

ATTACHMENT B**GENERAL****B.1. Applicant Details**

- The Company's registration number is: 316510
- A copy of the Certificate of Incorporation is contained in Attachment B, Appendix 1.
- Particulars of the registered office of the company
 - Previous name: Besford Ltd.
 - Type: Single Member Private Company Limited by Shares
 - Date Incorporated: 07/12/99
 - Last Annual Return: 30/09/06
 - Company Directors: Gerry Collins, Keneth J Tompkins, Michelle Drigneault

B.2 Location of Activity

- The location of the site is shown on Figure 1.1, Figure 1.2 at a scale of 1:250 and Figure 1.3.
- The National Grid Reference for the centre of site is 207628865 139031898.
- The Site Plan is illustrated on Figure 2. The boundary of the Site to which the license application relates is outlined in red.

B.3 Class of Activity

The facility is involved in the following activity as defined in the First Schedule of the PoE Act 2003

Schedule	Class	Description
First Schedule	12.2.2	"The use of coating materials in processes with a capacity to use at least 10 tonnes per year of organic solvents"

B.4 Employees/Capital Costs

The gross capital cost of the total project is €200 million. The total number of employees once the additional facility is operational is estimated at 500.

B.5 Planning Authority

South Tipperary County Council is the relevant Planning Authority in whose functional area the facility is located. The planning history of the site is outlined in the Table B.5 overleaf.

Table B.5 Planning History

File No.	Grant Date	Description	Applicant
	Not submitted to date	East entrance for commercial traffic	Cordis Cashel Ltd.
	Application made Nov 07	Cordis QC Laboratory	Cordis Cashel Ltd.
07/1682	Application made 03/10/07	Planning Permission was being sought to demolish an existing single storey dining area of 85m ² and to construct a new dining area of 557m ² complete with 133m ² of 1 st floor office space overhead. The proposed development is located within an existing enclosed courtyard on the ALZA site.	ALZA Ireland Ltd.
07/1409	19/09/07	Planning granted for the amendment to the existing planning permission ref 06/2081, for the construction of a new manufacturing facility of 7682m ² . The facility consisted of a 2 storey manufacturing building with the plant room at the first floor level, a 2 storey final packaging and dispatch building and a 2 storey central utilities building and separate single storey electrical sub-station building together with all associated ancillary site development works, the existing vehicular and service entrances of Cahir Road to be retained.	Cordis Cashel Ltd.
07/359	28/05/07	Planning granted to retain pre-fabricated offices which comprised of an area of 557m ² in total over two storeys including associated site works.	ALZA Ireland Ltd.
06/2081	23/03/07	Planning granted for the construction of a new manufacturing facility of 21,365m ² which consisted of a 3 storey administration building, a 2 storey manufacturing building, a 2 storey final packing and dispatch building and a 2 storey utility building and substation, including a new services entrance from the Old Road adjoining the eastern boundary of the site, 204 new car parking spaces and a new entrance lobby which is shared with the existing building and all associated ancillary site development works.	Cordis Cashel Ltd.
06/926	17/10/06	Planning granted for the construction of a drum store and associated paving and drainage at the facility.	ALZA Ireland Ltd.
05/1129	15/11/05	Planning granted for the construction of 112 car parking spaces and associated drains, lighting and footpaths, 3 flag poles a smoker shelter and to raise the level of 5 exhaust stacks on the roof of the facility by no more than 3 meters.	ALZA Ireland Ltd.
01/157	29/06/01	Planning granted for the construction of a two storey administrative/production space, warehouse with loading dock and associated site development works including new entrance. The development linked and utilized the existing	IDA Ireland

		industrial unit on site to house laboratories, offices and mechanical equipment.	
P37771	24/08/81	Planning granted for construction of an industrial development.	IDA Industrial Estate

Attachment B Appendix 5 contains the following documents:

- IPC Licence No. P0645-01
- Planning Conditions in relation to File Number 06/926, 06/2081 and 07/1409 as described in the previous table.

B6 Relevant Sanitary Authority

South Tipperary County Council is the relevant Sanitary Authority in whose functional area the facility is located.

B7 Relevant Health Board Region

South Eastern Health Board Region

Lacken

Dublin Road

Kilkenny

Phone: 056 7784100

B.8 Site Notice, Newspaper Advertisement and Planning Authority Notice.

Notice of this Application has been provided to the public by means of an advertisement in the Examiner newspaper dated 28/11/07 and a site notice which was posted on 28/11/07 and will be displayed for a period of two months after submission of this application. Notice was given to the Local Authority in the form of a letter to South Tipperary County Council dated 26/11/07. Attachment 5 Appendix 8 contains the following:

- Newspaper in which the notice was displayed. Examiner newspaper, on the 28/11/07
- Text of the Site Notice.
- Figure 1.2 showing the location of Site Notice
- A copy of the letter notifying the planning authority of the application.

B.9 Seveso II Regulations

The current operations at the ALZA facility are not considered to represent a risk of generating a major accident involving dangerous substances as outlined under the European Communities (Control of Major Accidents Hazards Involving Dangerous Substances) Regulations, 2006 (SI No.74 of 2006). As part of this application an assessment was carried out to establish whether the proposed development would result in site falling within the Seveso II Regulations. The assessment concluded that the site does not fall within the criteria for being either a Tier 1 or Tier 2 site in relation to the Seveso II Regulations.

B.10 IPPC Directive

This category of industrial activity is not referred to in Annex I of the IPPC Directive (96/61/EC).

*For inspection purposes only.
Consent of copyright owner required for any other use.*

ATTACHMENT B**GENERAL****B.1. Applicant Details**

- The Company's registration number is: 316510
- A copy of the Certificate of Incorporation is contained in Attachment B, Appendix 1.
- Particulars of the registered office of the company
 - Previous name: Besford Ltd.
 - Type: Single Member Private Company Limited by Shares
 - Date Incorporated: 07/12/99
 - Last Annual Return: 30/09/06
 - Company Directors: Gerry Collins, Keneth J Tompkins, Michelle Drigneault

B.2 Location of Activity

- The location of the site is shown on Figure 1.1, Figure 1.2 at a scale of 1:250 and Figure 1.3.
- The National Grid Reference for the centre of site is 207628865 139031898.
- The Site Plan is illustrated on Figure 2. The boundary of the Site to which the license application relates is outlined in red.

B.3 Class of Activity

The facility is involved in the following activity as defined in the First Schedule of the PoE Act 2003

Schedule	Class	Description
First Schedule	12.2.2	"The use of coating materials in processes with a capacity to use at least 10 tonnes per year of organic solvents"

B.4 Employees/Capital Costs

The gross capital cost of the total project is €200 million. The total number of employees once the additional facility is operational is estimated at 500.

B.5 Planning Authority

South Tipperary County Council is the relevant Planning Authority in whose functional area the facility is located. The planning history of the site is outlined in the Table B.5 overleaf.

Table B.5 Planning History

File No.	Grant Date	Description	Applicant
	Not submitted to date	East entrance for commercial traffic	Cordis Cashel Ltd.
	Application made Nov 07	Cordis QC Laboratory	Cordis Cashel Ltd.
07/1682	Application made 03/10/07	Planning Permission was being sought to demolish an existing single storey dining area of 85m ² and to construct a new dining area of 557m ² complete with 133m ² of 1 st floor office space overhead. The proposed development is located within an existing enclosed courtyard on the ALZA site.	ALZA Ireland Ltd.
07/1409	19/09/07	Planning granted for the amendment to the existing planning permission ref 06/2081, for the construction of a new manufacturing facility of 7682m ² . The facility consisted of a 2 storey manufacturing building with the plant room at the first floor level, a 2 storey final packaging and dispatch building and a 2 storey central utilities building and separate single storey electrical sub-station building together with all associated ancillary site development works, the existing vehicular and service entrances of Cahir Road to be retained.	Cordis Cashel Ltd.
07/359	28/05/07	Planning granted to retain pre-fabricated offices which comprised of an area of 557m ² in total over two storeys including associated site works.	ALZA Ireland Ltd.
06/2081	23/03/07	Planning granted for the construction of a new manufacturing facility of 21,365m ² which consisted of a 3 storey administration building, a 2 storey manufacturing building, a 2 storey final packing and dispatch building and a 2 storey utility building and substation, including a new services entrance from the Old Road adjoining the eastern boundary of the site, 204 new car parking spaces and a new entrance lobby which is shared with the existing building and all associated ancillary site development works.	Cordis Cashel Ltd.
06/926	17/10/06	Planning granted for the construction of a drum store and associated paving and drainage at the facility.	ALZA Ireland Ltd.
05/1129	15/11/05	Planning granted for the construction of 112 car parking spaces and associated drains, lighting and footpaths, 3 flag poles a smoker shelter and to raise the level of 5 exhaust stacks on the roof of the facility by no more than 3 meters.	ALZA Ireland Ltd.
01/157	29/06/01	Planning granted for the construction of a two storey administrative/production space, warehouse with loading dock and associated site development works including new entrance. The development linked and utilized the existing	IDA Ireland

		industrial unit on site to house laboratories, offices and mechanical equipment.	
P37771	24/08/81	Planning granted for construction of an industrial development.	IDA Industrial Estate

Attachment B Appendix 5 contains the following documents:

- IPC Licence No. P0645-01
- Planning Conditions in relation to File Number 06/926, 06/2081 and 07/1409 as described in the previous table.

B6 Relevant Sanitary Authority

South Tipperary County Council is the relevant Sanitary Authority in whose functional area the facility is located.

B7 Relevant Health Board Region

South Eastern Health Board Region

Lacken

Dublin Road

Kilkenny

Phone: 056 7784100

B.8 Site Notice, Newspaper Advertisement and Planning Authority Notice.

Notice of this Application has been provided to the public by means of an advertisement in the Examiner newspaper dated 28/11/07 and a site notice which was posted on 28/11/07 and will be displayed for a period of two months after submission of this application. Notice was given to the Local Authority in the form of a letter to South Tipperary County Council dated 26/11/07. Attachment 5 Appendix 8 contains the following:

- Newspaper in which the notice was displayed. Examiner newspaper, on the 28/11/07
- Text of the Site Notice.
- Figure 1.2 showing the location of Site Notice
- A copy of the letter notifying the planning authority of the application.

B.9 Seveso II Regulations

The current operations at the ALZA facility are not considered to represent a risk of generating a major accident involving dangerous substances as outlined under the European Communities (Control of Major Accidents Hazards Involving Dangerous Substances) Regulations, 2006 (SI No.74 of 2006). As part of this application an assessment was carried out to establish whether the proposed development would result in site falling within the Seveso II Regulations. The assessment concluded that the site does not fall within the criteria for being either a Tier 1 or Tier 2 site in relation to the Seveso II Regulations.

B.10 IPPC Directive

This category of industrial activity is not referred to in Annex I of the IPPC Directive (96/61/EC).

*For inspection purposes only.
Consent of copyright owner required for any other use.*

ATTACHMENT B
APPENDIX 1

*For inspection purposes only.
Consent of copyright owner required for any other use.*

Number 424180

Certificate of Incorporation on change of name

I hereby certify that

DISCOR LIMITED

having, by a Special Resolution of the Company,
and with the approval of the Registrar of Companies,
changed its name, is now incorporated
as a limited company under the name

CORDIS CASHEL LIMITED

and I have entered such name on the Register accordingly.

Given under my hand at Dublin, this

Wednesday, the 4th day of October, 2006


for Registrar of Companies

For inspection purposes only.
Consent of copyright owner required for any other use.

Number 316510

Certificate of Incorporation on change of name

I hereby certify that

BESFORD LIMITED

having, by a Special Resolution of the Company,
and with the approval of the Minister for Enterprise,
Trade and Employment, changed its name, is now
incorporated as a limited company under the name

ALZA IRELAND LIMITED

and I have entered such name on the Register accordingly.

Given under my hand at Dublin, this

Wednesday, the 10th day of January, 2001


for Registrar of Companies

For inspection purposes only.
Consent of Copyright owner required for any other use.

ATTACHMENT B
APPENDIX 5

*For inspection purposes only.
Consent of copyright owner required for any other use.*



Headquarters,
Johnstown Castle Estate,
County Wexford, Ireland

INTEGRATED POLLUTION CONTROL LICENCE

*For inspection purposes only
Consent of copyright owner required for any other use*

Licence Register Number:	645
Licensee:	Alza Ireland Limited
Location of Activity:	Cahir Road, Cashel, County Tipperary.

Table of Contents

	Page No.
Glossary of Terms	1
Reasons for the Decision	3
Activities Licensed	3
Condition 1. Scope.....	4
Condition 2. Management of the Activity	4
Condition 3. Interpretation	6
Condition 4. Notification	8
Condition 5. Emissions to Atmosphere	9
Condition 6. Emissions to Sewer.....	11
Condition 7. Waste Management.....	12
Condition 8. Noise	13
Condition 9. Non-Process Water	14
Condition 10. Energy Use	15
Condition 11. Monitoring	16
Condition 12. Recording and Reporting to Agency.....	17
Condition 13. Accidents and Emergency Response	18
Condition 14. Residuals Management	18
Condition 15. Financial Provisions.....	19
<i>Schedule 1(i) Emissions to Atmosphere</i>	<i>21</i>
<i>Schedule 1(ii) Emissions to Atmosphere: Abatement/Treatment Control.....</i>	<i>22</i>
<i>Schedule 1(iii) Monitoring of Emissions to Atmosphere.....</i>	<i>23</i>
<i>Schedule 2(i) Emissions to Sewer</i>	<i>24</i>
<i>Schedule 2(ii) Monitoring of Emissions to Sewer</i>	<i>24</i>
<i>Schedule 3(i) Hazardous Wastes for Disposal/Recovery.....</i>	<i>25</i>
<i>Schedule 3(ii) Other Wastes for Disposal/Recovery</i>	<i>25</i>
<i>Schedule 3(iii) Waste Analysis</i>	<i>26</i>
<i>Schedule 4(i) Surface Water Discharge Monitoring.....</i>	<i>26</i>
<i>Schedule 5(i) Groundwater Monitoring</i>	<i>26</i>
<i>Schedule 6(i) Recording and Reporting to the Agency.....</i>	<i>27</i>

Glossary of Terms

The Agency	Environmental Protection Agency.
The Licensee	Alza Ireland Limited, Cahir Road, Cashel, County Tipperary.
AER	Annual Environmental Report.
Annually	All or part of a period of twelve consecutive months.
BATNEEC	Best Available Technology Not Entailing Excessive Cost.
Biannually	All or part of a period of six consecutive months.
Biennially	Once every two years.
BOD	5 day Biochemical Oxygen Demand.
COD	Chemical Oxygen Demand.
Daily	During all days of plant operation, and in the case of emissions, when emissions are taking place; with no more than 1 measurement on any one day.
Day	Any 24 hour period.
Daytime	0800 hrs to 2200 hrs.
dB(A)	Decibels (A weighted).
DO	Dissolved Oxygen.
EMP	Environmental Management Programme.
EPA	Environmental Protection Agency
EWC	European Waste Catalogue (94/3/EEC as amended)
Fortnightly	At least 20 measurements in a calendar year with no more than one measurement in any one week.
GC/MS	Gas Chromatography/ Mass Spectroscopy
HFO	Heavy Fuel Oil.
ICP	Inductively Coupled Plasma Spectroscopy.
IPC	Integrated Pollution Control.
K	Kelvin.
kPa	kilo Pascals.
Leq	Equivalent continuous sound level.
Lighting-up time	30 minutes after sun set.

List I	As listed in the EC Directives 76/464/EEC and 80/68/EEC and amendments.
List II	As listed in the EC Directives 76/464/EEC and 80/68/EEC and amendments.
Local Authority	Tipperary South Riding County Council.
Mass Flow Limit	An Emission Limit Value which is expressed as the maximum mass of a substance which can be emitted per unit time. The limit is usually expressed in kilograms per hour (kg/h).
Mass Flow Threshold	A mass flow rate, above which, a concentration limit applies. The rate is usually expressed in kilograms per hour (e.g. at mass flow rates > 2 kg/h).
Monthly	At least 12 times per year at approximately monthly intervals.
Night-time	2200 hrs to 0800 hrs.
Noise sensitive location	Any dwelling house, hotel or hostel, health building, educational establishment, place of worship or entertainment, or any other facility or area of high amenity which for its proper enjoyment requires the absence of noise at nuisance levels.
PER	Pollution Emission Register.
ppm	Parts per million.
Quarterly	All or part of a period of three consecutive months beginning on the first day of January, April, July or October.
Regional Fisheries Board	Southern Regional Fisheries Board
Sanitary Authority	Tipperary South Riding County Council.
Standard Methods	As detailed in "Standard Methods for the Examination of Water and Wastewater", (prepared and published jointly by A.P.H.A., A.W.W.A & W.E.F) 20th Ed. 1998, American Public Health Association, 1015 Fifteenth Street, N.W., Washington DC 20005, USA; or, an alternative method as may be agreed in writing with the Agency.
VOC	Any organic compound having at 293.15K a vapour pressure of 0.01kPa or more, or having a corresponding volatility under the particular conditions of use.
Waste disposal operation	Means any of the operations included in the Third Schedule to the Waste Management Act 1996.
Waste recovery operation	Means any of the operations included in the Fourth Schedule to the Waste Management Act 1996.
Weekly	During all weeks of plant operation, and in the case of emissions, when emissions are taking place; with no more than one measurement in any one week.
WWTP	Waste Water Treatment Plant.

Reasons for the Decision

The Agency is satisfied, on the basis of the information available, that subject to compliance with the conditions of this licence, any emissions from the activity will comply with and not contravene any of the requirements of Section 83(3) of the Environmental Protection Agency Act, 1992.

In reaching this decision the Agency has considered the application and supporting documentation received from the applicant, all objections received and the report of its inspectors.

Activities Licensed

In pursuance of the powers conferred on it by the Environmental Protection Agency Act, 1992, the Agency hereby grants a licence to:

Alza Ireland Limited, Cahir Road, Cashel, County Tipperary,

under Section 83(1) of the said Act to carry on the following activity

- :- the use of coating materials in processes with a capacity to use at least 10 tonnes per year of organic solvents

at Cahir Road, Cashel, County Tipperary, subject to the following fifteen Conditions, with the reasons therefor and associated schedules attached thereto.

Conditions

Condition 1. Scope

- 1.1 The activity shall be controlled, operated, and maintained and emissions shall take place as set out in this Integrated Pollution Control (IPC) licence. All programmes required to be carried out under the terms of this licence, become part of this licence.
- 1.2 No alteration to, or reconstruction in respect of, the activity or any part thereof which would, or is likely to, result in
- (a) a material change or increase in:
- 1.2.1 The nature or quantity of any emission,
- 1.2.2 The abatement/treatment or recovery systems,
- 1.2.3 The range of processes to be carried out,
- 1.2.4 The fuels, raw materials, intermediates, products or wastes generated, or
- (b) any changes in:
- 1.2.5 The site management and control with adverse environmental significance,
- shall be carried out or commenced without prior notice to, and without the prior written agreement of, the Agency
- 1.3 This licence is for the purposes of IPC licensing under the EPA Act, 1992 only and nothing in this licence shall be construed as negating the licensee's statutory obligations or requirements under any other enactments or regulations.
- 1.4 Any reference in this licence to 'site' shall mean the plan area edged in red and labelled 'Site Plan' in the IPC licence application.

Reason: To clarify the scope of this licence.

Condition 2. Management of the Activity

- 2.1 The licensee shall establish and maintain an Environmental Management System (EMS) which shall fulfil the requirements of this licence. The EMS shall assess all operations and review all practicable options for the use of cleaner technology, cleaner production and the reduction and minimisation of waste, and shall include as a minimum those elements specified in the Conditions 2.2 to 2.9 below:
- 2.2 A schedule of Environmental Objectives and Targets
- 2.2.1 The licensee shall prepare a schedule of Environmental Objectives and Targets. The schedule shall include time frames for the achievement of set targets. The schedule shall address a five year period as a minimum. The schedule shall be reviewed annually and amendments thereto notified to the Agency for agreement as part of the Annual Environmental Report (AER) (See also Condition 2.9).

2.2.2 The licensee shall have regard to those matters listed in the appropriate section of *Schedule 6(i) Recording and Reporting to the Agency* when establishing the schedule of Objectives and Targets.

2.3 Environmental Management Programme (EMP)

2.3.1 The licensee shall, not later than six months from the date of commencement of the activity, submit to the Agency for agreement an EMP, including a time schedule, for achieving the Environmental Objectives and Targets prepared under Condition 2.2. Once agreed the EMP shall be established and maintained by the licensee. It shall include:

- (i) designation of responsibility for targets;
- (ii) the means by which they may be achieved;
- (iii) the time within which they may be achieved.

The EMP shall be reviewed annually and amendments thereto notified to the Agency for agreement as part of the Annual Environmental Report (AER) (Condition 2.9).

2.3.2 A report on the programme, including the success in meeting agreed targets, shall be prepared and submitted to the Agency as part of the AER. Such reports shall be retained on-site for a period of not less than seven years and shall be available for inspection by authorised persons of the Agency.

2.4 Pollution Emission Register (PER)

2.4.1 The substances to be included in the PER shall be agreed with the Agency each year by reference to the list specified in the AER guidance note. The PER shall be prepared in accordance with any relevant guidelines issued by the Agency and shall be submitted as part of the AER.

2.4.2 The licensee shall, not later than six months from the date of commencement of the activity and thereafter as part of the AER, agree with the Agency the list of substances to be included in the PER, and the methodology to be used in their determination.

2.5 Documentation

2.5.1 The licensee shall establish and maintain an environmental management documentation system which shall be to the satisfaction of the Agency.

2.5.2 The licensee shall issue a copy of this licence to all relevant personnel whose duties relate to any condition of this licence.

2.6 Corrective Action

2.6.1 The licensee shall establish procedures to ensure that corrective action is taken should the specified requirements of this licence not be fulfilled. The responsibility and authority for initiating further investigation and corrective action in the event of a reported non-conformity with this licence shall be defined.

2.7 Awareness and Training

- 2.7.1 The licensee shall establish and maintain procedures for identifying training needs, and for providing appropriate training, for all personnel whose work can have a significant effect upon the environment. Appropriate records of training shall be maintained.
- 2.7.2 Personnel performing specifically assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required.
- 2.8 Responsibilities
- 2.8.1 The licensee shall ensure that a person in charge, as defined under the terms of the Environmental Protection Agency Act, 1992 shall be available on-site at all times when the activity is in operation. The person in charge shall also be available to meet with authorised persons of the Agency at all reasonable times.
- 2.9 Communications
- 2.9.1 The licensee shall, within six months of the date of grant of this licence, put in place a programme to ensure that members of the public can obtain information concerning the environmental performance of the licensee at all reasonable times.
- 2.9.2 The licensee shall submit to the Agency and the Sanitary Authority, eighteen months from the date of commencement of the activity and by March 1st each year thereafter, an AER which shall be to the satisfaction of the Agency. This report shall include as a minimum the information specified in *Schedule 6(i) Recording and Reporting to the Agency* and shall be prepared in accordance with any relevant guidelines issued by the Agency.

Reason: To make provision for management of the activity on a planned basis having regard to the desirability of ongoing assessment, recording and reporting of matters affecting the environment.

Condition 3. Interpretation

- 3.1 Emission limit values for emissions to atmosphere in this licence shall be interpreted in the following way:-
- 3.1.1 Continuous Monitoring:
- (i) No 24 hour mean value shall exceed the emission limit value.
 - (ii) 97% of all 30 minute mean values taken continuously over an annual period shall not exceed 1.2 times the emission limit value.
 - (iii) No 30 minute mean value shall exceed twice the emission limit value.
- 3.1.2 For Non-Continuous Monitoring:

- (i) For any parameter where, due to sampling/analytical limitations, a 30 minute sample is inappropriate, a suitable sampling period should be employed and the value obtained therein shall not exceed the emission limit value.
 - (ii) For flow, no hourly or daily mean value, calculated on the basis of appropriate spot readings, shall exceed the relevant limit value.
 - (iii) For all other parameters, no 30 minute mean value shall exceed the emission limit value.
- 3.2 The concentration and volume flow limits for emissions to atmosphere specified in this licence shall be achieved without the introduction of dilution air and shall be based on gas volumes under standard conditions of :-
- 3.2.1 In the case of non-combustion gases:
 - (i) Temperature 273K, Pressure 101.3 kPa (no correction for oxygen or water content).
 - 3.2.2 In the case of combustion gases:
 - (i) Temperature 273K, Pressure 101.3 kPa, dry gas; 3% oxygen for liquid and gas fuels; 6% oxygen for solid fuels.
 - 3.2.3 In the case of the catalytic thermal oxidiser:
 - (i) Temperature 273K, Pressure 101.3 kPa (no correction for oxygen or water content).
- 3.3 Emission limit values for emissions to sewer in this licence shall be interpreted in the following way:-
- 3.3.1 Continuous monitoring:
 - (i) No flow value shall exceed the specified limit.
 - (ii) No pH value shall deviate from the specified range.
 - (iii) No temperature value shall exceed the limit value.
 - 3.3.2 Non-Continuous Monitoring:
 - (i) No pH value shall deviate from the specified range.
 - (ii) No temperature value shall exceed the limit value.
 - (iii) For parameters other than pH, temperature and flow, eight out of ten consecutive results, calculated as daily mean concentration or mass emission values on the basis of flow proportional composite sampling, shall not exceed the emission limit value. No individual result similarly calculated shall exceed 1.2 times the emission limit value.
 - (iv) For parameters other than pH, temperature, and flow, no grab sample value shall exceed 1.2 times the emission limit value.
- 3.4 Noise

- 3.4.1 Noise from the activity shall not give rise to sound pressure levels (Leq,T) measured at the boundary of the activity which exceed the limit value(s).

Reason: To clarify the interpretation of emission limit values fixed under the licence.

Condition 4. Notification

The licensee shall notify the Agency of any of the following incidents:

- 4.1 The licensee shall notify the Agency by both telephone and facsimile, if available, to the Agency's Headquarters in Wexford, or to such other Agency office as may be specified by the Agency, as soon as practicable after the occurrence of any of the following:
- 4.1.1 Any release of environmental significance to atmosphere from any potential emission point.
 - 4.1.2 Any emission which does not comply with the requirements of this licence.
 - 4.1.3 Any malfunction or breakdown of control equipment or monitoring equipment set out in;
Schedule 1(ii) Emissions to Atmosphere: Abatement/Treatment Control, which is likely to lead to loss of control of the abatement system.
 - 4.1.4 Any incident with the potential for environmental contamination of surface water or groundwater, or posing an environmental threat to air or land, or requiring an emergency response by the Local Authority.

Notification shall be made by telephone and facsimile, if available, immediately upon the occurrence of the incident, and shall contain as much detail as may be available at that time.

In addition, the licensee shall send written notification by facsimile or email within twelve hours of the occurrence of the incident setting out the date and time of the incident, details of what has occurred, and the steps being taken to minimise any emissions.

Within seven days of the incident the licensee shall notify the Agency in writing of full details of the incident and of the steps taken or proposed to prevent recurrence and the time within which it shall take those steps.

During and after the incident the licensee shall take such remedial and/or preventive action as the Agency may direct.

- 4.2 The licensee shall make a record of any incident as set out in Condition 4.1 above. This record shall include details of the nature, extent, and impact of, and circumstances giving rise to, the incident. The record shall include all corrective actions taken to; manage the incident, minimise wastes generated and the effect on the environment, and avoid recurrence. The licensee shall as soon as

- practicable following incident notification, submit to the Agency the incident record.
- 4.3 A summary report of reported incidents shall be submitted to the Agency as part of the AER. The information contained in this report shall be prepared in accordance with any relevant guidelines issued by the Agency.
- 4.4 In the event of any incident, as set out in Condition 4.1.2 above which relates to discharges to sewer, having taken place, the licensee shall notify the Local and Sanitary Authority as soon as practicable, after such an incident.
- 4.5 In the case of any incident as set out in Condition 4.1.2 above which relates to discharges to water, the licensee shall notify the Southern Regional Fisheries Board as soon as practicable after such an incident.
- 4.6 In the event of any incident, as set out in Condition 4.1.4 having taken place, the licensee shall notify the Local Authority as soon as practicable, after such an incident
- 4.7 The licensee shall notify the Agency in writing of the date of commencement of the activity at least one week prior to the activity being commenced on-site.

Reason: To inform the Agency and relevant bodies of the occurrence of any incident as soon as possible so that they may observe the incident and the steps taken by the Licensee, provide advice and assistance to the licensee thereby improving the efficacy of the steps taken, and make appropriate recommendations for future action.

Condition 5. Emissions to Atmosphere

- 5.1 No specified emission to the atmosphere shall exceed the emission limit value set out in *Schedule 1(i) Emissions to Atmosphere*, subject to Condition 3 of this licence. There shall be no other emission to the atmosphere of environmental significance.
- 5.2 Test programme:
- 5.2.1 The licensee shall prepare, to the satisfaction of the Agency, a test programme for abatement equipment installed to reduce emissions to air. This programme shall be submitted to the Agency, prior to implementation
- 5.2.2 This programme, following agreement with the Agency, shall be completed within three months of the commencement of operation of the abatement equipment.
- 5.3 The test programme shall include as a minimum, the following:
- 5.3.1 Establish all criteria for operation, control and management of the abatement equipment to ensure compliance with the emission limit values specified in this licence.

- 5.3.2 Assess the performance of any monitors on the abatement system and establish a maintenance and calibration programme for each monitor.
- 5.3.3 A report on the test programme shall be submitted to the Agency within one month of completion.
- 5.4 All equipment, including backup equipment, specified in *Schedule 1(ii) Emissions to Atmosphere: Abatement/Treatment Control* of this licence shall be provided on-site. All treatment/abatement, control and monitoring equipment shall be calibrated and maintained when in use, in accordance with the information submitted in Table 12A(iv) of the IPC licence application or as otherwise approved by the Agency under the Environmental Management Programme. The criteria for the operation of the abatement equipment as determined by the test programme, shall be incorporated into the standard operating procedures as approved by the Agency in *Schedule 1(ii) Emissions to Atmosphere: Abatement/Treatment Control*.
- 5.5 Monitoring and analyses of each emission shall be carried out as specified in *Schedule 1(iii) Monitoring of Emissions to Atmosphere* of this licence. A report on the results of this monitoring shall be submitted to the Agency on a biannual basis.
- 5.6 A summary report of emissions to atmosphere shall be submitted to the Agency as part of the AER. The information contained in this report shall be prepared in accordance with any relevant guidelines issued by the Agency.
- 5.7 Boilers shall be operated so as to give a smoke colour less than or equal to shade number 1 on the Ringelmann chart except during periods of start up. Such start up periods shall not exceed 30 minutes in any 24 hour period.
- 5.8 Fuel oil used on-site shall not exceed 0.2% sulphur by mass up to 1 January 2008 and 0.1% sulphur by mass thereafter. The licensee shall maintain a register, including the sulphur content, of all boiler fuels used on site.
- 5.9 All particulate emissions containing active ingredients shall pass through a suitable filtration system including a HEPA filter prior to discharge to atmosphere.
- 5.10 Thermal Oxidiser Shut-down:
- In the event of any of the following:
- 5.10.1 the failure of any piece of control equipment related to the thermal oxidiser or failure of any continuous monitor related to operating parameters or emissions of the thermal oxidiser, where a contingency system, which must have been previously agreed with the Agency, is not implemented;
- 5.10.2 the failure of the thermal oxidiser to achieve the operating parameters and emission limit values given in *Schedule 1(i) Emissions to Atmosphere* of this licence;
- 5.10.3 where a by-pass of the thermal oxidiser is initiated,
- the relevant processes shall, subject to Condition 5.2 of this licence, be shut down as soon as practicable and in a manner consistent with safety and the protection of the environment. All emissions of contaminated exhaust air through the by-pass shall be notified to the Agency in accordance with the requirements of Condition 4 of this licence

- 5.11 The licensee shall ensure that all operations on-site shall be carried out in a manner such that air emissions and/or odours do not result in significant impairment of, or significant interference with amenities or the environment beyond the site boundary.
- 5.12 The licensee shall prepare a programme, to the satisfaction of the Agency, for the monitoring of fugitive emissions to air. This programme shall be submitted to the Agency for agreement, within six months of the date of commencement of the activity and shall be fully implemented within three months of the date of such approval or such other time as the Agency may allow.
- 5.13 No halogenated solvents shall be used in the processes whose emissions are treated by the catalytic thermal oxidiser.

Reason: To provide for the protection of the environment by way of control, limitation, treatment and monitoring of emissions.

Condition 6. Emissions to Sewer

- 6.1 No specified emission to sewer shall exceed the emission limit values set out in *Schedule 2(i) Emissions to Sewer*, subject to Condition 3 of this licence. With the exception of domestic sewage there shall be no other emissions to sewer of environmental significance.
- 6.2 Monitoring and analyses of each emission shall be carried out as specified in *Schedule 2(ii) Monitoring of Emissions to Sewer* of this licence. A report on the results of this monitoring shall be submitted to the Agency biannually.
- 6.3 A summary report of emissions to sewer shall be submitted to the Agency as part of the AER. The information contained in this report shall be prepared in accordance with any relevant guidelines issued by the Agency.
- 6.4 A representative sample of effluent shall be screened for the presence of organic compounds and heavy metals. The report on this screening shall be submitted to the Agency and the Sanitary Authority within three months of commencement of the activity. Such screening shall be repeated at annually.
- 6.5 No heavy metals or surface water shall be discharged to the foul sewer.
- 6.6 No substance shall be present in such concentrations as would constitute a danger to sewer maintenance personnel, or sewer fabric or to the liberation of by-products which may be of environmental significance or interfere with the operations of a wastewater treatment works.
- 6.7 No substance shall be discharged in a manner, or at a concentration which, after initial dilution in the receiving waters to which the Sanitary Authority sewage is discharged, causes tainting of fish or shellfish.

- 6.8 The licensee shall permit authorised persons, of the Agency and Sanitary Authority, to inspect, examine and test, at all reasonable times, any works and apparatus installed in connection with the trade effluent and to take samples of the trade effluent.
- 6.9 Non-trade effluent wastewater (e.g. firewater, accidental spillage) which occurs on-site shall not be discharged to the sewer without the prior authorisation of the Sanitary Authority.

Reason: By way of control, limitation, treatment and monitoring of emissions to provide for the protection of the environment and to provide for the requirements of the Sanitary Authority in accordance with Section 97 of the EPA Act, 1992.

Condition 7. Waste Management

- 7.1 Disposal or recovery of waste shall take place only as specified in *Schedule 3(i) Hazardous Wastes for Disposal/Recovery and Schedule 3(ii) Other Wastes for Disposal/Recovery* of this licence and in accordance with the appropriate National and European legislation and protocols. No other waste shall be disposed of/recovered either on-site or off-site without prior notice to, and prior written agreement of, the Agency.
- 7.2 Waste sent off-site for recovery or disposal shall only be conveyed by an authorised waste contractor. The waste shall only be transported from the site of the activity to the site of recovery/disposal in a manner which will not adversely affect the environment and in accordance with the appropriate National and European legislation and protocols.
- 7.3 No amendment or variation in any agreed waste classification or consignment or haulage or disposal or recovery arrangements shall be made without the prior written agreement of the Agency.
- 7.4 The licensee shall ensure that waste transferred to another person is packaged and labelled in accordance with National, European and any other standards which are in force in relation to such labelling. While awaiting collection, recovery or disposal all waste shall be stored in designated areas protected, as may be appropriate, against spillage and leachate run-off. The waste is to be clearly labelled and appropriately segregated.
- 7.5 Unless approved in writing by the Agency the licensee is prohibited from mixing a hazardous waste of one category with a hazardous waste of another category or with any other non-hazardous waste.
- 7.6 Waste for disposal/recovery off-site shall be analysed in accordance with *Schedule 3(iii) Waste Analysis* of this licence.
- 7.7 No waste classified as green list waste in accordance with the EU Transfrontier Shipment of Waste Regulations (Council Regulation EEC No.259/1993, as amended) shall be consigned for recovery without the prior agreement of the Agency.
- 7.8 A full record, which shall be open to inspection by authorised persons of the Agency at all times, shall be kept by the licensee on matters relating to the waste

management operations and practices at this site. This record shall as a minimum contain details of the following:

- 7.8.1 The tonnages and EWC Code for the waste materials listed in *Schedule 3(i) Hazardous Wastes for Disposal/Recovery and Schedule 3(ii) Other Wastes for Disposal/Recovery*, sent off-site for disposal/recovery.
- 7.8.2 The names of the agent and carrier of the waste, and their permit details (to include issuing authority).
- 7.8.3 Details of the ultimate disposal/recovery destination facility for the waste and its appropriateness to accept the consigned waste stream, to include its permit details and issuing authority.
- 7.8.4 Written confirmation of the acceptance and disposal/recovery of any hazardous waste consignments sent off-site.
- 7.8.5 All shipments of wastes consigned abroad for Recovery and classified as 'Green' in accordance with the EU Transfrontier Shipment of Waste Regulations (Council Regulation EEC No. 259/1993, as amended).
- 7.8.6 Details of any rejected consignments.
- 7.8.7 Details of any approved waste mixing as per Condition 7.5.
- 7.8.8 The results of any analyses required under *Schedule 3(iii) Waste Analysis*.
- 7.8.9 The tonnages and EWC Code for the waste materials *listed Schedule 3(i) Hazardous Wastes for Disposal/Recovery and Schedule 3(ii) Other Wastes for Disposal/Recovery* recovered on-site.

A copy of this Waste Management record shall be submitted to the Agency as part of the AER for the site.

Reason: To provide for the disposal/recovery of waste and the protection of the environment.

Condition 8. Noise

- 8.1 The licensee shall carry out a noise survey of the site operations within six months of the date of commencement of the activity and annually thereafter. The licensee shall consult with the Agency on the timing, nature and extent of the survey and shall develop a survey programme to the satisfaction of the Agency. The survey programme shall be submitted to the Agency in writing at least one month before the survey is to be carried out. A record of the survey results shall be available for inspection by any authorised persons of the Agency, at all reasonable times and a summary report of this record shall be included as part of the AER.
- 8.2 Activities on-site shall not give rise to noise levels at the boundary which exceed the following sound pressure limits (Leq,30min) subject to Condition 3 of this licence:
 - 8.2.1 Daytime: 55 dB(A),
 - 8.2.2 Night-time: 45 dB(A).

- 8.3 There shall be no clearly audible tonal component or impulsive component in the noise emission from the activity at any noise sensitive location.

Reason: To provide for the protection of the environment by control of noise.

Condition 9. Non-Process Water

9.1 Surface water

9.1.1 The licensee shall monitor surface water discharges in accordance with *Schedule 4(i) Surface Water Discharge Monitoring* of this licence. A report on the results of this monitoring shall be submitted to the Agency biannually and a summary report shall be submitted as part of the AER.

9.1.2 The licensee shall determine the normal levels of TOC for uncontaminated surface water and shall, as part of the EMP, submit proposals to the Agency for the setting of warning and action levels, and establish a response programme when such approved action levels are reached.

9.1.3 No environmentally polluting substance or matter shall be permitted to discharge to off-site surface waters or off-site storm drains.

9.1.4 In the event that any analyses or observations made on the quality or appearance of surface water runoff should indicate that contamination has taken place, the licensee shall

- (i) carry out an immediate investigation to identify and isolate the source of the contamination,
- (ii) put in place measures to prevent further contamination and to minimise the effects of any contamination on the environment,
- (iii) and notify the Agency as soon as is practicable.

9.2 Firewater Retention.

9.2.1 In the event of a fire or a spillage to surface water, the site surface water shall be diverted to the containment pond. The licensee shall have regard to any guidelines issued by the Agency with regard to firewater retention.

9.3 Groundwater

9.3.1 No environmentally polluting substance or matter shall be permitted to discharge to ground or groundwater under the site.

9.3.2 Groundwater monitoring point shall be included in the site's maintenance programme.

9.3.3 Groundwater monitoring point shall be sampled and analysed in accordance with *Schedule 5(i) Groundwater Monitoring* of this licence. A report of such results shall be submitted annually as part of the AER.

9.4 Facilities for the Protection of Groundwater and Surface Water

- 9.4.1 All tank and drum storage areas shall be rendered impervious to the materials stored therein. In addition, tank and drum storage areas shall, as a minimum be bunded, either locally or remotely, to a volume not less than the greater of the following;
- (i) 110% of the capacity of the largest tank or drum within the bunded area,
 - (ii) 25% of the total volume of substance which could be stored within the bunded area.
- Drainage from bunded areas shall be diverted for collection and safe disposal. All bunds shall be tested at least once every three years. A report on such tests shall be included in the AER.
- 9.4.2 The integrity and water tightness of all the bunding structures and their resistance to penetration by water or other materials stored therein shall be tested and demonstrated by the licensee to the satisfaction of the Agency and shall be reported to the Agency prior to the commencement of the activity.
- 9.4.3 The loading and unloading of materials shall be carried out in designated areas protected against spillage and leachate run - off.
- 9.4.4 All pump sumps or other treatment plant chambers from which spillage of environmentally significant materials might occur in such quantities as are likely to breach local or remote containment or interceptors, shall be fitted with high liquid level alarms (or oil detectors as appropriate) prior to the commencement of the activity.
- 9.4.5 The licensee shall undertake a programme of testing and inspection of active underground tanks and pipelines to ensure that all such structures are tested at least once every three years. A report on such tests shall be included in the AER.
- 9.4.6 All flanges and valves on over-ground pipes used to transport materials other than uncontaminated water, where no permanent provision for containment of leaks is provided, shall be subject to weekly visual inspection or otherwise monitored for leaks to the satisfaction of the Agency. All such inspections shall be recorded in a log which shall be available for inspection by Agency.
- 9.4.7 The licensee shall have in storage an adequate supply of containment booms and suitable absorbent material to contain and absorb any spillage.

Reason: To provide for the protection of surface waters and groundwater.

Condition 10. Energy Use

- 10.1 The licensee shall carry out an audit of the energy efficiency of the site within one year of the date of commencement of the activity. The licensee shall consult with the Agency on the nature and extent of the audit and shall develop an audit

programme to the satisfaction of the Agency. The audit programme shall be submitted to the Agency in writing at least one month before the audit is to be carried out. A copy of the audit report shall be available on-site for inspection by authorised persons of the Agency and a summary of the audit findings shall be submitted as part of the Annual Environmental Report. The energy efficiency audit shall be repeated at intervals as required by the Agency.

- 10.2 The audit shall identify all opportunities for energy use reduction and efficiency and the recommendations of the audit will be incorporated into the Schedule of Environmental Objectives and Targets under Condition 2.2 above.

Reason: To provide for the efficient use of energy in all site operations.

Condition 11. Monitoring

- 11.1 The licensee shall carry out such sampling, analyses, measurements, examinations, maintenance and calibrations as set out in Schedules:-
Schedule 1(ii) Emissions to Atmosphere: Abatement/Treatment Control,
Schedule 1(iii) Monitoring of Emissions to Atmosphere,
Schedule 2(ii) Monitoring of Emissions to Sewer,
Schedule 3(iii) Waste Analysis,
Schedule 4(i) Surface Water Discharge Monitoring,
Schedule 5(i) Groundwater Monitoring,
of this licence.
- 11.2 Where the ability to measure a parameter is affected by mixing before emission, then, with prior written agreement from the Agency, the parameter may be assessed before mixing takes place.
- 11.3 All automatic monitors and samplers shall be functioning at all times (except during maintenance and calibration) when the activity is being carried on unless alternative sampling or monitoring has been agreed in writing by the Agency for a limited period. In the event of the malfunction of any continuous monitor, the licensee shall contact the Agency as soon as practicable, and alternative sampling and monitoring facilities shall be put in place. Prior written agreement for the use of alternative equipment, other than in emergency situations, shall be obtained from the Agency.
- 11.4 Monitoring and analysis equipment shall be operated and maintained as necessary so that monitoring accurately reflects the emission or discharge.
- 11.5 The frequency, methods and scope of monitoring, sampling and analyses, as set out in this licence, may be amended with the written agreement of the Agency following evaluation of test results.
- 11.6 The licensee shall install on all emission points such sampling points or equipment, including any data-logging or other electronic communication equipment, as may be required by the Agency. All such equipment shall be consistent with the safe operation of all sampling and monitoring systems.

- 11.7 The licensee shall provide safe and permanent access to the following sampling and monitoring points:
- 11.7.1 Final effluent as discharged from the site.
 - 11.7.2 Emission to atmosphere sampling points.
 - 11.7.3 Noise sources on-site.
 - 11.7.4 Waste storage areas on-site.
 - 11.7.5 Surface waters discharge.
 - 11.7.6 On-site ground-water monitoring wells.
- and safe access to any other sampling and monitoring points required by the Agency.
- 11.8 The licensee shall, within three months of the date of grant of this licence, install in a prominent location on the site a wind sock, or other wind direction indicator, which shall be visible from the public roadway outside the site.

Reason: To ensure compliance with the requirements of other conditions of this licence by provision of a satisfactory system of measurement and monitoring of emissions.

Condition 12. Recording and Reporting to Agency

- 12.1 The licensee shall record all sampling, analyses, measurements, examinations, calibrations and maintenance carried out in accordance with the requirements of this licence.
- 12.2 The licensee shall record all incidents which affect the normal operation of the activity and which may create an environmental risk.
- 12.3 The licensee shall record all complaints of an environmental nature related to the operation of the activity. Each such record shall give details of the date and time of the complaint, the name of the complainant and give details of the nature of the complaint. A record shall also be kept of the response made in the case of each complaint. The licensee shall submit a report to the Agency, during the month following such complaints, giving details of any complaints which arise. A summary of the number and nature of complaints received shall be included in the AER.
- 12.4 The format of all records required by this licence shall be to the satisfaction of the Agency. Records shall be retained on-site for a period of not less than seven years and shall be available for inspection by the Agency at all reasonable times.
- 12.5 Reports of all recording, sampling, analyses, measurements, examinations, calibrations and maintenance as set out in *Schedule 6(i) Recording and Reporting to the Agency* of this licence, shall be submitted to the Agency Headquarters as specified in this licence. The format of these reports shall be to the satisfaction of the Agency. One original and three copies shall be submitted as and when specified.
- 12.6 Provision shall also be made for the transfer of environmental information, in relation to this licence, to the Agency's computer system, as may be requested by the Agency.

- 12.7 All reports shall be certified accurate and representative by the licensee's Plant Manager or other senior officer designated by the Plant Manager.
- 12.8 All written procedures controlling operations affecting this licence shall be available on-site for inspection by the Agency at all reasonable times.
- 12.9 The frequency and scope of reporting, as set out in this licence, may be amended with the written agreement of the Agency following evaluation of test results.

Reason: To provide for the collection and reporting of adequate information on the activity.

Condition 13. Accidents and Emergency Response

- 13.1 The licensee shall, not later than two months prior to the commencement of the activity, ensure that a documented Accident Prevention Policy is in place which will address the hazards on-site, particularly in relation to the prevention of accidents with a possible impact on the environment.
- 13.2 The licensee shall, not later than two months prior to the date of commencement of the activity, ensure that a documented Emergency Response Procedure is in place, which shall address any emergency situation which may originate on-site. This Procedure shall include provision for minimising the effects of any emergency on the environment.
- 13.3 The policy and procedure referred to in Conditions 13.1 and 13.2 shall be reviewed annually and up-dated as necessary. They shall be made available on-site for inspection by the Agency at all reasonable times.

Reason: To provide for the protection of the environment.

Condition 14. Residuals Management

- 14.1 Following termination, or planned cessation for a period greater than six months, of use or involvement of all or part of the site in the licensed activity, the licensee shall, to the satisfaction of the Agency, decommission, render safe or remove for disposal/recovery, any soil, subsoils, buildings, plant or equipment, or any waste, materials or substances or other matter contained therein or thereon, that may result in environmental pollution.
- 14.2 Residuals Management Plan:
- 14.2.1 The licensee shall prepare, to the satisfaction of the Agency, a fully detailed and costed plan for the decommissioning or closure of the site or part thereof. This plan shall be submitted to the Agency for agreement within six months of the date of commencement of the activity.
- 14.2.2 The plan shall be reviewed annually and proposed amendments thereto notified to the Agency for agreement as part of the AER. No amendments may be implemented without the written agreement of the Agency.
- 14.3 The Residuals Management Plan shall include as a minimum, the following:

- 14.3.1 A scope statement for the plan.
 - 14.3.2 The criteria which define the successful decommissioning of the activity or part thereof, which ensures minimum impact to the environment.
 - 14.3.3 A programme to achieve the stated criteria.
 - 14.3.4 Where relevant, a test programme to demonstrate the successful implementation of the decommissioning plan.
 - 14.3.5 Details of costings for the plan and a statement as to how these costs will be underwritten.
- 14.4 A final validation report to include a certificate of completion for the residuals management plan, for all or part of the site as necessary, shall be submitted to the Agency within three months of execution of the plan. The licensee shall carry out such tests, investigations or submit certification, as requested by the Agency, to confirm that there is no continuing risk to the environment.

Reason: To make provision for the proper closure of the activity ensuring protection of the environment.

Condition 15. Financial Provisions

15.1 Agency Charges

- 15.1.1 The licensee shall pay to the Agency an annual contribution of €8,457, or such sum as the Agency from time to time determines, towards the cost of monitoring the activity as the Agency considers necessary for the performance of its functions under the Environmental Protection Agency Act, 1992. The licensee shall in 2004 and subsequent years, not later than January 31 of each year, pay to the Agency this amount updated in accordance with changes in the Public Sector Average Earnings Indices from the date of the licence to the renewal date. The updated amount shall be notified to the licensee by the Agency. For 2003, the licensee shall pay a pro rata amount from the date of this licence to December 31 2003. This amount shall be paid to the Agency within one month of the date of grant of this licence.

15.2 Sanitary Authority Charges

- 15.2.1 The licensee shall pay to the Sanitary Authority such sum as may be determined, having regard to the governments water pricing policy in

relation to the polluter pays principle (non-domestic rates shall apply), the variations in the cost of providing drainage and the variation in effluent reception and treatment costs. Payment to be made on demand.

15.2.2 The licensee shall pay an annual charge to the Sanitary Authority towards the cost of monitoring the trade effluent. This amount will be revised from time to time and payment to be made on demand.

15.3 Environmental Liabilities

15.3.1 The licensee shall arrange for the completion, by an independent and appropriately qualified consultant, of a comprehensive and fully costed Environmental Liabilities Risk Assessment for the operation. A report on this assessment to be submitted to the Agency for agreement within twelve months of date of commencement of the activity.

Reason: To provide for adequate financing for monitoring and financial provisions for measures to protect the environment and to provide for the requirements of the Sanitary Authority in accordance with Section 97 of the EPA Act, 1992.

*For inspection purposes only.
Consent of copyright owner required for any other use.*

Schedule 1(i) Emissions to Atmosphere

Emission Point Reference No.:	A2-1	
Location:	Thermal Oxidiser North East corner of Existing Building (Grid Ref. 1391 2075)	
Volume to be emitted:	Maximum in any one day:	156,000 m ³
	Maximum rate per hour:	6,500 m ³
Minimum discharge height:	11 m above ground	

Parameter	Emission Limit Value
Total VOC (as Carbon)	20mg/m ³
Nitrogen oxides (as NO ₂)	200mg/m ³
Total Dust	10mg/m ³

Emission Point Reference No.:	A3-13
Description of Treatment:	Dust Filtration (HEPA)

Parameter	Emission Limit Value
Pharmaceutically active ingredients	0.15mg/m ³

Schedule 1(ii) Emissions to Atmosphere: Abatement/Treatment Control

Emission Point Reference No.: A2-1

Description of Treatment: Thermal Oxidation

Monitoring:

Control Parameter	Monitoring to be Carried Out	Monitoring Equipment
Oxidiser Bed Temperature	Continuous temperature	Temperature probes
Inlet VOC Concentration	Continuous solvent content	VOC monitor (LEL)
Waste Air gas flow to thermal oxidiser	Continuous flow	Flowmeter

Equipment:

Control Parameter	Equipment	Backup Equipment
Airflows	Thermal oxidiser fans	To be agreed as part of Test Programme (Condition 5.2)
Temperature	Electrical Preheater	To be agreed as part of Test Programme (Condition 5.2)

Emission Point Reference No's.: A3-2, A3-3, A3-4, A3-5, A3-6, A3-7, A3-8, A3-9, A3-10, A3-11, A3-13

Description of Treatment: Dust Filtration

Monitoring:

Control Parameter	Monitoring to be Carried Out	Monitoring Equipment
Differential Pressure across Dust Extract Cartridge Filters	Weekly Inspection	Differential Pressure Gauge
Differential Pressure across HEPA Filters ^{Note 1}	Continuous	Pressure sensor and alarm

Note 1: Relevant to A3-13 only.

Equipment:

Control Parameter	Equipment	Backup Equipment
Differential Pressure	Cartridge Filters (EU Class 4 and 9)	Spare cartridge filters
Differential Pressure	HEPA filters ^{Note 1}	Spare HEPA filters

Note 1: Relevant to A3-13 only.

Schedule 1(iii) Monitoring of Emissions to Atmosphere

Emission Point Reference No.: A2-1

Parameter	Monitoring Frequency	Analysis Method/Technique
Total VOC (as Carbon)	Continuous TOC	To be agreed as part of Condition 5.2
Individual VOC's	Biannually	To be agreed as part of Condition 5.2
Nitrogen oxides (as NO₂)	Biannually	To be agreed as part of Condition 5.2
Total Dust	Biannually	To be agreed as part of Condition 5.2



Emission Point Reference No.: A3-13

Description of Treatment: Dust Filtration (HEPA)

Parameter	Monitoring Frequency	Analysis Method/Technique
Pharmaceutically active ingredients	Annually	To be agreed as part of Condition 5.2

For inspection purposes only.
Consent of copyright owner required for any other use.

Schedule 2(i) Emissions to Sewer

Emission Point Reference No.: SE-01

Volume to be emitted: Maximum in any one day: 50 m³ rising to 150 m³ **Note 1**
Maximum rate per hour: 2.5 m³ rising to 7 m³ **Note 1**

Parameter	Emission Limit Value	
	Temperature	35°C (max.)
pH	6-9	
	mg/l (hourly average)	mg/l (daily average)
BOD	600	400
COD	1500	1000
Suspended Solids	600	400
Oils, Fats and Greases	50	50
Total Phosphorus (as P)	5	5

Note 1: Initial discharge consent is 50m³/day. Any incremental increases up to the maximum 150m³/day shall be supported by a statement from the Sanitary Authority as to the available treatment capacity of the Cashel municipal WWTP. Such statements shall be copied to the relevant Fisheries Board. Any increases are to be notified to, and approved by, the EPA in accordance with Condition 1.2.

Schedule 2(ii) Monitoring of Emissions to Sewer

Emission Point Reference No.: SE-01

Parameter	Monitoring Frequency	Analysis Method/Technique
Flow	Continuous	On-line flow meter with recorder
pH	Continuous	pH electrode/meter and recorder
TOC	Continuous	On-line TOC meter with recorder
Chemical Oxygen Demand	Daily	Standard Method
Biochemical Oxygen Demand	Weekly	Standard Method
Suspended Solids	Daily	Gravimetric
Total Phosphorus (as P)	Weekly	Standard Method
Organic Solvents Note 1	Monthly	Gas Chromatography
Oils, fats & greases	Monthly	Standard Method

Note 1: Screening for priority pollutant list substances. (such as US EPA volatile and/or semi-volatile compounds). This analysis shall include those organic solvents in use in the process, which are likely through normal process operations to be diverted to the waste water streams.

Schedule 3(i) Hazardous Wastes for Disposal/Recovery

Waste Materials Note 1	Further Treatment, Recovery/Recycling On-Site Note 2	On-Site Reuse Note 2	Method of Disposal/Recovery Note 3
Mixed solvents	None	None	Agreed hazardous waste disposal contractor.
Solid/liquid waste contaminated with pharmaceutical ingredients	None	None	Agreed hazardous waste disposal contractor.
Aqueous wastes	None	None	Agreed hazardous waste disposal contractor.
Fluorescent lights	None	None	Agreed hazardous waste disposal contractor.
Utilities Waste Oils	None	None	Agreed hazardous waste recovery contractor.
Other Note 4			

Note 1: Refer also to waste classification, labelling and management obligations specified in Condition 7.

Note 2: The licensee may treat, reuse, recycle or recover waste subject to the prior written agreement of the Agency.

Note 3: The agreed method and any amendment thereto, shall include details of anticipated waste volumes, classification, transport arrangements, as well as identification (including authorisations and appropriateness) of facility of final destination of disposal/recovery.

Note 4: No other hazardous waste shall be disposed of/recovered off-site without prior notice to, and prior written agreement of the Agency.

Schedule 3(ii) Other Wastes for Disposal/Recovery

Waste Materials Note 1	Further Treatment, Recovery/Recycling On-Site Note 2	On-Site Reuse Note 2	Method of Disposal/Recovery Note 3
Canteen wastes	None	None	Agreed disposal contractor.
Administration and packaging waste	None	None	Landfill
Other Note 4			

Note 1: Refer also to waste classification, labelling and management obligations specified in Condition 7.

Note 2: The licensee may treat, reuse or recycle waste subject to the prior written agreement of the Agency.

Note 3: The agreed method and any amendment thereto, shall include details of anticipated waste volumes, classification, transport arrangements, as well as identification (including authorisations and appropriateness) of facility of final destination of disposal/recovery.

Note 4: No other waste shall be disposed of/recovered off-site without prior notice to, and prior written agreement of the Agency.

Schedule 3(iii) Waste Analysis

Waste Class	Frequency	Parameter	Method
Solvent wastes	Per consignment	Solvent content	Gas chromatography
Aqueous wastes	Per consignment	Solvent content	Gas chromatography
Other ^{Note 1}			

Note 1: Analytical requirements to be determined on a case by case basis.



Schedule 4(i) Surface Water Discharge Monitoring

Emission Point Reference No.: SW1

Parameter	Monitoring Frequency	Analysis Method/Technique
TOC	Continuous	TOC meter and recorder
BOD	Weekly	Standard Method



Schedule 5(i) Groundwater Monitoring

Emission Point Reference No's: BH-04

Parameter	Monitoring Frequency	Analysis Method/Technique
pH	Biannually	pH electrode/meter
BOD	Biannually	Standard Method
Conductivity	Biannually	Standard Method
Trace Organics ^{Note 1}	Biannually	GC/GC-MS

Note 1: Screening for priority pollutant list substances (such as US EPA volatile and/or semi-volatile compounds).



Schedule 6(i) Recording and Reporting to the Agency

Completed reports shall be submitted to:

The Environmental Protection Agency
P.O. Box 3000
Johnstown Castle Estate
County Wexford

or Any other address as may be specified by the Agency

Reports are required to be forwarded as set out below:

*For inspection purposes only.
Consent of copyright owner required for any other use.*

Recurring Reports:

Report	Reporting Frequency	Report Submission Date
Monitoring of emissions to atmosphere	Biannually	Ten days after end of the half being reported on.
Monitoring of emissions to sewer	Biannually	Ten days after end of the half being reported on.
Surface Water	Biannually	Ten days after end of the half being reported on.
Programme for an Energy Efficiency Audit	-	Within eleven months of date of commencement of activity and thereafter as may be required by the Agency.
Noise monitoring programme	Annually	One month prior to survey
Complaints (where these arise)	Monthly	Ten days after end of the month being reported on.
Annual Environment Report(AER)	Annually	Eighteen months from the date of commencement of the activity and by March 1 st each year thereafter.

Once-off Reports:

Report	Report Submission Date
Date of commencement of the activity	One week prior to commencement of activity
Test Programme as per Condition 5.2	Prior to the implementation of the test programme.
Test Programme report as per Condition 5.3.	Within one month of completion of the test programme.
Fugitive emissions programme	Within six months of the date of commencement of the activity.
Effluent screening report.	Within three months of the date of commencement of activity.
Bund integrity assessment.	Prior to the date of commencement of activity.
Pollution emission register proposal	Within six months of the date of commencement of activity.
Environmental management programme proposal.	Within six months of the date of commencement of activity.
Environmental Liabilities Assessment Report	Within twelve months of the date of commencement of activity.
Residuals Management Plan	Within six months of the date of commencement of activity.
Residuals Management Plan – Final Validation Report	Within three months of execution of the plan



Annual Environmental Report Content	Items to be Addressed in Establishing the Schedule of Objectives & Targets
<p>Emissions to atmosphere summary.</p> <p>Emissions to sewer summary.</p> <p>Surface water monitoring summary.</p> <p>Waste management report.</p> <p>Resource consumption summary.</p> <p>Complaints summary.</p> <p>Schedule of Environmental Objectives and Targets</p> <p>Environmental management programme – proposal</p> <p>Environmental management programme – report</p> <p>Pollution emission register – proposal</p> <p>Pollution emission register – report</p> <p>Report on List I & II substance reductions</p> <p>Noise monitoring report</p> <p>Groundwater monitoring summary</p> <p>Tank and pipeline testing and inspection report (every three years).</p> <p>Bund test report (every three years)</p> <p>Reported incidents summary</p> <p>Review of residuals management plan</p> <p>Energy efficiency audit report summary</p>	<p>The reduction of waste solvents discharged to sump and off-site disposal.</p> <p>Energy Use Reduction.</p> <p>The hourly balancing of effluent discharge loads.</p>

For inspection purposes only.
Consent of copyright owner required for any other use.

Signed on behalf of the Agency

Iain Maclean

Director/Authorised Person

Dated this 14th day of March 2003

SOUTH TIPPERARY COUNTY COUNCIL

PLANNING AND DEVELOPMENT ACTS, 2000 TO 2004

PLANNING AND DEVELOPMENT REGULATIONS 2001 - 2005

**NOTIFICATION OF DECISION TO GRANT IN ACCORDANCE WITH
SECTION 34 OF THE 2000 ACT.**

Alza Ireland Ltd
c/o Project Management Ltd
Lough Mahon Technology Park
Blackrock
Co Cork

Ref No. 06/926

APPLICATION RECEIPT DATE: 13/06/2006

FURTHER INFO RECD

Having regard to:

- the nature and extent of the proposed development;
- the planning history of the site
- the intended use of the proposed development,
- the policies of the Cashel Town and its Environs Development Plan 2003 and
- the pattern of development in the area,

it is considered that, subject to compliance with the conditions set out in the attached Schedule, the proposed development;

- would not seriously injure the amenities of the area or of property in the vicinity;
- would be acceptable in terms of traffic safety and convenience;
- would, therefore, be in accordance with the proper planning and sustainable development of the area.

In pursuance of the powers conferred upon it by the above-mentioned Acts, South Tipperary County Council has by Order dated 14th August 2006 decided to GRANT PERMISSION to the above named for development of land, as follows:-

to construct a drum store and associated paving and drainage at the facility. This site currently possesses an IPC licence

At: Owens & Biggs Lot Cahir Road Cashel

Subject to the 10 conditions and reasons therefore as set out in the schedule attached.

If there is no appeal against the said decision, a GRANT in accordance with the decision will be issued after the expiration of the period within which an appeal may be made to An Bord Pleanala (see appeal details overleaf).

IT SHOULD BE NOTED THAT UNTIL A GRANT OF PERMISSION OR PERMISSION CONSEQUENT ON THE GRANT OF AN OUTLINE PERMISSION HAS BEEN ISSUED, THE DEVELOPMENT OR RETENTION IN QUESTION IS NOT AUTHORISED.

Signed on behalf of South
Tipperary County Council..... *J.M. Gormack*
County Secretary.

Dated:..... *14th August 2006*.....

Consent of copyright owner required for any other use.
For inspection purposes only.

SOUTH TIPPERARY COUNTY COUNCIL

Planning & Development Acts 2000 to 2004

**Ref No. In
Planning Reg: 06/926**

Page 1/3

SCHEDULE

1 Save where modified by the following conditions, the proposed development shall be carried out in accordance with the drawings and documentation submitted with the planning application on the 13/06/2006.

Reason: In the interest of clarity.

2. Connection to the public water supply shall be carried out in a technically satisfactory manner to the requirements of South Tipperary County Council as Sanitary Authority. These requirements shall include payment of the appropriate connection fee in addition to the development contribution specified in condition 4.

Reason: In the interests of clarity and orderly development.

3. Connection to the public sewerage facilities services shall be carried out in a technically satisfactory manner to the requirements of South Tipperary County Council as Sanitary Authority. These requirements shall include payment of the appropriate connection fee in addition to the development contribution specified in condition 4.

Reason: In the interests of clarity and orderly development.

4. Before development commences, the developer shall pay to the Planning Authority a development contribution in respect of the provision of improved public water supply services, improved road infrastructure, and, improved recreational and community facilities and amenities.

(i) The **total amount** of the development contribution **€19,890.12** shall be in accordance with the Class 7 as detailed in the current South Tipperary Development Contribution Scheme, as set out hereunder:

(ii) The contribution payable will be based on the amount of contribution applicable at the date of payment and not on the rate of contribution in existence at the date of issue of the grant of permission.

Class 2		Rate 2006	Area sq. m	Total	TOTAL PAYABLE
Industrial	Water	€ 12.74 per m2	498m2	€6,344.52	€6,344.52
	Sewer	€ 6.95 Per m2	498 m2	€ 3,461.10	€ 3,461.10
	Roads	€ 5.61 per m2	498m2	€ 2,793.78	€ 2,793.78
	Community	€ 14.64 per m2	498m2	€ 7,290.72	€ 7,290.72
				€ 19,890.12	€ 19,890.12

SOUTH TIPPERARY COUNTY COUNCIL

Planning & Development Acts 2000 to 2004

**Ref No. In
Planning Reg: 06/926**

Page 2/3

SCHEDULE

- (iii) Where the contribution is not paid in accordance with the terms of this condition, any outstanding amounts due to South Tipperary County Council shall be paid together with interest that may have accrued for the period while withheld by the person required to pay the contribution. Interest shall be calculated in accordance with the overdraft rate of interest for the time being.

Reason: As a contribution towards the cost of the provision of improved water supply services, improved road infrastructure, and, improved recreational and community facilities and amenities in accordance with Development Contribution Scheme for the period 1 March 2004 to 28 February 2009 which was adopted, pursuant to Section 48 of the Planning and Development Act, 2000 by resolution of South Tipperary County Council, dated 1 December 2003. Such improvements will facilitate this development.

5. Prior to the commencement of development the applicant shall submit for the written approval of the planning a revised site layout to scale not less than 1:500 indicating the revised position of the proposed structure outside of the boundary of recorded monument TS061-07103 (Road). No part of the proposed development shall encroach of the boundaries of the recorded monument. ,

Reason: To ensure the preservation and protection of Recorded Monument TS - 061 07103, a Road, and

To ensure the continued preservation (either *in situ* or by record) of places caves sites, features or other objects of archaeological interest.

6. Prior to the commencement of development, the applicant / developer shall submit to the Planning Authority, for written approval, complete details of colour scheme and external finishes of all elements of the proposed development. This shall be accompanied by samples of the materials and colour scheme or a manufacturers catalogue detailing same.

Reason: In the interests of visual amenity and orderly development.

7. The surface water disposal from the site shall be attenuated within the site to the satisfaction of the Water Services Section, such that the rate of surface water discharge arising from the proposed development shall be limited to agricultural run-off rates. The details of the attenuation measures and rates of discharge shall be agreed in writing with the Water Services Section prior to commencement of development on the site, or, in default of agreement shall be as agreed with An Bord Pleanala.

Reason: In the interest of orderly development.

8. During development works, the developer shall ensure that material from the site is not spread or deposited on the public roadway and shall maintain the roadway in a clean, tidy and safe condition at all times.

Reason: To prevent any traffic hazard or nuisance arising from such material.

9. All service cables associated with the proposed development (such as electrical, telephone, broadband infrastructure and lighting cables) shall be run underground within the site.

Reason: In the interests of orderly development and of the visual amenities of the area.

SOUTH TIPPERARY COUNTY COUNCIL

Planning & Development Acts 2000 to 2004

Ref No. In

Planning Reg: 06/926

Page 3/3

SCHEDULE

10. Prior to commencement of development, a detailed landscaping plan for the eastern boundary of the site, having regard to soil conditions and orientation of the proposed site, proximity to residential development and prepared by a competent and qualified landscape architect or horticulturist, shall be submitted for the agreement of the planning authority.
- (i) The detailed landscaping plan shall include the location, density and size of the proposed planting, indigenous planting throughout the proposed site, in particular, the exposed site boundaries, including details of type/species, density (a minimum of two metres deep) and size.
 - (ii) The detailed landscaping plan of the boundary screening shall be completed within one year of the first occupation of the proposed development. Any trees or shrubs that fail shall be replaced. The landscaping and screening shall be maintained at regular intervals.
 - (iii) The landscaping plan shall ensure that the area is respected and enhanced.

Reason: In the interest of visual amenity.

*For inspection purposes only.
Consent of copyright owner required for any other use.*

SOUTH TIPPERARY COUNTY COUNCIL

PLANNING AND DEVELOPMENT ACTS, 2000 TO 2006

PLANNING AND DEVELOPMENT REGULATIONS 2001 - 2007

**NOTIFICATION OF DECISION TO GRANT IN ACCORDANCE WITH
SECTION 34 OF THE 2000 ACT.**

Cordis Cashel Ltd
C/o Killakee House PM Group
Belgard Square
Tallaght
Dublin 24

Ref No. 07/1409

APPLICATION RECEIPT DATE: 26/07/2007

FURTHER INFO RECD

Having regard to:

- the nature and extent of the proposed development;
- the intended use of the proposed development,
- the policies of the County Development Plan 2003 and
- the pattern of development in the area,

**it is considered that, subject to compliance with the conditions set out in the
attached Schedule, the proposed development;**

- would not seriously injure the amenities of the area or of property in the vicinity;
- would not be prejudicial to public health;
- would be acceptable in terms of traffic safety and convenience;
- would not be unduly obtrusive on the landscape;
- would, therefore, be in accordance with the proper planning and sustainable development of the area.

In pursuance of the powers conferred upon it by the above-mentioned Acts, South Tipperary County Council has by Order dated 18. 09. 2007 decided to GRANT PERMISSION to the above named for development of land, as follows: -

amendment to the existing planning permission ref 06/2081, for the construction of a new manufacturing facility of 7682 m sq the proposed facility consists of a 2 storey manufacturing building with the plant room at first floor level, a 2 storey final packaging and dispatch building and a 2 storey central utilities building and seperate single storey electrical sub-station building together with all associated ancillary site development works, the existing vehicular and service entrances of Cahir Road will be retained, the site currently possesses an IPC licence

At: Owen & Biggs Lot, Cahir Road, Cashel

Subject to the 13 conditions and reasons therefore as set out in the schedule attached.

If there is no appeal against the said decision, a GRANT in accordance with the decision will be issued after the expiration of the period within which an appeal may be made to An Bord Pleanala (see appeal details overleaf).

IT SHOULD BE NOTED THAT UNTIL A GRANT OF PERMISSION OR PERMISSION CONSEQUENT ON THE GRANT OF OUTLINE PERMISSION HAS BEEN ISSUED, THE DEVELOPMENT OR RETENTION IN QUESTION IS NOT AUTHORISED.

Signed on behalf of South
Tipperary County Council

M. Maffew
County Secretary.

Dated: 18th September, 2007

SOUTH TIPPERARY COUNTY COUNCIL

Planning & Development Acts 2000 to 2006

Ref No. In Planning Ref: 07/1409

Page 1/3

SCHEDULE

1. Save where modified by the following conditions, the proposed development shall be carried out in accordance with the drawings and documentation submitted with the planning application on the 26.07.07.
Reason: In the interest of proper planning and sustainable development.

2. Connection to the public water supply shall be carried out in a technically satisfactory manner to the requirements of South Tipperary County Council as Sanitary Authority. These requirements shall include payment of the appropriate connection fee.
Reason: In the interests of clarity and orderly development.

3. The applicant shall furnish to the Authority water main system drawings including longitudinal sections. Lay 150mm diameter Class D uPVC looped water main under footpath or grass margin generally. Connect to existing water main at 2 no. points for scouring purposes. Enlarge water main loops throughout development back to primary circuit and facilitate future development. Provide at least 0.9m clear cover to water mains i.e. 1.1m to invert level. Install fittings e.g. Sl.V.'s on all branch lines from junctions, A.V.'s at all high points, Sc.V.'s at low points and connect scour pipes to nearest foul manholes, F.H.'s, M., etc. Fit electromagnetic bulk water meter adjacent to connection from public water main. Fit meters, in compliance with County Council Specifications, on all connections. Ensure all works comply with – Recommendations for Site Development Works for Housing Areas (Manual produced by DEHLG). Furnish as-constructed service drawings upon completion. Provide at least 10.0 m wide wayleave for services across private property.
Reason: In the interest of orderly development

4. Connection to the public sewerage facilities services shall be carried out in a technically satisfactory manner to the requirements of South Tipperary County Council as Sanitary Authority. These requirements shall include payment of the appropriate connection fee..
Reason: In the interests of clarity and orderly development.

SOUTH TIPPERARY COUNTY COUNCIL

Planning & Development Acts 2000 to 2006

Ref No. In Planning Ref: 07/1409

Page 2/3

SCHEDULE

5. The surface water disposal from the site shall be attenuated within the site to the satisfaction of the Water Services Section, such that the rate of surface water discharge arising from the proposed development shall be limited to agricultural run-off rates. The details of the attenuation measures and rates of discharge shall be agreed in writing with the Water Services Section prior to commencement of development on the site, or, in default of agreement shall be as agreed with An Bord Pleanala.
Reason: In the interest of orderly development.
6. All service cables associated with the proposed development (such as electrical, telephone, broadband infrastructure and lighting cables) shall be run underground within the site.
Reason: In the interests of orderly development and of the visual amenities of the area.
7. During development works, the developer shall ensure that material from the site is not spread or deposited on the public roadway and shall maintain the roadway in a clean, tidy and safe condition at all times.
Reason: To prevent any traffic hazard or nuisance arising from such material.
8. The noise levels when measured at the boundaries of the site shall not exceed 55 dBA (10 minute Leq) between the hours 0700 and 1900, Monday to Friday and 08.00 and 16.30 on Saturdays, and shall not exceed an L(10) of 45 dBA at any other time. Measurements shall be made in accordance with I.S.O. Recommendation R.1996 "Assessment of Noise with Respect to Community Response".
Reason: To protect the amenities of the area.
9. Noise monitoring shall be carried out as determined by the Planning Authority, or, in default as determined by An Bord Pleanala. Full cost of monitoring shall be paid by the developer and all records shall be submitted to the Planning Authority within 3 weeks of monitoring.
Reason: To protect the amenities of the area.

SOUTH TIPPERARY COUNTY COUNCIL

Planning & Development Acts 2000 to 2006

Ref No. In Planning Ref: 07/1409

Page 3/3

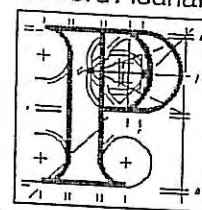
SCHEDULE

10. The applicant shall engage an archaeologist licensed under the National Monuments Acts 1930-1994 to monitor all ground disturbances associated with the development. If archaeological monitoring of the site reveals archaeological material preservation in situ or excavation may be required and the archaeologist shall be empowered to halt development works in order to record exposed archaeological material. The Planning authority and the Heritage and Planning Division of the department of environment, Heritage and Local Government shall be furnished with the report when completed.
Reason: The proposed development is on recorded monument TI 061:071, road that is subject to statutory protection in the record of Monuments and Places, established under section 12 of the national monuments (Amendment) Act 1994.
11. The applicant shall implement all the mitigation measures documented in the submitted Environmental Appraisal Report in relation to the entire proposal.
Reason: In the interests of Environmental quality and orderly development.
12. The applicant shall submit details of the site waste management plan, for agreement prior to commencement notice stage, the applicant shall refer to the Department of the Environment, Heritage and Local Government Guidelines on the Preparation of Waste Management Plan for Construction and Demolition Projects, published in July 2006. No waste materials should be burnt on site: a permitted contractor only should dispose of all wastes to an appropriately permitted or licensed site.
Reason: in the interests of orderly development.
13. Details of all proposed external finishes on the buildings shall be submitted for agreement prior to commencement on site.
Reason: In the interest of orderly development.

TO'M

A Guide to Making a Planning Appeal

An Bord Pleanála



The planning system includes a comprehensive appeals process. Under this, all planning decisions made by planning authorities may be subject to independent review by An Bord Pleanála (the Board). This leaflet gives details of the main features of the appeal process and is intended as a practical guide to the procedures under the 2000 Planning Act. It is not a definitive legal interpretation of the planning law. You are also advised to read 'A Guide to Fees Payable to the Board' leaflet. This and further information is available from the Board or your local planning authority.

1. Is there an appeal application form?

There is no statutory appeal application form. However, the Board has produced a 'Planning Appeal Form / Check List' which may be used as a cover page in an appeal. This document provides an easy-to-use guide which, if followed fully, should help to ensure that your appeal will be valid. Remember that the onus is on you to make a valid appeal. The document is available from the Board, may be downloaded from its website www.pleanala.ie and should be available from your local planning authority.

2. Who may appeal?

An applicant for planning permission (first party), and

any other person, body or interested group etc. who made submissions or observations in writing to the planning authority in relation to the planning application in accordance with permission regulations (third party). There are two exceptions to the requirement to have made prior submissions or observations:

- (1) where a prescribed body was entitled to be notified of a planning application by the planning authority and was not notified in accordance with law, the body may lodge an appeal against the decision of the planning authority without having made submissions or observations on the planning application.
- (2) A person with an interest in land adjoining the application site (e.g. a landowner/occupier) may apply to the Board for leave to appeal the decision of the planning authority (see question 28).

3. Is there a time limit on appeals?

Except where a person is granted leave to appeal by the Board (see questions 2(2) and 28), appeals must be received by the Board within four weeks beginning on the date of the making of the decision by the planning authority (N.B. not the date on which the decision is sent or received). The day the decision is made is counted as the first day. For example, if the decision of a planning authority is made on Wednesday 2nd of a month, the last day for receipt of the appeal is Tuesday 29th of the same month.

Where a person is given leave to appeal, the appeal must be received by the Board within two weeks of him/her receiving notification of that fact.

These are strict statutory time limits. The Board has no discretion to accept late appeals, whether they are sent by post or otherwise. It is your responsibility to ensure that the appeal or other material is delivered or posted in time for delivery within the appropriate period. An appeal or other material posted within the permitted period but received outside it will be invalid. Further explanation of the time limits is given in questions 24, 25 and 26.

4. **How may I appeal?**

Every appeal must be made in writing and must be:

sent by post to: The Secretary,
An Bord Pleanála,
64 Marlborough Street,
Dublin 1,

or, delivered by hand to an employee of the Board at the Board's offices during office hours (9.15 a.m. to 5.30 p.m. on Monday to Friday except on public holidays and other days on which the offices are closed). Appeals placed in the Board's letterbox are invalid.

The appeal must be fully complete from the start – you are not permitted to clarify, elaborate or submit any part of it at a different time, even within the time limit. (See also question 13).

5. **What must I include with my appeal?**

Your own name and address must be clearly stated. Where an agent makes the appeal on your behalf, he/she must state clearly his/her own name and address and your name and address.

The subject matter of the appeal - you must give sufficient details to enable the Board to readily identify the application the subject of the appeal (e.g. a copy of the planning authority decision, or details of the nature and the site of the proposed development, or the name of the planning authority and the planning register reference number of the decision you are appealing).

The grounds of appeal and supporting material and arguments. The Board cannot take into consideration any grounds of appeal or information submitted after the appeal (except information specifically requested by the Board) and it cannot consider non-planning issues; grounds of appeal should not, therefore, include such issues. (See also question 22).

The correct fee. Details of fees are available from the Board or your local planning authority.

In the case of a third party appeal, the acknowledgement by the planning authority of receipt of the submission or observation made by the person to the planning authority at application stage to show that the submission or observation was made at that stage. (A copy of the notification of the decision or similar is not accepted as an acknowledgement of receipt of the submission or observation).

6. **What if my appeal is incomplete?**

If the appeal does not meet all the legal requirements at the time the appeal is made (see the preceding paragraphs for guidance), it will be invalid and cannot be considered by the Board. (See also question 13).

7. **Can I see the planning authority file before appealing?**

Yes. The planning authority will make available for public inspection the planning application and any submissions or observations received in relation to the application at its offices as soon as may be after they are received.

Within 3 working days of its decision, the planning authority will also make available for public inspection at its offices-

the complete application and any additional information supplied by the applicant,

its own reports on the application,

its decision and notification of this to the applicant and any other person or body who made submissions or observations in relation to the application.

8. **Can I get copies of documents relating to a planning application?**
Yes. Copies of the documents referred to at 7 above may be purchased from the planning authority at reasonable cost.
9. **Are there certain decisions or conditions of a planning authority on a planning application which cannot be appealed?**
- (a) There is no appeal to the Board where a planning authority is granted authorisation by the Courts to refuse permission on the basis of past failures of a developer or a related person to comply with a previous permission.
 - (b) There is no appeal to the Board against a decision to grant permission consequent on the grant of an outline permission in respect of any aspect of the decision which was decided in the outline permission.
 - (c) Generally, there is no appeal to the Board in relation to conditions against financial contributions imposed under Development or Supplementary Development Contribution Schemes.

However, appeals are permitted against special contribution conditions imposed by a planning authority and appeals are also permitted where a developer considers that the terms of a Development or Supplementary Development Contribution Scheme were not properly applied. In such cases, where there is no other appeal against the decision of the planning authority, the planning authority may make the grant of permission notwithstanding the appeal to the Board provided that the person taking the appeal furnishes to the planning authority security for payment of the full amount of the contribution or special contribution, as appropriate.

10. **Can I make my views known to the Board without appealing?**
Where an appeal has already been made, another person can become an "observer" and make submissions or observations on the appeal. A copy of the appeal can be seen at the planning authority's office. The time limit for such submissions or observations is four weeks from the receipt of the appeal by the Board (or the last appeal where more than one is made) or, in the case where an Environmental Impact Statement has been submitted, four weeks from the date the Board publishes notice of its receipt or, where the Board has requested the applicant to publish a further site or newspaper notice, four weeks from the date of the publication of the notice. So, if an appeal is received on Wednesday 2nd of a month, the last day for receipt of submissions or observations on the appeal by an "observer" is Tuesday 29th of the same month. See also questions 24, 25 and 26 regarding time limits. Should the appeal (or all the appeals where there is more than one) be withdrawn by the person who made it, the decision of the planning authority will stand and your submission will lapse.

11. **How may I make my views known to the Board?**

An "observer" should submit his/her submissions or observations in writing by: -

• sending them by post to: The Secretary,
An Bord Pleanála,
64 Marlborough Street,
Dublin 1.

• or, delivering them to the Board's offices. (Office hours are 9.15 to 5.30 on Monday to Friday except on public holidays and other days on which the offices are closed).

12. **What must I include with my submissions or observations?**

Your submissions or observations must be accompanied by: -

Your own name and address should be clearly stated. Where an agent makes the submissions or observations on your behalf, he/she must clearly state his/her own name and address and your name and address.

The subject matter of the submissions or observations – you must give sufficient details to enable the Board to readily identify the application/appeal e.g. a copy of the planning authority decision or the appeal reference number.

The full grounds of the submissions or observations and supporting material and arguments. The Board cannot take into consideration any further submissions, observations or other information submitted after the initial submissions or observations are submitted (except information specifically requested by the Board) and it cannot consider non-planning issues.

The correct fee (except in the case of certain bodies specified by the Board). Details of fees are available from the Board or your local planning authority.

13. **If my appeal or observation is invalid, can I re-lodge the appeal or observation?**

If you comply fully with ALL the requirements at the time you re-lodge the appeal or observation, then it will be accepted. The requirements are that the appeal or observation must be received within time (see question 3 or 10, as appropriate), be made correctly (see question 4 or 11) and must include all the information and documents (see question 5 or 12) when it is re-lodged. Even if a fee (correct or not) was lodged with the invalid appeal or observation, the full fee must always accompany the new appeal or observation.

Where the time limit has not expired for re-lodging a fresh appeal or observation, the Board does not guarantee that it will notify appellants or "observers" in sufficient time that would allow a fresh appeal or observation to be made within the statutory time limit.

14. **Can I ask for an oral hearing?**

Any party to the appeal (not an "observer") may request an oral hearing provided the correct non-refundable fee is paid in addition to the appeal fee. The appellant must make the request within the period for lodging the appeal but, where a party to an appeal other than an appellant is sent a copy of an appeal, he/she may make the request within four weeks from the date the copy is sent to him/her.

If you request an oral hearing, you still must state your grounds of appeal in full and comply with the other legal requirements when lodging your appeal.

The Board has absolute discretion to hold an oral hearing with or without a request from a party and will generally only hold one where this will aid its understanding of a particularly complex case or where it considers that significant national or local issues are involved. The Board may also direct the holding of an oral hearing to determine whether an appeal is made with the sole intention of delaying development or of securing the payment of money, gifts, considerations or other inducement by any person.

15. **What happens next?**

The Board sends a copy of the appeal to the planning authority and, in the case of a third party appeal, to the developer. These have four weeks to submit their views. The Board cannot consider any views that are late and no party is allowed elaborate on his/her views in writing once they have been submitted to the Board.

16. **How does the Board ensure fair play for all?**

Where the Board considers it appropriate in the interests of justice, it can ask any party, observer or any other person or body to make submissions or observations on any matter that has arisen in the appeal. This will allow the Board, for instance, to seek comment on any significant new matter arising in the appeal. The Board also has powers to require any party or observer to submit any document, information etc. which it considers necessary. The Board will specify a time limit (minimum 2 weeks) for submission of the invited material and this limit will be strictly enforced.

17. **Can the Board consider matters which have not been raised in the appeal?**

Yes. Generally, the Board is required to consider the application, the subject of the appeal, afresh. Accordingly, all the relevant planning issues relating to the application are considered by the Board in its determination of the case whether or not they were raised by the planning authority, the parties or observers. As stated at 16 above, if a new issue arises the parties and observers will be given an opportunity to comment on these.

Where an appeal relates to conditions only which are attached to a decision of a planning authority to grant permission and there is no other appeal, the Board may generally use its discretionary powers not to consider the application afresh but, instead, to issue directions to the planning authority to amend, remove or attach new conditions to the decision. Where it decides not to use its discretionary powers, the Board may either grant or refuse permission for the development even where conditions only are appealed. However, see also answer to question 9 relating to Development and Supplementary Contribution Scheme conditions and special contributions where different provisions may apply.

18. **Can the Board contravene the provisions of the local Development Plan?**

Yes. The Board, while obliged to have regard to the provisions of a local development plan, may contravene its provisions in certain circumstances. In circumstances where the planning authority decides to refuse permission on the grounds that the proposed development materially contravenes the Development Plan, the Board may grant permission on appeal but only if it considers that –

- the proposed development is of strategic or national importance, or
- there are conflicting objectives in the Development Plan or the objectives are not clearly stated, insofar as the proposed development is concerned, or
- permission should be granted having regard to regional planning guidelines for the area, Ministerial guidelines, Ministerial policy directives, the statutory obligations of any local authority in the area, and any relevant policy of the Government or any Minister of the Government, or
- permission should be granted having regard to the pattern of development and permissions granted in the area since the making of the Development Plan.

The Board can, of course, refuse permission for other reasons even where the proposed development would be in accordance with the provisions of the local Development Plan.

19. **What is the time limit for deciding appeals?**

The Board's objective is to dispose of appeals within 18 weeks. However, where the Board does not consider it possible or appropriate to reach a decision within 18 weeks (e.g. because of delays arising from the holding of an oral hearing), it will inform the parties of the reasons for this and must say when it intends to make the decision.

20. **Will I be informed of the Board's decision?**

Yes. Generally, a decision will be made either-

- to grant permission/outline permission with or without conditions, or
- to refuse permission/outline permission

and all parties and observers involved in the appeal will be notified by post. A copy of the Inspector's Report, the Board's Direction (e.g. whether to grant or refuse, what conditions, if any, should be attached to a permission, other instructions etc), and the Board's decision order is posted on the Board's website at www.pleanala.ie. The reasons and considerations for the Board's decision will be included in the decision order and, in any case where the Board does not accept the Inspector's recommendation in relation to granting or refusing permission, the main reasons for not accepting it.

21. **Is the Board's decision final?**

Yes. Its validity may only be challenged by way of judicial review in the High Court within 8 weeks. The Court will not re-open the planning merits of the case and may only give leave to pursue the review process where it is satisfied that there are substantial grounds for contending that the Board's decision is invalid or ought to be quashed and that the person seeking the judicial review has a substantial interest in the matter.

22. **Can the Board dismiss appeals?**

Yes. The Board has discretion to dismiss an appeal where it is satisfied the appeal is vexatious, frivolous or without substance or foundation or where the appeal is made with the sole intention of delaying development or of securing the payment of money, gifts, considerations or other inducement by any persons. The Board can also declare a planning application or an appeal withdrawn where it is satisfied it has been abandoned.

23. **Can I withdraw my appeal?**

Yes. An appeal can be withdrawn by an appellant and the planning application can be withdrawn by the applicant at any time prior to the determination of the case by the Board. Where an appeal is withdrawn (or all the appeals where there is more than one), the original decision of the planning authority takes effect. Where the planning application is withdrawn by the applicant, no permission can be granted by the planning authority in relation to the application.

24. **How strict are the time limits?**

So that the Board can determine appeals generally within 18 weeks, all the time limits are very strict and the Board has no discretion to extend the dates. This applies to the lodging of appeals, submission of comments by parties, the making of submissions and observations to the Board by "observers" and others and, where invited by the Board, to additional submissions.

25. **What if the offices of the Board are closed on the last day allowed?**

When the last date for receipt of an appeal or other material falls on a weekend, public holiday or other day when the offices of the Board are closed, the latest date for receipt will be the next day on which the offices of the Board are open.

26. **What if the period for making an appeal falls over the Christmas or New Year?**

The period from 24th December to 1st January inclusive (i.e. 9 days) is excluded for the purposes of calculation of all periods of time in relation to planning appeals. Therefore, if the period for making an appeal falls between 24th December to 1st January (both dates inclusive), the last day for making the appeal is extended. So, for example, if the last day of the four-week period falls on 24th December, the last day for making an appeal is 2nd January, and if the last day of the four-week period falls on 29th December, the last day for making an appeal is 7th January.

The exclusion of the Christmas/New Year period also applies to any other matter in relation to an appeal where a time period is specified. So, if the last day of the 18-week statutory objective period within which the Board should decide an appeal falls within the Christmas/New Year period, the period is extended by an appropriate number of days.

27. **Can the Board's documents be inspected and purchased?**

Files on appeals can be inspected by members of the public after the appeals are determined by the Board. These files can be inspected free of charge at the Board's offices on weekdays between 10 a.m. - 12.30 p.m. and 2.30 p.m. - 4.30 p.m., except on public holidays and other days on which the offices are closed. Copies of any documents on these files can be purchased at the Board's offices during these hours for the reasonable cost of copying the documents. Further details concerning inspection and purchase of documents etc., are available from the Board and on its website, www.pleanala.ie

28. **Can I apply to the Board for leave to appeal a decision of a planning authority? (See also answers to questions 2 and 3).**

A person with an interest in land adjoining the application site (e.g. a landowner/occupier) who did not make submissions or observations to the planning authority in relation to the planning application may apply to the Board for leave to appeal the decision of the planning authority within four weeks of the decision of the authority to grant permission. The Board may grant leave to appeal where the person shows that the decision of the planning authority to grant permission differs materially from the application because of the conditions imposed and the conditions imposed will materially affect his/her enjoyment of the land or reduce the value of the land.

Like a planning appeal, the person seeking leave to appeal must state his/her name and address, the grounds on which he/she is basing the leave to appeal (see above), a description of his/her interest in the land and the correct fee.

Where a person is granted leave to appeal, the planning appeal must be received by the Board within two weeks of him/her receiving notification of leave to appeal and must otherwise comply with the requirements for lodging the planning appeal (see questions 4 and 5) including a further fee. Details of fees are available from the Board or your local planning authority.

Can I refer the planning authority's refusal to deal with a second planning application to the Board?

Where a decision of a planning authority in relation to a planning application is on appeal to the Board, a second application for the same development or development of the same description may not be made to the planning authority. Where a dispute arises as to whether an application is for the same development or development of the same description, the matter may be referred to the Board for a determination.

Are appeal fees likely to change?

Under the 2000 Planning Act, the Board is required to review the level of fees payable to it for making appeals, referrals, applications for leave to appeal, submissions or observations and oral hearing requests at least every 3 years. You should always check the latest position to ensure that you know the current applicable fee.

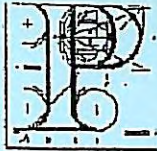
An Bord Pleanála
64 Marlborough Street
Dublin 1

Tel: (01) 858 8100
LoCall: 1890 275 175
Fax: (01) 872 2684
Web site: <http://www.pleanala.ie>
Email: bord@pleanala.ie

Revised 10th January 2005

Fees payable to the Board

From 28th February 2005

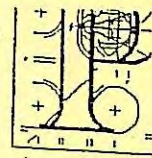


Case Type	On or before 25 th February 2005 ¹	On or after 28 th Februar 2005 ¹
Planning Acts¹		
a. Appeal against a decision of a planning authority on a planning application relating to <u>commercial development</u> , made by the person by whom the planning application was made, where the application relates to <u>unauthorised development</u> .	€1,800	€1,900
b. Appeal against a decision of a planning authority on a planning application relating to <u>commercial development</u> , made by the person by whom the planning application was made, other than an appeal mentioned at (a).	€600	€630
c. Appeal against a decision of a planning authority on a planning application made by the person by whom the planning application was made, where the application relates to <u>unauthorised development</u> , other than an appeal mentioned at (a) or (b).	€600	€630
d. Appeal other than an appeal mentioned at (a), (b) (c) or (f) ² .	€200	€210
e. Application for leave to appeal.	€100	€105
f. Appeal following a grant of leave to appeal.	€100	€105
g. Referral.	€200	€210
h. Reduced fee (payable by specified bodies ³).	€100	€105
i. Submissions or observations (by observer).	€50	€50
j. Request from a party for an oral hearing.	€90	€95
Water Pollution Acts		
Appeal.	€126	€126
Reduced fee (payable by certain prescribed bodies).	€63	€63
Submissions or observations (by observer).	€38	€38
Request from a party for an oral hearing.	€63	€63
Air Pollution Act		
Appeal.	€60	€60
Submissions or observations (by observer).	€10	€10
Request from a party for an oral hearing.	€60	€60
Building Control Act		
Appeal.	€250	€250

1. Fees under the Planning and Development Acts 2000 to 2002 above only apply to appeals and referrals where the application was made to the planning authority on or after 11th March 2002. Otherwise, fees under the Local Government (Planning and Development) Regulations 2001 (SI 525 of 2001) apply.
2. Applies to:- All third party appeals except where the appeal follows a grant of leave to appeal; First party (section 37) planning appeals not involving commercial or unauthorised development; All other (non-section 37) first party appeals.
3. These bodies are specified in the Board's order which determined fees. They include planning authorities and certain other public bodies e.g. National Roads Authority, Irish Aviation Authority.

N.B. This guide does not purport to be a legal interpretation of the fees payable to the Board. A copy of the Board's order determining fees under the Planning Acts is obtainable from the Board. Further information about fees under other legislation may be found in the appropriate legislation and is also available from the Board.

(Please read notes overleaf before completing)



1. The appeal must be in writing (e.g. not made by electronic means).
2. State the -
 - name of the appellant
(not care of agent) _____
 - address of the appellant
(not care of agent) _____
3. If an agent is involved, state the -
 - name of the agent _____
 - address of the agent _____
4. State the Subject Matter of the Appeal*
 - Brief description of the development _____
 - Location of the development _____
 - Name of planning authority _____
 - Planning authority register reference number _____
- * *Alternatively, enclose a copy of the decision of the planning authority as the statement of the Subject Matter of the Appeal.*
5. Attach, in full, the grounds of appeal and the reasons, considerations and arguments on which they are based.
6. Attach the acknowledgement by the planning authority of receipt of your submission or observations to that authority in respect of the planning application, the subject of this appeal. (Not applicable where the appellant is the applicant).
7. Fee of € _____ attached in respect of the appeal.
8. Fee of € _____ attached in respect of request for an oral hearing of the appeal, if a request is being made.
9. Ensure that the appeal is received by the Board in the correct manner and in time.

Signed _____ Date: _____

A format similar to the above may also be used where a person is making submissions or observations on an appeal in accordance with section 130 of the Planning and Development Act 2000. Substitute 'observer' for 'appellant' and 'submission/observation' for 'appeal' at each reference. Items 6 and 8 above are not applicable to the making of submissions or observations.

/Over.....

Rules for Making Appeals

You are advised to check the latest version of "Making a Planning Appeal under the 2000 Planning Act" issued by the Board. It is available from the Board, telephone (01) 858 8100 and on our website www.pleanala.ie. It may also be available from your planning authority.

A significant number of appeals are invalid because they are not made in accordance with the statutory rules.

Appeal Fees

You are advised to check the appropriate fee for making an appeal. Different fees apply depending on the nature of the appeal. A leaflet "Guide to Fees payable to the Board" is available from the Board, telephone (01) 858 8100 and on our website www.pleanala.ie. It may also be available from your planning authority. Note that appeal fees may change from time to time.

A significant number of appeals are invalid either because no fee or an incorrect fee is included.

Time Limits

The time limit for making an appeal is, except where the appeal is made following a successful application for leave to appeal, four weeks beginning on the date of the planning authority decision (not the day it is sent or received). Day one is the day the planning authority decision is made. For example, if the decision of a planning authority is made on Wednesday 2nd of a month, the last day for receipt of the appeal is Tuesday 29th of the same month, NOT Wednesday 30th. There are special rules where the last day falls on a day the Board's offices are closed or where the appeal period falls over the Christmas/New Year period. Check our leaflet for further information.

A significant number of appeals are invalid because they are late – sometimes, just one day late.

1. Delivering the Appeal

- Send the appeal by post to *The Secretary, An Bord Pleanála, 64 Marlborough Street, Dublin 1*,
 - or,
 - deliver it by hand, to an employee of the Board (not a security person), during office hours (9.15 a.m. to 5.30 p.m.) on Monday to Friday,
- so that the appeal reaches the Board by the last day for making an appeal.

Do not place the appeal in the Board's letterbox. A significant number of appeals are invalid because they are incorrectly delivered.

5. Completeness

The appeal must be fully complete from the start. You are not permitted to submit any part of it at a later time, even within the time limit. Neither are you permitted to clarify, elaborate or make further submissions either for the purposes of complying with the rules for making an appeal or otherwise, unless invited by the Board.

This document is issued as an aid to making a valid planning appeal to the Board. It may be used as a 'cover page' in making such an appeal but there is no legal or other requirement to do so. The document should be read in conjunction with the latest versions of the Board's leaflets "Making a Planning Appeal under the 2000 Planning Act" and "Guide to Fees payable to the Board". The guidance given in those leaflets and in this document also applies generally to the making of submissions and observations by 'observers' under section 130 of the 2000 Planning Act. A significant number of submissions and observations by 'observers' are also invalid because the appropriate rules are not observed.

This document does not purport to be a legal interpretation of the law in relation to making a planning appeal – you should consult the appropriate legislation, including sections 37 and 127 of the Planning and Development Act 2000 for the statutory rules governing the making of appeals (section 130 for 'observers').

An appeal or a submission or observation on an appeal that is not made strictly in accordance with the statutory rule will be invalid. The Board has no discretion to relax or vary the rules. The onus is on YOU to meet all the legal requirements at the time you make the appeal/submission/observation.

26th January 2006

SOUTH TIPPERARY COUNTY COUNCIL

PLANNING & DEVELOPMENT ACT 2000 TO 2006

PLANNING & DEVELOPMENT REGULATIONS 2001 TO 2006

NOTIFICATION OF A GRANT

TO:

Cordis Cashel Ltd
c/o Killakee House PM Group
Belgard Square
Tallaght
Dublin 24

PLANNING REGISTER NUMBER:06/2081
APPLICATION RECEIPT DATE: 15/12/2006

In pursuance of the powers conferred upon it by the above mentioned Acts, South Tipperary County Council have by Order decided to grant PERMISSION to the above named, for the development of land, namely:-

construction of a new manufacturing facility of 21365m2 consisting of a 3 storey administration building, a 2 storey Manufacturing Building, a 2 storey Final packaging and dispatch building, and a 2 storey Utility and sub-station, including a new service entrance from the Old Road adjoining the eastern boundary of the site, 204 new car parking spaces and a new entrance lobby to be shared with the existing building and all associated ancillary site development works. The site currently possesses an IPC Licence

At Owens & Biggs Lot Cahir Road Cashel Co Tipperary

in accordance with the plans and documentation lodged with this application hereby GRANT the PERMISSION subject to 17 conditions. It should be noted that this PERMISSION will expire on:

22 day of March, 2012.

Signed on behalf of
South Tipperary County Council.

J Power
PP County Secretary

Date: 23 March, 2007

NOTE:

The permission herein granted shall, on the expiration of the period indicated above, cease to have effect as regards:-

- (1) In case the development to which the permission relates is not commenced during the period, the entire development and
- (2) In case such development is so commenced, so much thereof as is not completed within that period.

It should be noted that the grant of outline permission does **NOT AUTHORISE** commencement of works. Permission consequent on the grant of an Outline Permission **must** be obtained **before** any works commence.

You must submit a COMMENCEMENT NOTICE in accordance with the Building Control Regulations 1991 prior to starting any work as a result of this Grant of Permission, except in the case of a permission for retention.

BC

SOUTH TIPPERARY COUNTY COUNCIL

Planning & Development Acts 2000 to 2006

Ref No. In Planning Ref: 06/2081

Page 1/4

SCHEDULE

1. Save where modified by the following conditions, the proposed development shall be carried out in accordance with the drawings and documentation submitted with the planning application on the 15/12/06.

Reason: In the interest of proper planning and sustainable development.

2. This development shall be restricted to the works proposed, the building shell and exterior finishes only, **excluding** the service entrance from the 'Old Road'. This section of the proposal should be revised and reapplied for under separate cover as an additional application.

Reason: In the interest of proper planning and sustainable development.

3. Before development commences, the developer shall pay to the Planning Authority a development contribution in the sum of € **853,318.10** (subject to an increase on the 1st March each year) in respect of the provision of improved public water supply services, improved road infrastructure and improved recreational and community facilities and amenities.

(i) The amount of the development contribution shall be in accordance with the following class as detailed in the current South Tipperary Development Contribution Scheme:

Class 2	€ x sq.m	Area sq. m	Total
Industrial building and light industrial building	Water	21365	€272,190.10
	Roads	21365	€119,857.65
	Community	21365	€312,783.60
	Sewerage	21365	€148,486.75
			€853,318.10

(ii) The contribution payable will be based on the amount of contribution applicable at the date of payment and not on the rate of contribution in existence at the date of issue of the grant of permission.

(iii) Where the contribution is not paid in accordance with the terms of this condition, any outstanding amounts due to South Tipperary County Council shall be paid together with interest that may have accrued for the period while withheld by the person required to pay the contribution. Interest shall be calculated in accordance with the overdraft rate of interest for the time being.

Reason: As a contribution towards the cost of the provision of improved water supply services, road infrastructure and improved recreational and community facilities and amenities, in accordance with Development Contribution Scheme for the period 1 March 2004 to 28 February 2009 which was adopted, pursuant to Section 48 of the Planning and Development Act, 2000 by resolution of South Tipperary County Council, dated 1 December 2003. Such improvements will facilitate this development.

SOUTH TIPPERARY COUNTY COUNCIL

Planning & Development Acts 2000 to 2006

Ref No. In Planning Ref: 06/2081

Page 2/4

SCHEDULE

4. Connection to the public water supply shall be carried out in a technically satisfactory manner to the requirements of South Tipperary County Council as Sanitary Authority. These requirements shall include payment of the appropriate connection fee in addition to the development contribution specified in Condition 3 above.

Reason: In the interests of clarity and orderly development.

5. The applicant shall furnish to the Authority water main system drawings including longitudinal sections. Lay 150mm diameter Class D uPVC looped water main under footpath or grass margin generally. Connect to existing water main at 2 no. points for scouring purposes. Enlarge water main loops throughout development back to primary circuit and facilitate future development. Provide at least 0.9m clear cover to water mains i.e. 1.1m to invert level. Install fittings e.g. Sl.V.'s on all branch lines from junctions, A.V.'s at all high points, Sc.V.'s at low points and connect scour pipes to nearest foul manholes, F.H.'s, M., etc. Fit electromagnetic bulk water meter adjacent to connection from public water main. Fit meters, in compliance with County Council Specifications, on all connections. Ensure all works comply with – Recommendations for Site Development Works for Housing Areas (Manual produced by DEHLG). Furnish as-constructed service drawings upon completion. Provide at least 10.0 m wide wayleave for services across private property.

Reason: in the interest of orderly development

6. Connection to the public sewerage facilities services shall be carried out in a technically satisfactory manner to the requirements of South Tipperary County Council as Sanitary Authority. These requirements shall include payment of the appropriate connection fee in addition to the development contribution specified in condition 4.

Reason: In the interests of clarity and orderly development.

7. The applicant shall submit details of the wastewater disposal arrangements to the Authority.

Reason: in the interests of orderly development

8. The surface water disposal from the site shall be attenuated within the site to the satisfaction of the Water Services Section, such that the rate of surface water discharge arising from the proposed development shall be limited to agricultural run-off rates. The details of the attenuation measures and rates of discharge shall be agreed in writing with the Water Services Section prior to commencement of development on the site, or, in default of agreement shall be as agreed with An Bord Pleanála.

Reason: In the interest of orderly development.

9. All service cables associated with the proposed development (such as electrical, telephone, broadband infrastructure and lighting cables) shall be run underground within the site.

Reason: In the interests of orderly development and of the visual amenities of the area.

SOUTH TIPPERARY COUNTY COUNCIL

Planning & Development Acts 2000 to 2006

Ref No. In Planning Ref: 06/2081

Page 3/4

SCHEDULE

10. During development works, the developer shall ensure that material from the site is not spread or deposited on the public roadway and shall maintain the roadway in a clean, tidy and safe condition at all times.

Reason: To prevent any traffic hazard or nuisance arising from such material.

11. The noise levels when measured at the boundaries of the site shall not exceed 55 dBA (10 minute Leq) between the hours 0700 and 1900, Monday to Friday and 08.00 and 16.30 on Saturdays, and shall not exceed an L(10) of 45 dBA at any other time. Measurements shall be made in accordance with I.S.O. Recommendation R.1996 "Assessment of Noise with Respect to Community Response".

Reason: To protect the amenities of the area.

12. Noise monitoring shall be carried out as determined by the Planning Authority, or, in default as determined by An Bord Pleanala. Full cost of monitoring shall be paid by the developer and all records shall be submitted to the Planning Authority within 3 weeks of monitoring.

Reason: To protect the amenities of the area.

13. Prior to the commencement of development, the developer shall submit to the Planning Authority a program for implementation of the submitted landscaping plan. It shall also describe the maintenance and management procedures which will be followed during operations to protect and enhance existing screening while ensuring new planting thrives. The extent, timing and phasing of the installation of landscape works shall be agreed in writing with the Planning Authority. Failing agreement, the matter shall be determined by An Bord Pleanala.

Reason: In the interest of visual amenity.

14. The applicant shall engage an archaeologist licensed under the National Monuments Acts 1930-1994 to monitor all ground disturbances associated with the development. If archaeological monitoring of the site reveals archaeological material preservation in situ or excavation may be required and the archaeologist shall be empowered to halt development works in order to record exposed archaeological material. The Planning authority and the Heritage and Planning Division of the department of environment, Heritage and Local Government shall be furnished with the report when completed.

Reason: The proposed development is on recorded monument TI 061:071, road that is subject to statutory protection in the record of Monuments and Places, established under section 12 of the national monuments (Amendment) Act 1994.

15. The applicant shall implement the mitigation measures documented in the submitted Environmental Appraisal Report in relation to the entire proposal.

Reason in the interests of Environmental quality and orderly development.

SOUTH TIPPERARY COUNTY COUNCIL

Planning & Development Acts 2000 to 2006

Ref No. In Planning Ref: 06/2081

Page 4/4

SCHEDULE

16. The applicant shall submit details of the site waste management plan, for agreement prior to commencement notice stage, the applicant shall refer to the Department of the Environment, Heritage and Local Government Guidelines on the Preparation of Waste Management Plan for Construction and Demolition Projects, published in July 2006. No waste materials should be burnt on site: a permitted contractor only should dispose of all wastes to an appropriately permitted or licensed site.

Reason: in the interests of orderly development.

17. Prior to commencement, the applicant shall submit road design drawings for the realignment of the Old Road for the written approval of the Roads Section of South Tipperary County Council. The applicants will be required to undertake these works at their own expense prior to completion of the main development.

Reason: In the interests of traffic safety and for the proper planning and sustainable development of the area.

RH

For inspection purposes only.
Consent of copyright owner required for any other use.

Form of Commencement Notice for Development

Notice to a Building Control Authority pursuant to Part II of the Building Control Regulations, 1997



Building Control Authority:
South Tipperary County Council

OFFICE USE ONLY

Date received: _____
Register Ref: _____
Entered on: _____
Entered by: _____
Fee Received: _____

the undersigned, hereby give notice/give notice on behalf of the person(s) named below*, to the above Building Control Authority (in accordance with Part II of the Building Control Regulations) that I/the persons named below intend to carry out the development as described below. (* Cross out whichever is inappropriate)

Signature: _____ Date: _____ Tel: _____ Fax: _____
Name of person(s): _____ Email: _____
Address: _____
Commencement date (of works): _____ Fee payable (€): _____

a. PROJECT PARTICULARS: (In addition, for Residential Developments, please complete Section 2b below)

Description of proposed development:

Planning permission no.: _____ Date of grant: _____ Date of expiry: _____
Fire Safety Certificate Number (if applicable): _____
Location of development: _____

2. Residential Development Information:
Total number of developments (all phases): _____ Total no. of phases: _____
Phase to which commencement notice refers: _____ The date of the commencement notice: _____
Commencement date for this phase: _____ The date of the commencement notice: _____
Where applicable, the planning notice (and/or site notice) number: _____

3. Builder:
Name: _____ Tel: _____ Fax: _____
Address: _____ Email: _____

4. Building Owner Details: (if different from Section 1 above)
Name: _____ Tel: _____ Fax: _____
Address: _____ Email: _____

5. Building Designer Details:
Name: _____ Tel: _____ Fax: _____
Address: _____ Email: _____

6. Information: Person(s) from whom such plans, documents and any other information, as are necessary to show that the building or works will, if built in accordance with design, comply with the requirements of the Building Regulations may be obtained.
Name: _____ Tel: _____ Fax: _____
Address: _____ Email: _____

7. Drainage System Foundations: Person(s) from whom notifications of the pouring of any foundations and/or the covering up of any drainage systems may be obtained
Name: _____ Tel: _____ Fax: _____
Address: _____ Email: _____

NOTICE

Building Control Act 1990
&
Building Control Regulations 1997

It is a legal requirement to submit a valid commencement notice *BEFORE* any works start.

A commencement notice will be returned as invalid if *ALL* sections, including fee, planning permission number and safety certificate number (where applicable) are not clearly and fully completed.

The fully completed notice must be submitted between 14 and 28 days prior to the commencement of the work.

Appropriate legal action will be taken for breaches of the Building Control Regulations 1997.

The fee is €30,

or where

- (a) the proposed works or the material change of use (as the case may be) relate to more than one building and
- (b) neither Part III, nor part III of the Building Control Acts, 1991 and 1994, apply such works or buildings

the fee is €30 in respect of each building

Completed Forms should be returned to:

The Building Control Authority
Fire Station
Heywood Road
Clonmel
Co. Tipperary

For inspection purposes only.
Consent of copyright owner required for any other use.

ATTACHMENT B
APPENDIX 8

*For inspection purposes only.
Consent of copyright owner required for any other use.*

Toyota

**D Stunning
Toyota BB-SUV
A/T €8,995**

4-4319111
accardymotors.ie

Automatic

saloon silver 87k
Tel: 087-6035555 B

ane Motors

DUNMANWAY
576 or 087-9984355
's 3 dr & 5dr, Choice
'96-'03. All serviced,
ed & guaranteed.

GX 2.0L, 5dr, silver
70k mls, abs, a/c,
net 03/09, immacu-
086 8355583

VW

Passat TDI, €10,500
mo. Tel: 087-2267657

***03 Golf*
Van TDI
8,500+vat**

Luceys Charleville
2222

Comfortline, 1.2L
fully serviced, NCT
09, €8450, Tel:
523939 Cork

Golf, 1.9 TDI, new
1.5dr, grey met, 60k,
mer, fwsh, €15,500,
37-7514659

'05 Golf

line, 1.4, 5dr,
silver, alloys, as new,
00. Ph: 087-6035555.

VW AT KINGDOM AUTOPOINT

Passat TDI estate only 39k
silver €22,950. Over
ore VW's to choose
Phone Sales on
26060 / 086-4179319
d cars on

kingdomautopoint.com

pple Carriers

7-Seaters

Licensed Premises

FOR sale, full ordinary 7 day
publicans licence, apply to
Donal Mulcahy 026-20099.

Offices To Let

200 to 1000 sq ft, Cork City
centre, highly flexible
terms. 021 4861400

500sq ft self contained
office with parking,
Tramore Road, Cork. Ph:
086-8115060.

ATRIUM Conference Rooms
with parking in Cork. For
details Tel: 021 4217400.
Visit: www.atriumbc.ie

CITY centre offices to let.
021-4275786/086 2555110

SELECTION of offices to let
at Marina Commercial
Park, Centre Park Road,
Cork. Sizes: 33sq.m. (350
sq.ft), 70sq.m. (750 sq.ft);
246sq.m. (2650sq.ft);
1200sq.m. (13000sq.ft).
Ph 021-4313466

Property Commercial

COMMERCIAL Investment in
Europe 8% return -10
year lease blue chip tenant
-Bank approved.
Tel: 0861026728

FOR Sale/ To Let: Modern
light industrial/commercial
units. Fit out to 3rd gen-
eration specification. 3,000 -
29,000 sq. ft. available.
Call Access Properties
(021) 4280 999 or (087)
6767 427.

HARBOUR POINT BUSINESS PARK

Little Island. For Sale/To Let
New commercial units 165
Sq.M - 330 Sq.M (1,776
Sq.Ft - 3,552 Sq.Ft)
LISNEY 021-4275079

MARINA Commercial Park
Centre Park Road, Cork.
Industrial / Warehousing /
Storage units available to
rent. Sizes : 246 sq.m.
(2650 sq.ft.); 279 sq.m.
(3000 sq.ft); 372 sq.m.
(4000 sq.ft); 400 sq.m.
(4300 sq.ft); 465 sq.m.
(5000 sq.ft); 743 sq.m.
(8000 sq.ft); 836 sq.m.
(9000 sq.ft) 2044 sq.m.
(22000sq.ft) Ph
021-4313466

TO Let 3,100sq ft Commer-
cial unit, City North Busi-
ness Park. Contact Absol-
ute Property 021-4251288.

Warehouse

4,500sq ft for rent, 15 mins
from Bishopstown, fully

Property For Sale

Warehouse

Youghal, C.10, 000 sq.ft on C
1 acre, Close to N25, Tel
(021) 4639474.

SITE Carrignavar / Glenville
area. 087-2051565

Property To Let

3 bedroomed house & bungalow
in Blarney, ff/unff,
vgc, no RA. 087-2513310

5 bedroomed bungalow to
let, Ballincurragh, near
Midleton. ff, ra accepted.
Ph: 086-2410804

Car parking

space City Centre, secure
parking. Rent €40pw. Tel:
087-2594901

CASHEL (5mins walk from
town centre) new 3 bed-
room semi, ff and all new
appliances, €820pm.
Tel: 087-9310548

NEW house, 3 bed, ff, Lyre
Banteer. €800 p.m.
087-6798665/ 023-45290
after 4pm

PARKING Spaces to let,
adjacent to Kent Train Sta-
tion, Cork. Ph:
086-1708920 for details.

To let Castlemartyr 3 bed
duplex, 2½ bathrooms all
mod cons, ff, suit prof cou-
ple €200pw : 086-6033136

Property Wanted

SITE wanted for single
house in Waterfall/Goggins
Hill area. 085 7074158

Farm Buildings

SLURRY tanks/ formwork
Cork. Tel: 086-3410020

Farm Produce

GOOD Black Turf by the bag
Delivered Tel: 087-1200402

ROUND Hay and Wheaten
Straw bales €18, delivered
or ex-yard. 087-2890492.

WHITETHORN, beech, etc,
etc. All trees & tree plants.
John 087-2743914 anytime.

Machinery

PERKINS Spares 24 Hr
Nationwide Delivery. Tel.
01-8824884 or Fax

Personal

HYPNOTHERAPY Clinic can
successfully treat smoking,
slimming, anxiety, stress,
phobias, blushing, personal
problems. Free
explanatory brochure. Tel.
021 4273575, Therapy
House, 6 Tuckey Street,
(Registered, Certified,
D.H.P.)
www.hypnosiseire.com

AT Euro Introductions.
Today is the first day of the
rest of your life.
Romance/friendship. (021)
4315180 / (087)2902320.

Tenders

INVITATION TO TENDER

Tenders are invited from
competent building contractors
for the following:

ALTERATIONS AND EXTENSIONS TO CLASHMORE NATIONAL SCHOOL

CLASHMORE, CO. WATERFORD
Drawings and Specifications are
available from Damien Dillon and
Company Architects, 18 Mitchell
Street, Dungarvan, Co. Waterford.
Tel: 058-42806.

It is a condition for the award of
this Contract that the successful
tenderer and all sub-contractors
produce a valid Tax Clearance
Certificate or C2 Certificate from
the Revenue Commissioners.

The successful tenderer will also
be required to produce current
relevant insurance policies, a
safety statement and confirmation
that he is operating the CIP Pen-
sion and Sick Pay Schemes.

Sealed Tenders, clearly marked
"Alterations and extensions to
Clashmore National School,"
should be lodged with Damien
Dillon and Company not later
than 4pm on Tuesday, December
18, 2007.

The lowest or any tender need not
necessarily be accepted.

Board of Management
Clashmore National School

INVITATION TO TENDER

Tenders are invited from
competent building contractors
for the following:

ALTERATIONS AND EXTENSIONS TO HOLY FAMILY JUNIOR MERCY PRIMARY SCHOOL, MILITARY ROAD, WATERFORD

Drawings and Specifications are
available from Damien Dillon and
Company Architects, 18 Mitchell
Street, Dungarvan, Co. Waterford.

Public Notices

Cuthbert Environmental, on
behalf of Denis Quinn, wishes
to make an Application to
Limerick County Council for a
Waste Collection Permit relating
to activities in Limerick County
Council/Limerick City Council/
Clare County Council/Kerry
County Council areas.

Denis Quinn, Flunfield, Millstreet,
intends to make an application
to Limerick County Council for
the collection of Industrial/
Commercial/C&D waste.

A copy of the application will
be available for inspection or
purchase at the principal office
of each Local Authority in whose
functional area the activity is
or will be carried on and that
any member of the public may,
within a period of six weeks
of the application having been
published, make a written
submission to Limerick County
Council in relation to the said
application.

APPLICATION TO THE ENVIRONMENTAL PROTECTION AGENCY FOR AN IPPC LICENCE REVIEW

ALZA Ireland Ltd., Cahir Road,
Cashel, Co. Tipperary is applying
to the Environmental Protection
Agency for an Integrated
Pollution, Prevention and Control
(IPPC) Licence Review for an
extension to their existing facility
under Class 12.2.2 "The use of
coating materials in processes
with a capacity to make or use
at least 10 tonnes per year of
organic solvents" of the First
Schedule of the Protection of the
Environment Act 2003. The site is
located on Cahir Road, Cashel,
Co. Tipperary - National Grid
Reference 20762E 13903N.

A copy of the application
for a licence review may be
inspected at or obtained from the
headquarters of the Agency (EPA
Headquarters, PO Box 3000,
Johnstown Castle Estate, Co.
Wexford) as soon as practicable
after the receipt by the Agency
of the application for the licence
review.

Planning Notices

DUBLIN CITY COUNCIL:
We, L. Crowe & R. Payne
intend to apply for Planning
Permission at this site No.
22 St. Kevin's Cottages,
Dublin 8.

The development will consist
of the demolition of
existing two storey building
of (circa 107.9m²) and the
construction of a new two

Public Notices

APPLICATION TO THE ENVIRONMENTAL PROTECTION AGENCY FOR A WASTE LICENCE

Notice is hereby given in
accordance with the provisions of
the Waste Management Acts 1996
to 2007 and Articles 5 and 6 of the
Waste Management (Licensing)
Regulations, 2004 (S.I. No. 395
of 2004), that Padraig Thornton
Waste Disposal Ltd (Trading as
Thorntons Recycling) having its
registered offices at Unit S3B
Henry Road, Park West Business
Park, Dublin 10 will apply to the
Environmental Protection Agency
(EPA), P.O. Box 3000, Johnstown
Castle Estate, County Wexford, for
a Waste Licence in respect of a
new Materials Recovery Facility
(MRF) at Millennium Business
Park, Cappagh Road, Grange,
Dublin 15 (National Grid
Reference: E 3131; N 2482).

The activity will consist of
Materials Recovery Facility (MRF)
with a capacity for a maximum
annual intake of 100,000
tonnes of dry mixed recyclable
material and construction and
demolition waste collected
from the commercial/industrial
and domestic sectors. The
incoming waste material will be
separated using a combination of
sophisticated mechanical sorting
and manual quality control
screening systems. A majority
(c. 90%) of the waste materials
will be sorted into a variety of
targeted material fractions which
will be sent for beneficial reuse
or recycling. Remaining waste
material will be disposed to an
appropriate licensed facility. The
process is entirely a separation
process and does not employ any
biological or chemical treatment
of the waste. It is not proposed
to handle hazardous waste at this
facility. The classes of activity
concerned are specified as per
the Third and Fourth Schedules
of the Waste Management Acts
1996 to 2007, as follows:
Third Schedule:

Class 11: Blending or mixture
prior to submission to any
activity referred to in a preceding
paragraph of this Schedule.

Class 12: Repackaging prior to
submission to any activity referred
to in a preceding paragraph of
this Schedule.

Class 13: Storage prior to
submission to any activity
referred to in a preceding
paragraph of this Schedule, other
than temporary storage, pending
collection, on the premises
where the waste concerned is
produced.

APPLICATION TO THE ENVIRONMENTAL PROTECTION AGENCY FOR AN IPPC LICENCE REVIEW

ALZA Ireland Ltd., Cahir Road, Cashel, Co. Tipperary is applying to the Environmental Protection Agency for an Integrated Pollution, Prevention and Control (IPPC) Licence Review for an extension to their existing facility under Class 12.2.2 “The use of coating materials in processes with a capacity to make or use at least 10 tonnes per year of organic solvents” of the First Schedule of the Protection of the Environment Act 2003. The site is located on Cahir Road, Cashel, Co. Tipperary – National Grid Reference 20762E 13903N.

A copy of the application for a licence review may be inspected at or obtained from the headquarters of the Agency (EPA Headquarters, PO Box 3000, Johnstown Castle Estate, Co. Wexford) as soon as practicable after the receipt by the Agency of the application for the licence review.

Consent of copyright owner required for any other use.
For information purposes only.



To: Administrative Officer
Planning Section, South Tipperary County Council
County Hall
Clonmel
Co Tipperary

Monday, November 26th 2007

Dear Sir or Madam,

ALZA Ireland Ltd. wish to inform you that we are applying to the EPA for an Integrated Pollution, Prevention and Control Licence Review for an extension to our existing facility under Class 12.2.2 "The use of coating materials in processes with a capacity to make or use at least 10 tonnes per year of organic solvents" of the First Schedule of the Protection of the Environment Act 2003. The site is located on Cahir Road, Cashel, Co. Tipperary – National Grid Reference 207628865E 139031898N.

Notification of this application will be published in the Examiner dated 28th November 2007.

Yours sincerely


Gearoid McDermott
Financial Controller

ATTACHMENT C MANAGEMENT OF THE INSTALLATION

C.1 Site Management & Control

ALZA Ireland Ltd. places great emphasis on the management of potential environmental risks and liabilities and the prevention of pollution arising from site operations. In order to best facilitate the overall management of these risks and liabilities, which involves all levels of personnel within each and every department, an environmental manual has been produced, which is part of the site environmental management system. The objective of the manual is to provide an overall guide of the structures, responsibilities and procedures used by the company to manage environmental risks and pollution prevention in accordance with the objectives of the ALZA Ireland Ltd Environmental Policy and the Johnson & Johnson Corporate Policy. Implementing and complying with the management systems outlined in this manual is the direct responsibility of all ALZA Ireland Ltd personnel within their own individual sphere of operations and influence. However, key personnel on-site have designated responsibilities for the day-to-day operation of the activity from an environmental perspective. These are standard responsibilities and do not include any additional responsibilities which may be designated under the schedule of environmental targets and objectives.

The following summarises the responsibilities of key site personnel:

General Manager

Overall responsibility for site operations. To liaise with all departments on a regular basis, including the Management Operations Committee (MOC) and the Production Manager, Environmental Health and Safety (EHS) Co-ordinator, and Engineering on a regular basis to ensure efficient environmental information transfer. Ensuring the environmental management system is integrated into the operation of the business and adequate resources are provided for site environmental requirements.

Management Operations Committee (MOC)

Representative management member from each department, with responsibility for ensuring integration and promotion of environmental responsibility and awareness in their department.

Production Manager

Responsible for all environmental matters onsite including the licence compliance, regulatory compliance, corporate compliance and ensuring the environmental management system is established, implemented and maintained in accordance with the scope of the Environmental Management System (EMS). The Production Manager has overall responsibility for the site's correspondence with the Environmental Protection Agency, local authorities and Southern Regional Fisheries Board. Also responsible for the efficient operation of the production facility, including reporting on production matters, waste generation management, emissions, good working practices and production housekeeping procedures.

Environmental, Health & Safety (EHS) Co-ordinator

The EHS Co-ordinator is responsible for the management and supervision of environmental programmes on site, management of all environmental documentation on site, documentation of waste movement off site, environmental monitoring at the facility in accordance with licence requirements and maintenance of the environmental management system.

Supply Chain Manager

Responsible for warehouse and materials management on site, including organising waste consignment in conjunction with the EHS Co-ordinator and reporting on material and waste storage matters including internal and external storage of waste materials and loading and unloading of materials. Also responsible for ensuring adequate supply of waste drums and labels in stock, compaction of cardboard and plastic recycling waste and good working practices.

Engineering & Maintenance

Responsible for management of utilities, including air abatement units, wastewater storage, etc. Also responsible for environmental monitoring (wastewater, surface water, bund emptying etc) as required in the licence. Responsible for the efficient mechanical and electrical maintenance and preventative maintenance including efficient response to equipment breakdown. Responsible for the safe collection of waste oils and maintenance wastes and storage of same.

Human Resources

Responsible for training including environmental training in accordance with EMS requirements and management of the ALZA conservation and community outreach programme.

Security

Security are responsible for the following;

- Proper direction of visitors/complaints e.g. media, complainants and for the handling of the public information programme.
- Public access of information as required under the licence.
- Carrying out tasks during the activation of the Emergency Response Plan.

Internal Environmental Auditors

Responsible for carrying out internal environmental auditing at planned intervals, reporting the findings to the EHS Co-ordinator who will tracking findings to closure and report to top management.

Emergency Response Team

Responsible for carrying out key tasks during emergency response, as detailed in the site Emergency Response Procedure.

Environmental Implementation Team (EIT)

The Environmental Implementation Team is comprised of one representative from each department. They are involved in compiling departmental data for the environmental aspects and impacts assessment of the organization. The Environmental Implementation Team subsequently report to the EHS Co-ordinator who carries out the scoring and final assessment of the Environmental Aspects/Impacts. The EIT are also actively involved in the development and implementation of environmental objectives and targets in each department and onsite. The EIT are also involved in generating environmental awareness in their own departments, specifically training and awareness in environmental aspects & impacts and environmental objectives and targets. They also provide input into awareness topics or activities and reports these to the EHS Co-ordinator.

Environmental Section Owners/ MAARS

Nominated individuals from each department actively partake in the Johnson & Johnson Environmental Management Awareness and Action Review System (MAARS). J&J Worldwide Sustainability Practices are corporate requirements, which outline minimum operating and management standards to ensure the protection of humans, health and the environment. These Practices also serve as the basis for MAARS and Section Owners are assigned responsibility for these practices.

Company Personnel & Contractor Employees

All ALZA personnel and Contractor employees are responsible for co-operating fully with the implementation of all environmental policies and programmes at their workplace and for care of the environment in all activities undertaken. All employees (including contractor employees where appropriate) are actively involved in Licence compliance and the development and ongoing maintenance of the environmental management systems within their operational area.

A Management Organisational Chart for the proposed expansion is included in Attachment C Appendix 1.1. The Chart illustrates the key personnel on-site who will have designated responsibilities for the day-to-day operation of the activity. The EHS Co-ordinator will continue to have input at all levels of site management with regard to environmental matters.

The existing facility operates under a site based environmental policy in support of the Johnson & Johnson Corporation Environmental Policy Statement and J&J Worldwide Environmental Sustainability Practices. The General Manager of the facility has issued the statement under his signature. The policy covers all activities at the facility and states in broad terms ALZA's commitment to the protection of the environment. Specifically, the policy includes a commitment to continual improvement and prevention of pollution, in addition to a commitment to comply with relevant environmental legislation, regulations and other requirements.

Attachment C Appendix 1.2 contains a copy of the Environmental Policy Statement.

C.2 Environmental Management System (EMS)

An Environmental Management System is operated by the existing facility, ALZA Ireland Ltd. The scope of the EMS is for the testing, release and manufacture of pharmaceutical products. The EMS is accredited to ISO14001:2004 by the accreditation body SGS. The EMS has been developed in order to improve upon the environmental performance of the site, comply with the requirements of the operating IPC licence and comply with Johnson & Johnson corporate requirements. It is anticipated that the scope of the existing EMS will be expanded to incorporate the new facility and preliminary discussions with SGS have already taken place.

Attachment C Appendix 2 contains a copy of the Certificate of Accreditation to ISO14001:2004.

C.3 Hours of Operation

(a) Proposed hours of operation

The existing facility operates on a twenty-four hours per day seven days per week. The new facility will also operate twenty four seven.

(b) Proposed hours of construction and development works and timeframes.

Construction and commissioning works for the new facility commenced in June 2007 and will be completed in February 2009.

Hours of operation are 7am to 8pm Monday to Saturday. Working hours may vary slightly depending on weather conditions and daylight hours during winter months. Heavy construction activities will be avoided where possible outside the normal working hours outlined above.

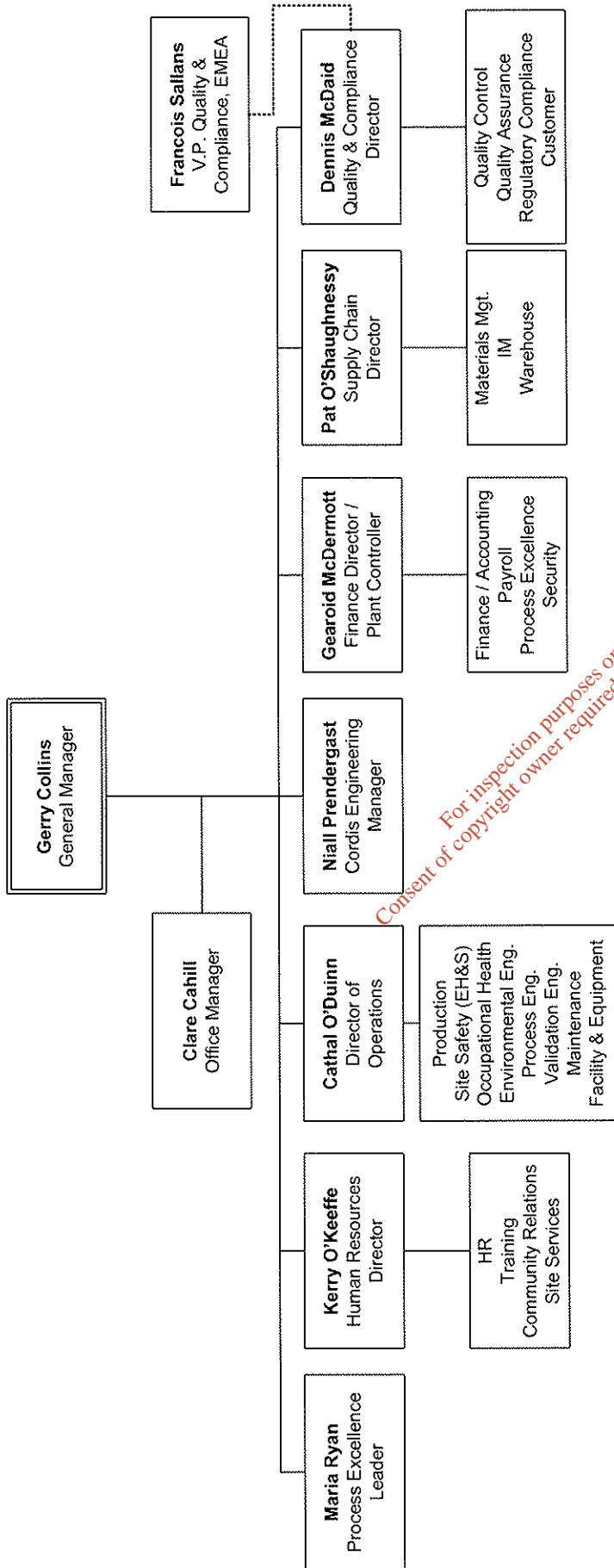
(c) Any other relevant hours of operation expected.

N/A

ATTACHMENT C
APPENDIX 1.1

*For inspection purposes only.
Consent of copyright owner required for any other use.*

ATTACHMENT C, APPENDIX 1.1, ORGANISATIONAL CHART



For inspection purposes only.
Consent of copyright owner required for any other use.

ATTACHMENT C
APPENDIX 1.2

*For inspection purposes only.
Consent of copyright owner required for any other use.*

Environmental Policy

Alza Ireland Ltd & Cordis Cashel Ltd are dedicated to the protection of the environment, by conducting our business and operations responsibly and in an environmentally safe and sustainable manner.

Consistent with 'Our Credo' Alza Ireland Ltd & Cordis Cashel Ltd are committed to;

- o Prevention of pollution by applying best practices for environmental management throughout our business.
- o Achieving environmental excellence in every aspect of our business through continuous improvement.
- o Improving the efficiency of our operations to minimise resource and materials consumption and waste and emissions generation.
- o Engaging, developing and enabling all visitors, contractors, employees and persons working for or on behalf of our organisation by providing training, information and supervision to achieve performance excellence.
- o Complying with all corporate, national and local statutory and regulatory requirements.
- o Minimising the environmental impact of our business on our neighbours and all visitors, contractors, employees and persons working for or on behalf of our organisation.
- o Creating awareness among all visitors, contractors, employees and persons working for or on behalf of our organisation on environmental matters and integrating environmental awareness as standard practice regarding all aspects of our operations.
- o Establishing, developing and maintaining environmental objectives and targets to provide the framework for implementing this environmental policy.
- o Reviewing the Environmental Policy and Programme on an annual basis to ensure that they remain current and effective.

It is the responsibility of the Management and Employees of Alza Ireland Ltd & Cordis Cashel Ltd to communicate this policy to all visitors, contractors, other employees and persons working for or on behalf of our organisation. It is the responsibility of all employees to comply with this policy.

Signed: _____

Gerard Collins
General Manager

Date: _____

29th June 2007

ATTACHMENT C
APPENDIX 2

*For inspection purposes only.
Consent of copyright owner required for any other use.*

Certificate IE05/66143

The management system of

Alza Ireland Limited

Cahir Road, Cashel,
Co. Tipperary, Ireland



has been assessed and certified as meeting the requirements of

ISO 14001:2004

For the following activities

Testing, Release and Manufacture of pharmaceutical products

This certificate is valid from 05 December 2005 until 05 December 2008
Issue 1. Certified since 05 December 2005

*For inspection purposes only.
Consent of copyright owner required for any other use.*

Authorised by

P. Earl

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com



005

SGS EMS 04 0105

Page 1 of 1



Certificate IE05/66143

The management system of

Alza Ireland Limited

Cahir Road, Cashel,
Co. Tipperary, Ireland



has been assessed and certified as meeting the requirements of

ISO 14001:2004

For the following activities

Testing, Release and Manufacture of pharmaceutical products

This certificate is valid from 05 December 2005 until 05 December 2008
Issue 1. Certified since 05 December 2005

*For inspection purposes only.
Consent of copyright owner required for any other use.*

Authorised by

P. Earl

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com



SGS EMS 04 0105

Page 1 of 1



ATTACHMENT D INFRASTRUCTURE AND OPERATION

D1. Operational Information Requirements

The operational aspect of this development will involve four main processes as follows;

1. Existing licensed ALZA transdermal products process (existing process)
2. Cordis drug eluting stent process (proposed process)
3. Pharmaceutical / medical device combination process (proposed process)
4. Development Lab for Processes 2 and 3 (existing process)

For the purpose of this application each of the above processes are described separately under the following headings;

- Introduction
- Plant / Equipment
- Process Description
- Operating Procedures
- Emissions and Abatement System
- Laboratory Facilities

D1.1 Existing Licensed ALZA Transdermal Products Process

D.1.1.1 Introduction

At present, only two products are manufactured on site, although multi-purpose production facilities have been provided so that the facility has the flexibility to manufacture a range of transdermal products. Transdermal products are manufactured from raw materials and active ingredients. There is no bulk synthesis of active ingredients on site. The main processing operation involves the application of active ingredients to transdermal patches. Raw materials are imported and delivered to site from suppliers and other Johnson and Johnson (J&J) sites. The transdermal products are packaged on site, with one product shipped to another J&J facility in Belgium for secondary packaging and distribution and similarly for the second product to a technical partner. In addition, the quality control laboratory also conducts testing of J&J products from the United States (US) for the release into the European market.

D.1.1.2 Plant and Equipment

The main features of the production operation are summarised as follows;

- Production Area
- Warehousing (raw materials, intermediates, finished goods, waste)
- Quality Control Laboratory and Offices
- External materials storage
- Wastewater storage tank
- Site services including de-ionised water, compressed air, etc.
- Engineering office and workshop

- Administration area
- Canteen

A list of the equipment used in the manufacture of products is presented below and it's location is shown on Figure 3: Process 1 (ALZA): Process and Equipment Arrangement;

- Mixing vessels
- Packaging Equipment
- Die cutter
- Extruder
- Calender/Laminator
- Casting Coater
- Pouchers with auto trayers

D.1.1.3 Process

The ALZA Transdermal Products Process has three production lines producing skin patches and transdermal pharmaceuticals. The first production line is used to produce Nicoderm, a skin patch containing nicotine used as an aid to smoking cessation. The second production line is used to produce transdermal pain relief products. This production line involves using a solvent casting process that uses organic solvents. A third production line will be used to produce an intermediate used in the primary products described above. The intermediate requires mixing and solvent casting operations using heptane. A summary of the past and future system production for production line 1 and 2 is outlined in Table D.1.1.3 below.

Table D.1.1.3 System Production

Product	Year	System Production (millions/year)
Pain Relief Transdermal	2006	43.291
	2007	53.976
	2008	56.913
Nicoderm	2006	48.082
	2007	66.979
	2008	57.47

Manufacturing processes are currently carried out by completing a series of "Unit Operations" in the Production Building. Each of the Unit Operations is briefly described below and each description includes details on plant capacity and throughput, Refer to Figure 3 (ALZA): Process and Equipment Arrangement and Figures 4 to 7 for Flow Diagrams.

The following unit operations are carried out in the ALZA facility

- Inerting
- Charging
- Mixing/Dissolution
- Extrusion/Pumping
- Casting and Lamination
- Corona Treatment
- Split Release Liner Lamination
- Die Cutting
- Pouching
- Packaging
- Cleaning

Inerting

Certain processes can only be undertaken in the absence of oxygen as it can lead to degradation of the product. A vacuum is pulled on the vessel and when a certain vacuum is reached, nitrogen is allowed to enter the vessel. Typical inertion is via Pressure Swing where vacuum is only pulled once the vessel is pressurised 2-3 times with N₂ rather than multiple evacuations. The operation is repeated a number of times until the reactor contains an inert atmosphere, with an O₂ concentration less than 2%. A small nitrogen purge is maintained to ensure the oxygen level is maintained below 2%.

Charging

Liquid pharmaceuticals are pumped or nitrogen pressure transferred into the mixing vessels. Solids charging is done manually through the manhole at the top of the vessel.

Mixing/Dissolution

Active pharmaceuticals and solvents are agitated until a uniform solution has been achieved. Heating/cooling may be applied to the mixing vessel to aid the mixing/dissolution process.

Extrusion/Pumping

The mixture of the mixing vessel is transferred via a pump or an extruder if the mixture is very viscous to the casting/laminating machine.

Casting and Lamination

The solution obtained from the mixing process is metered onto a processing film and passed through a series of ovens for solvent evaporation. The resulting drug adhesive film is then laminated to a backing film.

Corona Treatment

The laminate obtained from the casting process is corona-treated.

Split Release Liner Lamination

The processing film is then replaced with a pre-slit protective film, and print is applied to the backing.

Die Cutting

Die cutting is the process of cutting out the patches from the laminate. This process is designed in order to eliminate the amount of waste laminate. The die cutting process generates plastic solid waste in the form of a solid ladder waste.

Pouching & Packaging

The sealing of a single system in its primary protective pouch or sachet. Die cut systems are subjected to visual inspection for manufacturing defects before being placed between two layers of multi-laminate pouch stock. The pouch stock is heat sealed on four sides, then slit and cut to form individual pouched systems. Packaging waste will generally be a result of waste paper, cardboard and plastic.

Cleaning

The mixing vessel, pump, extruder and downstream equipment need to be cleaned at regular frequencies. The cleaning process is carried out manually, by spraying small amounts of alcohol onto the contaminated process surfaces and scrubbing the equipment through the manhole. The mixing vessels and the pharmacy dispensing isolator will be cleaned using solvents.

D.1.1.4 Operating Procedures

The ALZA production facility has been designed as a secondary manufacturing facility for transdermal products. ALZA is approved by the US Food and Drug Administration (FDA) for certain products. In addition, ALZA conforms to current Good Manufacturing Practices (cGMP) and will operate under the Irish Medicines Board (IMB) directives for cGMP manufacture in Ireland. All manufacturing is carried out in strict compliance with statutory requirements. The requirements of all regulatory agencies are strictly enforced.

ALZA operates under a site based environmental policy in support of the Johnson & Johnson Corporation Environmental Policy Statement & J&J Worldwide Environmental Sustainability Practices. The General Manager of the facility has issued the statement under his signature. The policy is displayed in the reception area of ALZA and all employees at the facility are made aware of the content of the Environmental Policy. The policy is available for public viewing upon request and is found on a Public Information Folder. The policy covers all activities at the facility and states in broad terms the commitment to the protection of the environment. Specifically, the policy includes a commitment to continual improvement and prevention of pollution, in addition to a commitment to comply with relevant environmental legislation, regulations and other requirements. The policy is reviewed annually as part of the Environmental Management Review process.

To satisfy regulatory requirements, but also to reflect the commitments in the ALZA environmental policy statement, specific site operations and activities at the Cashel facility are controlled. Where such operations and activities are complex and/or potential environmental impacts are significant, documented procedures have been developed. These procedures are established and maintained as their absence could lead to IPPC licence non-compliances and/or deviations from the environmental policy statement and environmental objectives and targets. The site operational controls which assist in

the management of site environmental aspects, ensure IPPC licence compliance and assist in the attainment of the goals specified in the site environmental policy statement and site developed environmental objectives are detailed in Section F of this application.

D.1.1.5 Emissions and Abatement System

The emissions associated with Process 1 (ALZA) are covered in detailed in Section E of this application however for the purpose of this section the stage of the process in which emissions are possible is detailed together with the abatement system in place.

Air Emissions & Abatement

VOC's are generated in the casting and the Active Pharmaceutical Ingredient (API) waste concentration process. Both VOC laden air streams are routed to the Catalytic Thermal Oxidiser, which reduces thermal heat loads and provides effective VOC destructive efficiencies.

There are three licensed main air emission points onsite associated with the current operations, Refer to Figure 8: Air Emission Points. The primary air emission point, licence reference: A2-1, is the emission to atmosphere from the site thermal oxidizer. The other main emission points are the emission points from the boilers (reference points A1-1, A1-2). There are a number of licensed minor emission points to atmosphere from the ALZA site. These comprise of air handling units, laboratory fume hood, generator flue, specific extract, vacuum headers and drum store booth. There is a continuous emissions monitoring system (CEMS) for VOC monitoring from the thermal oxidizer emission point, which is linked to the Building Management System (BMS). There is an operating criterion that if the VOC level goes above a certain threshold the BMS alarms and the casting line is shutdown in response (not automatic). The air-handling units are also linked to the site BMS and are subject to weekly checks by maintenance. A Standard Operating Procedure is in place which details how air emissions are managed, controlled and monitored.

Wastewater Emissions

Activities generating wastewater in the Quality Control (QC) laboratory include environmental cleaning, the dishwasher and general washing of glassware plus discharges from the sinks in the laboratory. There is no wastewater generated from the process. This process wastewater is directed to the warehouse sump, located adjacent to the warehouse and the laboratory sump located to the rear of the facility and then subsequently piped to the wastewater tank. It is routinely discharged to sewer, in accordance with current IPPC licence specified monitoring requirements, and directed to the local authority wastewater treatment plant.

The foul sewer system collects wastewater from the bathrooms, canteen, janitor store in production, condensate from boilers, compressors and air handling units and discharges directly to the local authority wastewater treatment plant. Process wastewater is monitored and controlled in accordance with a Standard Operating Procedure.

Noise Emissions & Control

The primary noise emissions on-site arise from the chiller units that are located on the roof of the facility, the boilers in the utility building and a minor source is from traffic to and from the site. During installation of the site equipment such as air handling units and fans on the roof, noise attenuation measures were taken into consideration. The boilers were located inside the facility, to minimize the impact of any noise emissions on the environment. Deliveries to and from the site generally take place during daytime hours. A Standard Operating Procedure is in place to ensure noise is monitored and controlled.

Hazardous and Non Hazardous Waste Generation

The arrangements for the disposal of hazardous and non hazardous waste together with a description of the nature and source of the waste are detailed in Section H Materials Handling. All hazardous and non hazardous waste will be collected on site and shipped using an approved and vetted waste management company, which are audited by ALZA and J&J corporate environmental personnel on a bi-annual basis for adherence to European Legislation and corporate requirements. ALZA employ Indaver to classify any waste stream before it is moved off site. Therefore ALZA ensure all waste is appropriately categorised and is accompanied with correct TFS form if applicable. Outlined below is a summary of the areas where waste is generated.

Laboratory

- Class 3: Flammable Liquid
- Class 4.1: Flammable Solids
- Class 6.1: Toxic Substances
- Lab Smalls
- Non Hazardous Waste; cardboard, paper, printer cartridges, glass winchester bottles

Production

- Class 3: Flammable Liquid
- Class 4.1: Flammable Solids
- Class 6.1: Toxic Substances
- Non Hazardous Waste; plastic, cardboard, paper, uncontaminated PPE, shrink wrapping

Warehouse

- Non Hazardous Waste; cardboard, general waste, wooden pallets, empty drums, uncontaminated pouch stock, confidential paper

Maintenance

- Class 2.1 Flammable Gases
- Class 3: Flammable Liquid
- Class 4.1: Flammable Solids
- Class 6.1: Toxic Substances
- Class 8: Corrosive Substances
- Class 9: Miscellaneous Dangerous Substances

- Non Hazardous: waste metal and wire cable, general waste, paper, cardboard, oils, fats and grease, glass.

Note: Classification of waste from Indaver Waste Classification Report and is based on UN Committee of experts on the Transport of Dangerous in the UN Orange Book.

D.1.1.6 Laboratory Facilities

The laboratory monitors quality and consistency of all process materials including raw materials, process intermediates and products to ensure conformance with the relevant specifications. Normal routine analyses include GC analysis, HPLC analysis, density measurement and acid/base titration. While the majority of testing falls into one or other of the above categories, the list is not exhaustive. Certain testing requiring specialised equipment or methods is completed using the services of contract laboratories located in Ireland and Europe. The scale of the operation is small so that the emissions are negligible. Process samples are retained after use and returned either to production or disposed of as hazardous wastes using approved agents.

D.1.2 Proposed Cordis Drug Eluting Stent Process

D.1.2.1 Introduction

The proposed Cordis manufacturing facility will manufacture drug-eluting stents which combine a coronary stent platform with a unique drug delivery system that works to keep arteries open after a cardiac procedure while releasing small amounts of medication to prevent scar tissue from forming inside the vessel. The stents offer an effective, safe treatment alternative to open-heart surgery for millions of people every year.

D.1.2.2 Plant and Equipment

Equipment required;

- Polymer Coating suite containing PDS coating machine
- Annealing oven (post-polymer coating)
- Work station for stent placement on fixture
- Stent coating machine
- Vacuum packaging suite
- Crimp and pack line

The location of equipment is shown on Figure 9: Process 2 (Cordis) Process and Equipment Arrangement.

The utilities for the Cordis facility will be housed with the CUB (central utilities building) at the rear of the site. The main utilities equipment items are as follows;

- Two 4.4MW boilers (1 duty, 1 standby)
- Two air compressors
- Three chillers
- Two emergency generators

In addition there will also be a number of air handling units positioned on the plant floor of the Commercial Manufacturing Building.

The existing ALZA site infrastructure already has capacity to provide warehouse space, drum store, canteen and car parking for the Cordis project, the location of which is shown on Figure 2 Site Plan.

D.1.2.3 Process

A stent is a wire metal mesh tube used to prop open a clogged artery, thereby improving blood flow to the heart muscle. Stents can be coated with pharmaceuticals which are slowly released into the bloodstream and help prevent the artery from reclosing. The main activities at the proposed facility will consist of coating, and packaging of stents. The bare metal stents will be supplied to the facility from a third-party manufacturer.

The commercial manufacturing area of the facility will be comprised of two separate production area. Initially only one of these areas will be fitted out for stent production. The remaining area will lie fallow and will be available for future expansion. In the production area the stents will be cleaned, pre-treated, coated with a solution mix containing the API, and vacuum-dried. Formulation of the stent coatings will also be carried out in the production area. The stents will be transferred to container vehicles in the dispatch area at the rear of the site for removal off-site. This area will provide temporary storage space for the final product. Each of the Unit Operations is briefly described below. Refer to Figure 9: Process 2 (Cordis): Process and Equipment Arrangement and Figures 10-12 for Flow Diagrams.

Stent Preparation

- Raw materials, in laboratory scale flask containers, are dispensed and mixed according to menu in contained areas including glovebox and fume cupboards.
- Base stents are cleaned and washed in preparation for coating.

Coating Preparation

- API is weighed and dispensed within an isolator.
- The API is dissolved in mixed solvents.

All waste liquid generated in the solution preparation room is collected for disposal in accordance with existing site procedures.

Stent Coating & Drying

After being received, washed and pre-treated, the bare stents are coated to form a conformal, bio-compatible and biostable coating. The prepared stent will be coated with the API in a proprietary coating machine. The stent will then be dried. All coating solutions will be prepared in a coating preparation room.

- Coating solutions and solvent wash are delivered and applied.
- Stents are dried.
- Stents are then transferred to the weight/inspect room for testing/ weighing/ inspection prior to delivery to the crimp and pack line.

Crimp and Pack

The crimp and pack operation describes attachment of the stent to the delivery device, the catheter.

An outline description follows:

- The stent is placed over the catheter.
- The stent is crimped to the catheter.
- The catheters are then inserted onto trays, heat sealed and labelled.
- The finished product containers boxes are stored in cold storage before shipping offsite.

D.1.2.4 Operating Procedures

The operating procedures for the Cordis facility will be carried out in line with the ALZA operating procedures as outlined in Section D.1.1.4. The environmental policy will be updated to reflect the entire site. Existing documented procedures will be updated to include Cordis operations. Proposed site controls are detailed in Section F of this application.

D.1.2.5 Emissions and Abatement

The emissions associated with this process are covered in detailed in Section E of this application however for the purpose of this section the stage of the process in which emissions are possible is detailed together with the abatement system in place.

Air Emissions and Abatement

Gaseous waste streams, potentially containing hazardous solvent vapour, are generated by the following equipment;

- Annealing, curing and vacuum drying ovens
- Spray coating machines
- Polymer coating machines
- Fume cupboards
- Formulation isolator

It is proposed to install carbon adsorption in order to abatement air emissions. This method of waste treatment involves routing the waste gas stream through a vessel filled with activated carbon. The carbon has a sponge like structure with a high surface area relative to its volume in order to maximise the area for mass transfer to take place. The organic chemical species are chemically bonded to active sites on the surface of the carbon thereby remaining in the vessel while the cleaned gases pass through.

Eventually the carbon material will become saturated with VOC's and will need to be regenerated or replaced. This period of time will be determined by sampling. It is proposed to install two alarm limits on the analyser;

1. High Alarm: Set at 50% or some other percentage of the TA Luft release limit. The alarm will signal (via either the BMS or EMS) that the activated carbon is approaching saturation and that it should be replaced at the next opportunity. (This is a procedural safeguard).
2. High-high alarm: Set at the TA Luft release limit. A hard-wired interlock from the TOC analyzer will cause the SPRAY COATER machine to shutdown in the event that the TA Luft release limit has been reached. An interlock panel will send an alarm signal to a pair of volt-free contacts in the SPRAY COATER Control Panel. As an option the alarm setting could be fixed at 90% of the TA Luft release limit so that the current batch of stems (max. 1 hour process time) can be completed.

Due to the sensitivities of the spray coating process it is proposed that each spray coater machine have a dedicated Carbon Adsorption Unit for VOC Abatement. This ensures that each spray coater operates independently of the others and pressures within the spray zone can be more easily controlled.

Wastewater Emissions

At present process wastewater is primarily generated from environmental cleaning, quality control operations, from the glassware washing equipment, and general washing and cleaning activities onsite. The wastewater is collected via two onsite sumps (warehouse and QC laboratory) and is then pumped to the site wastewater storage tank. As part of the proposed development pH adjustment is to be introduced to the wastewater storage tank which is discussed in more detail in Section E Emissions.

Noise Emissions and Control

The principal noise sources associated with the Cordis operation include the following;

- Boiler in the Central Utilities Building
- Two air compressors in the Central Utilities Building
- Three air-cooled chillers situated externally to the south of the Central Utilities Building

A noise modelling assessment was carried out as part of the planning application to South Tipperary County Council which indicated that the proposed new equipment for the site facility, if unattenuated, would have a significant impact on noise levels along the eastern site boundary, especially at night. In order to mitigate this impact a number of attenuation measures have been incorporated into the design, namely: individual acoustic enclosures around the chiller units, general acoustic around the chiller compound and acoustic louvers on the east-facing facade of the central utilities building. The noise model predicted that with the proposed attenuation measures incorporated the new equipment items will not cause a significant increase in noise levels at the site boundaries and nearest noise sensitive locations, either during the day or at night.

Waste Generation

Due to potential API contamination all waste is considered hazardous and will be disposed of accordingly. All waste liquid that may be generated in the coating suites will be collected for disposal as hazardous waste through the existing site waste controls. Likewise the local ventilation is considered contaminated and precautions will be established in SOP's for HEPA filter change and cleaning. Bag-in/bag-out filters will also be utilized.

The current site waste management programme will accommodate the new hazardous and non-hazardous waste streams arising, and the management system will be modified to include appropriate classification by external technical experts, necessary labelling, handling and storage arrangements onsite and inclusion in the waste monitoring system.

Outlined below is a summary of the areas where waste is generated.

Access Area

- Non Hazardous Waste; plastic, PPE, wipes

Polymer Coating

- Class 3: Flammable Liquid
- Class 4.1: Flammable Solids
- Class 8: Corrosive Substances
- Non Hazardous Waste; packaging, containers

Prep Room

- Non Hazardous Waste; glass and plastic containers, uncontaminated PPE, labels
- Class 4.1: Flammable Solids
- Class 3: Flammable Liquid

Oven Room

- Class 4.1: Flammable Solids

Weigh and Inspect

- Class 4.1: Flammable Solids
- Non Hazardous Waste; labels, confidential paper

Crimp and Pack

- Non Hazardous Waste; labels, confidential paper, plastic packaging, foil pouches, reject stents and catheters, printer ribbon
- Class 4.1: Flammable Solids

Clean Room

- Class 3: Flammable Liquid
- Class 4.1: Flammable Solids

Analytical Lab

- Class 3: Flammable Liquid
- Class 4.1: Flammable Solids
- Non Hazardous Waste; plastic packaging, uncontaminated PPE, wipes

D.1.2.6 Laboratory Facilities

Equipment and facilities;

- Two fume hoods with a combined air extraction rate of approximately 0.75 m³/s
- Two high performance liquid chromatographs
- One gas chromatograph
- One sink unit for general hygiene purposes
- Chemical storage units
- One UV Vis Spectrophotometer
- One Infra-red Spectrophotometer
- One Karl Fisher titrator
- One Oven
- One Refrigerator
- One Freezer

The laboratory will perform analytical testing to support cleaning validation and raw material/product testing. This will entail;

- High Performance Liquid Chromatography (HPLC)
- Infra-red spectroscopy (FTIR)
- Gas chromatography
- Moisture analysis using Karl Fischer Titration

D.1.3 Proposed Pharmaceutical Medical Device Combination Process

D.1.3.1 Introduction

Combination pharmaceutical and medical device products capitalize on the full therapeutic potential of drug elution through the development of a medical device specifically designed for drug delivery. This involves applying a drug coating to a bare medical device or by using reservoirs incorporated into the device design into which drug-polymer compositions can be loaded. Through proprietary design the control of the rate and direction of drug delivery can be enhanced, a wider range of drug therapies can be enabled and the effectiveness and range of clinical application of medical devices can potentially be increased.

D.1.3.2 Plant and Equipment

The production facility will consist of the following;

- ISO Class 8 clean room
- Packaging room for pre-sterile assembly
- Packaging room for final labelling after sterilization
- Raw materials room
- Analytical laboratory (to be facilitated within ALZA/Cordis)
- Mechanical laboratory (to be facilitated within ALZA/Cordis)
- Warehouse (to be facilitated within ALZA/Cordis)
- Office space (to be facilitated within ALZA/Cordis)

The main production equipment will consist of custom built drug application machines for loading polymer and drug solution onto stents or devices.

The location of the above is illustrated on Figure 13: Process 3: Process and Equipment Arrangement.

D.1.3.3 Process Description

The process will be carried out by the following unit operations;

- Solution Preparation / Formulation
- Device Preparation
- Coating / Filling Process
- Fixing Device to Delivery System
- Final Packaging

Solution Preparation / Drug Formulation

This is the process of dissolution of drug and or polymer in solvent solutions, using precise dispensing of solid drug into reactors under a controlled atmosphere. The coating solution is then stored in containers suitable for the coating or filling machines. The process utilizes two formulations: one formulation consists only of the polymer and the processing air, while the other consists of the polymer, processing air and drug. Both formulations are used in the filling process. The formulation without the drug is used to make the base and cap deposits while the second formulation is used to make the drug deposits. Refer to Figure 14: Process 3: Drug Formulation.

Device Preparation

The medical devices to be coated or filled are prepared by being mounted on mandrels custom designed for the drug application stage, and cleaned prior to application.

Coating / Filling Process

Drug is applied either to the surface of the medical device or filled into reservoirs in the device using multiple pass application. A base coat will be initially applied, followed by multiple passes of active ingredient followed by a top coat. Base and top coats may or may not have active ingredient. The completed device is then dried in an oven. Refer to Figure 15: Process 3: Coating / Filling.

Fixing Device to Delivery System

The medical device is then assembled onto its delivery system, and the assembly tested to prove integrity. The assembled device is then packaged for sterilisation. Refer to Figure 16: Process 3: Fixing Device to Delivery System.

Final Packaging

Post sterilization the device is repackaged into final packaging and combined with instructions, device information and statutory information.

D.1.3.4 Operating Procedures

The operating procedures for this process will be carried out in line with the ALZA operating procedures as outlined in Section D.1.1.4.

D.1.3.5 Emissions and Abatement

All drug formulations are produced in filtered fume hoods, the volume of solvent emitted is so small that the emissions are negligible.

The current site waste management programme will accommodate the new hazardous and non-hazardous waste streams arising, and the management system will be modified to include appropriate classification by external technical experts, necessary labelling, handling and storage arrangements onsite and inclusion in the waste monitoring system. Outlined below is a summary of the waste to be generated.

- Class 3: Flammable Liquid
- Class 8: Corrosive Substance
- Lab Smalls

D.1.3.6 Laboratory Facilities

The laboratory facilities for this process will be accommodated within the ALZA and Cordis facilities. The laboratory will monitor the quality and consistency of all production process solutions using HPLC analysis.

D.1.4 Development Laboratory for Processes 2 and 3

The development laboratory for Process 2 (Drug Eluting Stent Process) and Process 3 (Pharmaceutical / medical device combination process) will have identical plant and equipment, process description, operating procedures, emissions and abatement and laboratory facilities as those described in Sections D.1.2 and D.1.3, although on a smaller scale. Refer to Figure 17 Process 4: Development Laboratory: Process and Equipment Arrangement.

D.2 Development and Operational History of the Site

The site was purchased by ALZA in 2001. Prior to this, the site was an IDA owned unoccupied site, with an advance building already constructed. ALZA constructed a modern manufacturing facility (comprising a production area, warehousing and loading bay, administration areas, canteen and changing room facility) and used the original IDA advance building as a site quality control facility, central utilities and site maintenance areas. Construction activities commenced onsite in November 2001. Commercial manufacture commenced onsite in March 2004.

In November 2005 planning was granted by South Tipperary County Council for an extension to the car parking facilities on site and the construction of a smoking shelter. In August 2006 ALZA informed the Agency of a proposed new drum store building to be located to the rear of the warehouse. The purpose of the drum storage building was to replace the existing drum storage "chemstore type" units that were in use and to eliminate/reduce the storage of materials at the rear of the warehouse. The function of the drum store is to house raw materials and wastes awaiting shipment offsite. The proposal was approved by the Agency in September 2006, construction subsequently commenced in October 2006 and was completed by the end of March 2007.

In October 2006 ALZA informed the Agency of the proposed establishment of a development laboratory on site. As part of the overall site development strategy it was proposed to fit-out a fallow area of the existing North Building as a development laboratory for the future Cordis manufacturing plant. The laboratory fit-out was entirely within the existing building envelope. Approval was given for the proposed development laboratory on a trial basis in January 2007.

In February 2007 ALZA informed the Agency of a minor fit-out to an analytical/quality laboratory adjacent to the above mentioned development laboratory in order to facilitate the dedicated analysis of products from the development lab. Approval was given for the analytical laboratory in March 2007.

A planning application was lodged with South Tipperary County Council and subsequently granted in March 2007 for the construction of the Cordis manufacturing facility of 21,365m² consisting of a 3 storey administration building, a 2 storey manufacturing building, a 2 storey final packing and dispatch building and a 2 storey utility building and substation, including a new services entrance from the Old Road adjoining the eastern boundary of the site, 204 new car parking spaces and a new entrance lobby to be shared with the existing building and all associated ancillary site development works. Construction began in June 2007.

A planning application was lodged with South Tipperary County Council and subsequently granted in April 2007 to retain pre-fabricated offices comprising of an area of 557m² in total over two storeys including associated site works.

A planning application was lodged with South Tipperary County Council and subsequently granted in September 2007 for an amendment to the existing planning permission ref 06/2081, for the construction of a new manufacturing facility of 7682m². The proposed facility consists of a 2 storey manufacturing building with the plant room at the first floor level, a 2 storey final packaging and dispatch building and a 2 storey central utilities building and separate single storey electrical sub-station building together with all associated ancillary site development works, the existing vehicular and service entrances of Cahir Road will be retained.

Planning Permission was lodged with South Tipperary County Council in October 2007 to demolish an existing single storey dining area of 85m² and to construct a new dining area of 557m² complete with 133m² of 1st floor office space overhead. The proposed development is located within an existing enclosed courtyard on the ALZA site.

Planning permission was lodged in November 2007 for the establishment of a QC laboratory for the Cordis process as shown on Figure 2 Site Layout.