

## **THE IMPLEMENTATION OF IPPC UNDER SCHEDULE 1, SECTION 4.5 PART A (1) A), FOR A SMALL MANUFACTURING ENTERPRISE, PRODUCING CONTRACT CHEMICALS UNDER A MULTIPRODUCT PROTOCOL**

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NPIL Pharma (UK) Ltd at Huddersfield manufactures contract pharmaceutical intermediates and products in three plants ranging from kilo lab to 6.3 m<sup>3</sup> scale. Our business relies on rapid response to customers' demands with a constantly changing product portfolio. The site we are based on is owned by Signet, and five companies are present on the site. This paper describes how we managed our IPPC application, and the resulting maintenance activities and Improvement Conditions of the Permit.

### **1. BACKGROUND TO THE SITE AND APPLICATION**

Chemicals have been manufactured at the Leeds Road, Huddersfield site for almost one hundred years. Initially British Dyestuffs, it was part of ICI for about sixty years before demerger to Zeneca in 1993. Further sales of parts of Zeneca (from 1999 until 2005) have now caused the site to be split into five legal entities running plants. These are Syngenta, Arch, Noveon, NPIL and Dalkia who own and operate a power house. The site is owned by Syngenta with other companies owning their plants but leasing the land from Syngenta. All the companies use the Syngenta on-site effluent treatment plant, and services (electricity, steam, nitrogen) are supplied by Syngenta. There are also a number of other contracts between Syngenta and the tenant companies by which services such as site security, emergency response, domestic waste disposal etc are provided. There are no internal barriers within the site, although green fencing to designate the GMP areas surrounds the NPIL GMP plants.

An Application was prepared under the requirements of Schedule 1 of the Regulations, Section 4.5 Part A (1) a).

Preliminary discussions with the EA about how the companies were going to implement IPPC were held, and it was decided that the site would be one Installation, due to the one effluent treatment plant, but with five separate Permits; one for each legal entity manufacturing on site.

NPIL Pharmaceuticals Limited (formerly Avecia) manufactures contract pharmaceutical intermediates and products on three plants at Huddersfield, and occupies approximately 3 hectares of the total 100 hectare site. The plants are relatively small scale, ranging from kilo laboratory to a reactor size of 6.3 m<sup>3</sup>. Our business relies on a rapid response to customers' demands, and while we have some long-term processes, we have a constantly changing product portfolio with the products and processes at different stages of development.

The site was already regulated under IPC with the three NPIL plants gathered together under one fairly generic authorisation. Every time a new process was introduced we wrote and applied for a Variation and appended it to our authorisation, which resulted in more than thirty variations in the last five years. The frequently changing portfolio, relatively low emission levels and batchwise nature of manufacture meant that all the emissions were calculated. Only one programme of measurement ever took place, measuring certain VOCs at the site boundary, which proved to be barely detectable.

When IPPC started to be introduced for other business sectors, it contained the concept of the Multi-product Protocol, which seemed a much better fit for our manufacture. It was agreed between ourselves and our local Inspector that this would be a slicker way of managing our new sitings into existing assets, and so we operated an IPPC Multi-product Protocol for about two years before applying for an IPPC Permit.

Our Application for an IPPC Permit was Duly Made in February 2006, (number UP 3738 LY) and a Permit was granted in December 2006.

## **2. PERMIT APPLICATION PREPARATION**

Historically on Site, the chemical engineers who supported the plants also performed any necessary calculations to support the emissions also wrote IPC authorisations and variations. The Authorisations were “owned” by the plant managers, with the site SHE function acting in an advisory capacity, and operating as Site contact with the regulatory authorities. The splitting of the site into (in our case) much smaller identities meant that there were three process engineers on site, and one part time SHE manager. Nevertheless, it was decided to use in-house effort to prepare the permit due to the complex site situation and fluctuating manufacturing programme. A process engineer was appointed full time to this role to prepare the documentation and gather information from other sources as necessary.

Meetings began between the site partners around a year before the deadline for applications. The meetings were held monthly to discuss the approaches of the companies to various parts of the legislation, and feed back any comments received from the EA. One area debated was how the users of the effluent treatment plant were going to approach the section requiring reporting on emissions to sewer. After discussions with the EA and between ourselves it was decided that Syngenta would report on behalf of all the companies, as they held the license to discharge to sewer. As the Site was being taken as one installation, the site partners were keen to adopt similar standards and principles across all the permits.

Items prepared for the permit application were:

- Application Form
- Application Form Appendices (contained our multiproduct protocol)
- H1 Assessment
- Application Site Report and Appendices
- EOPRA

The applications for the whole site were delivered in person (in approximately 20 boxes!) on schedule in February 2006.

The costs to NPIL up to the point of application were approximately

- Application fee of £30,000
- Cost of staff time to prepare application, approximately £50,000
- Purchase of additional material for application, approximately £3,000

Giving a total cost to NPIL of £83,000.

An estimated cost for the whole Huddersfield site is £500,000.

### **3. THE APPLICATION FORM**

NPIL decided to use the electronic form provided and recommended by the EA. The application was written as generically as possible, assuming the maximum possible production rates. As we operate batch processes, with different cycle times, chemistries, unit operations and number of stages the figures used in the application were approximately double the annual production capacity achieved in the previous year. The activity was divided into two aggregations across the three plants.

The chemistry listed fifty different types of reaction, which we have either operated, or might possibly wish to operate in the future. The equipment and plant operations were also described generically. Emissions were not listed but comments made referring to the multi-product protocol, and generic categories used for VOCs. The raw material list was three pages long, which represented all those we had used in significant quantities in the last year. We stated that we had no routine monitoring and that all figures given were by calculation.

In general we found that using the electronic templates in the application were helpful, as they led us through the application process. However, they were not written with plants operating under a multi-product protocol in mind, so we had occasionally to extend boxes, or write lengthy comments either on the form, or on separate sheets and append to the application.

### **4. THE MULTI-PRODUCT PROTOCOL (MPP)**

This was written in line with guidance from the EA, and in operation for two years before the Application was filed. Our MPP is a Company Procedure that described the environmental assessments undertaken by project teams (mainly by the chemical engineer) during the siting project. There is also another internal company document called the User Guide that gives more detailed information to project teams, and a calculation spreadsheet to aid in the estimation of emission quantities and concentrations. We then decide if the change is minor, or requires a variation. So far, we have sited new processes within existing assets and required no new abatement equipment, so changes have been minor. To date in 2007 we have submitted around 20 assessments, mainly for low quantity short campaign

manufactures in our two small development plants. The main issues we face in operating under the MPP are:

- Time pressures  
In our smallest plants, often we have about four weeks between a customer order and starting manufacture. It can take two for the plant to decide how they are going to run the process in the assets, and then they write the MPP document and perform the calculations. The EA have been very co-operative in turning round these minor changes in a few days, and even by return of e- mail on occasion, and have not held us up from manufacturing.
- It's not our process!  
Some customers allow or require us to develop their processes, in which case we have scope and time to replace more environmentally damaging solvents, remove some operations, reduce waste etc. However, some contracts are "take and make" with the customer specifying no development and a very short timescale. Some processes are from outside the EU, and have been developed in places with different legislative requirements. (For example a lot of processes developed in USA contain DCM.)

## **5. THE H1 ASSESSMENT**

Again, we used the software provided by the EA, adapting our answers to our multi-product manufacturing. We chose eight processes as example processes, across the three plants. The processes included long term manufactures and some worst case examples of short term manufactures we had seen in the recent past. These used a wide variety of raw materials, chemistry and operating conditions. We assumed all the processes ran simultaneously, in effect doubling the capacity of our plants. The figures we used for emissions were those we had previously generated by calculation for our Environmental Impact Assessments using H1 (and E1) in previous years. All air impacts were insignificant with three exceptions and further detailed modelling was performed on these, which then proved to be insignificant.

## **6. THE APPLICATION SITE REPORT**

The land for the whole site is owned by Syngenta, and NPIL holds a long term lease for certain areas. As the site had made chemicals for such a long period, before the site was split into more than one legal entity, a significant study was undertaken by Zeneca in 1999 to assess the ground contamination. It was agreed at this point that as the land would not be sold, the potential liability for any historical contamination would not be passed on to the buying company. The results of this study were made available to NPIL for the preparation of our Site Report. This report, conducted by an external specialist consulting company, contained information about the hydrogeology of the site, and a conceptual site model as well as various other items relevant to a site report. This has served as our baseline, as the enclosed nature of our operations and incident reporting system made us

confident we had not contaminated the land between 1999 and the time of application. Our Site Report was again written by our in-house staff.

Two factors specific to our location are

- The River Colne runs through our site, and is approximately 20 metres away from our closest plant.
- The site is adjacent to the A62, Leeds Road, and our plants are the closest on site to the road and human habitation.

Fortunately, our plants are relatively modern (20, 8 and 5 years old), self contained and enclosed, with high environmental integrity, and use of the D2A assessment table identified only two potential sources of pollution of the land or river, for which we proposed improvements. These were then included in our Improvement Conditions by the EA.

## **7. EPOPRA**

This is the spreadsheet produced by the EA to calculate both the application fee, and the ongoing maintenance costs for IPPC, based on the principle that “the polluter pays”. On the positive side, the plants are relatively small and low polluting, have good records, and the site has a history of good procedures and practices handed down from ICI / Zeneca/Avecia / NPIL. On the negative side, we are close to a river and human habitation, and operate complex and potentially hazardous chemistry, with a wide range of raw materials.

Our application fee came to £30,000, and our subsistence fee is £15,000, which is slightly higher than we were paying under IPC.

## **8. THE PERMIT**

This was received in late December 2006, after two meetings to discuss the application with the EA, and NPIL providing some additional clarification and information as requested. No “Schedule 4” notices were issued. The permit contains a number of clauses common to all operators, such as a training plan, producing the Site Closure Plan and Site Protection and Monitoring Programme, reporting requirements etc with schedules of requirements specific to each company at the back. There is a schedule of emission concentration limits and annual emission limits to air, and a schedule of Improvement Conditions. The emission concentration limits were not set in the permit in our case. As we had not monitored what our concentrations actually were, the limits were subject to us undertaking a monitoring programme. This was recorded as one Improvement Condition.

There were ten Improvement Conditions, of which five were fairly minor, and common to all the companies on the Huddersfield Site. The most costly improvements identified specific to NPIL were:

- Improvements identified by us in the Site Report, to a roadway drain, and an area used for drum storage. The drain has been routed to an effluent drain from a Clearwater

drain. The modifications to the drum storage area are significant, and so far a scope has been agreed, designed, and has been estimated at around £100,000.

- A monitoring programme of all registered release points to air, to demonstrate that the calculations performed are correct. This will then also confirm the annual losses to air, and demonstrate the abatement equipment is functioning as predicted. This programme was also required to demonstrate that the conditions of the Solvents Emissions Directive (SED) are being met, with regard to the emission limits of certain toxic solvents. Following the programme, we were then required to run the H1 software again, and confirm our releases are insignificant.

These improvement conditions will take at least a full year to complete, and costs in 2007 are estimated to be:

- NPIL staff time approximately £30,000
- VOC monitoring (External contractor) approximately £20,000
- Roadway drains improvements approximately £15,000
- Subsistence fee for 2007 of £15,000

Giving a total cost of IPPC work in 2007 of approximately £80,000.

A further expenditure in 2008 of around £100,000 is expected for upgrading the drum storage compound area.

## **9. THE SITE PROTECTION AND MONITORING PROGRAMME (SPMP)**

This was written in house and sent to the EA as required, in February 2007. A response accepting our proposals was received in November 2007. Our proposals were based primarily on preventative measures, with only one baseline groundwater sample proposed. Our preventative measures consisted of existing procedures and policies as follows :

- Maintenance policies include the statutory preventative maintenance required of pressure vessels, registered pipelines, etc. plus a list of other work specified by the engineering manager which includes inspections to confirm bund, sump and drain integrity.
- Plant Environmental compliance checklists, which have daily/weekly checks for such things as sumps, leaks from vessels, pipes and storage drums and tanks, scrubber operation, condenser glycol system operation etc.

The one proposed groundwater sample utilised an existing borehole, originally dug for the 1999 study. This was inspected and judged to still be usable. It is located in the hydraulic gradient between our plants and the river, not far from the drum compound described above as requiring improvement. Our plan was this would be a one- off sample to establish a baseline, and not repeated unless we had a loss of containment onto unmade ground. An external specialist company has been appointed to undertake this work, as we do not have the appropriate UKAS accreditation in house.

It is proposed that sampling will take place in January, with the results sent to the Environment Agency by the end of February 2008.

## 10. MONITORING OF EMISSIONS TO AIR

One of the conditions imposed by the EA was that monitoring was conducted to MCERTs standards. Our small analytical department, which while being highly skilled and able to test pharmaceutical products to GMP standards, has no MCERTs accreditation. Hence, an external contracting company was appointed to undertake the measurement. Sampling took place between July and October 2007.

Our plants have 17 registered vents, and the EA initially required all of them being sampled. After discussion, our sampling plan involves actually sampling from only seven of these points. Four vents are used specifically for hydrogen, and it was argued that it was not safe to attempt sampling from these as they were nitrogen swept. They were highly inaccessible, with no sampling points already present, and it was agreed that drilling holes (and hence allowing air ingress) and taking electrical equipment to the vicinity would be too hazardous. Three vents were eliminated on the grounds of triviality, and two vents are not currently in use. One vent, from a dust scrubber, could not physically be sampled. It was situated on the top floor of a plant with the vent going straight through the roof, with no space after the fan to locate a sample point. The roof is not accessible, except under a special permit, using either a “cherry picker”, scaffold, or roof boards. At a plant shutdown in April 2006, the scrubber vent was inspected, as well as the area of the roof around the vent. There was no evidence of any solids being emitted, and this was accepted as proof of triviality by the EA.

The three plants operated are at different scales, and also operate at different levels of occupation. The largest plant (called Pharms. Intermediates Plant, or PIP) operates mainly established processes with long term contracts for large quantities, with campaigns measured in months, and a planning horizon of several months. The plants operate at high levels of occupation and the batch processes are highly optimised for efficiency. Around 90 to 95% of the tonnage capacity of the company is from these plants, and an estimated 85% of the emissions. The plant has two manufacturing units, and can have as many as four batches in progress in one unit, and three in the other. For this plant, it was planned to sample from the aqueous packed scrubbers associated with each unit, for a continuous period lasting a full batch cycle, at a time when the plant was fully loaded. This meant 24 hour sampling for four days on each unit.

The two smaller plants, called Pharms. Development Plant (PDP) and the Early Phase Development Team (EPDT) manufacture products on a smaller scale, with the products generally being in clinical trial phase. The processes operated in PDP are generally being optimised, in clinical trial phase 3, with around 50% of one-off campaigns, often with less than ten batches. EPDT operates at even smaller scale, at the earliest clinical phases, and with even more one-off campaigns. In both plants, there is often only one batch in progress at any one time in each unit, with the overall batch time being long, with

7 to 10 days being common. Hence it was decided not to monitor these continuously, but the monitor when certain operations known to cause emissions such as vacuum distillations, product drying etc occurred on the plants.

The aim of the programme was to measure emission concentrations and quantities, and compare these with the calculated values, for generic unit operations. This was to demonstrate to the Agency that our calculation methods were reliable, and hence allow the plants to continue to operate under the multi-product protocol using these calculated values, and avoid installing on-line sampling, or having frequent routine monitoring.

As expected, the monitoring showed that our emission levels ranged widely depending on the operations performed by the plant, with a great many low duration peak concentrations relating to plant operations such as batch charges, blown transfers, and vessel purges with nitrogen. The interpretation of the data gathered on PIP was complicated by the fact that four batches were performing many such operations at the same time. However, by use of our GMP Process Instruction sheets, which have times of operations listed, and spending significant amounts of time on the plant, it was possible to attribute peaks to operations.

The data analysis showed reassuring agreement between our measured values of emission and our mass balance calculations for total emissions per batch. Our system appears to give more smoothing of peaks than we had allowed for, as in general the peak concentrations measured were lower than those calculated.

A report of the findings, including revised H1 assessment, was submitted to the Agency on 30th November 2007, as required. These figures will become the baseline for our Emission Limit Values in future.

## **11. AQUEOUS EFFLUENT MONITORING**

One joint Improvement Condition was placed upon the site as a whole. This was to monitor the efficiency of the Syngenta Effluent Treatment Plant at removal of specific impurities. The plant already has on-line analysis at the outlet, and meets certain standards set by Yorkshire Water. Syngenta has an environmental group who test all process effluent for suitability of discharge into their system. All the site partners were to take composite samples from their plant effluent drains over the same three month period, with Syngenta also taking samples of what came out of the effluent plant. For continuous plants, or those making a set product portfolio, and discharging relatively large amounts into the plant, this is reasonable.

NPIL plants discharge relatively low volumes, in a batchwise manner, from a variety of processes using many different raw materials. The two smaller plants do not always run fully loaded, and for new, one-off and small tonnage manufactures, aqueous effluent is packed off and disposed of off-site. Also, the plants have large drum storage areas, and these plus the plant gutters and internal roadways are routed to the effluent plant. It is quite possible that any sampling could be misleading in wet weather, with the rainwater greatly in excess of process effluent. Sampling a composite sample out of the drain points would



mean in our case attempting to analyse for extremely small amounts of pharmaceutical intermediates and solvents. It was decided to propose an alternate method for this Improvement Condition for NPIL as follows.

### SAMPLING PHILOSOPHY

The streams that enter the Syngenta ETP were listed, and divided into categories as described below.

It is believed that Syngenta intends to run the sampling plan in early 2008. Therefore NPIL decided that for manufactures which are long term and ongoing, (i.e. those in PIP) to sample in July and August 2007. This sampling was **at source** rather than from the effluent drains/ sumps etc. As the plants operate to GMP, it will be possible to track which batches and discharges were made during the sampling period selected by Syngenta. This smoothes the analytical load on NPIL staff.

Other manufactures in PIPDEV and EPDT will be sampled as they occur during the sampling period set by Syngenta.

#### “Strong” streams

These streams are the process effluent streams, generally from aqueous wash and splits done during the work up of processes, or screening of salts and then dissolving them before disposal to Syngenta ETP. Syngenta Environment Group has tested all these as suitable for discharge. All the processes, which are considered to be long term manufactures and have “strong” effluent, were sampled. These streams were all from the PIP plant. They were sampled in August, and analysed by our internal NPIL Analytical Development Group for solvents and pharmaceutical products.

#### “Weak” streams

There are two sources of these streams; gas scrubbing containing traces of solvents, and plant cleaning containing traces of solvents and products. (During product changeovers, the plants are cleaned with solvents which are not sent to Syngenta ETP. However, before maintenance work, the plants are cleaned first with solvent, and then with water which is disposed of to Syngenta ETP.) Streams from established manufactures on PIP were sampled in July and August 2007. They were, as expected, weak, containing less than one per cent of solvents. Sources from PDP and EPDT will be sampled from manufactures that occur during the Syngenta monitoring period.

#### Streams which were not sampled or analysed

The plant gutters, and floors and roads close to the plants also drain to the Syngenta ETP either directly, or via the plant sumps. The sumps are overpumped daily to Syngenta, if there have been no losses of containment on the plants or storage areas. The normal sources of these streams are rainwater, or water from mopping floors, which is an operation that is performed daily for GMP plants. It is not proposed to sample these streams. In an

emergency situation such as a loss of containment, the plant sumps are not pumped to Syngenta ETP.

This plan was accepted by the EA, and will be completed in 2008, concurrently with all the other companies on site.

## 12. THE SOLVENTS EMISSIONS DIRECTIVE (SED)

The aim of SED is to prevent or reduce the direct and indirect effects of emissions of volatile organic compounds (VOCs) into the environment, primarily air. The manufacture of pharmaceutical products is an IPPC Part (A)1 activity, that is also a SED activity, if the amount of solvents input in a year is >50 tonnes.

Initially, it was not clear whether NPIL at Huddersfield was subject to this legislation, as we do not ferment, formulate, package or sell any finished drug products. The majority of our output is pharmaceutical intermediates (not subject to SED). However, we do perform the chemical synthesis of crude API's in small quantities for clinical trials in our two smaller plants, and wished to retain this capability. This meant that all the activities on site, including intermediates, are subject to SED.

We were classed as an existing installation, and hence demonstration of compliance was required by the end of October 2007, using the emission limit values (ELVs) as below:

- VOCs with the risk phrase R40 (in our case, dichloromethane, DCM) – if emissions are >100 g/hr, the ELV is 20 mg/m<sup>3</sup>.
- VOCs with the risk phrases R45,46,49,60,61 – if emissions are >10 g/hr, the ELV is 2 mg/hr. Our current product portfolio did not use any such materials, but in the past we have used dimethylformamide (DMF), which is R61.

In general, we have adopted a policy of removal of DCM (and DMF) during process development. We are seeing less customer inquiries from Europe that use DCM, but in other parts of the world, for example, USA, where DCM is not classed as a carcinogen, it is more common. During the early clinical trial phases of a drug life, when relatively small amounts of material are required, with short lead times and high probability the drug will not actually reach the market, there may not be time or customer willingness to spend time (and money!) developing out the use of DCM. In this case, we use hired carbon absorber units to remove DCM on our smaller plants.

One such process was manufactured in PDP in September 2007, in parallel with laboratory work to replace DCM with a less toxic solvent. This campaign consisted of twenty batches of 60 kg each. This campaign was monitored to demonstrate compliance generically for the plant and technology of using carbon absorption. We gained prior acceptance from the EA that measuring emissions during a series of generic batch operations (charging from drums, vessel transfer, distillation etc) on one product would validate our equipment and the technology, and hence no variations would be required in the future for different processes using DCM on any of the three plants. However, monitoring during manufacture on the other plants could be required.

During the trial manufacture, process engineers performed mass balancing for every batch from the weights of solvent charged and discharged to calculate how much DCM was being lost into the carbon beds, and compare this with their previous assumptions. Monitoring both before and after the beds demonstrated that the beds could achieve the 20mg/m<sup>3</sup> SED limit, and confirmed the reduction in concentration achievable across the beds. This was found to be greater than 99%, unless the bed had become exhausted.

The mass balancing work showed that on the initial batches, the plant was losing more DCM into the beds than we had thought. A review of exactly how the plant was operating was reviewed, and some re-training of the operators reduced this to close to the design figures. Some operational improvements which reduced loss of DCM into the absorber were slowing down the rate of distillation, and reducing or eliminating line and vessel nitrogen purge volumes or rates.

The results were shared with the local Inspector in mid October 2007, and the report was sent to the Environment Agency on 31st October.

In December, 2007, the company received a number of inquiries for manufactures using either dimethyl formamide (DMF), or dimethyl acetamide, DMAc, which are both R61 compounds. It was necessary for NPIL to apply for a variation to handle these compounds since we had not had the opportunity to demonstrate compliance with the SED limits before the 31st October deadline. The Variation Application has been submitted, and will be determined as a Simple Standard Variation, by our local Inspector. We expect to start manufacture in March 2008, with a monitoring survey similar to that conducted for DCM.

### **13. IPPC MAJOR AUDIT – 30TH OCTOBER 2007**

This was the first major audit NPIL had had under IPPC. The audit lasted one day, and was conducted by two Inspectors. The areas audited in depth were maintenance, emergency procedures, our use and application of the multi-product protocol, operation of abatement plant, and general management procedures. There was also a Site Inspection. The audit report was issued within two weeks by the Agency.

The conclusions were very positive overall, with the Agency reporting, “NPIL illustrate sound overall compliance against their PPC authorisation. No breaches of the permit were noted”.

Four actions were identified by the EA, which are being progressed by NPIL.

### **14. TOTAL COSTS, AND FUTURE WORK (BEYOND APRIL 08)**

It is estimated that the costs to NPIL so far are £83,000 up to the point of application, and £80,000 between application and the end of 2007. Costs (not including the routine subsistence fee) in 2008 are expected to be around £120,000.

The EOPRA was reviewed by the Inspector in December 2007 following the major audit and the return of VOC monitoring results from NPIL. The Inspector concluded that our score was unchanged from that which we had calculated ourselves at the time of application.

## 15. CONCLUSIONS

Compliance with the IPPC Regulations has been a considerable exercise for our company, requiring significant technical time, effort, and expenditure. The nature of our batchwise, non steady state, and multi-product manufacturing has made the process complicated, as the legislation was clearly not written with this in mind. We have been able to demonstrate to the Agency that we are operating BAT, and that our procedures for manufacture and calculation of emissions to atmosphere are good. Hence for normal emissions there has been no net benefit either to the company, or the environment.

However, the modifications around drainage should reduce the likelihood of pollution of the ground in the unlikely event of a spillage in the future.

## REFERENCES

The following guidance produced by the Environment Agency was used.

1. Sector Guidance Note IPPC S4.02, Guidance for the Speciality Organic Chemicals Sector.
2. Guidance Note from the Department for Environment, Food and Rural Affairs and the National Assembly of Wales on the Implementation of the Solvents Emissions Directive.
3. Introductory Guidance on the new 2004 Solvents Emissions Regulations.
4. Solvents Emissions Directive – Overview of requirements.
5. Technical Guidance Note M1, sampling for stack – emission monitoring, version 4, July 2006.
6. Technical Guidance Note M2, monitoring of stack emissions to air, version 4.1, January 2007.
7. Technical Guidance Note H7, Guidance on the Protection of Land under the PPC regime: Application Site Report and Site Protection and Monitoring Programme.
8. Technical Guidance Note H8, Guidance on the Protection of Land under the PPC regime: Surrender Site Report.
9. Guidance on the use of a multi-product protocol (MPP) at chemical installations, version 2.1, March 2005.
10. Technical Guidance Note H1, Environmental Assessment and Appraisal of BAT.