

*This Report has been cleared for submission to the Board by Programme Manager, Marie O'Connor*

Signed: 

Date: 13/06/2019



**OFFICE OF ENVIRONMENTAL  
SUSTAINABILITY**

**INSPECTOR'S REPORT ON AN INDUSTRIAL EMISSIONS LICENCE REVIEW,  
LICENCE REGISTER NUMBER P0005-03**

**TO: DIRECTORS**

**FROM: Gavin Clabby**

**DATE: 13 June 2019**

|  |   |
|--|---|
| Licensee:  | MSD International GmbH, trading as MSD Ireland (Brinny)   |
| CRO number:  | 908472  |
| Location/address:  | Rural site located at Brinny, Innishannon, Cork   |
| Application date:  | 15 <sup>th</sup> November 2018  |
| Class of activity:   | 5.16 The production of pharmaceutical products including intermediates  |
| Category of activity under IED (2010/75/EU):   | 4.5 Production of pharmaceutical products including intermediates   |
| European Directives/Regulations relevant to this assessment are listed in the appendix of this report.   |   |
| Main CID/BREF:   | Reference Document on Best Available Techniques for the Manufacture of Organic Fine Chemicals<br>CID for common waste water and waste gas treatment/management systems in the chemical sector ((EU) 2016/902) |
| Any other relevant BREF documents/CIDs/national BAT notes are listed in the appendix of this report  |   |
| Activity description/background: <i>Manufacturing facility for biological based pharmaceutical products, vaccine products and sterile manufacturing.</i> |   |
| Additional information received:   | Yes (Unsolicited information: 4 April 2019, 5 April 2019)   |
| No of submissions received:  | None  |
| EIS submitted: Yes   | NIS submitted: No   |
| Site visit: 20 May 2019  | Site notice check: 14 December 2018   |

## 1. Activity description/background

MSD Ireland (Brinny) (hereafter referred to as MSD Brinny or the licensee) is a manufacturing installation for biopharmaceutical products (for oncology, hepatitis C and rheumatoid arthritis) located approximately 6 km north of Bandon, and just north of Ballinacurra Bridge in the townland of Brinny.

MSD Brinny has applied for a review of its existing IE licence (P0005-02) to accommodate three new main emission points to air. The new emission points are due to changing manufacturing operations from a single fermentation process to a multi-product fermentation process. This change in manufacturing process mainly involves retrofitting existing internal building structures to allow for these new processes. A change to the site boundary is also proposed to accommodate any future development at the site.

## 2. Scope of Review

| Proposed change     | Details/comment   |
|---------------------|---|
| Site related change | Extension of site boundary to accommodate future development of the MSD Brinny site. The extension of the site boundary only includes areas which have previously been granted planning permission. |
| New emission points | Three new process emission points to air  |

## 3. Licence History

| Licence                   | Details   | Date              |
|---------------------------|---|-------------------|
| P0005-01                  | Original IPC licence issued.  | 7 April 1995      |
| P0005-01 TA(A)            | Technical Amendment in relation to decommissioning and residual management  | 17 October 2005   |
| P0005-02                  | Agency-initiated revision of IPC Licence Reg. No. P0005-01 in light of the European Communities Environmental Objectives (Surface Water) Regulations 2009 and the European Communities Environmental Objectives (Groundwater) Regulations 2010. | 8 October 2012    |
| P0005-02 IE amendment     | IE Amendment to bring it into conformity with the Industrial Emissions Directive (IED) (2010/75/EC).  | 18 December 2013  |
| P0005-02 Licence transfer | Licence transferred from Schering-Plough (Ireland) Company, to MSD International GmbH, trading as MSD Ireland (Brinny).   | 29 September 2016 |
| P0005-02 TA(A)            | Technical Amendment in relation to the removal of emission point ref: A1-2 from the air emission schedule in the licence (P0005-02)   | 7 March 2017      |

## **4. Compliance and Complaints Record**

There are six complaints on record; all in relation to noise and vibration (five of these were from the same complainant, while the other was anonymous). The complaints appear to be mainly related construction activity. All six files are now closed. However, no significant non-compliance issues in relation to the operation of this installation under the current licence (P0005-02) have been recorded. All complaints, non-compliances and investigation investigations have been closed off to the satisfaction of the Agency.

## **5. Best Available Techniques**

Section 86A(3) of the EPA Act 1992 as amended, requires that the Agency to apply BAT conclusions as a reference for attaching one or more conditions to an Industrial Emissions Directive (IED) licence, or revised IED licence. Therefore, BAT for the installation was assessed against the BAT conclusions and guidance contained in the relevant Commission Implementing Decision (CID) and BREF documents specified in this report.

In the absence of any BAT associated emission levels (AELs) in a Commission Implementing Decision (CID), BAT-AELs were taken from the relevant national BAT note for the sector, or are set with regard to the sectoral BREF.

For existing installations, for which a CID on BAT conclusions is published, Article 21(3) of the IED (in relation to the main activity of the installation) requires that within four years of publication date, the EPA must ensure that 'all permit/licence conditions for the installation concerned are reconsidered, and where necessary updated' and 'ensure compliance with the BAT. There is currently no applicable CID specifically for this installation (pharmaceutical sector). There is, however, a relevant common CID which is applicable to the whole chemical sector, namely the Common Waste Water (CWW) CID (see appendix for full title). This CID was published on 30/05/2016. Therefore, the RD has been drafted to comply with certain requirements by 30/5/2020.

The assessments below demonstrate the RD will comply with all applicable BAT conclusion requirements specified in the CWW CID and will be in line with the guidance specified in the relevant BREF Documents and relevant national BAT note.

I consider that the applicable BAT conclusion requirements are addressed through the technologies and techniques as described in the application, as well as the standard conditions specified in the RD. Minor additional conditions to address BAT conclusion requirements are specified throughout the RD.

BAT associated emission levels (BAT-AELs) as specified in the CWW CID have also been included in the RD, as outlined in this report, and are applicable from 01/06/2020, or sooner where specified in the licence. The monitoring frequency of emissions to air and water has been set in the RD, in line with the CWW CID, where relevant.

## **6. Planning Permission, EIS and EIA Requirements**

### **6.1 EIA Screening**

In accordance with Section 83(2A) of the EPA Act 1992 as amended, the Agency must ensure that before a licence or revised licence is granted, that the application is made

subject to an environmental impact assessment (EIA), where the activity meets the criteria outlined in Section 83(2A)(b) and 83(2A)(c). In accordance with the EIA Screening Determination, the Agency has determined that the activity is likely to have a significant effect on the environment, and accordingly is carrying out an assessment for the purposes of EIA.

## **6.2 Planning Status**

A number of planning applications have been made by the licensee for the area within the installation boundary. Details of these planning applications and permissions have been provided in the application form.

The licensee has submitted the EIS associated with planning application 17/4830 submitted to Cork County Council on 6 April 2017 (planning granted 5 July 2017). As this EIS was submitted to the planning authority before the 2014 EIA Directive (2014/52/EU) transposition deadline (16 May 2017), the EIA for this licence application has been assessed against the previous EIA Directive (2011/92/EU).

## **6.3 Content of EIS and licence application**

I have considered and examined the content of the licence application, the EIS and other relevant material submitted with it.

I consider that the information as submitted contains a satisfactory description of the project, the alternatives studied by the licensee, the aspects of the environment likely to be significantly affected by the activity, the likely effects of the activity on the environment, the forecasting methods used, the prevention and mitigation measures envisaged, any difficulties and deficiencies encountered and a non-technical summary.

I consider that the EIS, when considered in conjunction with the additional material submitted with the application, also complies with the requirements of the *EPA (Industrial Emissions)(Licensing) Regulations 2013*.

## **6.4 Environmental Impact Assessment Directive**

Having specific regard to EIA, this Inspector's report as a whole is intended to identify, describe and assess for the Agency the likely significant direct and indirect effects of the proposed activity on the environment, as respects the matters that come within the functions of the Agency, for each of the following environmental factors: human beings, flora, fauna, soil, water, air, climate, the landscape, material assets and cultural heritage.

This Inspector's report addresses the interaction between those effects and the related development forming part of the wider project. The cumulative effects, with other developments in the vicinity of the activity have also been considered, as regards the combined effects of emissions. The main mitigation measures proposed to address the range of predicted significant effects arising from the activity have been outlined. This Inspector's report proposes conclusions to the Agency in relation to such effects.

In preparing this Inspector's report I have considered and examined:

- the application, Register Number: P0005-03 and the supporting documentation received from the licensee;
- the EIS

- the documents associated with the assessments carried out by Cork County Council related to planning application no. 17/4830, and the issues that interact with the matters that were considered by that authority and which relate to the activity.

While the environmental factors have been considered throughout my entire assessment, the following table identifies, for ease of reference, the sections of this report where each environmental factor has been predominantly discussed.

Table of Environmental Factors

| <b>Environmental Factor</b> | <b>Addressed in the following Sections:</b>   |
|-----------------------------|---|
| Human Beings                | Emissions to Air, Discharges to Water and Ground, Noise, Waste, Other matters relating to EIA |
| Flora and Fauna             | Emissions to Air, Water and Ground, Noise, Waste  |
| Soil                        | Discharges to Water and Ground  |
| Water                       | Discharges to Water and Ground  |
| Air                         | Emissions to Air  |
| Climate                     | Emissions to Air  |
| Landscape                   | Other matters relating to EIA   |
| Material Assets             | Use of Resources, Other matters relating to EIA   |
| Cultural Heritage           | Other matters relating to EIA   |

## **6.5 Consultation with Competent Authorities**

As statutory consultees under the EIA process, the Agency consulted with Cork County Council. Cork County Council, in response to the Agency, made no observations on the licence application and EIS.

## **7. Submissions**

There were no submissions made on this application.

## **8. Emissions to Air**

This section addresses the following:

- channelled emissions to air
- fugitive emissions
- Greenhouse gases and climate impact

## 8.1 Channelled Emissions to Air

The table below gives details on all main channelled emissions at the installation (either existing under current licence, or proposed in this application, including emission points planned for future instalment on some unspecified date), their location, the processes which gives rise to each emission, and whether the type of abatement is considered BAT.

There are other emission points to air at the installation which, due to their emission characteristics are regarded as minor emissions to atmosphere, and are not, therefore, considered environmentally significant.

| Main channelled emission point descriptions |                                   |                    |   |                      |           |
|---|-----------------------------------|--------------------|---|----------------------|-----------|
| Emission Reference                          | Location                          | Proposed/ Existing | Process Description   | Abatement            |           |
|   |                                   |                    |   | Description          | BAT (Y/N) |
| A1-1, A1-3, A1-4                            | Building 7, Boilers and Utilities | Existing           | <5 MW Natural gas boilers   | n/a                  | -         |
| A1-5  | Building 7, Boilers and Utilities | Existing           | 1.5 MW combined heat and power plant                                | n/a                  | -         |
| A2-1  | North of Building 18              | Proposed           | Biologics production (once-daily process venting from ammonia tank) | Water-based scrubber | y         |
| A2-2  | Building 18                       | Proposed (Planned) | Biologics production  | To be proposed       | -         |
| A2-3  | Building 13                       |                    |   |                      |           |

The following table outlines the limits for each emission point proposed as specified in the application.

| Main channelled emissions characteristics |  |                            |                           |
|---|--|----------------------------|---------------------------|
| Emission Reference                        | Parameter                                    | Limits in proposed licence | Relevant applicable limit |
| A1-1, A1-3, A1-4                          | Volumetric flow rate (Nm <sup>3</sup> /hour) | 26,000                     | -                         |
|   | NO <sub>x</sub> (mg/m <sup>3</sup> )         | 350 (up to 01/01/25)       | Limit in P0005-02         |
|   |  | 200 (after 01/01/25)       | MCP Directive             |
|   | Carbon monoxide                              | 100                        | Limit in P0005-02         |

| Main channelled emissions characteristics |   |                            |                             |
|---|---|----------------------------|-----------------------------|
| Emission Reference                        | Parameter   | Limits in proposed licence | Relevant applicable limit   |
| A1-5                                      | Volumetric flow rate (Nm <sup>3</sup> /hour)        | 4,602                      | -                           |
|   | NO <sub>x</sub> (mg/m <sup>3</sup> )                | 350 (up to 01/01/29)       | Limit in P0005-02           |
|   |   | 190 (after 01/01/30)       | MCP Directive               |
|   | Carbon monoxide (mg/m <sup>3</sup> )                | 500                        | None, proposed by licensee  |
| A2-1 <sup>Note 1</sup>                    | Volumetric flow rate (Nm <sup>3</sup> /hour)        | 20 <sup>Note 2</sup>       | -                           |
|   | Ammonia (mg/m <sup>3</sup> )                        | 10                         | BAT-AEL (national BAT note) |
| A2-2, A2-3<br>(Planned emission points)   | Volumetric flow rate (Nm <sup>3</sup> /hour)        | 200                        | -                           |
|   | Organic Substances Class II (mg/m <sup>3</sup> )    | 50                         | BAT-AEL (national BAT note) |
|   | Inorganic Substances Class II (mg/m <sup>3</sup> )  | 3                          | BAT-AEL (national BAT note) |
|   | Inorganic Substances Class III (mg/m <sup>3</sup> ) | 30                         | BAT-AEL (national BAT note) |

Note1: Pre-abatement mass emissions from proposed A2-1 process vent are calculated to exceed the BAT mass threshold of 150 g/hour; therefore, it is scheduled as a main emission in the RD, with the applicable BAT-AEL.

Note 2: 20 Nm<sup>3</sup>/hour limit is the calculated hourly flow rate, based on once-daily emission event from ammonia tank. The RD also specifies 20 Nm<sup>3</sup> as a daily limit to ensure emission occurs once daily only, as screened by the licensee.

### *Assessment*

As part of the application process, air dispersion modelling to predict the ambient pollutant concentrations resulting from main combustion emissions (A1-1, A1-3, A1-4 and A1-5) was submitted.

The modelling used was in accordance with published Agency guidance and was considered sufficiently detailed and conservative to adequately assess the impact of these combustion emissions to air.

Output data from the combustion emission modelling shows that the maximum predicted environmental concentrations (PECs) are below the relevant air quality standards (S.I. 180/2011), as detailed in the table below.

| Parameter                              | Averaging Period | PEC as % of Air Quality Standard | Air Quality Standards ( $\mu\text{g}/\text{m}^3$ ) |
|--|------------------|----------------------------------|--|
| Nitrogen Oxides<br>(as $\text{NO}_2$ ) | 99.8%ile hourly  | 31.9                             | 200  |
|  | Annual           | 51.3                             | 40   |
| CO                                     | Maximum 8 hour   | <0.1                             | 10,000   |

Also, as part of the application, air dispersion screening was carried out to determine whether there is potential for any environmental impact from the process discharges (A2-1, A2-2 and A2-3). The screening used was in accordance with published Agency guidance (which refers to UK EA H1 guidance), and was considered sufficiently conservative to assess the impact of the main emissions to air.

Output data from the process emission screening shows that the maximum ground level concentrations (GLCs) are well below the strictest environmental assessment levels (EALs) relevant to each class, as detailed in the table below.

| Parameter   | Averaging Period | GLC as % of EAL | EAL ( $\mu\text{g}/\text{m}^3$ ) <sup>Note 1</sup> |
|---|------------------|-----------------|--|
| Ammonia   | hourly           | <0.1            | 2,500  |
|   | annual           | <0.1            | 180  |
| Organic substances Class II (methyl formate)      | hourly           | 0.1             | 37,400   |
|   | annual           | <0.1            | 2,500  |
| Inorganic substances Class II (bromine)           | hourly           | 0.3             | 200  |
|   | annual           | 0.4             | 6.6  |
| Inorganic substances Class II (hydrogen chloride) | hourly           | 0.8             | 800  |
|   | annual           | 1.2             | 20   |

Note 1: Environment Agency. 2003. IPPC H1 – IPPC Environmental Assessment for BAT. Appendix D.

Considering the combustion modelling assessment above, it is unlikely that the proposed combustion emissions to air from the installation will have a significant impact on the environment. Also, considering the screening modelling completed for A2-1, A2-2 and A2-3, it is considered that there is no potential for impact from these new small process emission points.

### *Mitigation*

Emission limit values have been set in the RD, with regard to the emission rates modelled/screened by the licensee. These emission limit values are in accordance with the BAT guidance note for the sector and in compliance with the relevant legislation on emissions (MCP Directive).

In addition, the RD specifies abatement controls, monitoring requirements and other licence conditions, which will ensure the emissions to air will not negatively impact on air quality and will minimise the potential risk to human beings, flora and fauna, and air.

## **8.2 Fugitive Emissions**

Fugitive emissions at the installation arise during cleaning and sanitisation operations.

### *Assessment*

The licensee does not undertake activities listed in Chapter V (for installations using Organic Solvents) of the Industrial Emissions Directive (2010/75/EU): However, fugitive VOC emissions may occur during process operations mainly associated with cleaning, sanitisation and laboratory activities.

IPA products are used to clean the surface of equipment and parts throughout production facilities from spray bottles or from wipes. Furthermore, a series of cleaning reagents are used in solution to clean room internal surfaces. IPA spray bottles are sealed when not in use and the wipes are also stored in sealed packaging. Waste IPA packaging is stored in sealed containers for offsite disposal as per standard waste management practices at the installation. The VOC content of the cleaning reagents is low and reagents are stored in sealed containers when not in use.

A low vapour pressure organic solvent is used in a vaccine process at the installation. Fugitive emissions associated with this process are breathing losses from process vessels. These breathing losses have been estimated as 0.0001kg/hr per vessel during production. Therefore, the total VOC fugitive loss from this process is considered an insignificant quantity.

### *Mitigation*

The RD requires the licensee to maintain a programme for the identification and reduction of any fugitive emissions using an appropriate combination of best available techniques.

## **8.3 Climate Impact**

Climate change is a significant global issue which affects weather and environmental conditions (air, water and soil) which consequently affects human beings, material assets and cultural heritage, and flora and fauna. Climate change is caused by warming of the climate system by enhanced levels of atmospheric greenhouse gases (GHG) due to human activities.

### *Assessment*

The sources of emissions of climate altering substances at the installation are from the natural gas combustion plants on site. For an installation of its type and size combustion requirements are considered small (3 No. <5MW boilers and 1 No. 1.5 MW CHP).

### *Mitigation*

Regarding reducing the climate impact of the installation under IED, the RD requires an energy efficiency and use of cleaner production to be addressed as part of the Environmental Management System. It also requires an energy efficiency audit and an assessment of resource use efficiency to be undertaken in accordance with Condition 7.

### **EIA on emissions to air**

For the purposes of EIA, the environmental factors potentially affected by installation's emissions to air include: human beings, flora and fauna, and air. Based on the above assessment of the installation's emissions to air, the direct, indirect and cumulative effects have been identified, described and assessed, and are detailed in the sections below.

#### *Direct and indirect effects*

Should emission levels cause an exceedance of air quality standards, this could have implications for human health, air quality and the health status of flora and fauna beyond the site boundary.

The above assessment of the installation's air dispersion modelling and screening, as well the assessment of the installation's GHGs and fugitive emissions, indicates that the installation under normal operation is not likely to have a significant direct effect on the above environmental factors.

In addition, consideration was given to odour impacts from the installation's proposed ammonia emissions. Human's detect odour at concentrations >5ppm. However, the screening for ammonia emissions calculated that ground level concentrations of ammonia due to MSD Brinny emissions would be very low (long term 0.0082  $\mu\text{gm}^3$ , short term 0.22  $\mu\text{gm}^3$ ), and consequently, would not be detectable. Therefore, the installation under normal operation is not likely to have a significant direct effect on human health, and flora and fauna.

#### *Cumulative effects*

Regardless of whether the emissions to air from the installation, by themselves, have the potential to affect the above environmental factors, it must also be considered whether the cumulative impact with other installations/sources may have an effect.

In this assessment, consideration was given to cumulative ammonia emissions from MSD Brinny and two licensed intensive agriculture installations (P0661-10 and P0942-01) in the vicinity (5 km). However, as stated above, the screening for ammonia emissions calculated that ground level concentrations of ammonia due to MSD Brinny emissions would be very low (non-detectable using standard laboratory methods), and consequently would have a negligible contribution to cumulative ammonia emissions in the vicinity.

Other than the ammonia emissions discussed above, there are no other installations with significant emissions to air, near the proposed activity (Anglo Irish Beef Processors (P0188-02) is in the vicinity but is not permitted for significant emissions to air). Therefore, it is considered that there is not likely to be a significant cumulative effect from emissions to air from the activity and other air emissions generated by other major activities/developments in the area.

Therefore, it is considered that there is not likely to be a significant cumulative effect on air quality, or climate, from ammonia emissions to air from the activity and other ammonia emissions generated by intensive agriculture installations in the area.

*Overall conclusions in relation to effects of air emissions from the activity on the environment*

I am satisfied that there will not be significant effects on climate, air quality, human beings, flora and fauna or any other aspect of the environment from air emissions arising from the operation of the activity when operated in accordance with the conditions of the Recommended Determination.

## 9. Discharges to Water and Ground

This section addresses the following:

- Emissions to Waters
- Emissions to ground/groundwater
- Storm water discharges

### 9.1 Discharges to Waters

#### 9.1.1 Emissions to Waters

The table below gives details on the installation's direct emissions to waters; the processes which contribute to the emissions, the emission characteristics, the type of on-site treatment, and the proposed maximum daily flows, as well as details of the receiving water.

| <b>Process emissions</b>   |                     |  |   |     |   |
|--|---------------------|--|---|-----|---|
| Emission Reference   | Proposed / Existing | Process Description (and emission characteristics)   | Abatement   | BAT | Proposed max. flow  |
| SW1  | Existing            | Biopharmaceutical process emissions and sanitary effluent (pH, temperature toxicity, BOD, COD, TOC, SS, total nitrogen, ammonia, total phosphorous, zinc, copper, nickel.) | Phosphate removal, Biofiltration and extended aeration, Nitrification, Denitrification. | Y   | 800 m <sup>3</sup> /day, 70 m <sup>3</sup> /hour (a proposed increase from 50 m <sup>3</sup> /hour) |
| General comment: Proposed emission characteristics are similar to the current licence (P0005-03). However, due to process changes at the installation, trichloro acetic acid, has been removed, and nickel and copper have been added. |                     |  |   |     |   |
| <b>Details of the receiving water</b>  |                     |  |   |     |   |
| Receiving water name and code: Lower Bandon Estuary (IE SW 080 0100)   |                     |  |   |     |   |

|   |   |                                  |
|---|---|----------------------------------|
| Waterbody type: transitional (salinity near discharge point: 10.5 p.s.u.)   |   |                                  |
| WFD status: Moderate (2010-2015) (chemical status good, DO and general conditions moderate.)  | WFD risk: 1a, at risk (identified as being at risk from UWWTPs and overflows, not from IPC/IE discharges) | WFD target date: Restore by 2021 |
| WFD protected areas: Lower Bandon estuary is designated as Nutrient Sensitive Area. Shellfish waters 9 km further downstream.   |   |                                  |
| Trophic status: Potentially Eutrophic (2015-2017)   |   |                                  |
| General comment: Considering nature of discharge and the distance to the Shellfish Waters, SW1 emissions are not considered to have any potential for impact on Shellfish waters. |   |                                  |

### *Assessment of emissions impact on receiving water*

There are thirteen parameters which are considered characteristic of the installation's emissions to waters. Of these, the relevant parameters were assessed against the EO Surface Water Regulations for the purposes of a receiving water impact assessment, namely: BOD, molybdate reactive phosphate (MRP) (as total phosphorous), zinc, copper, nickel and suspended solids.

Mass balance calculations, in conjunction with Agency monitoring data, was used to determine the impact of the emission on the receiving water. The emission was modelled at the proposed limits for effluent concentration and flow.

| <b>Impact of Emissions to waters</b>  |  |   |  |  |   |
|---|--|---|--|--|---|
| <b>Parameter</b>  | <b>Background Concentration (mg/l)</b> | <b>Proposed ELVs (mg/l) (daily average)</b> | <b>Contribution from the emission (mg/l)</b> | <b>Predicted total concentration in receiving water (mg/l)</b> | <b>EQS good status (mg/l) <sup>Note 1</sup></b> |
| European Communities Environmental Objectives (Surface Waters) Regulations 2009 as amended. |  |   |  |  |   |
| BOD   | 2.0                                    | <b>25</b>                                   | 0.09   | 2.1  | 4.0   |
| Molybdate reactive phosphorous  | 0.038                                  | <b>10 (as total P)</b>                      | 0.0163                                       | 0.05   | 0.06  |
| Zinc  | 0.0342                                 | <b>0.5</b>                                  | 0.0015                                       | 0.036  | 0.04  |
| Copper  | 0.0023                                 | <b>0.05</b>                                 | 0.0003                                       | 0.0026   | 0.005   |
| Nickel  | 0.0057                                 | <b>0.05</b>                                 | 0.0002                                       | 0.0059   | 0.02  |

**Note 1:** European Communities Environmental Objectives (Surface Waters) Regulations 2009 as amended (EO Regulations).

As can be seen from table above, these emission limit values will ensure that the installation's discharges will not cause a breach of the relevant environmental quality

standards (EO Regulations). The predicted concentration for MRP is close to the EQS, but it should be noted here that modelling was completed using maximum daily average limits. Due to BAT requirements, the RD also specifies more stringent annual average limits for total phosphorous (and zinc) (see table below), thus giving further confidence that the installation's discharges will not cause a breach of the annual median MRP EQS specified in the EO Regulations.

*Assessment of emissions against BAT*

In addition, the proposed ELVs have been assessed against BAT, as detailed in the table below. BAT for the installation's discharges to waters were assessed principally against the Common Waste Water CID (CWW CID). The relevant national BAT note for the sector (see appendix) was also considered for the proposed BOD and ammonia limits.

| Parameter         |                  | Proposed ELV       | BAT-AEL    | Comment  |
|-------------------|------------------|--------------------|------------|--|
| pH                |                  | 6-9                | 6-9        | In accordance with National BAT note   |
| Temperature       |                  | 35 deg C           | n/a        | -  |
| Toxicity          |                  | 10 TU              | 5-10       | In accordance with National BAT note   |
| Parameter         | Averaging period | Proposed ELV (mg/) | BAT-AEL    | Comment  |
| BOD               | Max daily        | 25                 | n/a        | No applicable BOD limit in CWW CID. Treatment plant achieves efficiency limit set in National BAT note (>91%). |
| COD               | Max. daily       | 200                | n/a        | Compliant with CWW CID   |
|                   | Annual average:  | 100                | 100 (CID)  |  |
| Suspended solids  | Max. daily       | 35                 | n/a        | Compliant with CWW CID   |
|                   | Annual average:  | 35                 | 35 (CID)   |  |
| Total nitrogen    | Max. daily       | 25                 | n/a        | Compliant with CWW CID   |
|                   | Annual average:  | 25                 | 25 (CID)   |  |
| Ammonia (as N)    | Max. daily       | 10                 | n/a        | No applicable limit in CWW CID. In accordance with National BAT note   |
| Total phosphorous | Max. daily       | 10                 | n/a        | Compliant with CWW CID   |
|                   | Annual average:  | 3                  | 3 (CID)    |  |
| Zinc              | Max. daily       | 0.5                | n/a        | Compliant with CWW CID   |
|                   | Annual average:  | 0.3                | 0.3 (CID)  |  |
| Copper            | Max. daily       | 0.05               | n/a        | Compliant with CWW CID   |
|                   | Annual average:  | 0.05               | 0.05 (CID) |  |

|        |                 |      |            |                        |
|--------|-----------------|------|------------|------------------------|
| Nickel | Max. daily      | 0.05 | n/a        | Compliant with CWW CID |
|        | Annual average: | 0.05 | 0.05 (CID) |                        |

As can be seen from the table above the proposed ELVs for emissions to water comply with BAT for the sector. For the revised licence to be compliant with BAT, additional annual average ELVs for certain parameters above have been specified in the RD, namely: COD, total phosphorous and zinc. The remaining parameters do not have separate annual average ELVs, because either annual average BAT-AELs do not apply or else are identical to the daily limit.

In accordance with the preferred method of analysis specified in CWW CID (due to toxicity of COD reagents), the RD requires the licensee to substitute the above COD limits with a TOC ELV of 66 mg/l and a TOC annual average limit of 33 mg/l (From the CWW CID, these TOC limits are equivalent to the COD limits, based on a COD:TOC ratio of 3:1.) TOC is widely accepted as a surrogate parameter for COD. There is no receiving water EQS for COD or TOC, and therefore, no revision of the impact assessment would be required.

### 9.1.2 Storm water discharges to waters

#### *Assessment*

The table below gives details on the installation's storm water discharges to waters; the sources of potential contamination of these discharges, the type of on-site abatement (if any), as well as details of the receiving water.

| <b>Stormwater discharge point details</b>  |                     |  |                                  |
|--|---------------------|--|----------------------------------|
| Emission Reference   | Proposed / Existing | Monitored parameters (monitoring frequency)          | Trigger levels established (Y/N) |
| SW-2   | Existing            | Visual (daily); pH, temperature and TOC (continuous) | Y                                |
| <b>Drainage areas:</b> Buildings, site roads and walkways, car parks.  |                     |  |                                  |
| <b>Abatement:</b> Class I full retention interceptor for Yard 1 (Diesel loading area), Yard 2 (Standby generator and warehouse delivery). All other drainage areas connected to Class II by-pass interceptors. |                     |  |                                  |
| <b>Receiving water:</b> River Brinny   |                     |  |                                  |
| <b>Automatic diversion in place:</b> Yes. Any contamination detected by continuous TOC monitoring leads to automatic diversion to 4,000 m <sup>3</sup> retention lagoon.                                       |                     |  |                                  |

#### *Mitigation*

The RD requires the licensee to maintain its existing storm water collection system. It requires that the storm water discharge is monitored as per the table above, in accordance with Schedule C.2.3 *Monitoring of Storm Water Emissions*, and specifies

that there can be no unauthorised emission of polluting matter from the storm water drainage system.

The RD contains standard conditions in relation to the storage and management of materials and wastes. The RD also requires that accident and emergency response procedures are put in place. The controls pertaining to accidents and emergencies are addressed in the Prevention of Accidents section below. These measures will help to control any impacts which could occur should any mitigation measures fail.

## **9.2 Emissions to Sewer**

There are no process emissions to sewer at the installation.

## **9.3 Discharges to ground/groundwater**

There are no process emissions or surface water discharges to ground/groundwater at the installation.

## **EIA on discharges to water and ground**

For the purposes of EIA, the environmental factors potentially affected by installation's emissions to include: human beings, flora and fauna, and water. Based on the above assessment of the installation's emissions to water and ground, the direct, indirect and cumulative effects have been identified, described and assessed, and are detailed the sections below.

### *Direct and indirect effects*

Should emission levels cause an exceedance of Environmental Quality Standards, this could have implications for human health, water quality and the health status of flora and fauna beyond the site boundary.

The above assessment of the installation's process discharges, as well the assessment of the installation's storm water runoff, indicates that the installation under normal operation is not likely to have an effect on the above environmental factors.

In particular, the hardstanding footprint of the proposed development will further reduce the natural recharge rate to ground that is already affected by the installation's existing infrastructure. However, the installation, as part of its planning, is required to install surface run-off attenuation that is equivalent to greenfield run-off rates, thereby reducing any contribution to the risk of flooding in the River Brinny catchment.

Flora and fauna within and around the site have the potential to be indirectly effected by the proposed activity, due to potential effects on the water quality. However, the above assessments of the installation's discharges to the Bandon estuary, as well as storm water discharges to the River Brinny, indicate that water quality impacts are not likely. It is therefore considered that no secondary or indirect effects are likely because of these emissions to water and ground from the installation.

### *Cumulative effects*

Regardless of whether the discharges from the installation, by themselves, have the potential to affect the above environmental factors, it must also be considered whether the cumulative impact with other installations/sources may have an effect.

No largescale developments have been identified within proximity to the MSD installation, other than Anglo Irish Beef Processors (P0188-02) which discharges to the Bandon river. As previously identified, the Bandon estuary's WFD status is moderate. This less than good status is due to oxygenation conditions and chlorophyll. However, the WFD Transitional and Coastal Action Plan identifies the Estuary is not at risk from EPA-licensed industrial discharges. In addition, the Agency's assigned trophic status for the estuary is intermediate/potentially eutrophic, due to excess nitrogen input. This input has been identified by the Agency as coming from non-point sources (agriculture). So while there is no likely significant impact from cumulative large scale industrial discharges to the estuary, it is likely that industrial discharges in the catchment contribute to the negative nitrogen impact from agricultural sources.

Therefore, it is considered that there is likely to be a cumulative effect from the installation's discharges in combination with intensive agriculture activity. However, any significant impact would be considered to come from the agricultural sector, and that the contribution from the installation would be considered insignificant.

#### *Overall conclusions in relation to effects of water emissions from the activity on the environment*

I am satisfied that there will not be significant effects on water quality, human beings, flora and fauna or any other aspect of the environment from emissions to water and ground arising from the operation of the activity (emissions to sewer and storm water) when operated in accordance with the conditions of the Recommended Determination.

## **10. Noise**

### *Assessment*

The main sources of noise at the installation include chillers, air handling units, boiler operation and vehicular movement.

There have been six noise complaints in 2018 relating to this installation. However, these complaints have been closed to the satisfaction of the Agency. As part of enforcement action on foot of these noise complaints, the Agency carried out unannounced noise monitoring at the installation. This monitoring did not indicate any noise issues in the vicinity.

It should be noted here that the proposed change in site boundary is to accommodate potential future development at the MSD Brinny site and only includes areas with previously granted planning permission. The proposed site boundary expansion does not impact on any noise sensitive locations.

### *Mitigation*

As part of the current licence, a noise monitoring survey is carried out bi-annually at two noise sensitive receptors outside the boundary. Historical data from these surveys indicate that the installation is consistently compliant with the licence limits.

Noise propagation modelling has been used to predict worst-case impacts of noise sources from the proposed installation at nearby sensitive locations. For assessment purposes, limits specified in the Agency guidance<sup>1</sup> were used as ambient standards. The results indicate that the impact is low, and well within the standard noise emission limit values in the RD.

Standard noise conditions and emission limit values, which apply at the noise sensitive locations, have been included in the RD. In accordance with the EPA document Guidance Note for Noise: Licence Applications, Surveys and Assessments in relation to Scheduled Activities (NG4) (2016), the day time ELV has been changed from 55dB LAeq to 55dB LAr, to allow for corrections for tonal noise, and an evening time ELV has been introduced.

Furthermore, in accordance with BAT 23 of the CWW CID, the Condition 2.2 of RD requires that the licensee to maintain a schedule of targets and objectives which includes noise reduction using a combination of specified techniques.

### **EIA on noise emissions**

For the purposes of EIA, the environmental factors potentially affected by the installation's noise emissions include: human beings, and flora and fauna. Based on the above assessment of the installation's noise emissions, the direct, indirect and cumulative effects have been identified, described and assessed, and are detailed in the sections below.

#### *Direct and indirect effects*

Should emission levels cause an exceedance of the noise limits specified in Agency guidance, this could have implications for human health, and the health status of flora and fauna beyond the site boundary. Noise arising from site could have the potential to cause nuisance for those living near the activity or effect noise sensitive species near the site.

The above assessment of the installation's noise emissions indicates that, under normal operation, the installation is not likely to have an effect on the above environmental factors. The installation is in a rural area with residents but would not be considered as a designated Quiet Area as specified in Agency guidance (The town of Bandon (population ~6960) is less than the threshold distance of 10km). Ecological impact assessment carried out as part of the EIS determined there were indications of the presence of rare/protected species in the locale, but not within the site boundary or in the lands (tillage fields) immediately surrounding the installation. The EIS concluded that rare/protected species would not be affected by noise during the operational phase of the activity.

It is also considered that no secondary or indirect effects are likely as a result of noise emissions from the installation.

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<sup>1</sup> NG4 Guidance Note for Noise: Licence Applications, Surveys and Assessments in Relation to Scheduled Activities (EPA, 2016)

### *Cumulative effects*

Regardless of whether noise emissions from the installation, by themselves, have the potential to affect the above environmental factors, it must also be considered whether the cumulative impact with other installations/sources may have an effect.

Background noise monitoring undertaken as part of the application, shows that background noise levels at the sensitive receptor locations exceed the modelled noise levels from the proposed activity. Furthermore, noise contour maps from the modelling exercise indicate that noise levels at the sensitive receptors, due to the proposed activity, would be well below Agency guidance levels, and would therefore, not add to background levels to any significant amount. Therefore, it is considered that there would not likely to be a significant cumulative effect from noise emissions from the proposed activity and other noise emissions generated by other activities/developments in the area.

### *Overall conclusions in relation to effects of noise emissions from the activity on the environment*

I am satisfied that there will not be significant effects on Human Beings, Flora and Fauna or any other aspect of the environment from noise arising from the operation of the activity when operated in accordance with the conditions of the Recommended Determination.

## **11. Use of Resources**

### **Use of Resources**

#### *Assessment*

The licensee has provided a comprehensive list of resources consumed at the installation; these are listed in the application form (ref: Attachment 4.6.2 – Raw Materials, Intermediates and Products)

MSD Brinny has three production wells which are used to source all water used on site. There are three natural gas boilers on site, and a natural gas fuelled Combined Heat and Power (CHP) plant. The CHP plant generated approximately 40% of the site electricity usage and low pressure hot water.

The operation of the installation involves the consumption of water, natural gas and electricity. The quantities used in 2017 and the estimated future usage are given below.

| <b>Resource</b>  | <b>Quantity per annum</b> | <b>Future usage per annum</b> |
|--|---------------------------|-------------------------------|
| Electricity purchased  | 20,277,000 kWh            | 27,100,000 kWh                |
| Total Non-Renewable Electricity Generated and Used at the site | 9,618,000 kWh             | 12,000,000 kWh                |
| Water  | 173,740 m <sup>3</sup>    | 335,000 m <sup>3</sup>        |

| Resource       | Quantity per annum       | Future usage per annum   |
|----------------|--------------------------|--------------------------|
| Natural Gas    | 5,828,447 m <sup>3</sup> | 7,034,490 m <sup>3</sup> |
| Light fuel oil | 33.54 m <sup>3</sup>     | 30 m <sup>3</sup>        |

### *Mitigation*

Condition 7 of the licence provides for the efficient use of resources and energy in all site operations. This condition also requires an energy audit to be carried out and repeated at intervals as required by the Agency.

### **Hazardous materials**

Diesel will be stored on-site for use as back-up fuel in boilers and standby generators.

A large range of acids, bases, organic solvents, laboratory chemicals and oils are stored onsite in small quantities (<0.005 tonnes) for use in the laboratory, manufacturing and plant maintenance. The annual use of any one of these substances is less than 0.05 tonnes per annum.

The main substance of concern related to the activity is diesel (Hazard statement H351, H411). The amount of hazardous materials to be consumed for the proposed activity is considered low. None of the above substances are emitted directly to the environment. The likelihood of accidental releases of these substances to the environment, as a result of the licensable activity, is low.

### **Waste generation**

Other waste substances and materials are generated on-site which must be disposed of, or treated, appropriately. Of concern in this assessment would be any process waste that is considered hazardous to the environment or human health. The table below lists the main hazardous waste related to the activity. A comprehensive list of all types of waste is supplied in the application form.

| Waste Description   | Quantity generated (tonnes per month) | EWC code | Location of recovery or disposal | Method of recovery or disposal |
|---|---------------------------------------|----------|----------------------------------|--------------------------------|
| Packaging containing residues or contaminated by dangerous substances | < 1                                   | 15 01 10 | Off site                         | Incineration                   |

| Waste Description                       | Quantity generated (tonnes per month) | EWC code | Location of recovery or disposal | Method of recovery or disposal   |
|---|---------------------------------------|----------|----------------------------------|----------------------------------|
| Aqueous hazardous waste (waste solvent) | 3                                     | 16 10 01 | Off site                         | Solvent reclamation/regeneration |

### *Assessment and mitigation*

These hazardous wastes are exported off site for authorised disposal/recovery. Most the other production wastes generated by the activity will be recyclable or recoverable, eg. Scrap metal, plastic packaging, timber, cardboard and glass. Mixed municipal waste from the installation will be removed from site by an authorised waste operator.

The RD requires that disposal or recovery of waste on-site shall only take place in accordance with the conditions of this licence and in accordance with the appropriate National and European legislation and protocols. Furthermore, as part of the Environmental Management System (Condition 2 and 7 of the RD) the licensee must annually review of all operations and processes with respect to the reduction of waste.

### **EIA on Resource Use, Hazardous Materials and Waste Generation**

For the purposes of EIA, the environmental factors potentially affected by the installation's consumption of resources and waste generation include: material assets, human beings, and flora and fauna. The associated impacts have been identified, described and assessed in the sections above, and have been considered as part of this EIA.

### *Direct and indirect effects*

The operation of this installation requires the consumption of certain material assets; in particular natural gas, electricity and potable water. The amounts used are listed above, and while the amounts may be considered significant on a general basis, from an industrial perspective the amounts used would be considered small, especially when compared with traditional chemical manufacturing processes.

It is therefore considered that the installation's consumption and waste generation under normal operation is not likely to have an effect on the above environmental factors.

It is also considered that no secondary or indirect effects are likely as a result of these emissions aspects of the installation's activities.

### *Cumulative effects*

Regardless of whether waste generation and resource use from the installation, by itself, has the potential to affect the above environmental factors, it must also be considered whether the cumulative impact with other installations/sources may have an effect.

Unlike emissions, it is generally not considered relevant to discuss consumption and waste in terms of local impact, but rather should be discussed in the national context.

Any new activity is likely to contribute to the cumulative effect from consumption and waste generation at a national level. However, any new activity which uses significantly less energy, substances and materials, and generates less waste, than existing equivalent activities, should be considered sustainable development. As this installation is making increasing use of biotechnology, rather than chemical processes, it uses considerably less water, energy and chemicals than traditional pharmaceutical installations.

*Overall conclusions in relation to effects of consumption and waste generation from the activity on the environment*

I am satisfied that there will not be significant effects on material assets, human beings, and flora and fauna or any other aspect of the environment from waste generation and resource use from the operation of the activity when operated in accordance with the conditions of the Recommended Determination.

## **12. Accidents and Cessation**

### **12.1 Prevention of Accidents**

The operation of any activity involves a certain amount of risk to the environment and human health. The table below specifies the risks and associated safety measures relevant to this installation.

| Potential accidents & measures for prevention/limitation of consequences   |   |
|--|---|
| Potential for an accident or hazardous/ emergency situation to arise from activities at the installation.  | <ul style="list-style-type: none"> <li>• Fire leading to emissions to air, water and/or soil</li> <li>• Spillage/leakage due to accidents on-site</li> <li>• Spillage of chemicals, raw materials and diesels during delivery and unloading operations</li> </ul>   |
| Preventative/Mitigation measures to reduce the likelihood of accidents and mitigate the effects of the consequences of an accident at the installation | <ul style="list-style-type: none"> <li>• Storm water passes monitored by on-line continuous TOC, pH and temperature monitoring, and will automatically divert to firewater retention lagoon should trigger values be exceeded.</li> <li>• Firewater retention pond and firefighting facilities.</li> <li>• Provision and maintenance of adequate bunding</li> <li>• No bulk storage of chemicals is required. Only small quantities will be stored onsite.</li> </ul> |

| Potential accidents & measures for prevention/limitation of consequences |                |
|--|----------------|
| Additional measures provided for in the RD                               | None specified |

Condition 9 of the RD requires procedures to be put in place to prevent accidents with a possible impact on the environment and to respond to emergencies so as to minimise the impact on the environment. (see Fit and Proper Person Assessment section below for further details).

## 12.2 Cessation of Activity

The application details a range of measures to be employed upon cessation of the activity. These include:

- Full decontamination and decommissioning of all production equipment. Clean uncontaminated equipment will be left in place while contaminated equipment will be removed.
- All bunded areas will be left cleaned and tested and repaired where required.
- All waste material will be collected and stored on site pending recovery/disposal off-site.
- Temporary office portacabins will also be removed.
- The WWTP will be fully decommissioned. All balance tanks, aeration basins and clarifiers will be cleaned and left in-situ.
- Survey will be undertaken to fully quantify and manage the asbestos material on site.
- As the date of plant shut down will be known in advance it is assumed that the stocks of raw materials will be reduced accordingly. However, at plant shut down there is likely to be an amount of raw material which may not have been shipped from the site and may be treated as hazardous waste.

Condition 10 of the RD requires the proper closure of the activity with the aim of protecting the environment.

### Baseline Report

Article 22(2) of the IED requires that where the activity involves the use, production or release of relevant hazardous substances and having regard to the possibility of soil and groundwater contamination at the site of the installation, the operator shall prepare and submit a baseline report to the competent authority.

The baseline report is a tool that permits, as far as possible, a quantified comparison between the state of the site described in that report and the state of the site upon definitive cessation of activities, in order to ascertain whether a significant increase in pollution of soil or groundwater has taken place.

A baseline report (ref: Attachment 4.8.3 of the licence review application, date: 15/11/2018) was submitted with the application. A review of the soil and groundwater

quality baseline assessment confirms that there is no evidence of significant historic or current contamination of soil or groundwater at the site. The possibility of soil and groundwater contamination at the site of the installation is considered low.

Condition 6.17 and Schedule C.6 of the RD require monitoring of soil and groundwater for any relevant hazardous substances.

### **EIA on Accidents and Cessation**

The environmental factors potentially affected by accidents at the installation, or the cessation of activity, include: material assets, human beings, flora and fauna, air, soil and water. The direct, indirect and cumulative effects have been identified, described and assessed, and are discussed below.

Accidents relating to any aspect of the activity has the potential to give rise to emissions which could cause significant effects on the environment.

The assessment in the Prevention of Accident's section above details the most likely risks associated with the site, along with the specific measures for their prevention or the limitation of their consequences. It is considered that these measures are sufficient to ensure that significant effects on the environment are not likely. Below, for the purposes of EIA, are details of other general risks and measures associated with the installation, as well as details of any likely significant effects.

#### *Direct and indirect effects*

Accidental emissions to air and water could occur if abatement failed on the main emissions, causing releases of potentially significant quantities of polluting matter. Accidental noise emissions could also occur due to malfunction of the plant and equipment listed above, or due to failure/damage to acoustic abatement. However, it is considered that the infrastructure, monitoring, maintenance and notification measures in the RD make the risk of such accidents unlikely.

Accidental emissions could occur from improper storage of materials and waste on-site. I am satisfied that there will not be significant effects on the environment from storage provided the measures specified in the RD for site management, operation, infrastructure and materials handling have been correctly implemented.

It is stated in the application that the basis of the closure plan is to aim for the MSD Brinny facility to be in a suitable state for future industrial use and in any event would not be a risk to public health and safety or the environment. The licensee's Decommissioning Management Plan (DMP) states that despite the low risk nature of the site, the costings for closure include a two-year restoration and aftercare management plan.

Given the above, and noting the general low risk nature of the manufacturing and site processes it is considered that the proposed activity is not likely to lead to residual issues upon eventual closure of the site. I am further satisfied that there will not be significant effects on the environment from cessation of the activity provided the measures specified in Condition 10 of the RD have been correctly implemented.

### **13. Other matters relating to EIA**

### **13.1 Effects on landscape, material assets and cultural heritage**

#### *(a) Disturbance of archaeology and architecture from the operation of the activity*

Any loss of archaeological or architectural heritage could impact negatively on human beings. These matters are dealt with in the decision of the planning authority to grant planning permission for the developments on site and are not controlled by the Agency. The planning authority has considered the effect to be acceptable.

There are no buildings or features of architectural significance and no known archaeological features at or near the site of the installation, and it is very difficult to envisage any pathway by which emissions from the operation of the activity could impact any feature which might be present.

#### *(b) Landscape, visual and cultural effects*

Any disturbance of the landscape or the cultural heritage of an area has the potential to impact on human beings and their enjoyment of the surrounding area. These matters are dealt with in the decision of the planning authority to grant planning permission for the developments on site and are not controlled by the Agency. The planning authority has considered the effects to be acceptable.

The installation is located in an agricultural area that is not highly populated. Emissions from the operation of the activity will not affect the agricultural landscape and culture of the area.

#### *(c) Material assets*

Material assets is taken to mean roads, built services and waste generation. The latter item is presented in Section 11 of this report. The impact of traffic movements associated with the development is dealt with in the decision of the planning authority to grant planning permission for the poultry unit and are not controlled by the Agency. There are sufficient supplies of electricity and water to serve the requirements of the development. These matters are dealt with in the decision of the planning authority to grant planning permission for the developments on site and are not controlled by the Agency. We are satisfied that there will not be significant effects on materials assets from the operation of the activity, as respects the matters that come within the functions of the Agency.

No mitigation measures have been proposed in relation to (a), (b) (c) above.

### **13.2 Interaction of effects**

I have considered the interaction between human beings, flora and fauna, soil, water, air, climate, landscape, material assets, cultural heritage and the interaction of the likely effects identified throughout this report.

The most significant interaction, as addressed in the earlier parts of this report, is as follows:

#### Water, soil and flora and fauna

Accidental discharges of contaminated storm water or other substances to ground may directly and indirectly effect soil, ground water quality, surface water quality downstream and aquatic flora and fauna. As demonstrated in Accidents and Cessation section above, such effects are considered not to be likely or significant.

Based on the assessment carried out throughout this report, and the mitigation measures proposed (including the relevant conditions in the licence), I do not consider that the interactions identified are likely to cause or exacerbate any potentially significant environmental effects of the activity.

### **14. Reasoned Conclusion on Environmental Impact Assessment**

Having regard to the effects (and interactions) identified, described and assessed throughout this report, I consider that the mitigation measures proposed will enable the activity to operate without causing environmental pollution. I also consider that the potential effects on the environment identified above, even if they occur, are unlikely to damage the environment, and the risk of them occurring is not unacceptable.

Accordingly, if the activity is carried out in accordance with the RD and the conditions attached, the operation of the activity will not cause environmental pollution. The conditions of the RD and the mitigation measures proposed will significantly reduce the likelihood of accidental emissions occurring and limit the environmental consequences of an accidental emission should one occur.

### **15. Appropriate Assessment**

The installation is in a rural location near Innishannon, in south County Cork. The main emissions from the installation are principally combustion emissions to air, and sanitary and process discharges to waters (Bandon Estuary). There are also controlled uncontaminated storm water discharges at the installation.

The Appropriate Assessment table in the appendix lists the European Sites assessed, their associated qualifying interests and conservation objectives.

A screening for Appropriate Assessment was undertaken to assess, in view of best scientific knowledge and the conservation objectives of the site, if the activities, individually or in combination with other plans or projects are likely to have a significant effect on any European Site. In this context, particular attention was paid to the European Site(s) at Courtmacsherry Estuary SAC (001230) and Courtmacsherry Bay SPA (004219) (13 and 14 km respectively from installation).

The activity is not directly connected with or necessary to the management of any European Site and the Agency considered, for the reasons set out below, that it can be excluded, on the basis of objective information, that the activity, individually or in combination with other plans or projects, will have a significant effect on any European Site and accordingly determined that an Appropriate Assessment of the activity was not required.

This determination was made in light of the scale and nature of emissions to the environment; in particular the scale and nature of the emissions to air from the

installation, and the distance to habitats. Air dispersion modelling demonstrates that emissions from the proposed activity will not result in ground level concentrations which exceed the relevant air quality standards for the protection of vegetation and the environment. With regards to the hydrologically linked sites, it has been determined that the proposed emissions to the Brinny River will not have a significant effect on the receiving environment. Furthermore, there are no emissions to groundwater from the installation.

## **16. Fit & Proper Person Assessment**

The Fit & Proper Person test requires three elements of examination:

### Technical Ability

The licensee has provided details of the qualifications, technical knowledge and experience of key personnel. The licence application also includes information on the on-site management structure. It is considered that the licensee has demonstrated the technical knowledge required.

### Legal Standing

Neither the licensee nor any relevant person has relevant convictions under the Environmental Protection Agency Act 1992, as amended, or under any other relevant environmental legislation.

### Financial Provision/Strength

*ELRA, CRAMP & FP*

The licence category and proposed installation/facility was assessed for the requirements of Environmental Liabilities Risk Assessment (ELRA), Closure, Restoration and Aftercare Management Plan (CRAMP) and Financial Provision (FP), in accordance with Agency guidance. Under this assessment it has been determined that ELRA, CRAMP and FP were not required.

### Fit & Proper Conclusion

It is my view, and having regard to the Conditions of the RD, that the licensee can be deemed a Fit & Proper Person for the purpose of this review.

## **17. Cross Office Consultation**

I consulted OEE Inspectors, Pamela McDonnell, Denise O' Riordan and Maria Lenihan as well as Victor Olmos from the air monitoring team) in relation to this site. In general, the OEE have no significant concerns regarding the proposed activity. I also consulted with OEA Scientific Officer, Sorcha NiLongphuirt, in relation to receiving water conditions.

## **18. Charges**

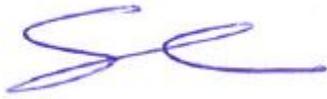
The annual enforcement charge recommended in the RD is €9,662 which reflects the anticipated enforcement effort required and the cost of monitoring.

## **19. Recommendation**

The RD specifies the necessary measures to provide that the installation shall be operated in accordance with the requirements of Section 83(5) of the EPA Act 1992 as amended, and has regard to the AA screening and EIA. The RD gives effect to the requirements of the Environmental Protection Agency Acts 1992 as amended.

I recommend that a Proposed Determination be issued subject to the conditions and for the reasons as drafted in the RD.

Signed

A handwritten signature in blue ink, consisting of stylized, overlapping loops and lines, positioned above a horizontal line.

Gavin Clabby

## **Procedural Note**

In the event that no objections are received to the Proposed Determination on the application, a licence will be granted in accordance with Section 87(4) of the Environmental Protection Agency Acts 1992 as amended, as soon as may be after the expiration of the appropriate period.

## Appendices

### AA table

List of European Sites assessed, their associated qualifying interests and conservation objectives.

| Site Name                           | Approx Distance from Installation (Km) | Qualifying Interests<br>(* denotes a priority habitat)   | Conservation Objectives   |
|-------------------------------------|--|--|---|
| Courtmacsherry Estuary SAC (001230) | 13                                     | <b>Habitats</b><br>1130 Estuaries<br>1140 Mudflats and sandflats not covered by seawater at low tide<br>1210 Annual vegetation of drift lines<br>1220 Perennial vegetation of stony banks<br>1310 Salicornia and other annuals colonising mud and sand<br>1330 Atlantic salt meadows ( <i>Glauco-Puccinellietalia maritimae</i> )<br>1410 Mediterranean salt meadows ( <i>Juncetalia maritimi</i> )<br>2110 Embryonic shifting dunes<br>2120 Shifting dunes along the shoreline with <i>Ammophila arenaria</i> (white dunes)<br>2130 Fixed coastal dunes with herbaceous vegetation (grey dunes)*  | NPWS (2014) Conservation Objectives: Courtmacsherry Estuary SAC 001230. Version 1. National Parks and Wildlife Service, Department of Arts, Heritage and the Gaeltacht (9 <sup>th</sup> July 2014). |
| Courtmacsherry Bay SPA (004219)     | 14                                     | <b>Birds</b><br>A156 Black-tailed Godwit ( <i>Limosa limosa</i> )<br>A149 Dunlin ( <i>Calidris alpina</i> )<br>A142 Lapwing ( <i>Vanellus vanellus</i> )<br>A179 Black-headed Gull ( <i>Chroicocephalus ridibundus</i> )<br>A140 Golden Plover ( <i>Pluvialis apricaria</i> )<br>A182 Common Gull ( <i>Larus canus</i> )<br>A069 Red-breasted Merganser ( <i>Mergus serrator</i> )<br>A157 Bar-tailed Godwit ( <i>Limosa lapponica</i> )<br>A160 Curlew ( <i>Numenius arquata</i> )<br>A050 Wigeon ( <i>Anas penelope</i> )<br>A048 Shelduck ( <i>Tadorna tadorna</i> )<br>A003 Great Northern Diver ( <i>Gavia immer</i> )<br><br><b>Habitats</b><br>Wetlands | NPWS (2014) Conservation Objectives: Courtmacsherry Bay SPA 004219. Version 1. National Parks and Wildlife Service, Department of Arts, Heritage and the Gaeltacht (3 <sup>rd</sup> October 2014).  |

## Relevant European (and international) legal instruments

|   |
|---|
| The following Irish and European instruments are regarded as relevant to this application assessment and have been considered in the drafting of the Recommended Determination. |
| Industrial Emissions Directive (IED). (2010/75/EU)  |
| S.I. No. 272/2009, European Communities Environmental Objectives (Surface Waters) Regulations 2009  |
| Environmental Impact Assessment (EIA) Directive (2011/92/EU)  |
| Habitats Directive (92/43/EEC) & Birds Directive (79/409/EC)  |
| Water Framework Directive [2000/60/EC]  |
| Air Quality Directives (2008/50/EC and 2004/107/EC)   |
| Dangerous Substances Directive (2006/11/EC)   |
| Medium Combustion Plant Directive (MCP). (EU) 2015/2193   |
| Regulation (EC) No 1907/2006 (REACH Regulation)   |

## Other BREF documents and National BAT notes relevant to this assessment

| Sectoral/Common Commission Implementing Decisions   | Publication date |
|---|------------------|
| COMMISSION IMPLEMENTING DECISION (EU) 2016/902 of 30 May 2016 establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for common waste water and waste gas treatment/ management systems in the chemical sector ((EU) 2016/902) | June 2016        |
| Sectoral BREF   | Publication date |
| Reference Document on the Best Available Techniques for the Manufacture of Organic Fine Chemicals   | August 2006      |
| Horizontal BREF   | Publication date |
| Reference Document on the Best Available Techniques on Emissions from Storage   | July 2006        |
| Reference Document on the Best Available Techniques for Energy Efficiency   | February 2009    |
| Reference Document on the application of Best Available Techniques to Industrial Cooling Systems  | December 2001    |
| National BAT notes  | Publication date |
| BAT Guidance Note Pesticides, Pharmaceuticals & Speciality Organic Chemicals Sector   | 2008             |