

Chemicals and Pharmaceuticals

Introduction

This Environmental and Social Risk Briefing (ESRB) covers Chemicals and Pharmaceuticals. Both industries manufacture products that are effectively the basis for almost every other manufacturing activity. It is therefore, a highly complex sector.

Chemicals and Pharmaceuticals

The industries includes the manufacture of paints, medicines, fertilisers, pesticides and other agro-chemicals, animal health products, water treatment materials, colouring agents, man-made fabrics, detergents, disinfectants, polishes and cleansers, cosmetics and toiletries. While potentially considered a service industry, due to the intensive use of hazardous chemicals, Laundries and Dry Cleaning has been included in this ESRB.

For the purposes of this ESRB, Chemicals and Pharmaceuticals sector is subdivided as follows:

- ◆ Chemicals manufacture;
- ◆ Pharmaceuticals manufacture;
- ◆ Fertilisers and pesticides manufacture; and
- ◆ Research and Development;
- ◆ Chemical Storage and Hazard Management; and
- ◆ Laundries and Dry Cleaning.

Chemicals Manufacture

Chemicals manufacture is the processing of raw materials or other chemical feedstocks into a product or series of products. The processing may involve a chemical reaction or simply the mixing of feedstocks which when combined exhibit different physical properties than the raw materials individually.

Effective process control is required to ensure that appropriate conditions are maintained throughout the process. Ineffective process control can result in explosions. Poor process control might result in the generation of products that do not display desired characteristics.

Chemical manufacturing processes may be relatively simple, single reactions or alternatively require a series of complex reactions with by-products being generated at each stage. By-products may be sold as products in their own right with or without further processing or be managed as a waste product.

Low margin chemical products will typically be manufactured through bulk processes with the resulting requirement for bulk storage and transfer of raw materials, products and potentially by products. The scale of processing for high margin chemical products may be considerably smaller with the majority of storage occurring in small tanks or drums.

The management of liquid or gaseous chemicals may be considered as more significant in terms of environmental and / or social risks (e.g. emissions to air, land and / or water) but it is important to note that there can also be inherent risks in plants managing bulk powders (e.g. explosions).

Pharmaceuticals Manufacture

Many different biological and chemical substances are discovered, developed and used in the manufacture of pharmaceuticals. Biological substances (e.g. bacteria and viruses) are used in applications such as vaccine production, fermentation and biotechnology. Many agents used in pharmaceutical research and development and manufacturing are potentially hazardous to workers.

Pharmaceutical manufacturing includes extraction, processing, purification, and packaging of chemical materials to be used as medications. The major manufacturing stages are primary processing, which is the production of the active ingredient or drug and secondary processing, which is the conversion of the active ingredient into products suitable for administration. These manufacturing stages generate air emissions, liquid effluents and / or solid wastes.

Pharmaceutical products are available as tablets, capsules, liquids (in the form of solutions, suspensions, emulsions, gels, or injectables),

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creams (usually oil-in-water emulsions), ointments (usually water-in-oil emulsions) and aerosols, which contain inhalable products or products suitable for external use. In the past chlorofluorocarbons (CFC) were used as the primary aerosol propellant but now, butane is more commonly used.

In many pharmaceutical production operations, a high degree of automation is used including milling to reduce bulk chemicals to the required size, mixing and tablet capsulation, pressing, printing and coating. Machines also fill, seal, label, and package the bottles.

Quality control of the pharmaceuticals manufacturing process from raw material supply to finished product and testing is extremely onerous as the products are for human consumption. Hygiene and cleanliness requirements are very strict.

Pesticides and Fertilisers Manufacture

A pesticide may be a chemical substance (most commonly hydrocarbons derived from petroleum) or biological agent (such as a virus or bacteria) used against pests, such as insects, plant pathogens and microbes. There are three main types of chemical pesticides:

- ♦ Chlorinated hydrocarbons (e.g. DDT) - long life and have the capacity of being

concentrated in the food chain for extensive periods of time;

- ♦ Organophosphates - short lived and degrade to harmless end products; and
- ♦ Artificial pyrethrums - originally based on natural sources but now synthesised in very large amounts.

Each of the principle manufacturing steps may generate air emissions, liquid effluents and / or solid wastes.

Pesticide Formulation

Pesticide formulation produces a product that has optimum biological efficiency, is convenient to use and minimizes environmental impacts. The active ingredients are mixed with solvents, adjuvants (boosters) and fillers as necessary to achieve the desired formulation for controlled release into the environment. The formulation steps may generate air emissions, liquid effluents and / or solid wastes.

Fertiliser Manufacture

Fertilisers are organic or inorganic compounds applied to plants with the intention of promoting growth. Such compounds can be naturally occurring (peat or mineral deposits), manufactured through natural processes (composting) or chemical processes.

There are three different phases in the production of solid fertiliser (a) the conversion of the raw

material plant foods from the form in which they exist naturally to a usable form (using air, steam and a fuel); (b) combining the individual plant foods into the desired mixture (blending); and (c) particle formation, in which solid fertilisers are assembled into granules or prills (involves heating and drying).

Research and Development

There is significant research and development activity within the Chemicals and Pharmaceuticals industry. A controversial activity associated with research is animal testing / animal research being the use of non-human animals in experiments. There is evidence of investors in companies, active in or using third parties involved in animal testing, being targeted by animal rights campaigners. Proponents argue however, that animal research has played a vital role in many major medical advances of the last century - for both human and animal health. Animal rights groups and critics have questioned whether animal research was necessary to achieve these results.

Chemicals Management

Sound management of chemicals includes addressing transport, storage and handling issues.

Chemicals should only be transported in purpose designed vehicles that are clearly labelled as hazardous materials transport vehicles. Drivers should be appropriately trained and transport

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companies fully and appropriately registered / licensed. Transport routes should be selected so as to avoid as far as possible built up and urbanised areas. Copies of the latest version of MSDS should accompany the chemicals during transportation.

Chemical storage areas should be secure (i.e. fenced and lockable), bunded sites with appropriate hazardous material signage. All stored chemicals should be inventoried and current MSDS kept at hand. Procedures for emergency response should be clearly indicated including emergency contact numbers. Spill clean-up material and equipment should be readily accessible.

Personnel handling hazardous chemicals should always wear appropriate PPE and should be fully trained in both handling procedures and emergency response.

Laundries and Dry Cleaning

Despite the name, dry cleaning uses a liquid solvent (not water) in which items being cleaned are fully immersed. Historically, dry cleaning used a variety of solvents including kerosene.

Process

There are two basic types of dry cleaning systems, "transfer" and "dry-to-dry". In transfer systems, garments are immersed in a solvent and then

transferred by the operator to a drying machine. In dry-to-dry system, the garments are immersed in a solvent, the solvent is extracted and the garment dried all in one machine.

Dry cleaning machines hold 9kg to 45kg of cleaning items in a rotating, perforated stainless-steel basket. As items rotate in the perforated basket, a constant flow of clean solvent from the pump and filter system is injected. The solvent sprays into the chamber constantly immersing the items. Dirty solvent is pumped continuously through the filter and re-circulated. The next cycle drains and rapidly spins the items to expel the solvent then moves to a dry cycle by circulating warm air. Fumes and solvent are vaporized, taken off and condensed over cooling coils. Distilled solvent is subsequently separated from any water that may have condensed during the process.

Specialised "wet cleaning" processes are gradually replacing traditional dry cleaning processes for delicate fabrics. Wet cleaning is a system that uses water and biodegradable soap. Computer-controlled dryers and stretching machines ensure that the fabric retains its natural size and shape.

At the end of the cleaning process, solvents are separated from wastewater by distillation. In the past, the wastewater was often poured down floor drains but today it is typically collected and evaporated or removed by hazardous waste contractors.

Solvents

The most commonly used solvent in the dry cleaning process is perchloroethylene, or "perc", a clear, colourless liquid that has a sharp, sweet odour and evaporates quickly. The benefits of perc are that it removes stains and dirt from all common types of fabrics, usually does not cause clothes to shrink nor dyes or bleeds them, is not flammable, can be reused and is efficient and cost-effective. Perc is however, a toxic chemical.

Perc can get into the air, water and ground during the cleaning, purification and waste disposal phases of dry cleaning. Once outdoors, perc can remain in the atmosphere for several weeks but perc itself does not deplete the ozone layer of the atmosphere - after a few weeks, it breaks down into other chemicals, some of which are toxic and some of which are suspected to deplete the ozone layer.

Perc is known to be toxic to plants. It can enter the ground in liquid form through spills, leaky pipes, leaky tanks, machine leaks and from improperly handled waste. A small amount of perc can contaminate a large amount of water. Small amounts of perc in the water have been shown to be toxic to aquatic animals that can store the chemical in their fatty tissues.

People can be exposed to perc by drinking or using contaminated water. People exposed to high levels of perc, even for brief periods, may

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experience serious symptoms including dizziness, fatigue, headaches, confusion, nausea and skin, lung, eye and mucous membrane irritation. Repeated exposure to high levels can also irritate the skin, eyes, nose and mouth, and can cause liver damage and respiratory failure.

Petroleum Solvents

Petroleum solvents are highly flammable and therefore operations using this solvent must also have more advanced fire prevention measures. The solvent is lighter than water and the two mix easily making separation from wastewater more difficult. There is also a need for higher temperatures to dry and deodorize the garments thus potentially increasing energy consumption.

Other Solvents

Two other relatively new solvents in the dry cleaning process include

- ♦ **Silicone and Liquid CO₂ Solvents:** use of both liquid carbon dioxide (usually obtained

as a recycled by-product of other industrial processes) and silicone - dry cleaners using these solvents are currently few in number; and

- ♦ **Alternative Petroleum Solvents:** more akin to standard dry cleaning processes but uses alternative hydrocarbon solvents such as "Exxon DF-2000" or Chevron-Phillips' "EcoSolv" - these alternative solvents tend to be much less effective than the typically used perc and are very flammable.

Other potential pollutants arising from the dry cleaning process include chlorofluorocarbons (CFC) and hydrochlorofluorocarbons (HCFC), both of which are ozone "depleters".

Dry Cleaning Wastes

Wastewater from dry-cleaners ideally is discharged direct to public sewer system. At some larger sites, wastewater may be subject to a degree of pre-treatment prior to discharge as large volumes of wastewater with elevated concentrations of contaminants may adversely

affect sewage treatment processes within the sewage treatment plant.

Other wastes produced by the dry-cleaning process consist of insoluble materials, such as extracted dirt / soil and filter powder, soluble fats and mineral oils, together with small quantities of spotting chemicals water and solvent residues which have not been recycled.

The waste material generated by cooking down or distilling muck is called Cooked Powder Residue which is a hazardous waste that contains solvent, powdered filter material (diatomite), carbon, non-volatile residues, lint, dyes, grease, soils and water.

The waste sludge or solid residue from the still contains solvent, water, soils, carbon and other non-volatile residues. The chlorinated solvent from the dry cleaning operations is hazardous waste.

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Key Sector Risks and Headline Issues

In large-scale chemical and pharmaceutical manufacturing some critical issues of particular public concern may result in reputation or credit risk to a lender or an investor, these include:

Universal

- ♦ Climate change - long term impact and phase out of greenhouse gases;
- ♦ Air / water / soil pollution caused by industrial manufacturing activities including accidental events;
- ♦ Legality of supply chain and ethical sourcing of raw materials.
- ♦ Products create high volumes of packaging material, including paper and plastics which must be responsibly disposed of through recycling or biodegradability;
- ♦ Political and litigious issues resulting from environmental risks (e.g. transboundary impacts resulting from air and water contamination);
- ♦ Human rights and occupational safety of workers / affected communities – poor working conditions and labour standards in regions with little or no regulation;
- ♦ Costs of waste management - e.g. changes in legislation surrounding waste disposal, especially hazardous waste.

Chemical Manufacture

- ♦ Petro-chemicals are slow to biodegrade and are more damaging in terms of toxicity, contribution to global warming and acidification;
- ♦ Chemical ingredients such as mineral acids (hydrochloric, sulphuric and phosphoric acids) are known to be toxic in the environment;
- ♦ High levels of water consumption for the cleaning of machinery, packaging systems and pipelines, and wastewater require responsible management;
- ♦ Energy consumption for production, refrigeration, lighting and transportation produces CO₂ emissions, particularly when raw material sourcing and product delivery, is organised on a global scale;
- ♦ The risk of terrorist attack on chemical plants;

Pharmaceutical Manufacture

- ♦ Generic substitutes of patented medicines could be manufactured in defiance of the patent laws particularly for drugs that are too expensive for emerging countries to afford (e.g. HIV);
- ♦ Health risks from testing and use of pharmaceuticals;
- ♦ Pharmaceutical trials targeting low income and or other vulnerable groups;
- ♦ Affordable access to medicines / pharmaceuticals in developing nations (e.g. HIV / AIDS treatments);
- ♦ Product stewardship - consumer health and safety, product safety and labelling and responsible marketing;
- ♦ Litigation risks (e.g. consumer damage claims); and

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- ♦ Risk of boycotting and negative publicity (e.g. ethical issues surrounding animal welfare).

Laundries and dry cleaning

- ♦ Contamination of land and water from solvents and detergents from the dry cleaning process;
- ♦ Mismanagement of materials may lead, or have led, to contamination of ground or groundwater. The contamination may, in extreme cases, result in the business being prosecuted and/or being forced to remediate the site. The value of the security may also be adversely affected.
- ♦ Costs of less environmentally detrimental new technologies - dry-cleaning businesses are characterised by their small size and low profitability and may face financial failure through inability to meet the required conversion costs.

The following tables detail potential environmental and social risks associated with industry processes and appropriate control measures. These may include **Environmental and Social Management Plans** and may form part of a wider **Environmental and Social Management System**.

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Environmental Risks

Life Cycle Phase and Activity	Environmental	
	Risks	Controls
Raw Materials Supply		
	<ul style="list-style-type: none"> ◆ Unethical supply chain - raw materials could be sourced from countries where standards for environmental management are not rigorous 	<ul style="list-style-type: none"> ◆ Environmental and ethical sourcing policy
Manufacturing Operations		
	<ul style="list-style-type: none"> ◆ Pressure on natural resources - excessive / unmonitored use of water and energy ◆ Atmospheric emissions <ul style="list-style-type: none"> - Pollutants (VOC, NOX, SOX, PM10, CO, CO2, etc) - Greenhouse gas production - Dust and noise ◆ Liquid waste (production and disposal) - hazardous waste (i.e. process and effluent treatment sludges, spent catalysts and container residues containing significant concentrations of spent solvents and other toxic organics) ◆ Accidental spills - wastewater to storm water system and drift of pesticides due to aerial application, adverse health effects of pesticide coated produce ◆ Storm water runoff - contamination resulting from poor materials transportation, storage and handling practices ◆ Disruption and pollution to surface water (hydrological) and groundwater (hydrogeological) systems and flows - accidental releases of chemical pollutants to surface and / or groundwater and / or soil 	<ul style="list-style-type: none"> ◆ Minimize facility footprint- optimisation of operations and processes to minimise energy and water consumption ◆ Use of Best Available Technique not Entailing Excessive Cost (BATNEEC) – especially in emission stack design; development of emissions inventory; wastewater treatment design implement air quality monitoring ◆ Emissions management - greenhouse gas / climate change offset programmes - phase out of ozone-depleting substances ◆ Waste management and end of life process <ul style="list-style-type: none"> - Re-use and recycling and appropriate waste disposal (chain of custody) - - Return toxic materials packaging to the supplier for reuse or incinerate / destroy in an environmentally acceptable manner ◆ Emergency preparedness and spill response plans - management and training measures ◆ Hazardous materials storage, transport and containment <ul style="list-style-type: none"> - Label and store toxic and hazardous materials in secure, bunded areas - Use automated filling to minimise spillage ◆ Water disposal and monitoring systems – continuous monitoring of water quality and appropriate waste water disposal

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Life Cycle Phase and Activity	Environmental	
	Risks	Controls
Transport and Product Distribution		
	<ul style="list-style-type: none"> ♦ Atmospheric emissions <ul style="list-style-type: none"> - Noise impacts from transport vehicles in residential areas along transport routes - Pollutants (VOC, NOX, SOX, PM10, CO, CO2, etc) - Greenhouse gas production ♦ Liquid waste (production and disposal) - spills of hazardous chemicals and substances resulting from accidents involving transport vehicles 	<ul style="list-style-type: none"> ♦ Waste and hazardous materials transport, storage and handling plans <ul style="list-style-type: none"> - Plan transport routes to avoid highly populated areas where possible - Only use vehicles designed to carry specified hazardous substances - Ensure vehicles are properly maintained to manufacturers specifications and switch to cleaner fuel vehicles if feasible ♦ Emergency preparedness and spill response plans - for transport vehicle accidents ♦ Emissions management - greenhouse gas / climate change offset programmes - phase out of ozone-depleting substances
Bulk Storage		
	<ul style="list-style-type: none"> ♦ Explosion and fire risk – due to poor segregation of chemicals/hazardous materials ♦ Disruption and pollution of surface water (hydrological) and groundwater (hydrogeological) systems and flows - due to spills and leakages 	<ul style="list-style-type: none"> ♦ Emergency preparedness and spill response plans - equipment maintenance and integrity testing ♦ Hazardous materials transport, storage and handling plans <ul style="list-style-type: none"> - Improved handling, storage and use of hazardous materials - Use automated filling to minimize spillage and “closed” feed systems into batch reactors - Secondary containment (e.g., berm, sump areas, and pumping / removal facility) ♦ Water disposal and monitoring systems – continuous monitoring of water quality and appropriate waste water disposal
Product Use		
	<ul style="list-style-type: none"> ♦ Solid waste (production and disposal) - disposal of waste products and / or waste packaging 	<ul style="list-style-type: none"> ♦ Waste management - Eco-design of products to minimise amounts and toxicity of the wastes and to allow re-use or

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Life Cycle Phase and Activity	Environmental	
	Risks	Controls
	<ul style="list-style-type: none"> ♦ Bioaccumulation and contamination of food chain <ul style="list-style-type: none"> - Chemicals not appropriately removed in the wastewater treatment process (e.g. endocrine disrupters such as alkyl phenols can cause sex change in fish) - Toxic chemicals leaching out of food packaging contaminating food ♦ Liquid waste (production and disposal) - rainwater runoff contaminating surface and / or groundwater due to Pesticide and fertilizer application 	<ul style="list-style-type: none"> recycling, ensure non-toxic package design ♦ Water disposal and monitoring systems - continuous monitoring of water quality and appropriate waste water disposal especially monitoring of chemical release in stormwater
Laundries and Dry Cleaning		
	<ul style="list-style-type: none"> ♦ Pressure on natural resources - high energy use and overuse of water in water scarce areas ♦ Atmospheric emission <ul style="list-style-type: none"> - Pollutants (VOC, NOX, SOX, PM10, CO, CO2, etc) - Greenhouse gas production e.g. chlorofluorocarbons (CFCs) and Hydrochlorofluorocarbons (HCFCs), 'perc' - Dust and noise ♦ Disruption and pollution of surface water (hydrological) and ground water (hydrogeological) systems and flows - accidental spillage and inappropriate storage/packaging of solvents ♦ Accidental spills and fire risk - storage and handling of chemicals, materials storage and transportation can lead to contamination of air and land and to fire risk from flammable and combustible dry cleaning liquids ♦ Liquid/solid waste (production and disposal) - storage and handling of non-hazardous and hazardous waste 	<ul style="list-style-type: none"> ♦ Use of Best Available Technique Not Entailing Excessive Cost (BATNEEC) e.g. control of emissions of ozone depleting gases and harmful chemical residues and appropriate discharge of wastewater ♦ Hazardous materials storage, transport and containment <ul style="list-style-type: none"> - Label and store toxic and hazardous materials in secure, bunded areas - Improvement and regular third party audits of chemicals storage facilities ♦ Waste management - responsible waste management ♦ Partnering with and supporting host governments <ul style="list-style-type: none"> - Encourage revenue transparency and good governance - Compliance with national / regional / local regulations

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Social Risks

Life Cycle Phase and Activity	Social	
	Risks	Controls
Raw Materials Supply		
	<ul style="list-style-type: none"> ♦ Employee health and safety <ul style="list-style-type: none"> - Weak enforcement of labour standards; - Labour relations (e.g. employee organisation, representation and negotiation); - Working conditions (H & S standards, training and monitoring of risk exposure); and - General employee welfare (including employee compensation, benefits, and training). 	<ul style="list-style-type: none"> ♦ Supply chain sustainability and employee health and safety risk management system <ul style="list-style-type: none"> - Ethical sourcing policy - Commitment to company-wide and supplier-wide employment and H & S standards
Manufacturing Operations		
	<ul style="list-style-type: none"> ♦ Employee health and safety <ul style="list-style-type: none"> - Employee / Occupational Health and Safety (e.g. exposure to hazardous chemicals (e.g. carcinogens such as asbestos), dust and noise; unguarded machinery; fire and explosion risks; ergonomics issues). - Employment and poor labour standards - child labour and working conditions (labour intensive, long working hours, pay, work by hand) ♦ Community health and safety - noise, vibration, dust creation, traffic movement, emissions and air quality ♦ Communicable diseases - spread of diseases by workforce to local / foreign populations ♦ Land acquisition – displacement - need for resettlement and relocation with compensation ♦ Social / community cohesion and exclusion of vulnerable groups - socio-cultural tensions between local and foreign workforce ♦ Loss of livelihood - economic displacement - e.g. job competition 	<ul style="list-style-type: none"> ♦ Community health and safety plan and awareness raising on communicable diseases - administration of vaccinations ♦ Partnering with and supporting host governments <ul style="list-style-type: none"> - Encourage revenue transparency and good governance - Compliance with national / regional / local regulations

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Life Cycle Phase and Activity	Social	
	Risks	Controls
	<ul style="list-style-type: none"> ♦ Host country governance, national economy and revenue transparency - e.g. security around operations, bribery and corruption ♦ Ethical issues <ul style="list-style-type: none"> - Surrounding animal testing and the use of xenotransplantation - i.e. use of genetically modified animal organs for human transplants) - Drug testing on vulnerable communities resulting in Human Rights violations 	
Transport and Product Distribution		
	<ul style="list-style-type: none"> ♦ Community health and safety - noise, vibration, dust creation, traffic movement, road safety, emissions and air quality ♦ Strain on infrastructure and public nuisance - strain on transport networks and local infrastructure - disruption to road users both pedestrian and other vehicles (e.g. refrigeration of vaccines while in transit to rural clinics) 	<ul style="list-style-type: none"> ♦ Community health and safety plan - Enforce strict driver skills standards and implement driver and road safety behaviour training ♦ Transport management plans <ul style="list-style-type: none"> - Mitigate delays and avoid peak hour times - Road safety awareness for communities and employees
Bulk Storage		
	<ul style="list-style-type: none"> ♦ Site security and vandalism - risk of terrorist attack on chemical plants ♦ Community health and safety - accidental spills and tank leakage, water contamination 	<ul style="list-style-type: none"> ♦ Site security plans - ensure appropriate security measures are in place ♦ Emergency preparedness and spill response plan - including provision of emergency water supply
Product Use		
	<ul style="list-style-type: none"> ♦ Community health and safety <ul style="list-style-type: none"> - Noise, vibration, dust creation, traffic movement, emissions and air quality - Controversial prescription and use of medicines / pharmaceuticals (e.g. Ritalin for diagnosed attention deficit disorder) 	<ul style="list-style-type: none"> ♦ Community health and safety plans - Warning labels and effective education of the dangers of inappropriate use and consumption ♦ Use of BATNEEC and weather monitoring - mitigate effects on local communities ♦ Community awareness and education - washing and

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Life Cycle Phase and Activity	Social	
	Risks	Controls
	<ul style="list-style-type: none"> - Drift of pesticides due to aerial application, adverse health effects of pesticide coated produce - Inappropriate / ill informed use of chemicals / pharmaceuticals leading to illness or death ♦ Affordability of best available products in developing countries 	<p>careful preparation of produce</p> <ul style="list-style-type: none"> ♦ Community awareness and education - Toxic substances present in certain products availability of alternatives - appropriate labelling' – including clear and specific instructions as well as contradictory symptoms, overdose information and contraindicators - Pesticides labels should include directions for use, mixing instructions, expiry date, health hazards and first aid measures in case of accidental exposure or ingestion
Laundries and Dry Cleaning		
	<ul style="list-style-type: none"> ♦ Employee health and safety - Poor employment and labour standards, - Dangerous employee conditions including health and safety, exposure to chemicals - Risk from exposure to hazardous chemicals and e.g. chlorinate solvents and heavy machinery - Manual handling/musculoskeletal injuries - Noise induced hearing loss from noisy machines, e.g. cleaning plant, packaging machinery - Respiratory irritation from breathing fumes such as chlorine, hypochlorite, ammonia and sulphur dioxide - Occupational dermatitis from chemical cleaners ♦ Public nuisance - odour if operations in close proximity to residential areas ♦ Changing technology and regulation - costs of less environmentally detrimental new technologies 	<ul style="list-style-type: none"> ♦ Health and safety management systems - Adjust the employees work, temporary and long term - Introduce a occupational health system - Information about occupational ill health - Risk assessment and safety instructions for all employees ♦ Emissions management - odour control

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Key considerations

1. How long has the site been used for this purpose? The contamination risk increases with time.
2. Are all necessary environmental authorisations and permits held and is the operation in full compliance with their requirements?
3. Has any on-site waste disposal (e.g. spent solvents or expired medicines etc.) ever taken place? How are waste products treated and disposed of in general?
4. Has the company been prosecuted or served with any warnings for environmental offences? Are there any outstanding prosecutions against the site?
5. What procedures/resources exist to manage environmental risks (e.g. an environmental management system or personnel with specific responsibility for risk mitigation)? Are these procedures considered to be adequate/robust? Are the same environmental standards applied to facilities in different countries (if applicable)?
6. Is live animal testing or genetic engineering/research undertaken?
7. Has company received negative media coverage in the last three years?
8. Is there an emergency response plan in place for use in the event of an accident? Does the plan taken into account neighbouring land uses and the potential consequences of an emergency?
9. Does the company face any significant expenditure to meet conditions attached to process authorisations or permits (both current and pending)?
10. Is it anticipated that changes to environmental legislation or environmental pressures (e.g. from the public or supply chain) will lead to an increase in the cost of raw materials or changes in the means of manufacture, the product mix and/or waste disposal or wastewater treatment?
11. Does the company report externally on their sustainability / corporate social responsibility (CSR) issues (environmental, social and economic)?
12. If an external report exists, is it independently verified?
13. Does the company identify its non-financial risks in a systematic manner?
14. Does the company score well in any of the sustainability ratings, rankings or indices (e.g. Dow Jones Sustainability Index (DJSI), FTSE4Good)

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Regulation and Best Practice

Permits, consents and licences are likely to be required for chemicals and pharmaceuticals manufacturing operations, the specifics of which will depend on the relevant regulatory framework in the location of an operation/facility. In developing regions, weaker governance structures may mean that there is less stringent implementation of local controls and regulations or indeed there may be no controls at all. In such cases the project proponent as a demonstration of best practice should ideally adopt international environmental and social standards and industry Best Practice.

In the case of almost all large-scale new build, expansion and development projects an Environmental and Social Impact Assessment (ESIA) will be required particularly where project debt financing is being sought. A comprehensive ESIA undertaken to international standards allows both the project sponsor and the investors to assess the full range of potential environmental and social impacts related to a project development, operation and decommissioning. Part of the ESIA process is to design appropriate mitigation measures and to set a framework for monitoring the performance of these measures on a long-term basis. This limits and controls compliance and remediation costs as well as long term credit and reputation risks.

For smaller scale projects and operations a full ESIA may not be required. Focused studies on particular issues of concern may however, be helpful in identifying potential environmental and social risks associated with certain project activities.

The table below lists key international standards and publicly available best practice reference materials relevant to the chemicals and pharmaceuticals industry:

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Source	Agency / Body
Multilateral	<p>IFC Performance Standards http://www.ifc.org/ifcext/enviro.nsf/Content/PerformanceStandards</p> <p>World Bank Group Pollution Prevention and Abatement Handbook http://lnweb18.worldbank.org/ESSD/envext.nsf/51ByDocName/PollutionPreventionandAbatementHandbook</p> <p>World Bank Group: Energy Sector Management Assistance Program http://wbln0018.worldbank.org/esmap/site.nsf</p> <p>Greenhouse gas Protocol Initiative (a tool that can be used to determine the emissions of your specific project/industry) from the World Business Council for Sustainable Development http://www.ghgprotocol.org/templates/GHG5/layout.asp?type=p&MenuId=OTAx&doOpen=1&ClickMenu=No</p> <p>Intergovernmental Panel on Climate Change 'IPCC Special Report on Carbon dioxide Capture and Storage' http://arch.rivm.nl/env/int/ipcc/pages_media/SRCCS-final/IPCCSpecialReportonCarbondioxideCaptureandStorage.htm</p> <p>Stockholm Convention on Persistent Organic Pollutants http://www.pops.int/</p> <p>UNESCO Conference on Indigenous People and http://portal.unesco.org/sc_nat/ev.php?URL_ID=3854&URL_DO=DO_TOPIC&URL_SECTION=201&reload=1092045126</p> <p>EU Directive for Waste Management http://www.wbcsd.org/Plugins/DocSearch/details.asp?ObjectId=MTq4OTE</p> <p>The International Finance Corporation has a fund GEF grants support projects related to biodiversity, climate change, international waters, land degradation, the ozone layer, and persistent organic pollutants. http://www.ifc.org/ifcext/enviro.nsf/Content/GEF</p> <p>EU Policies: Integrated Pollution prevention and control. http://europa.eu/scadplus/leg/en/lvb/l28045.htm</p> <p>International Labour Organization: Mandate http://www.ilo.org/public/english/about/index.htm</p> <p>ILO's Lists of Subjects Standards have been decided upon- http://www.ilo.org/ilolex/english/subjectE.htm</p> <p>Agenda 21, Chapter 20 On Environmentally Sound Management of Hazardous Wastes. Including Prevention of Illegal International Traffic in Hazardous Wastes http://www.un.org/esa/sustdev/documents/agenda21/english/agenda21chapter20.htm</p> <p>Basel Convention The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal was adopted in 1989 and entered into force on 5 May 1992. http://www.basel.int/about.html</p>

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Source	Agency / Body
Multilateral	<p>Security Issues and Human Rights http://www.voluntaryprinciples.org/principles/private.php Agenda 21 http://www.un.org/esa/sustdev/documents/agenda21/index.htm Agenda 21, Chapter 21 Environmentally Sound Management of Solid Wastes and Sewage-related Issues. http://www.un.org/esa/sustdev/documents/agenda21/english/agenda21chapter21.htm <u>Aarhus</u> Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters http://www.unece.org/env/pp/ <u>Stockholm Convention on Persistent Organic Pollutants (POPs)</u> <u>United Nations</u> Convention on Climate Change http://unfccc.int/2860.php OECD waste decisions UNEP International Declaration on Cleaner Production http://www.uneptie.org/pc/cp/declaration/ World Tourism Organization http://www.world-tourism.org/frameset/frame_sustainable.html World Bank Handbook for estimating the socio-economic and environmental effects of disasters http://siteresources.worldbank.org/INTDISMGMT/Resources/tourism.pdf World Bank Tourism and Sustainable Development http://info.worldbank.org/etools/docs/library/107771/SD_Communication/epublish/zip_files/biodiversity_russia2003/pdf/TourismandSDMarkandya.pdf The Code of Conduct for the Protection of Children from Sexual Exploitation in Travel and Tourism http://www.thecode.org/dokument/images/downloads/code_summary_english_4.pdf International Telecommunication Union an international NGO separate but equal to United Nations. www.itu.int/org</p>

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Government	<p>Environment Agency UK Monitoring Guidance notes for emission levels http://www.environment-agency.gov.uk/business/444217/444661/444671/466158/monitoring/?version=1&lang=e</p> <p>Health and Safety Executive Noise Regulations (complete) http://www.hse.gov.uk/noise/regulations.htm</p> <p>Health and Safety Executive Guidance for Employers for the Control of Noise at Work Regulations 2005 http://www.hse.gov.uk/pubns/indg362.pdf</p> <p>Air Quality Criteria for Particulate Matter Environmental Protection Agency United States Government http://cfpub2.epa.gov/ncea/cfm/recordisplay.cfm?deid=87903</p> <p>Environment Canada Convention on Biological Diversity http://www.ec.gc.ca/international/multilat/biodiv_e.htm-act</p> <p>Health Canada Guidelines on Noise in the Workplace http://www.hc-sc.gc.ca/ewh-semt/pubs/noise-bruit/insider7/index_e.html</p> <p>Traffic Noise Information and Recommendations http://www.hc-sc.gc.ca/ewh-semt/pubs/noise-bruit/insider8/index_e.html</p> <p>Canada Labour Code Federal Law and Regulations http://www.hrsdc.gc.ca/asp/gateway.asp?hr=/en/lp/lo/fll/part2/index-fll.shtml&hs=oxs</p> <p>Animal welfare act www.nal.usad.gov</p>
Industry Association	<p>Health and Safety Executive www.hse.gov.uk</p> <p>International Solid Waste Association http://www.iswa.org</p> <p>Waste Industry Safety and Health Forum (WISH)</p> <p>The United States Occupational Safety and Health Administration (OSHA)</p> <p>The Regional Waste Management Task Force (RWMTF)</p> <p>National Pesticide Information Center http://npic.orst.edu/manuf.htm</p> <p>National Paint and Coatings Association http://www.paint.org/con_info/facts.cfm</p>

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