
M E M O R A N D U M

DATE: 12 June 2000
TO: Each Board Member
FROM: Annette Prendergast
RE: Summary report on review of IPC Licence Register No. 89 (Iropham) New Reg. No. 540.

Application Details	
Name and address of activity	Iropharm Plc. Vale Road, Arklow, Co. Wicklow
Class of activity:	5.6 Manufacture of pharmaceutical or veterinary products and their intermediates.
Request from activity requesting review of IPC licence	10/01/2000
Notices under section 85 (i)(b) issued:	10/02/2000
EIS Received	24/02/2000
Information under article 16 (4) received:	24/02/2000, 14/03/2000
Article 17(2) Request issued	31/03/2000
Article 14(1) Request Issued	31/03/2000
Information Received under Article 14	18/04/2000
Information received under article 17	18/04/2000, 23/05/2000
EIS in Compliance	18/04/2000
Site visit	28 March 2000, 8 June 2000

Company

Iropharm Plc. a member company of Honeywell International manufactures bulk active pharmaceutical chemicals and intermediates using organic synthesis in batch processes. A typical synthesis involves an initial condensation reaction followed by a series of crystallisation purification steps. The existing facility produces products and intermediates in three production buildings and a pilot plant. The plant produces approximately 30 different products and they are a combination of generic powdered drugs, intermediate powdered active ingredients and intermediate pure bases. The products include antidepressants, anti histamine beta-blockers and a veterinary tranquilliser.

The normal working hours is 24 hours per day, 5 days per week. There are currently 83 employees.

A new Powder Handling Facility has been constructed on-site. This will accept raw materials from other buildings on site. The facility will process the

incoming materials in one or more of the following ways: drying, blending, sieving and milling.

Reason for IPC Licence Review

A new Powder Handling facility has been constructed on site and there will be two new pharmaceutical dust emission points associated with this building. The company proposes to install a thermal oxidiser to meet emission limit values for discharge to air. Effluent discharge volume will increase from 144m³/day to 225 m³/day to allow for increased production. The company has just installed a new WWTP to meet current and future licence limits and anticipates that in general existing load limits set from 2002 will be achieved even with the increased volume proposed.

The changes proposed under the licence review are not such that they may have significant negative effects on human beings or the environment (defined as substantial change in Article 10 (b) of the IPPC Directive 1996). Article 12 (2) of the IPPC Directive 1996 requires that a permit be issued in accordance with the Directive for substantial change.

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

- Condition 1 updated.
- Condition 3.2.2 slightly modified to include for a thermal oxidiser (TO).
- Condition 5.2 is a new condition.
- Condition 5.3 is a new condition
- Condition 5.9 is new and requires the conducting of a study on nitrogen oxide emissions to air from the site
- Condition 5.10 is new and controls the waste gas exit temperature from the proposed heat recovery boiler
- Condition 5.11 requires the monitoring of dioxins in the scrubber liquor after the thermal oxidiser
- Condition 5.12 requires that the plant is shut down for bypasses in excess of one hour
- Condition 5.13 controls the shut down of the thermal oxidiser
- Condition 5.14 requires a detailed programme on fugitive emissions
- Condition 6.3 requires maintenance details to be submitted for the WWTP
- Condition 6.6 requires that effluent streams are examined for biodegradability and only biodegradable streams are permitted to discharge to the WWTP
- Condition 6.9 requires a study on the adequacy of the effluent outfall

- Condition 7.2 prohibits the use of solvents or waste solvents as a fuel for the thermal oxidiser
- 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 9.3.3 requires that a hydrogeological survey is conducted
- Condition 10 is new and requires an energy audit to be conducted by the company and recommendations implemented through the EMP.
- Condition 13.1 on emergency response has been updated.
- In relation to emissions from the proposed thermal oxidiser, the existing emission point will change location. 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 SO₂ 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.
- 2 new pharmaceutical dust emission point has been included.
- The abatement treatment section for the Thermal oxidiser has been included.
- Modified limits have been included for the WWTP

Air:

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

- The installation of 2 additional pharmaceutical dust emission points 192 and 193. These dust emission points are at the new plant BATNEEC limit value for pharmaceutical dust.
- The installation of a distillate fired thermal oxidiser with heat recovery boiler and post combustion scrubber for SO₂ and HCl to treat combined emissions from the site.

Air abatement system

Currently all significant emissions from production buildings 1, 2 and 3, the solvent stripper and the pilot plant are combined into a polypropylene vent header which leads to a two stage caustic/water scrubbing system, this discharges through a single discharge point Vent 72. The existing scrubber system is not achieving the BATNEEC emission limit values, applied in the existing licence from June 1999. The company proposes to install a thermal oxidiser to treat scrubbed emissions from the scrubber and ensure compliance with new plant BATNEEC emission limit values. This proposal has been included in the PD. In relation to planning permission the company states that there has been some correspondence with the Planning Authority but planning permission will not be applied for until detailed design engineering is complete. At a meeting with the company on the 8/06/2000 they stated that they hoped to have detailed design complete by mid July. (Condition 1.3 of

the PD states that the licence is for the purpose of IPC licensing only) They anticipate that the TO should be operational by end of March 2001. The existing emission point will be decommissioned and emissions will discharge via the thermal oxidiser to vent 194.

The proposed design of the thermal oxidiser system is as follows: The thermal oxidiser system contains a reaction chamber designed to provide a residence time of at least 2 seconds at a temperature of 1,100 °C under oxidising conditions. Flue gas leaving the reaction chamber enters a steam raising boiler where the flue gas is cooled to 300 °C. The boiler is of single pass fire tube design and will produce a maximum of 1700 kg/hr of steam at 21 bar. Flue gas leaving the boiler enters a hastalloy quench where fresh and re-circulated water is sprayed into the flue gas to cool the gas to the adiabatic saturation temperature. The cooled gas then enters a packed tower scrubber where HCl and SO₂ are removed from the gas prior to discharge to atmosphere. Emission limit values for the thermal oxidiser although not a hazardous waste incinerator have been set in accordance with the Agency's BATNEEC note on hazardous waste incineration. The PD requires continuous monitoring of TOC, HCl, SO₂, NO₂, CO and oxygen from the thermal oxidiser. If the thermal oxidiser shuts down due to problems, pre scrubbed emissions will by pass the thermal oxidiser and discharge through vent 194 (this incident requires notification of the Agency in the PD).

The decision to select the thermal oxidiser was made by the company in order to meet BATNEEC emission limit values. The company states the following reasons for selecting s thermal oxidiser over other abatement techniques: The production schedule at Iropharm is client driven and hence technical production facilities must maintain a high degree of flexibility. The most flexible of the available abatement technologies is thermal oxidation. Based on the design mass flow-data for both VOC's and inorganics in the vent header system, thermal oxidation results in the least significant residual streams. Thermal oxidation will result in the lowest residual emissions of VOC's to atmosphere, usually less than 5mg/Nm³ TOC. Thermal oxidation will produce usable energy to supplement/replace steam generated on-site by oil-fired boilers. It will also provide the option at a later date, for the economic reuse of clean solvent streams generated onsite to recover the high inherent energy potential (this issue is discussed in more detail in the waste section).

Chlorinated VOC loading to the thermal oxidiser

The design specification of the thermal oxidiser (TO) is based on a total VOC loading maximum of 40.1 kg/hr and an average of 7.6 kg/hr. The total chlorinated VOC loading is a maximum of 0.16 kg/hr (as DCM) and an average of 0.03 kg/hr. In addition, inorganic chlorine compounds-HCl- may also be present in the vent gas up to 2 kg/hr.

The combustion chamber of the proposed TO, to be supplied by KEU, is designed to achieve complete combustion, i.e. high temperature (> 1,100 °C), excess air and a residence time of 2 seconds. The chamber and arrangements of gas ports and burner nozzle also promotes very high turbulence and consequently good mixing. The flue gas leaving the reaction chamber is cooled to less than 300 °C in one single-pass fire-tube boiler. The system is designed to

treat vapour phase VOC's and uses light fuel oil as support fuel. Based on the inputs specified in the design brief, the maximum level of free HCl/Cl in the flue gas travelling through the boiler is expected to be less than 800 mg/Nm³. Based on the VOC's to be treated and the relatively clean support fuel coupled to the low HCl/Cl content of the untreated flue gas, KEU (the suppliers of the TO) have guaranteed a final PCDD/PCDF level in the flue gas of less than 0.1 ng/Nm³. This limit has been applied in the PD. Condition 5.10 of the PD requires that the temperature of the flue gas leaving the waste heat recovery boiler shall not be less than 450 °C until such time as the licensee can demonstrate compliance with licence limits at lower temperatures. This can be assessed through out the test programme. Quarterly monitoring for dioxins is required (this can be reduced pending satisfactory operation of abatement equipment). The company is required to conduct a test programme for the abatement equipment. Condition 5.11 requires the licensee to conduct dioxin monitoring on the scrubber liquor. Condition 5.12 requires the plant to be shut down for any bypass of the thermal oxidiser in excess of one hour's duration. Condition 5.13 requires that the thermal oxidiser be shut down if control or monitoring equipment malfunctions or if the TO fails to reach its operating parameters. A footnote in schedule 1(i) allows the minimum operation temperature of the TO to be reduced where it is demonstrated that emission limit values (including dioxin) will not be exceeded.

Impact of air emissions

Powder Plant Impact

Dust emissions from the new powder handling plant were modeled and the maximum predicted ground level concentration was 10.6 ug/m³. This was compared against acute toxicity (inhalation data) available for some compounds present in the powder handling plant. Inhalation data ranged from 0.53 g/m³ to >200 g/m³, which is orders of magnitude greater than the predicted ground level concentrations.

Dioxin emissions

The total maximum licensed emission for dioxins from the plant is 3mg/ annum. Modelling submitted by the company predicts a maximum 1 hour average concentration for dioxin of 60 fg/m³ and a maximum annual average of 1 fg/m³. In the UK annual mean values range from 80- 390 fg TEQ/m³ in coastal rural areas.¹

Normal operations

The US EPA Industrial Source Complex Short model (ISCST3, version 95250) was used to predict maximum 1 hour ground level concentrations of individual pollutants outside the boundary from the thermal oxidiser. The maximum predicted hourly or annual average ground level concentrations of the individual compounds based on maximum emissions were less than the relevant Air Quality Standard (for SO₂ and particulate) or guideline such as the WHO and the OEL/40 for individual solvents and combined solvents and HCl. In relation to NO₂ the maximum annual average values predicted are well below the EC limit values. The EC limit for NO₂ is 200 µg/m³ (1-hour average) not to be exceeded more than 18 times a year. The margin of tolerance is 50% (i.e. 300 ug/m³) on commencement of the directive falling linearly to 0% by 2010.

Modeling conducted by the company assuming all NO_x emitted is NO₂ and not taking background into consideration predicts that at a worst case 200 µg/m³ would be exceeded nine times a year. In reality up to 95% of NO_x exits as NO and in TA Luft it is estimated that there is an approximate conversion of 60% NO to NO₂. Taking this into account reduces the predicted maximum by approximately 38% and all the maximum one hour values are reduced below 200 µg/m³. However if the nearest available background concentrations (99%tile ambient monitoring data from IFI background 70 µg/m³) are added to this the maximum 1 hour average predicted is 221 µg/m³. The EC limit value of 220 µg/m³ applies from 2008. Condition 5.9 of the PD requires the following: the licensee shall conduct a dispersion modeling study (using up-to-date data) for Oxides of Nitrogen (NO_x and NO₂) emissions from the site. Results shall be compared to relevant ambient air quality standards specified in EU Council Directive 1999/30/EC. A report on this study and modifications, if any, required to ensure continued compliance with relevant ambient air quality standards shall be submitted to the Agency within two years of the date of grant of this licence. Any modifications required shall be implemented within a time frame to be agreed with the Agency.

As a comparison Iropharm are licensed in this PD to discharge a maximum of 1.4 kg/hr NO₂ compared with 6.4 kg/hr from Schering Plough Avondale and up to 98 kg/hr from IFI.

By-pass of thermal oxidiser

A by-pass event was modelled for the proposed thermal oxidiser. The assessment was conducted on the basis of the expected maximum average VOC loading of the waste gas stream of 7.35 kg/hr. However, the thermal capacity of the TO is based on the maximum short term peak VOC loading in the waste gas stream of 32.13 kg/hr. This peak value on the inlet to the TO is expected to occur infrequently and to be of durations of less than 1 hour. The maximum 1 hour ground level concentration was predicted also for this event, however it is unlikely to reflect a realistic situation.

Results of the maximum average VOC loading (7.35 kg/hr) predicted are less than the relevant Irish OEL/40 for individual components. Taking the additive combined effects of all the compounds, the threshold limit values do not exceed unity. Results for maximum short term peak (32.13 kg/hr) predicted are less than the relevant Irish OEL/40 for individual components. However taking the additive combined effects of all the compounds, the threshold limit values exceed unity. As stated above this event is likely to be infrequent and less than one hour. The model prediction is based on this emission occurring on a continuous basis through out the year. Condition 5.12 of the PD requires that the plant be shut down for any bypass in excess of one hour's duration.

Effluent Discharge to surfacewater

The existing IPC licence sets limit values for discharge to the Avoca river until June 01 2002. From June 02 2002 more stringent limits have been applied in the existing licence. The company have requested that the volume limit be increased from 144 m³/day to 240 m³/day to account for future proposed increases in production and seven day plant operation (current plant operation is 5 day). However the company also submitted a projected maximum flow of

225 m³/day. This flow value has been applied in the PD. Allowing a further increase to 240 m³/day does not encourage waste minimisation. The company request similar limits to the existing licence up to the June 2002 deadline and these limits have been included in the PD with the exception of toxicity which has been reduced from 20 TU to 10 TU. The new WWTP, designed to meet more stringent limits being applied from June 2002, has already been installed and is being commissioned; this should enable the company to achieve the tighter toxicity limit. The limits for chloride and sulphate have also been reduced to the maximum values reported by the company to date and taking account of the increased volume.

The company is currently commissioning a new secondary WWTP. This system consists of 2 pH correction chambers, segregation precipitation tank, aerated balance tank with odour scrubber, sequential batch reactor basin, final effluent buffer tank, emergency tank and waste sludge processing system. The company have requested that reduced limits based on secondary treatment not be applied until June 2002. This is to allow for detailed investigation to be conducted on ammonia streams and measures to reduce ammonia, to conduct detailed assessment of individual waste streams, to conduct pilot trials, and to source a suitable outlet for sludge disposal. The company further requested that existing licence limits set from 2002 be applied. They stated that they are not requesting an increase in mass emissions (to be applied from June 2002) even though the volume will increase from 144 m³/day to 225 m³/day. They have submitted projected data for quality of effluent discharge from 2002. However the company have also requested (in the emissions table) emission limit values which are higher than the projected values, no justification is included for these increased figures and they have not been included in the PD. The limit values included in the existing licence from June 2002 (consistent with projected values submitted by the company) have been included in the PD with the exception of volume flow which has been increased to 225m³/day and BOD load which has been increased from 170 kg/day to 250 kg/day (50% removal) and ammonia from 7.2 kg/day to 12 kg/day. However a further reduction in BOD to 120 kg/day (75% removal) has been applied from June 2003. Chloride and sulphate limits have been reduced for reasons discussed above.

Impact of Effluent Emissions

Recent monitoring data for the Avoca River show that water quality is similar to quality conditions when the existing licence was issued in 1997. The biological quality rating of the river is 1. Existing and proposed orthophosphate limits for effluent discharge would cause an increase in river orthophosphate concentration of 7 µg/l PO₄ as P and 6 µg/l PO₄ as P. There are only three orthophosphate values recorded for the river upstream of the discharge point in the last year and these range from 0.098 µg/l PO₄ as P to 0.036 µg/l PO₄ as P. In accordance with the regulations, median concentrations should be determined on the basis of a minimum of ten samples taken at intervals of four weeks or longer in twelve consecutive months. The water quality standards for phosphorus regulations require that seriously polluted rivers achieve a minimum quality standard of moderately polluted (70 µg/l PO₄ as P) by 2007. The waste assimilative capacity of the river for ammonia as N (based on salmonid quality)

is approximately 87 kg NH₃N /day. While achieving BATNEEC the limit from 2002 has been increased from 7.2 kg/day to 12 kg/day due to increased volumes associated with increased production. The company is required to address in the EMP the reduction of ammonia and nitrogen emissions with the aim of achieving BATNEEC to ensure that limits applied from 2002 are achieved. The waste assimilative capacity of the river for BOD (based on salmonid river quality) is in excess of 580 kg /day BOD. The PD sets a limit of 250 kg /day BOD from June 2002 to June 2003 and a limit of 120 kg/day BOD from June 2003.

Surfacewater

A proposal to construct a firewater retention pond has been agreed with the Agency. Condition 9.2.3 requires the licensee to submit details on the operation of the diversion system, including a detailed plan of the firewater system and associated drainage and diversion systems, within six months of the date of grant of the licence, as details have yet to be finalised. A continuous TOC monitor has been installed on surfacewater discharge, W 2.

Waste:

The handling of hazardous and non hazardous wastes is carried out in accordance with the existing IPC licence, some additional waste contractors have been agreed with the Agency. Waste sludge from the WWTP has been included with non hazardous wastes for disposal.

The company states that one of the reasons that thermal oxidation was chosen was to provide the option, at a later date, for the economic reuse of clean solvents streams generated on-site to recover the high inherent energy potential. The company has not requested that the use of solvent as a fuel in the thermal oxidiser, be considered in this review. Therefore it is not considered in the PD and condition 7.2 states that waste solvent streams or solvents shall not be used as an alternative fuel for the thermal oxidiser. This can be assessed at a later date if requested by the company. However the company are required to address in the schedule of environmental objectives and targets, the on-site reuse of waste solvent for energy recovery under class 11.

Groundwater:

Groundwater monitoring conducted at the site, as a requirement of the existing IPC licence, shows that 1,2 dichloroethane concentrations have ranged from 600 to 900 ug/m³ and chlorobenzene, toluene, xylene, ethylbenzene, alkylbenzenes, naphthalene, styrene and chloroform have also been detected in trace concentrations. No discrete points of entry for the contaminants into the subsurface have yet been identified and the use of 1,2 DCE was discontinued circa 1989. The company propose, through the use of consultants, to conduct a detailed assessment of the site and the magnitude and distribution of contamination and prepare a report including a semi-quantitative risk assessment and corrective action strategy. This has been included as condition 9.3.3 of the PD. Additional monitoring boreholes constructed by the company have also been included in the monitoring schedule.

Noise:

There has been no change in limits for noise levels off-site, from the existing licence. Limits on noise sources have been removed from the licence. If noise surveys show a problem with noise the company can address reduction of noise from relevant sources where required. No complaints have been received in relation to noise from this activity.

Submissions:

There was 1 submission received from Duchas on this application. They state that they have no objections to the application. However they recommend that precautions be put in place to prevent leaks and spills. The “Arklow Town” pNHA site no 1931 is downstream of the site.

Conditions relating to bunding, and the loading and unloading of materials in a manner to prevent spills have been included in the PD.

Complaints:

There were no complaints received in relation to this activity.

Summary of enforcement.

Iropharm have been in non-compliance for combined emissions to atmosphere for organics. The existing scrubber system is incapable of achieving the limits set. The company proposes the installation of a thermal oxidiser to ensure compliance with emission limit values. An effluent sample taken in 1998 exceeded toxicity limits. The company conduct microtox tests on raw effluent streams to establish toxicity and treatability. The company also moved forward plans to install a WWTP, which is being commissioned at present. Toxicity tests conducted in 1999 were in compliance with licence limits. There were two bursting disc ruptures reported for 1999 and one to date for 2000. There was an elevated COD and pH recorded for surfacewater discharge. An automatic diversion system has been installed to divert contaminated streams to the WWTP. Work is due to begin on a firewater retention pond. Contaminated streams will be automatically diverted to this pond. Contaminants have been detected in groundwater. This is discussed in detail in the groundwater section above. The TOC monitor on surfacewater malfunctioned twice in 1999. Corrective and preventative action was taken. On a recent site visit it was noted that chemical drums were unbunded. A request for information has been sent to the company in relation to this.

Recommendations:

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

Signed

Annette Prendergast

References

1 November 1991, Society for Clean Air in the Netherlands (Vereniging LUCHT), Expertise on the Measurement and Control of Dioxins.