M E M O R A N D U M

DATE: 11 January 1999

TO: Each Board Member

FROM: Annette Prendergast

RE: Summary report on review of IPC Licence Register No. 134 (Irotec) New Reg. No. 461.

Application Details	
Name and address of activity	Irotec Laboratories Ltd., Wallingstown, Little Island Co. Cork.
Class of activity:	5.6 Manufacture of pharmaceutical products and their intermediates.
Request from activity requesting review of IPC licence	26 June 1998
Notices under section 85 (i)(b) issued:	17 July 1998
EIS Received	23 July 1998
Information under article 16 (4) received:	23 July 1998
Article 17(2) Request issued	19 August 1998
Article 14(1) Request Issued	19 August 1998
Information Received under Article 14	12 October 1998
Information received under article 17	13 October 1998
EIS in Compliance	12 October 1998
Article 17(3) Clarification request issued	05 November 1998
Information Received	23 November 1998
Section 97 notice issued:	05 August 1998
Information under section 97 received:	09 September 1998, 12 September 1998, 04 November 1998
Site visit	06 January 1999

Company

Irotec Laboratories Ltd. is a manufacturer of fine chemical, pharmaceutical substances and their intermediates for generic and contract manufacturing markets. It is also a Research and Development facility, developing a number of in-house products. Presently there is a product range of 29 products. The product list includes a wide range of active materials which are used in the formulation of final dose forms at secondary pharmaceutical facilities off-site. The therapeutic use of Irotec's products include: anti-rheumatic, anti inflammatory, anti coagulant, anti-depressant. The total reactor capacity in the production plant is 18.83 m^3.

The normal working hours are 24 hours per day, 5 days per week. The shut down period is two weeks in summer and one week at Christmas. There are 77 employees.
The new production building will be involved in the manufacture of an identical range of products to those which are currently being manufactured at the existing facility. A total of six reactors with a total capacity of 15.7 m^3, two centrifuges, two dryers and a milling unit will be provided in the new production building. A range of additional facilities will be provided to support production building two which include; a new utilities plant, a new drum store, fire water retention pond, an additional scrubber plant for air emissions, a thermal oxidiser to treat combined emissions from both production plants and upgraded waste water treatment plant facilities.

Reason For IPC Licence Review

It is proposed to construct a new production building to increase production capacity. In support of this expansion of production capacity, it is proposed to replace the existing gas fired boiler with a boiler, that has double the capacity of the existing boiler. There will be a new pharmaceutical dust emission point associated with the new milling unit. A new scrubber plant will be installed to treat air emissions from the new production plant and a new thermal oxidiser will be installed to treat combined emissions from both production plants. Emissions from the thermal oxidiser will discharge to the existing main air emission point A1/2. Effluent discharge volume will increase from 120 m^3/day to 255 m^3/day. Maximum loading for BOD, COD, ammonia and suspended solids discharge will double in line with increased production capacity.

Summary of Main Changes from existing Licence to proposed review Licence .

- Condition 1 updated.
- Condition 3.2.2 slightly modified.
- Condition 3.3.2 (iii) slightly modified.
- Condition 5.5 is a new condition.
- In emissions to sewer Sanitary Authority conditions have been included. Condition 6.9 and 6.14 are new conditions.
- Condition 9.2 on firewater retention has been updated as a proposal to construct a firewater retention pond has been agreed with the Agency.
- Condition 9.3.4 is updated on groundwater quality.
- The updated bund condition 9.4 has been included.
- Condition 10.2 on fugitive emissions modified.
- Condition 12.1 on emergency response has been updated.
- The Residuals Management condition has been included because the company have included an outline plan in the review application.

Groundwater underneath the site has been contaminated but indications to date suggest off-site sources. Following the isolation and elimination of the off-site sources of ground water contamination the company are then required to determine if there are any on-site sources of groundwater contamination. If on-site sources are identified a groundwater remediation plan will be required.

- Sanitary Authority charges have been included.
- In relation to emissions from the proposed thermal oxidiser, the emission point has not changed. However as a result of the Thermal Oxidiser it is necessary to set limits for dioxins, nitrogen oxides, sulphur dioxide and carbon monoxide. Additional monitoring requirements for CO, NO_x dioxins, and SO_2 are included . The company propose in the review application to install a continuous TOC monitor on the thermal oxidiser and this has been included in the licence.
- 1 new pharmaceutical dust emission point has been included.
- The abatement treatment section for the Thermal oxidiser has been included.
- In relation to emissions to sewer a limit for sulphate at the request of the Sanitary Authority has been included. The volume limit has been increased to take into account increased production. A limit value for phosphorus has been included. The loading limit for BOD, COD, suspended solids and ammonia has been increased. The time limits for achieving reduced ammonia and FOG, limits has been increased to allow for additional assessment of the impact of PB2 on the current WWTP. An additional 15 months to achieve reduced ammonia limits has been included in the PD.
- The waste analysis requirements have been expanded to ensure complete records for all hazardous wastes are maintained by the company.

Air:

The principal changes from the original IPC application with regard to air are:-

- The upgrade in size of the existing natural gas boiler.
- The installation of 1 additional pharmaceutical dust emission point A 2/17. This dust emission point is at the new plant BATNEEC limit value for pharmaceutical dust.
- The installation of an acid and basic scrubber system for production building two and a gas fired thermal oxidiser to treat combined emissions from production buildings one and two, and associated emission limits.

<u>Air abatement system</u>

Currently all significant emissions from production building 1(PB1) are collected into a vent header and sent to either the acid or caustic scrubbers for treatment. There is a third vent header system with scrubbers which is used infrequently to treat pilot plant emissions and assist in characterisation of emissions from new processes. The existing scrubber systems are ineffective in removing water-immiscible solvents (e.g. toluene, ethyl acetate) and

hydrocarbon gases (methane isobutylene). It is proposed to install a regenerative catalytic thermal oxidiser to treat scrubbed emissions from the acid and basic vent header systems from PB1 and to ensure compliance with new plant BATNEEC emission limit values. Emissions will discharge to the existing emission point A 1/2. The third vent header system will bypass the thermal oxidiser and discharge to A1/2 also. This scrubbing system was installed for potential future use where small quantities of other emission types (e.g. hydrocarbon gases which need to be isolated from the acidic and basic vapour emissions) may be scrubbed in a specialist scrubber system. There will be continuous monitoring of TOC from Vent A 1/2 to ensure compliance with licence limits. The PD requires the licensee to notify the Agency of any by pass of the thermal oxidiser. The process emissions from production building 2 (PB2) will initially be scrubbed in two aqueous absorption column systems, operated in parallel with the existing scrubbing systems from PB1. The emissions from both scrubbing systems, including, chlorinated emissions will then be discharged to the regenerative catalytic thermal oxidiser. Emissions from the thermal oxidiser will then be discharged through the existing main emission point A 1/2. New plant BATNEEC limits will be achieved. There is an emergency vent located before the Thermal Oxidiser (A 3/32). This will be activated if there is a high LEL concentration of solvents in the vent header system. If the thermal oxidiser shuts down due to problems, pre scrubbed emissions will by pass the thermal oxidiser and discharge through vent A 1/2 .

The decision to select the regenerative catalytic thermal oxidiser (RCTO) was made by the company in order to meet BATNEEC emission limit values.
Solvent recovery was not chosen because the wide range of solvent mixtures, small quantities and purification difficulties mean that recovery is not economically attractive and not feasible. Liquid/solid waste incinerator was considered but the systems are much more expensive and complex than systems designed for vapours only and also the small quantities of liquid waste generated at Irotec would not justify liquid incineration with heat recovery. A regenerative heat exchanger allows heat efficiency of > 90%. A recuperative shell-and-tube exchanger would have about 70% efficiency under optimal conditions. Therefore a RCTO is preferred at Irotec as the waste gas loading is relatively low and may fluctuate. At low waste gas concentrations the RCTO can operate without a burner (autotherm). The plant will operate autotherm at waste gas concentrations between 0.7 and 1 g/m^3 depending on the nature of the VOC. Average loads at Irotec range from 1-2 g/m^3. An RCTO destroys VOC's at temperatures below 450^oC compared to non catalytic units which operate at temperatures of about 1000^oC. This reduction in temperature offers the following advantages; production of nitrogen oxides and carbon monoxide is negligible, VOC removal efficiency greater than 99%, fuel consumption is lower, start up time is shorter, flow rate through the unit can be varied, no waster water is produced and reliability is improved.
The supplier of the thermal oxidiser KEU has provided a written guarantee that the dioxin level of the emissions from the RCTO will not exceed a dioxin limit of 0.1 ng/m^3. A dioxin limit of 0.1 ng/m^3 has been included in the PD. The

total maximum licensed emission for dioxins from the plant is less than 5mg/ annum. This is much lower that any of the licensed hazardous waste incinerators. KEU has performed tests on dioxin formation in their catalytic thermal oxidisers. Tests confirm the capability of the catalytic thermal oxidiser to operate well below dioxin emission limit values. KEU also has years of experience with catalytic oxidation involving various chlorinated solvents from chemical plants, operating well below the dioxin emission limit value. The thermal oxidiser is equipped with a chromium-based catalyst. KEU give a *process guarantee* that the thermal oxidiser emissions will not exceed the dioxin limit of 0.1 ng/Nm^3 if the total inlet concentration of chlorinated hydrocarbons and HCl is less than 60 mg/Nm^3 over a 30 minute average. This has been included as condition 5.5 of the PD. The PD also requires continuous monitoring of HCl and quarterly monitoring for dioxins. (The chromium-based catalyst is able to handle chlorinated organics or HCl concentrations up to about 10g/Nm^3 without generating dioxin concentrations exceeding 0.1 ng/Nm^3). The material of construction of the thermal oxidiser is carbon steel, which limits the chlorinated/HCl inlet concentration to 60 mg/Nm^3.

<u>Impact of air emissions</u>

Normal operations

The US EPA Industrial Source Complex Short model was used to predict maximum 1 hour ground level concentrations of individual pollutants outside the boundary from the thermal oxidiser and boiler. The maximum predicted hourly or daily ground level concentrations of the individual compounds based on maximum emission rates for existing and proposed new sources were less that the relevant Air Quality Standard (for SO_2 and NO_2) or guideline such as the WHO and the OEL/40 for individual solvents. It is therefore predicted that the maximum emission rates for individual compounds for the main existing and proposed new sources will not have any adverse effects on the environment.

By-pass of thermal oxidisers

Modelling conducted on pre-scrubbed emissions from PB1, which would be similar to emissions discharged from an emergency vent, predicted no significant impact.

Sewer:

The company sought revision of the following emission limit value from the original IPC application with regard to emissions to sewer :-

- An increase in effluent discharge volume from 120 m^3 / day to 255m^3/day to cater for a doubling of production capacity and the installation of a sludge dewatering press.
- An increase in BOD load from 100kg/day to 200 kg/day due to a doubling of production capacity at the plant. Irotec state that they propose to reduce BOD concentration from 1670 mg/l to 1000mg/l by the end of 1999, by optimising WWTP performance. The company is currently achieving a BOD reduction of 78% and this is expected to be improved to 91% reduction by implementing planned modifications to the WWTP.
- An increase in COD load from 500 kg/day to 1000 kg/day to cater for a doubling of production capacity at the plant. Irotec state that they propose

to reduce COD concentration from 8500 mg/l to 5000 mg/l by the end of 1999, by optimising WWTP performance.

- An increase in suspended solids concentration from 100 mg/l to 200 mg/l and an increase in loading from 12kg/day to 30 kg/day. Recent results indicate that suspended solids levels in final effluent are generally below 100 mg/l however there are periodic exceedances. A limit value of 200 mg/l is achievable.
- An increase in the timeframe to achieve reduced ammonia concentrations.

The company have carried out several improvements to the WWTP in recent months to improve effluent quality and consistently meet licence limits. A sludge belt press was installed in May and this has reduced MLSS from 8,000-10,000 mg/l to 4,000-5,000mg/l. This has enhanced plant performance. A new surfacewater drainage system has been constructed in conjunction with a firewater retention pond. In the next few months all non process water will be diverted away from the WWTP. This will reduce greatly the volume of effluent in the WWTP. Irotec had problems in the past with periodic flooding of the WWTP during periods of heavy rainfall. Each waste stream from each process since the summer has been characterised for pH, COD, cyanide, ammonia and volume. Waste streams high in ammonia are held in a holding tank and fed slowly to the WWTP. Streams with very high ammonia concentrations are not discharged to the WWTP, but are disposed of off-site. A pH neutralisation system will be installed on the balance tank within a few weeks. Irotec propose to monitor the performance of the WWTP following the completion of the above works and also monitor the impact of additional effluent from PB2. Irotec propose to submit a report at the end of 1999 outlining any further measures that may be required to ensure continued compliance with licence limits. This has been included as condition 6.14 of the PD.

The volume, BOD, COD and suspended solids limits requested by the company have been included in the PD. A limit for phosphorus of 10mg/l has been included in the PD. A time extension from 1999 to 2000 has been given in the PD to reduce Ammonia limits from 200 mg/l to 50 mg/l. The limit values for Ammonia, sulphate, pH, and flow supplied by the Sanitary Authority have been included.

Impact of Effluent Emissions

The design organic load for the IDA outfall to Lough Mahon was 9000 kg/day. The spare assimilative capacity is 7000 kg/day. The current total BOD emission from the IDA outfall is in the order of 1000-2000 kg/day Irotec are licensed to discharge 200 kg/day. Modelling conducted on the impact of effluent emissions predict an increase in BOD levels of 0.05 mg/l at Blackrock and 0.03 mg/l at Lough Mahon. Background BOD levels for Blackrock vary between 3-5 mg/l while levels at Marino point are in the region of 3 mg/l.

The results of modelling predict that the maximum increase in background COD levels as a result of the licensed discharge of 1000kg/day will be 0.26 mg/l at Blackrock and 0.13 mg/l at Lough Mahon.

In relation to suspended solids, the vast bulk of suspended solids in the final effluent is likely to consist of bacterial biomass. Periodic analysis indicates that 50-75% of the suspended solids consist of organic matter. The discharge of suspended solids will be readily biodegradable.

Irotec are licensed in the PD to discharge 40kg/day ammonia until 2000 and from July 01 2000 Irotec are licensed to discharge 13 kg/day and a concentration limit of 50 mg/l. Ammonia inputs from industrial and domestic sources to Cork harbour have been estimated at 1619 kg/day. The effect of a discharge of 40kg/day of ammonia in the harbour were modelled. The results indicated that the maximum level encountered after 20 days would be 0.013mg/l at Blackrock and 0.007 mg/l at Lough Mahon. Ammonia-N levels tend to fall rapidly towards the mouth of the harbour where concentrations of 0.02-0.04 mg/l were reported by Cork Main Drainage Report in September 1991.[2] The deterioration in water quality in the harbour area is clearly attributable to discharges from Cork city's sewage system.[1] The proposed new sewage treatment works for Cork city should improve the overall water quality of the harbour area. (please refer to the Board Memo on the original licence for a more detailed discussion on Ammonia).

The effects of a discharge of 14 kg/day phosphorus were modelled and it was predicted that the levels of total phosphorus would be increased to 0.002 at Lough Mahon. Irotec are licensed to discharge 10mg/l and 3kg/day phosphorus. The most recent results submitted by the company since improvements have been made to the WWTP show that phosphorus levels are below 10mg/l.

Surfacewater

Due to incidents of contamination of surfacewater by contaminated cooling water Irotec propose in 1999 to replace the existing once-through cooling water system for PB1 with an indirect system. This system will virtually eliminate the potential for contamination of surfacewater from monoethylene glycol coolant. The new system will also minimise water consumption. The cooling system proposed for PB 2 is a recirculating cooling tower system.

A proposal to construct a firewater retention pond has been agreed with the Agency. Condition 9.2.1 requires the automatic diversion of contaminated firewater to the firewater retention pond. A continuous TOC monitor has been installed on surfacewater discharge. Irotec are nearing completion on a project to collect and isolate run-off from areas which could be potentially contaminated. This is termed the process area surface water drainage system (PASD). This will be collected in a separate tank which will be tested and then either discharged to surfacewater or to the WWTP for treatment. Previously this water drained to the WWTP and caused problems with flooding the WWTP in the past.

Waste:

The handling of hazardous and non hazardous wastes is carried out in accordance with the existing IPC licence. The proposed expansion to the site

will not alter these practices, but the quantities of waste generated will increase in line with increased production. Its anticipated that waste produced per tonne of product will be less for the new production building than the existing building because of improved production efficiency and solvent recovery systems in the new production building.

Groundwater:

The most recent report submitted to the Agency on groundwater quality underneath the Irotec site makes the following conclusions; Analytical results indicate that the groundwater quality beneath the Irotec site has deteriorated since April 1998. There appears to be a continued upgradient source of contamination based on elevated temperature, electrical conductivity and groundwater mound upgradient of the site. A detailed site inspection in August 1998 indicated that no evidence of on-site sources of groundwater contamination have been identified. Until the upgradient source(s) of contamination have been isolated and removed, an assessment of potential on-site impacts on groundwater quality cannot be made. The Local Authority and IDA Ireland have been made aware of the groundwater contamination problem on Little Island and have conducted their own investigations. The company propose to continue the groundwater monitoring programme. Condition 9.3.4 requires that where on-site contamination is identified it is isolated and any remediation deemed necessary carried out.

Noise:

There has been no change in limits from the existing licence. A new noise source has been included. The company exceeded noise limits for two noise sources and a work programme was put in place to bring emissions into compliance. No complaints have been received in relation to noise from this activity.

Submissions:

There were no submissions received on this application.

Complaints:

There were no complaints received in relation to this activity.

Summary of enforcement.

Irotec have been in non-compliance for emissions to sewer for various parameters such as flow, suspended solids, BOD, ammonia and cyanide. There was one toxicity exceedance of 18.1 versus a limit of 10. The company propose, in the near future, to conduct further toxicity testing and simultaneously carry out a complete characterisation of the effluent stream to identify any potential sources of toxicity in the effluent. The requirement for toxicity testing is included in the PD. The flow exceedance was due to very heavy rainfall. A new drainage system has been constructed for the site as detailed above and this should eliminate flow exceedance problems. There were interference problems with the method of analysis for cyanide. The USEPA distillation method has been validated and is now used for measurement of cyanide on site. A third neutralisation tank has recently become operational for the treatment of cyanide waste prior to discharge to the

WWTP. Details of work carried out on the effluent treatment system, to improve the quality of effluent discharged, are included in the section on emissions to sewer above. The company had an ongoing work programme in place while they were in non-compliance, to bring them into compliance again. Its expected that the proposed works carried out on the WWTP and any further measures identified as part of the study on the performance of the existing WWTP should eliminate non compliances in emissions to sewer. There were thirteen bursting disc ruptures. The company are in the process of installing bursting disc detectors with alarms on all reactors. This will give immediate notification of bursting discs. All operators have received training on the correct procedure for addition of pressure to reactors to avoid bursting disc failures. The new production building will contain a dump tank to contain emissions from bursting discs. The licensee is required to address in the EMP the minimisation of potential emissions to air. There were five exceedances for emissions to air. These are due to the inability of the current scrubber system to treat water immiscible solvents. The installation of the proposed thermal oxidiser should ensure compliance with licence limits.

There was one incidence of contamination of ground. During replacement of the clay effluent pipe with a polypropylene pipe a leak occurred in a 4m section of the pipe. It was presumed that the pipe was empty at the time but there was a fall away from the outlet to the WWTP which resulted in some effluent being retained in the pipe. Its estimated that 3-4 m^3 of soil was contaminated. This was removed for treatment off site. Groundwater quality while impacted by upgradient off-site contamination dose not appear to be contaminated as a result of the leakage from the pipe. However there is a monitoring well down gradient of the spill area and this will continue to be monitored to determine if there is any impact.

There were three spills of the coolant monoethylene glycol to surfacewater. Irotec propose in 1999 to replace the existing once-through cooling water system for PB1 with an indirect system cooled by horizontal fan units. This system will virtually eliminate the potential for contamination of surfacewater from ethylene glycol coolant. As part of the fire water retention project surfacewater will be continuously monitored and contaminated surfacewater will be automatically diverted to the fire water retention pond.

Recommendations:

That the proposed determination as submitted be approved by the Board.

Signed

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Annette Prendergast

References;

1 ERU Cork Harbour water Quality, A Summary and Assessment of the Present Position, 1989.

2. Forbairt, Synthesis of Existing Information on the Environment of Cork Harbour, 1995.