BAT Guidance Note on Best Available Techniques for Pharmaceutical and Other Speciality Organic Chemicals

(1st Edition)

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1. INTRODUCTION

1.1 GENERAL

This Guidance Note is one of a series issued by the Environmental Protection Agency (EPA), which provides guidance on the determination of Best Available Techniques (BAT) in relation to:

- applicants seeking Integrated Pollution Prevention and Control (IPPC) licenses under Part IV of the Environmental Protection Agency Acts 1992 to 2007,
- existing Integrated Pollution Prevention and Control (IPPC) Licensees, whose licence is to be reviewed under the Environmental Protection Agency Acts 1992 to 2007,
- applicants seeking Waste Licenses under Part V of the Waste Management Acts 1996 to 2008,
- existing Waste Licensees, whose licence is to be reviewed under Waste Management Acts 1996 to 2008.

This Guidance Note shall not be construed as negating the installation/facility statutory obligations or requirements under any other enactments or regulations.

1.2 BAT GUIDANCE NOTE STRUCTURE

This Guidance Note has been structured as follows:

Section	Details
1	Introduction
2	Interpretation of BAT
3	Sector(s) Covered by this Guidance Note
4	Process Description, Risk to the Environment and Control Techniques
5	Best Available Techniques
6	BAT Associated Emission Levels
7	Compliance Monitoring

Where relevant, references are made to other detailed guidance; such as the reference documents (BREF) published by the European Commission, Agency Guidance Notes for *Noise in Relation to Scheduled Activities*, and the determination of BAT should be made giving regard to these.

The information contained in this Guidance Note is intended for use as a tool to assist in determining BAT for the specified activities.

2. INTERPRETATION OF BAT

2.1 STATUS OF THIS GUIDANCE NOTE

This Guidance Note will be periodically reviewed and updated as required to reflect any changes in legislation and in order to incorporate advances as they arise.

Techniques identified in these Guidance Notes are considered to be current best practice at the time of writing. The EPA encourages the development and introduction of new and innovative technologies and techniques, which meet BAT criteria and look for continuous improvement in the overall environmental performance of the sectors activities as part of sustainable development.

2.2 INTERPRETATION OF BAT

BAT was introduced as a key principle in the IPPC Directive, 96/61/EC. This Directive has been incorporated into Irish law by the Protection of the Environment Act 2003. To meet the requirements of this Directive, relevant Sections of the Environmental Protection Agency Act 1992 and the Waste Management Act 1996 have been amended to replace BATNEEC (Best Available Technology Not Entailing Excessive Costs) with BAT.

Best available techniques (BAT) is defined in Section 5 of Environmental Protection Agency Acts 1992 to 2007 and Section 5(2) of the Waste Management Acts 1996 to 2008 as the “most effective and advanced stage in the development of an activity and its methods of operation, which indicate the practical suitability of particular techniques for providing, in principle, the basis for emission values designed to prevent or eliminate or where that is not practicable, generally to reduce an emission and its impacts on the environment as a whole” where:

B ***‘best’*** in relation to techniques, means the most effective in achieving a high general level of protection of the environment as a whole

A ***‘available techniques’*** means those techniques developed on a scale which allows implementation in the relevant class of activity under economically and technically viable conditions, taking into consideration the costs and advantages, whether or not the techniques are used or produced within the State, as long as they are reasonably accessible to the person carrying on the activity

T ***‘techniques’*** includes both the technology used and the way in which the installation is designed, built, managed, maintained, operated and decommissioned.

The range of BAT associated emission level values specified in Section 6 indicate those that are achievable through the use of a combination of the process techniques and abatement technologies specified as BAT in Section 5. The licensee must demonstrate to the satisfaction of the Agency, during the licensing process, that the installation/facility will be operated in such a way that all the appropriate preventative measures are taken against pollution through the application of BAT and justify the application of other than the most stringent ELV in the range.

At the installation/facility level the most appropriate techniques will depend on local factors. A local assessment of the costs and benefits of available options may be needed to establish the best option. The choice may be justified on:

- the technical characteristics of the facility;
- its geographical location;
- local environmental considerations;
- the economic and technical viability of upgrading the existing installation.

The overall objective of ensuring a high level of protection for the environment as a whole will often involve making a judgment between different types of environmental impact, and these judgements will often be influenced by local considerations. On the other hand, the obligation to ensure a high level of environmental protection including the minimisation of long-distance or transboundary pollution implies that the most appropriate techniques cannot be set on the basis of purely local considerations.

The guidance issued in this Note in respect of the use of any technology, technique or standard does not preclude the use of any other similar technology, technique or standard that may achieve the required emission standards and is demonstrated to the Agency to satisfy the requirement of BAT.

2.3 BAT HIERARCHY

In the identification of BAT, emphasis is placed on pollution prevention techniques rather than end-of-pipe treatment.

The IPPC Directive 96/61/EC and the Environmental Protection Agency Acts 1992 to 2007 (section 5(3)), require the determination of BAT to consider in particular the following, giving regard to the likely costs and advantages of measures and to the principles of precaution and prevention:

(i) the use of low-waste technology,

(ii) the use of less hazardous substances,

(iii) the furthering of recovery and recycling of substances generated and used in the process and of waste, where appropriate,

(iv) comparable processes, facilities or methods of operation, which have been tried with success on an industrial scale,

(v) technological advances and changes in scientific knowledge and understanding,

(vi) the nature, effects and volume of the emissions concerned,

(vii) the commissioning dates for new or existing activities,

(viii) the length of time needed to introduce the best available techniques,

(ix) the consumption and nature of raw materials (including water) used in the process and their energy efficiency,

(x) the need to prevent or reduce to a minimum the overall impact of the emissions on the environment and the risks to it,

(xi) the need to prevent accidents and to minimise the consequences for the environment, and

(xii) the information published by the Commission of the European Communities pursuant to any exchange of information between Member States and the industries concerned on best available techniques, associated monitoring, and developments in them, or by international organisations, and such other matters as may be prescribed.

3. SECTOR COVERED BY THIS GUIDANCE NOTE

This Guidance Note covers the following activities under the First Schedule of the Environmental Protection Agency Acts 1992 to 2007:

5.6 The manufacture of pesticides, pharmaceutical or veterinary products and their intermediates, not included in paragraphs 5.12 to 5.17.

5.8 The formulation of pesticides, not included in paragraphs 5.12 to 5.17.

5.10 The manufacture of vitamins involving the use of heavy metals, not included in paragraphs 5.12 to 5.17.

5.15 The production of basic plant health products and of biocides.

5.16 The use of a chemical or biological process for the production of basic pharmaceutical products.

4. PROCESS DESCRIPTION, RISK TO THE ENVIRONMENT, AND CONTROL TECHNIQUES

Note: any reference to BREF in this document means the *Integrated Pollution Prevention and Control (IPPC) Reference Document on Best Available Techniques for the Manufacture of Organic Fine Chemicals*, published by the European IPPC Bureau in December 2005.

4.1. DESCRIPTION OF PROCESS

The chemistry of intermediates and products in this sector (pesticides, pharmaceuticals and veterinary products) shows an enormous diversity but the number of processes and operations used remains reasonably small. The primary chemicals used for the manufacture of products are called intermediates and are prepared on an industrial scale from basic organic (usually) aromatic raw materials by various chemical procedures (unit processes). Biological unit processes (e.g. fermentation) are also used to manufacture specific products. The types of physical procedures (unit operations), which are applied in this sector, are also limited. The main unit process and operations are listed below with signposting to the relevant sections of BREF where available.

Unit Processes

- Acylation (see BREF Section 2.5.1)
- Addition
- Alkylation (see BREF Section 2.5.2)
- Carboxylation
- Carboxymethylation
- Condensation (see BREF Section 2.5.3)
- Diazotisation and modifications of the diazo group (see BREF Section 2.5.4)
- Esterification (see BREF Section 2.5.5)
- Fermentation (biological unit process) (see BREF Section 2.6)
- Halogenation (see BREF Section 2.5.6)
- Nitration (see BREF Sections 2.5.7 & 2.5.8)
- Oxidation (see BREF Section 2.5.9)
- Phosgenation (see BREF Section 2.5.10)
- Processes Involving Heavy Metals (see BREF Section 2.5.16)
- Rearrangements
- Reduction (see BREF Section 2.5.11)
- Substitution

- Sulphochlorination (see BREF Section 2.5.14)
- Sulphonation (see BREF Sections 2.5.12)
- Wittig Reaction (see BREF Section 2.5.15).

Unit Operations

- Absorption
- Adsorption
- Apparatus Cleaning (see BREF Section 2.3.4)
- Charging reactants and solvents (see BREF Section 2.3.1)
- Cooling (see BREF Section 2.3.3)
- Crystallisation
- Discharging
- Distillation (see BREF Section 2.3.2.3)
- Drying (see BREF Section 2.3.2.1)
- Electro dialysis
- Extraction (see BREF Section 2.3.2.4)
- Filtration
- Inerting
- Milling
- Phase separation (see BREF Section 2.3.2.2)
- Product washing.

Utilities

A number of different utilities support the unit processes and operations including electricity, steam, water, compressed air, vacuum, etc. (see BREF Sections 2.3.5 & 2.3.6)

4.2. RISK TO THE ENVIRONMENT

The key environmental issues of the sector are:

- Emissions of volatile organic compounds
- Waste waters with potential for high loads of non-degradable organic compounds
- Large quantities of spent solvents
- Non-recyclable waste in high ratio.

The enormous variety of substances used in these sectors can also include highly harmful and toxic substances.

4.2.1. Emissions to Air

Emissions to air from this sector include VOCs, Inorganics, Combustion By-products and Particulates (see BREF Sections 2.4.2.1, 2.4.2.2 & 3.1 which provide examples of specific emitted species).

4.2.2. Emissions to Water

Emissions to water from this sector include organic compounds (both biodegradable and recalcitrant compounds), suspended solids, and certain inorganic material (see BREF Sections 2.4.2.3, 2.4.2.4 & 3.2).

4.2.3. Waste

Solid and liquid waste generated by this sector includes solvent waste, waste containing pesticide/pharmaceutical/veterinary products and by-products, sludge from wastewater treatment, packaging waste and general municipal type waste (see BREF Section 3.3 for example).

4.2.4. Water Consumption

Water consumption in this sector is mainly used for cleaning, heat transfer and process (water for injection, solution makeup, fermentation, etc.) operations.

4.2.5. Energy Use

Energy consumption in this sector is associated with utilities (heating, ventilation, air conditioning and humidity control, etc.) and electrically driven process equipment.

4.3. CONTROL TECHNIQUES

The existing or possible measures for eliminating, reducing and controlling emissions are described in this Section under the following headings:

- Prevention of Environmental Impact
- Minimisation of Environmental Impact
- Management and Treatment of Residues
- Environmental Management.

References are given to relevant sections of the BREF document, which contain more detailed information.

4.3.1. Prevention of Environmental Impact

4.3.1.1. Green Chemistry

Process design focusing on alternative synthetic routes and reaction conditions to utilise more environmentally friendly processes (green chemistry) (see BREF Sections 4.1.1& 4.1.4).

4.3.1.2. Integration of Environmental, Health & Safety (EHS) Considerations into Process Development

Consider EHS issues at an early stage in process development to identify and prevent, minimise and design out environmental issues (see BREF Section 4.1.2).

4.3.1.3. Solvent Selection

Careful consideration and selection of solvents during process development to prevent and minimise environmental impact associated with solvent usage (see BREF Section 4.1.3).

4.3.1.4. Extraction from Natural Products

Minimise environmental impact of extraction process by using alternative extraction techniques, maximising extraction yield, and/or selection of optimum extraction solvent (see BREF Section 4.1.5).

4.3.1.5. Prevention of Major Accidents and Releases to the Environment

Hazard identification and risk assessment during process design to determine and implement appropriate control measures to prevent major accidents and associated releases to the environment (see BREF Section 4.1.6).

4.3.2. Minimisation of Environmental Impact

4.3.2.1. Plant Design

Consider environmental issues during plant design to maximise efficient use of natural resources and minimise releases to the environment (see BREF Sections 4.2.1 & 4.2.3 for examples).

4.3.2.2. Site Location Assessment and Selection

Consider environmental issues during selection of site location for product manufacture with a view to minimising environmental impact (see BREF Section 4.2.2).

4.3.2.3. Prevent/Minimise Water Contamination during Vacuum Generation

During vacuum generation prevent/miminise water contamination and reduce waste water load. Options may include the use of water-free vacuum generation, use of solvents as the ring medium in liquid ring vacuum pumps, and/or the use of closed cycle liquid ring vacuum pumps (see BREF Sections 4.2.5 to 4.2.7).

4.3.2.4. Indirect Cooling

Use of indirect instead of direct cooling processes to reduce waste water load (see BREF Section 4.2.9).

4.3.2.5. Pinch Technology

Application of pinch technology to maximise energy efficiency (see BREF Section 4.2.10).

4.3.2.6. Energetically Coupled Distillation

Conduct distillation in two steps (two distillation columns), so that energy flows in both columns can be coupled to reduce steam consumption (see BREF Section 4.2.11).

4.3.2.7. Optimise Equipment Cleaning

Optimise plant cleaning procedures to reduce waste water load and direct VOC releases (see BREF Sections 4.2.12 & 4.2.13).

4.3.2.8. Minimise VOC Emissions

Minimise fugitive/diffuse emissions of VOCs and ensure the tightness of vessels (see BREF Sections 4.2.14 to 4.2.16).

4.3.2.9. Shock Inertisation of Vessels

Shock inertisation of vessels to reduce exhaust gas volume flow and consumption of inert gas (see BREF Section 4.2.17).

4.3.2.10. Liquid Addition Into Vessels

Minimise pollutant load in displaced gases during liquid addition into vessels (see BREF Section 4.2.18).

4.3.2.11. Solid-Liquid Separation in Closed Systems

Use of closed systems such as Nutsche type pressure filter or filter dryer for solid-liquid separation to minimise VOC emissions (see BREF Section 4.2.19).

4.3.2.12. Minimisation of Exhaust Gas Volume Flows from Distillation

Optimise condenser layout to ensure adequate heat removal to minimise exhaust gas volume flows and VOC emissions from distillation (see BREF Section 4.2.20).

4.3.2.13. Segregation of Aqueous Residues

Adequate segregation to allow appropriate treatment for different aqueous waste streams (see BREF Section 4.2.21).

4.3.2.14. Countercurrent Product Washing

Minimise water consumption and wastewater generation using countercurrent product washing (see BREF Section 4.2.22).

4.3.2.15. Reactive Extraction

Recovery of organic acids from aqueous solutions to reduce waste water loading (see BREF Section 4.2.25).

4.3.2.16. Spill Containment

Use of spill containment and leak detection measures for hazardous materials to prevent ground, groundwater and surface water contamination (see BREF Sections 2.3.9 & 4.2.27).

4.3.2.17. Firewater Retention

Provide firewater retention facilities to retain contaminated firewater or surface water runoff in the event of a fire and prevent ground, groundwater and surface water contamination (see BREF Sections 2.3.9 & 4.2.28).

4.3.2.18. Training of Operators on Hazardous Materials

Provide training to operators to make them aware of hazards and ensure safe storage, handling and disposal of hazardous materials (see BREF Section 4.2.29 for example).

4.3.2.19. Storage and Handling of Hazardous Substances

Ensure proper procedures and facilities for the storage and handling of hazardous substances to prevent potential releases to the environment (see BREF Section 4.2.30 for example).

4.3.3. Management and Treatment of Residues

Note: BREF in this section means the IPPC Draft Reference Document on Best Available Techniques for the Manufacture of Organic Fine Chemicals, which provides information on treatment and recovery techniques for gaseous and aqueous residues in the organic fine chemicals sector. Further detailed descriptions on treatment and recovery techniques which are commonly applicable to the whole chemical manufacturing sector can be found in the IPPC Reference Document on Best Available Techniques in Common Waste Water and Waste Gas Treatment / Management Systems in the Chemical Sector.

4.3.3.1. Monitoring and Mass Balances

Conduct appropriate monitoring and analysis to characterise waste streams and prepare mass balances for individual substances. This will provide the necessary information for determining appropriate management, treatment and improvement strategies for the waste streams (see BREF Sections 2.4.1 & 4.3.1).

4.3.3.2. Recovery/Abatement of Residues from Unit Processes

Employ appropriate recovery and/or abatement techniques for residues (aqueous residues, exhaust gases, waste) from different unit processes (see BREF Section 4.3.2 for examples of recovery/abatement techniques for residues from specific unit processes (N-acylation, alkylation, condensation, diazotization & azo-coupling, halogenation, nitration, reduction, sulphonation, sulphochlorination)).

4.3.3.3. Recovery, Re-use and Recycling of Solvents

Recovery of solvents from solution or exhaust gases to minimise waste and emissions and allow for re-use / recycling. Purity requirements may restrict applicability in certain industrial sectors such as the manufacture of active pharmaceutical ingredients (see BREF Sections 2.3.10, 4.3.3, 4.3.4 & 4.3.5.9).

4.3.3.4. Treatment of Gaseous Residues

Employ appropriate technologies for treating/abating exhaust gas streams (see BREF Section 2.3.7):

- Recovery and/or scrubbing of HCl from exhaust gas (see BREF Sections 4.3.5.2 & 4.3.5.3)
- Absorption of excess chlorine from exhaust gas (see BREF Section 4.3.5.5)
- Recovery of bromine and HBr from exhaust gas (see BREF Section 4.3.5.4)
- Condensation of VOCs from reactors and distillations (see BREF Section 4.3.5.6)
- Thermal oxidation of VOCs with co-incineration of liquid waste (see BREF Section 4.3.5.7)
- Stream stripping of methanol from aqueous streams and thermal oxidation of methanol in exhaust gas (see BREF Section 4.3.5.9)
- Abatement and/or recovery of acetylene (see BREF Section 4.3.5.11)
- Catalytic oxidation of 1, 2-dichloroethane (see BREF Section 4.3.5.12)
- Non-thermal exhaust gas treatments (see BREF Section 4.3.5.14)
- Adsorption smoothing to minimise emission peaks (see BREF Section 4.3.5.16)
- Use of modular exhaust gas treatment set-up for multipurpose/multiproduct sites (see BREF Section 4.3.5.17)
- Abatement and/or recovery of NOx (see BREF Section 4.3.5.19)

- Scrubbing of NH_3 from exhaust gas (see BREF Section 4.3.5.20)
- Scrubbing of SOx from exhaust gas (see BREF Section 4.3.5.21)
- Particulate removal from exhaust gas (see BREF Section 4.3.5.22)
- Abatement and destruction of free cyanides (see BREF Sections 4.3.6.1 and 4.3.6.2).

4.3.3.5. Management and Treatment of Waste Water and Aqueous Residues

Employ appropriate technologies for treating/abating aqueous residues (see BREF Section 2.3.8):

- Consider toxicity, degradability and the refractory organic load of aqueous residues when determining treatment strategy (see BREF Sections 2.4.2.4 & 4.3.7.6 to 4.3.7.13)
- Determine appropriateness of on-site versus off-site treatment (see BREF Sections 4.3.8.3 to 4.3.8.5)
- Pretreatment of aqueous residues including pretreatment to protect biological waste water treatment plants (see BREF Sections 4.3.7.1 to 4.3.7.5, 4.3.8.7 & 4.3.8.9)
- Removal/Elimination of halogenated organic compounds from aqueous residues (see BREF Sections 4.3.7.14 to 4.3.7.20, & 4.3.8.12)
- Recovery of iodine from aqueous residues (see BREF Section 4.3.7.23)
- Removal of heavy metals from aqueous residues (see BREF Sections 4.3.7.21, 4.3.7.22 & 4.3.8.1)
- Segregation and discharge to sea of high salt content aqueous residues (see BREF Section 4.3.7.25)
- Abatement and destruction of free cyanides (see BREF Sections 4.3.6.1 & 4.3.6.2)
- Use of biological treatment for BOD and COD removal (see BREF Sections 4.3.8.6 to 4.3.8.8, 4.3.8.10 & 4.3.8.11)
- Use of biological treatment for nitrogen (N) removal (see BREF Sections 4.3.8.6, 4.3.8.8, 4.3.8.14 & 4.3.8.15)
- Segregation and disposal of residues containing high phosphorus (P) loads (see BREF Section 4.3.7.24)
- Use of biological treatment and/or chemical/mechanical treatment for phosphorus (P) removal (see BREF Sections 4.3.8.6, 4.3.8.16 & 4.3.8.17)
- Conduct appropriate level of effluent monitoring before, during and after treatment to provide the necessary information to operate the treatment plant, check effectiveness of treatment, indicate potential for improvement, and demonstrate compliance (see BREF Sections 4.3.8.13 & 4.3.8.18 to 4.3.8.20).

4.3.4. Environmental Management Tools

Establish and implement an Environmental Management System (EMS) (see BREF Section 4.4).

5. BEST AVAILABLE TECHNIQUES FOR PHARMACEUTICALS AND OTHER SPECIALITY ORGANIC CHEMICALS

5.1. INTRODUCTION

As explained in Section 2, this Guidance Note identifies BAT but obviously does so in the absence of site-specific information. Accordingly, it represents the requirements expected of any new activity covered by the Note, and ultimately the requirements expected of existing facilities, but exclude additional requirements which may form part of the granting of a licence for a specific site.

The technical feasibility of the measures listed below has been demonstrated by various sources. Used singly, or in combination, the measures represent BAT solutions when implemented in the appropriate circumstances. These circumstances depend on nature of process, plant scale, fuels used, etc.

5.2. PREVENTION OF ENVIRONMENTAL IMPACT

5.2.1. Integration of Environmental, Health & Safety (EHS) Considerations into Process Development

BAT is to develop new processes as follows (see BREF Section 4.1.1):

- Maximise efficient use of materials - improve process design to maximise the incorporation of all the input materials into the final product
- Use materials that possess little or no toxicity to human health and the environment
- Minimise energy requirements of process. Reactions at ambient temperatures and pressures should be considered where feasible
- Use renewable feedstock rather than depleting, where technically and economically practicable
- Avoid unnecessary derivatisation (e.g. blocking or protection groups)
- Use catalytic reagents which are typically superior to stoichiometric reagents in that less residues are generated where feasible
- Carefully choose the substances used in the chemical process in order to minimise potential for accidents, releases, explosions and fires.

BAT is to have EHS considerations integrated into process development where possible.

See BREF Section 4.1.4 for examples of alternative synthesis and reaction conditions.

5.2.2. Extraction from Natural Products

BAT is to:

- Select easily biodegradable solvents for extraction from natural products
- Use countercurrent band extraction for extraction from natural products

See BREF Section 4.1.5.

5.2.3. Process Safety and Prevention of Runaway Reactions

BAT is to carry out a structured safety assessment for normal operation and to take into account the effects of potential deviations in the chemical process and operation of the plant (see BREF Section 4.1.6).

BAT is to apply one or a combination of the following techniques to ensure the process is adequately controlled:

- Organisational measures
- Engineering controls
- Reaction stoppers (e.g. neutralization, quenching)
- Emergency cooling
- Pressure resistant construction
- Pressure relief.

BAT is to implement procedures and technical measures to limit risks from handling and storage of toxic substances (see BREF Section 4.2.30 for example).

BAT is to provide sufficient and adequate training of operators who handle toxic substances (see BREF Section 4.2.29 for example).

5.3. MINIMISATION OF ENVIRONMENTAL IMPACT

5.3.1. Plant Design

BAT is to design new plants to minimise environmental emissions by applying the following techniques (see BREF Section 4.2.1 for example):

- Use only closed and sealed equipment to minimise uncontrolled emissions
- Close the production building and ventilate it mechanically where feasible
- Use inert gas blanketing on process equipment where VOCs are handled
- Equip reactors with one or more condensers for solvent recovery and connect all condensers to the recovery/abatement system
- Where practicable, use gravity flow instead of pumps to minimise fugitive emissions
- Provide for the segregation and selective treatment of aqueous residues (see BREF Section 4.2.21)
- Use a modern process control system to enable a high degree of automation and ensure a stable and efficient operation.

5.3.2. Groundwater Protection and Water Retention Options (see BREF Sections 2.3.9 & 4.2.27)

BAT is to design, build, operate and maintain facilities, where substances (usually liquids) which represent a potential risk of contamination of ground and groundwater / surface waters, are handled in such a way that no spills occur. Facilities have to be sealed, stable and sufficiently resistant against possible mechanical, thermal or chemical stress.

BAT is to ensure leakages are quickly and reliably recognised.

BAT is to provide sufficient retention volumes to safely retain leaking substances in order to enable treatment or disposal.

BAT is to provide sufficient retention volume to safely retain fire fighting water and contaminated surface water.

BAT is to apply the following techniques:

- Carry out loading and unloading only in designated areas protected against leakage run-off
- Store and collect materials awaiting disposal in designated areas protected against leakage run-off
- Fit all pump sumps or other treatment plant chambers from which spillage might occur with high level liquid alarms or ensure regular supervision of same
- Establish programmes for testing and inspection of tanks and pipelines where tanks and pipes are not situated in bunded areas
- Inspect leaks on flanges and valves on pipes used to transport materials other than water (e.g. visual inspection or testing with water) and maintain a log of such inspections
- Provide supply containment booms and suitable absorbent material
- Test all bunded structures.

5.3.3. Minimisation of VOC Emissions

BAT is to apply the following techniques to minimise VOC emissions:

- Contain and enclose sources and close any openings to minimise uncontrolled emissions (see BREF Section 4.2.16 for example)
- Carry out drying by using closed circuits under an inert gas atmosphere, including condensers for solvent recovery where feasible
- Keep equipment closed for rinsing and cleaning with solvents
- Use vapour balancing.

See also BREF Sections 4.2.14 to 4.2.19, & 4.3.5.10.

5.3.4. Minimisation of Exhaust Gas Volume Flows and Loads

BAT is to close any unnecessary openings to prevent air being sucked into the gas collection system via the process equipment and thus minimise the volume flow (see BREF Section 4.2.16).

BAT is to ensure the tightness of process equipment, especially of vessels (see BREF Section 4.2.16).

BAT is to apply shock inertisation instead of continuous inertisation where feasible (see BREF Section 4.2.17).

BAT is to minimise the exhaust gas volume flows from distillations by optimising the layout of the condenser (see BREF Section 4.2.20).

BAT is to carry out liquid addition to vessels as bottom feed or with dip-leg where feasible (see BREF Section 4.2.18).

BAT is, unless reaction chemistry and/or safety considerations make it impractical, if both solids and an organic liquid are added to a vessel, to use solids as a blanket in circumstances where the density difference promotes the reduction of the organic load in the displace gas (see BREF Section 4.2.18).

BAT is to minimise the accumulation of peak loads and flows and related concentration peaks by:

- Process optimisation to equalize input to recovery / abatement systems (see BREF Section 4.3.5.16)
- Application of smoothing filters (see BREF Section 4.3.5.16).

5.3.5. Minimisation of Volume and Load of Aqueous Residues

BAT is to review processes and where feasible to retrofit in order to avoid mother liquors with high salt content or to enable the work-up of mother liquors by application of alternative separation techniques (e.g. membrane process, solvent based process, reactive extraction, or omit intermediate isolation) (see BREF Section 4.2.24).

BAT is to apply countercurrent product washing where the production scale justifies the introduction of the technique where feasible(see BREF Section 4.2.22).

BAT is to apply water-free vacuum generation where feasible (see BREF Sections 4.2.5 to 4.2.7).

BAT is to establish clear procedures for the determination of the completion of the reaction for batch processes (see BREF Section 4.2.23 for example).

BAT is to apply indirect cooling techniques (see BREF Section 4.2.9) where direct cooling techniques are not specifically required for process control.

BAT is to apply a pre-rinsing step prior to rinsing/cleaning of equipment to minimise organic loads in wash-waters (see BREF Section 4.2.12).

5.3.6. Minimisation of Energy Consumption

BAT is to assess and implement options to minimise energy consumption, e.g. apply pinch technology to optimise energy balance on production site (see BREF Section 4.2.10).

5.4. MANAGEMENT AND TREATMENT OF RESIDUES

5.4.1. Mass Balances and Process Waste Stream Analysis

BAT is to establish mass balances for VOCs (including chlorinated hydrocarbons), TOC or COD, AOX or EOX and heavy metals on a yearly basis (see BREF Sections 4.3.1.4 to 4.3.1.6).

BAT is to carry out a detailed waste stream analysis in order to identify the origin or the residues and a basic data set to enable management and suitable treatment of gaseous, aqueous and solid residues (see BREF Section 4.3.1.1).

BAT is to assess individual exhaust gas volume flows from process equipment to recovery/abatement systems (see BREF Section 4.3.1.7).

5.4.2. Re-Use of Solvents

BAT is to re-use solvents as far as purity requirements (e.g. cGMP requirements) allow, by:

- Use the solvent from previous batches of a production campaign for future batches (see BREF Sections 4.3.3 to 4.3.4)
- Collect spent solvents for on or off-site purification and re-use (see BREF Sections 4.3.3 to 4.3.4).

5.4.3. Treatment of Gaseous Residues

BAT is to individually monitor substances with ecotoxicological potential is such substances are released (see BREF Sections 4.3.1.8 & 5.2.1.1.4).

BAT is to monitor emission profiles, which reflect the operational mode of the production process (batch, semi-continuous, continuous) for gaseous emissions instead of monitoring levels for short sampling periods (see BREF Section 4.3.1.8 & 5.2.1.1.4).

5.4.3.1. Selection of VOC Recovery/Abatement Techniques and Achievable Emission Levels

With respect to recovery/abatement techniques for VOCs, BAT is to:

- Apply one or more condensers using temperatures suitable for the VOC in the gaseous residue concerned (see BREF Section 4.3.3 for example)
- Apply recovery/abatement techniques, such as scrubbing, cryogenic condensation, activated carbon adsorption, catalytic oxidation, and thermal oxidation/incineration or a combination of such techniques (see BREF Section 4.3.5.14) where the mass flows (kg/hour) detailed in Table 6.1 are not achievable by process optimisation or application of condensers
- Select higher recovery/abatement capacity or a more efficient recovery/abatement technique where the mass flows (kg/hour) detailed in Table 6.1 are not achievable (see BREF Section 4.3.5.14)
- Where catalytic or thermal oxidation (see BREF Sections 4.3.5.7, 4.3.5.8 & 4.3.5.12) is selected as a VOC abatement technique, catalytic oxidation is preferable with thermal oxidation advantageous if:
    - Autothermal operation is possible in normal operation, or
    - Autothermal operation can be enabled by stripping of organic compounds from aqueous residues, or
    - Overall reduction of primary energy consumption is possible (e.g. secondary heat option), or
    - The efficient destruction of the organic pollutants enables the recovery and market/re-use or other exhaust gas components (e.g. HCl or HBr), or
    - VOC loaded exhaust gases also require NOx abatement.

5.4.3.2. Recovery/Abatement of NOx

For thermal or catalytic oxidation/incineration, BAT is to minimise the NOx emissions and where necessary, to apply a DeNOx system (e.g. SCR or SNCR) (see BREF Sections 4.3.5.7 & 4.3.5.19).

For exhaust gases from chemical production processes, BAT is to minimise the NOx emissions and where necessary, to apply treatment techniques such as scrubbing or scrubber cascades with scrubber media such as H_2O and or H_2O_2 (see BREF Section 4.3.5.1).

5.4.3.3. Recovery/abatement of HCl, Cl_2 and HBr/Br_2

BAT is to minimise the HCl emissions and where necessary, to apply one or more scrubbers using scrubbing media, such as H_2O or NaOH (see BREF Section 4.3.5.3).

BAT is to minimise the Cl_2 emissions and where necessary, to apply techniques such as absorption of excess chlorine (see BREF Section 4.3.5.5) and/or scrubbing with scrubbing media such as $NaHSO_3$.

BAT is to minimise the HBr emissions and where necessary, to apply scrubbing (see BREF Section 4.3.5.4) with scrubbing media such as H_2O or NaOH.

5.4.3.4. Removal of NH_3 from Exhaust Gases

BAT is to minimise the NH_3 emissions and where necessary, to apply scrubbing with H_2O or acidic scrubbing media (see BREF Section 4.3.5.20).

5.4.3.5. Removal of SO_X from Exhaust Gases

BAT is to minimise the SO_X emissions and where necessary, to apply scrubbing with scrubbing media such as H^2O or NaOH (see BREF Section 4.3.5.21).

5.4.3.6. Removal of Particulates from Exhaust Gases

BAT is to minimise the particulate emissions and where necessary, to apply techniques such as bag filters, fabric filters, cyclones, scrubbing, or wet electrostatic precipitation (WESP) (see BREF Section 4.3.5.22).

5.4.4. Destruction of Free Cyanides

BAT is to recondition aqueous residues containing free cyanides in order to substitute raw materials where technically possible (see BREF Section 4.3.6.2).

BAT is to remove and destroy free cyanides from aqueous and gaseous residues (see BREF Sections 4.3.6.1 & 4.3.6.2), and to minimise the HCN waste gas emissions.

BAT is to minimise cyanide emissions in the treated aqueous residue (See BREF Sections 4.3.6.2 & 4.3.7.4).

5.4.5. Management and Treatment of Aqueous Residues

5.4.5.1. Segregation, Pretreatment and Disposal of Certain Aqueous Residues

BAT is to segregate and pretreat or dispose of:

- Mother liquors from halogenations (see BREF Sections 4.3.8.14 to 4.3.8.20), and
- Process waters, condensates and regenerates containing biologically active substances at levels which could pose a risk either to a subsequent waste water treatment or to the receiving environment after discharge (see BREF Sections 4.3.2.5, 4.3.7.5 & 4.3.7.9).

BAT is to segregate and collect separately spent acids (e.g. from sulphonations or nitrations) for on-site or off-site recovery unless it is not technically possible (see BREF Sections 4.2.24, 4.3.2.6 & 4.3.2.8).

5.4.5.2. Pretreatment of Residues with Relevant Refractory Organic Load

The refractory organic load of an aqueous residue passes through a biological WWTP more or less unchanged and therefore requires pretreatment prior to biological treatment (see BREF Sections 4.3.8.10 & 5.2.4.1). BAT is to:

- Segregate and pretreat aqueous residues containing relevant refractory organic loadings
- Classify as relevant those organic loadings which show a biodegradability of less than 80-90% (see BREF Sections 4.3.8.6 to 4.3.8.8) and/or carry a refractory organic load of about 7.5 – 40 kg TOC per batch per day (see BREF Sections 4.3.8.10, 4.3.8.12 & 4.3.8.13)
- For segregated waste streams carrying a relevant refractory organic load (see BREF section 5.2.4.2.1), BAT is to achieve overall COD elimination rates for the combination of pre-treatment and biological treatment of >95% (see BREF Section 5.2.4.2.3).

5.4.5.3. Removal of Solvents from Aqueous Residues

BAT is to:

- Recover solvents from aqueous residues for on-site or off-site re-use, using techniques such as stripping, distillation/rectification, extraction or combinations of such techniques where the costs for biological treatment and purchase of fresh solvents are higher than the costs for recovery and purification (see BREF Section 4.3.7.1).

5.4.5.4. Removal of Chlorinated Hydrocarbons (CHCs) from Aqueous Residues

BAT is to remove CHCs from aqueous residues (e.g. by stripping) to minimise the total concentration of CHCs at the inlet to the biological WWTP or at the inlet to the sewerage system (see BREF Sections 4.3.7.18 to 4.3.7.20).

5.4.5.5. Pretreatment of Residues Containing Adsorbable Organic Halogens (AOX)

BAT is to pretreat aqueous residues from processes with relevant AOX loads prior to the inlet to the biological WWTP or at the inlet to the sewerage system (see BREF Sections 4.3.7.15 to 4.3.7.17).

5.4.5.6. Pretreatment of Residues Containing Heavy Metals

BAT is to pretreat aqueous residues from processes where heavy metals are used intentionally and to minimise the heavy metal concentrations at the inlet to the biological WWTP or at the inlet to the sewerage system (see BREF Sections 4.3.7.3 & 4.3.7.22 for examples of pretreatment techniques).

5.4.5.7. Central Biological Waste Water Treatment Plant (WWTP)

BAT is to treat effluents containing a relevant organic load, such as aqueous residues from production processes, rinsing and cleaning water, in a central biological WWTP (see BREF Sections 4.3.8.6 to 4.3.8.8).

BAT is to minimise suspended solids, inorganic N, total P, heavy metal, AOX, and toxicity emissions.

5.5. ENVIRONMENTAL MANAGEMENT

BAT is to implement and adhere to an Environmental Management System (EMS) that incorporates, as appropriate to individual circumstances, a number of defined features (see BREF Sections 4.4 & 5.3 for a description of the key features in the EMS).

Further information on a number of waste gas and wastewater treatment techniques can be found in the BREF document on *Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector*, EIPPCB, February 2003.

6. BAT ASSOCIATED EMISSION LEVELS

6.1. EMISSION LEVELS FOR DISCHARGES TO AIR

Achievable emission levels for discharges to air based on BAT are given in Tables 6.1 to 6.2 below. The requirement for compliance with S.I. No 543 of 2002 - Emissions of Volatile Organic Compounds from Organic Solvents Regulations, 2002, need to be established by the licensee.

Table 6.1 BAT Associated Emission Levels for Emissions to Air*

Constituent Group or Parameter Note 1	**Class**	**Emission Level (mg/m^3)**	**Mass Flow Threshold** Note 2 **(g/hr)**
Carcinogenic Substances (Note 3)	**Class I (limits set for class total)** - arsenic and its compounds (except for arsine), as As - benzo(a)pyrene - cadmium and its compounds, as Cd - water-soluble compounds of cobalt, as Co - chromium (VI) compounds (except for barium chromate and lead chromate), as Cr	0.05	0.15
	Class II (limits set for class total) - acrylamide - acrylonitrile - dinitrotoluenes - ethylene oxide - nickel and its compounds (except for nickel metal, nickel alloys, nickel carbonate, nickel hydroxide, nickel tetracarbonyl) as Ni - 4-vinyl-1,2-cyclohexane-diepoxy	0.5	1.5
	Class III (limits set for class total) - benzene - bromoethane - 1,3-butadiene - 1,2-dichloroethane - 1,2-propylene oxide (1,2-epoxy propane) - styrene oxide - o-toluidine - trichloroethane - vinyl chloride	1	2.5

Organic Substances (Note 3)	**Class I (limits set for class total)** - Substances listed in Annex 1 - Substances not listed under their name in Annex 1 which comply with one of the following criteria as described in council Directive 67/548/EEC ; - R40, R62, R63 - They are toxic or very toxic (e.g. R26 R50, R54, R57,) - They may cause irreversible harm or damage (e.g. R39) - They may cause sensitisation when inhaled (e.g. R42) - They are highly odour intensive, - They are slowly degradable and accumulative (e.g. R33)	20	100
	Class II (limits set for class total) - 1-bromo-3-chloropropane - 1,1-dichloroethane - 1,2-dichloroethylene,cis and trans - ethanoic acid - methyl formiate - nitroethane - nitromethane - octamethylcyclotetrasiloxane - 1,1,1-trichloroethane - 1,3,5-trioxane	100	500
Total Organic Carbon (As C)	Not included in Class I or II above **(limits set for class total)**	50	500
Mercaptans		2	100
Amines (total)		10	100
Trimethylamine		2	100
Phenols, Cresols & xylols		2	100
Toluene di-isocyanate		1	100
Organic Substances with Photochemical Ozone Potential (R59)		20	500
Vaporous or Gaseous Inorganic Substances	**Class I (limits set on a per substance basis)** - arsine - cyanogen chloride	0.5	2.5

Note 2	- phosgene - phosphine		
	Class II (limits set on a per substance basis) - bromine and its gaseous compounds, as hydrogen bromide - chlorine - hydrocyanic acid (HCN) - fluorine and its gaseous compounds, as HF - hydrogen sulphide	3	15
	Class III (limits set on a per substance basis) - ammonia - gaseous inorganic compounds of chlorine, as HCl	30	150
	Class IV (limits set on a per substance basis) - sulphur oxides (sulphur dioxide and sulphur trioxide), as SO_2 - nitrogen oxides (nitrogen monoxide and nitrogen dioxide), as NO_2	350	1800
Inorganic Dust Particles (Note 3)	**Class I (limits set on a per substance basis)** - mercury and its compounds, as Hg - thallium and its compounds, as Tl	0.05	0.25
	Class II (limits set for class total) - lead and its compounds, as Pb - cobalt and its compounds, as Co - nickel and its compounds, as Ni - selenium and its compounds, as Se - tellurium and its compounds, as Te	0.5	2.5
	Class III (limits set for class total) - antimony and its compounds, as Sb - chromium and its compounds, as Cr - easily soluble cyanides (e.g. NaCN), as CN - easily soluble fluorides (e.g. NaF), as F - copper and its compounds, as Cu - manganese and its compounds, as Mn - vanadium and its compounds, as V - tin and its compounds, as Sn - Other substances with risk phrases R40, R62 or R63	1	5
Total Particulates		20	200
Dust - pharmaceutical		0.15	1
Other			Note 4

* For existing activities, BAT associated emission levels shall as a minimum, be considered TA Luft (Technical Instructions on Air Quality Control - TA Luft in accordance with art. 48 of the Federal Immission Control Law (BImSchG) dated 15 March 1974 (BGBI. I p.721). Federal Ministry for Environment, Bonn 1986, including the amendment for Classification of Organic Substances according to section 3.1.7 TA.Luft, published in July 1997).

Note 1: Where a substance falls into more than one category in Table 6.1, the lower emission limit value applies.

Note 2: The Mass Flow Threshold is calculated in g/hr or kg/hr and is determined to be the maximum emission which can occur over any one hour period of plant operation. Where the Mass Flow in the raw gas exceeds the mass flow threshold given in the Table, abatement will be required to reduce the emission to below the appropriate emission level or mass flow threshold.

Note 3: Where substances of several classes are present, in addition to the above limit, the sum of Classes I & II shall not exceed the Class II limit and the sum of Classes I & III, II &III or I, II & III shall not exceed the Class III limit.

Note 4: Any relevant polluting substances as specified in Schedule to S.I. No. 394 of 2004: EPA (Licensing)(Amendment) Regulations, 2004.

Table 6.2 Statutory Emission Limit Values (1) for VOCs for Installations Manufacturing Pharmaceutical Products Which Use Greater than 50 Tonnes of Solvents per Year (Extract from S.I. No 543 of 2002 - Emissions of Volatile Organic Compounds from Organic Solvents Regulations, 2002)

Activity **(Solvent Consumption in tonnes/year)**	**Emission Limit Values in Waste Gases (mg/C/Nm) (2)-**	**Fugitive Emission Values (Percentage of Solvent Input) (3,4)**	**Total Emission Limit Values (5)**
Manufacturing of Pharmaceutical Products (> 50)	20	New Installation: 5% Existing Installation: 15%	New Installation: 5% of Solvent Input Existing Installation: 15% of Solvent Input

Note 1: Installations must either comply with the requirements of the solvent reduction scheme specified in Schedule 3 of the Regulations or the emission limit values in waste gases and the fugitive emission values, or the total emission limit values, and other requirements specified in Schedule 2 of the Regulations (Table 6.2 is extract from Schedule 2). An existing installation shall comply with the requirements of Schedule 2 of the regulations no later than 31 October 2007. Any abatement equipment installed on or after 1 July 2003 in a new installation, or on or after 1 November 2007 in an existing installation, shall meet the relevant requirements of Schedule 2.

Note 2: If techniques are used which allow reuse of recovered solvent, the emission limit value shall be 150mg/m^3.

Note 3: The fugitive emission limit value does not include solvent sold as part of products or preparations in a sealed container.

Note 4: Fugitive emission values shall be applied to installations as an emission limit value. Where the operator demonstrates to the satisfaction of the EPA that for an individual installation this emission limit value is not technically and economically feasible, and provided the operator demonstrates to the satisfaction of the EPA that the installation provides no significant risk to human health or the environment and that the best available technique is being used at the installation, the EPA may exempt the installation from this requirement.

Note 5: An existing installation which operates existing abatement equipment and complies with:
(a) the emission limit value of 50 mg C/Nm^3 in the case of incineration; or
(b) the emission limit value of 150 mg C/Nm^3 in the case of any other abatement equipment:
shall be exempt from the waste gases emission limit values set out in Schedule 2 until 1 April 2013, provided the total emissions of the whole installation do not exceed those that would have resulted had all the requirements of Schedule 2 been met.

For any substance or preparation classified as a carcinogen, mutagen or toxic to reproduction or assigned the risk phrases R45, R46, R49, R60, R61 and where the mass flow of the sum of the compounds is greater than or equal to 10 g/hr, an emission limit value, referring to the mass sum of the individual compounds, of 2 mg/Nm^3 shall be complied with. The emission limit value applies even if the installation has implemented a solvent reduction scheme as specified in Schedule 3 of the Regulations.

For halogenated VOCs assigned the risk phrase R40, where the mass flow of the sum of the compounds is greater than or equal to 100 g/hr, an emission limit value, referring to the mass sum of the individual compounds, of 20 mg/Nm^3 shall be complied with. The emission limit value applies even if the installation has implemented a solvent reduction scheme as specified in Schedule 3 of the Regulations.

6.2. EMISSION LEVELS FOR DISCHARGES TO WATER

The following table sets out emission levels that are achievable using BAT for wastewater treatment. However establishing emission limit values within a licence for direct discharges to surface water from wastewater treatment plant and stormwater discharges must ensure that the quality of the receiving water is not impaired or that the current Environmental Quality Standards (EQS) are not exceeded.

All discharges to sewer are subject to approval from the Water Services Authority.

Compliance with the Water Framework Directive (2000/60/EC) is required where relevant, in particular Article 16.

Table 6.3 BAT Associated Emission Levels for Discharges to Water *

Constituent Group or Parameter	Emission Levels (mg/l)	Percentage Reduction[3]	Notes
pH	6 - 9		
Toxicity	5 -10 TU		1
BOD_5	20	>91 - 99%	
COD	30 - 250	>75%	
Suspended Solids	10 - 35mg/l		
Total Ammonia (as N)	10mg/l		
Total Nitrogen (as N)	5 - 25mg/l	>80%	2,4
Total Phosphorus (as P)	2mg/l	>80%	4
Oils Fats and Greases	10mg/l		
Mineral Oil (from interceptor)	20mg/l		
Mineral Oil (from biological treatment)	1.0mg/l		
Phenols			5
Metals			5
Organohalogens			5
Priority Substances (as per Water Framework Directive)			5
Cyanides			5
Other			5, 6

* All values refer to daily averages based on a 24-hour flow proportional composite sample, except where stated to the contrary and for pH, which refers to continuous values. Levels apply to effluent prior to dilution by uncontaminated streams, e.g. storm water, cooling water, etc.

* Temperature measured downstream of a point of thermal discharge must not exceed the unaffected temperature by more than 1.5^{o}C in salmonid waters and 3^{o}C in cyprinid waters (Freshwater Fish Directive 79/659/EEC).

Note 1: The number of toxic units (TU) = 100/x hour EC/LC50 in percentage vol/vol so that higher TU values reflect greater levels of toxicity. For test regimes where species death is not easily detected, immobilisation is considered equivalent to death.

Note 2: Total Nitrogen means the sum of Kjeldahl Nitrogen, Nitrate N and Nitrite N.

Note 3: Reduction in relation to influent load.

Note 4: Limits will depend on the sensitivity of the receiving waterbody.

Note 5: BAT associated emissions levels are highly dependent on production process, wastewater matrix and treatment. These parameters shall be considered on a site-specific basis when setting emission limit values.

Note 6: Any relevant polluting substances as specified in Schedule to S.I. No. 394 of 2004: EPA (Licensing)(Amendment) Regulations, 2004.

7. COMPLIANCE MONITORING

The methods proposed for monitoring the emissions from the sector are set out below. Licence requirements may vary from those stated below due to site-specific considerations, sensitivity of receiving media, and scale of the operations.

7.1. MONITORING OF EMISSIONS TO AIR

- Monitoring of minor boiler stack emissions for SOx, NOx, CO and particulates, as required by the licence, taking account of the nature, magnitude and variability of the emission and the reliability of the controls.
- Monitoring of boiler combustion efficiency in accordance with the manufacturer's instructions at a frequency determined by the Agency.
- Annual monitoring of driers, filter exhausts and powder transfer or conditioning units for particulates – $PM_{10.}$
- Continuous monitoring on main emissions where technically feasible (e.g. TOC, HCl, Particulates, CO, SO_2, NOx).
- Periodic monitoring of stacks for other parameters as determined by the Agency.
- Monitor solvent / VOC usage by annual mass balance reports (for example refer to methodology described in Schedule 6 of the Solvents Regulations S.I. 543 of 2002) and use to determine fugitive emissions.
- Olfactory (sniff) assessment for odours should be carried out daily or as directed by the Agency at a minimum at four boundary locations and at the nearest odour sensitive locations to be agreed with the Agency.

7.2. MONITORING OF AQUEOUS EMISSIONS

- For uncontaminated cooling waters, continuous monitoring of temperature and flow.
- Continuous monitoring of flow, volume, pH, temperature and any other relevant parameters deemed necessary by the Agency, taking account of the nature, magnitude and variability of the emissions and the reliability of the control technique.
- Establish existing conditions prior to start-up of key emission constituents and salient flora and fauna.
- Monitoring of influent and effluent for the waste water treatment plant to establish % BOD and COD reduction and early warning of any difficulties in waste water treatment, or unusual loads.
- The potential for the treated effluent to have tainting and toxic effects should be assessed and if necessary measured by established laboratory techniques.
- Periodic biodegradability checks where appropriate on effluents to municipal waste treatment plants, both prior to start-up and thereafter.
- BAT is to carry out regular biomonitoring of the total effluent after the biological WWTP where substances with ecotoxicological potential are handled or produced with or without intention. BAT is also to apply online toxicity monitoring in combination with online TOC measurement if residual acute toxicity is identified as a concern.
- BAT is to monitor regularly the total effluent from and to the biological WWTP for appropriate parameters. The monitoring frequencies should reflect the

operational mode of the production and the frequency of product changes as well as the ratio of buffer volume and residence time in the biological WWTP.

7.3. MONITORING OF EMISSIONS TO GROUNDWATER

There should be no direct emissions to groundwater, including during extraction and treatment of groundwater.

7.4 MONITORING OF SOLID WASTE

- The recording in a register of the types, quantities, date and manner of disposal/recovery of all wastes.
- Leachate testing of sludges and other material as appropriate being sent for landfilling.
- Annual waste minimisation report showing efforts made to reduce specific consumption together with material balance and fate of all waste materials.

Appendix 1

PRINCIPAL REFERENCES

1. EUROPEAN COMMISSION

1.1 European Commission (December 2004) IPPC Reference Document on Best Available Techniques for the Manufacture of Organic Fine Chemicals.

1.2 European Commission (February 2003) IPPC Reference Document on Best Available Techniques in Common Waste Water and Waste Gas Treatment / Management Systems in the Chemical Sector.

1.3 Council Directive 96/61/EC of 24 September 1996 concerning Integrated Pollution Prevention and Control.

2. IRELAND

2.1 Environmental Protection Agency (May 1996) Integrated Pollution Control Licensing - BATNEEC Guidance Note for the Chemical Sector.

2.2 Environmental Protection Agency (1995) Guidance Note for Noise in Relation to Scheduled Activities.

2.3 Environmental Protection Agency Guidance Note For Noise in Relation to Scheduled Activities - 2ND Edition (2006).

2.4 Environmental Protection Agency (2003) Environmental Noise Survey Guidance Document.

Appendix 2

GLOSSARY OF TERMS AND ABBREVIATIONS

AOX	Adsorbable Organic Halogens
BAT	Best Available Technique
BATNEEC	Best Available Technology Not Entailing Excessive Costs
BOD	Biological Oxygen Demand
BREF	Reference document on Best Available Techniques for the Manufacture of Organic Fine Chemicals published in draft format by the European Commission in December 2004
cGMP	Current Good Manufacturing Practice
CHC	Chlorinated Hydrocarbon
CO	Carbon Monoxide
COD	Chemical Oxygen Demand
DeNOx	Elimination of Nitrogen Oxides from Waste Gas
EHS	Environmental, Health & Safety
ELV	Emission Level Value
EMS	Environmental Management System
EOX	Extractable Organic Halogens
EPA	Environmental Protection Agency
g	Gram
IPC	Integrated Pollution Control
IPPC	Integrated Pollution Prevention & Control
kg	Kilogram
K	Degree Kelvin ($0^{o}C = 273.15K$)
m^3	Cubic metre
mg	Milligram
N_2	Nitrogen
Nm^3	Normal cubic metre (101.3 kPa, 273 K)
NH_3	Ammonia
NO_2	Nitrogen dioxide
NO_x	Oxides of nitrogen
SCR	Selective Catalytic Reduction
SNCR	Selective Non-Catalytic Reduction

SO_2	Sulphur dioxide
SO_x	Oxides of sulphur
t	Tonne (metric)
TOC	Total Organic Carbon
VOC	Volatile Organic Compound
WESP	Wet Electrostatic Precipitation
WWTP	Waste Water Treatment Plant

Annex 1

ORGANIC SUBSTANCES OF CLASS I PURSUANT TO TABLE 6.1

Substance	CAS–Number
1,1,2,2-Tetrabromoethane	79–27–6
1,2,3-Propanetriol, trinitrate	55–63–0
1,2,4-Benzenetricarboxylic acid	528–44–9
1,2-Benzenediol (Pyrocatechin)	120–80–9
1,2-Ethanediamine, N-(2-aminoethyl)-	111–40–0
1,2-Ethanediol, dinitrate	628–96–6
1,2-Propanediol, dinitrate	6423–43–4
1,3-Butadiene, 1,1,2,3,4,4-hexachloro–	87–68–3
1,3-Propanediamine	105–83–9
1,4-Dioxane	123–91–1
1,5-Naphthalenediamine	2243–62–1
1,6-Hexamethylene diisocyanate	822–06–0
1,6-Hexanediamine	124–09–4
1-Butanamine,	109–73–9
1-Butanethiol	109–79–5
1-Naphthalenamine	134–32–7
1-Propene, 3-chloro-2-methyl-	563–47–3
2,4,7-Trinitrofluorenone	129–79–3
2,5-Furandione	108–31–6
2-Butenal (Crotonaldehyde)	123–73–9
2-Butyne-1,4-diol	110–65–6
2-Chloro-1,3-butadiene (Chloroprene)	126–99–8
2-Cyclohexen-1-one, 3,5,5-trimethyl–	78–59–1
2-Ethoxyethyl acetate	111–15–9
2-Furancarboxaldehyde (Furfural)	98–01–1
2-Furanmethanamine	617–89–0
2-Hexanone	591–78–6
2-Imidazolidinethione	96–45–7
2-Methyl-m-phenylenediamine	823–40–5

Substance	CAS–Number
2-Naphthyl phenyl amine	135–88–6
2-Nitro–p–phenylenediamine,2	5307–14–2
2-Propanamine, 2-methyl-	75–64–9
2-Propenal (Acrolein, Acrylaldehyde)	107–02–8
2-Propenoic acid, butyl ester	141–32–2
2-Propenoic acid, ethyl ester (Ethyl acrylate)	140–88–5
2-Propenoic acid, methyl ester	96–33–3
2-Propyn-1-ol	107–19–7
3,3'-Diamino-benzidine	91–95–2
4,4'-Methylenebis(2-methylcyclohexylamine)	6864–37–5
4-Amino-2-nitrophenol	119–34–6
4-Methyl-3-oxa-1-pentanol	109–59–1
4-Tert-butyltoluene	98–51–1
Acetaldehyde	75–07–0
Acetamide	60–35–5
Acetamide, N-phenyl–	103–84–4
Acetic acid anhydride	108–24–7
Acetic acid ethenyl ester	108–05–4
Acetic acid, chloro-	79–11–8
Acetic acid, chloro-, methyl ester	96–34–4
Acetic acid, methoxy-	625–45–6
Acetic acid, trichloro–	76–03–9
Acrylic acid	79–10–7
Alkyl-lead compounds	
Aniline	62–53–3
Aniline, N-methyl-	100–61–8
Benzenamine, 2,4-dimethyl–	95–68–1
Benzenamine, 2-methyl-5-nitro-	99–55–8
Benzenamine, 4-methoxy-	104–94–9
Benzenamine, 5-chloro-2-methyl-	95–79–4
Benzenamine, N,N-dimethyl-	121–69–7
Benzene, (dichloromethyl)-	98–87–3
Benzene, 1,1'-methylenebis[4-isocyanato-	101–68–8
Benzene, 1,2,4,5-tetrachloro–	95–94–3

Substance	CAS–Number
Benzene, 1-chloro-2-nitro	88–73–3
Benzene, 1-chloro-4-nitro-	100–00–5
Benzene, 1-methyl-3-nitro–	99–08–1
Benzene, 1-methyl-4-nitro–	99–99–0
Benzene, 2,4-dichloro-1-methyl-	95–73–8
Benzene, nitro-	98–95–3
Benzenesulfonyl chloride	98–09–9
Benzoyl chloride	98–88–4
Benzoyl peroxide	94–36–0
Biphenyl (Diphenyl)	92–52–4
Bis(2-ethylhexyl)phthalate	117–81–7
Butylamine, iso–	78–81–9
Camphor	76–22–2
Caprolactam	105–60–2
Carbamic chloride, diethyl-	88–10–8
Carbon tetrachloride	56–23–5
Carbonyl sulfide	463–58–1
Chloroacetic acid isopropyl ester	105–48–6
Chloroform (Trichloromethane)	67–66–3
Chloromethane	74–87–3
Chloropicrin (Trichloronitromethane)	76–06–2
Diaminoethane (Ethylenediamine)	107–15–3
Dichlorophenols	
Diglycidyl ether	2238–07–5
Diisocyanattoluol,2,6–	91–08–7
Di-n-butyltindichloride	683–18–1
Dinitronaphthalene (all isomers)	27478–34–8
Diphenyl ether	101–84–8
Diphenylamine	122–39–4
Diphenylmethane–2,4´–Diisocyanate	5873–54–1
Ethanamine, N-ethyl-	109–89–7
Ethane, 1,1,2,2-tetrachloro–	79–34–5
Ethane, 1,1,2-trichloro–	79–00–5
Ethane, 1,1-dichloro-1-nitro-	594–72–9

Substance	CAS–Number
Ethane, hexachloro-	67–72–1
Ethane, pentachloro-	76–01–7
Ethanedial (Glyoxal)	107–22–2
Ethanethiol (Ethyl mercaptan)	75–08–1
Ethanol, 2-chloro-	107–07–3
Ethanolamine	141–43–5
Ethene, 1,1-dichloro-	75–35–4
Ethene, 1,1-difluoro- (Genetron 1132a)	75–38–7
Ethyl chloride	75–00–3
Ethyl chloroacetate	105–39–5
Ethylamine	75–04–7
Ethylene	74–85–1
Formaldehyde	50–00–0
Formamide	75–12–7
Formic acid	64–18–6
Glutaral	111–30–8
Hexahydrophthalic Anhydride	85–42–7
Hexanoic acid, 2-ethyl-	149–57–5
Hydrazine, phenyl-	100–63–0
Hydroquinone (1,4-Benzenediol)	123–31–9
Isophorone diisocyanate	4098–71–9
Ketene	463–51–4
Kresole	1319–77–3
Lead acetate (monobasic)	1335–32–6
Mecrylate	137–05–3
Methanamine, N-methyl-	124–40–3
Methane, isocyanato-	624–83–9
Methane, tribromo–	75–25–2
Methanethiol (Methyl mercaptan)	74–93–1
Methyl bromide	74–83–9
Methyl chloride	107–05–1
Methyl iodide	74–88–4
Methylamine	74–89–5
Methylene chloride	75–09–2

Substance	CAS–Number
m-Nitroaniline	99–09–2
Montanic acid waxes, Zn–salts	73138–49–5
Morpholine	110–91–8
N,N,N',N'',N''- Pentamethyldiethylenetriamine	3030–47–5
Naphthalene, 1,5-diisocyanato-	3173–72–6
Nitrocresols	
Nitrophenols	
Nitropyrenes	5522–43–0
Nitrotoluene (all isomers)	1321–12–6
N-Methyl-N,2,4,6-tetranitroaniline (tetryl)	479–45–8
N-Vinylpyrrolidone	88–12–0
o-Nitroaniline	88–74–4
Oxalic acid	144–62–7
p-Benzoquinone	106–51–4
Pentachloronaphthalene	1321–64–8
Phenol	108–95–2
Phenol, 2,4,5-trichloro–	95–95–4
Phenol, p-tert-butyl	98–54–4
Phenyl–1–(p–tolyl)–3–dimethylaminopropane,1–	5632–44–0
Phthalic anhydride	85–44–9
Phthalonitrile	91–15–6
Piperazine	110–85–0
p-Nitroaniline	100–01–6
Propane, 1,2-dichloro-	78–87–5
Propane, 1-bromo-	106–94–5
Propanoic acid, 2,2-dichloro-	75–99–0
p-Toluidine	106–49–0
Pyridine	110–86–1
Sodium chloroacetate, Sodium salts	3926–62–3
Sodium Trichloroacetate	650–51–1
Tetrachloroethylene	127–18–4
Thioalcohols	
Thioethers	
Thiourea	62–56–6

Substance	CAS–Number
Toluene-2,6-diisocyanate-	584–84–9
Trichloroaphtalene	1321–65–9
Trichlorobenzenes (all isomers)	12002–48–1
Trichloroethylene	79–01–6
Trichlorophenols	
Tricresyl phosphate (ooo,oom,oop,omm,omp,opp)	78–30–8
Triethylamine	121–44–8
Trimellitic anhydride	552–30–7
Tri-n-butylphosphate	126–73–8
Trinitrotoluene (TNT)	118–96–7
Xylenols (except for 2,4–Xylenol)	1300–71–6