Annual Environmental Report (AER)

2022

Company Name: Novartis Ringaskiddy Limited

Licence Number: P0006-04

Address: Ringaskiddy, County Cork, P43 FR63

Class of Activity[1]:

Paragraph: 5.16

Description: The production of pharmaceutical products including intermediates (production means the production on an industrial scale by chemical or biological processing).

Paragraph: 11.2 (c)

Description: Disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving blending or mixing prior to submission to any of the activities listed in paragraph 11.2 or 11.3

[1] See Appendix I

Purpose of this Report

One of the functions of the Environmental Protection Agency (EPA) is to licence and regulate the activities[2] of large scale industrial (e.g. chemical, food processors, power plants) and waste facilities. Submitting an Annual Environmental Report (AER) is a requirement of all EPA licences.

An AER is a public document. To this end, this format has been developed for industrial and waste licence holders (other than the intensive agriculture sector) to use as a template. This is to assist any member of the public to interpret and understand the environmental performance of the licensed facility.

The AER is a **summary** of environmental information for a given year. It includes:

- Details of the licence holder's environmental goals achieved, goals to maintain compliance and/or improve their environmental performance;
- Answers to questions regarding their facility's activities;
- Tables of results from monitoring emissions such as air, water, noise, and odour; and
- Details of waste generated, accepted and treated.

An AER does **not** provide detailed technical data. Such information is available in three ways:

1) Contacting the licence holder directly. The Contact Us section of this template enables the licence holder to provide details of where a member of the public can obtain further information on topics reported in this document.

[2] See Appendix I

2) Some documents[3] are available on the EPA website via the licence details page for each individual licence. This can be found by browsing either the http://www.epa.ie/licensing/ or http://www.epa.ie/enforcement/ pages of the EPA website.

3) All formal enforcement correspondence exchanged between the EPA and a licence holder during the regulatory process is available for public viewing by appointment at any EPA Office.

If you have a question or query about an AER or an individual EPA licensed facility see the EPA's website or contact the relevant EPA office. See http://www.epa.ie/about/contactus/ for contact details.

[3] This includes EPA site inspection and compliance monitoring reports, licence holders' self-monitoring reports, AERs and special reports

Contents

Glossary

Abatement Equipment	Technology used to reduce pollution
AER	Annual Environmental Report.
Beyond Compliance	Beyond compliance is concept to help deliver greater organisational performance and long-term value for the environment, society and the economy.
CRAMP	Closure, Restoration and Aftercare Management Plan.
ELRA	Environmental Liability Risk Assessment.
Emission Limit Value	Limits set for specified emissions, typically outlined in Schedule B of an EPA licence.
EMS	Environmental Management System.
Environmental Goal	An objective or target set by a licensee as part of an environmental management system (EMS).
Environmental Pollutant	Substance or material that due to its quantity and/or nature has a negative impact on the environment.
Facility	Any site or premises that holds an EPA industrial or waste licence.
FP	Financial Provision.
GJ	Giga joules, an international unit of energy measurement.

Groundwater	All water which is below the surface of the ground in the saturation zone and in direct contact with the ground or subsoil.
Incident	As defined by an EPA industrial or waste licence.
Inert Waste	Is waste that will not undergo physical, chemical or biological change thereby, is unlikely to cause environmental pollution or harm human health.
List of Wastes (LoW)	A list of wastes drawn up by the European Commission and published as Commission Decision 2014/955/EU.
Noise Sensitive Location	Any dwelling house, hotel or hostel, health building, educational establishment, place of worship or entertainment, or any other installation or area of high amenity which for its proper enjoyment requires the absence of noise at nuisance levels.
Non-Renewable Resource	A resource of economic value that cannot be replaced at the same rate it is being consumed e.g. coal, peat, oil and natural gas.
Oil Separator	Separator system for light liquids (e.g. oil and petrol).
PRTR	Pollutant Release and Transfer Register.
Renewable Resource	Wind, solar, aerothermal, geothermal, hydrothermal and ocean energy, hydropower, biomass, landfill gas, sewage treatment plant gas and biogases.
Sanitary Waste	Waste water from toilet, washroom and canteen facilities.

Storm Water	Rain water run-off from roof and non-process areas.
Surface Water	Lakes, rivers, streams, estuaries and coastal waters.
Trigger Level	A value set for a specific parameter, the achievement or exceedance of which requires certain actions to be taken by the licence holder.
Volatile Organic Compounds	Gases produced from solids or liquids that evaporate readily in ambient conditions.
Waste	Any substance or object which the holder discards or intends or is required to discard.

Disclaimer

These are **not** legal definitions. Legal definitions can be found in the corresponding legislation.

Declaration

I, Vincent Boyton (Environmental Services Manager), confirm that by ticking the box below, all information in this report is truthful and accurate to the best of my knowledge and belief.

In addition, I confirm that all monitoring and performance reporting required by our EPA licence and summarised herein is available for inspection by the EPA.

Tick here Yes

1) Introduction

See below a brief description of our facility and a summary of our environmental performance this year.

Novartis Ringaskiddy Limited currently employs approximately 373 associates and manufactures a wide range of speciality drug substances used in the treatment of respiratory, immunologic, cardiovascular, oncological and central nervous system diseases. The end products are exported worldwide to formulation and packaging plants, for incorporation into forms suitable for the end user (tablet, phial, etc.).

The overall environmental compliance of Novartis Ringaskiddy Limited in respect of the imposed licence conditions was greater than 99.99 % during the period from January 2022 to December 2022 (inclusive). One reading out of a total of more than 181,000 was judged to be in non-compliance and was reported to the Environmental Protection Agency. This non-compliance was judged to be a minor deviation and did not present the potential for having an adverse effect on the local environment.

Contact Us

If you have any questions or would like further information on any aspect of our licensed activity, please contact us directly.

See below details:

Health, Safety and Environment (HSE) Support Unit,
Novartis Ringaskiddy Limited,
Ringaskiddy,
County Cork,
P43 FR63
Telephone 021 4862000

2) How we Manage our Facility

Environmental Management System

Explanation
To ensure our facility's activities do not cause environmental pollution we are required to have detailed documentation systems in place to help us manage and track our environmental performance. These systems are referred to as Environmental Management Systems (EMS). We review our EMS every year and set up-to-date **environmental goals** to continually improve our environmental performance.

The information below sets out the environmental goals for our facility to help us prevent environmental pollution and reduce our impact on the environment. Target dates for completing each goal and progress towards achieving the goal are outlined in Table 1.

Table 1 Environmental Goals

Environmental Goal	Target Date	Progress
Climate 2025 Target: Become carbon neutral in our own operations (Scope 1 and 2).	31-Dec-2025	The interim 2022 goal was to reduce total energy consumption (natural gas and electricity) by 2% compared to 2021 (2021 actual 19,972 GJ/month giving a target of 19,572 GJ/month. The average energy consumption during 2022 was 19,075 GJ per month (natural gas and electricity only), which was ahead of target.

Water Resources 2025 Target: Reduce water consumption in our operations by half vs 2016, with no water quality impacts from manufacturing effluents.	31-Dec-2025	The interim 2022 goal was to fully implement the use of the new tertiary treatment module, which was added to the Wastewater Treatment Plant. This was successfully undertaken with significant reductions in the emissions of biosolids, the associated Chemical Oxygen Demand (COD) and residual nutrients such as Nitrogen and Phosphorus.
Waste 2025 Target: Eliminate polyvinyl chloride (PVC) in packaging and reduce waste disposal by half versus 2016 levels.	31-Dec-2025	The interim 2022 goal, which was met, was to 1. Reduce total operational waste by 2% from 711 t/month in 2021 to 696 t/month in 2022; and 2. Reduce total non-recycled operational waste by 2% from 182 t/month in 2021 to 175 t/month in 2022 The average total operational waste generated during 2022 was 410 t/month; and The average total of non-recycled operational waste generated during 2022 was 135 t/month. Both figures reflect reduced production activity during 2022; and the latter figure also reflects higher shipments of slow and non-moving stock.

Add rows as necessary

Comment

Environmental goals and targets are set within the Novartis Corporate HSE five- and ten-year programmes between 2021 and 2025; and 2021 and 2030 respectively.

The company's Environmental Management system is certified to ISO14001:2014

The most recent ISO14001 recertification audit was undertaken during November 2022. No non-conformances were noted and four opportunities for improvement were identified, all of which were followed up on. The outcome was that certification was confirmed for the period 09-Jan-2023 to 09-Jan-2026, with two annual surveillance audits scheduled.

Beyond Compliance

Explanation
We are legally required to comply with our environmental licence. However, the EPA realise that some sites go further than just complying with their environmental licence requirements. Some projects carried out at facilities can have long-term positive impacts on the environment and local communities.
The EPA's beyond compliance initiative is encouraging us to identify and report on these environmental and sustainability projects. For example, the project could involve renewable energy, biodiversity, water conservation or exemplar community engagement.

Did any project completed on your site in the reporting year go beyond your licence requirements?

Yes [Yes] No [ ]

If yes, provide details of one case study in Appendix III that demonstrates how the project went beyond compliance of your licence.

3) Energy & Water

Energy

Explanation
Fossil fuels such as coal, gas and oil are non-renewable resources. As a result, our EPA licence requires that we measure our energy use and set targets to improve the energy efficiency of our activities and reduce our overall use, where possible. Where we have the means and technology on-site to generate energy, this is also captured in this report.

The information below summarises the energy used this year compared to the previous year and includes renewable and non-renewable energy types.

Table 3 Energy Used

Energy Used	Quantity (GJ)	% Increase/ decrease on previous year
Electricity	129,050	8% decrease
Heavy Fuel Oil	N.A.	N.A.
Light Fuel Oil	723	11% decrease
Natural Gas	106,132	1% increase
Coal / Solid Fuel	N.A.	N.A.
Peat	N.A.	N.A.
Renewable Biomass	N.A.	N.A.
Renewable Energy Generated On-site	68,441	13% increase
Total Energy Used	304,346	< 1% decrease

Comment

There was a very marginal decrease in the overall amount of energy used at the facility when 2022 is compared to 2021. However, proportionately more solvent waste was incinerated on site with heat recovery (in the form of steam for heating), which was up by 13% and which helped displace the use

of both natural gas and electricity. Also of note was the 8% reduction in the use of electricity at the facility, which was due to both the implementation of conservation initiatives; together with a reduced level of production at the facility in 2022.

The information below summarises the energy we generated on our site this year with specific focus on renewable energy generation.

Table 4 Energy Generated

Energy Generated	**Quantity (GJ)**	**% Increase/ decrease on previous year**
Renewable Energy	N.A.	N.A.
Total Energy Generated	N.A.	N.A.

Comment

This section is not applicable as Table 2 captures the energy inputs that were required in 2022 to operate the facility.

Water

Explanation
Water is a natural resource and we are required by our EPA licence to identify ways to reduce our use where possible. Water used in industry can be extracted from groundwater, rivers and lakes (surface water), taken from public water supplies (Irish Water), recycled from the facility's processes or harvested from rainwater.

The information below summarises and compares the quantity of water used this year compared to the previous year.

Table 5 Water Used

Source of Water Used	Quantity (m^3/year)	% Increase/ decrease on previous year
Groundwater	0	N.A.
Surface Water	0	N.A.
Public Supply	265,493	6% increase
Recycled Water	0	N.A.
Rainwater	0	N.A.
Total Water Used		

Comment

Overall consumption of water has not varied significantly between 2015 and 2022 and is typically of the order of 250,000 m3/annum. The increased consumption in 2022 most probably reflects a much greater degree of equipment cleaning activity than the previous year; and also additional water required to support the incineration of solvent waste with heat recovery. Additional metering is due to be implemented in 2023 with a view to having greater visibility on the internal consumption patterns across the site.

4) Environmental Complaints

Explanation
Our EPA licence requires that activities do not cause environmental nuisance such as odour, dust or noise. Our licence also requires that we have procedures in place to record, investigate and respond to environmental complaints if or when they arise.
We have an environmental complaints procedure in place where you can contact us[4] directly. You can also contact the EPA[5] if you wish to make an environmental complaint, confidentially or not.

See the information below for a summary of **all** the environmental complaints relating to our activities made directly to us and to the EPA this year.

Table 6 Summary of All Environmental Complaints Received in

Type of Complaint	Number of Complaints	Number Closed
Odour / Smells		
Noise	1	1
Dust		
Water Quality		
Air Quality		
Waste		
Litter		
Vermin/Flies/Birds		
Soil Contamination		
Vibration		
Other		

[4] See Section 1, Introduction – Contact Us

[5] If you wish to contact the EPA to make an environmental complaint about an EPA licenced facility, please go to https://lema.epa.ie/complaints

Comment

The company received one complaint, which was related to noise. There was no unusual noise from the facility at the time, nor noise of a tonal nature. A full follow up was undertaken and the complainant updated. The annual site noise survey was completed on 01-Mar-2022 and 11-Mar-2022, which indicated continued compliance with the requirements of the company's Industrial Emissions Licence.

A query was also received in relation to odours in the Ringaskiddy area but this was not related to this facility (person enquiring was upwind of the facility at the time in question). Another query was received in relation to alleged pest control in the managed landscape part of the site. The company was happy to confirm that no such activities take place in these publically accessible areas.

5) Environmental Incidents

Explanation
It is our responsibility as an EPA licensed facility to ensure we have systems in place to prevent incidents that have the potential to cause environmental pollution. If an incident occurs, we are required to report it to the EPA, investigate the cause and fix the problem.
The EPA classify environmental incidents into 5 categories based on the potential impact on the environment:

- Minor
- Limited
- Serious
- Very Serious
- Catastrophic

See Table 7 for the number of the environmental incidents we reported to the EPA this year.

Table 7 Number of Environmental Incidents

Incident Category	Minor	Limited	Serious	Very Serious	Catastrophic
Abatement Equipment Offline	0	0	0	0	0
Breach of Ambient ELV	0	0	0	0	0
Breach of Emission Limit	1	0	0	0	0
Explosion	0	0	0	0	0
Fire	0	0	0	0	0
Monitoring Equipment Failure	0	0	0	0	0
Odour	0	0	0	0	0
Spillage	0	0	0	0	0
Breach of trigger Level	0	0	0	0	0
Uncontrolled Release	0	0	0	0	0

Incident Category	Minor	Limited	Serious	Very Serious	Catastrophic
Other	0	0	0	0	0

Comment

The overall environmental compliance of Novartis Ringaskiddy Limited in respect of the imposed licence conditions was greater than 99.99 % during the period from January 2022 to December 2022 (inclusive). One reading out of a total of more than 181,000 was judged to be in non-compliance and was reported to the Environmental Protection Agency. The non-compliance was judged to be a minor deviation and did not present the potential for having an adverse effect on the local environment.

The reported incident related to the quality of the treated effluent as discharged from the company's Wastewater Treatment Plant. One deviation for Total Suspended Solids was notified. This was of a short-term nature with no adverse environmental consequences noted. Corrective actions were instigated at the time of the incident; and preventative actions were put in place following an investigation of the incident.

6) Our Environmental Emissions

Explanation
We are required to ensure the emissions from our activities do not cause environmental pollution.
We are required to monitor any of the following emissions that we make:

- Storm water
- Waste water
- Air
- Groundwater
- Noise

We regularly test any such emissions for specific pollutants and materials to ensure they do not contain levels of pollution that exceed emission limit values (ELVs) or cause environmental pollution. If monitoring of an emission indicates an ELV is exceeded, we are required to report this to the EPA[6].

The next sub-sections of this report summarise our compliance with any ELVs set in our EPA licence. Some emissions monitored do not have specific ELVs, but we still carry out monitoring and report all incidents that may give rise to environmental pollution.

[6] See section 5, Incidents

Storm Water

Explanation
Storm water is rain water run-off from roof and non-process areas of a facility, e.g. carparks, and generally shall not contain any pollution.
Storm water is usually released into a local water body after a basic form of treatment. Our EPA licence requires that we manage storm water to ensure no polluting substances or materials are released into the environment.

The information below summarises how the storm water from our facility is treated, where it is released and the results of monitoring this year.

1. **Storm water from our facility is managed prior to release by;**

The storm water is routed to one continuous monitoring point, which discharges into one of two compartments of the company's storm / fire water retention pond. The discharge from the operational compartment is automated and only allows discharge if the parameters listed on table 7 are within specification. Any quarantined storm water can be transferred directly to the company's wastewater treatment plant if necessary.

2. **Storm water from our facility is released into the following water bodies:**

The storm water is discharged to a local Cork County Council storm sewer, which in turn discharges into the nearby Owenboy estuary.

Table 8 Summary of Storm Water Monitoring

Parameter measured	No. of Samples	% Compliant[7]	Comment
pH	Continuous measurements	100%	N.A.
Total Organic Carbon (TOC)	Continuous measurements	100%	N.A.

Add rows as necessary

Comment

There were no surface water discharges from the facility that exceeded the warning (trigger) or action limits in 2022.

[7] % compliant = [(number of samples compliant) / (number of samples taken)] x 100. Compliance could refer to emission limit values or trigger levels. The EPA commonly use trigger levels on stormwater discharges.

Waste Water

Explanation

There are two types of waste water that can be produced:

- Process waste water produced from the activities and;
- Sanitary waste water from toilets, washrooms and canteens.

Our EPA licence requires us to manage our waste water on or off-site and ensure that it does not cause environmental pollution when discharged into the environment.

The information below summarises how we treat the waste water produced from our activities, where it is released and the results of monitoring this year.

1. **Waste water produced by our activities is treated as follows before discharge to a receiving waterbody**;

The company operates an enclosed biological wastewater treatment plant. The pH of the wastewater is corrected prior to biological treatment. The excess biological material that is produced as part of the treatment process is removed prior to discharging treated effluent. Tertiary treatment of the effluent has been incorporated since 2021. Any off-gases and vapours arising in the process are captured and routed for thermal treatment on-site. The excess biological material undergoes an aerobic digestion process followed by dewatering. The dewatered material is shipped for thermal treatment off-site.

2. **Treated waste water from our facility is released into the following water bodies:**

The company's treated effluent is discharged to an industrial sewer, which was installed by the Irish Industrial Development Authority (IDA). The sewer, which is also used and maintained by Irish Water, discharges in deep water at the Dognose Bank in Cork Harbour.

Table 9 Summary of Waste Water Monitoring

Parameter measured	No. of Samples	% Compliant	Comment
Total Suspended Solids	365	>99%	One minor deviation
Chemical Oxygen Demand	365	100%	N.A.
Biological Oxygen Demand	16	100%	N.A.
Total Nitrogen	365	100%	N.A.
Total Phosphorus	365	100%	N.A.
Ammonium Nitrogen	365	100%	N.A.
Nitrate Nitrogen	365	100%	N.A.
Conductivity	365	100%	N.A.
pH	Continuous	100%	N.A.
Toxicity	3	100%	N.A.
Copper	12	100%	N.A.
Zinc	12	100%	N.A.
Chromium	12	100%	N.A.
Nickel	12	100%	N.A.
Flow	365	100%	N.A.
Volatile Organic Compounds	4	100%	N.A.
AOX	12	100%	N.A.

Add rows as necessary

Comment

Most results that were recorded in 2022 were significantly below the licence limits. The one minor deviation that was reported to the EPA was of a short-term nature. The underlying treatment efficiency of the biological section of

wastewater treatment was not affected during this time. There were no adverse environmental consequences.

Also of note was the issue of a revised Industrial Emissions Licence in October of 2021, which significantly reduced the discharge limits for many parameters in addition to including new parameters; and increasing the test frequency for many parameters. A tertiary treatment module was installed at the Wastewater Treatment Plant to ensure on-going compliance with the new requirements. 2022 was the first full year of operation under the revised licence.

Air

Explanation
Generally, three types of air emissions are monitored from industry in Ireland: gases, dust (particulates) and odour. Our EPA licence requires us to ensure that any air emissions from our activities do not cause air pollution or create an odour nuisance.

The information below details the number of air emission points we monitor, the results from testing the air emissions and any odour assessments carried out by us and the EPA this year.

1. We monitor air emissions from the following number of emission points at our facility.

Emission Point Reference Number 04 (Liquid Vapour Incinerator) Operating continuously during 2022.
Emission Point Reference Number 03 (Solid Waste Incinerator) This unit was not operated during 2022.

Table 10 Summary of Air Emissions Monitoring

Parameter measured	No. of Samples	% Compliant	Comment
Carbon Monoxide	67,971	100%	Continuously monitored
Sulphur Dioxide	17,244	100%	Continuously monitored
Nitrogen Oxides	17,418	100%	Continuously monitored
Total Organic Carbon	17,141	100%	Continuously monitored

Hydrochloric Acid	17,184	100%	Continuously monitored
Total Particulates	17,567	100%	Continuously monitored
Hydrogen Bromide	4	100%	Sampled quarterly
Hydrogen Fluoride	4	100%	Sampled quarterly
Dioxins	1	100%	Sampled annually
Metals	1	100%	Sampled annually
Flow	17,838	100%	Continuously monitored

Add rows as necessary

Comment

Emissions of all licensed parameters were substantially below the relevant emission limit values.

Table 11 Summary of Odour Assessments Carried Out

Assessment Conducted By	No. of Odour Assessments	% Compliant[8]	Comment
Licence Holder	0	N.A.	N.A.
EPA	0	N.A.	N.A.

Add rows where necessary

Comment

The Novartis Ringaskiddy Limited facility has central thermal treatment for all process related activities generating off-gases and vapours – the Liquid Vapour Incinerator. This permits accurate, and in many cases continuous, monitoring of emissions from the facility to the environment. Of further special note in this context is the fact that the wastewater treatment plant is fully enclosed and that the air used in the treatment of wastewater is subsequently used as the combustion air for the incinerator. The Tank Farm where bulk solvent is stored is also connected to the vent network of the Liquid Vapour Incinerator. The concept dramatically reduces emissions and avoids odours, which are generally not noticeable in the external areas of the facility.

[8] A compliant odour assessment is based on EPA Odour Impact Assessment Guidance available at Air Enforcement | Environmental Protection Agency (epa.ie)

Fugitive Solvent Emissions

Are you required to monitor fugitive solvent air emissions from your facility?

Yes ☐ No ☐

Explanation
The use of solvents is regulated under Irish and European Union (EU) Regulations[9]. Solvents are chemicals that, by their nature, are volatile (evaporate readily under ambient conditions). Solvents can be found in many inks, glues and cleaning agents. Due to the volatility of solvents, some emissions may be released into the atmosphere during our activities before being captured in our air treatment system. This type of emission is called a **fugitive solvent emission**.

The information below summarises the quantity of solvents used this year, the percentage of fugitive solvent emissions (% of total quantity used) and whether the percentage complied with the targets set in the EU Regulations.

Table 12 Summary of Fugitive Solvent Emissions

Quantity of Solvents Used (Kg)	% Fugitive Solvent Emissions	Compliant
5,704,960	0.4%	Yes.

Comment

The requirement in the company's Industrial Emissions Licence to monitor fugitive emissions of solvents, is a relatively new one since P0006-4 was issued in October 2021. The company operates has central thermal treatment for all process related activities generating off-gases and vapours, which significantly reduces the potential for generation of fugitive emissions.	

[9] See Annex VII of the Industrial Emissions Directive
https://ec.europa.eu/environment/industry/stationary/ied/legislation.htm

This system includes the solvent bulk storage facility (Tank Farm) and also the main modules of the Wastewater Treatment Plant in addition to the production buildings. A fugitive emissions programme for the facility was agreed a number of years ago with the EPA and implementation has minimised fugitive losses. The figure quoted on Table 12 is based on measured values of the main bulk solvents in use at the facility during 2022. An additional approach to fugitive emissions assessment is to be trailed in 2023 to meet the new requirements of the revised IE Licence, in particular Schedule C.1.2 This will involve the use of optical gas imaging; and will complement the existing monitoring program.	

Groundwater

Explanation
Groundwater is an important and sensitive resource in Ireland. Our EPA licence requires that we monitor groundwater to ensure our activities do not cause groundwater pollution.
Understanding how groundwater flows through soil and rock layers and eventually into surface and coastal waters is a complex science. Sometimes groundwater pollution that occurred in the past can take years and even decades to disappear. Therefore, it is important that experts help us monitor and interpret results from groundwater monitoring and testing.

The information below is a basic summary of the condition of the groundwater this year.

1. **Do you have a groundwater monitoring programme in place?**

Yes [Yes] No [ ]

2. **Have the groundwater monitoring results over the last 5 years indicated the presence of groundwater pollution?**

Yes [ ] No [No]

Table 13 List of Groundwater Pollutants Identified

Pollutants
No groundwater pollutants identified.

Add rows as necessary

3. Give details of the investigations and subsequent actions taken, where applicable, to manage the groundwater pollution.

No action needed as there are currently no identified groundwater issues of concern.

Comment

The company's hydrogeological consultants completed a Stage 1 hydrogeological assessment of facility using groundwater monitoring data from March 1995 and from 2013 to 2020 in order to evaluate the current groundwater quality underlying the site.

The subsequently developed a Conceptual Site Model (CSM) for the site which shows the site is underlain by a varying thickness of glacial till, which overlies Cork Group mudstones and sandstones to the north of the site and karstified Waulsortian limestone to the south of the site (both of which are classified as locally important aquifers). The depth to groundwater at the site is generally between 10m and 20m below ground level.

The CSM does not highlight any clear Source-Pathway-Receptor linkage which would lead to a worse than low risk classification for the site. While there are potential sources of contamination on the site, there are adequate mitigation measures in place to act as a barrier to groundwater pollution, breaking the pathway link.

This outcome was confirmed in both the 2021 and 2022 groundwater monitoring reports.

Noise

Explanation
Our EPA licence requires that we monitor noise emissions from our facility. Noise monitoring can be conducted at the boundary of our facility and/or at locations beyond the boundary referred to as “noise sensitive locations”. Noise monitoring requires the use of special noise monitoring equipment. Our EPA licence requires that noise produced by our facility shall not exceed the noise limit values and/or give rise to nuisance.

The information below gives a summary of when and where we conducted noise monitoring this year and if results complied with our EPA licence limits.

1. **We conducted noise monitoring on the following dates this year:**

Daytime monitoring was carried out on Tuesday 01-Mar-2022. Evening and night-time monitoring was undertaken later that day. The evening measurement at monitoring location N5 was carried out Friday 11-Mar-2022.

2. **Where was the noise monitoring carried out?**
   - i. **the boundary of our facility;**
   - ii. **noise sensitive locations off-site; or**
   - iii. **both.**

At the boundary of the facility at five reference monitoring points, which are used on an annual basis.

3. **Were measured noise levels compliant with your EPA licence limits?**

Yes [Yes] No [ ]

If No, we took the following actions to address the noise level exceedances?

Not Applicable.

Comment

At all five monitoring stations, site-specific noise levels throughout the daytime survey were significantly less than the 55 dB daytime limit specified in licence P0006-04. Evening and night-time levels were less than the respective 50 and 45 dB limits. No audible impulsive or tonal emissions were noted. Facility emissions were continuous, steady and broadband in character.

7) Waste

Waste Generated

Explanation
Our EPA licence requires us to manage the waste we generate in a manner that does not cause environmental pollution.
We manage, store and record hazardous, non-hazardous and inert waste we generate in accordance with our licence. We ensure that this waste is subsequently treated or disposed of in accordance with the relevant waste Regulations.

The information in Table 14 is a summary of waste we generated this year and the percentage increase or decrease on the previous year. The percentage recovery is the amount of total waste generated that was reused, recycled or recovered.

Table 14 Waste Generated

Type	Quantity (Tonnes)	% Increase/ decrease on previous year	% Recovery
Hazardous	8,033.98	32% decrease	82%
Non-Hazardous	562.90	14% decrease	97%
Inert	N.A.	N.A.	N.A.
Total Tonnes	8,596.88	31% decrease	83%

Comment

There was a reduction of approximately 3,856 tonnes of waste generated when 2022 is compared to 2021. This reflected a decrease in production activity at the facility, a trend that is expected to continue into 2023. A significant quantity of the waste material that was generated was reused or

recycled – approximately 82% of all waste arising, which was in keeping with previous years (and up on the figure of 74%, which was reported for 2021).

Waste Accepted

Did you accept waste onto your facility for storage, treatment, recovery or disposal this year?

Yes [ ] No [No]

Explanation
Our EPA licence requires us to manage the waste we accept in a manner that does not cause environmental pollution.
We manage, store and record all incoming and outgoing hazardous, non-hazardous and inert waste. The waste we accept may be treated, recovered, disposed or stored at our facility depending on our licence requirements.

The information in Table 15 provides a summary of waste we accepted this year and the percentage increase or decrease on the previous year. The percentage recovery is the amount of total waste accepted that was reused, recycled or recovered.

Table 15 Waste Accepted

Type	Quantity (Tonnes)	% Increase/ decrease on previous year	% Recovery
Hazardous	N.A.	N.A.	N.A.
Non-Hazardous	N.A.	N.A.	N.A.
Inert	N.A.	N.A.	N.A.
Total Tonnes	N.A.	N.A.	N.A.

Comment

Not Applicable.

8) Financial Provision

Explanation
Our EPA licence requires us to assess the risk our activities pose to the environment if we cease our activities or if an incident occurred. If we are identified as a high risk facility[10] by the EPA, we are required to put provision in place such as a financial bond or insurance to cover the cost of restoring our site to a satisfactory condition. This financial provision can then be used to cover the cost of managing the restoration or clean up should such an event occur.

1. Are you required to have an agreed financial provision in place?

Yes [Yes] No [ ]

2. What year was your Closure, Restoration and Aftercare Management Plan (CRAMP) last agreed by the Agency?

2022

3. What year was your Environmental Liability Assessment Report (ELRA) agreed by the Agency?

2023 (financial provision due for renewal at the end of April 2023)

4. Has there been any significant changes on your site since the last agreements?

Yes [ ] No [No]

If yes, have you submitted details to the EPA?

Yes [ ] No [ ] N/A [N/A]

[10] See Appendix II

Appendix I

Class of Activity

Industrial and waste facilities are classed into different sectors depending on the nature of their activity and its potential impact on the environment. The EPA Act 1992 as amended, outlines these as follows:

Class 1	Minerals and other materials
Class 2	Energy
Class 3	Metals
Class 4	Mineral fibres and glass
Class 5	Chemicals
Class 6	Intensive Agriculture[11]
Class 7	Food and drink
Class 8	Wood, paper, textiles and leather
Class 9	Fossil fuels
Class 10	Cement, lime and magnesium oxide
Class 11	Waste
Class 12	Surface Coatings
Class 13	Other Activities

[11] This reporting template is not applicable to the **intensive agriculture sector**. Their annual environmental reporting structure is different and can be found at Compliance & Enforcement: Licensees: Reporting Publications | Environmental Protection Agency (epa.ie)

Appendix II

High Environmental Risk Categories

If an industrial or waste licence falls into one of these categories it is deemed, by the EPA, as a high environmental risk. As a result, the licence holder is required to have financial provision in place. See section 8, Financial Provision.

1. Landfills
2. Non-Hazardous Waste Transfer Station
3. Incineration and Co-Incineration Waste Facilities
4. Category A – Extractive Waste Facilities
5. Upper and Lower Tier Seveso Facilities
6. Hazardous Waste Transfer Stations
7. High Risk Contaminated Land
8. Exceptional Circumstances

NOTE:

This list is subject to change.

See the link below for further information.

Compliance & Enforcement: Financial Provisions Publications | Environmental Protection Agency (epa.ie)

Appendix III

Beyond Compliance

The case study below shows how we went beyond the requirements of our licence in the reporting year.

Biodiversity Area to the Northwest of the Ringaskiddy Campus.

Novartis Ringaskiddy Limited actively manages a number of areas across the campus to optimise local biodiversity and promote pollinating and many other species. One of the lesser known ones is the Dry Meadows, which can be found on the northwest side of the site between the large concrete water tanks on the west and the Tank Farm area to the east.

In this part of the site the grassland is not subject to intensive management. Yorkshire-fog is dominant with abundant Creeping Bent and Creeping Buttercup and frequent Broad-leaved Dock, Bush Vetch, Cock's-foot, Common Knapweed, Common Ragwort, Creeping Bent, Creeping Buttercup, Curled Dock, False Oat-grass, Greater Bird's-foot trefoil and Ribwort Plantain. Cock's-foot is dominant in the strip of grassland under the electric pylons to the north.

A wide range of other species also occur with higher species diversity in the section inside the security fence, probably due to the presence of areas of disturbed ground and occasional mowing of the vegetation. Pennyroyal is quite frequent in areas of disturbed ground inside the security fence.

All of these support a thriving population of pollinating species, seed-eating birds and insect eating birds. The company’s ecologist was on-site in late 2021 to revaluate the management practices associated with this area and issued a report with recommendations, which were implemented in late 2022. The ecologist is due to return to site in the Spring of 2023, with a view to documenting the cutting patterns that are required to keep this grassland areas in an optimal state to support biodiversity.