Ringaskiddy Active Pharmaceutical Ingredient Plant
P.O. Box 140, Ringaskiddy, Co. Cork, Ireland
Tel: +353-21-4378701
Fax: Admin./Finance 4378698; Engineering/E.H.S. 4378432;
Production 4378168; Quality Operations 4378342;
Human Resources 4378353; Customer Services 4378087; Q.C. 4378509;
www.pfizer.ie

Pfizer Ireland Pharmaceuticals

Environmental Protection Agency,
Licensing Unit,
Office of Climate, Licensing and Resource Use,
P.O. Box 3000,
Johnstown Castle Estate,
County Wexford.

06-January-2009

Ref. **IPPC Licence Register Number P0013-04 (Pfizer Ringaskiddy)**

Re : **Request for Technical Amendment**
Re: Acceptance of Effluent from Adjacent Pfizer Biotechnology Ireland Facility

Dear Sir/Madam,

Further to discussions with the Agency's Office of Environmental Enforcement (OEE) regarding the proposed treatment of effluent from the Pfizer Biotechnology Ireland facility in the Pfizer Ringaskiddy wastewater treatment plant, it is our understanding that a technical amendment of Condition 8 (Materials Handling) of our site IPPC licence P0013-04 is required to facilitate the proposal upon commencement of scheduled activities in the Pfizer Biotechnology Ireland facility.

We request herein a technical amendment of Condition 8 of our IPPC licence under Section 96 of the Environmental Protection Agency Act as amended in order to facilitate the acceptance by Pfizer Ringaskiddy of effluent arising from scheduled activities in the adjacent Pfizer Biotechnology Ireland facility.

We submit proposed amendments to Condition 8 in Section 3.0 herein for Agency consideration.

1.0 Background

1.1 Pfizer Biotechnology Ireland Development

The development by Pfizer of a small scale biologics facility is currently underway on the former Corrin MDA (previously ADM) site in Shanbally, Ringaskiddy, Co. Cork. The site is located immediately to the west of and directly adjacent to the Pfizer Ringaskiddy site.

The new facility, which is termed Pfizer Biotechnology Ireland, is intended to be a monoclonal antibodies small scale facility which will manufacture, purify, formulate and bulk fill mammalian cell culture derived proteins in cancer treatment pharmaceutical products, for the purposes of clinical trials and small commercial volumes.

The Pfizer Biotechnology Ireland facility will be a separate site from the existing adjacent Pfizer Ringaskiddy site which operates under IPPC licence register P0013-04. We understand that Pfizer Biotechnology Ireland is in the process of applying for an IPPC licence and, if successful, will operate under this new licence.

Pfizer has assessed the potential for operational and business synergies between the Pfizer Biotechnology Ireland facility and the adjacent Pfizer Ringaskiddy facility. It is considered that a significant opportunity for such synergies exists in the area of wastewater treatment.

1.2 Treatment of Pfizer Biotechnology Ireland Effluent in Pfizer Ringaskiddy WWTP

In particular, we note that the Pfizer Ringaskiddy site has a substantial wastewater treatment plant (WWTP) which can accept and treat both process effluent and domestic effluent (sanitary sewage) from the Pfizer Biotechnology Ireland site.

We remark that a formal Quantitative Treatability Assessment (QTA) has been developed by Pfizer Ringaskiddy which assesses the treatability of effluent from manufacturing activities on the Pfizer Biotechnology Ireland site in the Pfizer Ringaskiddy WWTP, and which was previously submitted to the Agency's Office of Environmental Enforcement.[1] For convenience, we reproduce the QTA in full as Appendix 1 herein.

We recall that the QTA demonstrated that these effluent streams from Pfizer Biotechnology Ireland can be treated by the Pfizer Ringaskiddy WWTP within both its design parameters and current operational parameters, and will not comprise a significant incremental loading.

We understand that Pfizer Biotechnology Ireland has provided a submission to the Agency as part of the application process which outlines the procedures and arrangements they intend to implement in order to monitor and control the process effluent which they shall transfer to the Pfizer Ringaskiddy site. For convenience, we reproduce this submission from Pfizer Biotechnology Ireland as Appendix 2 herein.

[1] We refer to the Quantitative Treatability Assessment submitted by Pfizer Ringaskiddy to OEE under cover dated 16-Sep-2008 and subsequent Agency correspondence dated 18-Sep-2008, ref. P0013-04/ap15nod.doc

2.0 Agency Approvals

2.1 Waste Solvent Discrete Loads

We remark that the Pfizer Ringakiddy site is licensed to carry out the following activities :

"the use of a chemical or biological process for the production of basic pharmaceutical products"

and

"the recovery or disposal of waste in a facility, within the meaning of the [Waste Management] Act of 1996, which facility is connected or associated with another activity specified in this Schedule in respect of which a licence or revised licence under Part IV is in force or in respect of which a licence under the said Part is or will be required"

We note that the site accepts waste solvent in discrete loads from other Pfizer Ireland facilities for the purposes of onsite recovery under IPPC licence P0013-04.

We acknowledge that conditions governing the acceptance of waste loads onsite are provided in Condition 8 of our existing licence.

2.2 Domestic and Commissioning Streams from Non-Scheduled Activities in Adjacent Site

We recall that domestic effluent from the former Corrin MDA (previously ADM) site had been ducted to the Ringaskiddy WWTP during the period of demolition activities on that site, with Agency approval (ref. our letter to the Agency dated 28-March-2006 and subsequent Agency letter of approval M542/ap48mo, dated 03-May-2006).

In addition, domestic effluent from the existing construction site for the Pfizer Biotechnology Ireland facility is currently treated in the Pfizer Ringaskiddy WWTP, with Agency aproval (ref. our letter to the Agency dated 01-August-2007 and subsequent Agency letter of approval P0013-04/ap08nod.doc, dated 03-August-2007).

We further note that commissioning and qualification streams from the pre-operational Pfizer Biotechnology Ireland facility are routed to the Pfizer Ringaskiddy wastewater treatment facility. We refer to our submission to the Agency dated 27-Nov-2008 and subsequent Agency approval ref. P0013-04/ap16nod.doc, dated 03-Dec-2008.

3.0 Technical Amendment : Acceptance of Effluent from Future Manufacturing Activities in Pfizer Biotechnology Ireland Site

We acknowledge furthermore that approval has been provided by OEE for the treatment of effluent generated from scheduled activities in the adjacent Pfizer Biotechnology Ireland facility in the Pfizer Ringaskiddy wastewater treatment plant. We refer in this context to our Quantitative Treatability Assessment submitted to OEE under cover dated 16-Sep-2008 and reproduced in Appendix 1 herein, and subsequent Agency correspondence dated 18-Sep-2008, ref. P0013-04/ap15nod.doc.

In addition, it has been recommended by OEE that we also request a concomitant technical amendment of Condition 8 of our IPPC licence as described earlier.

We therefore propose the technical amendments for Agency consideration below. The proposed amendments refer to Condition 8.2.3(a) and Condition 8.6 of the site IPPC licence. In each case, we provide corresponding justifications for the amendments.

We submit that the amendments proposed below adequately extend the applicability of Conditon 8 from discrete waste loads as at present, to effluent transferred continuously by pipeline from the adjacent Pfizer Biotechnology Ireland facility.

Condition 8.2.3(a)

Current Wording

[Prior to commencement of waste acceptance at the installation, the licensee shall establish and maintain, and submit to the Agency for written approval, detailed procedures for the acceptance and handling of wastes.]

These procedures shall include the following :

(a) Waste inspection, waste characterisation and waste profiling of wastes accepted at the solvent recovery plant

Proposed Amended Wording

[Prior to commencement of waste acceptance at the installation, the licensee shall establish and maintain, and submit to the Agency for written approval, detailed procedures for the acceptance and handling of wastes.]

These procedures shall include the following :

(a) Waste inspection as appropriate, and waste characterisation and waste profiling of wastes accepted onsite

Summary of Proposed Change

(i) Substitution of the words "at the solvent plant" by the word "onsite".

(ii) Insertion of the words "as appropriate" after the words "waste inspection".

Justification

(i) Since wastes received onsite shall now also include effluent from the Pfizer Biotechnology Ireland facility, we note that waste material shall now be accepted on the site rather than exclusively at the area of the solvent recovery plant. We submit that the proposed wording above would better reflect the acceptance of waste materials including effluent at the site, rather than those wastes accepted exclusively at the solvent recovery area.

(ii) Wastes accepted shall now include effluent which shall be continuously transferred by pipeline from the adjacent Pfizer Biotechnology Ireland facility. We note that the current phrase "waste inspection" in the context of Condition 8.2.3(a) is applicable to the inspection of discrete waste loads such as waste solvent that is currently transported to Pfizer Ringaskiddy for recovery. We submit that the insertion of the phrase "as appropriate" as proposed above would allow the condition to cover both such discrete waste loads as currently accepted and effluent from Pfizer Biotechnology Ireland that shall be continuously transferred by installed pipeline.

Condition 8.6

Current Wording

The licensee shall ensure that any waste generated/accepted onsite, prior to transfer to another person or prior to acceptance onsite respectively, shall be classified, packaged and labelled in accordance with National, European and any other standards which are in force in relation to such labelling.

Proposed Amended Wording

The licensee shall ensure that any waste generated/accepted onsite, prior to transfer to another person or prior to acceptance onsite respectively, shall be classified, packaged and labelled as applicable in accordance with National, European and any other standards which are in force in relation to such labelling.

Summary of Proposed Change

Insertion of the words "as applicable" after the phrase "shall be classified, packaged and labelled".

Justification

Whereas classification, packaging and labelling requirements may be applicable to discrete waste loads being transferred to and accepted by the site, we note that effluent from the Pfizer Biotechnology Ireland shall be pumped continuously by installed pipeline to the Pfizer Ringaskiddy facility. Classification, packaging and labelling, such as may be applicable to discrete waste loads, are therefore not appropriate activities in this case. We submit that the insertion of the words "as applicable" as proposed above would allow the condition to cover both such discrete waste loads as currently accepted and effluent from Pfizer Biotechnology Ireland that shall be continuously transferred by installed pipeline.

4.0 Conclusion

In summary, we request a technical amendment of Condition 8 of our IPPC licence under Section 96 of the Environmental Protection Agency Act as amended, for the reasons described herein.

In this context, we request that consideration be given to the proposed amendments to Condition 8.2.3(a) and Condition 8.6 as detailed earlier.

In accordance with Agency instructions, we enclose herein an original of this submission plus two photostat copies.

We trust that this is to the satisfaction of the Agency.

Yours Sincerely,

Pfizer Ireland Pharmaceuticals

Ringaskiddy Active Pharmaceutical Ingredient Plant

Peter Hetherington,

Head of Environment, Health and Safety

Enc (2)

Appendix 1

Quantititative Treatability Assessment as previously submitted to the Agency

Quantitative Treatability Assessment

Treatment of Pfizer Biotechnology Ireland Effluent in the Adjacent Pfizer Ringaskiddy Wastewater Treatment Plant

Pfizer Ireland Pharmaceuticals
Ringaskiddy Active Pharmaceutical Ingredient Plant
IPPC Licence P0013-04

September 2008

Pharmachemical Ireland Responsible Care

Contents

1.0 Introduction

1.1 Pfizer Biotechnology Ireland Development

The development by Pfizer of a small scale biologics facility is currently underway on the former Corrin MDA (previously ADM) site in Shanbally, Ringaskiddy, Co. Cork. The new facility, which is termed Pfizer Biotechnology Ireland, is intended to be a monoclonal antibodies small scale facility which will manufacture, purify, formulate and bulk fill mammalian cell culture derived proteins in cancer treatment pharmaceutical products, for the purposes of clinical trials and small commercial volumes.

The Pfizer Biotechnology Ireland facility will be a separate site from the existing adjacent Pfizer Ringaskiddy site which operates under IPPC licence register P0013-04. Pfizer Biotechnology Ireland intends to apply for its own IPPC licence and, if successful, will operate under this new licence.

Pfizer has assessed the potential for operational and business synergies between the Pfizer Biotechnology Ireland facility and the adjacent Pfizer Ringaskiddy facility. It is considered that a significant opportunity for such synergies exists in the area of wastewater treatment.

1.2 Treatment of Pfizer Biotechnology Ireland Effluent in Pfizer Ringaskiddy WWTP

In particular, we note that the Pfizer Ringaskiddy site has a substantial wastewater treatment plant (WWTP) which can accept and treat both process effluent and domestic effluent (sanitary sewage) from the Pfizer Biotechnology Ireland site.

It is demonstrated in this assessment that these effluent streams from Pfizer Biotechnology Ireland are expected to be treatable to a high degree by the Pfizer Ringaskiddy WWTP within both its design parameters and current operational parameters, will not comprise a significant incremental loading, and that consequently the emission limit values for emissions to sewer for Pfizer Ringaskiddy emission point TE1 will continue to be achieved.

1.3 Agency Approval

It is our understanding that the Pfizer Ringaskiddy IPPC licence P0013-04 allows, under its existing conditions, the acceptance of wastewater from the Pfizer Biotechnology Ireland facility, subject to the prior approval of the Agency.

As noted in previous discussions with the Agency, the Pfizer Ringakiddy site is licensed to carry out the following activities :

"the use of a chemical or biological process for the production of basic pharmaceutical products"

and

"the recovery or disposal of waste in a facility, within the meaning of the [Waste Management] Act of 1996, which facility is connected or associated with another activity specified in this Schedule in respect of which a licence or revised licence under Part IV is in force or in respect of which a licence under the said Part is or will be required"

We note that the site accepts waste solvent from other Pfizer Ireland facilities for the purposes of onsite recovery under IPPC licence P0013-04.

We further note that the Agency has previously approved the acceptance of additional waste types under the existing conditions of IPPC licence P0013-04.

We refer for example to our correspondence to the Agency dated 29-Sep-2006 in which we notified our intention to accept contaminated waste drums for onsite washing (Section D of the quoted correspondence) and also plastic, cardboard, paper and fibre drums for processing in our onsite Recycling Centre (Section E of the quoted correspondence). These proposals were approved by the Agency by letter dated 24-Nov-2006 (Agency ref. P0013-04/ap02mo).

In accordance with such previous approvals for waste acceptance under P0013-04, we acknowledge that Agency approval for the treatment of Pfizer Biotechnology Ireland effluent in the Pfizer Ringaskiddy WWTP is contingent upon Pfizer assessing that the accepted wastewater is treatable in the site WWTP, with current emission limit values continuing to be achieved.

We provide this treatability assessment herein.

Based upon the Quantitative Treatability Assessment (QTA) detailed herein, we request, in Section 8.0 herein, Agency approval to accept process effluent and domestic effluent from the Pfizer Biotechnology Ireland facility for treatment in the Pfizer Ringaskiddy WWTP.

2.0 Methodology for Quantitative Treatability Assessment of Pfizer Biotechnology Ireland Effluent[1]

2.1 Description of Pfizer Biotechnology Ireland Effluent

The process effluent generated by the Pfizer Biotechnology Ireland facility will be an aqueous stream typical of biotechnology activities. The process effluent will derive from manufacturing activities, utilities water discharge, cleaning activities, facility washings, laboratory, and ancillary activities. The effluent will therefore comprise deactivated biological cell residues in an aqueous medium.

The effluent stream will be pH-neutralised within the Pfizer Biotechnology Ireland site. The stream will be thermally inactivated to destroy any remaining live cells. In common with typical biowastes of this type, the stream is expected to have a low BOD/COD load. Because the bioorganic content of the stream will consist primarily of biological residues, it is expected to be highly biodegradable. In terms of composition therefore, the stream is expected to be highly amenable to effective and efficient treatment in the existing Pfizer Ringaskiddy WWTP.

[1] Domestic effluent (sanitary sewage) from the Pfizer Biotechnology Ireland site is a separate minor stream and this is addressed in Section 5.4 herein.

The key characteristics of the Pfizer Biotechnology Ireland effluent are presented in the Table 1 below.

Table 1

Pfizer Biotechnology Ireland Process Effluent

Key Effluent Characteristics

Parameter	Typical Daily Average	Maximum Daily	Instantaneous Peak
Flow (m^3/day)	119	240	N.A.
COD (tonnes/day)	0.225	0.450	1.00
pH	Range 6-9		

Table 1 shows typical daily average and maximum values for each key parameter as projected to occur under the normal operating conditions of the Pfizer Biotechnology Ireland facility.

Typical daily averages are shown for information purposes. The key values for the current treatability assessment are the maximum daily values and the instantaneous peak value.

For COD, Table 1 includes an instantaneous intra-day peak which may intermittently occur during times of batch failure. In the event that a product batch fails for quality, sterility or other reasons, then the batch contents will continue to be deactivated as usual. The waste liquor will likely however contain a higher COD content due to an increased level of biological residues remaining. Such batch failures are expected to be relatively infrequent and may occur at a rate of several (potentially two or three occasions) annually. This QTA nevertheless takes account of such instantaneous COD peaks.

Other parameters such as nitrogen and phosphorus occur at low levels and are less significant for the purposes of assessing treatability in the Ringaskiddy WWTP. Nevertheless, these and other minor parameters are assessed in detail in Section 5.0. Similarly, pH is addressed in Section 5.3.

We note that the domestic effluent stream (sanitary sewage) from the Pfizer Biotechnology Ireland facility is also intended to be accepted for treatment in the Pfizer Ringaskiddy WWTP. The domestic effluent stream is minor and is addressed separately in Section 5.4 of this QTA.

2.2 Key Parameters for Quantitative Treatability Assessment

The key parameters which determine whether the Pfizer Ringaskiddy WWTP has sufficient capacity to efficiently and effectively treat the Pfizer Biotechnology Ireland effluent stream are :

Key Parameter 1 : Volumetric Flow
Key Parameter 2 : COD Loading.

2.2.1 Key Parameter 1 : Volumetric Flow

For the purposes of the assessment, the volumetric flow capacity of the WWTP will be compared to the expected volumetric flows of the Pfizer Biotechnology Ireland effluent stream under typical daily average and maximum daily conditions.

The typical daily average flow of the Pfizer Biotechnology Ireland effluent stream will be included for illustrative purposes only. For the purposes of this assessment, however, the maximum daily flow remains the key value.

The expected Pfizer Biotechnology Ireland effluent flows will be compared to :

A. The design volumetric throughput of the Ringaskiddy WWTP
B. The actual volumetric throughput of the Ringaskiddy WWTP for the calendar years 2006-2007.

2.2.2 Key Parameter 2 : COD Loading

The COD load of the Pfizer Biotechnology Ireland effluent stream is also a key treatability parameter. The COD capacity of the WWTP will be compared to the expected COD load of the Pfizer Biotechnology Ireland effluent stream under typical daily average and maximum daily conditions

The typical daily average COD loading of the Pfizer Biotechnology Ireland effluent stream will be included for illustrative purposes only. For the purposes of this assessment, however, the maximum daily COD loading and the instantaneous COD peak remain the key values.

Again, the expected Pfizer Biotechnology Ireland effluent COD loading will be compared to :

A. The design COD loading of the Ringaskiddy WWTP
B. The actual COD loading of the Ringaskiddy WWTP for the calendar years 2006-2007.

2.2.3 Criteria of Treatability in Ringaskiddy WWTP

In all cases, the comparisons described above will be provided in terms of the actual parameter numerical values involved, and also in terms of the Pfizer Biotechnology Ireland parameters expressed as a percentage of the Ringaskiddy WWTP parameters.

For the key parameters of volumetric flow and COD loading, the essential determinant as to the treatability of the Pfizer Biotechnology Ireland effluent stream is whether the projected maximum increases in volumetric flow and COD loading introduced by Pfizer Biotechnology Ireland remain small relative to the **design capacity** of the Ringaskiddy WWTP for these parameters.

The design capacity values for the Ringaskiddy WWTP are the key comparator parameters since these values represent the designed and intended treatment capability of the WWTP and its ancillary equipment. The WWTP is designed such that influent values up to the design maxima will be treated to a quality which complies with the emission limit values of IPPC licence P0013-04.

The use of maximum (and, for COD, also instantaneous peak) values for the Pfizer Biotechnology Ireland effluent stream will ensure that worst-case conservative comparisons are made. Typical average values of the Pfizer Biotechnology Ireland effluent stream are also included in the comparisons for information and illustrative purposes.

2.2.4 Criterion of Treatability for Key Parameter 1 : Volumetric Flow

The **key comparison for treatability** in the case of **volumetric flow** is the comparison of **Pfizer Biotechnology Ireland average and maximum daily volumetric flows** versus the **average and maximum design volumetric flows of the Ringaskiddy WWTP** respectively.

If the Pfizer Biotechnology Ireland average and maximum daily volumetric flows remain small in comparison to the average and maximum design volumetric flows of the Ringaskiddy WWTP respectively, then the Pfizer Biotechnology Ireland effluent stream does not represent a significant change to existing design conditions and is therefore treatable in terms of volumetric flow.

It is demonstrated below that the projected volumetric flow increase is indeed a small percentage of the design capacity of the Ringaskiddy WWTP and does not represent a significant change. The Pfizer Biotechnology Ireland effluent stream is therefore considered to be treatable in, and constitutes a minor influent stream of, the Ringaskiddy WWTP.

2.2.5 Criterion of Treatability for Key Parameter 2 : COD Loading

The **key comparison for treatability** in the case **COD loading** is the comparison of **Pfizer Biotechnology Ireland average and maximum daily COD loadings** versus the **average and maximum design COD loadings of the Ringaskiddy WWTP** respectively. In addition, **the instantaneous peak COD load** of the Pfizer Biotechnology Ireland effluent stream will be compared to the **maximum design COD loading of the Ringaskiddy WWTP.**

If the Pfizer Biotechnology Ireland average and maximum daily COD loadings remain small in comparison to the average and maximum design COD loadings of the Ringaskiddy WWTP respectively, and if the instantaneous peak COD load of the Pfizer Biotechnology Ireland effluent stream remains small in comparison to the maximum design COD loading of the Ringaskiddy WWTP, then the Pfizer Biotechnology Ireland effluent stream does not represent a significant change to existing design conditions and is therefore treatable in terms of COD loadings.

It is demonstrated below that the projected COD loading increase is indeed a small percentage of the design capacity of the Ringaskiddy WWTP and does not represent a significant change. The Pfizer Biotechnology Ireland effluent stream is therefore considered to be treatable in, and constitutes a minor influent stream of, the Ringaskiddy WWTP.

2.2.6 Supporting Comparisons

In addition to the comparison of Pfizer Biotechnology Ireland characteristics with Ringaskiddy WWTP design values, we also include comparisons of Pfizer Biotechnology Ireland characteristics with actual Ringaskiddy WWTP influent values for the calendar years 2006-2007. This comparison is included for illustrative purposes and is intended to demonstrate that the treatment of the Pfizer Biotechnology Ireland effluent stream does not represent a significant increase on existing operating conditions.

2.2.7 Other Parameters

Other parameters characterising the Pfizer Biotechnology Ireland effluent stream, such as nitrogen, phosphorus, temperature and pH, are less significant for the Ringaskiddy WWTP, particularly in view of the low effluent volumes generated. These minor parameters are nevertheless also quantified and assessed herein in Section 5.0.

Domestic effluent (sanitary sewage) from the Pfizer Biotechnology Ireland facility is also addressed in Section 5.4.

3.0 Quantitative Treatability Assessment - Volumetric Flow Capacity

3.1 Key Parameter 1 : Volumetric Flow Data

Table 2 below presents the average and maximum daily volumetric flows expected from the Pfizer Biotechnology Ireland process effluent.

The table includes the design average and design maximum daily flows for the Ringaskiddy WWTP, and also the actual average and maximum daily flows for the Ringaskiddy WWTP as measured in the calendar years 2006-2007.

Table 3 below presents the same information whereby these Pfizer Biotechnology Ireland flows are expressed as a percentage of the corresponding Ringaskiddy WWTP flows.

In both tables, the Ringaskiddy WWTP **design** parameters are highlighted since they are the **key values** for the comparative assessment as described in Section 2.2.4.

Table 2

Volumetric Flow Data for Pfizer Biotechnology Ireland and Pfizer Ringaskiddy WWTP

	Volumetric Flow (m^3/day)	
	Average	**Maximum**
Pfizer Biotechnology Ireland Effluent	119	240
Ringaskiddy WWTP Design	**2285**	**2900**
Ringaskiddy WWTP Actual 2006	1421	2210
Ringaskiddy WWTP Actual 2007	1331	2211

Table 3

Pfizer Biotechnology Ireland Volumetric Flow as Percentages of Pfizer Ringaskiddy WWTP

	Pfizer Biotechnology Volumetric Flow as % of Ringaskiddy WWTP	
	Average	**Maximum**
Ringaskiddy WWTP Design	**5.21**	**8.28**
Ringaskiddy WWTP Actual 2006	8.37	10.86
Ringaskiddy WWTP Actual 2007	8.94	10.85

A discussion of the above data is presented in Section 3.2 following.

3.2. Key Parameter 1 : Volumetric Flow : Quantitative Treatability Assessment

3.2.1 Comparison with Ringaskiddy WWTP actual measured values 2006-2007

Reference to Table 3 above confirms that the treatment of Pfizer Biotechnology Ireland effluent in the Pfizer Ringaskiddy WWTP represents 8.37-8.94% of measured average daily volumetric flows over the period 2006-2007. In a multi-product variable-flow plant such as Ringaskiddy, this is considered an insignificant increase in the volumetric flow to the WWTP.

Similarly, the maximum daily Pfizer Biotechnology Ireland effluent volume is projected to be approximately 10.85-10.86% of corresponding maximum influent flows over the period 2006-2007. Again, this is not considered a significant increase in maximum volumetric flows under typical Ringaskiddy WWTP operating conditions.

We remark that variable WWTP influent flows are characteristic of batch-based bulk pharmaceutical manufacturing operations such as the Pfizer Ringaskiddy facility.

The Pfizer Biotechnology Ireland process effluent therefore does not represent a significant increase on typical operating conditions in terms of volumetric flow.

3.2.2 Key Comparison : Comparison with Ringaskiddy WWTP Design

With respect to the Pfizer Ringaskiddy WWTP design parameters, representing the full treatment capacity of the WWTP, we note from Table 3 above that the expected average Pfizer Biotechnology Ireland process effluent volume will represent 5.21% of design average influent volumetric flows.

Similarly, the maximum daily Pfizer Biotechnology Ireland effluent volume is projected to be equivalent to 8.28% of design maximum influent flow.

On this key design comparison, the maximum Pfizer Biotechnology Ireland volumetric flow is not considered a significant proportion of the design volumetric flow capacity of the Ringaskiddy WWTP.

3.2.3 Conclusion : Volumetric Flow

We conclude that the Pfizer Ringaskiddy WWTP has sufficient volumetric flow capacity to accept and treat Pfizer Biotechnology Ireland effluent even under maximum flow conditions. We conclude that the effluent will continue to be treated to achieve the emission limit values specified in IPPC licence P0013-04.

We confirm that the Pfizer Biotechnology Ireland effluent stream will remain a minor component of the Ringaskiddy WWTP influent even at these maximum conditions.

4.0 Quantitative Treatability Assessment – COD Loading

4.1 Key Parameter 2 : COD Loading Data

Table 4 presents the average and maximum daily COD loadings expected from the Pfizer Biotechnology Ireland process effluent. As described in Section 2.1, Table 4 also includes the instantaneous COD peak anticipated for the effluent stream, which could potentially occur infrequently during times of batch failure.

The table includes the design average and design maximum COD loadings for the Ringaskiddy WWTP, and also the actual operational average and maximum COD loadings measured in the calendar years 2006-2007.

Table 5 below presents the same information whereby the Pfizer Biotechnology Ireland effluent COD loadings are expressed as a percentage of the corresponding Ringaskiddy WWTP COD loadings.

In both tables, the Ringaskiddy WWTP **design** parameters are highlighted since they are the **key values** for the comparative assessment described in Section 2.2.5.

Table 4

COD Loading Data for Pfizer Biotechnology Ireland and Pfizer Ringaskiddy WWTP

	COD Loading (tonnes/day)		
	Average	**Maximum**	**Instantaneous**
Pfizer Biotechnology Ireland	0.225	0.450	1.00
Ringaskiddy WWTP Design	**12.2**	**21.2**	**21.2**
Ringaskiddy WWTP Actual 2006	6.19	12.2	N.A.
Ringaskiddy WWTP Actual 2007	6.98	11.31	N.A.

Table 5

Pfizer Biotechnology Ireland COD Loading as Percentages of Pfizer Ringaskiddy WWTP

	Pfizer Biotechnology COD Loading as % of Ringaskiddy WWTP		
	Average	**Maximum**	**Instantaneous**
Ringaskiddy WWTP Design	**1.84**	**2.12**	**4.72**
Ringaskiddy WWTP Actual 2006	3.63	3.69	N.A.
Ringaskiddy WWTP Actual 2007	3.22	3.98	N.A.

A discussion of the above data is presented in Section 4.2 following.

4.2. Key Parameter 2 : COD Loading : Quantitative Treatability Assessment

4.2.1 Comparison with Ringaskiddy WWTP actual measured values 2006-2007

Reference to Table 5 above confirms that the treatment of the Pfizer Biotechnology Ireland effluent stream in the Ringaskiddy WWTP represents 3.22-3.63% of measured average daily influent COD

loading during the period 2006-2007. In a multi-product variable-load plant such as Ringaskiddy, this is considered an insignificant increase in the COD load to the WWTP.

Similarly, the maximum daily Pfizer Biotechnology Ireland effluent COD load is projected to be equivalent to 3.69-3.98% of typical measured maximum WWTP influent COD loads during the period 2006-2007. Again, this is not considered a significant increase in typical maximum COD loads under typical Ringaskiddy WWTP operational conditions.

As in the case of volumetric flows, we remark that variable WWTP influent COD loads are characteristic of batch-based bulk pharmaceutical manufacturing operations such as the Pfizer Ringaskiddy facility.

The Pfizer Biotechnology Ireland process effluent therefore does not represent a significant increase on typical operating conditions in terms of COD loading.

We remark that the instantantaneous peak COD effluent loading would occur infrequently at times of batch failure, estimated at potentially two or three occasions annually. A comparison with the Ringaskiddy WWTP design maximum loading is therefore the only valid comparator in this case and this is provided in Section 4.2.2 following.

4.2.2 Key Comparison : Comparison with Ringaskiddy WWTP Design

With respect to the Pfizer Ringaskiddy WWTP design parameters, representing the full treatment capacity of the WWTP, we note from Table 5 above that the average Pfizer Biotechnology Ireland effluent load will represent 1.84% of design average influent COD loads to the WWTP.

Similarly, the maximum daily Pfizer Biotechnology Ireland effluent COD load is projected to be equivalent to 2.12% of design maximum influent COD load. This is considered an insignificant proportion of design maximum COD capacity.

An instantaneous peak COD loading during a time of batch failure in the Pfizer Biotechnology Ireland facility would represent 4.72% of the design capacity of the Ringaskiddy WWTP. Again, this is not considered a significant proportion of design maximum capacity.

On this key design comparison, the maximum Pfizer Biotechnology Ireland effluent COD loading is not considered a significant proportion of the design COD loading capacity of the Ringaskiddy WWTP.

4.2.3 Conclusion : COD Loading

We conclude that the Pfizer Ringaskiddy WWTP has sufficient COD loading capacity to accept and treat the Pfizer Biotechnology Ireland effluent stream even under maximum and instantaneous peak loading conditions. We conclude that the effluent will continue to be treated to achieve the emission limit values specified in IPPC licence P0013-04.

We confirm that the Pfizer Biotechnology Ireland effluent stream will remain a minor component of the Ringaskiddy WWTP influent even at these maximum and peak conditions.

5.0 Other Parameters : Treatability Assessment

5.1 Nitrogen and phosphorus

In common with many industrial WWTPs, the influent to the Pfizer Ringaskiddy WWTP tends to be deficient in nitrogen and phosphorus. Since both elements are important nutrients and are essential to the maintenance of a healthy biomass, they are both regularly added to the WWTP influent. Nitrogen is added in the form of urea and phosphorus as phosphoric acid.

The presence of low levels of nitrogen and phosphorus in the Pfizer Biotechnology Ireland effluent stream, in easily bioavailable form, is therefore expected to be beneficial to the Pfizer Ringaskiddy WWTP. Nitrogen is expected to be present in the Pfizer Biotechnology Ireland effluent stream at an average level of 8.0 kg/day, with a maximum of 12.0 kg/day. Phosphorus is expected to be present in the Pfizer Biotechnology Ireland effluent stream at an average level of 7.5 kg/day, with a maximum of 15.0 kg/day.

Although we remark that the nutrient levels available in the Pfizer Biotechnology Ireland effluent stream are unlikely to replace the ongoing supplementary nutrient addition to the Ringaskiddy WWTP, they may nevertheless permit some reduction in the required frequency of such supplementary additions.

In view of the fact that the Ringaskiddy WWTP is deficient in nitrogen and phosphorus, we conclude that the levels of both elements available in the Pfizer Biotechnology Ireland process effluent will be taken up as nutrients by the biomass in the WWTP and will therefore have no impact on final effluent quality.

We conclude that the low levels of nitrogen and phosphorus in the Pfizer Biotechnology Ireland effluent stream will be beneficial to the maintenance of an efficient biomass in the Pfizer Ringaskiddy WWTP.

5.2 Temperature

The Pfizer Biotechnology Ireland effluent stream is projected to have a maximum daily temperature of 40°C. The stream is of very low volume relative to the existing volume of the Ringaskiddy WWTP and will therefore very quickly thermodynamically equilibrate to the surrounding temperature of the WWTP mixed liquor within the large aeration basins.

We note that the Pfizer Ringaskiddy WWTP has cooling water heat exchangers installed on its first stage aeration basins. Mixed liquor from the aeration basins is continuously passed through these heat exchangers in order to maintain a relatively constant temperature in the approximate range 26-29 °C.

For these reasons, we confirm that the addition of the Pfizer Biotechnology Ireland effluent stream to the Ringaskiddy WWTP will not impact significantly on temperature profiles within the WWTP.

5.3 pH

The aqueous biowaste will be pH neutralised to the range 6-9 within the Pfizer Biotechnology Ireland facility and will not therefore impact on the pH profile within the Pfizer Ringaskiddy WWTP.

5.4 Domestic Effluent (Sanitary Sewage)

It is proposed that domestic effluent (sanitary sewage) from the Pfizer Biotechnology Ireland facility will be treated in the Pfizer Ringaskiddy WWTP. Sanitary sewage is highly biodegradable and is expected to be treated to a high degree in the WWTP.

We note that domestic effluent from the former Corrin MDA (previously ADM) site had been ducted to the Ringaskiddy WWTP during the period of demolition activities on that site, with Agency approval (ref. our letter to the Agency dated 28-March-2006 and subsequent Agency letter of approval M542/ap48mo, dated 03-May-2006).

We further note that domestic effluent from the existing construction site for the Pfizer Biotechnology Ireland facility is currently treated in the Pfizer Ringaskiddy WWTP, with Agency aproval (ref. our letter to the Agency dated 01-August-2007 and subsequent Agency letter of approval P0013-04/ap08nod.doc, dated 03-August-2007).

As described earlier, we propose to continue to treat domestic effluent from the operational Pfizer Biotechnology Ireland facility.

We confirm that the treatment of domestic effluent from the Pfizer Biotechnology Ireland facility will comprise a negligible additional load on the WWTP even at peak expected employment levels.

Although flows and loadings of domestic effluents are generally variable, we provide below for illustrative purposes an estimate of the loading of the domestic effluent from the Pfizer Biotechnology Ireland facility :

Estimated Peak Employment	100 persons
Sewage BOD[2] Factor	25 g per person per day
Sewage BOD Load	25 x 100 = 2,500 g/day = 2.50 kg/day
BOD:COD Ratio for Sewage[3]	0.37
Sewage COD Load	2.50/0.37 = 6.76 kg/day

We note that the projected domestic effluent COD load is therefore negligible compared with the available capacity and typical measured loadings in the Ringaskiddy WWTP.

We also provide below a typical estimate of the volumetric loading of the domestic effluent :

Estimated Peak Employment	100 persons
Sewage Volume Factor	60 litres per person per day

[2] A typical sewage BOD factor for an urban residential area is ca. 55 g per person per day. This accounts for sanitary sewage in addition to wastewater from domestic appliances such as washing machines, dishwashers, sinks, etc., over a 24 hour period. For activities such as schools and factories, a BOD factor of 25 g per person per day is typical, since the domestic wastewater sources tend to be more limited. The latter factor is therefore considered appropriate.

[3] Ref. "Activated Sludge Treatment of Industrial Wastewater", Eckenfelder and Musterman, Technomic Publishing Co. Inc.

Sewage Volume	60 x 100 = 6,000 litres/day = 6 m^3/day

Again, we note that the projected domestic effluent volume is negligible compared with the available capacity and typical measured volumes in the WWTP.

In summary, we confirm that the treatment of domestic effluent (sanitary sewage) from the Pfizer Biotechnology Ireland site is expected to be highly efficient in the WWTP and that the additional load is negligible.

5.5 Toxicity and Inhibition

We note that the products manufactured in the Pfizer Biotechnology Ireland site are protein-based compounds. Any residues of such proteins which may be present in the waste stream will be degraded during cleaning-in-place (CIP) routines and during the thermal deactivation step within the Pfizer Biotechnology Ireland facility.

The resultant waste stream will consequently comprise biological cell residues in an aqueous medium. The Pfizer Biotechnology Ireland effluent stream is therefore not expected to exhibit any significant toxicity or inhibitory activity towards the Pfizer Ringaskiddy WWTP.

6.0 Overall Conclusion of Quantitative Treatability Assessment

As demonstrated above, the effluent from the Pfizer Biotechnology Ireland facility can be comfortably accepted and treated in the Pfizer Ringaskiddy WWTP. The WWTP is capable of providing a high degree of treatment, thereby producing a high quality effluent in compliance with emission limit values.

The addition of the Pfizer Biotechnology Ireland effluent stream does not represent significantly increased flows or loadings on the Ringaskiddy WWTP and is comfortably within both the key design capacity and the recent operational ranges of the WWTP. We confirm that the treatment of the Pfizer Biotechnology Ireland effluent stream does not represent a significant change.

We conclude therefore that the final treated effluent quality will continue to remain within the emission limit values specified in Schedule B.3 "Emissions to Sewer" of the Pfizer Ringaskiddy IPPC licence P0013-04.

7.0 Advantages of Treatment in Pfizer Ringaskiddy WWTP

In addition to the Quantitative Treatability Assessment provided in earlier sections, we note that the treatment of the Pfizer Biotechnology Ireland effluent stream in the Pfizer Ringaskiddy WWTP has significant advantages in terms of environmental benefit and energy/resource usage.

We outline these advantages below.

7.1 Environmental Benefit

The Pfizer Biotechnology Ireland process and domestic effluents will comprise low volumes of highly biodegradable biological-based material. Addition of biodegradable effluent of this type typically tends to be beneficial to industrial wastewater treatment plants.

As described in Section 5.1 above, we noted that industrial wastewater treatment plants are typically deficient in the nutrients nitrogen and phosphorus. These nutrients are important to the maintenance of a healthy and effective biomass. We noted therein that nitrogen and phosphorus are therefore regularly added to the Pfizer Ringaskiddy WWTP.

As described, the presence of low levels of nitrogen and phosphorus in the Pfizer Biotechnology Ireland effluent stream, in easily bioavailable form, is therefore expected to be beneficial to the Pfizer Ringaskiddy WWTP.

Although we noted earlier that the nutrient levels available in the Pfizer Biotechnology Ireland effluent stream are unlikely to replace the ongoing supplementary nutrient addition to the Ringaskiddy WWTP, they may nevertheless permit some reduction in the required frequency of such supplementary additions.

We therefore expect a modest reduction in nutrient material usage in the Ringaskiddy WWTP.

7.2 Energy and Resource Usage

The use of the existing Pfizer Ringaskiddy WWTP to treat effluent from the Pfizer Biotechnology Ireland facility is considered to be significantly more effective in terms of overall energy and resource usage than the alternative of providing standalone treatment on the Pfizer Biotechnology Ireland site.

Provding standalone effluent treatment on the Pfizer Biotechnology Ireland site would likely require a small-scale biological treatment plant, for example a membrane bioreactor or a conventional extended aeration unit. However, it is highly unlikely that the projected effluent load from the Pfizer Biotechnology Ireland facility would be sufficient to maintain effective treatment in such a system without being supplemented with another BOD/COD food source, togther with associated nutrients. In addition, the energy input required to maintain aeration would also likely make such a system significantly energy inefficient.

The use of the existing Pfizer Ringaskiddy WWTP to treat the Pfizer Biotechnology Ireland effluent stream is therefore the most effective and efficient treatment method in terms of energy and resource usage.

We further note that, in addition to the environmental and resource benefits, the use of the existing Pfizer Ringaskiddy WWTP leads to significant cost avoidance by not requiring a standalone onsite treatment system.

8.0 Conclusion

We conclude that the Quantitative Treatability Assessment provided herein confirms that the Pfizer Biotechnology Ireland effluent stream can be comfortably accepted and treated in the Pfizer Ringaskiddy WWTP. The WWTP is capable of providing a high degree of treatment, thereby producing a high quality effluent in compliance with emission limit values.

The maximum projected key values for the Pfizer Biotechnology Ireland process effluent stream as used in this Quantitative Treatability Assessment are as follows :

Process Effluent Parameter	Maximum Projected Value
Flow (m^3/day)	240
COD (tonnes/day)[4]	1.00

On the basis of these maximum projected values, the Quantitative Treatability Assessment has confirmed that the addition of the Pfizer Biotechnology Ireland effluent stream does not represent significantly increased flows or loadings on the Ringaskiddy WWTP and is comfortably within both the key design capacity and the recent operational ranges of the WWTP. The Pfizer Biotechnology Ireland effluent will constitute a minor influent stream of the Pfizer Ringaskiddy WWTP. We confirm that the treatment of the Pfizer Biotechnology Ireland effluent stream does not represent a significant change.

We further confirm that the treatment of domestic effluent (sanitary sewage) from the Pfizer Biotechnology Ireland site is expected to be highly efficient in the Pfizer Ringaskiddy WWTP and that the additional load is negligible.

We conclude therefore that the final treated effluent quality will continue to remain within the emission limit values specified in Schedule B.3 "Emissions to Sewer" of the Pfizer Ringaskiddy IPPC licence P0013-04.

We acknowledge the requirement to continue to conform to the emission limit values in IPPC licence P0013-04.

On the basis of this Quantitative Treatablity Assessment, we therefore request Agency approval to :

(i) treat Pfizer Biotechnology Ireland process effluent in the Pfizer Ringaskiddy WWTP
(ii) treat domestic effluent (sanitary sewage) from the Pfizer Biotechnology Ireland site in the Pfizer Ringaskiddy WWTP

We trust that this is to the satisfaction of the Agency.

[END]

[4] Taken as the worst-case instantaneous COD peak load described in Section 2.1.

Appendix 2

Information from Pfizer Biotechnology Ireland as previously submitted to the Agency

Pfizer Biotechnology Ireland IPPC Licence Application

Proposal for Control, Monitoring and Limits on the Pfizer Biotechnology Ireland Process Effluent

26th Nov 2008

1. Introduction:

Pfizer Biotechnology Ireland is keen to ensure that the information available to the EPA and others during the licensing processes is as comprehensive as possible, with the information provided under constant review as to its accuracy and relevance. Following the most recent consideration of our IPPC licence application information, the following outlines the project schedule, controls, monitoring, and control limits, and offers a series of options to more closely define measurement and responsibilities in relation to licence limit values.

2. Licensing:

An Integrated Pollution Prevention & Control (IPPC) Licence has been applied for, to the Environmental Protection Agency (EPA). This licence covers activities once the facility become operational. The commencement of the activity is targeted for Q3 2009. The Proposed Determination (PD) of the licence is targeted for issue in Q1 2009.

3. Continuous Control of Process Effluent Treatment Plant on the Pfizer Biotechnology Ireland Site

Comprehensive monitoring controls for the Pfizer Biotechnology Ireland effluent treatment system have been designed into the treatment process control logic. These controls and monitoring procedures are in themselves in accordance with the OFC BAT Bref Guidance Note for the sector and also conform to GMM control requirements.

- The Process Effluent Treatment Plant is an automated setup, with PLC (Programmable Logic Controller) control on the neutralisation skid, and alarm, remote start/stop DCS (Distributed Control System) interface.
- The treatment plant is a three stage system, consisting of:
  - Heat Inactivation (see Biowaste Inactivation below)
  - Equalisation
  - Neutralisation

  (See Appendix 1)

- The untreated wastewater from the process areas (excluding Cell Culture – see Biowaste) on the upper floors will be gravity drained into an Equalization Tank.
- A number of first (ground) floor waste streams (primarily utility area floor drains) route to a process waste sump tank (located in a sealed concrete containment pit) under first floor level, from which they are pumped over to the Equalization tank via 10 lpm sump pumps.
- Heat inactivated Biowaste (from the biowaste inactivation system) is transferred over from the Biowaste inactivation skid directly into the Equalization tanks.
- The Equalization Tank is sized for a working volume of 18,000 litres and will be installed on the first floor in a contained area. The Equalization Tank liquid level will be monitored and also alarmed at high liquid level. From the Equalization Tank, the wastewater will be pumped into the Neutralization System. The Waste Feed Pumps are rated for 150 lpm (design flow), with the final effluent discharge pump rated for 166 lpm (design flow).
- The Neutralization System will consist of two agitated tanks in series. The first stage tank is sized for a minimum of 10 minutes retention at design flow. The second stage is sized for a minimum of 15 minutes retention at design flow.
- The pH in the first stage will be measured and monitored. This pH signal will stroke the opening / closing of the acid / caustic addition valves to add reagent to the first stage based on split range control.
- The pH of the second stage will be measured and monitored. At any pH outside the permitted range, this pH controller will add acid or caustic. The first/second stages of the Neutralization System and the acid/caustic storage area will be within an enclosed room at grade elevation.
- Acid and Caustic will be transferred from these to separate acid and base supply tanks from which their contents will be metered into the neutralisation system.
- Reagent can be added, based on the automatic controller, to the first stage and/or second stage of the Neutralization System.
- The treated process waste is pumped via an 80 mm double contained Polypropylene line underground to a point at the North East corner of the site where it rises onto a pipe rack and routes to Pfizer Ringaskiddy WWTP.
- The system will be treated as environmentally critical, with the associated preventative maintenance and calibration measures applied.
- All controls with be alarmed and included as critical alarms on the site alarm system. Controls and alarms will be supported by a back up generator and placed on a UPS System (Uninterrupted Power Supply)

Biowaste Inactivation

- Cell Culture is designed according to Biosafety Level 1 - Large Scale (BL1-LS) per the United States National Institute of Health (NIH) guidelines and meets the requirements of Containment Level 2 (CL2) per European Union Council Directive 98/81/EC (26 October 1998).
- Cell Culture includes bioreactors and recovery. Biowaste from the BL1-LS areas is collected, transferred to the Biowaste Inactivation System for inactivation, and discharged into process waste drain. (see Appendix 2)

- The facility provides a Biowaste Inactivation System to collect and heat inactivate waste from the BL1-LS areas. A hot caustic circulation rinse and the first rinse and wash from the CIP skids cleaning equipment in the BL1-LS areas is also routed to biowaste inactivation.
- Biowaste from gravity drains in the manufacturing building is collected in the Biowaste Surge Vessel. The Biowaste Surge Vessel is located on the first floor at grade in a contained area and has a working volume of 5,000 litres. A biowaste transfer pump transfers the biowaste to the Biowaste Inactivation System. The pump is rated at 35 LPM. An inlet duplex strainer is provided on the supply line to the Biowaste Transfer Pumps.
- The Biowaste Inactivation Skid consists of an economizer exchanger, a steam heating eductor and a retention tube. The biowaste transfer pump transfers biowaste from the surge vessel through the economizer. The economizer preheats the cool feed with the hot inactivated waste from the retention tube. The eductor injects 4.5-barg plant steam to bring the biowaste to the inactivation temperature.
- Time-at-temperature is provided as the hot biowaste flows through the retention tube. The economizer cools the hot inactivated waste from the retention tube with the cool feed. Off-specification biowaste is returned to the Biowaste Surge Vessel.
- Inactivated biowaste is discharged to the Process Waste Neutralization System.
- The Biowaste Inactivation System is designed to process a flow rate of 35 lpm.
- The system will be validated during the start-up phase of the project. It will also be treated as an environmentally critical system with the associated preventative maintenance, calibration and re-qualification measures applied. All controls with be alarmed and included as critical alarms on the site alarm system. Controls and alarms will be supported by a back up generator and placed on a UPS System (Uninterrupted Power Supply)

4. Monitoring of Process Effluent on the Pfizer Biotechnology Ireland Site

The flow rate, pH, temperature & TOC of the treated process wastewater from the second stage Neutralization System tank will be measured using on-line instruments and recorded on the DCS (Distributed Control System), with associated automated interlocks to ensure compliance with the license limit values. i.e.

On-Line Monitoring					
Monitoring Parameter	**Monitoring Equipment**	**Equipment Preventative maintenance**	**Analysis**	**Sample**	**Monitoring Frequency**
TOC	TOC Probe	Computerised PM Schedule	On-Line	Continuous	Continuous
pH	pH Probe	Computerised PM Schedule	On-Line	Continuous	Continuous
Flow	Flow Meter	Computerised PM Schedule	On-Line	Continuous	Continuous
Temperature	Temperature Probe	Computerised PM Schedule	On-Line	Continuous	Continuous

It should be recognised that the effluent will be of a consistent (batch) quality as the biowaste arises from a standardised batch process and accompanying cleaning regime. Upper and lower (i.e. for pH) control limits will be set, and in the event of an excursion outside these control limits – the final effluent discharge valve will close automatically, with alarm activation and response.

Monitoring against the Pfizer Biotechnology Ireland IPPC License limit values, will be carried out using a flow proportionate composite sampler, with subsequent analysis for COD & pH on a daily basis, and Nitrogen, Phosphorus and Toxicity on a lesser frequency. (To be agreed with the licensing inspector) i.e.

Flow Proportionate Sampling & Monitoring					
Monitoring Parameter	**Monitoring Equipment**	**Equipment Preventative maintenance**	**Analysis**	**Sample**	**Monitoring Frequency**
pH	Lab Equipment	Contract Analysis Accredited Lab	Lab Analysis	Flow Proportionate Composite Sample	Daily
COD	Lab Equipment	Contract Analysis Accredited Lab	Lab Analysis	Flow Proportionate Composite Sample	Daily
Total Nitrogen	Lab Equipment	Contract Analysis Accredited Lab	Lab Analysis	Flow Proportionate Composite Sample	To be agreed with Agency
Total Phosphorus (as P)	Lab Equipment	Contract Analysis Accredited Lab	Lab Analysis	Flow Proportionate Composite Sample	To be agreed with Agency
Toxicity	Lab Equipment	Contract Analysis Accredited Lab	Lab Analysis	Flow Proportionate Composite Sample	To be agreed with Agency

Limit values imposed on the Pfizer Biotechnology Ireland IPPC License will be based on figures submitted as part of the Process Effluent Treatability Assessment which was included in the original application. i.e.

Discharge Limits	
Monitoring Parameter	**Monitoring Limit(s)**
pH	6-9
COD	I Tonne COD/Day
Flow	240 m^3/day

Note: limit values for Nitrogen, Phosphorus and Toxicity to be agreed with the Agency.

5. Communication of Monitoring Results

Monitoring results will be communicated to the Agency in accordance with the Pfizer Biotechnology Ireland IPPC license requirements.

On-line monitoring results (i.e. flow rate, pH, temperature & TOC) will be accessible on a 24 hour basis by the Ringaskiddy API site via software, and on a daily basis via data spreadsheet located on a common computer shared drive.
Pfizer Biotechnology Ireland is committed to providing this data to the Ringaskiddy site in accordance with Condition 8 of the Pfizer Ireland Pharmaceuticals Ringaskiddy IPPC Licence, and the Pfizer Biotechnology Ireland IPPC license requirements.

6. Pfizer Biotechnology Ireland Response Plan for Effluent Related Incidents

In the event of an engineering control failure at the Shanbally WWTP, resulting in a license limit value being exceeded on the Shanbally final effluent discharge point, the following actions will be taken:

a. initiation of preventative action to prevent further discharge, i.e. immediate isolation of the Shanbally treatment discharge point
b. notification to the Ringaskiddy API site of the monitoring condition/limit exceeded
c. notification to the Agency
d. data gathering, i.e. DCS, Walk down, and staff input
e. investigation using Six-Sigma Right First Time Tools
f. implementation of corrective actions
g. communication of investigation report and corrective actions to both the Ringaskiddy API Plant and the Agency

Conclusion:

Pfizer Biotechnology Ireland is committed to protecting the health and safety of everyone at our facility and the environment of the community in which we operate.

To ensure that we meet this commitment, we have installed a fully automated Treatment Plant, with on-line control equipment measuring Flow, pH, Temperature, and TOC. The monitoring equipment used will be classified as environmental critical, and placed on an elevated preventative preventative maintenance program.

Verification of controls, and monitoring against Pfizer Biotechnology Ireland IPPC License limit values, will be carried out using a flow proportionate composite sampler, with analysis for COD & pH on a daily basis, and Nitrogen, Phosphorus and Toxicity at a lesser frequency. (To be agreed with the licensing inspector)

We will commit via Licence limit values imposed on our licence to operate within the maximum allowable range for the parameters proposed.

Under the interface between Pfizer Biotechnology Ireland and Pfizer Ringaskiddy, the effluent to be transferred has been fully profiled in terms of its typical and maximum composition, volume, characteristics, etc. In this regard, we remark that the effluent from Pfizer Biotechnology Ireland has been fully characterised in these terms in the licence application, based on known production volumes, prior to its future transfer to Pfizer Ringaskiddy. This characterisation data has been provided to Pfizer Ringaskiddy, who have conducted a detailed assessment and have confirmed its treatability and acceptability, in accordance with condition 8 of the existing Pfizer Ringaskiddy licence.

In addition, on-line representative monitoring data will be made available by Pfizer Biotechnology Ireland to Pfizer Ringaskiddy so that continuous data is available in real-time on the effluent being transferred. This will be complemented by composite sampling and testing by Pfizer Biotechnology Ireland for parameters such as COD, Nitrogen, Phosphorus, etc, under the terms of its licence. Arrangements will be made to electronically make available to Pfizer Ringaskiddy both the totalised continuous data and the results of composite sampling by means of a shared drive.

With a detailed process map in place identifying the key data for transfer to, and communication channels with, the receiving Ringaskiddy API Site, we commit to the supply of data on a set frequency to meet the existing condition 8 of the Ringaskiddy licence.

In the event of an upset condition, an exceedence of a Pfizer Biotechnology Ireland IPPC License limit value, a defined course of action, involving the activation of a response plan (as per Section 6) at the Pfizer Biotechnology Ireland site will be implemented. This will also involve notification to the relevant EPA Inspector.

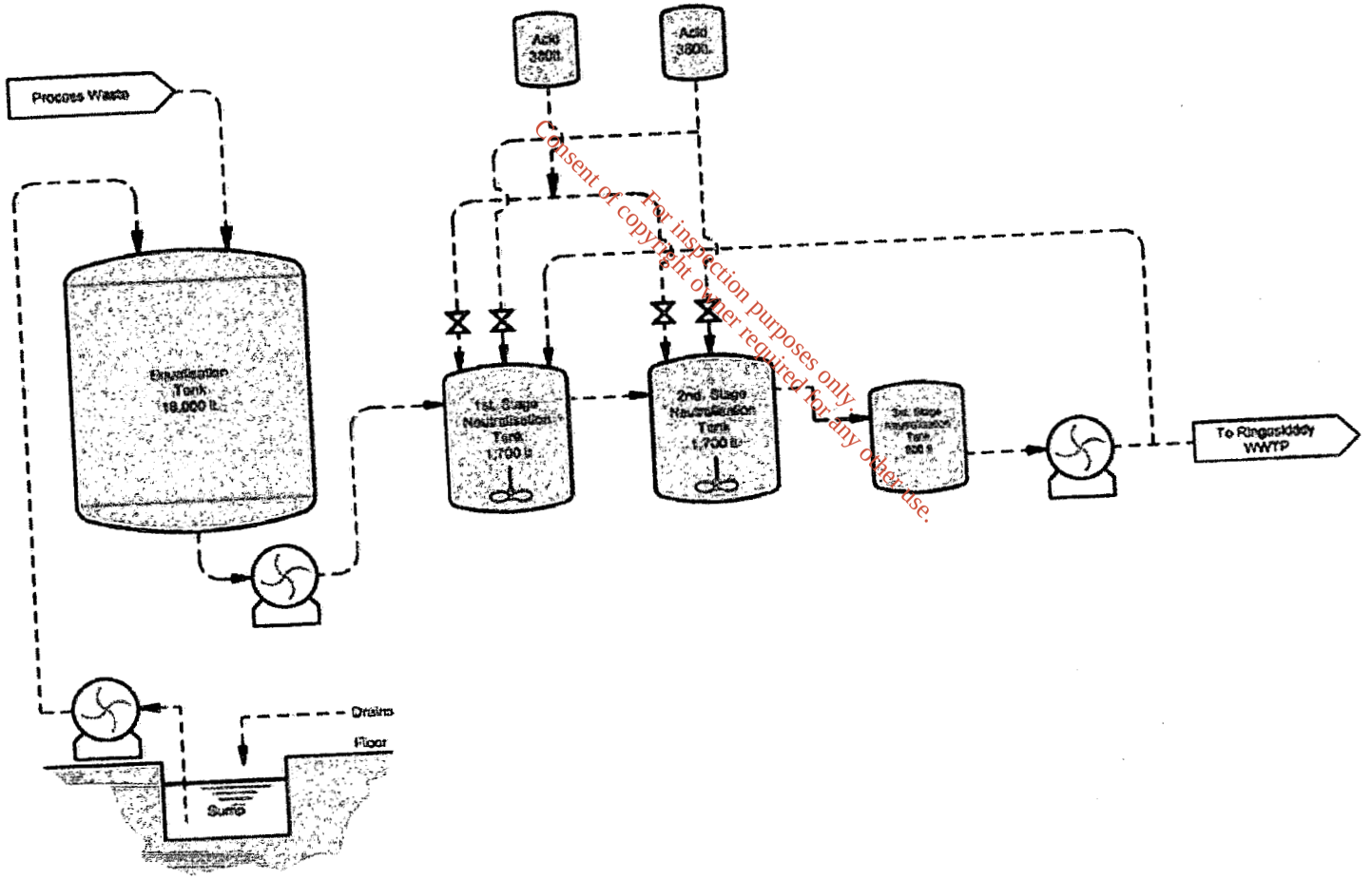
We further confirm that in the event of a significant change in production volumes or the introduction of new product lines, etc., then the projected effluent composition and

characteristics will again be fully profiled as before by Pfizer Biotechnology Ireland. Pfizer Ringaskiddy and the EPA will be notified well in advance of any such change and will be provided with a full effluent characterisation by Pfizer Biotechnology Ireland prior to transfer of such effluent. Effluent transfer will only then commence once Pfizer Ringaskiddy, under condition 8 of its existing licence, have assessed the data, confirmed acceptance in advance, and agreed an acceptance date for commencement of transfer.

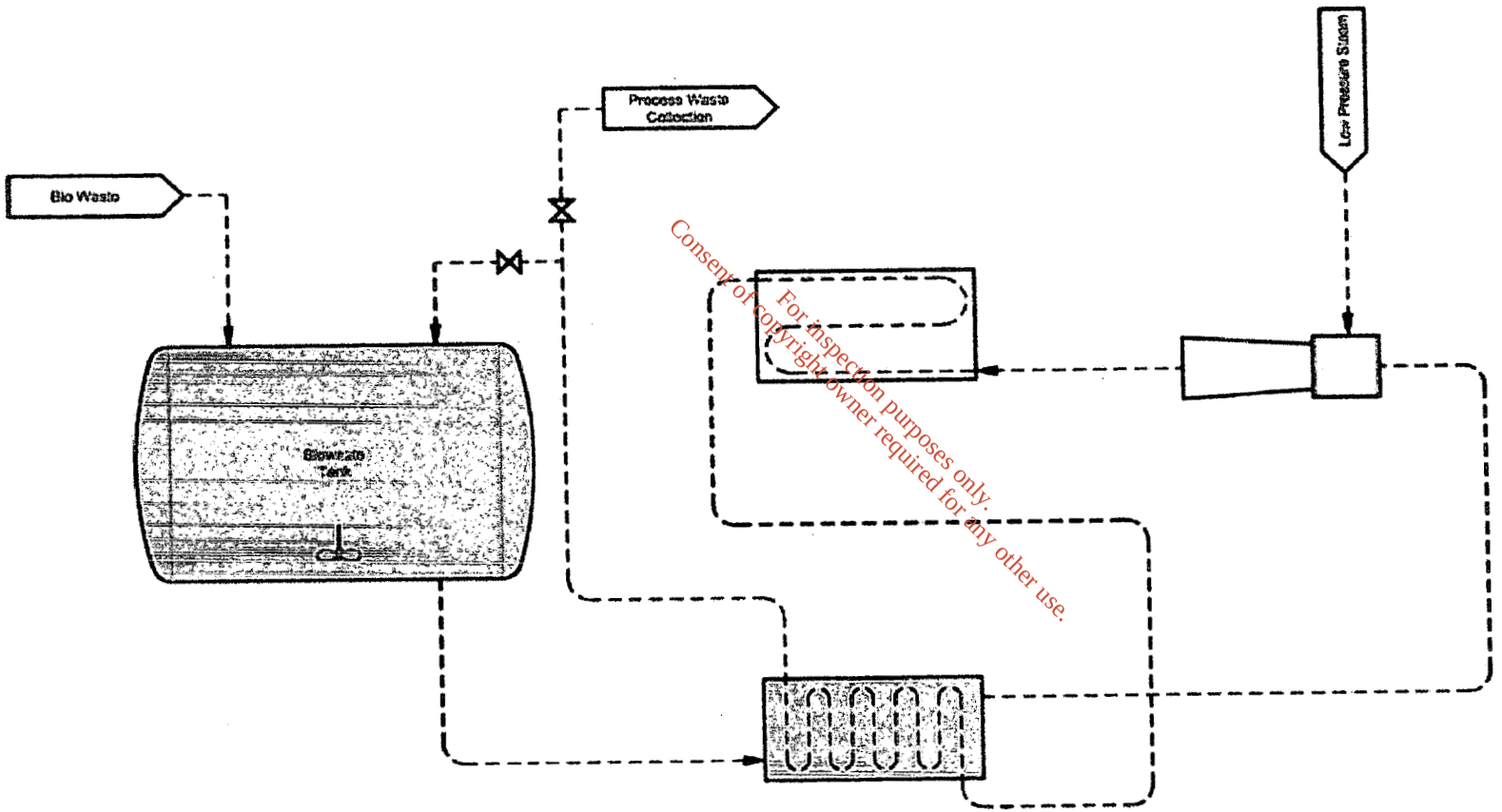
Taking into account the existing Ringaskiddy IPPC Licence, and the operating intent of the Shanbally application, it is proposed that the discharge limits set out in section 4 above be included in the Pfizer Biotechnology Ireland IPPC License.

Taking this approach ensures that responsibility and accountability lie on the Pfizer Biotechnology Ireland Shanbally License, and eliminates the need for duplicate engineering controls on both the Pfizer Biotechnology Ireland site and Ringaskiddy API sites, thereby reducing energy & resource consumption.

Appendix 1: Pfizer Biotechnology Ireland Waste Water Treatment Plant



Appendix 2: Pfizer Biotechnology Ireland Biowaste Inactivation System



Appendix 3: Pfizer Biotechnology Ireland Waste Water Treatment Plant Monitoring