installation for the purposes of meeting these requirements.

Details of the procedure used to ensure regular reviews are carried out to identify any planned or effective changes to the capacity activity level and operation of the installation that have an impact on the installation's allocation:

The procedure specified below cover the following:

- planning and carrying out regular checks to determine whether any planned or effective changes to the capacity activity level and operation of an installation are relevant under Commission Decision 2011/278/EC; and
- Procedures to ensure such information is submitted to the competent authority by 31 December of each year.



<p>Title of procedure</p> <p>Reference for procedure</p> <p>Diagram reference</p> <p>Brief description of procedure. The description should cover the essential parameters and operations performed</p>	<p>Operating Procedure for Management of Fuel Usage and ETS Emissions</p> <p>TBC</p> <p>N/A</p> <p>The Utilities Engineer, or their delegate, or their delegate, shall ensure that automated monthly generator emissions data is maintained to show planned and unplanned generator runs with the emissions based on the run-time and load being delivered by the generators. The Utilities Engineer, or their delegate shall also ensure a monthly utility saves report is produced to indicate whether the site was “saved” via UPS batteries or the stand-by generators. These will be reviewed regularly by the Plant Engineering Operations Lead, or their delegate, to record and plan for any changes which may affect the capacity of the generators or the amount of onsite fuel storage.</p> <p>No changes will be made without prior EPA approval (including, but not limited to, changes in the nature or functioning of the installation, the capacity of the installation, the fuels used in the installation, and the range of activities carried out at the installation). In the case of a required change in the operation, the EHS Lead or their delegate shall liaise with the EPA. All required documentation including detail on new generators and/or fuel tanks, drawings with revised generator layouts, and any other relevant detail will be supplied by the Plant Engineering Operations Lead or their team.</p> <p>Following application for free allocation, a procedure will be put in place to ensure regular reviews are conducted to identify any planned or effective changes to capacity, activity level or Operation at the installation that impact on the installations allocation (as per Com Decision 2011/278/EC and 2019/331 EC and future Activity Level changes Regulations). All such changes shall be submitted to the EPA by 31 December of each year or any other deadline applied by the Regulations.</p>
<p>Post or department responsible for the procedure and for any data generated</p> <p>Location where records are kept</p> <p>Name of IT system used</p>	<p>Site Lead, supported by Utilities Engineer and Plant Engineering Operations Lead</p> <p>Building Automation System (BAS) and internal IT system</p> <p>N/A</p>

**13. Abbreviations**

## II. Abbreviations Acronyms or definitions

Abbreviations acronyms or definitions that have been used in this monitoring plan:

Abbreviation	Definition
MRR	Monitoring and Reporting Regulations
EPA	Environmental Protection Agency (Ireland)
GHG	Greenhouse Gas
EHS	Environmental, Health & Safety
BAS	Building Automation System

## 14. Additional Information

Any other information:

Attachment	Description
Updated Joint Declaration for Permit_Transfer_IRL_ETS_013 - signed.pdf	Joint (Takeda-MSD) Declaration for Permit Transfer

## 15. Confidentiality

### mm. Confidentiality Statement

It is the Environmental Protection Agency's policy to make information received by it in the course of its work open to inspection by any person on request. This is in accordance with the provisions of the European Communities (Access to Information on the Environment) Regulations 2007 to 2011.

In the event that you considered that some of the information being submitted of a confidential nature, then the nature of this information and the reasons why it should be considered confidential, with reference to the European Communities (Access to Information on the Environment) Regulations 2007 to 2011 and any amendments must be explicitly requested using the facility below. The Board of the Environmental Protection Agency will consider the requests and if the information can be deemed as confidential and necessary.

Notwithstanding any request for confidentiality, the Environmental Protection Agency explicitly reserves the right to release data to the Commission, including emissions and allocations to the public, on the basis that the data will be used for the purposes foreseen in Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC.

Please tick this box if you consider that any part of your form should be treated as commercially confidential/sensitive:  false

**END of Appendix I.**