



Headquarters,
Johnstown Castle Estate,
County Wexford, Ireland

GREENHOUSE GAS EMISSIONS PERMIT

Permit Register Number: IE-GHG022-10351-4

Operator: Genzyme Ireland Limited
IDA Industrial Park
Old Kilmeaden Road
Waterford

Installation Name: Genzyme Ireland Limited

Site Name: Genzyme Ireland Limited (Waterford Facility)

Location: IDA Industrial Park
Old Kilmeaden Road
Waterford
X91 TP27
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^o IE-GHG022-10351.

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 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):

Status Log

Current Permit

Permit number	Date application received	Date Permit issued	Comment
IE-GHG022-10351-4	18 November 2019	16 June 2020	Measurement Devices Table updated with serial number of replacement Natural Gas meter.

Previous Permits

Permit number	Change Type	Date application received	Date Permit issued	Comment
IE-GHG022-10351-1	GHG Permit Application	13 June 2013	25 June 2013	
IE-GHG022-10351-2	GHG Variation	30 November 2017	06 December 2017	Correction of Thermal Input Capacities of emission sources S1-1, S1-2, S2-3, S2-5, S1-3 and S1-5 following review of documentation ; update of details of authorised individual and service contact; correction of description of Natural gas meter in Measurement Devices Table; update of procedure descriptions.
IE-GHG022-10351-3	GHG Variation	08 January 2019	19 June 2019	Boiler S1-1 was upgraded to a new more efficient boiler with thermal input capacity of 2.31 MW; Replacement Natural Gas Meter located at the Fill Finish natural gas supply skid; Change to butane activity data methodology.

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)	Genzyme Ireland Limited
“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.

Activities Permitted

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

The Operator:

Genzyme Ireland Limited
IDA Industrial Park
Old Kilmeaden Road
Waterford

Company Registration Number: 316537

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)
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at the following installation(s):

Genzyme Ireland Limited **Installation number: 20**

located at

IDA Industrial Park
Old Kilmeaden Road
Waterford
X91 TP27
Ireland

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

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.: 20

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
S1-1	SD Boiler 1	2.31	MW
S1-2	SD Boiler 2	2.24	MW
S2-1	FF Boiler 1	8.65	MW
S2-2	FF Boiler 2	8.65	MW
S2-3	FF EG1 (Emergency Generator)	5.55	MW
S2-5	FF EG2 (Emergency Generator)	5.55	MW
S1-4	SD Boiler	2.2	MW

Emission Source Reference	Emission Source Description	Capacity	Capacity Units
S1-5	OD Gen (Emergency Generator)	0.22	MW
S1-3	SD Sprinkler Pump	0.82	MW
S1-6	QC Laboratories	0.01	MW
S2-4	FF Sprinkler Pump	0.5	MW
S1-7	QC Laboratories AA	0.01	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.
- 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.

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. 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 16 June 2020:



Dr Suzanne Monaghan
Inspector/ Authorised Person

Appendix 1 to Greenhouse Gas Emissions Permit Number IE-GHG022-10351

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

(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

Monitoring and Reporting in the EU ETS: 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

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	Genzyme Ireland Limited
Site name	Genzyme Ireland Limited (Waterford Facility)
Address	IDA Industrial Park Old Kilmeaden Road Waterford X91 TP27 Ireland

Grid reference of site main entrance	257955 E, 111625N
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Licence held pursuant to the Environmental Protection Agency Act 1992, as amended.	No
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Has the regulated activity commenced at the Installation? Yes

Date of Regulated Activity commencement	01 January 2008
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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.

Operator name Genzyme Ireland Limited

Company Registration Number 316537

Operator Legal status

The legal status of the operator is: Company / Corporate Body

(c) Company / Corporate Body

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

Registered office address

Address Line 1	IDA Industrial Park
Address Line 2	Old Kilmeaden Road
City/Town	Waterford
County	N/A
Postcode	N/A

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 Genzyme International Holdings Limited

Holding company address

Address Line 1	70 Sir John Rogerson's Quay,
Address Line 2	N/A
City/Town	Dublin 2
County	N/A
Postcode	N/A
Company registration number	409980

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

IDA Industrial Park
Old Kilmeaden Road
Waterford
Ireland

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.

Established in 2001, Genzyme Ireland is situated on a 37 acre site in Waterford. This multi phased biopharmaceutical facility employs over 450 personnel. It is a state-of-the-art facility for finishing of biopharmaceuticals and employs a high level of automation, including Manufacturing Execution Systems. The first phase of development, a tableting suite with packaging lines, for manufacture of Renagel has been supplying product to dialysis patients globally since 2003. The Biologics Fill Finish facility commenced commercial supply of thymoglobulin in 2006 to global markets. This facility uses isolator technology in its aseptic process. The third manufacturing plant commenced operations in 2009. This facility enabled the expansion of our Oral Dose capacity allowing a number of new product introductions. New products introduced during 2010 in both biologics and oral dose, brought to 8 the products being supplied globally to our patients. In February 2008 the site finalised plans to expand its Biological Fill/Finish operations and associated site infrastructure. There are four source streams onsite generating CO₂ emissions. Natural gas, diesel oil, butane and acetylene. Natural gas is combusted in the boilers onsite providing hot water and steam. This is measured in gross kWh.

Diesel oil is used for back-up emergency generators and for fire sprinkler pumps. This is measured in litres.

Butane is used in laboratory bunsen burners. This is measured in grams. Acetylene is used in Quality Chemistry laboratory for a test method.

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 MW (except in installations for the incineration of hazardous or municipal waste)	36.71	MW	Carbon Dioxide

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
Genzyme GHG Emission points 2013.pdf	Genzyme Emission points drawing 2013
Process Flow of Genzyme Ireland LTD Fuel usage.pptx	Process flow of Genzyme Fuel
OD Gas Meter Certs 646281 EPA Response 10-02-12.pdf	Calibration Cert for OD Natural Gas meter
D335578 - Material Certification - R34284.pdf	Calibration cert - Fill Finish G650 Turbine RABO Meterserial number: 83049816

i. Estimated Annual Emissions

Detail of the estimated annual emission of CO₂ 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 CO₂ excluding CO₂ from biomass.

Estimated Annual Emissions (tonnes CO_{2(e)})

5174

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
S1-1	SD Boiler 1
S1-2	SD Boiler 2
S2-1	FF Boiler 1
S2-2	FF Boiler 2
S2-3	FF EG1 (Emergency Generator)
S2-5	FF EG2 (Emergency Generator)
S1-4	SD Boiler
S1-5	OD Gen (Emergency Generator)
S1-3	SD Sprinkler Pump
S1-6	QC Laboratories
S2-4	FF Sprinkler Pump
S1-7	QC Laboratories AA

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

Emission Source Reference	Emission Source Description
S1-1	SD Boiler 1
S1-2	SD Boiler 2
S2-1	FF Boiler 1
S2-2	FF Boiler 2
S2-3	FF EG1 (Emergency Generator)

Emission Source Reference	Emission Source Description
S2-5	FF EG2 (Emergency Generator)
S1-4	SD Boiler
S1-5	OD Gen (Emergency Generator)
S1-3	SD Sprinkler Pump
S1-6	QC Laboratories
S2-4	FF Sprinkler Pump
S1-7	QC Laboratories AA

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
A1-1	SD Boiler 1 Stack
A1-2	SD Boiler 2 Stack
A2-1	FF Boiler 1 Stack
A2-2	FF Boiler 2 Stack
A2-3	FF EG1 Vent
A2-5	FF EG2 Vent
A1-4	SD Boiler Stack
A1-5	OD Gen Vent
A1-3	SD SP vent
A1-6	QC Laboratories
A2-4	FF SP Vent
A1-7	QC AA Vent

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
NG-001	Combustion: Other gaseous & liquid fuels	Natural Gas
NG-002	Combustion: Other gaseous & liquid fuels	Natural Gas
DSL-001	Combustion: Commercial standard fuels	Gas/Diesel Oil

Source Stream Reference	Source Stream Type	Source Stream Description
BUT-001	Combustion: Commercial standard fuels	Butane
ACT-001	Combustion: Other gaseous & liquid fuels	Acetylene

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
NG-001	S1-1,S1-2,S1-4	A1-1,A1-2,A1-4	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)
NG-002	S2-1,S2-2	A2-1,A2-2	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)
DSL-001	S1-3,S1-5,S2-3,S2-4,S2-5	A1-3,A1-5,A2-3,A2-4,A2-5	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)
BUT-001	S1-6	A1-6	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)
ACT-001	S1-7	A1-7	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_{2(e)} 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_{2(e)} per year.

Note: the above data shall include transferred CO₂ but exclude CO₂ 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 ₂ O	No

Monitoring of PFC	No
Monitoring of transferred / inherent CO ₂	No

9. Calculation

r. Approach Description

The calculation approach including formulae used to determine annual CO₂ emissions:

For Natural Gas, diesel (gas oil) and butane, default values for calculation factors are used. Calculation Factors for Natural gas (Emission Factor), gasoil (diesel) (NCV and Emission Factor) and butane (NCV and Emission Factor) are obtained from "Country Specific Net Calorific Values and CO₂ Emission Factors for use in the Annual Installation Report" for the reporting year. The activity data is first summed up, then the calculation formula, according to Article 24(1) of MRR is used. CO₂ emissions are calculated as follows:

Natural Gas consumption (kWh) x gross to net calorific value conversion factor x conversion factor to TJ (3.6 x 10⁻⁶) x country specific emission factor x oxidation factor (1.0).

Diesel (gas oil) consumption (m³) x density x country specific net calorific value x country specific emission factor x oxidation factor (1.0)

Butane consumption (t) x country specific net calorific value x country specific emission factor x oxidation factor(1.0)

As a de minimis source stream, the total acetylene consumed in the reporting period (estimated from purchase of cylinders) is multiplied by the Tier 1 net calorific value and emission factor for Acetylene (from EPA website) and an oxidation factor of 1.0 is then applied. In summary CO₂ emissions arising from the combustion of Acetylene is calculated as follows:

EU-ETS Annual CO₂ emissions from Acetylene = Estimated Total Acetylene consumed (kt) *NCV (TJ/kt)*Emission Factor
(tCO₂/TJ)* Oxidation Factor (1.0)

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
NG-001	S1-1,S1-2,S1-4	83048537	Turbine meter	32-650	m3/h	1.41	Gas Networks Ireland Skid (SD Supply)
NG-002	S2-1,S2-2	83049816	Turbine meter	50-1000	m3/h	1.41	Gas Networks Ireland Skid (FF Supply)
DSL-001	S2-3,S2-5,S1-5,S1-3,S2-4	Diesel truck meter	Delivery Vehicle certified meter	N/A	liters	N/A	Diesel holding tank
BUT-001	S1-6	Gas cylinder - Requisition issue report	Gas Cylinder replacement	0-52	grams	N/A	Adjacent to QC Labs
ACT-001	S1-7	Gas cylinder supply invoices	Gas cylinder replacement	0-7000	litres	N/A	QC Gas skid

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
NG-001	83048537	Continual	Trade partner	Yes	Yes	Yes
NG-002	83049816	Continual	Trade partner	Yes	Yes	Yes
DSL-001	Diesel truck meter	Batch	Trade partner	Yes	Yes	Yes
BUT-001	Gas cylinder -	Batch	Trade partner	Yes	Yes	Yes

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
	Requisition issue report					
ACT-001	Gas cylinder supply invoices	Batch	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 _{2(e)}	% of Total Estimated Emissions	Source Category	Highest Tiers Applied	Justification for not applying the highest tiers	Improvement Plan Reference (where applicable)
NG-001	S1-1,S1-2,S1-4	83048537	<5.0%	Standard	2	2b	2a	N/A	1	N/A	N/A	1773	34.34	Major	Yes	n/a	n/a
NG-002	S2-1,S2-2	83049816	<5.0%	Standard	2	2b	2a	N/A	1	N/A	N/A	3380	65.47	Major	Yes	n/a	n/a
DSL-001	S2-3,S2-5,S1-5,S1-3,S2-4	Diesel truck meter	N/A	Standard	No tier	2a	2a	N/A	1	N/A	N/A	9	0.17	De-minimis	Yes	n/a	n/a
BUT-001	S1-6	Gas cylinder - Requisition issue report	N/A	Standard	No tier	2a	2a	N/A	1	N/A	N/A	0.008	0	De-minimis	Yes	n/a	n/a
ACT-001	S1-7	Gas cylinder	N/A	Standard	No tier	1	1	N/A	1	N/A	N/A	1	0.02	De-minimis	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 _{2(e)}	% of Total Estimated Emissions	Source Category	Highest Tiers Applied	Justification for not applying the highest tiers	Improvement Plan Reference (where applicable)
		supply invoices															

Total Estimated Emissions for Calculation (tonnes CO_{2(e)})

5163.008

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
NG-001	S1-1,S1-2,S1-4	2	2b	2a	N/A	1	N/A	N/A
NG-002	S2-1,S2-2	2	2b	2a	N/A	1	N/A	N/A
DSL-001	S2-3,S2-5,S1-5,S1-3,S2-4	No tier	2a	2a	N/A	1	N/A	N/A
BUT-001	S1-6	No tier	2a	2a	N/A	1	N/A	N/A
ACT-001	S1-7	No tier	1	1	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.

Source Stream Ref.	Emission Source Refs.	Justification for the applied tier	Improvement Plan Reference (where applicable)
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)
DSL-001	S2-3,S2-5,S1-5,S1-3,S2-4	NCV and Emission Factor	Ireland's National Greenhouse Gas Inventory	n/a
BUT-001	S1-6	NCV and Emission Factor	Ireland's National Greenhouse Gas Inventory	n/a
NG-001,NG-002	S1-1,S1-2,S2-1,S2-2,S1-4	Emission Factor	Ireland's National Greenhouse Gas Inventory	n/a
ACT-001	S1-7	NCV and Emission Factor	As published on the EPA website.	n/a
NG-001,NG-002,DSL-001,BUT-001,ACT-001	S1-1,S1-2,S2-1,S2-2,S2-3,S2-5,S1-4,S1-5,S1-3,S1-6,S2-4,S1-7	OxF	MRR	1.0

Sampling and Analysis

Do you undertake sampling and analysis of any of the parameters used in the calculation of your CO₂ 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
HSE Specialist	Compiles and reviews data, calculates emissions, files copies of bills for audit and other reason, prepare GHG data monitoring reports, update of MRR plan and review of permit.
HSE Manager	Cross check all data sources and calculations, approve final report, submit allowances, determine status of balance (if any), purchase additional allowances if necessary, secure services of verifier, review of permit.
Facilities Team Leader	Project usage of energy by Genzyme Ireland LTD on an annual basis, record deliveries of diesel during the year per diesel tank, retaining receipts for audit purposes, ensure that diesel tanks are 75% full at the start and end of each year, inform HSE of any changes or additions to sources of emissions.

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	Greenhouse Gas Monitoring Procedure
Reference for procedure	WAT_SOP-000141
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	<p>1. HSE Manager will assign responsibilities for ensuring that monitoring and reporting requirements are met in accordance with Article 58 (3)(C) of EU Directive 601/2012.</p> <p>2. HSE Manager will review annually the training requirements of individuals involved in the monitoring and reporting of emissions to ensure that they have the necessary competencies for their role and the understand the relevant requirements of EU Directive 601/2012. This will be carried out with the Training and Development department.</p>
Post or department responsible for the procedure and for any data generated	HSE Department
Location where records are kept	Electronic HSE drive Q/EU ETS
Name of IT system used	Genzyme IT
List of EN or other standards applied	NA

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	Greenhouse Gas Monitoring Procedure and EHS Change Management Checklist
Reference for procedure	WAT SOP_000141 and WAT_CFU-000234
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	An EHS Change Management checklist is completed for every new project, equipment or system in conjunction with the HSE Team. A question is asked if the Greenhouse Gas Permit/Monitoring Plan will be impacted. If 'yes', then the project will be referred to WAT SOP_000141 to determine

<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>List of EN or other standards applied</p>	<p>whether the EPA need to be notified and the monitoring plan updated or the monitoring methodology improved.</p> <p>HSE Department, Quality</p> <p>Electronic HSE driveQ:/EU ETS and internal Quality system</p> <p>Genzyme IT</p> <p>NA</p>
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aa. Data Flow Activities

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

<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>Greenhouse Gas Monitoring Precedure</p> <p>WAT SOP_000141</p> <p>N/A</p> <p>Calculations of greenhouse gas emissions are made on the basis of gas, diesel butane and acetylene fuel consumed by Genzyme Ireland Ltd. The quantities of gas, diesel, butane and acetylene consumed are taken from bills or requisition reports for all types of fuel. For the site natural gas fired boilers, Tier 2b of Table 1 of Annex 5 EU Directive 601/2012 applies for NCV. Calculation of CO2 emissions from the boilers will be based on gas meter readings provided by Genzyme’s gas provider. Tier 2a is applied for the emission factor for natural gas. For the site emergency generator and fire pumps, fuelled by diesel fuel, Tier 2a of Table 1 of Annex 5 EU Directive 601/2012 applies for the NCV and also for the emission factor. Calculation of CO2 emissions from these units will be based on a mass balance calculation using fuel delivery bills to total diesel additions per tank per annum. For Bunsen burner usage fuelled by butane, the minimum tier requirements for the calculation factors (NCV and emission factor) as specified in Table 1 of Annex 5 EU Directive 601/2012 is applied. Calculation of CO2 emissions from these units will be based on stock transfer requisition reports from the on site laboratory material supplier to total butane consumption per annum. For QC Laboratory equipment fuelled by acetylene, calculation of CO2 emissions from this unit will be based on invoices from the supplier to total acetylene consumption per annum.</p>
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Post or department responsible for the procedure and for HSE Department

any data generated	
Location where records are kept	Electronic HSE driveQ:/EU ETS
Name of IT system used	Genzyme IT
List of EN or other standards applied	N/A
List of primary data sources	Natural Gas supplier invoices (Gross kWh)
	Diesel oil supplier invoices and annual stock take (litres)
	Butane gas supplier invoices and requisition issue report (g)
	Acetylene (litres)
Description of the relevant processing steps for each specific data flow activity.	For Natural Gas, diesel (gas oil) and butane, default values for calculation factors are used. Calculation Factors for Natural gas (Emission Factor), gasoil (diesel) (NCV and Emission Factor) and butane (NCV and Emission Factor) are obtained from the EPA Annual "Country Specific Net Calorific Values and CO2 Emission Factors for use in the Annual Installation Report" for the reporting year. The activity data is first summed up, then the calculation formula, according to Article 24(1) of MRR is used. CO2 emissions are calculated as follows:
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>Natural Gas consumption (kWh) x gross to net calorific value conversion factor x conversion factor to TJ (3.6 x 10⁻⁶) x country specific emission factor x oxidation factor (1.0).</p> <p>Diesel (gas oil) consumption (m3) x density x country specific net calorific value x country specific emission factor x oxidation factor (1.0) Butane consumption (t) x country specific net calorific value x country specific emission factor x oxidation factor(1.0) As a de minimis source stream, the total acetylene consumed in the reporting period (estimated from purchase of cylinders) is multiplied by the Tier 1 net calorific value and emission factor for Acetylene (from EPA website) and an oxidation factor of 1.0 is then applied. In summary CO2 emissions arising from the combustion of Acetylene is calculated as follows:</p> <p>EU-ETS Annual CO2 emissions from Acetylene = Estimated Total Acetylene consumed (kt) *NCV (TJ/kt)*Emission Factor</p> <p>(tCO2/TJ)* Oxidation Factor (1.0)</p>
	These calculations are carried out using MS Excel worksheets and saved on the Genzyme Internal Drive Q:/EU

ETS

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	Greenhouse Gas Monitoring Procedure
Reference for procedure	WAT SOP_000141
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	<p>Risk Assessment</p> <ol style="list-style-type: none"> 1. Assess the inherent risks and control risks of the control system in accordance with Article 58 of 601/2012. 2. Record any findings or corrective actions in Entropy system (HSE Management system).
Post or department responsible for the procedure and for any data generated	HSE Department
Location where records are kept	Entropy (HSE Management system)
Name of IT system used	Genzyme IT
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	Greenhouse Gas Monitoring Procedure
Reference for procedure	WAT SOP_000141
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	It is the responsibility of the HSE Specialist to request meter Calibration certificates from external suppliers annually. It

is the responsibility of Trade Suppliers to

- Provide calibration certs for metering equipment, as and when requested by the HSE Department.
- Notify Facilities or HSE Department before any maintenance work is undertaken on the on-site natural gas meters.
- Notify Facilities or HSE Department of any breakdown of metering equipment.

Genzyme Ireland Ltd HSE Manager or designee will periodically review progress against projected natural gas, diesel and propane consumption figures. If discrepancies occur between projected and actual energy consumption figures (>20% increase or decrease), a non-conformance will be raised in the HSE Software Management system "Entropy" and an investigation into the root cause will be initiated. All investigations will comply with the requirements of Genzyme's Greenhouse Gas Emissions Permit IE-GHG022. This will include the notification of any incidents and corrective actions to the EPA, if required.

Post or department responsible for the procedure and for any data generated	HSE Department
Location where records are kept	Electronic HSE driveQ:/EU ETS
Name of IT system used	Genzyme IT
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	Greenhouse Gas Monitoring Procedure
Reference for procedure	WAT SOP_000141
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Calculations carried out by the HSE Specialist are reviewed and checked by the HSE Manager on a six-monthly basis. The Excel workbook for the calculations is password protected. IT systems are backed-up every day and files are recoverable.
Post or department responsible for the procedure and for any data generated	HSE Department
Location where records are kept	Electronic HSE driveQ:/EU ETS
Name of IT system used	Genzyme IT
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	Greenhouse Gas Monitoring Procedure
Reference for procedure	WAT SOP_000141
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	<p>Calculation of GHG emissions will be made monthly. As part of this calculation the HSE Specialist must check the following:</p> <ul style="list-style-type: none"> •Accuracy of the data used in the calculation versus data in the relevant fuel bills or mass balance calculation. •Calculation accuracy independent of spreadsheet tool used to generate the calculation. •Calculated level of GHG emission for that period versus the projected GHG emission level for that same period •If the calculated GHG emission level for the period has increased or decreased by greater than 20% when compared with the projected emission for the period, the reason for this must be investigated and the outcome of the investigation documented. This must be done using the ES-051 Accident, Incident & Observation Reporting and Investigation procedure.
Post or department responsible for the procedure and for any data generated	HSE Department
Location where records are kept	Electronic HSE driveQ:/EU ETS and Entropy HSE system
Name of IT system used	Genzyme IT
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	Greenhouse Gas Monitoring Procedure
Reference for procedure	WAT SOP_000141
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	In the event of a failure of the monitoring and reporting methodology for the site, the site will put in place an interim monitoring and reporting methodology (to the

highest tier available) until the conditions for application of the approved tiers have been restored. All necessary measures shall be taken to allow prompt restoration of the agreed monitoring methodology. The EPA will be notified without undue delay. This notification will include details of the reasons for deviation from monitoring methodology, interim measures taken and the plan of action to achieve a prompt restoration of compliance.

Genzyme Ireland Ltd HSE Manager or designee will periodically review progress against projected natural gas, diesel, butane and acetylene consumption figures. If discrepancies occur between projected and actual energy consumption figures (>20% increase or decrease), a non-conformance will be raised in HSE Software Management system Entropy and an investigation into the route cause will be initiated. All investigations will comply with the requirements of Genzyme’s Greenhouse Gas Emissions Permit IE-GHG022. The site M+T system and the Gas Networks Ireland telemetry system alerts for loss of data from the meters, this ensures that any meter issue is resolved within 48 hours. The historical data available on gas usage from the site M&T system allows for a very close estimation of fuel usage during the meter down time. Any breakdown of equipment or loss of data will be treated onsite as an environmental incident and is captured and tracked as per WAT_SOP-000162 (HSE Accident, Incident and observation reporting and Investigation).

Post or department responsible for the procedure and for any data generated	HSE Department
Location where records are kept	Electronic HSE driveQ:/EU ETS and Entropy HSE system
Name of IT system used	Genzyme IT
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	Greenhouse Gas Monitoring Procedure
Reference for procedure	WAT SOP_000141
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Genzyme Ireland Ltd has two meters for measuring the quantity of natural gas consumed at IDA Industrial Estate, Old Kilmeaden Road, Waterford. These are meter 83048537 or equivalent and meter 83049816 or equivalent

and are the property of Gas networks Ireland. These meters are accurate to less than ± 2% and measure in m³/hour. Certificates for the calibration of these meters (issued by Gas networks Ireland) are kept by HSE. Diesel is delivered to Genzyme Ireland Ltd and the quantity delivered is measured using a Liquid Fuel Meter on oil company delivery vehicles. Certificates for the calibration of these meters (issued by diesel vendor) are kept by HSE. Butane and acetylene is delivered to Genzyme Ireland LTD in gas cylinders from external vendors.

Post or department responsible for the procedure and for any data generated HSE Department
 Location where records are kept Electronic HSE drive Q:/EU ETS
 Name of IT system used Genzyme IT
 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 Greenhouse Gas Monitoring Procedure
 Reference for procedure WAT SOP_000141
 Diagram reference N/A
 Brief description of procedure. The description should cover the essential parameters and operations performed All documentation relating to the Greenhouse Gas Permit, including fuel bills, data compilation/calculation sheets, final reports will be filed in a dedicated EU ETS Folder. This folder will be filed chronologically and held for at least 10 years in accordance with Article 66 and Annex IX of the Monitoring and Reporting Regulation.
 Post or department responsible for the procedure and for any data generated HSE Department
 Location where records are kept Electronic HSE drive Q:/EU ETS
 Name of IT system used Genzyme IT
 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? Yes

The standard to which the Environmental Management System is certified: ISO 14001

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>Greenhouse Gas Monitoring Procedure</p> <p>WAT SOP_000141</p> <p>N/A</p> <p>An annual review of the Monitoring plan will be carried out as part of the annual GHG requirements with the external verifier. A review will also be undertaken in the event of one of the following:1.Changes to metering equipment; 2. New emission points or changes to existing emission points; 3. New source streams or changes to existing source streams; 4. Changes to EU/EPA requirements and 5. Changes to the capacity, activity level and operation of the</p>
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installation.

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 under Commission Decision 2011/278/EC using Tool 1 and Tool 2b of the template provided by the Commission . If it is determined that there has been a change in capacity or activity level in that year, the template is filled in by the responsible person and submitted by the Operator to the EPA by 31 December each year in accordance with Article 24(1) of the Commission Decision 2011/278/EC.

Post or department responsible for the procedure and for any data generated HSE Department
 Location where records are kept HSE Drive Q:/EU ETS
 Name of IT system used Genzyme IT

13. Abbreviations

II. Abbreviations Acronyms or definitions

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

Abbreviation	Definition
FF	Fill/Finish Facility
SD	Solid Dose Facility
OD	Oral Dose Facility

14. Additional Information

Any other information:

Attachment	Description
100212 Genzyme Tableting Metering Summary 2016.pdf	SD Tableting Meter Details
ES-106-10.pdf	WAT_SOP-000141 GHG Monitoring and Measuring Procedure

Attachment	Description
FF Generators S2-3 and S2-5.pdf	FF Generators
FF Emergency Generator S2-3& S2-5.jpg	FF Emergency Generator
SD Boiler 2 Hoval ST 1500 S2-2.pdf	SD Boiler 2 Technical Information
SD Boiler 1 Max-3+plusTTE+Technical+Information.pdf	SD Boiler 1 Technical Information
Thermal Input Capacity overview.xlsx	Thermal Input Capacity Overview
GNI Acceptance test certificate documentation.pdf	NG-001 Gas Turbine Meter Serial Number 83048537

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.