Sterling Chemical Malta Ltd - IPPC- Project Description

Installation of manufacturing plant and obtainment of an operating permit for the production of active pharmaceutical ingredients (API)

11/06/2015
Sterling Chemical Malta Ltd

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B.1.1 The installation and its activities

COLUMN 1	COLUMN 2	COLUMN 3
Activities in the "stationary technical unit"	*Schedule 1 of Legal Notice 10/2013*	*Operator*
Installations using a chemical or biological process for the production of basic pharmaceutical products	Point 4.5 Production of pharmaceutical products including intermediates	Sterling Chemical Malta Ltd
Directly associated activities		
1.	LPG storage and loading area	
2.	Loading liquid nitrogen in tank;	
3.	Storage, Transfer and loading/unloading raw materials and API;	
4.	Storage, transfer and loading of waste off-site for disposal, recycling, reuse and recovery;	
5.	Emission on air by euroboiler and steam generator	
6.	Emission on air by production area, weighing area, laboratories after opportunities filtration system	
7.	Emission on public sewer discharge, only domestic discharge;	
8.	Storage the rainwater in underground tank reservoir	
9.	Storage the aqueous wastewater in case of emergency from production area in underground tank	
10.	Boiler and Steam Generator	
11	Water softener	
12	grit chambers self-cleaning,filters for drinlking water or to use technological	
13	cooling tower and scrubber	
13	Heating, Ventilation and Air conditioning	
14	Active Carbon filter. HEPA filters and DUST filters	

Table 1 The installation and its activities

B.1.2 Non-technical description

B.1.2.1 Company profile

Sterling S.N.I.F.F. ITALY was founded in 1976 by the current shareholders, as a chemical limited liability company (Ltd.) in order to produce flavours for the food and pharmaceutical industry. The head office is located in Corciano - Perugia. In 1981 the synthesis of S - Carboxymethyl cysteine was developed and the next year the new plant, which is still located in Solomeo, (Corciano - Perugia) was built in order to produce the active pharmaceutical ingredient that followed S - Carboxymethyl Cysteine: the Ketoprofen Lysine Salt. In 1985 the company changed its business name and became a joint-stock company. In 1992 Sterling SNIFF ITALY S.p.A set up a joint venture with the company "Amino Chemicals" in Malta which produces pharmaceutical substances such as Pentoxifylline, Erdosteine, and N - acetylcysteine on behalf of the Sterling itself which supervised all the activities performed in Malta. Two years later (1994) the company decided to develop a research project on steroids which begun three years earlier. By 1995 the synthesis of the Medroxyprogesterone Acetate

(MPA) was refined and the product was produced, with the know-how and the supervision of the company over the Maltese Amino Chemicals plant. The product is sold on the Asian, Spanish and South African market.
In 1997, the company improve the "steroids" project; in particular it expanded and developed the research field by recruiting new technicians and purchasing new instruments specifically reserved for the chemical-pharmaceutical sector. Since the Amino Chemical production represented a strategic strong point for the company, in 1998 STERLING SNIFF ITALY S.p.A. decided to purchase the 52% of the Maltese firm.

Between 1997 and 1999, additional steroid substances, such as Chlormadinone, Megestrol acetate, Mometasone Furoate, Cyproterone acetate and L - Norgestrel, were developed.

In 1998 the company decided to sale the steroids produced in the United States and started building a new plant in Solomeo (Corciano - Perugia). This plant will cover the entire production process, from the preparation of materials to packaging operations in order to make the plant completely independent from the existing one. Since technicians could not devote their time in assisting external productions and taking into account the enormous economic resources needed, the company decided to sell the shareholding of the Amino Chemicals plant. Such operation was completed in early 1999, while all agreements concerning production activities carried out on behalf of Sterling SNIFF ITALY S.p.a were maintained. Furthermore, looking at a future perspective, new technicians were hired and the research department was developed. This has led to the development of 26 active pharmaceutical ingredients over the last ten years that the company is exporting all over the world. 2007 was an important year for SNIFF ITALY SPA as it decided to make further investments in the Umbrian territory by building a new production plant which could double the production and speed up processes. Such operations allowed the company being more reliable in the market in terms of working flexibility, time used for producing the different batches by ensuring a better flexibility in terms of quantity of product made available to the customer.

On the 31st of December 2008 SNIFF ITALY S.p.A changed its business name into Sterling S.r.l. This was the last step for the corporate restructuring of SNIFF ITALY S.p.A, consisting in the realization of corporate structures belonging to the same holding company that will manage individual branches concerning their specific areas of operation. In this way the new Sterling Srl company will keep on producing in the same pharmaceutical plant made available by SNIFF ITALY S.p.a., who receives a rent for the building.

On the 21st of September 2012 Sterling become a limited company.

B.1.2.2 Maltese project

The expansion of activities and corporate restructuring projects are still ongoing today, with a constant research of new products. The company got international with the opening of a new plant in the island of Malta. For this reason, Sterling Chemical Malta Ltd, a company controlled by SNIFF Italy Spa, was set up as it aimed to become an important connection with the world. The company was set up in the Maltese island after carrying out a careful analysis of the international pharmaceutical market, which is more and more active, skilled and

aggressive. Generally, the competitive scenario of the chemical industry has led to a major reorganization of companies within the industrial field over the past few years. The dismantling of several multinational groups present on the market into many units corresponding to a wide range of chemicals sectors, created a situation that allowed individual units to operate in the market even with a low profit and competitiveness. The breakup of the single units and the raising of the competitiveness lead to a consolidation of the supply through partnerships, joint ventures, acquisitions and mergers. All that allowed customers to have a supplier able to ensure an important coverage in terms of products and services. Basically, the supplier becomes more and more a "global partner" for his customer. This new configuration of the sector had significant consequences for Italian products. The strategic reasons behind the reorganization are mainly found in the need to focus efforts on specific market segments by operating at a global level. In this way, since the new subjects are much more specialized and link their development to a single sector, they can and must develop aggressive policies of productive globalization and boost innovation. The first are driven by the geographical demand tendency; the second results from the effort not to let the majority of products get old and outdated. Both policies are led by business reasons, bureaucracy and patent monitoring. The market globalization can change the traditional districts which, in order to keep on representing an engine for the "made in Italy", must revitalize their competitive characteristics: from flexibility to specialization, from low costs to the advantages coming from the connection with the territory. The chemicals demand records an important development in developing countries, which tend to become the world leaders in the main sectors (textile, leather, plastic processing sectors and especially in chemical formulation and generic formulation). Consequently, the European market losts its importance not only in quantitative terms, but also as a reference in determining the operative conditions (prices and margins) for a company such as Sterling S.r.l which works with fine chemicals which are an auxiliary raw material for pharmaceutical activities. Malta has been considered as a destination for a production branch thanks to its geographical position, as it is an entrance to the Mediterranean and a connection with new areas (Far East, India, Turkey, Saudi Arabia). Malta has been chosen since it is close to the new booming demand and to the head office. Export activities will prevail as far as those products with an high added value and innovative content, whose production can still be carried out throughout the country. While production relocation will prevail where the costs (bureaucracy, patents, logistics, distribution, cost, etc..) and the proximity to the final demand area will lead to the convenience of producing directly in the end markets in a way that is not an unbearable weight to intuition and entrepreneurial courage. In detail, the Malta project is divided into three stages in order to amortise the cost and risk of the investment made (not only for the research but also for the start-up of a multinational enterprise) over time. The first step is about research and development, a strategic factor for succeeding in the field of fine chemical intermediates and auxiliaries. So far, process innovations implemented by Sterling tend to reduce the consumption of raw material and maximize the development in terms of a synthesis yield and working time. Now, with the launch of Sterling Malta, the aim will be to search new products to be placed on an international market, interact with international universities and find a competitive and encouraging area in terms of know-how as the one of the isle resulting from the past chemical-industrial point. The scientific-cultural contamination to which Sterling aims, allows a mix of chemical know-how (a first level chemical synthesis

through a comparison of the methods known and applied in the Maltese and Italian universities), but also makes it possible to reach a high quality product in terms of health, safety and environment. These are the added values that allow the made in Italy to deal with the industrial giants.

The second step consists in activating the production through a system that enables to transfer on an industrial scale what the research and development laboratories have synthesize. In the last stages of an investment, a full speed production will meet the needs of an evolving market (such as the cystic market) requiring the Italian small and medium chemical enterprises to be extremely flexible by maintaining a very high production level, to never stop searching for the highest level of quality, to fight and to emerge as well as the developed economic powers (such as China and India).

The whole project aims to positively influence the Maltese chemical industry and to start a virtuous cycle based on technological innovation and sustainability, with important consequences for the employment. The new research centre will ensure a continuous development and innovation of products and processes by collaborating with research centres of the head office and with national and international institutes and universities.

B.1.2.3 Architectural structure and activities

The Sterling organization is internally divided into departments in order to meet the various needs. The following table shows such departments with a short and non-technical description of the activity performed.

Department	Activity	Description
Technical Office	Engineering	From the engineering point of view, this activity produces all calculations, assumptions, rules and specifications of a system that ensures an operation to be computerised, in order to find solutions that facilitate all activities performed in the production plant (from the production to the storage of raw materials and products up to the air-conditioning system of a workplace)
	Maintenance	The technical department coordinates all maintenance works such as the repair/replacement of the entire production plant.
	Supplies	This department manages all estimates, the raw materials needed for the project and it follows the entire process until it is completed.
Maintenance		The maintenance of the plant can be accidental, if it results from a fault or failure in the system, or programming depending on the works and the deadlines established by the various user manuals of the equipment. With regard to the scheduled annual maintenance, a tolerance of thirty working days is allowed to complete the maintenance. For all other scheduled maintenance works to be performed less than once a year, a tolerance of 15 working days is allowed. The company already has a maintenance program that will be consulted and followed for routine operations and for checking the functionality of certain machinery, such as air duct systems, abatement systems, suction hoods, etc... The main activities that will be carried out are listed below: • Repair of hydraulic pumps, hydraulic ducts and valves, solenoid valves for compressed air and vacuum, various types of pipes, electrostatics, pumps and vacuum generators, etc.

		• Repair of air conditioning systems, lubrication of pipes for technical gases (nitrogen, compressed air, etc. ...). • Welding wire used for installations that require a mechanical seal. • TIG (tungsten inert gas) welding used for tools or mechanical parts that require a pressure seal. • Welding and Cutting • Repair works on buildings, shaping, sawing, etc. • Works for repairing any deficit of the electrical system. • Construction and Energy • Automotive devices such as pressure gauges, thermometers, pressure switches, barometers, timers, etc...
Production	Transformation of raw materials into finished products	The activity consists in producing active pharmaceutical ingredients through several work steps. Each step entails using raw materials such as solvents, reagents or starting materials which, once mixed, lead to an intermediate solid and then the finished product (in case of the last step). Such operations are carried out inside reactors, centrifuge filters or dryers by using resources such as water, energy, air and nitrogen.
	Utilities management	The activity aims to check the utilities used for the production or the functioning of equipment/systems.
Quality Control	Sampling of raw materials, production intermediates and finished products	The activity consists in carrying out the sampling of raw materials or finished products. Such sample takings are performed in the weighing chamber.
	Chemical laboratory tests	The lab checks the quality of the raw materials as defined by the various international protocols.
	Goods storage	The activity consists in storing the reagents needed for analysing samples of raw materials, intermediate or finished products. It also provides the storage of finished products counter-samples.
Research and Development	Experimental chemical analysis	The activity conducts research campaigns aimed to develop new synthesis or to improve the existing ones.
	Sample production	The department is equipped with a pilot plant (Scale Up department) reproducing in an intermediate scale, (between the laboratory scale and the industrial one) the synthesis identified for the production of the various active ingredients.
	Goods storage	The activity consists in storing the raw materials needed for synthesis and promoted in the research and development field
Warehouse	Goods storage	Raw materials and products are placed in different warehouses depending on their nature (flammable or non-flammable materials) and within the same warehouse in two separate and distinct areas called "quarantined" and “approved”. The quarantined area houses the goods that have not been analysed yet by the quality control laboratory and cannot be putted into production. The "approved" area houses those goods that passed the quality control laboratory analysis. All incoming and outgoing goods must be recorded. Raw materials will be stored both inside the warehouse (since they must keep certain temperature and humidity features), and outside, but they must be protected from the weather conditions with a roofing.
	Goods Reception and shipment	This activity aims to check the goods compliance as well as the quantity, integrity, cleanliness and identity of goods from external suppliers with the subsequent unloading of the transport carriers. Such activity includes the labelling of the different batches, the request for analysis and sampling operations, and finally the storage of goods. In case of shipment, if it is necessary to handle a portion of the product

		because just a portion of it is needed, it is necessary to perform this operation in a drying room within the finishing area.
	Moving goods to other departments	The activity includes the transfer of goods into other departments after checking their identity, labelling and perfect state.
	Weighing and Fractionation	The weighing or fractionation of goods is performed only in reserved areas. At the end of such operations the area involved must be cleaned from any residue of the previous product.
Environment Health and Safety (EHS)	Management of issues relating to the environment and safety	This activity consist in managing the issues relating to the environment and safety, through documents, procedures, and practices aimed to respect the regulation of all the activities established by the Company.
General Activities	Offices	Any activity that has a close relationship with the environment, such as the consumption of paper and toner for printers, the need for air conditioning in a room, the use of natural resources such as water, energy, fuels, etc. ..
	Canteen	It is a canteen for workers.
	Parking	Below the road surface there is a parking lot for employees, customers or guests.

Table 2 Description of the activities that will be performed in Sterling Chemical Malta Ltd.

The property covers an area of 3,295 m^2 and is characterized by a structure built on three levels. Such structure is made up of 1,408 m^2 interior surface divided by functional areas, a 1,887 m^2 outdoor area used for the reception of incoming raw materials (loading and unloading area), a garden (only for aesthetic reasons) and an unspecified area that will host any future buildings. The interiors are designed by following the functional criterion of GMP guidelines (Good Manufacturing Product) according to which there is a fixed separation between the various workplaces. Below the level of the road there is a parking lot for employees, customers and external guests with a 589.00 m^2 area that can be accessed from the south side of the property. The first floor (which is above the road surface) can be accessed through an external staircase or by internal stairs and/or lift directly from the garage area. From such entrances it is possible to enter the reception lobby with an adjoining office for a total of 93 m^2 circulation area (which also includes hallways). From here you enter the first section of the building, which is entirely reserved to the administration offices. Such offices covers a 145 m^2 area. Toilets cover an area of 23 m^2 (including a toilet for disabled people) while the dining area (33 m^2) is separated by a glass wall. From the entrance hall, through large windows, you have a direct view of the sea and so much natural light illuminate the interiors, by reducing the need for artificial lighting and the electricity consumption. The block plan also provides an empty area within the building in which a small garden has been created (for aesthetic reasons) to break the rigidity and to highlight the outer space. Through the dining area it is possible to enter the locker room, equipped with two showers and toilets made available to workers. The locker room opens directly to the outer corridor which encloses the entire building. By leaving the dining area and turning left it is possible to enter the quality control laboratory through a hallway. You can enter the laboratory also through the adjoining office. Quality Control laboratory has an area of 55 m^2 and includes a 19 m^2 adjoining office. In addition, it is possible to access the weighing chamber and the stability room (18.5 m^2) from the laboratory. On the other side of the hallway it is possible to enter the decontamination area in which you must wear the appropriate personal protective equipment, bypass the

separation bench and then enter the pilot area. This area has a surface of 99 m^2 and is 12 m high because of its internal structure characterized by a galvanized steel loft which allows the operators performing and controlling the operations within the individual reactors. In this area raw materials will be transformed with the production of wet active principles that will be sent into dryers to remove water and any residual solvents. From here it is possible to enter the cleanrooms, a space reserved for completing the packaged product which is isolated from the outside. This area covers 194 m^2. From the clean rooms it is possible to access to the finished products warehouse (29 m^2) and the Pilot Production (127 m^2). The first level of the building is made up of raw materials warehouse, the maintenance workshop, a sampling room for finished products and raw materials to be analysed and a technical room in which the boiler is placed. The second level, in which the third production stage will be performed, will include a new laboratory, exclusively reserved for the research and development of existing synthesis or new molecules and a pilot plant, which aims to establish an intermediate step between the small quantity processed on a laboratory scale and the large amount processed on an industrial scale. In addition to such rooms, other areas will be reserved for production utilities, with installations servicing the systems (pumps, chillers, etc...), for a total area of about 550.00 m^2.

With regard to outer facilities, a half-open depository will be added in which both raw materials and flammable wastes resulting from production process will be stored. Production activities will generate hazardous and non-hazardous waste, both flammable liquids waste (e.g. mother liquors or rinse water) and solid wastes. The company decided to collect wastes by separating them according to their nature and their EWC (European Waste Code) identification code, in the place in which they are produced in order to collect them right from the start in a temporary storage area.

The management of the temporary storage area (there will be 2 areas) provides that waste is collected and sent for recycling or disposal when the quantity stored reaches 10 m^3. While, non-hazardous waste will be collected and sent for disposal at least every six months, or when it is necessary, depending on the laboratory needs (for glass and iron) and when the amount stored reaches 20 m^3 (as far as other types of waste). Hazardous waste such as used oil and exhausted batteries will be sent for recycling or disposal at least every two months regardless of the amount collected. This distinction with respect to other hazardous waste is required due to the different types of waste produced by the company. Waste will be stored and divided by type. Each category of waste has an appropriate collecting container labelled with the following information: EWC code, description of the waste, origin and weight (in kg). A sign is affixed at the entrance of the depository showing the type of waste stored and the relevant EWC code.

Solid waste (filter cakes, exhausted buffers, exhausted catalysts) is collected in closed containers. Non-hazardous waste is collected industrial bins which is Sulo bins and wheeled container system with a capacity equal to 10 m^3 (there are three containers for three different types of waste: paper, plastic and iron). The depository consists of three paved containment tanks equipped with a 30 cm curb. Each containment tank is equipped with appropriate wells for collecting washing water or any spills due to a rupture of the tank tap for example. Such

wells act as containers for liquid waste. The wells are blind and the pollutant collected in them will be sucked by using a dewatering pump and poured into another container. The Tanks containing industrial waste water from the production process are filled in the production department and sealed while waiting for their disposal. Tanks are arranged on four levels and each one is filled so as to leave a residual security volume of 10%. The containment basins in the external flammable warehouse have a storage capacity of at least 110% of the largest above container. This consideration is valid both for the basins that will host the waste, and for the raw materials.

This is a temporary area since a warehouse for storing and separating materials will be built: 3/4 of the area will be reserved for flammable materials while the remaining space (1/4) will be for waste. Hazardous and flammable liquid waste are stored in containment basins. The open-air storage area is covered by a steel roof in order to protect the waste from the elements (rain, excessive heat, etc.). The inner quartz surface will be paved with an industrial sealed flooring that will slope towards the collection tanks arranged at the ends of the basin itself. The basin will be equipped with curbs needed to support the pallet on which the tanks are placed. Such beads will form the backbone of the basin and will be as height as the curbs bordering the basin itself which allow handling the tank. The solid waste depository is located in front of the flammable waste and raw material warehouse. This area is reserved for the storage of non-hazardous waste such as paper, cardboard, plastic, glass, metal that will be collected in closed containers such as industrial bins which is Sulo bins and wheeled container system.

Also containers for hazardous solid waste, such as activated carbon or contaminated tanks are placed in this area.

Once obtained the IPPC permission, there will be activated the line 2 of production and its clean room with rooms dedicated to the filters, dryers and centrifuges, a new laboratory, located on the second level which brings together all the research and development, leaving to the "level 0 "only the activities related to the quality control. In the second stage the structure will change just a little bit, while the activation of the installations and the goal will be crucial, since, once obtained the IPPC permit, the company will be ready to market the active ingredients on the basis of research and development so far perpetrated and by the market demands. In the third stage it will be activated the third production line and its finished area with the extension of the structure. There will also be the moving to Level 2 of the pilot plant in the room next to the research and development laboratory.

The following **Table 3** summarizes all the functional areas within the company. Each room is associated with an activity that is carried out and a reference number which can be found in the general floor plans (of all levels of the structure) shown in Annex B.1.2-A1 "Lay Out Factory" in relation to the stages I and II. The operations that Sterling held within each room are then described using block diagrams in annexed B.1.4-A3 "Description Sterling plant by block." In the table are also shown the functions assigned to the parts to be built in the factory, in this case the comparison has to be done with the attached plan B.1.2-A2 including a third production line and finishing area where we will proceed to the centrifuge, filtration, drying

and packaging operations of the product generated in the third line. In the B.1.2-A2 annex there is only the floor plan of the level 0 as it is only on this level that, compared to the existing structure, it will be necessary a new building.

General Description	Reference number	Level	Annex Project Description	Drawing title reference	Stage Activation
Sub station	1	-1	B.1.2-A1	Lay out factory-Level -1	I
Switch room	2	-1	B.1.2-A1	Lay out factory-Level -1	I
Reception lobby	3	- 1	B.1.2-A1	Lay out factory-Level -1	I
Parking area	4-5	-1	B.1.2-A1	Lay out factory-Level -1	I
Shaft	6	-1	B.1.2-A1	Lay out factory-Level -1	I
Court yard	7	0	B.1.2-A1	Lay out factory-Level 0	I
R&D Manager	8	0	B.1.2-A1	Lay out factory-Level 0	I
QA office	9	0	B.1.2-A1	Lay out factory-Level 0	I
Production Manager	10	0	B.1.2-A1	Lay out factory-Level 0	I
Corridors	11-21	0	B.1.2-A1	Lay out factory-Level 0	I
Conference room	12	0	B.1.2-A1	Lay out factory-Level 0	I
General Manager	13	0	B.1.2-A1	Lay out factory-Level 0	I
administration	14	0	B.1.2-A1	Lay out factory-Level 0	I
Reception	15	0	B.1.2-A1	Lay out factory-Level 0	I
Canteen	16	0	B.1.2-A1	Lay out factory-Level 0	I
Disabled & Visitor WC	17-18	0	B.1.2-A1	Lay out factory-Level 0	I
Stability Chamber	19	0	B.1.2-A1	Lay out factory-Level 0	I
Weighing room	20	0	B.1.2-A1	Lay out factory-Level 0	I
QC/RD Office	22	0	B.1.2-A1	Lay out factory-Level 0	I
Laboratory	23	0	B.1.2-A1	Lay out factory-Level 0	I
Laboratory dressing room	24-26	0	B.1.2-A1	Lay out factory-Level 0	I
Staff WC	25	0	B.1.2-A1	Lay out factory-Level 0	I
Production Dressing room	27	0	B.1.2-A1	Lay out factory-Level 0	I
Clean room plant	28	0	B.1.2-A1	Lay out factory-Level 0	I
Staff Air lock	11EP/11QC/11CP	0	B.1.2-A1	Lay out factory-Level 0	I
Material Air lock	11EM/11CM	0	B.1.2-A1	Lay out factory-Level 0	I
Dryer room	11E/12E	0	B.1.2-A1	Lay out factory-Level 0	I
Centrifuge room	11 C	0	B.1.2-A1	Lay out factory-Level 0	II
Material SAS	12CM/12EM	0	B.1.2-A1	Lay out factory-Level 0	II
STAFF SAS	12 WP	0	B.1.2-A1	Lay out factory-Level 0	II
Centrifuge-Buckner room	12 C	0	B.1.2-A1	Lay out factory-Level 0	II
Packaging room	12 W	0	B.1.2-A1	Lay out factory-Level 0	II
Pilot Area – Line 2	29	0	B.1.2-A1	Lay out factory-Level 0	II
Pilot production – Line 1	30	0	B.1.2-A1	Lay out factory-Level 0	I

Finished Good Warehouse	31	0	B.1.2-A1	Lay out factory-Level 0	I
Raw Material Warehouse	32	0	B.1.2-A1	Lay out factory-Level 0	I
Boiler room	33	0	B.1.2-A1	Lay out factory-Level 0	I
Sampling room	34	0	B.1.2-A1	Lay out factory-Level 0	I
Maintenance	36	0	B.1.2-A1	Lay out factory-Level 0	I
Maintenance office storage	35	1	B.1.2-A1	Lay out factory-Level 0	III
LPG tank area	60	0	B.1.2-A1	Lay out factory-Level 0	I
External utilities area	61	0	B.1.2-A1	Lay out factory-Level 0	I
Water Washing reservoir	62	0	B.1.2-A1	Lay out factory-Level 0	I
Rain Water reservoir	63	0	B.1.2-A1	Lay out factory-Level 0	I
External Flammable warehouse	55	0	B.1.2-A1	Lay out factory-Level 0	I
External weighing room	55 B	0	B.1.2-A1	Lay out factory-Level 0	I
Pump room	55 C	0	B.1.2-A1	Lay out factory-Level 0	I
Meeting room	37	1	B.1.2-A1	Lay out factory-Level 1	II
Office	38	1	B.1.2-A1	Lay out factory-Level 1	II
Corridor	39	1	B.1.2-A1	Lay out factory-Level 1	II
Office	40A	1	B.1.2-A1	Lay out factory-Level 1	II
Archive	40B	1	B.1.2-A1	Lay out factory-Level 1	II
R&D office	41	2	B.1.2-A1	Lay out factory-Level 2	II
Electrica switchgear	42	2	B.1.2-A1	Lay out factory-Level 2	I
R&D Laboratory	43	2	B.1.2-A1	Lay out factory-Level 2	II
Future pilot plant	44	2	B.1.2-A1	Lay out factory-Level 2	III
Utility plant area	45	2	B.1.2-A1	Lay out factory-Level 2	I
Maintenance office	46-47	2	B.1.2-A1	Lay out factory-Level 2	III
Cooling tower	64	3	B.1.2-A1	Lay out factory-Level 3	I
Production plant- Line 3	56	0	B.1.2-A2	Lay out Factory-level 0 – Stage III	III
Future Finishing area	57	0	B.1.2-A2	Lay out Factory-level 0 – Stage III	III
Centrifuge room	58	0	B.1.2-A2	Lay out Factory-level 0 – Stage III	III
Dryer room	59	0	B.1.2-A2	Lay out Factory-level 0 – Stage III	III
Air lock finishing area	54 A-B-C	0	B.1.2-A2	Lay out Factory-level 0 – Stage III	III

Table 3 Division building for work and areas.

B.1.2.4 Annual production capacity of the facility

The plant production capacity will be divided into three phases. However, please note that this is a valuation date based on the research and development that is taking place, the yield of the synthesis that will apply in the different lines of the plant and of course the business orders made by the customers. So far, it is possible to produce this type of business

Phase	Amount (kg per year)
Stage I	5,000
Stage II	10,000
Stage III	20,000

Table 4 Annual production capacity

B.1.3 Justification for application

The Sterling project is divided into 3 steps. During the first one a building for the research and development of the organic chemical synthesis has been built as described in the Project Description Statemen for which the Full Development Permission No PA/04236/08it was achieved. However, in order to fully realize what has been written in the PDS it is necessary to subject the project to the Environment Impact Assessment procedure, in fact, according to article. 3, paragraph 4 of LN 114/2007 Sterling Chemical Malta Ltd pertains to Class 8.3.1.1 section i) Category I of the Schedule IA. This extension is also considered in the IPPC regulation as a "substantial change" and for this reason the project must be analyzed also through this report that complies with the guidelines indicated in the FORM IPPC Part B "application for a new permit". The table below shows the information needed to frame the type of activities that will be carried out in the company according to the classification by the European IPPC regulations subsequently implemented in Malta.

n° progr.	IPPC[1] Industrial Activities	cod IPPC[2]	cod NOSE-P[3]	cod NACE[4]
1	Installations by using a chemical or biological process for the production of basic pharmaceutical products	4.5	107.03	24

Table 5 IPPC Activities Identification

The IPPC procedure will be jointed to the EIA procedure in order to easily understand the new activity by saving time and human resources.

[1] See Attachment I of D.Lgs 372/99
[2] See Attachment I of D.Lgs 372/99
[3] Code NSE-P: European Standard classification for emissions (C.f.r. 2000/479/CE of 17th of July 2000)
[4] Codice NACE: Economic activities European Standard classification (see Tab. 1.6.1, attachment 1, D.M. 23/11/2001).

n° progr.	Source	Law	Law Identification Code
1	Legal Notice of Development Planning Act and Environmental Planning Act	Industrial Emissions (Integrated Pollution Prevention and Control) Regulations, 2013	LN 10/2013
2	Legal Notice of Development Planning Act and Environmental Planning Act	Environmental Impact Assessment Regulations, 2007 - Arrangement of Regulations	LN 114/2007
3	European Community	On the assessment of the effects of certain public and private projects on the environment	Directive 85/337/EEC
4	European Community	Amendment of Direcitive 85/337/EEC	Directive 97/11/EC
5	European Community	Amendment of Direcitive 85/337/EEC	Directive 2003/35/EC

Table 6 Relevant legislation for this application.

B.1.4 Site maps and reports

B.1.4.1 Site hystory report

The HAL FAR Sterling Chemical Malta Ltd production facility is located in the southern part of Malta, an area between the city of Birzebbugia and Zurric. Such area hosts an important industrial zone which is still growing. The following table shows the main information of the area.

Plant address					
Local council	Birzebbuggia	cod.	BBG 3000	Region	Marsa Xlokk
Town	HAL FAR Industrial Estate				
Address	HF 51				
telephone	+356 27781224	fax	+390755294001	e-mail	ehs@sterling.it
coordinate Gauss-Boaga	35°48’54’’	N	14°30’36’’	E	

Table 7 Plant address.

The development site proposed is located just off the Triq Ħal Far, an arterial road which connects Hal Far with the Freeport, in Birżebbuġa.

Before starting with the current modification, this site was vacant. In order to have a reliable reference on the conditions of the ground water in the past, (before achieving the MEPA permission to develop the R&D project and the pilot plant) it is necessary to refer to the report submitted in 2009, 2010 and 2011 by the Water Services Corporation, which continuously monitored the water quality in several villages to check if it was harmful to the health. As far as HAL FAR the following downsides have been recorded:

- Chloride: it originates from natural sources. The standard is not related to health but set to avoid taste and corrosion potential. It is mainly attributed to the island hydrogeological characteristics and environmental conditions;

- Sodium: this substance occurs naturally in water. Standard set due to its unacceptable taste. It is primarily attributed to the island hydrogeological characteristics and environmental conditions;

- Iron: it is very abundant in nature. Drinking water supplies can be contaminated because of a corrosion of steel and cast iron pipes during distribution.

The surrounding industrial area is already developed, as well as other companies located in the vicinity of the site which produce active pharmaceutical ingredients. The area covers about 3,295 square meters and the exact location of the site is shown in the site plan attached. The facilities proposed will be housed in a new-built plant authorized by a Full Development Permit - PA/04236/08. Previously, the site was a vacant plot and no previous activities were established there.

The land was covered by the typical coastal vegetation characterized by asphodels and asteraceae and it represented an ecological discontinuity since it was surrounded by other industrial activities in the North, East and WEST side. A road was its SOUTH borderline and over the SOUTH-EAST border, the first sea inlets with industrial buildings lead to a walk along the irregular southern coastline after 500 meters. There is no significant habitat, except for the Montpellier snake (*Malpolon monspessulanus)* and the False smooth snake (*Macroprotodon cucullatus)*, two North African snakes, and the *Large Psammodromus*: a type of North African lizard.

Now the site is dived into a built area and one with no buildings. The built area covers approximately 1,430.00 square meters and is divided into three different zones:

1. The administration/offices area,
2. The Research and develpoment area (laboratory, clean room, production pilot area indoor warehouse, maintenance).
3. The External Flammable warehouse and the other external utilities (LPG Tank)

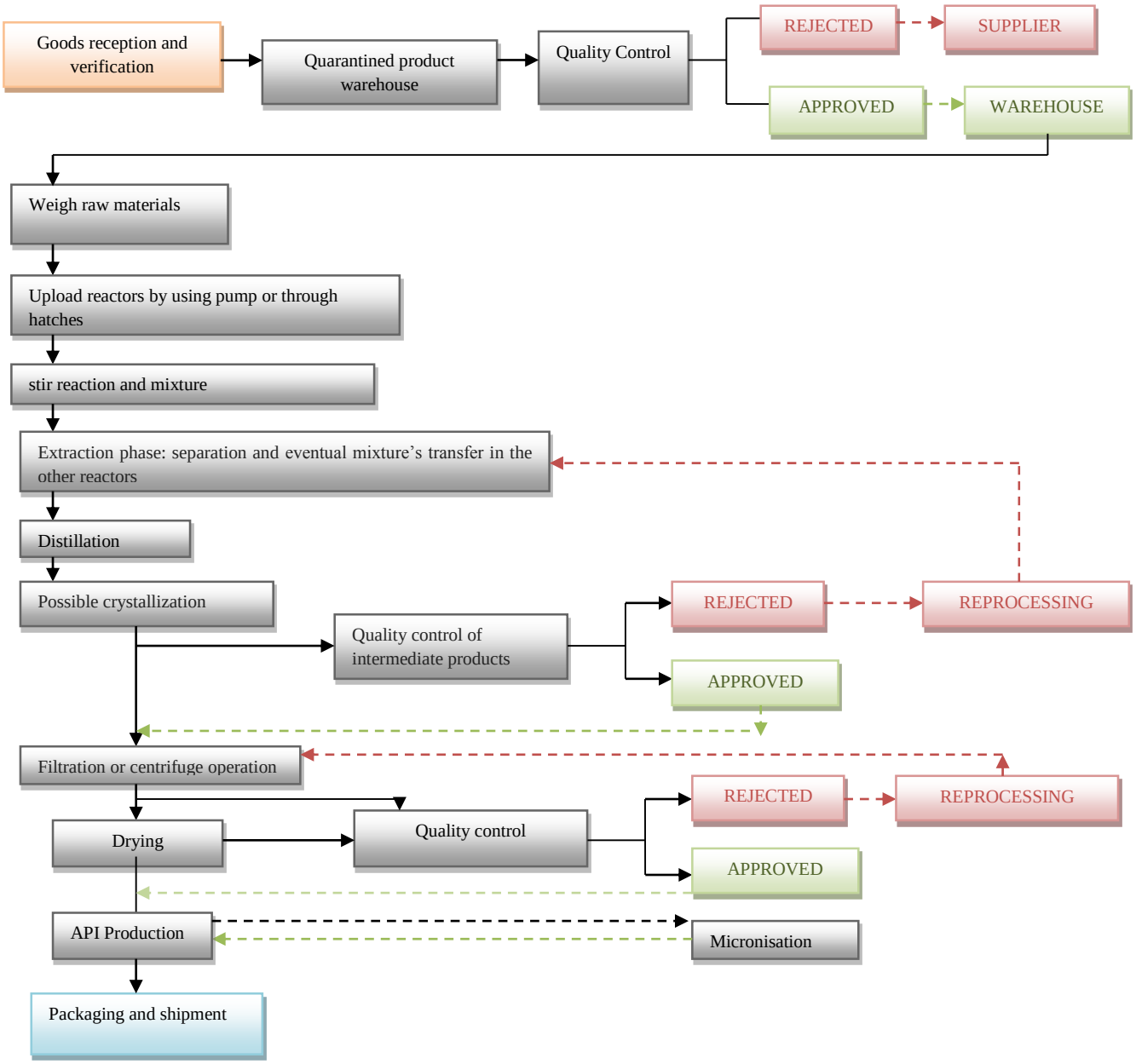
Such areas cover about 410 square meters and 1,020.00 square meters respectively. These three areas in turn are divided as shown in the plants in annex B.1.2-A1

B.1.4.2 Site Map

An appropriate ***map*** showing the site location, as well as the entire area covered by the site is attached to ***annex B.1.4-A1.***

B.1.4.3 Site plan and the relative activities

This paragraph flow chart shows the different activities carried out inside the building. Every block explains the type of activity in detail.



Flow Chart 1 API production.

B 1.4.3.1 Production cycle

The production process begins with the reception of goods that are verified in terms of identity, quantity and quality before being considered as suitable for producing steroids. Depending on the active ingredient to be produced, the production manager and/or his assistants will request the warehouse operators to prepare all the materials needed in the right quantity by submitting them a "bill of weights". Weighing operations and all activities carried out by the operators involved in such working step will be performed in suitable areas of the production plant and, in particular, in the room identified as the "External Flammable Warehouse" within the loading/unloading area or in the sampling room (depending on the starting material needed, the original packaging and the quantity to be taken). Large amounts of flammable starting materials are weighed in the flammable material warehouse by using a steel platform scale. Such balance is placed on a tank with a grid surface having a capacity equal to 1,134 m^3 for a supporting surface of 3.8m^2. The whole tank is 10 cm off the ground level and is separated from the first containment tank by a REI 60 wall. On the steel plate of the scale, located on the right side of the tank, the tank or the drum to be filled is placed. Such plate lays on a stainless steel mesh which represents the upper side of the containment tank made of high density polyurethane. On the left side of the tank, directly on the steel mesh, the tank containing the raw material will be placed. Liquids will be transferred from one tank to another through a closed circuit in order to avoid that such liquids and their gas (volatile organic compounds) come in contact with the open air. In this way no explosive mixtures are generated and the dispersion of vapours is avoided. This circuit entails using a progressive cavity pump connected to a flexible tube that, starting from the top of the container to be emptied, conveys the liquid into the tank/drum to be filled. Another tube, with a smaller diameter, conveys the saturated air with vapours, gas or volatile organic compounds from this second container to the first container that is slowly emptied. The extraction of vapours from the container to be filled is assisted by the depression created inside the container to be emptied due to a leakage of the liquid (made with a pump since the containers are placed at the same level). In this way, in addition to prevent dangerous mixtures, (for example inside the weighing chamber where a classic intake system equipped with a filter conveying into the atmosphere is installed) it also avoids a leakage of the liquid since a containment tank is placed below by minimizing the transfers of tanks containing raw materials. Area-source emissions will only be limited to the time necessary for opening or closing the full tanks or drums. The weighing area of external flammable warehouse will only take place the weighing of liquids, or solids in the case there should be no splits. The scale in the external flammable warehouse will be used only for solids on arrival of the goods for weight control but the containers will never be opened.

Weighing operations are carried out inside the room located at level zero. The weighing chamber is equipped with a scale and a suction hood, that is a localized suction system that must be activated during the whole weighing operation of raw materials in order to avoid

spreading volatile compounds or powders in the room. Such gases are conveyed into an abatement system made up of a pre-filter, a HEPA type filter and a filtration system with activated carbon cells. The first two filters will be used to capture powders resulting from weighing or decanting operations, while the third system will clean the air conveyed in the atmosphere from all volatile organic compounds. The work concerning the chamber will not be limited only to the replacement of the abatement system but it will also include a structural investment .
The chamber is made up of:

1. An ante-room where the operator changes their clothes and wear the personal protective equipment and shoe covers. The operator carrying drums (transported by using a trans pallet) must lay down them at the entrance of the chamber where raw materials needed for production are loaded. Before going ahead the operator must wear the disposable coverall, appropriate shoes, a half-mask and a hairnet (if it is necessary). In this way the internal room, in which pouring and weighing operations are performed, is kept aseptic.
2. A fixed hood; this hood is combined with a suction fan having an airflow of 3,500 m^3/h, a low pressure ATEX extractor fan made up of an antistatic polypropylene body adjustable up to 8 positions with a corrosion-resistant gasket protecting it against the risk of fumes leakage.

At the first level of the abatement system an electrostatic air-filter is used. Such filter has an efficiency > 90% on particles with a diameter higher than 0.5 μm and an efficiency of 80 – 85 % on particles with a smaller diameter. This filter is a G4 filter (European code EU4) and is placed inside of a case consisting of a sturdy frame made of anodized extruded aluminium. Panels made of galvanized sheet with a single wall are equipped with an inspection hatch to allow the cleaning and the replacement of the filter. The second level of the abatement system is made up of a packed-bed filter with granular activated carbon (dimensions 0.5 – 1.5 mm) that absorbs volatile organic compounds. The particular affinity of the virgin activated carbon for organic substances, is due to its non-polarity. The effectiveness of the activated carbon in absorbing the residual organic pollutant is inversely proportional to the solubility of the residue in water, which is a function of the residues polarity. A polar substance (a substance that can be dissolved in water) cannot be completely removed from the activated carbon or is only slightly removed. On the contrary, a non-polar substance can be completely removed. Furthermore, the affinity increases as the size of the residual increase (the specific surface increases and the Van der Waals intermolecular forces increases) and as the functional groups of the molecules adsorbed increase in turn (by adding functional groups to the molecule the polarity of the molecule itself decreases, for example, methyl phenol is more adsorbed than phenol). The third level of the abatement consists of a scrubber which involves the use of a liquid (generally water or an aqueous solution containing an additive) for separating powders, gas and vapours from the air. Abatement is essentially an impact between the abatement liquid nebulized and powders and pollutants in the air. For this particular purpose the air is conveyed at a low speed through a vertical or horizontal pipe (scrubber) by passing through a system of fixed or mobile bodies sprayed with water jets. Such jets are supplied by a pump connected

to a containment tank. A vapour-liquid separator is placed at the head of the tower in order to remove water drops from the air flow. In this way the outgoing air into the atmosphere is treated.

The SCRUBBER always uses the same abatement liquid that after the washing falls into the underground tank placed outside the building. During this phase abated air pollutants are collected and left to sit (in case of powders) in the form of sludge or suspension. The system is able to constantly work, with no interruptions except for periodic maintenance services. Once goods have been weighed, they must be moved into the production area. Solvents or liquid raw materials are loaded in each reactor through a closed-circuit progressive cavity pump, while solid raw-materials are loaded by using a hatch hopper. When loading material, the operators are required to wear the personal protective equipment (PPE) and to turn on the mobile extractor fans that come with each reactor This extractor will be used in the areas .which is contained and equipped with appropriate filtration. Such fans are placed next to the hatch or the solvent loading area. The activation is followed by the first transformation phase consisting of a reaction. In this phase the operator puts a reactor under vacuum through an appropriate circuit. The reactors used have different volumes in order to ensure reagents have the necessary time to perform the chemical reaction. Such reactors carry out the required heat exchange and, through mechanical agitation, bring these phases into close contact in order to facilitate the mixing. The reactors placed in the production lines are of different size, they have different technical specifications and auxiliary equipment but the basic operative principle is the same. However, all equipment runs in batch, that is as a closed thermodynamic system, without incoming and outgoing currents, with loading and unloading phases necessary to fill and empty the equipment. A steady state of the mixture is almost never reached except for a transitional period during which distillation occurs and the subsequent transfer to the reactor is performed. Considering the high temperature reached (the maximum operating temperature reaches 120 °C) the heat produced or absorbed by the reaction has been taken into account during the planning phase. For this reason the reactors have been equipped with heat exchangers such as jackets (gaps on the tank wall crossed by a cooling fluid consisting of drinking water and glycol at 50% solution). Equipment can operate under vacuum by using a trap for the process vacuum which ensures a lower pressure within the reactor with respect to the room temperature. Such trap ensures an excellent insulation and makes it possible to work in the best possible conditions. Also the vacuum trap, as the other utilities servicing the reactor, works at high temperatures. For this reason a cooling system has been added. Such system is made up of a shell and tube heat exchanger, in which the fluid flowing in the shell of the exchanger is still water and 50 % of glycol solution. The reaction is always conducted in a discontinuous way since the mixture of reagents and solvents is loaded (reagents and other solvents are suctioned with portable tanks through a fixed dip pipe. Otherwise it is possible to use a progressive cavity pump, while powders are inserted through an hopper from the reactor hatch). Reactors are heterogeneous since reagents, the products and the possible catalysts can be present in different phase. Reactions occur into vat-shaped tanks while agitation is mechanically performed by propeller mixers that allow the fluid to come in contact with the heat exchanger surfaces. A wheel-mounted

pump is used for liquid substances, that must be used in small quantities, while solids are loaded through an hatch in the presence of local suctions. Reactions consecutively occur in all reactors of each line. The last reactor of each line is a crystallizer in which crystals are generated by following the monitored precipitation of the reaction mass in a solvent. Eventually it can be separated from the same solvent. Also in this case the tank is cooled down through a jacket in which the same heat transfer fluid (seen for the previous reactors) flows. The handling of raw materials within the production plant consists in moving tanks or drums in which such materials are contained from the loading warehouse (for the new plant) or directly from storage warehouses (for the old plant) next to the loading sections of the reactors in which they will be loaded. Only here, after putting the local extraction system into operation, the tanks can be opened and the raw materials are transferred by vacuum suction, pump and hopper. The second operation that will be carried out within the plant is the extraction. During this phase the reaction mass is made up of two immiscible phases: an aqueous and an organic phase. This is left to sit and cool down until they are completely separated. The solvents used for the extraction are organic, such as dichloromethane or ethyl acetate solvents. At the end of the reaction, water or organic solvent, or both the elements, will be added in the reactor depending on the type of reaction previously occurred. The new mixture is then agitated for about 20 min – 30 min and is left to settle and cool down. Reaction mass will be moved into a new reactor while the organic solvent remains in the reactor previously used and then will be removed. Usually extraction operations entail adding a solvent and they have different duration depending on the product being analysed.

A further separation between the products resulting from reaction is performed by heating and distilling the mixture. The products within the mixture have different boiling points that are reached in the cylindrical distillation column equipped with a temperature gradient. Sometimes distillation can occur under vacuum because the boiling point is reached at too high temperatures to allow working under atmospheric pressure. The vacuum makes it possible to reduce such temperatures. Solvent is then collected in tanks and subsequently removed. The mass is left cooling down to let it reach a room temperature. After the crystallization of the reaction mass, the mixture is moved into the “finishing” department: the area of the plant in which the last part of the production process is carried out. In particular, two main processes are performed here. The first one is about liquid – solid separation through filtration, centrifugation and drying operations; the other one involves the various intermediates or finished products which can be sent for micronisation. The centrifuges used are vertical; this means that, at the end of centrifugation, the product (powdered solid material wet with solvent) must be unloaded by opening the top cover and removing it with a small shovel. Otherwise the filter bag can be extracted with a hoist and the content unloaded in a suitable tank.
The filtration process, made with a Buchner funnel is usually performed under vacuum by using a water pump and by following the suction principle. In this way the liquid passes through the filter and drips. The mother liquor is unloaded after being collected at the bottom of the filter while the powdered and wet solid remain in the steel basket.

Centrifugation is an alternative to filtration. It is intended to speed up the separation between bodies having different density by using the centrifugal acceleration. The centrifuges supplied work with a filter. The discharge areas for solids and liquids are separated and equipped with a permeable basket for liquids (but not solids) acting as a real filter. The drum consists of a vertical axis with a filter-bag that can be extracted from the top by using an appropriate hoist. The three-phase motor is made of an explosion-proof material and is ignited through a specific button on the control panel, in turn made of an explosion-proof material.
Drying is an operation carried out in rooms with a slight overpressure by using a double-cone rotary (or fixed) dryer. Both of them are put under vacuum and equipped with a heating jacket with water circulation and a condensing set of the solvents suctioned by the vacuum pump. The product resulting from centrifugation is loaded into special trays and directly placed in the fixed or rotary dryer. During the drying, the product is kept at a constant temperature and under vacuum through a specific unit.
Once the product has been dried, it is loaded into cardboard or aluminium drums and carried to the warehouse for the packaging and storage of intermediates.
Production process will generate flammable hazardous and non-hazardous wastes, in a liquid and solid state (e.g. mother liquors or waste water).

The production phase is completed with the collection of waste water. In order to ensure high quality products, the entire plant must be thoroughly cleaned once this phase has been completed. The cleaning of the plant is a delicate operation because of the type of products processed by the company and the materials used for cleaning operations. Generally reactors are cleaned by using a solvent, so it is possible to detect volatile organic compounds in the emissions canalized into different lines and finishing chimneys. In order to describe how such phase is managed, it is necessary to specify that cleaning is divided into 2 stages: The real plant cleaning, which is different depending on the product processed and the execution time (detailed in the Master Production Record of the company, that is a document containing all information necessary for producing the product) and the Cleaning validation, which certifies the quality of the cleaning performed. Before cleaning the plant, the operators must follow some preliminary procedures and comply with certain good-manufacturing rules. During the handling of products operators must wear the clothes provided (coverall) and personal protection equipment (gloves, mask with organic vapour filter) and they must connect with earthing system the containers and dip pipes. In order to prevent any emissions within the work place during the suction of solvents, the local extraction system (as well as the general one) must be turned on. Each reactor will be equipped with two local suction fans having an airflow of 40 m^3/h. One is placed in the loading area and the other in the unloading zone. Such system captures the pollutants (liquid, solid or steamy pollutant) directly at the point in which they are produced by providing an adequate protection for the operator. In particular, this system is made up of an adjustable suction tube with a fan installed at the ends of the pipe. During the processing such fan can be placed near the pollutant source and moved next to any pollutant emission point, if necessary. The other end of the tube is connected to the extraction system.

All the mobile extractor fans will be limited to areas which is contained and equipped with appropriate filtration

Both systems (the local and general one) must be kept on at least for 30 minutes after loading the cleaning solvent. The operations to be performed are the following:

1. Fill the round-bottom flasks of the reactor to be cleaned with drinking water supplied by a stainless steel pipe. Pour water in the reactor and discharge it through a check valve into portable tanks. Create the vacuum within the round-bottom flask and restore the atmospheric pressure with nitrogen (supplied by stainless steel tubes). Then load the solvent and restore the atmospheric pressure by using nitrogen;
2. Create the vacuum in the reactor and restore the atmospheric pressure with nitrogen. Open the discharge valves and pour the content in the round-bottom flask for washing the drip line (Vacuum pipes are made of polypropylene);
3. Stir the mass by heating it with the hot water in the jacket that encloses the reactor until re-entry. Maintain such conditions for 15 minutes and distil the solvent in each round-bottom flask.
4. Cool down the mass until it reaches a room temperature and discharge the content of the reactor and the round-bottom flasks into the portable tanks that will contain non-chlorinated organic solvents. Such tanks will be labelled and sent for disposal with code EWC 070704*.
5. Repeat the cleaning operation by creating the vacuum in the reactor and restore the atmospheric pressure with nitrogen Load the solvent through vacuum and restore the atmospheric pressure by using nitrogen. Then stir the mass.
6. Heat the reaction mass with the hot water in the heating jacket until re-entry. These conditions are maintained for about fifteen minutes and then the solvent is then distilled in each round-bottom flask;
7. After cooling the mass down to a room temperature, load the content of the reactor into collecting tanks which are labelled with code EWC 070704* (non-chlorinated organic solvent);
8. Empty pipes and collecting containers and create the vacuum within the reactor by heating it up until it reaches a temperature of about 40°C. Such temperature conditions must be kept for twenty minutes. Then cool down the reactor vat and restore the atmospheric pressure by using nitrogen.

The filter and centrifuge cleaning will be completed by transferring the mass previously used in the last reactor/crystallizer of the line to the filter or the centrifuge subjected to passivation with nitrogen and assembled canvas. Then the solvent mass is centrifuged and discharged into portable tanks labelled with code EWC 070704*. The filter and centrifuge must be cleaned with lint-free wipes soaked in solvent used for cleaning the production line. Then they are sent for disposal, as a special waste, and disposed of through incineration. The code that will be associated at this wipes are 150202*.

All tools used for cleaning operations, such as shells, tubes, sampling valves for liquids and anything else that has been used must be cleaned. The validation will be performed by collecting swabs or samples of the rinse water resulting from cleaning operations, for each type of tool in use for three consecutive production batches. As far as the plant, the cleaning validation consist in checking the effectiveness of the cleaning carried out in three consecutive production batches. The maximum acceptable limit of residual is calculated based on the daily therapeutic dose, since the active pharmaceutical products have a very low toxicity but a very high activity. All cleaning operations must be carried out within one week from the last time in which equipment and tools have been used by wearing the appropriate PPE, and they are valid for one month. After this deadline, and before using such equipment, it is necessary to repeat the cleaning operation corresponding to the last processing performed.
The water needed for cleaning the system is supplied by a public aqueduct.

B.1.4.3.1.1 Production department

The production department consists of a multipurpose building divided into three working areas: the Steroid production area in which reactors, centrifuges and filters required for handling and processing raw materials are located; the Steroid finishing area, in which dryers are placed. Here operators carry out all drying operations for wet products coming from the steroid production area. The Utilities area houses the equipment which manage the process fluids. The following tables shows the structural characteristics of the above-mentioned areas.

The production lines have different areas and volumes. The same goes for the corresponding finishing areas. A description of the active first production line is provided below. The last tables provide a comparison of the two areas in terms of structural features and dimensions.

STEROID PRODUCTION AREA	
DIMENSIONS	• Area _130__ m^2 • Height __12_ m • Volume _1560_ m^3
WALLS AND CEILING	• Brick walls plastered with gypsum and painted. • Ceiling made of sandwich panels (Aluminum composite panels)
DOORS	• 1 Double skinned, galvanised and painted folding door. • 3 Double skinned, galvanised and painted steel door. • 1 Double skinned, galvanised and painted 2 leaf steel door.
FLOOR	• Conductive Epoxy screed.
LIGHTING	• Fluorescent lights with explosion-proof fixtures.
DRAINAGE GULLIES	• Drainage gullies are connected to waste water reservoir.
STRUCTURE	• 4.2 meters steel frame painted with epoxy resin, with a stainless steel deck.

PIPING AND FLUID CONDUCTION LINES WITH SUPPORTS	• Stainless steel pipes for chilled water, cold water, hot water, steam, condensate, nitrogen, and compressed air. • Polypropylene pipes for vacuum and process vent. • PVC pipes for service vent.
ELECTRICITY CABLES WITH SUPPORTS	• PVC conduit for light fixtures and circuits. • Galvanised cable trays and harmoured cables for process equipments.

Table 8 Technical description of the Steroid Production Plant

The production plant is divided into different production lines depending on the features of the reactors used.

In particular they may vary in number, they have different volumes and are made of materials having different construction features. However, the operative procedures, the purpose and utilities used are the same. So, in order to ensure a linear and shortest study it is possible to detail line 2, which is the one immediately active. The first line will have identical work methods with reactors having different volumetric capacities. All production activities start in the first reactor (reference code R2201-M[5]), which has an higher capacity (4,000 liters) in which the operator, through a closed-circuit progressive pump, loads the liquid raw materials prepared in the plant as specified in the processing record sheet. It also uses an hatch with the help of a hopper for lifting solids. Loading and unloading operations will be carried out only after turning on the local extraction fans placed in the contact points between the reactor and the external environment (next to the opening hatch) and between the raw material container and the dewatering pump. The suction arm is a part of the extraction system for smoke or fumes. The arm allows the suction of the pollutant fluid as close as possible to the working area. In this way it is possible to reduce the workers exposure to the pollutant produced. The arm consists of a series of adjustable pipes in which smokes, fumes or dust captured by the emission zone are captured. The arm consists of two segments (whose length changes depending on the need) linked together with a junction. At the ends of such pipe you find: an extractor fan, next to the catching area, and a rotating platform, next to the contact point with the extraction system. The junction of the central piping with the external components is made up of adjustable joints. The fumes sucked arrive at a duct heading to the abatement system located outside the building.

The reactor is made of AISI steel and is provided with a thermal-insulated jacket and a mechanical paddle stirrer at an adjustable angular velocity. The jacket is connected to the heating/cooling system consisting of an axial-flow pump for heat-transfer fluid (water-ethylene glycol at 50%), a shell-and-tube heat exchanger for heating through steam and a plate heat exchanger for cooling through water-propylene glycol at 50%. The reactor is equipped with a fractionating column, a shell-and-tube condenser, an hydraulic guard and a borosilicate glass connecting lines for flushing vapors that evaporate inside. The equipment used for checking key parameters, such as temperature and pressure, consists of two temperature and pressure transmitters placed inside the vessel and a temperature transmitter of the jacket fluid. Once the reaction is completed, the mass can be transferred in a centrifuge or a filter, in order to ensure that the different stages in the second reactor

[5] See detailed plant map in ***Annex B.2.5-A1 Maintenance plan***

are separated (depending on the type of process performed) through a connecting flexible pipe.
The second reactor (R code 2301 M) is made of carbon steel which is internally enameled. It has a capacity of 2,34 L. It is equipped with a thermal-insulated jacket and a mechanical impeller with adjustable angular velocity. The jacket is connected to the heating/cooling circuit consisting of a flow pump for heat-transfer fluid (water-ethylene glycol at 50%), a shell-and-tube heat exchanger for heating through steam, a plate heat exchanger for cooling through water-propylene glycol at 50% and an expansion tank (for the thermal expansion of the heat-transfer fluid). The reaction cell may act as a boiler for a batch-type reactor at a single working-stage: in fact, in the upper part of the reactor is connected, through a fractionating column to a shell-and-tube condenser (supplied with water-propylene glycol at 5°C). From here the condensate, after passing through an hydraulic guard, is collected in two parallel tanks otherwise it is redirected into the reactor through a reserved reflux line.
Non-condensable gases are conveyed to the abatement system after passing through a coil heat exchanger (supplied with water-propylene glycol at -25°C). Reagents can be placed within the reactor through dropping operations from two parallel tanks connected to the reactor. The entire circuit described is connected to the top of the reactor and is made of borosilicate glass. The third Reactor (R code 2401 M) is made of carbon steel and is internally enameled. It has a capacity of 335 L. It is equipped with a thermal-insulated jacket and a mechanical impeller with adjustable angular velocity. It is located next to reactor R2801 M, the smallest reactor involved in production operations. However, this reactor is rarely used only for operations concerning the synthesis of the active ingredient Fulvestrant. The reactor has a capacity of 215 L.
The jacket is connected to the heating/cooling circuit, which consists of a flow pump for the heat-transfer fluid (water-ethylene glycol at 50%), a shell-and-tube heat exchanger for heating through steam, a plate heat exchanger for cooling through water-propylene glycol to 50% and an expansion tank for the thermal expansion of the heat-transfer fluid. The reaction cell can act as a boiler for a batch-type reactor at a single working-stage: in fact, the upper part of the reactor is connected, through a fractionating column, to a shell-and-tube condenser (supplied with water-propylene glycol at 5°C). From here the condensate, after passing through an hydraulic guard, is collected in two parallel tanks, otherwise it is redirected into the reactor through a reserved reflux line. Non-condensable gases are conveyed to the abatement system after passing through a coil heat exchanger (supplied with water-propylene glycol at -25°C). The entire circuit described is connected to the top of the reactor and is made of borosilicate glass. Two pilot-reactors having a capacity of 5 and 10 liters respectively (reference code LR-01M, LR-02M) complete the line. Later they will be a part of the pilot plant exclusively used by the research and development laboratory.
If reaction and distillation occur inside a reactor, separation occurs through filters and centrifuges. Such operation begins with the centrifuge inertization, by using the system combined with it. When the centrifuge is saturated with nitrogen and there are no risks of explosion, connect the reactor check valve containing the suspension to the centrifuge flange and put it in a slow rotation. Once the product is well distributed on the filter bag,

the real centrifugation starts by increasing the rotation speed of the drum. The wet solid unloaded from the centrifuges is moved in the drying area, where it is dried and packaged in appropriate drums to be stored in the finished products and intermediates warehouse. The centrifuge that will be used has a capacity of 400 liters while the Buchner funnel or the Sparkler filter have a volume of 500 dm^3 respectively.

In the future the pilot reactor (LR-01M, LR-02M) will be moved at the second level and two new production lines (line L1 and L3) will be added. Line L1 will be almost identical to line L2 with the same (or a little higher) production capacity since a reactor of 10,000 liters will be added too. Since line L3 is a start-up plant, it is impossible to predict the production needs that are strongly linked to the market. For this reason it is not possible to attach a detailed document on the equipment.

Once processing and mixing operations of raw materials have been completed, the resulting product (or its intermediate) will be wet with solvent (water, acetone, methanol, dichloromethane, etc.). So, the processing has not yet been finished and a drying operation must be carried out by placing the solid mass in special static dryers (in the future they could be also rotary-type dryers for meeting costumer or production needs). The product is in the steroid finishing area where the other operations such as the weighing and packaging of the final product are performed. This is very important for GMP regulations since this is a sterile area with an higher pressure with respect to the outside. The following table shows the characteristics of the materials used for building the entire area and the total dimensions. In fact, there are several rooms used for different operations within the area.
The finished area described refers to the area at stage I associated with production line L2. The characteristics for the other two finishing areas associated to lines L1 and L3 are identical in terms of the work performed and architectural materials used, but they are geometrically different for a matter of space.

STEROID FINISHING AREA (clean room plant)	
DIMENSIONS	• Area _100__ m^2 • Height __3_ m • Volume _300_ m^3
WALLS AND CEILING	• Freestanding Gypsum board walls partitions covered with vinyl. • Ceiling made of 600 X 600 mm aluminium panels.
DOORS	• 9 single leaf GPR doors. • 1 double leaf GPR doors.
WINDOWS	• 2 locked windows.
FLOOR	• 2 mm homogeneous vinyl.
LIGHTING	• Fluorescent light fixtures.
VENTILATION, AIR CONDITIONING AND PURIFICATION	• System composed by N°2 Air Handling Units. • Galvanised steel ventilation ducts. • Air supply filtered with G4, F9 and H14 Hepa terminal filters. • Air velocity sensors allow to adjust the speed of the fan in order to adjust the airflow. • Humidity and temperature probes allow to adjust the parameters. • Exhaust air filtered with G3, F9 and H13 Hepa filters.

	• Differential pressures controlled by electronic sensors.

Table 9 Steroid finishing area (clean room plant)

The utilities area is located at level 2 and will remain as it is even for the following structural developments of the plant (stage II and III). This area can only be accessed by maintenance staff and technical experts appointed by the company.

UTILITIES AREA	
DIMENSIONS	• Area _315__ m^2 • Height _6__ m • Volume _1,900_ m^3
WALLS AND CEILING	• Bricks walls, Gypsum plastered and painted. • Roof made of PCC slabs.
DOORS	• 4 Single skinned, galvanised and painted steel door.
FLOOR	• Powerfloat finish to concrete floor.
LIGHTING	• Fluorescent light fixtures.

Table 10 Utilities area

The locations of the reactor is shown in Annex B.1.4-A4, while the table below shows the technical data for individual reactors into lines L1 and L2. In this moment they were not detected in neither the number and type of reactors that can be used in the future line 3. You can see the identification code of each reactor listed in Column 1 on **Table 11** and find them in the plan shown in annex B.1.4-A4.

Technical data of reactors									
Reactor Code	***Construction Year***	***Factory code***	***Type***	***Volume Body Reactor (L)***	***Volume Jacket Reactor (L)***	***Gauge (mm)***	***Material***	***Operating Temperature (°C)***	***Operating Pressure (barg)***
R-1101M	2014	1210	CE 6300	7590	695	150	Carboon steel with rockwool technical insulation	-25/+200	-1/+6
R1201M	2014	1189	CE 4000	4930	520	150	Carboon steel with rockwool technical insulation	-25/+200	-1/+6
R1301M	2014	19214	CE 0948	10000	270	150	Steel AISI 316 on vessel and AISI 304 on Jacket with rockwool technical insulation	-20/+150	-1/+0,49
R-2201M	2012	859	CE 4000	4930	250	150	Carboon steel with rockwool technical insulation	-25/+200	-1/+6
R-2301M	2012	807	CE 1600	2340	127	150	Carboon steel with rockwool technical insulation	-25/+200	-1/+6
R-2401M	2012	858	CE 0035	335	84	150	Carboon steel with rockwool technical insulation	-25/+200	-1/+6
R-2801M	2013	1105	AE160	215	67	150	Carboon steel with rockwool technical insulation	-25/+200	-1/+6
LR-01M	2012	17791	KC11350	10	1	100	Borosilicate glass	-15/+180 °C	-1/+0,5
LR-02M	2012	17792	KC11351	5	1	100	Borosilicate glass	-15/+180 °C	-1/+0,5

Table 11 Technical data of reactors in line 1 and 2

B.1.4.3.1.2 Quality Control Cycle-Work

As highlighted in the first block-diagram, the production activity is coordinated with the activities carried out in other departments.

During all process phases, the proper quality controls are guaranteed on raw materials, finished products, starting materials, packaging materials, cleaning materials, materials used during production activities (for example filters, cloths, centrifuges, etc.). The "Specification Sheets" are the basis of all activities performed within the laboratory. Such documents show all technical and qualitative information regarding each product/material analysed and checked. These Specification Sheets are issued by complying with the international laws in force in the pharmaceutical sector (Good Manufacturing Practice), as well as with the regulations issued by the Ministry of Health of the Italian Republic and by the "International Pharmacopoeia". The specification sheets are divided into six/seven chapters:

- Counter-Samples Sampling: It establishes which operators are in charge with sampling operations, the equipment and the containers to be used. It also specifies the quantity of the sample and how counter-samples must be stored by detailing the preparation instructions and the management of the samples themselves);
- Chemical-physical properties: It lists all tests to be carried out to in order to approve the product/material analysed;
- Conservation and Re-Check: It establishes all conditions under which the product/material analysed must be stored by specifying the maximum storage time;
- Packaging description;
- Manufacturing procedures and validity time for finished/Intermediate products: Based on the stability data, this chapter establishes when re-tests must be performed or the expiry dates;
- References: It refers to international regulations, safety data sheets, etc..

Each material and product/intermediate is equipped with a specification that specifies all tests to becarried out. The list below shows the activities carried out within the laboratory:

1. Counter-samples preparation and conservation: Sampling operations are carried out in the appropriate weighing chamber located in building A. The analyst within the laboratory must keep a quantity of the sample necessary to carry out at least two complete analyses required by the specification. Samples are stored in tightly closed containers that must be protected from light. In particular some cabinets equipped with a thermo-hygrograph are used for monitoring the temperature and relative humidity;
2. Preparation and registration of internal chemical-physical standards: The standards are products whose chemical-physical characteristics define and ensure reference

parameters at a very high and stable level of accuracy and precision, for a sufficiently long time. There are two types of standards: the official ones, certified by national or international bodies (Pharmacopoeias, WHO, etc.) and the internal ones, when they are prepared and characterized by the company itself. The preparation consists in:

- Selection of a batch of material/product with the highest possible quality characteristics;
- Then proceed to its characterization through:
  - ✓ Identification: it is performed with Spectroscopy analyses (Nuclear Magnetic Resonance analyses (NMR), Spectrophotometry, IR, UV, Elemental Analysis), HPLC or other type of analyses which, with the aid of any possible data, allows to uniquely identify the substance being tested;
  - ✓ Titration (in case of primary internal standards): It is performed by using a Pharmacopoeia and it is necessary to determine the Titration by estimating the purity, the content of solvents, the ashes and the Karl Fisher (water content);
  - ✓ Recordings: The execution of trials and tests must be recorded in the analysis notebooks relating to reference standards.

3. Glassware washing: Glassware consists of flasks, pipettes, beakers, flasks, stoppers, spatulas, etc., used in the laboratory or for sampling the material/product/intermediate to be analysed. All glassware used (except for cuvettes, sample cell holders and syringes) is washed by using a glassware washer equipped with three washing racks. Two racks are provided with a spindle rack for positioning beakers, flasks, etc. Cuvettes, sample cell holder and syringes are washed manually with acetone and deionized water.
4. Weighing: The sample of the material/product to be analysed must necessarily be weighed under an exhaust hood regardless of the physical state or the nature of the material being tested;
5. Analysis: As said before, there are different analysis and tools used. A brief but not exhaustive list is provided below. Such list roughs in all tools that could be employed:
   - ➢ HPLC: It is a chromatographic technique which allows separating a complex mixture of molecules. In particular, it is based on a mobile base flushed through pumps and a monolithic HPLC column with a solid stationary phase. The difference between a liquid chromatography is that high pressures are used for separating complex mixtures in a short time. The sample that we want to separate is mixed at a mobile phase and then moved in the column in contact with the stationary phase. Depending on its chemical structure, the molecule has a different "affinity" for the mobile and stationary phase. The higher is the affinity for the stationary phase, more time will be necessary to the molecule for leaving the column. The time needed for a molecule to leave the column is called the retention time.
   - ➢ DSC: It is the acronym for Differential Scanning Calorimetry. It is an analytical method for determining and quantifying a second polymorph in addition to the main one, present in the active ingredient (finished product or starting materials) being

tested. The instrument used is a calorimeter. The basic principle of this technique consists in obtaining information on the material by heating or cooling it in a monitored process. In particular, DSC is based on the measurement of the difference of temperature between the sample tested and a reference sample. The two samples are bound to a variable temperature defined by a pre-established program;

- PSD (Particular Size Distribution): This analytical method represents the sieve analysis of the raw material or the product/intermediate.
- GC (Gas Chromatography): It is an analytical technique for establishing the quality and quantity of organic compounds in gaseous, liquid or solid samples. Liquids or solids (<1 mg) are analysed after a wet chemical pre-treatment: depending on the analytes, different stages of extraction, hydrolysis, derivatization can be necessary. The sample is injected into a gas-chromatographic system consisting of a capillary column in a thermostat oven, crossed by a helium flow. The various chemical species which constitute the sample are separated during their path in the column and detected by the mass spectrometer. The GC/MS analysis provides a detailed description of organic compounds, which are identified through a comparison with standard compounds or mass spectral database.
- Ultraviolet-Visible Spectroscopy: This type of analysis is used to determine whether a certain analyte is present or not within a matrix. In order to perform a qualitative analysis it is necessary to prepare a solution containing the matrix and a blank to reset the spectrophotometer. After performing this preliminary operation, you can run a spectrum of the matrix by establishing the wavelengths interval that the instrument must sound. The result of this operation will be a spectrum (a set of peaks) which give information on how many substances have been absorbed in the wavelengths interval previously set. Each peak corresponds to a different substance and to a wavelength, so if we know at what wavelength the analyte absorbs, we can determine what type of substance it is and proceed to a further confirmation or a quantitative analysis.
- Other analyses performed are the water content, the loss on drying, pH, conductivity, the presence of metals, etc..
- Storage of reagents and raw materials needed for analyses: Probably, the reagents and raw materials analysed need to be stored and conserved under different conditions. For this reason the laboratory will be equipped with a storage area for raw materials and reagents used for analyses. The raw materials that need to be stored under special temperature and humidity conditions different from the usual will be stored in appropriate cold rooms.

The quality check of products, intermediates, starting material and raw material, is entrusted to the laboratory whose structure is described in **Table 12**

Lab QC – R&D I stage

DIMENSIONS	• Area _56__ m^2 • Height __4_ m • Volume _224_ m^3
WALLS AND CEILING	• Bricks walls, Gypsum plastered and painted. • Ceiling made of 600 X 600 mm vinyl coated panels.
DOORS	• 1 double skinned, galvanised and painted steel double leaf door. • 1 double skinned, galvanised and painted steel door. • 2 Single glazed aluminium door
WINDOWS	• 1 locked window.
FLOOR	• 900 X 900 mm tiles.
LIGHTING	• Recessed mounted electronic light fixtures.

Table 12 Lab QC/R&D architectural structure.

In the first and second stage a unique laboratory will be available for both research and development and quality control activities. Each operation which entails handling raw materials, regardless of their nature and their danger level, must be carried out under the fume hood. 3 fume hoods are installed within the room. Each one has an airflow of 700 m^3/h and an Average face speed of 0.7 m/sec in order to ensure an high security level. The three workstations will be reserved to different activities:

1. Preparation of solutions and micromanipulation of samples, products and raw materials;
2. Weighing of reference standards, samples and solid counter-samples;
3. Washing of working tools.

The suction pipeline will convey all pollutants (dust, solvents, vapors, etc. ..) into a suitable filter system. For a more accurate description of such abatement system see paragraph **B.3.6 Emission to air.**

Another important activity performed within the laboratory is the storage and preservation of samples, counter-samples and external and internal reference standards. It is possible to store in adequately aspirated cabinets and where a datalogger for monitoring the temperature and relative humidity is installed. Other samples/standards/raw materials will be stored in appropriate refrigerators at a controlled temperature. In particular for the standards stored in refrigerators, the temperature must fall within 2 and 8°C, while those to be kept in a freezer must be stored at -15/ -25 ° C.

The laboratory is completed with a stability chamber where environmental chambers are located. They are the main tool which allow to test and learn how the substance quality changes over time under the influence of several environmental factors such as temperature, moisture and light. In this way it is possible to define the following information related to the substance in question:

- Storage conditions
- Validity time

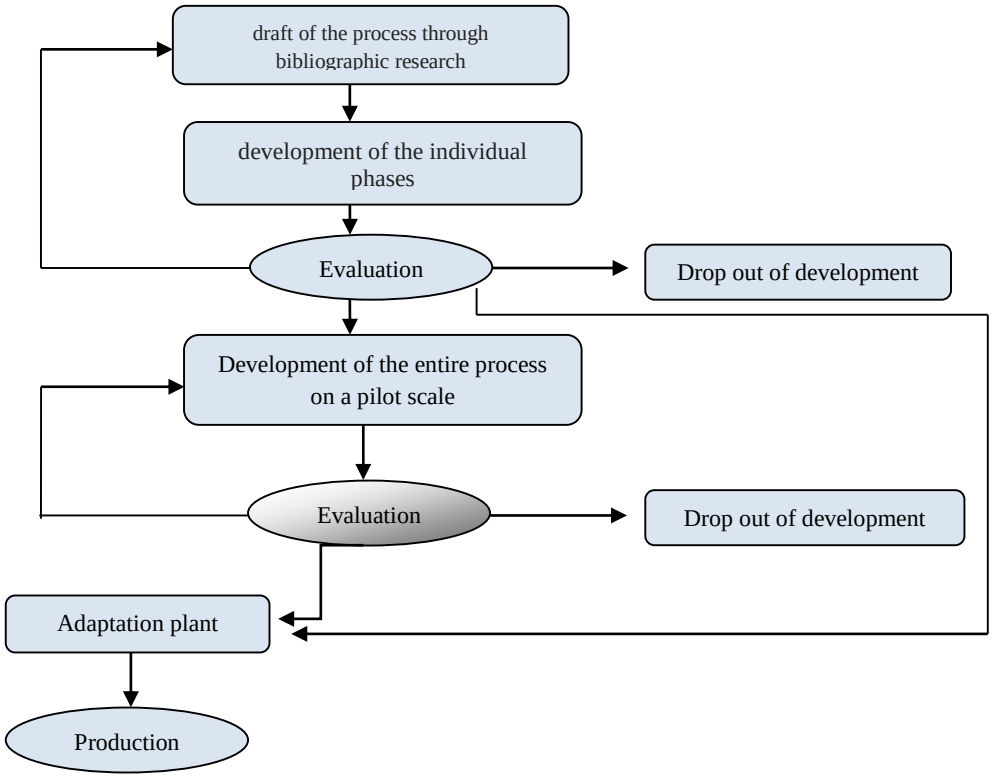
The environmental chambers allow to perform such stability tests by keeping the temperature required with an accuracy of ± 2 °C and the relative humidity with an accuracy

of ± 5%. Temperature and relative humidity values are recorded every 10 minutes by special detectors placed within the same environmental chambers.
The weighing area and the office are located next to the stability chamber. All laboratory rooms are connected.

The development of a chemical process adopted by the company is a quite complex procedure, which starts from the laboratory and ends with the building of an industrial production plant. This is a successful project if the wanted product is placed on the market in the time required and with the potential preset. Other important factors for this success are the production costs which must be competitive, together with the quality standards that the process must ensure. The development of an industrial chemical process useful to the Sterling Chemical Malta Ltd cause goes through different stages, each of which is followed by a monitoring and evaluation step which may cause a return to a previous stage according to a repetitive procedure illustrated here. The beginning of the iterative procedure for developing the process consists in analysing several alternative processes or variants of the same process by keeping this wide range of possibilities for the laboratory scale where costs are relatively low and by making a choice during the construction of the mini-pilot plant. Generally speaking, the development process goes ahead through three stages that can be defined as follows: (a) theoretical study phase also based on the sectorial literature researches, (c) preliminary laboratory study phase, (b) study phase on a mini-pilot plant. Preliminary laboratory operations are typically batch-type operations, while if we imagine a continuous process we proceed with continuous laboratory testing. Then in the pilot plant by studying the chemical reactor characteristics, by examining all other unit operations and collecting all physical-chemical data of interest for each substance involved. In particular, the study of a process entails an accurate inspection of its various aspects: (a) thermodynamic aspects (they refer to the reaction for establishing the equilibrium conditions and the Q-value). They also refer to the chemical equilibrium, such as the liquid-vapour equilibrium of different components and their mixtures or any liquid-liquid or liquid-solid chemical equilibrium); (b) catalytic aspects (they identify the best catalyst in terms of activity, selectivity, strength of materials and thermal resistance); (c) kinetics and material and heat transfer aspects (they are essential for sizing the plant and optimizing the operations); (d) technological aspects (they refer to the structure that the plant must have in order to achieve the best operations necessary for production processes); (e) cost reduction (choose materials that allow reducing costs by avoiding corrosion phenomena).
The time needed to realize a running business process starting from an idea is about two or three years (or more). When passing from a small scale to a larger one, the dimensions of the unitary operations that make up the process must be increased by multiplying them by several factors: "scale factors" or "scale-up factors". Such factors are typical of each unitary operations class or equipment. The higher is the confidence to increase dimensions, more factors are needed. Currently, Sterling Chemical Malta Ltd is between the first and second phase.

B.1.4.3.1.3 Research & Development Cycle-Work

The research and development laboratory is in charge with optimizing the synthesis of products already present in the business portfolio and the new ones identified depending on the market needs. The development of a chemical process adopted by the company is a quite complex procedure which starts in the laboratory and ends with the building of an industrial production plant. This is a successful project if the wanted product is placed on the market in the time required and with the potential preset. Other important factors for this success are the production costs which must be competitive, together with the quality standards that the process must ensure. The development of an industrial chemical process useful to the Sterling Chemical Malta Ltd cause goes through different stages, each of which is followed by a monitoring and evaluation step which may cause a return to a previous stage according to a repetitive procedure shown below.



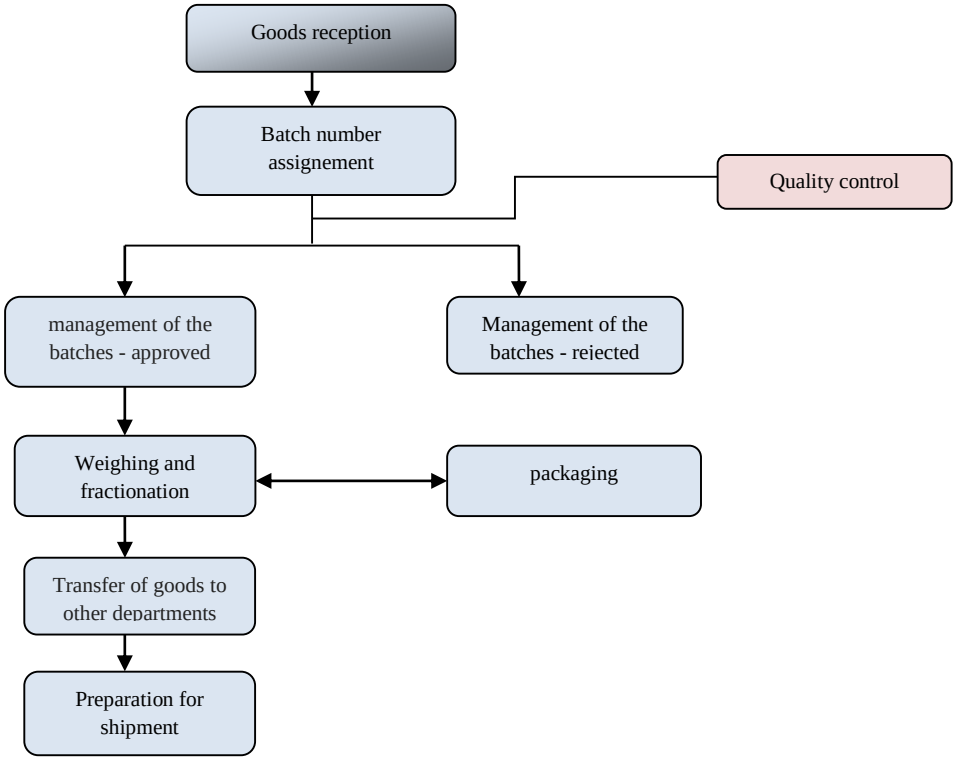
Flow-chart 1 The cyclic structure of the development process.

The beginning of an iterative procedure for developing the process consists in analysing several alternative processes or variants of the same process by keeping this wide range of possibilities for the laboratory scale where costs are relatively low and by making a choice during the construction of the mini-pilot plant. Generally speaking, the development process goes ahead through three stages that can be defined as follows: (a) theoretical study phase also based on the sectorial literature researches, (c) preliminary laboratory study phase, (b) study phase on a mini-pilot plant. Preliminary laboratory operations are typically batch-type operations, while if we imagine a continuous process we proceed with continuous laboratory testing. Then in the pilot plant by studying the chemical reactor characteristics, by examining all other unit operations and collecting all physical-chemical

data of interest for each substance involved. In particular, the study of a process entails an accurate inspection of its various aspects: (a) thermodynamic aspects (they refer to the reaction for establishing the equilibrium conditions and the Q-value). They also refer to the chemical equilibrium, such as the liquid-vapour equilibrium of different components and their mixtures or any liquid-liquid or liquid-solid chemical equilibrium); (b) catalytic aspects (they identify the best catalyst in terms of activity, selectivity, strength of materials and thermal resistance); (c) kinetics and material and heat transfer aspects (they are essential for sizing the plant and optimize the operations); (d) technological aspects (they refer to the structure that the plant must have in order to achieve the best operations necessary for the production processes); (e) cost reduction (choose materials that allow reducing costs but try to avoid corrosion phenomena).
The time needed to realize a running business process starting from an idea is about two or three years (or more). When passing from a small scale to a larger one, the dimensions of the unitary operations that make up the process must be increased by multiplying them by several factors: "scale factors" or "scale-up factors". Such factors are typical of each unitary operations class or equipment. The higher is the confidence to increase the dimensions, more factors are needed. Currently, Sterling Chemical Malta Ltd is between the first and second phase.

B.1.4.3.1.4 Warehouse work cycle

Warehouse activity includes a series of operations to start the real production process and to end it with the shipment of the finished product. A detailed warehouse work-cycle is shown below.



Flow chart 1 Warehouse work-cycle.

The reception of goods is the first operation performed within the warehouse. The check of incoming-goods, the acceptance of goods and the relative data registration and labeling, the quarantine as well as the management of unusual cases are operations carried out when receiving goods in warehouse. Once goods have passed all checks required by the quality department procedures, the safety and environment department (already available in the Italian plant and adopted by the Maltese plant), the goods received can be stored. In order to ensure the identity of each batch of raw material, packaging materials, intermediates and finished products during all their technical, administrative and commercial management, each batch must be uniquely identified through an alphanumeric (and non-repeatable) code. In case of batches coming from external suppliers, the code is assigned when the good is accepted and recorded by the warehouse. In case of internal products, the code is assigned once the Production Record has been issued. It is important to specify that warehouse is divided into different areas. In fact, all goods will be subjected to quality tests and, while waiting for the response, they will be quarantined and placed in appropriate shelves within the indoor warehouse or in special basins in the outdoor flammable material warehouse. Rejected goods are moved to the specific area and identified through a red label. Those goods that passed quality tests are reallocated in the areas with a green label. Quarantined batches cannot be used until they are approved by the quality control department.

When the goods (and specially chemical raw materials) will be accepted, the warehouse worker will be obliged to storage such as description on SDS.

The management system also provides a procedure for loading - unloading. In this procedure, in a first phase there is the receiving goods for which the operator will verify the type and will verify the storage proposal in the SDS (Safety Data Sheet). Typically we will have to deal with three types of storage:

- At controlled temperature, and in this case, they will be stored in the refrigerator for small amounts.
- If the raw material is sensitive to water it is stored in "raw materials warehouse"
- If flammable it will be stored in "external flammable warehouse"
- The raw materials that are incompatible, such as acids and bases, and oxidizing reagents, etc. will be kept separate.

Another important activity is the weighing and/or fractionation of raw materials. The fractionation is carried out when it is necessary for preparing a production charge. The procedures are different, but in any case they must be carried out with the appropriate personal protective equipment such as disposable, antacid and anti-static overalls, safety shoes, full or half-face mask equipped with the relative filters. Such activities must be performed only in appropriate areas such as the indoor weighing and fractionating chamber and the outdoor weighing area. The choice is strictly related to the type of raw material handled. In fact, when you have to take a small amount stored in containers with a small volume, you need to perform this operation indoor. On the contrary, for larger quantities, usually designed for production activities, such operation is carried out outdoor since raw materials are stored in 1 m^3 IBC or 200 liters (and more) drums. In case of a flammable substance the containers must be grounded through clamps and cable as to keep the metal masses to the ground potential, under normal operative conditions, and provide a ground protection. The earthing system consists of a series of measures taken to ensure the ground potential to the metal masses by avoiding they come in tension between them or with the ground. The earthing system protects you from the risk of an electric shock. If it is necessary to handle the product, this operations must be performed in the packaging, sampling and sieving room indicated by the initials 12w in the plan. Once the product has been packaged in closed drums it will be moved into the Finished product warehouse and stored in appropriate shelves while waiting for being sold.

The warehouse is divided into the following rooms:

FINISHED GOOD WAREHOUSE	
Dimensions	• Area _30__ m^2 • Height _5__ m • Volume _150_ m^3
Walls and Ceiling	• Bricks walls, Gypsum plastered and painted. • Ceiling made of 600 X 600 mm vinyl coated panels.
Doors	• 1 double skinned, galvanised and painted steel door.
Floor	• Epoxy paint to concrete floor
Lighting	• Metal Halide light fixture
Temperature and Humidity Registration	• Temperature and humidity recorded by data logger

Table 13 Finished goods warehouse

Finished products and intermediates will be stored inside the said warehouse. The packaging is performed in cylindrical containers of different sizes. Active ingredients are packed in double polyethylene bags (with a gooseneck closure). All containers must be tightly closed and placed in shelves according to the principle "the heavier platform on the lowest shelf" in order to minimize the potential accidents that could occur when they are moved with a forklift. The warehouse temperature is monitored. It is not possible to handle finished or intermediate products within the warehouse.

RAW MATERIAL WAREHOUSE	
DIMENSIONS	• Area _110__ m^2 • Height _12__ m • Volume _1,320_ m^3
WALLS AND CEILING	• Bricks walls, Gypsum plastered and painted. • Roof made of PCC slabs.
DOORS	• 1 Double skinned, galvanised and painted steel folding door. • 3 Double skinned, galvanised and painted steel door. • 3 Double skinned, galvanised and painted 2 leaf steel door.
FLOOR	• Powerfloat finish to concrete floor.
LIGHTING	• Metal Halide light fixture
TEMPERATURE AND HUMIDITY REGISTRATION	• Temperature and humidity recorded by data logger

Table 14 Raw material warehouse architectural.

This large area is intended to receive raw materials with certain chemical-physical characteristics as reported by the different safety data sheets. Non-flammable or explosive raw materials and the raw materials sensitive to changes in temperature and/or to water will be stored here. at the arrival in the plant, all incoming raw materials will be checked when unloaded from the carrier. In fact, raw materials can be stored here only if tanks, drums and containers are intact. Then goods are quarantined until quality control department issues the approval or rejection judgment by sending the corresponding labels to the warehouse. The area is divided into shelves that will host some of the quarantined raw materials (marked with red label) and other approved raw materials (green label). The transport of raw materials, from the unloading area to the final warehouse is carried out by placing the containers of each batch on pallets which are moved from the reception area to the specific one, with the help of a forklift. All vehicles used for moving goods must be cleaned with the appropriate detergent before entering warehouses.

EXTERNAL FLAMMABLE MATERIAL WAREHOUSE	
Dimensions	• Area __130__ m^2 • Distance from the factory __23 m__ • Maximum Volume __100__ m^3
Collection Wells	• Each bath has a collection well. Channel drain connected to main drain with valves to be opened in case of rain.
Containment Basin	• 5 containment baths.

Table 15 Outdoor flammable material warehouse.

On the outside, another area designed for storing flammable materials will be prepared. It will also act as a temporary storage for flammable hazardous waste (according to the European regulations).
Such area will be divided into 3 working areas. Raw materials will be separated from the waste by dividing them into different categories so that the chemically incompatible material is not mixed.
The above-mentioned areas can be identified as follows:

- The area used as a temporary storage for waste;
- The area used for storing raw materials;
- Weighing area.

Line 1 is intended for storing industrial waste. The area will be delimited by a steel overlay with an iron support (it is 5.14 mt. heigh in correspondence to the sides of the structure and 5.35 mt. heigh at the center where not-channeled chimneys are installed. They act as a natural escape for any vapors that can be accumulated under the covering in case of spilling or leaking from the containers). Such covering will allow to protect waste against the atmospheric agents, especially from the sun and the continuous thermal expansion to which the containers may be subjected. In fact, this could lead to a structural expansion and the subsequent breakage of the container which will release hazardous material. The area is made up of a storage basin consisting of a reinforced concrete tank (length: 10.2 m, width: 1.54 m, depth: 0.4 m) with a volumetric capacity of 12.14 m^3 for collecting any liquid spilled. The basin is divided into two areas through a vertical divider which separates the waste whose EWC codes are not compatible. The curbs will be about 30 cm high and they will be made of the same material of the basin. The IBCs containing liquid waste will be rest on platforms (typically made of wood) which are placed on stops installed along the shed walls. The IBCs will be stored in three vertical rows. Each area of the basin will have a slope of 0.1% which allow collecting the liquid spilled in a closed well situated in the center of the reference area. In this way the liquid spilled will be collected in a quicker way. Curbs for supporting pallets on which IBCs and drums will be rested run parallel to the long side of the basin. The whole area will be waterproofed since it is designed as a reinforced concrete platform equipped with a welded wire mesh (thickness: 20 cm) and a waterproof cloth arranged between the floor slab and the ground. The surface will be completed with industrial quartz: a resistant material to mechanical wear (to which it will be subjected as a result of the passage of handling means, such as forklifts) and to chemical aggressions due to industrial waste spills. It is possible to enter this area through a ramp. Operators can arrange waste tanks through such ramp by using forklifts.
A larger basin compared to the one reserved for waste is located in the central area. This is larger than the other since it can be accessed from both sides by using forklifts. It has a storage capacity of 24.30 m^3 and it will be used for approved and flammable raw materials. The basin will have the same structure as the waste-basin: a floor sloping towards the center which channel waste-waters in a containment well; both longitudinal and latitudinal curbs along the long side of the basin that separate incompatible raw materials in case of spillage. They also ensure a stable support to the platforms supporting drums or IBCs.

This area (**Line 2**) can be entered through two ramps. The basin is always covered in order to prevent the possible wear due to atmospheric agents.
The third area is made up of the quarantined raw materials basin and is still waiting for a quality assessment by the internal laboratory. It is as large as the waste basin and has a collecting volumetric capacity of the liquid spilled of 12.14 m^3. As if you empty more than 1 m^3 12 IBCs.
Raw materials will be weighed in (**External weighing room)** through a steel platform scale arranged on a basin with a grilled surface (dimensions: 2.7 * 1.4 * 0.3). It has a containment capacity equal to 1,134 m^3 and a supporting surface of 3.8 m^2 which act as a support for tanks or drums. The entire basin is 10 cm raised from the ground level through steel mounting feet. In this place only liquid raw materials will be weighed because this manipulation will happen in closed circuit. The solid raw materials will be weighed at the time of their arrival in the company to control the correspondence of the weight. The solids are then weighed in their original container without opening it and without manipulation, so that to exclude the emission of dust into the air without abatement system. All solid raw materials will be weighed in the sample room where there is a scale, a hood and a suitable filtration system.
Weighing is carried out as follows.
The tank or drum to be filled must be placed on the steel plate of the scale, placed in the right side of the basin. The plate leans on a stainless steel mesh which is the upper side of the containment basin made of high density polyurethane. The tank containing raw material will be placed directly on the steel grid, on the left side of the basin. Liquids will be transferred from one tank to another by using a closed circuit, in order to avoid liquids and their gas (volatile organic compounds) coming in contact with the air. In this way you prevent explosive mixtures and vapors from being generated and dispersed. This circuit consists of a progressive-cavity pump to which a flexible tube is connected.
Starting from the top of the container to be emptied, it conveys the liquid in the tank/drum to be filled. Another tube (with a smaller diameter) channel the saturated air with vapors, gases or volatile organic compounds from this second container to the first container which is slowly emptied. The extraction of vapors from the container to be filled is eased by the depression inside the container to be emptied due to the liquid escape (through the pump, being the containers placed at the same level); doing so, in addition to preventing the formation of dangerous mixtures for example inside the weighing chamber where it is expected a classic intake system then conveying into the atmosphere after a filter group, it is also avoided the liquid dispersion, thanks to a containment basin and reducing to the minimum the raw material's tank transport. Fugitive emissions will be exclusively limited at the opening or closing time of the filled tanks or barrels. This area is completely separate from the storage warehouse through a concrete wall that allows to isolate the area in case of a possible fire.
In the line 3 there will be stored solid waste, ethylene glycol, water coming from the scrubber, and identified as waste with the code EWC 161001* and, in case, even the raw materials. These will be stored on 3 sideways containment basins in concrete with a collection capacity of 6 m3. These basins will always have a storage capacity equal to 110% of the largest container that will be stored. Even the line 3 is covered with a roof,

following the approval of the Minor Amendment to Permission PA / 04236/08 of 18 March 2015 attached to the specific drawing of the External flammable warehouse. The glycol is considered as a raw material for all purposes as used in utilities to prevent the freezing of the fluid system. The glycol will be stored in the external flammable warehouse being present with a limited number of IBC (about 4) for which doesn't take much space. The tanks will then be placed on the containment basins of the External Flammable Warehouse with storage capacity of 110% compared to the larger tank above them.
In front of the external flammable warehouse it is located a temporary solid waste storage area with the access from the outside by two entrances in a way to facilitate the means of transport required to pick up the waste, so there will be an entrance and one exit to the production site in a way to avoid dangerous operations. The loose waste such as paper and cardboard, metal, plastic, glass and humid will be collected through various sizes and colors skips, the large dimension solid waste such as previously containing the raw material's containers will be packed on a single pallet.

The ***External flammable warehouse*** is attached annex ***B.1.4-A2.***

B.2 Your proposed techniques

B.2.1 Environmental Management System

Sterling Chemical Malta Ltd, under the expert guidance of the mother company, plans to implement a management system designed to protect the environment. However, the Maltese plant at the time of the preparation of this document is in an embryonic stage devoted exclusively to research and development, so that the system, which in the future will expect to be certified according to ISO 14001, will have a first stage of experimental work to verify if what it has already been run in Italy it will be useful, effective, and fully satisfactory to prevent and preserve the environment.

A fundamental part to describe the system in place, is the manual (***annex B.2.1-A1***) leaning on the guidelines established by ISO 14001, initially defining environmental policy, as it represents and expresses the organization strategic approach (and therefore exclusively cured by the Management), but also establishing a framework for the planning of objectives and targets and fixing the management guidelines through procedures, operating instructions, programs and more. The policy, in line with the overall vision of the organization, must provide the strategic direction for the interventions on the main highlighted "problems". In such a way, even from the IPPC-EIA examination, the policy must therefore be clearly linked to activities, products and services of the organization and to its environmental aspects and it has the following key points:

- The commitment to the continous improvement and prevention of pollution is one of the founding element of the management system, because they involve a "dynamic" approach based on the areas's identification concepts of potential improvement, goal settings, target achievements and their evaluation;

  Therefore, the Sterling policy will also include, together with a precise recall to the improvement and prevention, an indication of the areas where to achieve these commitments.
- The commitment to respect the applicable legal requirements and other voluntary standards that the organization has signed: a policy complying with the voluntary standards reference, must contemplate that the company commits to:
  - the existing environmental legislation and health and safety at work;
  - If appropriate, eventual voluntary rules to which it has adhered by itself, without being forced, or other commitments that it has voluntarily assumed.

Defining a framework for setting and reviewing environmental objectives and targets and health and safety at work: Provided that the company complies with legislative and regulatory requirements and intends to continuously improve the management and their own performances, the policy should clarify in which areas, in which way and "how much" to improve. Therefore, taking into account the information obtained from the analysis, the policy will have to set the management guidelines, that will be reflected in subsequent activities, and in particular in the planning of objectives and targets and the program development. In this sense, it is recommended to take into account both the internal and external's stakeholders needs, together with the observations and contributions of the staff (or its representatives).

In addition to the policy it will be step by step described the management system as part of the operating controls or to all of those operations associated with the identified significant environmental aspects, in accordance with its environmental policy, its objectives and targets.
Given the current state of the art with a production plant not at full speed, it can be made the interaction's evaluation with the environment.
The procedures and operating instructions so far implemented have a general nature since it is matter of management and not of operational control, except regarding the hazardous substances, shipments of goods under the ADR and control and waste management. For the implementation of effective management controls on other environmental aspects such as emissions to water, air, noise, soil management and water management, it is expected the IPPC permit and the related requirements having both physical (introduction of additional abatement systems) and managerial nature.

B.2.1.1 Purpose and scope of Environmental Management System (EMS)

To ensure that external stakeholder satisfy the commitments in Sterling's environmental policy, certain operations and activities must be controlled. Where operations or activities are complex and/or the potential environmental impacts are significant, operational controls should include documented procedures. Procedures can help Sterling Chemical Malta organization to manage its Significant Environmental Aspects (SEAs), ensure regulatory compliance, and achieve environmental objectives. Procedures can also play an important role in employee training.
Documented procedures also called operational control procedures should be established where the absence of procedures could lead to deviations from the environmental policy (including the commitments to compliance and pollution prevention) or from Sterling's objectives and targets. Determining which operations should be covered by documented procedures and how those operations should be controlled is a critical step in designing an effective EMS. Remember that you might need operational controls to manage SEAs that have legal requirements, regardless of whether Sterling established objectives and targets for each of them. As mentioned previously, for every SEA you identify, it is desirable that one of two actions be taken. The action may include either:

- Evaluating alternatives to make changes in processes in order to reduce the potential for impact, or
- Writing operational control procedures for activities or steps in a production process where the potential impact can be controlled.

In writing operational control procedures for an SEA, consider the environmental objectives desired, the targets set for performance and write the procedures to ensure that the objective will be met. Your company may already have many procedures in place. These should be reviewed to make sure that they are consistent with EMS objectives. This module describes the process for setting objectives, developing operational controls, and creating the organizational support for ensuring that those objectives are met. If Sterling determine that process changes should take place in order to address an SEA, the EMS emphasizes the need to evaluate alternatives before setting targets. In determining which operations and activities

need to be controlled, look beyond routine production or service delivery. Activities such as equipment maintenance, start-up, and shutdown, management of onsite contractors, and services provided by suppliers or vendors could affect your organization's environmental performance significantly.
The following are some examples of the kinds of activities that might be improved with operational controls:

- · management/disposal of wastes
- · approvals for using new chemicals
- · production processes or operations
- · storage & handling of raw materials and chemicals
- · wastewater treatment
- · building and vehicle maintenance
- · transportation
- · operation and maintenance of equipment
- · management of contractors
- · marketing and advertising
- · acquisition or construction of property and facilities

All procedures, environmental instruction (operative control), form and other basic documents shows in annex ***B.2.1-A2.***

B.2.1.2 Integration of Quality Management System (QMS) and EMS

Sterling Chemical Malta Ltd already has a quality management system (based on Good manufacturing Practice,) -- you will find significant synergy between what you need for quality management and for environmental management (see below)

QMS	**EMS**
• Quality Policy	• Environmental Policy
• Adequate Resources	• Adequate Resources
• Responsibilities and Authorities	• Responsibilities and Authorities
• Training	• Training
• System Documentation	• System Documentation
• Process Controls	• Operational Controls
• Document Control	• Document Control
• System Audits	• System Audits
• Management Review	• Management Review

Table 16 Some Common Aspects of Quality and Environmental Management Systems

For this reason, some procedures will be integrated and unambiguous.

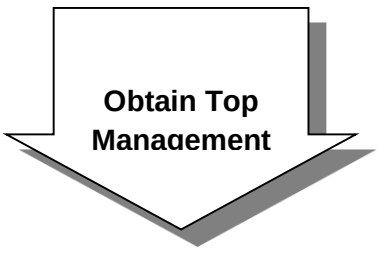
Sterling's Health and Safety (H&S) program can play a significant role in EMS because it reflects how your company currently handles human health concerns; in many areas, H&S and environmental concerns and requirements may be similar and some requirements may be addressed concurrently. Therefore, before reaching the EMAS or ISO14001 certification many procedures and instructions will be integrated with those under HS program.

B.2.1.3 Laying the Groundwork for an EMS: Key Steps

The structure of EMS is following description.

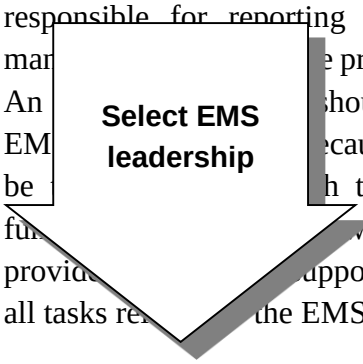
1.	Define organization's goals for EMS.
2.	Obtain top management commitment.
3.	Select EMS leadership.
4.	Build implementation team.
5.	Hold kick-off meeting.
6.	Conduct gap analysis.
7.	Prepare budget and schedule.
8.	Secure resources and assistance.
9.	Involve employees.
10.	Monitor and communicate progress

A first step in Sterling's EMS planning is to **decide why the company is pursuing the development of an EMS**. Is Top Management trying to improve sterling's environmental performance (for example, reducing risk associated with regulatory non-compliance or increasing pollution prevention)? Is Top Management trying to promote involvement throughout the organization? Write down your goals and refer to them frequently as Sterling move forward. As Top Management design and implement the EMS, ask: How is this task going to help us achieve sterling goals? This also is a good time to define Sterling's **EMS scope** or **"fenceline**" (i.e., what is the "organization" that the EMS will cover? One location? Multiple locations? Should we "pilot" the EMS at one location then implement the system at other locations later?). See **Tips on Defining an Appropriate Scope** at the end of this section.



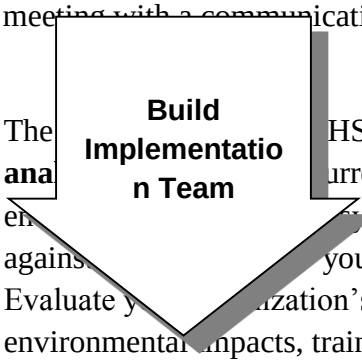
One of the most critical steps in the planning process is **gaining top management's commitment** to support EMS development and implementation. Management must first understand the benefits of an EMS and what it will take to put an EMS in place. Explain the strengths and limitations of your current approach and how those limitations can affect your financial and business performance. Then explain how an EMS can help address these limitations. Management also has a role in ensuring that the **goals** for the EMS (see above) are clear and consistent with other organizational goals. Management's commitment should be communicated across the organization.

An **Environmental Management Representative (RSGA)** should be chosen from the organization's top management group to be responsible for the functioning of the EMS (i.e. making sure that all tasks relating to the EMS are identified and completed in a timely manner). The RSGA is responsible for reporting periodically to the top plant mar e progress and results of the RSGA. An should have time to commit to the EM ecause his or her responsibility will be h the RSGA and with the cross fu) to identify, assign, schedule, provide upport for, and ensure completion of all tasks re the EMS.

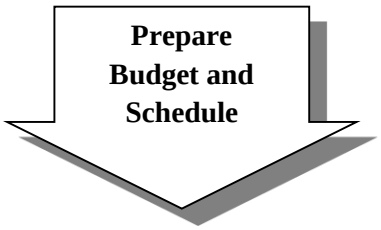


A **HSE committee (CFT)** with representatives from key management functions (such as engineering, finance, human resources, production and/or service) can identify and assess issues, opportunities, and existing processes. Consider including contractors, suppliers or other external parties as part of the CFT, where appropriate. The CFT will need to meet regularly, especially in the early stages of your EMS efforts. A CFT can help to ensure that procedures are practical and effective and can build commitment to and "ownership" of the EMS.

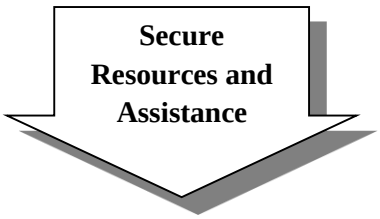
Once the team has been selected, **hold a kick-off meeting** to discuss the organization's goals in implementing an EMS, the steps that need to be taken initially, and the roles of team members, among other topics. If possible, get top management to describe its commitment to the EMS at this meeting. The kick-off meeting also is a good opportunity to provide some EMS training for HSE members. Follow this meeting with a communication to all employees.



The HSE committee to conduct a **gap ana** urrent compliance and other en stems and to compare these agains your EMS (such as ISO 14001). Evaluate y ization's structure, procedures, policies, environmental impacts, training programs and other factors. Determine which parts of your current EMS are in good shape and which need additional work.

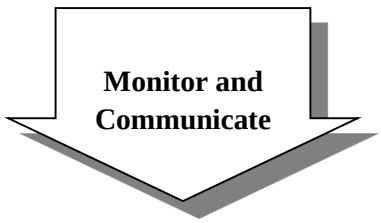


Based on the results of the preliminary review, prepare an **implementation plan, with a budget and schedule**. The plan should identify what key actions are needed, who will be responsible, what resources are needed, and when actions will be completed. Keep the plan flexible, but set some stretch goals. Think about how you will maintain project focus and momentum over time. Look for potential "early successes" that can help to build momentum and reinforce the benefits of the EMS



The plan and budget should be reviewed and **approved by top management**. In some cases, there may be **outside funding or other types of assistance** available (from a trade association, a state technical assistance office, etc.).

Employees are a great source of knowledge on environmental and health & safety issues related to their work areas as well as on the effectiveness of current processes and procedures. They also can help the project team in drafting procedures. **Ownership** of the EMS will be greatly enhanced by meaningful employee involvement in the EMS development process.



As Sterling's build the EMS, be sure to regularly **monitor company's progress** against the plan and **communicate** this progress within the organization. Be sure to communicate the **accomplishments** that have been made and describe what happens next. Build on small successes. Be sure to keep top management informed and engaged, especially if additional resources might be required.

The Sterling group is committed to improving environmental performance through the use of innovative techniques such as EMS and to meeting customer requirements that we implement EMS in accordance with ISO 14001 standards. We will implement EMS in a phased approach, one facility at a time. The concept of continual improvement assumes that no organization is perfect. While an EMS should help your organization improve compliance and other measures of performance, problems may still arise. However, an effective EMS should help Sterling Chemical Malta Ltd find and fix these problems and prevent their recurrence. It can be said that it is possible to obtain the ISO 14001 and OH SAS 18001 certification within two years from the authorization. This is to ensure the following timing:

1. Complete the structure and update it as prescribed after the EIA and IPPC autorization.

2. It will take three months of operation of the entire system (including warehouses);
3. It will be necessary to develop all the procedures adapting them to the requirements of the pending proceedings, to all the Maltese and Community law. This system of procedures, operating instructions and registers shall be active for at least three months after the 3 months of activation of the system (although it is strongly recommended a year of the management system);
4. The inspection validation of the certification lasts two months;
5. The inspection confirmation of the safety certification is 6 months after the first validation certification

B.2.2 Proposed activities

B.2.2.1 Describe the proposed installation activities

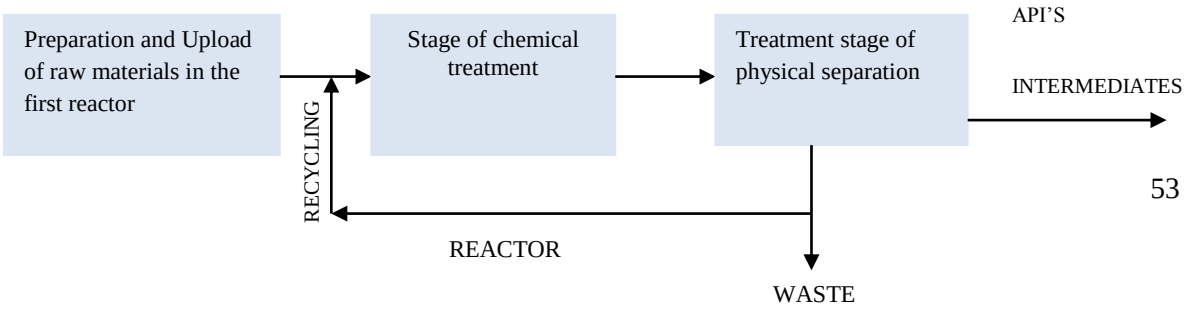
The production plant's main features are listed below:

- Reaction Units (synthesis reactor and auxiliary systems);
- Fixing Unit (drying, grinding and packaging)
- Service Unit (steam, nitrogen, vacuum, water, brine);
- Auxiliary units (technologies and measures for the environment, health and safety protection);
- Configuration variables systems (management software);
- Construction materials;

each unit is technically described in full in the Validation Master Plan i.e. a quality management system procedure.

B.2.2.1.1 Reaction Units

The heart of the chemical process that will be implemented in the system is represented by the reactor which is the main place in which reactions take place. Its characteristics and the conditions in which it operates, largely influence the overall process structure and the type of unit operations to be performed. The following block diagram represents in extremely simplified way the first part of "activities" for the purpose of processing and mixing of raw materials in order to obtain a finished product or an intermediate of production.



Flow Chart 2 **Activities for the processing of raw materials.**

As one can see, in an industrial chemical process there is the alternation of different operations: physical characteristics such as weighing, transfer and loading, to provide the raw materials to the reaction; typically chemical in the reactor, and then other physical separation to get the product to the desired level of purity, as well as any sub-products or intermediates of production. If the reaction is not complete, as it often happens, the initial part of the substances which have not reacted, after being separated from the product, are recycled in the reactor. If then the system has an inert component, in order to maintain steady conditions in the plant (i.e. conditions constant over time, avoiding the aggregate accumulation in the reactor), there will be the need to operate the purge, ie the elimination of a part of the recycle stream. During the physical separation that can occur using centrifuges, filters or more reactors, a part of the mass can be re-processed, it may constitute an intermediate of production or, in case of the final processing stage it can represent the wet finished active ingredient (then wet by water or solvent and therefore likely to be dried, micronized and packaged). It is interesting to note that such a scheme, very simplified, neglects all the details in which a plant consists (pumps, heat exchangers, filters, control systems and control etc..) and to understand the role of each part of the plant, one it is forced to represent it in a timetable (P & ID, Pipe and instrumentation diagram). It is more complex compared to the process diagram, because it contains a greater amount of information. In this case, the purpose is to represent in greater detail the connection of all the equipments installed in an industrial plant. The information contained in the timetable are: code, function and elevation of the equipment, process lines, start-up lines; discharge; chemical additives, etc..; Service lines, tracking and isolation of the lines, full instrumentation of indicators, recorders, alarms, controls, etc..; valves and safety devices, control valves and related bypass. Furthermore, the lines are all coded in a way to provide: nominal diameter of the line; generic service line; progressive number and class of the material. However, all the utilities used (nitrogen, chiller, vacuum, steam generator) are also adequately dimensioned to support the third production line without the addition of any equipment, but increasing the working capacity only of those activated for lines L1 and L2.

The L2 line will consist of 4 reactors which will be used also for the production of business quantities of active pharmaceutical ingredients and two small reactors (LR-01M and LR 02M) that will be used for the constant research and development of the synthesis of new or already existing products. In addition to 4 reactors, there are two small reactors currently employed for the research and development

All the reactors have a different volume because they must be used at different stages of synthesis or for different synthesis. The reactors are described with some technical data in Table 11 **Technical data of reactors in line 1 and 2**" to this document and those with the code beginning with the number 2 belong to the L2 line.

The line is on two floors. The ground floor is made with a floor in industrial quartz and covered by an antistatic and anti-slip sheath. All the transactions on the ground floor are just a manual because from here there is the access to the manual valves regulating the access of elements such as water, air or nitrogen, or outgoing such as vents.

On the ground floor there are the following operations:

- Transporting the liquid raw material by means of pallet trucks. Generally this raw material is in IBC 1 m^3 or 200 liter drums. They are positioned in the loading/unloading valve area. At this point the sleeve which closes the valve it is opened. It is approached the suction arm that has the task of sucking off vapors (VOC) in the output.
- The tank or barrel is opened, the pump at closed-circuit "dip-leg" type is inserted sticking the tube inside the tank. The pump is activated and the aspirated liquid is fed into the reactor. In general, the first operation takes place on the largest reactor available in the line.
- Once finished the introduction of the raw materials, it will start the operations by setting via computer all the parameters such as temperature, pressure, speed. The control station is located on the mezzanine floor.

Along the perimeter walls of the there are gutters used only in case of emergency because the floor is leaning towards them so that in case of spillage from the tank, drum or reactor, the liquid can collect in these ducts which lead to the wash water tank that is buried outside,

On the ground floor, through a door, there is access in the finishing area where there are the dryers. Here comes the product wet from the solvent, to dry out. It is an area in aseptic conditions where it is possible to enter only according to the quality procedure in order not to contaminate the air and the products.

Also from the production line via another input there is the access to the area of filtration and centrifugation.

The ground floor is connected to the head of the reactor by galvanized steel stairs. The stairs give access to the mezzanine. On the mezzanine there is the visual control of the reactions inside the reactors through the computer, through the control panel placed on each hatch of each reactor. The hatch the solids (if present) are possibly loaded with sealing system in such a way as not to contaminate the environment. From the mezzanine there is the access to the control of the stirring group, the electric motor of the reactor and the tube bundle exchangers. Through a door there is access from the utilities floor where chillers, electrical panels, water softener etc ..are located.

The line L1 will have the same structure of the L2 with different reactors and the floor that will be three and not 2 such as L2. The location of reactors shown in the Annex B.1.4-A4 “lay out equipments” of this document with the R-1xxx. Even in this case there will be a ground floor with the manual control through piping valves of production, the load through the valve

and the pump. On the upper floors (there are two levels of mezzanine) there is the control area and the management of the operations.

Also for the L1 line there will be a finishing area in which there is the provision of dryers used for drying the products and a centrifugation and filtration area.

The first reaction unit includes the steps of reaction, separation, filtration and centrifugation of the production process. The first one, fully occurs in reactor devices normally consisting of a vessel (container) with an agitation and thermal conditioning system to complete the chemical reaction. The agitation is provided by the agitators or propeller blades, depending on the type of circulation fluid to be achieved in the reactor. The agitation is necessary both to achieve an effective contact of the fluid with the surfaces responsible for the heat exchange (and this need is also valid for homogeneous systems), and to ensure a good dispersion between the phases present in heterogeneous systems resulting in their close contact. The reactors in the plant are at stirred tank and they can operate in discontinuous mode (batch reactors) thanks to the wide range of products to achieve. In fact, this type of reactor allows a better management of the business needs. The management of the discontinuous reaction has the following operating characteristics:

- loading of the reagents mixture, including the catalyst, (through empty-drums pump and adduction mobile line in case of liquids, through the hopper and hatch in the case of;
- solids, starting materials and dust) in rapid sequence at the beginning of the process, the reaction starts once the system has been brought under the operation conditions, for example after a heating phase;
- there is no subsequent reagents addition, since the recipe has already been set at the start, the process is managed through the parameters control through external intervention;
- the composition of the reaction mass continuously changes during the process, because at the beginning it is constituted by the preloaded reagent mixture, while at the end there is only the product;
- the reaction rate depends on the concentration of the reagents; however, provided that this is an exponential function of the temperature, the process control it is substantially entrusted to the control from the outside of this parameter.

Inside the reactors it will take place the following chemical operations:

REACTION In this phase, an operator places a vacuum reactor by appropriate wiring. The reactors used have different volume as to ensure the necessary time to the reagents to fulfill the chemical reaction, implement the heat exchange required, and through mechanical stirring, to bring into close contact the phases present in order to facilitate the mixing. The reactors in the different production lines are different for dimensions, specifications and auxiliary equipment, but the principle of the basic operation is the same. Anyway all the equipment work in batch or as a closed thermodynamic system, without power in entry and exit, having in the specific, at the beginning and at the end of the process, loading and unloading phases to

the filling and emptying equipment. Hardly it is ever reached a mixture steady state but only a transitional period during which the distillation is carried out and transfer to the next reactor. Due to the high temperature reached (the maximum working reaches 120° C) it was taken into account, in the planning, the heat produced or absorbed by the reaction, therefore the heat exchangers such as the jackets (ie the cavities on the tank wall crossed by a cooling fluid consisting of mains water and glycol in 50% solution) have been prepared. The equipment can operate under vacuum using a trap to the vacuum process ensuring a pressure inside the reactor which is lower than the environment one, and therefore an insulation and processing under the best conditions of workable inerting. Even the vacuum trap, as the other utilities serving the reactor, work at high temperatures so that it has been added a cooling system consisting of a tube bundle heat exchanger where the fluid is still water and 50% glycol flowing in the side coat of the heat exchanger. The reaction's conduction is always of discontinuous type because charging the reagents and solvent's mixture (reagents and other solvents are aspirated from portable tanks through a dip tube fitted on the fixed line or via empty-drums pump, while the dusts through hopper with entrance from the reactor's hatch); the reactors are of heterogeneous type as reactants, products and eventual catalyst can be present in different phases; the reactions take place in tanks vat shaped while the stirring is mechanically provided by propeller stirrers to allow effective fluid contact with the surfaces responsible for the heat exchange. For liquid substances to be used in small quantities thee is the need of a trailer pump while the solid is loaded through hatch in the presence of local exhaust ventilation. The reactions take place in a consecutive manner in all the reactors of each line. The last reactor of each line is a crystallizer in which there is the formation of crystals due to the controlled precipitation of the reaction mass in a solvent at the end resulting separable from the solvent itself. Also in this case it is expected a tank cooling through a jacket in which it flows the heat-transfer fluid as seen for the previous reactors.

EXTRACTION: During this step the reaction mass consisting of two immiscible phases, one watery and one organic, it is allowed to decant in cold until a complete separation of the same. The solvents used in the extraction are organic in nature, typically dichloromethane or ethyl acetate. In the reactor at the end of the reaction it will be added either just water or only organic solvent or both elements depending on the type of reaction earlier occurred. The new mixture is put under stirring for about 20 min - 30 min and it is allowed to settle in the cold. The reaction mass is transferred into a new reactor, while the organic solvent remains in the used reactor to be removed after.

DISTILLATION: Further separation between the products of the reaction takes place by heating the mixing and subsequent distillation. The products present in the mixture have different boiling points that are achieved in the cylindrical shape distillation column characterized by a gradient temperature. Sometimes the distillation can be done under vacuum because the achievement of boiling takes place at high temperatures, too high to work in atmospheric pressure, the vacuum can reduce these temperatures. The solvent is collected in tanks and then removed. The mass is then allowed to cool to reach room temperature.

In order to carry out and control these operations, beside the Vessel the points of loading/unloading and the mass stirring, there are other systems connected to the reactor:

a. *Control systems of the physical parameters:*

The good achievement of a chemical process is closely connected to the process parameter's optimal setting and control. The more or less automated management of these parameters, however, it is affected by many factors, from the economic one, affecting the process complexity, the intrinsic danger of the reaction, as well as the age of the plant.
In many cases, some physical parameters such as temperature, pressure, level and flow are continuously monitored, while other properties such as pH, viscosity and turbidity, are controlled through sampling or at the end of the cycle. In general, the regulation systems of these quantities are composed of the following components:

- ✓ the sensitive element which detects the change in the process parameter that must be maintained at a certain value of set-point;
- ✓ the transducer, able of receiving the signal (usually electric) by the sensing element and to transmit it to the organ of intervention;
- ✓ the organ of intervention, the attending plant element, according to the transduced and amplified signal, on a process parameter whose change has directly or indirectly effect on the parameter controlled by the sensitive element.

The signals from the transmitters are sent to visual alarms when the action control requires human intervention. The main intervention devices are placed on water and drainage pipes of the reactor and on the reactor itself.

b. *Heat exchange system*

One of the most important parameters of the chemical reactions within the various reactors is the temperature. The technology used by Sterling, implements a double heat exchange system consisting of a internal coil constituting the jacket of the reactor where it flows the heat transfer fluid steam, the water, the brine, the glycol water, and a cooling by an external condenser through sprayable liquid. This mode offers the possibility to subtract to the system the evaporation's latent heat of the volatile solvent, heat which, as known, is far greater than the sensible heat which is possible to subtract with other systems.

c. *Systems emergency lock*

The measurement, indication and recording systems of the parameters of interest are connected to alarm devices and automatic locks. The alarm signals (audible and/or visual) warn the operators on certain variable process tending to have exceeding-safety-limits values . These variable processes are the temperature and the pressure
The locking devices stop the process or some operations both for the effect of the intervention of an operator and automatically, when one or more variable processes exceed the values of predetermined guard, after the ordinary adjustment systems resulted ineffective.

d. *Security systems*

The last level of security installed on the reactor is represented by protection systems (passive protection) such as rupture discs, relief valves and blow-down line that allow to limit the damages to persons, systems and the environment, but usually imply the waste of the reaction mass.
The safety valves (PSV) are vent valves' additional systems. They have larger dimensions and they intervene when the internal pressure exceeds certain set limits and the vents are not enough. These valves are connected to a "conveying" system (blow-down) which, by collecting the emergency vent, reduces the consequences of a release to the atmosphere.
This blow-down line is constituted by a series of equipment: safety valve, scrubber, storage tank, fluid abatement recirculation pumps, active carbon abatement system and finally chimney. In the plant system they are also positioned in correspondence of the reactor jacket where it circulates steam, brine, water or glycol-water with venting opening to 6 bar.
The rupture discs (RD) are security devices ready to intervene in case of non-intervention of the other systems previously discussed or, in case of higher overpressure, effective to prevent the collapse of the reactor. The ones used in Sterling are constituted by a metallic hat, pinched between two flanges having a flat peripheral portion and a central portion generally convex in the direction of breaking pressure. The thickness of the rupture disk is very small, in the order of one hundredth of a millimeter. To protect it from the corrosion it is coated with polymeric material. The breaking occurs when the pressure inside the vessel exceeds 0.49 bar. The vent of such rupture disc is connected to the blow-down systems

e. *Stirring system*

The system adopted for reactors includes:

- ✓ a drive unit (electric motor or fluid dynamic) whose power depends on the volume of the reactor (on average 1-2 kW theoretical for each m3 of volume);
- ✓ by a reduction group which transmits the motor motion reducing it to the correct speed of the agitator (80-150 rpm / min);
- ✓ by a shaft, equipped with a seal system of mechanical type (O-ring plus other mechanical elements finely processed to minimize the friction phenomena) guaranteeing that the reactor's content does not spill passing through the shaft and its passage hole in the reactor dome;
- ✓ from a transmission coupling that allows the transmission of torque from the motor shaft in rotation; the joint is designed to break when exceeding the maximum of the torque permitted to the engine and it is installed to protect the latter; if the engine rescue has an undoubted economic impact, the breaking of the coupling and the consequent arrest of the stirring can lead to critical situations for the impairment of the cooling capacity;

At the end, there are the reactive units acting and touching the raw materials centrifuges and filters. The centrifugation allows the separation of solids from liquids due to centrifugal force, generated by the rotation of a drum contained within a shell. The type of centrifuges used has an horizontal axis with automatic management of the cycle and the unloading. The typical cycle is as follows:

- ✓ Suspension Power

- ✓ centrifugation
- ✓ Panel washing (possibly repeating several times)
- ✓ Final centrifugation
- ✓ Product discharge
- ✓ Automatic discharge of the residual panel (in the presence of particularly fine product)

The power supply has a typical concentration of 10% or more. The pannel washing serves to replace the mother liquors (displacement). The residual panel removal at the end of each cycle of centrifugation is typical of applications in the pharmaceutical industry, with panels having a particle size of the order of 5 to 30 microns. The discharge is on the bottom, having through the inverter variable speed.
The centrifuge blocking conditions is controlled by the security system with redundant circuits and act directly on the power contactors; also included are the following electronic locking systems:

- ✓ Value exceeding the maximum speed rotation
- ✓ Fixed tub to allow the lid opening
- ✓ Exceeding the unbalance maximum level
- ✓ Closed lid position
- ✓ High concentration oxygen
- ✓ Centrifugal very low pressure

To be sure that the centrifuge is inerted maintained (i.e. devoid of internal flammable mixtures which could cause explosions) it is used a control system that, once replaced the oxygen present in the centrifuge process chamber with an inert gas (nitrogen), it keeps the latter in overpressure and occurs in a continuous way the concentration of the oxygen. The inerting system is directly controlled by the PLC while the redundant safety systems prevent the starting or cause the machine to stop, if the latter was not sufficiently inerted.
There are two control sequences:

- ✓ Sequence of scouring, in which the oxygen present in the process area is replaced with inert gas.
- ✓ Hold Sequence, in which it is activated a continuous monitoring on the oxygen concentration

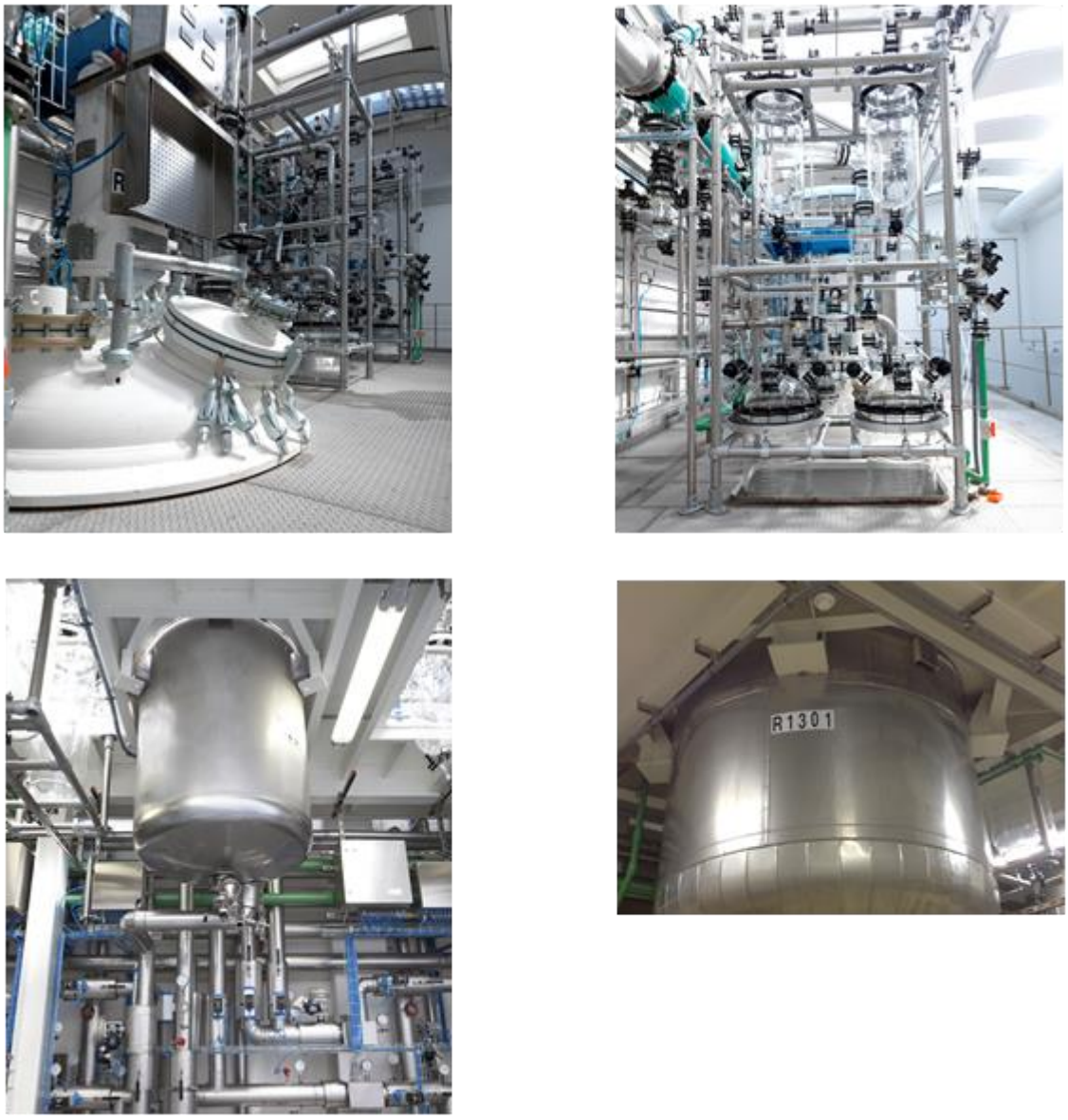
in the presence of pressure.

Scouring or reclamation sequence

Before starting with the production, it is necessary to introduce an inert gas (nitrogen) to obtain an inert atmosphere in the interior of the tank. The operator activates the inert phase through the switch installed on the local panel. This action causes the valve opening with higher nitrogen's flow rate in centrifuge to a pressure valve in centrifuge determined by the hydraulic guard. Once achieved the safety conditions (pressure greater than the minimum and nitrogen concentration lower than the limit), the spin is considered inert and it can be launched.

Maintenance or compensation Sequence

Once the inerted centrifuge condition is reached, the maintenance sequence checks that the pressure values and oxygen concentration remain within the permitted limits throughout the operational functioning. The centrifugal pressure is maintained at a predetermined value by the flow device. If the percentage of oxygen suppose to increase, the maximum flow purge it is re-activated to bring the concentration under the permitted limits.
The oxygen analysis performed with paramagnetic analyzer allows NOT have ordinary maintenance, unlike what required by electrochemical or polarographic analyzers, since there are no elements that wear out during the analysis (eg.electrochemical liquid, membrane, etc..), the instrument maintenance at a controlled temperature and the avoiding or liquid introductions into the analysis cell, constitute the only essential constraints to obtain a correct operation of the instrument.
The electronics control and the gas system treatment to be sampled guarantee the cell's maintaining temperature and prevent any liquid entrainment or cell condensing.



Pics 1 particular reactor and glassware.

An alternative system to centrifugation is represented by the solid-fluid filtration in which the solid particles in suspension in a liquid or a gaseous substance are held by a porous septum (filtering body) that allows, instead, the passage of the fluid, made so clear (filtered); the removed solid particles form on the septum the so-called panel (or mass).
The passage of the fluid to be treated through the filter takes place under the action of a pressure drop, as for the crossing it must overcome a certain resistance essentially due to the solid material panel retained by the filtering body (presenting instead a generally much less significant resistance).
Typical is the use of the Buckner filter with perforated bottom funnel inserted, sealed with a suitable gasket, on a cylinder with wheels at the base and raised above the walking surface. Inside the bottom of the funnel, leaning on the wall with holes, is it possible to insert a filter paper disc that must be immediately moistened and must be large enough to touch the edges of the filter.
Connecting the cylindrical container to a vacuum pump (usually a water pump) it is possible to perform a very rapid filtration, in which the liquid passes through the filter while the solid is deposited on it.
The operation of an industrial plant as the one in HAL FAR requires the availability of energy and a series of auxiliary fluids for the realization of the various phases of the process, for the control of the process itself and for maintenance. Alongside the production units, there are also the ones used in the production, processing and supply of auxiliary fluids, which collectively go under the name of utilities.
The all functional services set to the procedural needs are:

- ✓ Refrigerated water (7 ° C)
- ✓ Freezing water (-25 ° C)
- ✓ Vacuum
- ✓ Compressed air
- ✓ Nitrogen
- ✓ Steam/condensate
- ✓ Drinking water
- ✓ Blow down process (low pressure)
- ✓ Blow down service (high pressure)
- ✓ Vent and service process
- ✓ Fire prevention system

Water

Under this heading are generally included the following types:

- cooling water
- process water
- Fire water

Cooling water

Considering that it is essential to ensure the refrigeration to the plant units it is necessary to ensure either the operation continuity of the cooling water pumps, installing a reserve, and the power supply to the motor pumps with electric motors. The circuits of the cooling water and fire fighting water are separated, to avoid that in case of fire, problems of refrigeration could happen to the plant units.
The circuit consists of a refrigeration unit with a capacity of 750 kW, characterized by 3 independent refrigerant circuits freon powered R404-A, with an air cooled condenser and evaporator tube bundle. The cooling fluid consists of a water-propylene glycol solution to 50% whose operating temperature is 7 ° C in the output. The solution circulation is ensured by a pumping unit consisting of two parallel centrifugal pumps (one for the circuit-chiller tank and one for the users), from a storage tank acting as a thermal flywheel and delivery and return manifolds; in correspondence of the latter there are the connections to the various devices.
The circuit consists of a refrigeration unit with a capacity of 300 kW, characterized by 3 independent refrigerant circuits freon powered R404-A, with a water cooled condenser and evaporator tube bundle.
An evaporative cooling tower, with a power output of 430 kW (at a air temperature of 25 ° C wet-bulb (W.B.), a water temperature drop of 5 ° C and a water outlet temperature of 30 ° C), provides the water for the condensation of the refrigerant gas in the chiller evaporator.
The solution circulation is ensured by a pumping unit consisting of four parallel centrifugal pumps (two for the circuit-chiller tank and two for the users), from a storage tank, which acts as a thermal flywheel and delivery and return manifolds; in correspondence of the latter there are the connections to the various devices. In addition there are two pumps for water condenser circulation between the cooling condenser tower and the chiller evaporator.
The circuits are activated by the MTA Chiller, in this case the refrigerated fluid into each circuit more than 3 kg and their will be subject to the regulation on F-gases

Process water

The water can be used as a raw material in the plant and its purity depends on the needs of the process. Generally there is no use of cooling water for trial purposes. There is also the need to ensure a supply of treated water to the boiler steam production.

Fire-control water

The fire-control water is arranged in the underground tank capacity of 600 m^3, in appropriate amounts to face for a predetermined time the maximum credible accident hypothesized in the plant. In case of a big fire, the necessary water flow, varies generally between 750 and 1,500 m^3 / h. The time for which this magnitude must be able to be delivered also depends on the location of fire-fighting units external to the plant: typically considered to ensure a 2-3 hours coverage. The fire fighting's water circuit is closed ring type, to ensure that each point is served from at least two sides

Inert gases

The inert gases are used in the systems process industry for:

- ✓ washing of equipment containing flammable or explosive
- ✓ creating inert atmosphere inside or outside certain equipment
- ✓ air replacement in all of those operations in which the presence of oxygen is dangerous or harmful

As an inert gas, it is used the nitrogen: consumption is generally low and in many cases a contained stock can meet the requests for many days. For very small requirements it is possible to use the cylinders, but more in general it is possible to use tanks in which liquid nitrogen is stored: from the tank starts a pipe distributing the required nitrogen

Vacuum

The vacuum circuit serves for the distillation operations, loading of liquid reagents in the reactors or in the dripping tanks and for the drying operations, and it is powered through vacuum pumps of ROBUSCHI liquid ring type and it works in total recirculation of the liquid.

From the various product lines the aspirated fluid arrives at the main collector and from there, through the liquid separators it reaches the vacuum pumps that can operate on any production line or drying. The pump transmissions are conveyed through a trap cooled coil. The output is conveyed to the quench column and to the active carbon. The pump, during the operation, must always be supplied with the operating fluid to remove the heat generated by the gas compression and for replenishing the liquid ring, as a part of the liquid is ejected with the gas.

The vacuum is not a fixed size, it indicates the range of the pressures below atmospheric pressure. Because of this different pressure, the system continuously attempts to achieve a balance. In a completely sealed system, there would never come to a balance. However, because such a system does not exist, through each not sealed point, no matter how small it is, the air will be drawn. The many faucets, beveled joints, gaskets etc.. have a very good grip, but anyway always allowing a small amount of air to enter, so that the internal pressure continues to increase. This pressure increase can become problematic for the system. In a vacuum distillation for example, the liquid boiling point to be separated, it is so lowered by the depression, to make possible the distillation at a lower temperature. If the pressure increases, it suddenly comes to a level in which the boiling point is again higher than the heating temperature, and the distillation stops. To prevent all of this, the vacuum must be continuously controlled and modulated. Stable pressure conditions also reduce the risk of foaming and over-boiling. In the Sterling processes contemplating the formation of the vacuum inside the reactor, it is also important the pressure value that must be, for this reason, regulated. In case of connecting a vacuum pump to a container, this one subtract air until its final vacuum. All of this, however, has no utility in most vacuum applications, since they do not require pressure values as low as possible, but a suitable vacuum to the system. If in a distillation the pressure is too low, it may happen that the external environmental temperature is higher than the boiling point of the components to be separated, and then all the solvent is sucked out of the system by the pump, since there is no more condensation. Although a vacuum system is not fully sealed, it is however necessary that the pressure remains more or less constant. It is then an advantage to be able to control the

continuous pressure of the system, in order to compensate eventual deviations from the required pressure by drawing the air from the system. In order to rationalize this complicated work there are devices measuring the pressure until reaching the theoretical value desired and then maintaining it constant in time, operating a pump and valves.

One of this type of device is the Vacuum Controller that maintains constant the desired pressure by activating a valve placed between the passage and the vacuum pump. The hysteresis is the control parameter to adjust the pressure. It is the pressure value above the request, which must not be exceeded. If this happens, the pump creates a vacuum in the system until it reaches the required value, and the controller closes the valve. Because of the losses, the pressure slowly increases until it reaches the hysteresis value, at which the controller opens again the valve and the pump starts, returning the pressure to the value imposed by the research and development and it is inserted in the processing sheets of the in progress production process.

Compressed air

The compressed air is produced by a special compressor with tank 725 L and operating pressure between 4.5 bar and 10 bar. The air is used to drive the actuated valves and for the system of inerting of centrifuges.

Azoto

The nitrogen circuit consists of a 18,000 L liquid nitrogen tank, an evaporator, a pressure reducer, a sterilizing filter cartridge, and a manifold distributing the gas to the different users. Nitrogen is used for the inerting of centrifuges, to wash the vacuum pumps and for breaking the vacuum in the reactors and in the dryers.

Steam/condensate

The plant is served by two instant generation's methane steam generators with a nominal capacity of about 1,000 kW and a productivity of 1,500 kg / h of steam. The design pressure is 12 bar.
The steam is used by the tube bundle exchangers for the reactor's heating and the dryers by the air handling units of the finishing and production areas.
The so formed condensates, sent away by special traps are collected and returned to the storage tank powering the boiler.

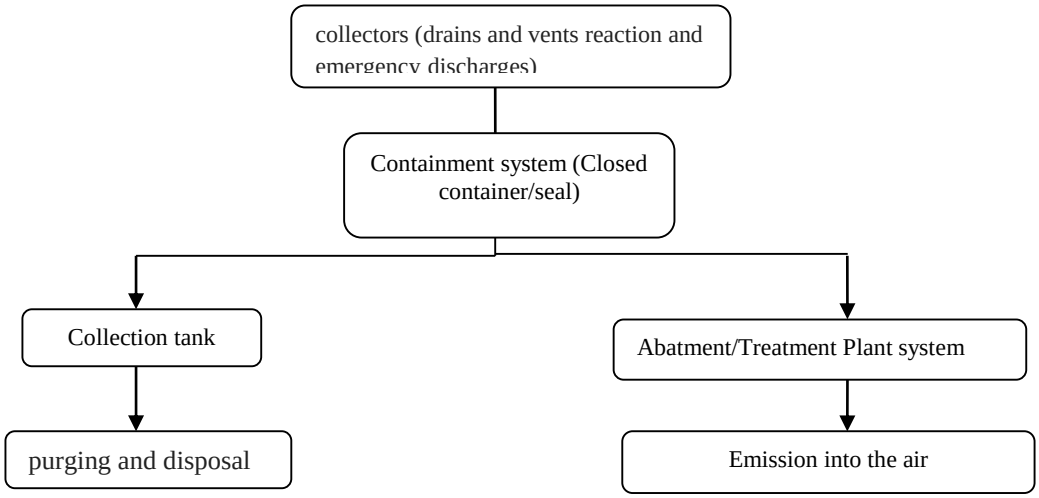
Blowdown system

The blowdown system is represented in **Errore. L'origine riferimento non è stata trovata.** and consists mainly of:

- ✓ a safety device's collector of emergency discharges for abnormal operating conditions or emergency of the process system which is the same for the vents and the discharges reaction:

- ✓ a collection device that in case of two-phase substances, could act at the same time, also as a separator;
- ✓ a treatment system consisting of an absorption system (scrubber + active carbon filter) for hazardous substances in liquid and/or gas;

In this system are collected eventual rupture disc vents, (calibrated at 0.49 bar) and the safety valves (calibrated to 6 bar).



Flow Chart 3 Operation blow down system: fume and vapor extraction

Vent and service process

A collector collects the vents from the process plant in case someone choose to operate at atmospheric pressure, without passing through the vacuum circuit and aspirations localized on board reactor. The output is conveyed to the quench column and to the active carbon treatment. The scrubber is made of polypropylene-filled rings in PPS (H = 6.2 m, Ø = 1.5 m) equipped with water closed-loop forced circulation and tail ventilator with a nominal capacity of 5,000 m^3 / h. The active carbon unit is constituted by a stainless steel cylindrical body with an internal grid tank for the coal (H = 3 m, Ø = 1.9 m).
In the quench column are conveyed:

- ✓ The ventilation service (localized aspiration);
- ✓ The ventilation process;
- ✓ The vacuum pumps flow;
- ✓ the blow down service;
- ✓ The blow down process

B.2.2.1.1.1 Loading and unloading of the manufacturing products

A basic requirement for the company is to avoid any possible contamination of the product. This requirement perfectly matches the safety and health's requirements both in the workplace and the environment. It's very important to avoid any contact between the different products or any human or environmental contamination. For this reason, in addition to the different operations more closely belonging to the quality scheme it is necessary that:

- each operation takes place while keeping the doors of the department closed, so any dust or fugitive emissions (including VOCs) can be adequately aspirated;

- The operations involving the loading and unloading products or raw materials by units of reactions such as reactors, filters or centrifuges will be carried out using the vacuum system consisting of localized movable-arm hoods. These movable-arm hoods must be positioned in the area above the equipment in use opening as to ensure the suction of the dust and volatile compounds that will be conveyed to the appropriate abatement systems;

B.2.2.1.2 Finishing Area (clean room)

There are three operations belonging to this group of activities representing the latest running of the finished product before the shipment to the customer. The most important is formed by drying of the solid mass coming from the processes of filtration and centrifugation. For this purpose the pharmaceutical drying process is always combined with the use of vacuum pumps, which allow to aspirate the solvent's vapors and the water present in the products to be treated. The dryers chosen for the Sterling Chemical Malta Ltd are static vacuum cabinet at displacement ventilation system. The main body consists of an entirely AISI 316L sheet steel cabinet for the parts in contact with the product and AISI 304 for the outer parts. The material is placed in 12 shelves in very tick AISI 316L sheet with internal conveying smooth at the top and bottom baffles fitted on a single extractable bunk structure. On these shelves are inserted trays containing the product dried by hot air circulating and heated by steam circulating in pipes. The system is driven in its functionality by:

- A heating/cooling group: the drying chamber and the floors are heated by circulating hot water with glycol up to a maximum temperature of 93 ° C, limited by a safety thermostat fitted on the heating circuit. This value, which prevents the water boiling is pre-set and unchangeable. The heating temperature is controlled by a transmitter that emits a signal to the control system displaying the temperature of the product. The circuit is open expansion vessel, and therefore subject to the normal atmospheric evaporation and is therefore present a floating feeding valve which automatically restores the level of the liquid. The group has its own frame in painted carbon steel complete with a centrifugal water circulation glycol. It has a flow rate of 10 m^3/h with a head of 6 m, a steam heater consisting of a carbon steel heat exchanger plate and an AISI 304 tube type suitable for steam up to 6 bar for the heating and also a cooler water consisting of a carbon steel heat exchanger plate and a copper tube bundle. The control parameters are the steam temperature and pressure, for this reason it is provided a temperature control set consisting of a temperature transmitter, a thermometer and a safety thermostat with manual reset. In case of excess of the range of working temperature, the tubular jackets used for the steam can be released by a pneumatic block valve and directionality of the fluid towards an expansion tank,

- A condensing unit mounted on its frame, complete with a vacuum with a coat condenser, tube bundle with internal conveying baffles and inputs and outputs hoods. There is also

a vacuum tank for the collection of condensed with cooling jacket, inspection ports and lighting. As for the reactors, there is a Vacuum Control with manual valves to be activated in order to exclude the tank, breaking vacuum to extract the product and condensate drain.

After the necessary drying time (varying from 2 to 48 hours) the product is discharged by breaking the vacuum desiccator, making it cool and only then opening the door to pull the basins. At this point the packaging operation starts.

In the fixing area, there is also included the finished product's local storage, as described in paragraph **B.1.4.3.1.4 Warehouse work** and the preparation and packaging of finished products area for the final customer. It falls in the fixing unit, as the pharmaceutical industries need a controlled environment area to monitor parameters such as temperature, relative humidity, which requires a number of air changes per hour and the air introduced in the environment is purified from contaminants and product potentially damaging.

In some areas of the fixing unit there is a pressure gauge able to measure the pressure difference. To ensure all of these conditions, the fixing area is served by a system consisting of No.3 Air Handling Units ensuring pharmaceutical areas classified as ISO. The system must maintain thermo-hygrometric parameters and therefore pressure such as to guarantee protection to the department operators as well as protection from cross-contamination. The system will be described in detail in paragraph **B.2.2.1.3 auxiliary units**

The filtration systems installed to cater for the air handling units in the finished product areas have the following type of filters:

- PRE-FIL class G4 with efficiency higher than 90% used as a prefilter for considered big dust with 4μ diameter. These are corrugated type of filter cells that due to their surface, the excellent mechanical strength and the low pressure losses, they have a high capacity of cleaning the input and output air from the department. In synthetic fiber calibrated density high-performance and equipped with plastic micro-net that by electrostatic effect, improves the performance. Upon reaching the recommended final pressure loss (250 Pa) they can be regenerated using warm water and detergents. The water is disposed as waste with a EWC 161001 * code
- ABSOLUTE FILTER with CEN EN classifictaion H14 and efficiency 99.995%. This type of filter are small folds, with limited depth. Consisting of a frame of extruded anodised aluminum. The filter medium is in glass fiber, water repellent and flame retardant; The low pressure drop of the filter allows to limit the power consumption of the fan. The filters are monitored with a differential manometer DWYER type. On the basis of the loss of load (exceeded 100 Pa) they are replaced; the filters are certified.
- ABSOLUTE FILTERS HEPA TYPE, H13 class with an efficiency of 99.95%. Made of paper in glass fiber-repellent, pleated with constant spacing achieved with the spacer threads continuous thermoplastic. The filter pack, uniformly close determines

a crossing surface for holding the fine powder. Also in this case a pressure gauge settable differential determines the load losses and the possible saturation.

- long lasting RIGID BAG MINIPLIT FILTER. They have a high filter surface and low pressure drop. With average efficiency 60-65% made of paper folded glass fiber with calibrated spacing. It is the last filter in the input and output.

In the circuits of Air Conditioning, Ventilation, and air intake (from inside to the outside and vice versa) the handling of the same is moved by the difference in pressure induced by the fans.
The pressure decreases, along the circuit, due to the frictions and resistances caused by variations of Section, Curve, Heat Exchangers, Latches and especially Filters.
The decrease of pressure, so called loss of load, caused by the filters, varies in time as a function of the amount of the retained impurities.
When the loss of load exceeds the design value, the air flow is reduced and the performance of the system is compromised with often serious consequences, to address what, sometimes, we resort to very frequent maintenance of filters.
This solution can result in high costs.
The Measurement of the Pressure Drop of filters allows to perform the maintenance in the most appropriate time and to maintain the system performance. The ignition of the light allows the operator that enters the area to have a pre-alarm on the first pressure loss so that he has time to warn the maintenance to replace or clean the filter. The alarm is activated only when the filter is clogged and therefore the circulation of air in the workplace is no longer guaranteed. By itself, the filter maintenance is planned at a rate that depends on the type of filter: bimonthly for flat filters G4, six months for the bag filters F9, annual for absolute recovering filters H13: the deadline for the change of absolute air inlet filters is every six years. Beyond the periodic maintenance procedures from the plan in case of the red light signaling, the maintenance will have eight hours for the replacing, in case it should also be activated the sound alarm, the filters should be replaced within two hours. During these hours they will not be carried out within the department activities involving the handling of the products.

B.2.2.1.3 auxiliary units

Auxiliary units are the machines and the systems used to operate the entire production system, below it is described as accurately as possible.

Steam generator:

The steam generator belongs to the two smoke ducts with dry back type with a minimum yield of 90% due to the high turbulence of the combustion gas as to facilitate the heat transmission. The accurate dimensioning of the combustion chamber and the flue ducts causes the combustion occurs with total absence of unburned and low NOx, in accordance with the stricter laws. The steam is generated by the water overheating supplied by the combustion coming from the buried tank placed outside of the structure. Since in general the flaw of a smoke-tube boiler is determined by the poor heat exchange efficiency (which

should be contained within the volume of water in the cylindrical body) in order to achieve high yields (≥ 90%). it has been chosen a boiler with double circuit of smoke. The generator is constituted by a cylindrical central body in which the water is supplied, this container has a large capacity and a substantial evaporating surface resulting in high thermal volume and a big amount of steam. All the combustion flows is completely immersed in water so as to significantly increase the surface area exposed to the flame, to ensure the removal of any refractory insulation, due to the maintenance costs, heat losses by radiation and the overheating of the rear tube plate.

Basically the boiler has two circuits:

Air-smoke circuit. The indoor air (combustion air) meets a first heat exchange zone, the pre-heater, where it is preheated at the expense of heat contained in the flue gas, before sending them to the fireplace to be released in the environment. The air is then sent into the combustion chamber where it reacts with the fuel generating combustion gases at high temperature, about 2000 ° C, giving off the heat, first of all, and above all, to the vaporizing section, and then, possibly, to a part of overheating. The flue gases, characterized by temperatures below 1000 ° C, encounter the predominantly convective heat exchange sections which is the convective superheater. The exhaust fumes pass through the economizer section of preheating air combustion (PA).

The water-steam circuit is divided into fall-pipes feeding with saturated water the pipes ascent to the cylindrical body. The rising pipes form the heat transfer section where the water receives the heat of vaporization from the fumes (such tubes constitute more precisely the containment wall of the combustion zone) while the descent pipes are not involved in heat exchange.

The generator implemented for Sterling Chemical Malta Ltd has the following technical characteristics (**Table 17** Steam generator characteristic.):

Steam generator		
measure characteristic	***units***	***value***
Steam production	Kg/h	500
Capacity	kW	349
Pressure	bar	12
Width	mm	1,800
Lenght	mm	2,300
Height	mm	1,500
Chimney	mm	250
Empty wight	kg	1,900
Rate Thermal input	Kw/th.	814.800
Estimated operation/year	h	4,000
Emission point	EM5	

Table 17 Steam generator characteristic.

The steam generator serves all of the following business activities:

- Production, the generated steam circulates in the reactor coils and it represent one of the heat transfer fluid and with which it rules the temperature control of the chemical reactions;
- Fixing unit, with particular reference to the dryers;
- The workplace conditioning;
- Cooling tower and chillers.

To ensure an energy and water saving it is also provided a net return of condensates that are retrieved through steam traps at a pressure equal to that of the entry of the vapor decreased from the exhaust leaks. This means that if the steam pressure at the entrance of the machine was 3 bar, the condensates would return to approximately the same pressure and, therefore, it could also trace a vertical duct and drain in a line of reasonable length, although in contrast. The condensates in this way rising up are accumulated in a collection reservoir with a double capacity of the amount of steam produced by the generator. The reservoir is thermally insulated in order not to waste energy and not to let the oxygen enter from the outside, and it has a vent with a safety valve in case of overpressure.

Boiler:

The chosen boiler is in steel RTQ 3S r, with flame inversion horizontal combustion chamber and concentric smoke battery tubes, it is a high-yield hot water generator for room heating, and also for the production of sanitary water because it is combined with a boiler. It has a moderate pressure ensuring a smooth operation and free of thermal shocks.

The main technical elements of the design are:

- A careful study of the geometries in order to obtain an optimal ratio between the volumes of combustion and heat transfer surfaces;

- The choice of the materials used, for the long life of the boiler.

Inside the tube bundle are the stainless steel turbulators, allowing to preset the pressure in the combustion chamber and the flue gas temperature, to homogenize the thermal load and optimize the combination boiler-burner.

The boiler body is insulated, in an accurate and effective way, with a pad of glass wool at high density.

To make easier the inspection, maintenance and cleaning of the internal part's operations and to reduce the response time, the front door and the smoke box can be completely opened.

The opening of the front door is also possible without removing the burner.

The hot water heater is associated with a flash type boiler and it is supplied with natural gas forced flow type with sealed combustion chamber and thermocouple safety device, or through solar panels. The water flow rate is a maximum of 26 liters per minute for a temperature differential of 25 ° C. The thermal work unit consists of a forced-draft wall mounted boiler with sealed circuit combustion fueled by natural gas. The boiler made of

aluminum or cast iron is equipped with a pre-mixer with modulating power for heating and electric ignition without pilot flame. The adjustment of the power and the temperature is electronic. The boiler is also equipped with a useful kit to reduce the emissions of NOx and CO_2 lower than 60 ppm;

The boiler implemented for Sterling Chemical Malta Ltd has the following technical characteristics

Rated Thermal input: 538.000 kW/th

Estimated operation/year: 4000 h

It has only one emission point on air, identified with code EM6.

Water treatment for boiler and steam generator

Many failures and sometimes serious accidents are caused by the use of water with not suitable characteristics, for this reason it has been installed a treatment system before they arrive in the body of the boiler consisting of a water softener and a set of resins causing the reverse osmosis.

The softener helps removing the limestone through an exchange process between sodium ions fixed on special resins, and ions of calcium and magnesium contained in the water. This continuous exchange transforms ordinary water into soft water. When all the sodium ions have been exchanged, the cycle is complete. To give the resins a new efficiency, it is necessary to regenerate them with sodium chloride. The electrical conductivity of an incoming and outgoing softener is basically equal because the difference in conductivity between the salts of calcium and magnesium content in the water and its salts of sodium, is negligible. Therefore, the conductivity of the raw water does not basically change by the softner. The conductivity will be used to determine the concentration of the sodium downstream of the softener as it represent an immediate, although brief, measure of the water salinity. The downstream softened water of the Cillit-BA-PILOT (softener type) prevents the formation of hardwater deposit inside of boilers, piping, valves and of the taps, as well as the interior of the heat exchange systems such as shirt reactors, helping to improve the performance of the same. The softener is used for:

- The network distribution of the cold and hot water;
- The hot water production circuits;
- Steam generator and its associated circuit flow and condensate return

Regeneration occurs through an electronic control constantly analyzing the various functions of the softener. This panel will enable Sterling to choose between different ways of resin rigenerations:

- in time;
- in volume;
- in statistical volumetric;

since for this object it does not exist an historical chronology it has been chosen a programming time for which, based on the Italian experience, it has been set a weekly regeneration of the resins.

Air compression central

One of the utilities used both in the production and in the laboratory is the compressed air. The chosen supercharger uses an innovative air compression system. In fact, the air compression is performed by the space reduction generated by two spirals contained in the compressor, one fixed and the other orbiting. Since the spirals have no points of contact between them, the system requires no lubrication, so the compressed air delivered by this type of compressor is strictly OIL-FREE. The selected unit is equipped with an Elekttronikon MKIV version microprocessor controller for the compressor adjustment and it is able to continuously monitoring the performance of the various components of the central unit. It keeps the pressure of the compressed air within the programmed limits by starting and stopping the compressors, depending on the air consumption. In addition, the selected system is able to equally distribute the operating time between the modules taking into account the availability and the operation hours of each, thus avoiding simultaneously starting and stopping of the individual compressors. These compressors are stationary type providing oil-free air and driven by electric motor. Each compressor is equipped with an air filter, the air is discharged through a non-return valve of each module, and a common air refrigerator. Each element of the compressor is cooled by a fan fitted on the motor shaft compressor element.

The atmospheric air is a gas mixture with the presence of water vapor that condenses when there is a pressure increase. For this reason the compressor station is equipped with a refrigeration dryer "FX" with ecological gas (R134a), a direct expansion dryer built for continuous operation and for indoor installations as it will happen in the special outdoor cabinet. This dryer guarantees a stable dew point and an immediately available power. This is important to avoid an immediate shutdown of the equipment which provides compressed air inside the reactors. The compressed air is dried until the dew point of +3 ° C in two distinct phases:

a) first, its temperature is dramatically lowered: the hot saturated air is cooled by the outgoing air through the air-to-air heat exchanger (tube in tube). By reducing the air temperature, the load on the refrigeration system is also reduced;

b) The air passes into the secondary refrigerant-air exchanger where the air is further cooled by heat exchange with the refrigerant gas until the dew point of +3 ° C, yielding then all the residual moisture which is subsequently separated from the condensate separator and discharged with an automatic unloading device.

The compressor used is sealed type, maintenance-free, gas-cooled engine with separation, the carcass is full of electrical resistance, thermal protection of the motor against overload and protection of high pressure gas. The revolutionary adjustment system ensures the always constant dew point, adjust the operation of the refrigerant circuit to the flow of

compressed air also eliminating any possible formation of ice inside the air circuit during the plant load operation, thanks to a revolutionary use of a by-pass valve that ensures a virtually perfect control system.

Cooling tower

The growing scarcity of the water resources occurred during the last decades, especially in the summer activities, prevents widespread use of refrigeration systems for air conditioning condensing into water. In fact, especially during the summer, when there is demand for a large production of cold, the capacitors must reject substantial amounts of heat, requiring the use of very conspicuous water flows for their cooling. Given the scarcity that occurs particularly during the summer period, the hot water output from the condenser can not be lost, both for problems related to the cost of its supply, and for environmental pollution problems. The idea on which the operation of the cooling tower is based, consists to allow the recycle of the condenser cooling water through an appropriate lowering of temperature. After the water has been restored to its original temperature it can be sent back to the condenser to steal the other heat. In this way it is possible to enjoy the benefits associated with the use of water as a capacitors cooling fluid and to mitigate the costs related to its retrieval. The key point of the effectiveness of a cooling tower operation is in partial cooled water self-evaporation. The use of evaporative cooling towers is convenient in the cooling water processes both for the reduced cost and for the substantial simplicity of the operation. Basically this operation is based on the use of two fluids that allow the rejection of a certain amount of heat: the amount of such heat is an important index for determining the efficiency of the system as a whole. The involved fluids are the hot water that must be cooled and the ambient air, the thermo-hygrometric characteristics of which are relevant in order to the obtain a good water cooling. Thanks to the evaporative cooling tower it is also possible to decrease the water temperature of 70 ÷ 80 C with reduced energy consumption compared to other forms of cooling. The air flow is axial in countercurrent, and in fact it is vertically guided upward, flowing in countercurrent relation to the water, which moves from top to bottom.
The movement of the air takes place with the help of fan-type discharges. The use of the fans becomes necessary when the sprayed flow of water is substantial, such as to allow with difficulty the lift upward in a natural air cooling.

As in the case of evaporative condensers, also for the cooling towers the use of water in an open circuit can cause problems of use. These problems are related to the management of water before, during and after the passage inside the tower. Normally, the water coming from the condenser must be clean and of normal composition. In the same way the water coming out from the tower and sent to the refrigeration system must be filtered to avoid that some impurities that have fallen into the water collection tank could cause problems in the feedback circuit. To avoid these problems, the cooling tower is installed in a closed circuit, in this way:

- ✓ the fluid to be cooled (typically water), circulates through the pipes of the exchange battery, without a direct contact with the external environment. In this way it is possible to preserve the fluid of the primary circuit from any form of dirt or pollution.
- ✓ The heat is transmitted from the fluid, through the walls of the tubes, to the water which is conducted countercurrent respect to water, evaporating a small amount, thus absorbing the latent heat from the evaporator and downloading it into the atmosphere.
- ✓ The rest of the water is recirculated by a pump that pushes the water from the tank up to the nozzles (secondary circuits).
- ✓ A small amount of heat is released in the air outside by convection, just like a dry cooler.

The water which serves to reintegrate the evaporated quantity may require an appropriate limescale or antialgae treatment, in function of its origin, to avoid problems with some internal components of the tower. Also with regard to the water, it may be necessary to install an electrical resistance within the water collection tank, in order to avoid freezing of the water during the periods in which the tower is not working, in the cold weather periods, but today the climate of the island does not make possible such a provision.
The cooling tower powers the chiller that can reach fluid temperatures used for temperature control in chemical reactors.

The cooling tower is allocatated on roof top, and shows on plans in annex B.1.4-A4 “Equipments lay out”.

Chiller -25 °C e -5 °C

The temperature control is powered by two chillers able to reach different ranges of temperature, which are mechanical groups assembled for the cooling water closed circuit, oils, and fluids of the system. The chiller achieving lower temperatures (- 25 ° C) is a water cooler with semi-hermetic compressors. The chiller is equipped with a control panel with IP54 protection and uses a refrigerant fluid R407C. The compressors are connected together in parallel on a common chassis mounted through anti-vibration supports on the machine base. Each compressor is equipped with a crankcase heater, a pump and lubrication oil from an oil pressure switch. The compressor's oil sump belonging to the same refrigerant circuit are in communication with each other through an equalization pipe in order to always guarantee the presence of oil in each casing. On the flow pipe each compressor is provided with a silencer device and a non-return valve which prevents any return of the liquid to the head of the compressors. The electric motor power is 4 poles. The evaporators and the condensers complete the machine. The first are direct expansion tube bundle type and are made from copper pipes conformed to the "U", expanded at their ends, connected to a tube plate and arranged inside a carbon steel casing. The refrigerant flowing inside of the copper pipes while the water flows externally to the tubes. The mantle is externally covered by an insulating layer and anti-condensation. The capacitors are tube bundle type and are equipped with service connections and connections for the safety valve. They are also thermally insulated with a polyurethane sheet.
The chiller serves the production plant.

HVAC system

The Sterling Chemical Malta Ltd as all pharmaceutical companies must ensure an area of absolute health through a constant exchange of air, controlled in terms of impurities present therein and certain characteristics such as temperature and humidity to ensure international standards for the welfare conditions of the operators and the maximum efficiency of the product.
If filtration can make the air degree cleanliness acceptable for the process, it is necessary that the air is introduced into the clean room in a way that contaminants generated within it do not cause damage.
The process of contamination control starts from an analysis of the risk of contamination in various stages of production, thus involving procedures, measurement systems, defining the parameters of alert and alarm, movement of people, equipment, raw materials, finished products and waste materials. The GMP decree both the requirements for the construction of environments for the production of drugs, the contaminants to be controlled are the volatile organic compounds and the dust that comes from the inside through the entrance of personnel or equipment closely linked to the production and through the outer in the moment of entry of the air. The systems used are of the type HVAC treatment with input and extraction of air and HVAC SAS with the only input, in both cases they are controlled parameters such as temperature, pressure and powders. Fundamental parameter is the relative humidity control for maintaining the purity of the air as it affects the material in production, and it can introduce impurities in the work environment.
These systems consist of the following units/components:

1. Air supply unit consisting of:
    a. Section of pre-filtration of air intake filters composed with efficiency G3 F9 filters;
    b. Preheating Battery;
    c. Cooling battery;
    d. Steam distribution;
    e. Droplet separator;
    f. Post-heating battery;
    g. Air supply fan motor with an inverter (it is intended for operation in normal driving and in low gear).
2. Air extraction unit composed of:
    a. Filtration section consisting of a containment system security (bag-in bag-out) with absolute filters H13;
    b. Fan unit with II3GD atex motor with inverter.

The areas served by the system are classified Atex Zone 2 therefore it is included the use of appropriate equipment/instrumentation. The treated air is supplied inside of the premises by efficiency HEPA filters H14 installed in the ceiling. The air will be extracted

from the intake grilles, stainless steel and equipped with pre-filters and then they will be sent to a security container equipped with HEPA filters H13 efficiency. The air will be extracted from the intake grilles, stainless steel equipped with two series of prefilters with efficiency G3 and F9. The air flow rate is constant, while the flow of extracted air will be modulated by the operation of clenching motorize driven by differential pressure transmitters. The transmitter references for differential pressures will be the external environment. There is an alarm indication in the event of a fault in the context of pressure. The premises managed by the systems will be always indicated on depression in relation to its surroundings. The installation is required in areas not classified as differential pressure indicators DWYER with scale -30 to +30 Pa. ATUs and extractors are designed for indoor installation. The filtration units will be equipped with DWYER differential pressure gauge for monitoring the clogging of the filters. The areas served by the system are classified ATEX zone 2, it is therefore provided the use of appropriate equipment/instrumentation. The ATU's are made to support the external conditions of work and therefore to suffer the weathering effects.
The HVAC-SAS system consist of the following units/components:

1. Air supply unit consisting of:
    a. Section of pre-filtration of air intake filters composed with efficiency G3 F9 filters;
    b. Preheating Battery;
    c. Cooling battery;
    d. Droplet separator;
    e. Air supply fan.

The treated air is supplied inside the premises by efficiency H14 filters installed in the ceiling. The filtration units will be equipped with DWYER differential pressure gauge for monitoring the clogging of the filters. For each area served by the system there must be the differential pressure indicator DWYER scale -30 to +30 Pa. There is an alarm indication in the event of a fault in the context of pressure. The premises served by the HVAC system SAS.01 will always be under positive pressure with respect to close areas served by the systems described in the previous paragraphs. The supply and return air ducts will be made of galvanized steel sheet. Where necessary, the pipes will be stiffened by special ribs. The ducts size and construction shall be made in accordance with ASHRAE requirements. The pair will be realized through flanges consisting of angles fixed to the channel through a welder. Every flange-channel and flange-flange junction will be appropriately silicone coated to ensure a tight seal. For the flanged couplings it is also provided an inserting of a neoprene seal adhesive. The manual adjustment shutters will be of the type with multiple fins ensuring a tight seal when the shutter is closed. The construction material is in galvanized steel.
The self-regulating shutters will be made of galvanized steel. The adjustment will be made intervening from the outside of the shutter. The sizing of the self-adjusting shutter will be made as to keep the flow constant in its ducting also to vary the degree of filter cloggings and they will be installed as shown on the operation diagrams.

The flexible pipes will be made of PVC with spiral steel reinforcement. Such flexible pipes will be used for the pipes connection to the terminal diffusion-recovery-filtration components.
The tightening of flexible pipes will be executed through tube- tighten collars with clamping screw
The HVAC systems and HVAC SAS have a regulation and control system. In particular, the thermostat control system will be implemented through hot steam with the following characteristics:

Cooling water	Industrial steam	Clean steam
Temperature 4 °C	Pressure 3 bar	Pressure 0.3 barg
Glycol 50%		

Table 18 HVAC Technical reference

The following table describes the reference areas in which the AHU's in the HVAC system work, the room identity code refers to the plan in B.1.2-A1 "factory lay out". The conditions will be repeated in case the company decides to initiate a second finishing area or new rooms having within the same tools (centrifugal or dryers)

HVAC system						
Id local	***Local description***	***Class ISO***	***ΔP (Pa)***	***Vol (m^3)***	***Air changes Vol/h***	***Temperature/ U.R.***
12.C	Centrifuge	8	-10 Rif.12CP	75	20÷30	20÷25°C <60%
12.W	Packaging room	8	-10 Rif.12WP	30	20÷30	20÷25°C <60%
12.E	Dryer	8	-10 Rif.12EP	30	20÷30	20÷25°C <60%
12.MF	Finished Good Warehouse	Nc	nc	180	5÷10	23÷27°C <60%

Table 19 Condition of internal project premises served by the HVAC finishing area.

The regulation system of the heating fluid flow will be realized through a control unit with a two-way valve. The cold temperature control system will be implemented through freeezing water produced by dedicated system.
The regulation system of the heating fluid flow will be realized through a control unit with a three-way valve. For the Air Handling Units where humidification is contemplated, it will be provided a humidification nozzle complete with condensate trap and modulating valve on the inlet steam. The design conditions for the different rooms are in **Table 20.**

HVAC – SAS system						
ID local	Local description	ISO	ΔP (Pa)	Vol (m^3)	Air changes Vol/h	Temperature
12.C.M	Input/Output Centrifuge material	8	+10 Rif. P.amb	25	20	20÷25°C
12.C.P	Entry/Next People local Centrifuge	8	+10 Rif. P.amb	25	20	20÷25°C
12.W.P	Entry/NEXT people local Packaging	8	+10 Rif. P.amb	20	20	20÷25°C
12.E.M	Input/Output Dryer material	8	+10 Rif. P.amb	20	20	20÷25°C
12.E.P	Entry/Next People local Dryer	8	+10 Rif. P.amb	15	20	20÷25°C

Table 20 Condition of interior design local finishing area.

All the rooms will be equipped with gauges used to measure differential pressure.
The indicators will be placed in the corridors of the entry to the departments in dedicated security. The pressure will be connected to the relative locations with Rilsan tubes. The indicators will be placed in the corridors of the entry to the departments in dedicated security.
The machine UTA are allocated on roof top, and shows into a plan of annex B.1.-A4.

B.2.2.2 Shut-down, start up, momentary stoppage and leak or malfunction

More than 20% of accidents occur during the start-up and shutdown phase. In addition, any accidents occurring during the normal plant operation, are due to thermal and mechanical stress, fatigue or excessive vibration occurred during the start-up and shutdown phase. Such incidents may result in:

- Fires;
- Explosions;
- Water-hammers;
- Professional accidents;
- Latch systems.

For this reason, in Italy the Sterling has successfully implemented a procedure to start and stop the system providing the following key points:

- Ensuring the safety of the operators;
- Do not damage the equipment.

For this type of business activity the typical risks are:

- Sudden evaporation or water freezing;
- Thermal or mechanical shock;
- Mixing of air and explosive vapors.

To fully embrace the whole field of probabilities in the examination of the risks, it should be noted that there are several types of shutdown:

- Programmed shutdown: occurring every Saturday morning when the plant stops working.
- Emergency shutdown;

For the programmed shutdown (as well as for the starting) there are the instructions in the Operating Production Manual[6] in which there is also a checklist, so that the operator does not have doubts about how to act.
The emergency shutdown is actually closely related to the nature of the emergency such as earthquake, fire, stop, pressure or temperature increasing, lack of electricity, etc. .. each event has certain codes of conduct. To sum up, at the warning sign that could also lead to the evacuation of the facility, the operators and supervisors before leaving their place of work, have to secure the facilities without risking their own safety, in the following manner:

In the production unit

a) suspend any reactive additions from the drippers by closing the drain valve and the vent may eventually be opened in the department.
b) put under cooling the reactors in use leaving the agitation working to optimize the cooling.
c) placing the reactors in use under a slight nitrogen flow with the exhaust chiller
d) put to reflux the discharge of condensate
e) verify that the load lines and drains are closed
f) close any open reagents or solvent's containers
g) remove the flammable material from the department, or at least from any heat sources

In the fixing unit
Close the eventually working heating and cooling stoves

In the utilities
Stop the vacuum pumps and verify the cooling operations.

Sterling has adopted procedures for prevention and action against possible accidents. In annex B.2.2-A5 " Emergency training and reaction" that is the main procedure in HSE system.

B.2.2.3 Flow diagram summarising

The flow diagram is shown in section **B.1.4.3 Site** plan and the relative activities **Sterling by block.** The following table shows all the operations that will be carried out within the production department.

[6] ***Operating Production Manual in Annex B.2.2-A1*** to this report

Process Description					
ID[7]	**Phase**	**Start**	**End**	**Control**	**Note**
F1	Set up Reactor RA: Nitrogen pressure cycles.	Operator start	Establish vacuum, assign number of cycles and stop by operator	Vacuum pressure	This phase has the objective of providing an inert atmosphere to avoid the formation of explosive mixtures. To do this, make a few vacuum/recovery cycles
F2	Loading Powders in RA	Finish cycles	Finish loading powders	Environmental temperature	Quantity of powders predefined
F3	Loading Solvents in RA	Finish loading powders	Finish loading solvents	Local suction hoods. Nitrogen flow. Environmental temperature	Predefined quantity of solvents (volumes written in notes)
F4	Dissolution of powders and solvents in RA	Finish loading solvents and powders	Mixing timer . Visual Visual observatiion	Temperature Pressure Mixing rate	There is no set pressure but a minimum nitrogen flow
F5	Reaction	Finish dissolution	Reaction timer and in-process control	Temperature Pressure (nitrose flow) Mixing rate	-
F6	Distillation	Finish reaction	Visual observation: volume of distillate collected and volume remaining in reactor	Temperature Pressure (nitrose flow) Mixing rate	-
F7	Re-cooling	Finish distillation	Set temperature Re-cooling	Temperature Pressure (nitrose flow) Mixing rate	-
F8	Phase separation: loading water	Finish re-cooling	Pre-established water volume	External control of loaded volumes	-
F9	Phase separation: high velocity mixing	Finishing loading water	Mixer timer	Temperature Mixing rate	-
F10	Phase separation: decanting	Finish mixing	Decantation and visual control	Temperature Pressure	
F11	Phase separation: discharge solid phase	Finish decantation	Visual observation	-	-
F12	Set up Reactor RB: pressure cycles	Finish phase separation in RA	Achieve vacuum pressure and operator stop	Vacuum pressure	-
F13	Loading acidic solution in RB	Finish phase separation	Visual observation	Quantity of solution (balance, meter) Mixing rate Temperature Pressure	-
F14	Transfer of aqueous phase from RA to RB	Finish loading acid solution in RB	Visual observation and inprocess control	Vacuum pressure (in RB)	IPC = pH control
F15	Reaction in RB: crystallization	Finish transfer from RA to RB	Timed settling (achieved after temperature is set)	Mixing rate Temperature Pressure	-
F16	Transfer of solid from RB to FT	Finish reaction RB	Visual observation	Mother liquor level; Inertization	-

[7] **ID**: Identification code for single operation.

F17	Filtration	Finish loading	Filtration timer	Mother liquor level; Inertization	-
F18	Filtration	Phase separation	Visual observation	Mother liquor level; Inertization	Can be done under pressure
F19	Filtration: Collect solid and transfer to DR	Finish filtration	Clean filter	-	Manual operation, cleaning useful to remove various impurities
F20	Dryer: Load solid in DR	Finish filtration	Visual observation	-	Manual operation
F21	Dryer: Termostating	Finish loading solid	Set temperature	Vacuum Temperature	-
F22	Drying	Finish termostating	Finish drying and in - process control	Vacuum Temperature	IPC = weight loss on drying
F23	Drying: re-cooling	Finish drying	Achieve set cooling temperature	Vacuum Temperature	
F24	Drying: upload solid	Finish re-cooling	Visual observation	-	-

Table 21 Process phase description.

In ***Annex B.2.2 –A2 "Block plan –production process"*** shows the block diagram of the productions where it is possible to deduce the formulation phase of the waste, consumption of raw materials (including water) and the exhaust fumes of the final process.

B.2.2.4 Best Available Technology (BAT)

In accordance with the pollution prevention principles established by the IPPC regulations, the design of new industrial complex has exploited the reference documents concerning the best available technologies for the industrial relevance of the company, by integrating them with some general principles described in other BREFs such as those for the preparation of the Monitoring Plan. The cross-cutting documents are related to themes and techniques that can affect some or all of the industrial sectors such as economic and environmental assessments, environmental monitoring, emission of volatile compounds or the general technologies for the treatment of industrial effluents. The documents formally adopted by the Bureau of Seville for the preparation of this application are as follows:

i. Reference Document on General Principles of Monitoring (GPM);
ii. Reference Documents on Best Available Techniques in Common
iii. Waste Water and Waste Gas Treatment/Management in the Chemical Sector (CWW);
iv. Reference Documents on Best Available Tecniques in the Organic Fine Chemicals. (OFC)

The already adopted BAT and the one to be adopted in the future are summarized in annex **B.2.2-A3 "Best Available Technology".**

B.2.2.5 Alternatives technology, techniques and measures

The technological alternatives can covers different topics:

1. Structure of the system: In relation to the market with the ability to impose new horizons or not, from the orders and sales, the company might decide to abandon the idea of enlargement of production in stage III and allocate the area used to welcome a new line of production in the warehouse area. This alternative solution may be fielded even in cases where it is considered excessive to offer new capacity of production but with consequent new dangers. Reduce the capacity of a chemical plant also means reducing the risk of major accidents. In ***annex B.2.2-A4 "Alternative Solutions-Lay out factory"*** the virtual floor plan in case of intended use change of the space provided in Stage III.

2. Replacement of the reactors of batch type with standard reactors of "clean reactor" type that largely satisfy the regulatory GMP enriching the production line of command groups for each reactor that will be equipped with a magnetic drag stirrer, mechanical seals "dry running" with non-contact rotating seats and sterilized, fixed CIP validated and certified to avoid "cross contamination".

3. Replacement of the dryers of the static type with continuous Flash Drier thin-layer drying plants, suitable to treat heat-sensitive products, also operating under vacuum or in inert environment, using a technology which operates with very low residence time and minimum hold up, avoiding the thermal degradation and allowing the interesting economies in energy level, given that the same installations operate exclusively for transferring the heat conduction, thus avoiding the use of air, which always implies lower energy yields in addition to the need for auxiliary equipment for the recirculation of the same and the final treatment of gaseous effluents.

4. Change the exhaust abatement systems with installation of a cryogenic condensation, assisted by activated carbon filters and macroporous resins when the need arose for the trapping of VOCs.

5. Variation in the technology of distillation column with the introduction of a batch type in internal reflux, which gets levels of yield and quality superior to conventional techniques, in particular in the recovery of solvents from complex mixtures with more components. The quality obtained allows the reuse of individual solvents in the pharmaceutical manufacturing processes in compliance with more stringent international standards The Polaris technique of distillation also allows the reduction of the disposal costs of the mother liquors of the process by separating the water from the solvents.

B.2.3 Raw Materials

The raw materials used by the company are part of a chain of the chemical industry base, which provides the key raw materials, while the export market is made by the pharmaceutical companies. In the portion of the supply chain that identifies the sector of pharmaceutical fine chemicals to which Sterling Chemical Malta Ltd belongs, few basic sub-steps can be identified, corresponding to the same amount of steps of the production process:

- Production of distant intermediates: the so-called building blocks, sometimes real chemical commodites (obtained by combining different processes with different core molecules);
- Production of advanced intermediates, obtained by combining the distant intermediate to other minor compounds;
- Active Ingredient production, which is the last step of production.

As part of the supply chain, pharmaceutical companies are involved in the finished pharmaceutical product's formulation for the patient use. Companies like Sterling provide the raw material in solid form through the organic chemical synthesis of the raw materials contained in ***Annex B.2.3-A1 "APIS & Raw Materials list"*** of this report. The list of such commodities does not intend to be exhaustive because of the intense research and development activity of the company having as its purpose the research of new molecules and the optimization of already in place processes. The trial involves the testing of new ingredients that, if successful, they will complement the raw materials in production. The attachment is a table containing the following information:

- IUPAC name of the raw material;
- CAS number for unique identification;
- Risk phrases;
- Hazard;
- Physical state;
- Exploitation department;
- Storage department;
- Maximum amount of storage;
- Estimate of the maximum amount used in a year of work;

The raw materials have different roles in the production process, each production cycle starts from the "starting material" It is a chemical compound that contributes to the final structure of the API. So, there are halogenated and non-halogenated organic solvents, catalysts and other reagents involved in the various production process stages in such a way that by the chemical reaction they allow a continuous evolution of the molecule structure in order to obtain the final product.

The raw materials production and processing aids are used basically in 4 departments. The Research and Development laboratory, the Department for the quality control of both finished products and raw materials to be used in the production cycle and for which there are required reagents of laboratory which are able to reproduce the tests required by the international regulations, obviously the production and the maintenance department.

All ***MSDS shows in annex B.2.3-A2.*** This attachment is only available on CD-rom since too many pages should be printed.

For any new APIs to be utilised within the facility, sterling will have to notify the Authority on their eventual use prior to commencement of R&D or commercial production. The period of notification will be decided with Authority.

B.2.3.1 Containment and protective measures

Each raw material has different physical and chemical characteristics, for this reason it is always necessary to follow the directions of safety data sheets sent by the supplier at the time of the purchase and delivery of the goods. These MSDSs (material safety data sheets) must be written in English or Italian in a way that it results easily understandable by all operators and must be placed in each department in which it is required the handling and storage of raw materials. It will also always be available:

- One electronic copy of each MSDS;
- One paper copy in a dry place and protected from the weather and that is not of working type or belonging to the building of production, because in case of emergency as fire, flood, earthquake and collapses it will be possible to identify the type of material involved in the accident.

The protective measures are identified from MIOS_4.4.6-L1 "PPE USE AND MAINTENANCE" operating instruction describing by department, by work activities and by macro-typology of manipulated raw material, how to behave and the PPE to be used.

With regard to structural containment measurements in case of spillage of raw materials, it is important to consider that all raw material can be stored in outdoor areas, except for LPG used as a fuel for the boiler and the steam generator. The raw materials in the External Flammable Warehouse will be stored in containment basins. In particular, there will be two containment basins having a capacity of 15 m^3 respectively. The raw materials stored in indoor areas are solid goods, so the containment basin is not necessary. Liquid raw materials will be stored in mobile basins within indoor areas. Such rooms are equipped with a waterproof sloping inward the building so as the liquid cannot reach the outside.

Regarding the containment measures, the company regularly buys absorbent and containment spill kits consisting of several parts and equipments to be used depending on the nature of the spilled raw material. Even in this case, it is necessary that each department has its own kit and that also outside, in the raw material's passage zones there are placed in more corners these kits to ensures a quick access by the operators and the immediate arrest of the loss. Below in **Table 22 Containment measures,** the list of products used for the containment post-accident protection. According to the rules, it has been defined a system of prevention and protection from spills of oil or other liquid pollutants in the activity.

A risk analysis, carried out through the combined use of land and operational surveys, but also based on the thirty years work experience in Italy it made possible to identify in advance the places where there might be more likely this kind of accident, assessing the pollution potential. In correspondence of these points are therefore arranged, adequate containment protection

and emergency that can be activated in a few minutes. In ***Annex B.2.8-A3 "Plans for actions to be taken in case of other environmental event"*** the layout showing the areas of highest spillage risk.

The pollutant's spread in the industrial environment and on the territory is in this way promptly blocked at the origin, containing the possible environmental damage within negligible dimensions of evidence and the relative remediation costs to very low levels.

Type of polluntant	Monitored area	Colour area	Type of container	N.o of containers	Absorption capacity	Contents
Oil and hydrocarbons resulting	Pump and utilities area	Blue	Portable kit	1	Lt 15	n.o 6 sheets; 2.5 kg of oil absorbent granules HG; n.o 1 scoop with brush, n.o 1 lot for scrap, n.o 1 pair of gloves, n.o 1 mask
Oil and hydrocarbons resulting	LPG tank area	Blue	wheeled containers	1	Lt 75	n.o 30 sheets, n.o 12 sleeve, n.o 3 bags for waste; 1 pair of gloves, 1 mask
Universal kit (solvents, acids&bases)	Labs	Yellow	Portable kit	2 for any Lab	Lt 19	n.o 20 sheets, n.o 1 sleeve; n.o 1 pillow, n.o 1 bag of 1.5 kg absorbent granules Ecosorboil ® Finish, n.o 1 bag for waste; n.o 1 pair of gloves
Universal and specific for aggressive liquids to absorb aggressive liquids, toxic and caustic	All production lines + Raw material warehouse + External inflammable warehouse + finished good warehouse, Finished area	Green	wheeled containers	2 for production line, 1 for warehouse, 1 for finished area	Lt 216	n.o 50 sheets; n.o 6 pillows, n.o 6 pillows; n.o 12 sleeves, 6 bags for waste; n.o 3 pairs of gloves, n.o 3 masks
Universal and specific for aggressive liquids to absorb aggressive liquids, toxic and caustic	External area	Red	storage cabinets	1	Lt 131	n.o 50 sheets; n.o 4 sleeves; n.o 6 pillows; 1 5 kg bag absorbent granules and neutralizing Neupas ®, n.o 1 pair of gloves, 1 pair of glasses, 1 mask; 5 bags for waste
Universal kit (solvents, acids&bases)	Sampling room and external weighing room	Pink	wheeled containers	2	Lt 108	n.o 25 sheets; n.o 6 pillows; 6 sleeves; 6 bags for waste; n.o 2 pair of glasses; n.o 2 masks
Manhole protective cover for drains and grate in case of accidental spill	External area	Red	Storage cabinets	4	- -	Carpet protective manhole cover to prevent infiltration of liquid pollutants into sewers, drains or water networks
Storage containment	Externale inflammable warehouse	green	Bunding	3+ area	Lt 50,000	- -

Table 22 Containment measures

B.2.4 Ozone depleting substances and fluorinated greenhouse gases

The EC Regulation no. EC 517/2014 also defines the rules on the imports from non-European countries and on the related use of controlled substances called ODS (Ozone Depleting Substances). The regulation defines the communication mode of information on these substances, and what measures for their import and their use. The controlled substances, including their isomers, whether alone or in a mixture, virgin, recovered, recycled or reclaimed they carry this name because they are able to destroy ozone molecules transforming them into simple oxygen. The ODS's found in the Sterling Chemical Malta Ltd's working activities are:

- The bromofluoromethane belonging to the category of Hydrobromofluorocarbons (HBFC), used for the production and imported from China, a country outside the EU;

all the equipments used for the air conditioning of the working environments, and the working fluid's refrigeration, typically water, have been chosen to prevent the presence of ODS; in fact, as seen from the following table all of the air conditioners and industrial chillers contain as the refrigerant R410-A an azeotropic mixture composed of R32 (difluoromethane, CH_2F_2) and R125 (pentafluoroethane, C_2HF_5), both fluorinated hydrocarbons. Not containing chlorine atoms, this mixture does not harm the ozone layer. It has a potential global warming of 1725 just more than R22 used until a European Union ban. The R410-A is still a greenhouse gas and therefore it is subject to the controls provided by EC Regulation no. 517/2014 and subsequent amendments in order to control and monitor gas leaks as specified in the operation providing an operational control and technical gases (ammonia, chlorine, F-GAS, nitrogen) management .[8] To maintain this standard of accurate choices it has been elaborate a control operational statement of technical gases which allow to study the applicability of engineering decisions to protect the environment. The operating instruction it is also applicable to all the gases control in the company.

[8] Work Instruction about ***control operating plan of industrial gases***, attachment ***into annex B.2.4-A1 rev.01***

Use equipment	Type of substance	Charge substance (Kg)	GWP	CO2 eq	Local service	Type of equipment	Frequency control
Air conditioner	R410-A	3.5	2088	7.29	Offices second floor	Fixed system	Yearly
Air conditioner	R410-A	6.5	2088	13.5	Laboratory area	Fixed system	Yearly
Air conditioner	R410-A	8.5	2088	17.7	Offices first floor	Fixed system	Yearly
Air conditioner	R410-A	3.5	2088	7.29	Offices second floor	Fixed system	Yearly
Air conditioner	R410-A	6.5	2088	13.5	Laboratory R&D	Fixed system	Yearly
Refrigeration Chiller MTA	R410-A	25.0	2088	52.08	Unità di fissaggio	Fixed system	Half-yearly
Refrigeration Chiller MTA	R404A	44.0	3922	169.2	Production area	Fixed system	Half-yearly
Refrigeratione Chiller MTA		46.0	3922	176.9		Fixed system	
Refrigeration Chiller MTA		46.0	3922	176.9		Fixed system	
Air compressor	R134-A	0.129	1430	0.198	Production area-Laboratories	Hermetically-sealed system	Not control

Table 23 Equipment and identify type of equipment that use F-GAS.

The air conditioning equipment ensure the air conditioning in all the workplaces, while the MTA chillers allow the process fluids cooling (exclusively water flowing in the shirts of the reactors or dryers). In this case, not being obligatory the control of eventual cooling fluid loss, the monitoring shall be annually conducted as required by the maintenance plan.

The Bromofluoromethane is employed in the production of Fluticasone Propionate and annually its consumption is estimated in 100.00 kg. Each year the Sterling Chemical Malta will therefore be obliged to register in the ODS Licensing System, to report the amount and the reasons for the ODS import and to wait for a confirmation of authorization to import.

The refrigerant in the air compression unit is less than 3 kg and is therefore not compulsorily subject to leakage periodic monitoring.

B.2.5 Maintenance

The maintenance of the plant may have an incidental character if it arises from a fault or failure in the system or may have a programming character depending on the interventions and deadlines according to the various equipment instruction manuals. Referring to all planned annual maintenance interventions there is a tolerance of thirty working days to complete the maintenance. For all other scheduled maintenance with frequency less than one year, however, there is a tolerance of 15 working days. The company already has a maintenance program

consulted and followed for routine operation and verify the functionality of some elements such as the air duct systems, the exhaust abatement systems, cooker hoods, etc.. The main activities that will be carried out are listed below:

- repairing of hydraulic pumps, hydraulic lines and valves, solenoid valves for compressed air and vacuum, various types of pipes, electrostatic, pumps and vacuum generators, etc.
- Repairing of air conditioning and cooling, lubrication technical gases piping (nitrogen, compressed air, etc. ..).
- Welding wire used for elements requiring a mechanical seal.
- TIG welding used for tools or mechanical parts requiring a pressure seal.
- Welding and Cutting
- Building repair, shaping, sawing, etc. ..
- Intervention to heal deficit on electrical installations.
- Construction and energy
- Automotive as pressure gauges, thermometers, switches, barometers, timers, etc ...
- Interventions in the plant with equipment supplied as a repair workshop vacuum pumps, pressure gauges, dryers, fittings, filters repair or cleaning etc..

All facility maintenances within the company are listed in the maintenance plan MN.SOP.001[9] .

The maintenance of the systems within the company was the subject of an accurate technical and economic analysis, this analysis showed that the optimal applicable solution (and currently applied) consists of a combination of recovery methods, law enforcement and corrections.
This business strategy is expressed through actions of:

- ✓ SCHEDULED MAINTENANCE
- ✓ PREVENTIVE MAINTENANCE INSPECTION
- ✓ EXTRA MAINTENANCE
- ✓ INCIDENTAL MAINTENANCE

The SCHEDULED MAINTENANCE is made, however, on the expiry of a period of time previously established on the basis of statistical fault data (information obtained from the manufacturer and also obtained from the experience) and how the machine has been used.
It is performed by external contractors or by internal operators in case of easier tasks on the devices with greater critical levels.

The PREVENTIVE MAINTENANCE INSPECTION is a wear and/or operation verification activity of a machine assuming that the fault is the ending point of a deterioration process,

[9] See ***Annex B.2.5-A1 Maintenance plan rev.05***

preceded by a series of detectable, visually or instrumentally signals and it provides objective criteria to proceed to the maintenance interventions and improvement condition.
It is carried out by the operators of the facility which is subject to verification, within the limits of its powers and responsibilities, during the course of normal business activities and it is part of the instructions for use.

The EXTRAORDINARY MAINTENANCE interventions provides functional recovery following the detection of a not predictable fault in the programming phase and it is then carried out with a frequency that depends on the contingent situation.

The INCIDENTAL MAINTENANCE plans intervention as a result of failure or malfunction and it is carried out, except for primary interventions, by specialized external companies. Whenever are requested periods of inactivity of the plant, or part of it, it is possible to suspend the scheduled maintenance of the plant or the inactive part. However, these periods of inactivity, not less than one month, must be taken from the production program and agreed with the management. Before the next reboot of the system or the inactive part, it will be necessary to repair the maintenance activities.

B.2.6 Energy

The IPPC complex is essentially characterized by two input energy flows:

- Thermal energy obtained by burning natural gas supply to the one boiler in the plant ,of mechanically driven type. The one boiler installed supply heat to the entire production complex.
- Electricity, medium voltage supplied to the main power supply cabinet and transformed into low before powering the entire facility.

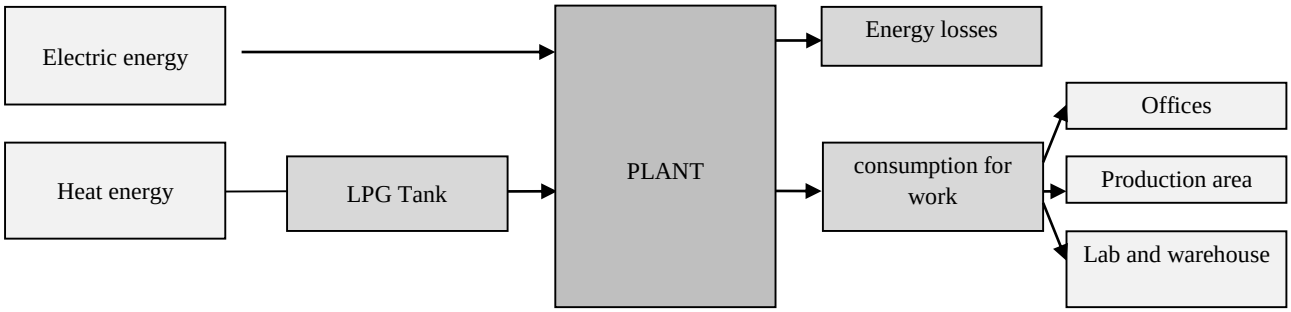
The energy gained from the outside, is then fully used, so there is no energy flows out of the system.

The maximum annual energy consumption, can be estimated as follows:

- Electricity: 250 MWh
- Thermal energy: 200 MWh

These values refer to the total consumption of the plant and not those specific to the IPPC. In the boiler there is a condensates recirculation system produced by the use of steam in the plant and for the heating, so as to reduce the energy consumption of the plant in terms of the brought calorific value.

For the production of hot water it was prepared a green energy system consisting in the use of a solar panel connected to two water storage tanks. The system is positioned on the flat roof of the plant and it is more precisely described in Section B.2.6.2.



Flow Chart 4 Generic Lay out of energy use.

The work involves a different energy as complex as the company. For an easier description the work has been divided into 8 groups where it is possible to encounter an indispensable energy consumption to achieve the goals. Each working group has its weaknesses, the following description comes from the Italian plant experience consisting in a varied consumption rate but also with an attempt to contain the wastes when designing the plant. The following are 8 sources of higher energy consumption:

- **Energy management:** Energy management means reserving a constant attention to the Energy use, and then dedicate resources (human and technical) to study and analyze the manner and intensity of its consumption in order to improve the energy performance and reduce the cost with it associated. To effectively manage the energy consumption it is essential to understand where, how, when and why the energy is being used. This level of understanding takes time and also thanks to the establishment of the environmental management system that, in the protection of energy section, it will be developed through the analysis of the conditions of the Energy use and through the invoices related to the various expenses. The same procedure should be carried out in the final balance for the analysis of what and how it is saved in the bill following the implementation of any measures to improve the energy efficiency. The departure will lead to an energy analysis that will nevertheless be made after the start of the system. The energy minimum data that must be measured and recorded by a management system are:

- all monthly energy flows, of all type (electric consumption, fuels, etc.). the supplier may be the only source of this information, or part of them.

- the monthly invoice related to the energy consumption;

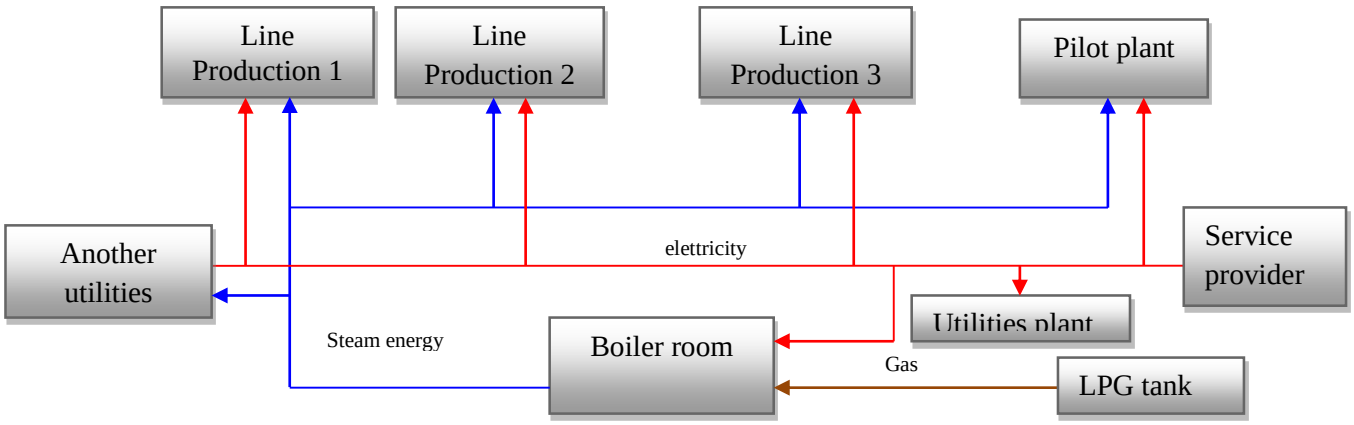
- the quantitative data relating to the monthly energy conversion (self-production of electricity, steam, hot water);

- the monthly consumption of the energy processes and of the main plants; detailed information corresponding to peaks in demand and peak loads in a given time interval. In order to analyze the energy consumption needed at a peak load, the consumption will be detected at short and regular time intervals

- the production data on a monthly basis, the hours of operation of the main processes and process plants together with the ancillary equipment such as air compressors, cooling towers and chillers.

The absence of a power management does not allow the company to understand, for example where there are the wastes, what are the anomalies that deviate from a time series of data if the time series of data is non-existent. The collection and the monitoring of as much information as possible will achieve a mapping energy and to focus on the peaks of not justified consumption in order to research and propose solutions in line with the available Best Practices.

For the accountant and management analysis that will be proposed within the environmental and safety management system the reference will be an extremely simplified flowchart:



Flow Chart 5 Energy distribution in the production area.

In which are highlighted the two main forms of energy, the electric one that directly serves the production lines, utilities and other working environments (eg offices and laboratories), and the thermal energy through transformation and collaboration of the LPG in external tank and electricity feeding the steam generator and the water heater.

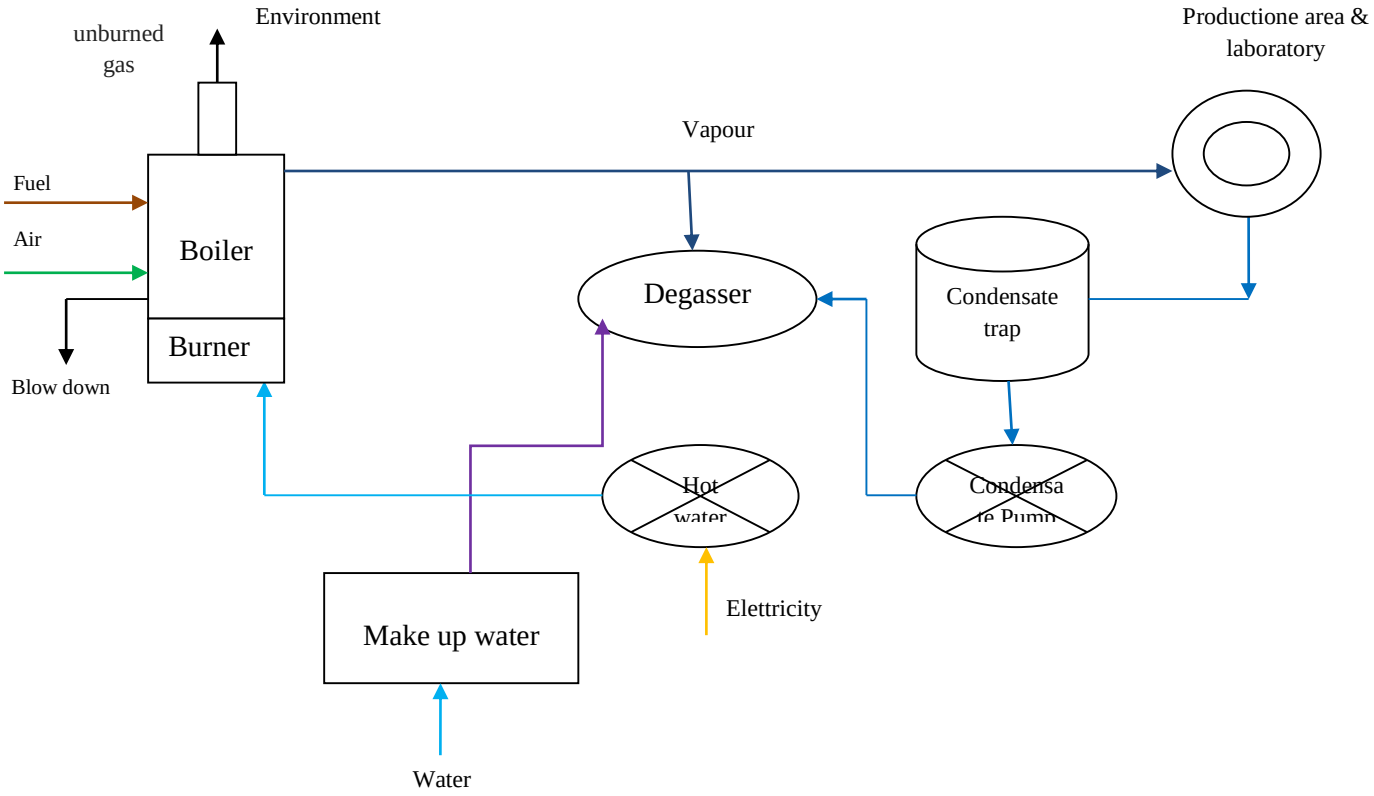
- Steam generator: The steam is the main heat vector chosen in the design of the system and it is therefore one of the main objectives of the analysis and the optimization of energy consumption management related flows. It is the efficiency of the steam generator that can be found many opportunities for energy savings. In **Flow Chart 6** it's highlighted the heat distribution except the boiler which is activated by the solar panel. The typical domestic utilities are therefore excluded from the users heading.

In the energy-saving field, the thermal power represents a key point, even though in order to optimize the benefit from its operation it is essential to independently implement a diligence program to prevent rather than to cure possible disparities in energy consumption standards. The important points where are concentrated the possible energy losses are:

i. Pressure and temperature conditions to which the steam is generated;
ii. Heat losses in the chimney of the boiler;

iii. Adjusting the burner and control of the air/fuel optimal ratio;
iv. Control and reduction of the temperature to the boiler's chimney;
v. Cleaning of the boiler's heat transfer surfaces and chimney's temperature;
vi. Radiation losses
vii. Degasser operation;
viii. Boiler escaping
ix. Steam distribution
x. Condensate return

The biggest energy consumers are the water supply pump to the boiler and the combustion air fans.



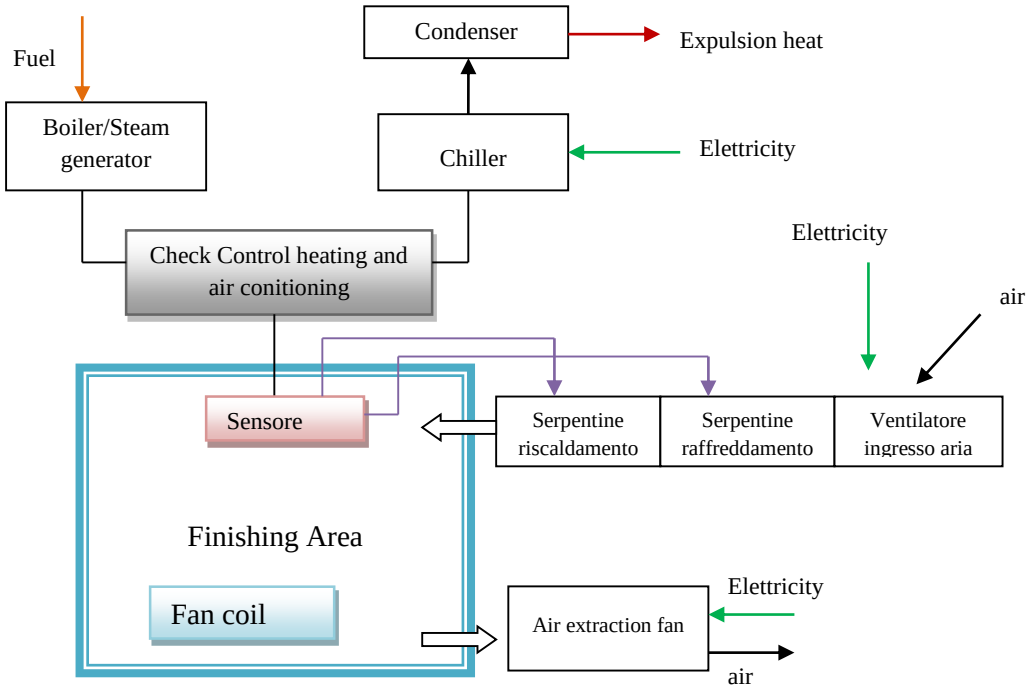
Flow Chart 6 Inputs and Outputs from the Boiler Energy (Map Process Steam Generation).

- **Compressed air central: the energy costs represent the majority of the Compressed** Air's total costs. Usually it can be done the following breakdown:
  - ✓ Energy costs: 75% of the total cost of the compressed air system;
  - ✓ Financial expenses: 13%
  - ✓ Maintenance: 12%

  The amount of energy required to produce about 1,000 Nm^3 at a supply pressure of 10 bar (it means usage in the plant to 8 bar) it is necessary to deliver a potency equal to 80 kWh.

- **Energy building:** In general, there is a significant interest in reducing the energy consumption of buildings, as it is significant the cost savings to be achieved by the measures available in this area of intervention. In fact, Heating, Ventilation and Air-Conditioning

(HVAC) represent the largest consumption of energy in buildings and are therefore a key objective on which to focus interventions for Energy Efficiency. Excessive heating in winter and cooling in summer are the main causes of energy waste. The second category in terms of importance is the use of electric energy in buildings for lighting and other components of the offices. The HVAC systems are designed to adjust the climate inside the buildings compensating the heat loss and the input of too much heat by delivering a sufficient quantity of fresh air. The HVAC systems have a wide range of settings, from systems that pass by a simple heating in winter with a Hot Water Boiler and radiators placed in the rooms, an air conditioning system that includes areas of Heating , Cooling and Humidification.



Flow Chart 7 Lay out HVAC for finishing area

There are four main factors causing the energy use of HVAC systems:

- The internal conditions of the application;
- The internal heat generation (such as lighting, computers);
- The design, layout and insulation quality of the building;
- The technical quality of the equipment

For the installed type the internal and external air fans and the heat exchange chiller are the sources of higher energy consumption.

- **Engines and transmission systems:** Such equipment is used for the transport of fluids, and for this reason, these systems absorb most of the total energy (mainly electricity) used by the company. In particular, in the implementation of the system and the motor populations, the oversizing is avoided .The fluid flow control equipment such as pumps, fans and

compressors driven by an electric induction motor and operating at fixed speeds, it is often obtained through the use of throttling valves in the intake or exhaust of the equipment, or through a flow bypass. In this case, part of the flow is directly sent back to the suction, bypassing the points of use.

It may happen that the production has the need for a flow, a pressure or an extremely variable temperature in the course of the same operation and for this reason they have been adopted:

- *Variable speed drives:* The variable speed mechanical transmissions use an adjustable strap and a pulley mechanism for the transmission of variable speed between the motor and the equipment driven by the motor, to convert a fixed speed in a variable speed. The variable speed hydraulic transmission uses a coupling between the engine and the driven equipment in which the moment of rotation is transmitted via hydraulic oil. The output speed is adjusted by controlling the sliding between the two parts of the hydraulic coupling (eg. the part of the constant speed from the motor side and the part of the variable speed of the driven part). The hydraulic coupling is controlled through an hydraulic oil system with chiller pumps.
- *VSD Electronic Power (Inverter):* A normal AC electric motor operates at a fixed speed determined by the frequency of the output power (50 Hz). The rotating magnetic field induced in the motor is directly connected with the frequency of the output power. The VSD electronic technology can convert alternating fixed voltage current and alternating fixed frequency current at variable voltage and variable frequency, using a special electronic technology.
- The AC induction motors can be equipped with different winding configurations in order to run the motor in two or four different speeds. The multiple motors are most commonly used in situations where a flow gradual control is required. Typical examples are systems of ventilation and cooling tower fans.

According to the installed equipment, the most energy-consumption comes from the cooling tower and the chiller at -25 ° C which is used for the production. The several pumps for lifting or for the liquid relaunch appear to be energy intensive.

- **Production processes:** as part of the manufacturing operations, there are three phases considered more energy-consuming:

  - The distillation is used to separate mixtures composed of components with different boiling points. The mixture is heated up until the boiling temperature of the mixture itself. For example, to purify the solvents the plant uses a reactor, in which the input mixture is heated up, a distillation column, in which the components of the mixture are separated, and a boiler that keeps the boiling conditions in the column. These basic components are integrated with each other and constitute a single separation process with a heat exchanger along the flow of the product.

  - ***Separation:*** it is used when it is required to concentrate a solution by removing the solvent. The biggest energy consumption is absorbed by the temperature to bring the solvent to the boiling point and convert it to steam, removed from the evaporator;

- ***Dryer:*** The drying is employed when it is necessary to eliminate the water or the solvent from a solid product, providing heat.

In the following table there is the estimated plant energy consumption and after that, the working area. It is good to point out how this is an estimate based on the Sterling experience in Italy and on the consumption characteristics of the main machines in the **Annex B.2.6-A1 "Defining the main energy consumption equipment "**

Energy type	Units	Purchase	Pilot plant	Finished Area	Laboratory R&D	Office	Utilities
Electricity	kWh	122,350	20%	25%	15%	10%	30%
LPG	Nm^3	16,500	35%	25%	15%	5%	20 %
Steam	Tonnes	5	50%	50%			

Table 24 Data forecasting energy consumption in the first phase.

Energy type	Units	Purchase	Production area	Finished Area	Labs	Office	Utilities
Electricity	kWh	350,00	30%	30%	10%	5%	30%
LPG	Nm^3	25,00	40%	30%	5 %	5%	20 %
Steam	Tonnes	12	50%	50%			

Table 25 Data forecasting energy consumption in the second phase.

Energy type	Units	Purchase	Production area	Finished Area	Labs	Office	Utilities
Electricity	kWh	500,00	35 %	25%	10%	5%	30%
LPG	Nm^3	65,00	50%	30%	5%	5%	10 %
Steam	Tonnes	30	50%	50%			

Table 26 Data forecasting energy consumption in the third phase.

This is a prospective analysis on consumption derived from a transposition of what historically found in the Italian company. This is because at the time of writing not all the minimum information are available and, in particular:

- The monthly invoice of the energy consumption; the energy bill or the contract, in particular what concerns the Electricity and Gas, contain important information for the analysis of energy consumption. For example, the natural gas is measured by the volume passing through the counter, and to calculate the corresponding amount of necessary energy it is important to know the gas quality. This data is supplied by the Gas producer. Especially concerning the Natural Gas with an important conceptual and monetary difference that runs between Upper and Lower Calorific Value. The difference is about 10%. So far, the company has not yet been billed so it is impossible to find appropriate information.

- The quantitative monthly data relating to the conversion of the Energy (self-production of electricity, value, hot water): this data will allow to specify the energy consumed for the production (both in terms of intermediate production and of the finished product);

- the monthly consumption of processes energy and of the major facilities: this information will allow to map the equipments, identifying the most energy consuming that often deviate from the available data on paper, because from the moment of the project choice to the start up, a lot of time passes and the production needs can be changed so that an equipment may have been reconsidered and therefore only partially employed;

- the detail information corresponding to the peaks in demand and peak loads in a given time interval. In order to analyze the energy consumption needed by the occurrence of a peak load, the consumption must be detected at short time intervals (eg with systematic readings of the electrical energy carried out every half hour); The consumption peaks are often related to the type of production and, despite that even within a single production can vary from batch to batch because it is the chemical nature of operations which are unlikely to always develop in the same mode;

- with reference to the company operation, the production data on a monthly basis, the hours of operation of the main processes and process plants together with the ancillary equipment such as air compressors, cooling towers and chillers. In addition, all data should be collected for the other parameters that affect the use of Energy, as the temperature of the environment, etc.. but this activity must be recorded in the field and therefore can only be done during the activation of the individual workplace, the individual functions and the individual machines and processes.

B.2.6.1 Heat Energy

The steam energy is derived from transformation with an LPG boiler stored in 3 vertical storage tank, each with a capacity of 2,250 ltrs water volume. The area earmarked for the storage facility is shown in the attached drawining n.o 9. There is about 39.0 mtrs from the public road to internal yard, and there is line of sight between the yard and the public road. The delivery truck can reverse into the yard since it is 4,8 mtrs wide, so we may consider unloading a safe procedure. The codes of practice require a minimum separation distance of 1,5 mtrs for such a tank (with a dispersion wall), and there is space in the area proposed as shown in the sketch attached. The cylinders will have a lockable plastic covers, and the keys for the covers would be with the administrator. The tanks will be supplied with all the necessary safety features and equipment as stipulated by the EU PED Directive, including a safety valve, contents gauge and pressure gauge. The tanks will be new ones, and CE stamped accordingly. In the vicinity of the tank installation, we shall install a hot water vaporizer and first stage regulation (including OPSO device). The first stage regulators will be in duplex format. A medium pressure gas line will be laid in the lower level, between the building foundation and the excavated rock face as shown in the attached drawing by the owner’s architect. The gas pressure from the first stage regulator train to the boiler room will be 700 mbar.

Prior to entry into the boiler room, the second stage regulator train will be installed (pressure reduction from 700 mbar to 35 mbar). The pipe from the first stage to the second regulators will be 1.5 inch galvanized steel. UPSO/OPSO devices will be installed on the second stage regulators.

Two quick closing valves has been installed. One near the first stage regulator, and one near the second stage regulator, just prior to building entry. These two emergency closing devices will be active by:

- An emergency stop switch in the boiler room;
- A gas sensor in the boiler room, adjacent to the burner;
- A gas sensor in the building cavity – tunnel, where the gas pipe will be laid.

Prior to building entry, we installed an isolating valve at the gas tank installation, and another one just prior to entry into the boiler room.
The pipework system has been tested at a minimum of 8.0 barg after installation. After testing, the pipe has been painted bright yellow, and indicative signs has been installed. All pipework in the building cavity has been covered in the bitumen coating, and installed on proper pipe supports, since this tunnel is actually a building services corridor for storm water pipes. This LPG tank feed the boiler located in the boiler room and you need the air conditioning system and air conditioning for the workplace, it produces steam to power the production activity in terms of fluid heat exchanger that circulates in the reactor serpentine.

B.2.6.2 Describe the proposed basic measures for improvement of energy efficiency

Several activities will be undertaken to improve the energy efficiency since the structure of the plant, for which it was provided a wide area (over 30%) of the entire building and 100% of offices, will have a glazed surface occupying a the entire wall. In this way it is maximized the use of the natural light. The following table summarizes the initiatives undertaken by Sterling Spa with different areas of work on which they impact.

Area intervento	Numero di riferimento	Funzione energetica	Tipologia di intervento	Risparmio energetico
Office and communal areas	1	Indoor lighting	LED lighting system with motion sensors	60 %
		Indoor lighting	Large glass surfaces	
	2	Air conditioning	New system: VRF inverter urban multi 4	20 %
	3	Sanitary Water heating	Installing a solar panel	30%
Production	4	Heating and Cooling program	Installing a deaerator head for the steam generator to the service of the production	20%
Production area, offices and Labs	5	Reshaping flow rate in according to the requirements	Adoption of engines and transmissions at different speeds.	20%
All plant	6	Energy management	Development of a management program	20%

Table 27 Operations for Energy Efficiency.

Many indoor environments such as refreshment room, corridors, meeting rooms, changing rooms and toilets were equipped with LED technology (LED is an acronym for Light-Emitting Diode (light emitting diode)- The device uses the optical properties of some semiconductor materials to produce photons from the recombination of electron-hole pairs. The electrons and holes are injected into an area of recombination through two regions of the diode doped with impurities of different types, n-type for the electrons and p for the holes. The color of the emitted radiation is defined by the distance in energy between the energy levels of electrons and holes and typically corresponds to the value of the band gap of the semiconductor in question.

The LEDs are a special type of p-n junction diodes, formed by a thin layer of doped semiconductor material. When subjected to a voltage to reduce the potential barrier of the junction, the electrons of the conduction band of the semiconductor will recombine with holes in the valence band releasing enough energy to produce photons. Because of the reduced thickness of the chip, a reasonable number of these photons can leave it and it can be emitted as light. The LEDs are formed by GaAs (gallium arsenide), GaP (gallium phosphide), GaAsP (gallium arsenide phosphide), SiC (silicon carbide) and GaInN (gallium nitride and indium). The exact choice of the semiconductors determines the wavelength of the peak emission of photons, the efficiency in electro-optical conversion and then the light intensity at the output.

The company has installed 20 LED light points, below there is a short calculation on the energy savings that led to the installation of these devices rather than the most commonly used such as neon or fluorescent lamps/bulbs.

In the following table there is a comparison of the operating cost, purchase and maintenance between the type of LEDs used and the neon that would have been the alternative.

Model neon tube	Power Neon tube	Leght neon tube	Lume neon tube	LED tube	Lumen LED tube
Small tube	18 W	60 cm	1600	8 – 10 W	800 – 1000 lumen
Medium tube	36 W	120 cm	3300	15 – 18 W	1500 – 1700 lumen
Big tube	58 W	150 cm	4500	20 – 25 W	2000 – 2500 lumen

Table 28 Compare consumer staples neon lighting and LED lighting.

In the following table compares instead the cost of operation, maintenance and purchase between the type of LED used and the neon that would have been the alternative.

Comparison parameter	Neon 36 W	LED 17 W
Elettricity cost	€ 0.20	€ 0.20
RAEE cost	€ 0.42	€ 0.42
average cost tube	€ 3.00	€ 50.00
n.o tube	20	20
tubes duration in hours	10,000	50,000

investment	€ 60.00	€ 1,000
Ignition days per month	26	26
Ignition hours per day	12	12
Ignition hours per month	312	312
Ignition hours per year	3,744	3,774
Daily consumption (kW)	8.64	4.08
Monthly consumption (kW)	224.64	106.08
Yearly consumption (kW)	2,695.68	1,272.96
Annual savings (kW)		**1,422.72 Kw**
Daily consumption (€)	1.72	0.816
Monthly consumption (€)	44.928	21.216
Yearly consumption (€)	539.136	254.592
Annual savings (€)		284.544

Table 29 Saving fluorescent tubes - led tubes compared against.

The consumption of electricity is half if compared to the tubes in neon. In addition to the costs, the main differences to the environment and the workplaces are:

- The quality of light: fluorescent lamps commonly called neon or low consumption emit a light rich in ultraviolet and infrared rays that endanger the health, and for this reason, since these lamps are lit thanks to a series of electric shocks, they generate an intermittent light that hurts the eye. The LEDs do not emit harmful rays but instead a pure and steady light that makes it ideal for precision work, reading, etc ...
- Toxic substances: the neon tubes and energy saving lamps are made with toxic substances such as mercury (Hg) and Krypton (Kr), their use should therefore endangers the health, while LEDs do not contain harmful substances;
- Heat: incandescent lamps emit a lot of heat, LED lighting does not have this kind of problem, in fact develop a very low heat allowing to reduce the need for cooling during hot weather;
- Duration: Neon or fluorescent lamps even though they (the best quality) are meant to work for 10,000 hours, if installed in places where the light is continuously switched on and off (corridors, stairs, etc.), they wear out very quickly, halving their lives. LED lamps do not suffer from the continuous ignition on/off and have an average life of 50,000 actual hours.

As integration of this lighting system, in the toilets are arranged motion detectors providing the switching on and off of the lighting devices only upon entry of a person in the room. In this way, the possibility that a light point remains lit up for hours without being properly used, it is reduced. Moreover, the wide windows of the structure allows the reduction of the lighting in the office.

Air conditioning

Thanks to the improved energy efficiency, the high performances are reflected on a lower fuel consumption. This increased efficiency is due to the fact that since the temperature in each room is individually controlled, only the rooms that actually require it are conditioned. Moreover, thanks to the inverter technology the level of air conditioning is controlled with greater precision based on the climatic conditions of each room. The high coefficient of the COP performance in our outdoor units is obtained with the use of technologically advanced components such as the G-type compressor with high efficiency and reduced friction losses, which contributes to make the operation quieter and cheaper. When the indoor units are turned off by remote control, external drives inverter are placed in standby: in this way, their consumption is reduced by 30%

At full working, usually during the summer, assuming that the cooling will be the main problem of the structure in a hot weather island as Malta, the Inverter+ further improves by 20% the characteristics of the traditional inverter. This means that the electric consumption and operating costs are reduced by 20%. An Inverter+ system also has an energy rating of "A" in both cooling and heating.

Outside, the units mounted on the roof of the building are equipped with an advanced control system based on the cooling load. The use of two different compressors (one fixed speed and the other equipped with the inverter) allows to accurately control the power of the operation even in case of only one low capacity indoor unit. An electronic expansion valve, equipped with PID, control in real time the quantity of refrigerant in circulation according to the load variations of the indoor units. The VRF system also maintains the ambient temperature at a more comfortable level, without the typical ON / OFF variations control system.

Domestic water heating with solar panel

The system chosen to adopt a friendly environmental heating of the domestic hot water, involves the use of the solar panel. This system provides thermal collectors having inside pipes in which flows a liquid (water + antifreeze) warming up when exposed to the sun. A control unit measures the temperature reached by the liquid in the panel and the one of the water contained inside the tank. If the liquid in the panels is hotter than the water in the tank, the controller starts up a pump that pushes the liquid within the circuit which go through an internal coil in the tank. Through such a coil there is the passage of heat from the liquid to the water of the reservoir, which then enters the sanitary water circuit.

WINTER

During the winter or in periods of long bad weather conditions, there is need for more water than the system can provide. In these cases there is the boiler that, heating the water that passes in a second coil positioned in the upper part of the reservoir, provides the heat useful to reach the desired temperature. In any case, the boiler will occur in a less extent and therefore it will consume less gas.

SUMMER

During the summer, the solar system is sufficient to ensure hot enough water for bathrooms, kitchen and laundry.

Considering the Maltese weather where the temperature remains pleasant for most of the year, the system will be independently sufficient without intervention of the boiler-

Thermostat control.

The condensate return and the top up water are sent to the getter to remove oxygen and CO_2 from the water supply of the boiler, in order to prevent its corrosion. To get all of this it is necessary to spray the condensate and top up water in the upper part of the degasser. Heating the water, these gases, together with part of the steam, are discharged from the degasser. Normally an increase in the inlet water temperature of 10-15 ° C is sufficient to achieve a residual content of oxygen in the supply water of the boiler acceptable to less than 10 ppb (parts per billion). The degasser operates at a fixed pressure (and saturation temperature), through the provision of a controlled amount of steam. The set up pressure should not be too high, because this would require too much steam to heat the incoming water (which is a rather inefficient way to heat the supply water of the boiler). A normal range of values for pressure setting ranges from 1.2 to 1.5 bar (temperature from 105 ° C to 110 ° C). The degasser allows a saving of energy through a heat recovery and preheating of the water entering the boiler with consequent energy savings (in terms of electric and thermal energy, it reduces the used fuel because it is easier to reach the water boiling point in the main body of the boiler).

Engines and transmissions at different speeds.

It consist in high efficiency electric motors that, thanks to specific constructive measures, equal power, they offer higher yields and more constant at varying load, compared to the standard electric motors.
Part of the consumption attributed to the electric motors operation are due to the many type of losses presence (mechanical losses, energy losses, eddy current losses, etc..). In the high-efficiency devices these losses have been reduced by intervening on the materials with which the motors are manufactured or changing some components such as:

- CORE, made with low losses lamination reducing the load losses;
- STATOR AND ROTOR'S CONDUCTORS, made with increased section in order to reduce the losses by Joule effect;
- CABLES, carefully selected both in number and geometry.

These devices also involve a low development of heat in the engine making possible the use of smaller cooling fans (with minor mechanical losses and lower power consumption).
The variable speed drives (consisting in INVERTER modulating the motor supply frequency and hence its speed according to the load) are used to change the speed of an electric motor which as a rule is instead fixed and depending on the number of motor

poles. These devices will be conveniently used to vary, for example, the flow rate of a pump or a fan: unlike the traditional control systems - throttling valves, dampers, etc.. - frequency controllers vary, depending on the need, the motor speed and consequently the electrical power absorbed by it (small speed decreases of the motor involve significant reductions in power consumption and therefore, on the generated energy consumption.
The equipment described, leading to a reduction in the electricity consumption, determine consequent environmental benefits in terms of reducing emissions of greenhouse gases and reducing the consumption of non-renewable sources attributable to thermal power stations feeding the network.

Management handbook and energy control: Energy management means reserving a constant attention to the Energy use, and then dedicate resources (human and technical) to study and analyse the manner and intensity of its consumption in order to improve the energy performance and reduce the cost with it associated. The Handbook of Energy Management has its roots in the business of the Company and constitutes an important part of the daily management. Once you start the program for the management and control of the energy contained in the manual also the Energy procedure management will be richer and more structured, which will be completely devoted to the energy accounting.

B.2.7 Water

The natural water resource is used in the production complex for a variety of purposes ranging from domestic nature such as toilets, changing rooms with showers, the canteen, to those of a technical- productive nature. In details, the water in this area is used both as a refrigerant in the plant system and as a raw material in the production process as a useful system to reduce pollutants in the flue gas of the process (in particular the scrubber is a wet system that allows the purification of the gaseous stream rich in pollutants). Obviously, in this category of macro functionality fall the laboratories in the production system. Other functions performed by this natural resource is definitely the washing of the system and other premises (both production and administrative), the green maintenance, the fire protection system, the safety compulsory for the operators (water delivery points service for washing eyes, the emergency shower or washing hands). The company has two sources of supply, the water supply and the rainwater which is collected in underground tanks and used exclusively for green and for fire-fighting.

The use of the water in the municipal network distribution is specified below:

- ✓ The tap water is used instead for the following purposes:
  - It represents a raw material necessary for the production and it is used in several operations as a solvent; as a result of the operations such as filtration and centrifugation the water is largely separated from the reaction mass and becomes waste;
  - Dry of the plant: the water is used for reactors cleaning of centrifuges, filters and heat exchangers or collecting balloons, upon termination of cleaning, the water is collected in cisterns and labelled as waste;

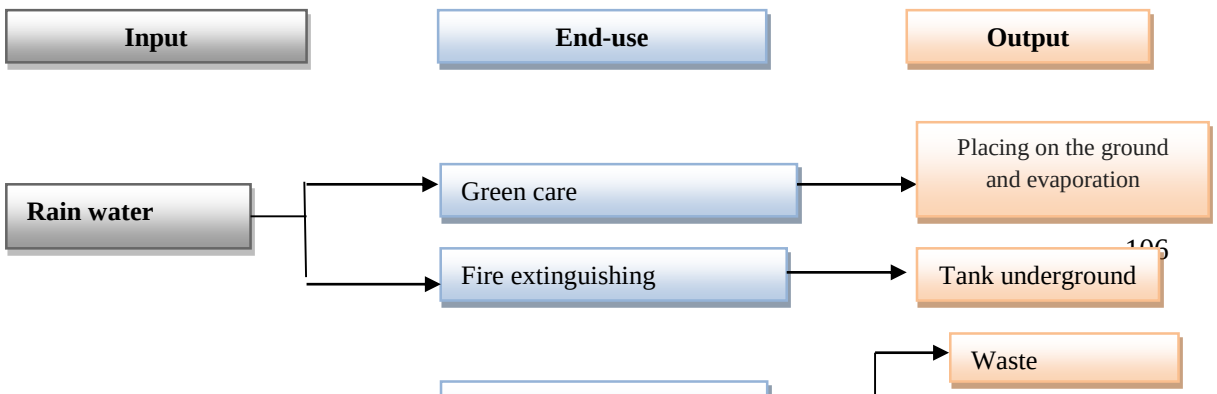
- Domestic use, for toilets and other utilities of domestic nature (such as dining room, changing rooms);
- Cooling water used in laboratories as cooling water inside the serpentine tools, but also as a raw material inside the reactions or for cleaning the used tools. In this case, the still dirty water is collected in an underground tank;
- Cooling water in the heat exchange circuits in the production departments so as to ensure the thermostating request in the various synthesis;
- In the steam form: after the water, the steam is without doubt the most widely used service fluid in the Sterling activity, for multiple functions such as heating and air humidification and above all, the use of more critical processes of thermal sterilization of materials, equipment and pharmaceuticals;
- Power equipment: many equipments use the water as the main element. In this sense, two important examples are the scrubber system used for removal of certain pollutants in manufacturing processes, and the cooling tower which is used to power the chiller -25 ° C which is required for production temperature control of facilities and finishing.

In the following **Flow Chart 8** it is summarized the water cycle within the complex production. The quantities that are assumed to be used are given in the **Table 30** and they also vary in relation to the processing provisions and the number of the involved employees.

Phase	N° worker	Amount consumption (m^3)	Worker consumption (m^3/wor)	Evaporation losses (m^3)	Production consumption (m^3)	Domestic consumption (m^3)	Water consumption per capita (m^3)
First	20	870	43.5	91,06	598.24	180.40	60,1
Second	40	2,000	50.0	195,46	3.000,0	500,0	82,7
Third	80	3,200	40.0	274,32	4.390,0	810,0	50,3

Table 30 Annual water consumption by aqueduct.

In addition to the public water supply there is a clear water reuse system and, in particular rainwater through the gutters from the roof of the building plans of production/administration will be collected in an underground polyethylene tank The system consists of a reinforced concrete tank sized 3,540 mm * 2,040 mm * 7.000 mm with a depth of 7.000 mm and a capacity of 50 m^3 equipped with an inspection pit and a floating water intake for drawing water surface. The reservoir receives water from rain using appropriate filters and it is equipped with "overflow" for the flowing of the water in excess of the capacity of the tank itself. The overflow water is then piped into the public sewer. The recycling rainwater is used for gardening activities and as a reserve to be used in case of fire.



Flow Chart 8 Water balance of Sterling Chemical Malta Ltd plant.

B.2.7.1 Water purification

In production processes can be used as drinking water and therefore for reasons of quality assurance of the product, the raw material coming from the public supply must be purified. For the water used as the refrigerant in the shirts of reactors are used resins with the softener, for the water used in the production cycle also uses a self-cleaning filter sediment trap this because the water may contain foreign objects such as grains of sand , flakes of rust and other impurities which penetrates inside the hydraulic system are capable of ruining the pipes, the valves and faucets, automatic blocking and triggering corrosion. The untreated water flows through a stanless steel filter element. Foreing particles >100 µm are thus retained. Depending on their size and weight, these particles fall directly into the lower part of the filter housing, or adhere to the filter element. During backwashing, the seal at the rising water outlet opens. The washing element move from the bottom to the top and back again over the entire filter by succetion with clean water at an extremely high flow rate. The unit functions fully automatically and requires no operation. Should the local water quality (degree of contamination) change, the backwashing interval set during commissioning must be correct. The filter is equipped with a differential pressure gauge so you know when it's dirty and clogged. The filter must be in backwashing cycle when the maximum permissible differential pressure (1.5 bar) is reached, or at least every 7 days, whichever period is shorter.

Water clean of the filter is collected in a small tank and disposed of as wash water with European Waste Code 070701*. The purification system is not collet to the public sewer.

For the treatment of boiler water or for steam production, the purification system is described in section **B.2.2.1.3 auxiliary units.**

2.7.2 Lay out drainage system

In the B.2.7-A1 attachment it is shown the drainage system involving the company. In this chart it is possible to observe 4 water discharge lines, with two output circuits and two from Sterling and two other conveying in underground tanks.

In particular:

- Sanitary drainage and Water discharge: it allows the water discharges flow which are comparable to the domestic ones (coming from the office, the canteen, the toilets) to fastens in public sewers and, in this regard Corporatio Water Service has issued the permit.
- Rain water line: it collects the rain water from the drainage grids and leads them in the collection tank "Rain water reservoir". In case of overflow, this is removed out from Sterling to rejoin rainwater collection from the road surface;
- Process drainage system: it collects the process water that can potentially be contaminated in case an accident could happen such as the spill of a chemical. In this regard these wastes are collected in the wash water reservoir tank which is a waterproof underground tank. In this tank comes the water coming from the laboratories, the production line, the boiler, the emergency wireways laterally placed to the production lines;
- External flammable drainage system (purple line): in this case the system provides a two-stage collection. The first stage consists of a pool of about one cubic meter into which convey any liquids that wet the floor of the External flammable warehouse. This tub is waterproof and is always closed out. In the case where the collected liquid is rain water the tub will be reopened and will feed into the rain water line. In case there was a spill of a raw material, the liquid will be collected in this tank and using submersible pump will then be transferred to an IBC, labeled as hazardous waste, an EWC code will be given and it will therefore be disposed of.

The connection between the external flammable warehouse and the rainwater system can stay as long as it excluded any possible contamination of rainwater which, falling across the roof can fill up the warehouse floor. In particular, the following measures will be adopted:

- Sterling adopts a procedure with which manages this aspect, placing a ban on the storage ground tanks or drums containing hazardous substances. All of this through an involved operators training process and signage which will visually identify the support places;

- All the raw materials are placed on waterproof containment basins (bund) so that any losses are collected and sucked in by pumps in IBC or Drums and then disposed of. The floor on which the forklifts move to take or store the raw materials or waste is waterproof.
- In case of human error of an operator who leaves the IBC or the DRUMS on the ground and this loses the inside liquid, this is collected in the first containment basin of about 1 cubic meter and subsequently it is aspirated and fed into an IBC or drum for disposal. This basin is waterproof and will always remain closed without any connection with the outside.
- In case of rain across the various warehouse doors and such as to flood the warehouse floor even partially, the basin that connects the warehouse to the rainwater system will be opened only after checking that there is no leakage from drums and tanks. A supervisor will then be appointed in order to certify the absence of pollutants and to open the drain to the rainwater system

B.2.8 Risk assesment

The risk assessment is the essential tool that allows the employer to identify the prevention measures and schedule the implementation, the improvement and the control in order to verify its effectiveness and efficiency. In this context, we can confirm the security measures already in place or make changes in order to improve the innovation in relation to the technical and/or organizational introduced for safety. In ***Annex B.2.8-A1*** the risk assessment is done by a competent external and independent from Sterling Chemical Malta Ltd engineer, and all other documents are as below:

a) Emergency and evacuation plans in case of fire and other emergencies (***Annex B.2.8-A2***)

b) Plans for actions to be taken in case of failure of abatement equipment, this plan is represented by the operating instruction MIOS_4.4.7-D ;

c) Plans for actions to be taken in case of other environmentally relevant incidents is attachment into ***annex B.2.8-A3*** . From the moment that the company will apply to the Malta plant the Environment Management and Health and Safety System, what it is required is a set of operating instructions that combine to produce a set of tasks that employees must perform according to the HSE emergencies that may arise. Listed below the procedures and the reference instructions:

Code	Name of Procedure/Istruction
MP_4.4.7	Training to emergency
MIOS_4.47-A	procedure to be followed in case of fire
MIOS_4.4.7-B	operational instructions for the use of fire extinguishers, fire hydrants and mobile groups in foam

MIOS_4.4.7-C	procedure to be taken in the event of a spill, release or contact dangerous substances
MIOS_4.4.7-D	Procedure to be taken in the event of malfunction or breakdown of equipment
MIOS_4.4.7-E	Procedure to be taken in case of accident or stroke
MIOS_4.4.7-G	Behavior in case of emergency earthquake, flooding, and emergency power
MIOS_4.4.7-I	Emergency and evacuation procedure

Table 31 Procedure and instruction in case of environmentally, health and safety emergency.

For Fire detection and alarm system and for **Fire and Ventilation Report see annex B.2.8-A4**

B.2.9 Training

Staff training and awareness are planned, programmed and implemented in accordance with the MP-4.4.2 (Training), with the coordination of the management representative and the security assistant for the aspects concerning the S&SL. It is up to each head department to report the need for training of its staff with the aim of ensuring an adequate understanding of the risks and the measures of S & SL and to inform all employees:

- policy and objectives;
- the implications of their work in terms of environmental and health and safety in the workplace;
- of their roles and responsibilities in order to achieve compliance with the policy;
- consequences arising from the deviation from the procedures

The procedure implemented within the management system will include in principle the following steps:

- Fixing the responsibility (even, possibly through proxies and/or assignment of tasks);
- Method and identifying process of the required skills/needs by also reporting of several supervisors;
- Programming: how to identify training needs, taking into account the skills required and the information on the situation going on, how and where to find this information, develop a program (content, method of delivery, identification and training of teachers, provision of educational materials, bodies in which the training takes place; records, verification of implementation of the program, the information system;
- Methods for evaluating the quality and effectiveness of training;
- Any formal management qualifications and deadlines, deadlines checks. For formal qualification, always refer to specific people, we intend to formally certify the successful acquisition of certain skills by the concerned persons. Normally, the formal qualification has an expiry date, determined by the management, after which it must be renewed, of course, on the basis of appropriate checks (just like for the driver's license);

- Management of the information relating to the training/information system; recording mode; verification of the program implementation ; eventual identification of performance indicators and data management;
- Review of the training and programming waiting for the Management review.

The training integration is linked not only to the contiguity and overlap between the two fields, but also to coincidence, or at least to a large overlap of the subjects. The training programs are well-coordinated and integrated as much as possible not only accomplish the purpose for which they were put in place, but they also make a vital contribution to the understanding of management systems and the identification of staff with the organization's policy. In few words: motivation, better communication and efficiency.

B.2.9.1 Training on environmental obligations

A begining and review of environmental management training needs of Sterling employees and other relevant personnel shall be undertaken by the appropriate Supervisor/Manager or Project Manager, with a training matrix developed and maintained in according to new national and European regulations. For this reason we can provide general training guidelinee furthermore, the environmenatal management system has not been implemented yet.

B.2.9.1.1 Environmental Training and Awareness

All employees and other relevant stakeholders shall be made aware of:

- the importance of conformance with the environmental policy, procedures, objectives and targets of the management system
- the significant environmental impacts of their work activities, and the potential environmental impacts of not following specified operating procedures
- their roles and responsibilities in achieving conformance with the requirements of the management system and striving for excellence in internal environmental management and
- opportunities to influence further environmental improvement.

B.2.9.1.2 Training components

Environmental training shall include:

- induction training for new staff and contractors covering the Sterling’s Health, Safety and Environmental Policy and the management system;
- training for all staff in the requirements of operating procedures relevant to the activities, projects, products and services being undertaken and
- competency training where required for those staff with specific roles and responsibilities under the management system.

B.2.9.1.3 Training Details

Training on environmental obligations will be divided based on the role of workers, an early indication of training includes the following points:

- Risk assessment about Sterling activities;
- National Environmental law;
- International environmental law;
- Compliance and enforcement of the National and International law for example:
  - Air pollution, transbourdary, risk, intelligenge activity and prevention;
  - Water pollution, transbourdary, risk, intelligenge activity and prevention;
  - Noise, transbourdary, risk, intelligenge activity and prevention;
  - Hazardous waste, Multilateral instruments on hazardous wastes, national permit, storage, collected and disposal;
  - Waste, Storage, collected and disposal;
  - Ozone depletion: International rules, compliance and enforcement in company;
  - Chemicals: REACH, CLP regulation, Application of the information contained in safety data sheets;
  - Freshwater resources: Water uses;
  - Energy, renewable energy: Energy uses,
- Maintenance plan
- Operation production manual
- Emergency training
- IPPC training: accordance with the guidelines and requirements present in the permit.

B.2.10 Cessation

Specifically, the study of the potential impact determined by the decommissioning phase is divided into three distinct parts:

1. Estimated useful lives of buildings and equipment;
2. Identification of potential environmental impact of phenomena associated with the decommissioning process.
3. Methods of investigation and monitoring in order to identify the impact phenomena and possible recovery measures.
4. The treatment of potential waste.

The study is in ***Annex B.2.10-A1 "Decommissioning and Cessation plan"*** but an evaluation will be made on the risk covering the soil and the groundwater. Through this evaluation it will be determined the need to create a starting profile on the physico-chemical state of the soil. Times and methods will be decided in accordance with the MEPA directions and the business needs.

B.2.11 Multi-operator installations

The operator is only Sterling Chemical Malta Ltd.

B.3 Your proposed emissions

B.3.1 Waste

B.3.1.1 Characterize and quantify each waste stream from the installation

It is considered to be waste any substance or object which the holder discards for need or for regulatory obligation. The Sterling Chemical Malta Ltd carries on a business of an industrial nature, and therefore produces hazardous and non-hazardous waste, both in the liquid and in the solid state. The company not only produces but participates in the process of managing the waste generator, the temporary storage and the transfer to a third party for the disposal, when the recycle is not possible. As a manufacturer of waste the company codifies and classifies the waste generated (whatever its nature is), and agrees to hold them under the conditions of the temporary storage facility established by the current legislation to provide for the recovery or disposal through delivery to qualified entities (disposal or recovery by third parties) and to comply with the administrative requirements.

B.3.1.1.1 Hazardous waste production

They are classified into special and hazardous waste from production activities and collateral. The first category includes the industrial production department's waste including the pilot plant, from the laboratories, from the maintenance activities and, in the case of a sensitive industry such as chemicals, also from the activities of storage and storage that can be added to vehicles and obsolete machinery, and those composed of construction materials, excavation and demolition. The hazardous materials are all those whose dispersion is an immediate danger to human life and the environment. Flammability, infectability, corrosivity and carcinogenicity are some of the main features of these types of substances, due to the presence of chromium compounds, beryllium, nickel, and copper, all of pollutant elements. Mineral oils, pesticides and pharmaceuticals, inks, paints and lacquers, adhesives and electrical batteries may fall into this category. The following table lists all the possible types of waste that can be generated by the activity of Sterling Chemical Malta except those related to the construction phase, and eventual demolition or decommissioning of all or only part of the system which are described in ***Annex B.2.10-A1.*** The first table, in addition to the European Waste Code as specified in the catalog associated to the Legal Notice 184 of 2011, also shows the department of the waste's origin.

Registered name	European Waste Code	Division producer
aqueous washing liquids and mother liquors	07 07 01*	Production line, Pilot plant, Lab QC, Lab R&D

organic halogenated solvents, washing liquids and mother liquors	07 07 03*	Production line, Pilot plant, Lab QC, Lab R&D
other organic solvents, washing liquids and mother liquors	07 07 04*	Production line, Pilot plant, Lab QC, Lab R&D
halogenated filter cakes and spent absorbents	07 07 09*	Lab R&D
other filter cakes and spent absorbents	07 07 10*	Production line, Pilot plant, Lab QC, Lab R&D
waste printing toner containing dangerous substances	08 03 17*	Office, Lab R&D, Lab QC
packaging containing residues of or contaminated by dangerous substances	15 01 10*	Warehouse, Lab R&D, Lab QC, Maintenance
absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by dangerous substances	15 02 02*	Warehouse, Lab R&D, Lab QC, Maintenance, Production line, Pilot plant
discarded organic chemicals consisting of or containing dangerous substances	16 05 08*	Production line, Maintenance
laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals	16 05 06*	Lab Qc, Lab R&D
spent catalysts contaminated with dangerous substances	16 08 07*	Lab R&D, Lab QC
aqueous liquid wastes containing dangerous substances	161001*	Water purification of chiller, boiler and steam generator, Scrubber
spent activated carbon from flue-gas treatment	19 01 10*	Utilities sectione for all plant
Ni-Cd batteries	16 06 02*	Office, Lab QC, Lab R&D, Maintenance
discarded equipment containing hazardous components other than those mentioned in 16 02 09 to 16 02 12	16 02 13*	Maintenance, Lab QC, Lab R&D, Office
mineral-based non-chlorinated engine, gear and lubricating oils	13 02 05*	Maintenance

Table 32 Characterize of Special Dangerous waste.

The first three types of waste listed in the table are primarily derived from industrial processes and are related to the transformation of raw materials. The washing and mother water indicated by a unique code EWC 070701 * have a double origin. In fact they come from:

- Flushing, cleaning reactors, filters and centrifuges plant, waste water coming from the scrubber, a wet scrubber used to trap the volatile organic compounds and other pollutants present in the flue gases from the production process, laboratory glassware washing;

- Mother liquors resulting from the working processes and developing after a separation of the phases. Specifically, the liquid solvent is filtered or centrifuged and separated from the reaction mass which continues its path of synthesis.

The solvents used are instead divided into halogenated and non-halogenated. In the first part there are all solvents in the chemical chain characterized by identifying carbon and chlorine (for what affects the workings of Sterling Chemical Malta Ltd) and typically

consisting in 80% of Dichloromethane and a remaining percentage of water, and they come from the workings in production (about 90%) provided by the synthesis to get the active pharmaceutical ingredient or an intermedia, for the 10% instead by reclamation operation of reactors used during the various synthesis or from research laboratories and development employing chlorinated solvents for testing optimization of the synthesis. The EWC code is associated with 070703*. The other solvents are classified as 070704* but what predominates is the acetone, the one intended for disposal or outside recovery derives from the processes of synthesis, during processing affects neither himself nor the solute. In this type of waste there may also be other solvents having different physical characteristics such as polarity, vapor pressure, boiling point and volatility such as tetrahydrofuran, toluene, dioxane, or alcohols such as methanol. Other types of waste produced in significant quantities are filters, also in this case a distinction is needed:

- Filters used within the processes of synthesis, such as activated charcoal, palladium, the celite. In this case the filters are wet by a solvent such as dichloromethane, methanol or acetone, and are discharged in a separate way from the fluid mass.

- Carbon filters used for the removal of pollutants in the exhaust gases from the production, from the weighing chamber and laboratories. This category also includes the HEPA filters.

Other waste produced in large quantities is identified with the code 150110*, the packaging containing the raw materials originally used by different departments. Such containers are typically HDPE plastic-type and metal with variable dimensions. From the laboratory come instead the glass containers, more rarely in aluminium and HDPE, and they still have modest capacity up to 10 liters.

Within the code 150202* there are gowns, gloves, masks, or material used for the absorption of chemical material, such as paper or rags or material used for the absorption of any chemical material accidentally spilled on the ground or on other work plans. In this code are included cleaning wipes contaminated with organic solvent and any production residue.

All other EWC codes have a lower impact. The following table estimates the amount that can be manufactured in a year, although it is closely linked to the production program (major source of waste creating), and then to the customer orders. The amount of waste annually produced is different depending on the phase of the project and it is rationally expected to an increase in the creation of it, which is parallel to the production and recruitment of new staff. It is indicated the destination of the special waste. For re-use we intend the re-use of waste within the same company and the production cycle that generated it.

	Yearly total amount (t)	**Destination**

European Waste Code	First	Second	Third	recovery	disposal	reuse
07 07 01*	170	250	350	0%	100 %	0%
07 07 03*	50	100	150	30%	50%	20%
07 07 04*	30	60	100	40%	0%	60%
07 07 09*	0,1	1	2	50 %	50%	0%
07 07 10*	5	10	25	100%	0%	0%
08 03 17*	0,003	0,015	0,025	100 %	0%	0%
15 01 10*	15	35	60	40%	20%	40%
15 02 02*	5	15	30	0 %	100 %	0 %
16 05 08*	0,3	0,7	1	0%	100 %	0%
16 05 06*	0,2	0,5	0,7	0%	100 %	0%
16 08 07*	0,01	0,02	0,02	0%	100%	0%
16 10 01*	50	100	150	0%	100 %	0%
19 01 10*	0	1	3	0%	100%	0%
16 06 02*	0,001	0,003	0,005	0%	100%	0%
16 02 13*	0,4	0,7	1	0%	100%	0%
13 02 05*	0,04	0,07	0,09	100%	0%	0%

Table 33 Quantify each hazardous waste stream.

The list of waste cannot be complete because the activity during or following particular evolution it may result in the production of other types of waste.

B.3.1.1.2 Non hazardous waste production

They are non-hazardous waste because although resulting from industrial activity they do not appear to be harmful to the environment and humans. The following table indicates the types and their origin.

European Waste Code	Registred name	Division producer
15 01 02	plastic packaging	Maintenance, Labs, Warehouse, Production line, Pilot plant, Office, Canteen
15 01 01	paper and cardboard packaging	Maintenance, Labs, Warehouse, Canteen, Office
15 01 04	metallic packaging	Maintenance, Labs, Warehouse, Production line, Pilot plant
15 01 07	glass packaging	Labs
15 01 06	Mixed packaging	Labs, canteen, office, warehouse
15 01 03	wooden packaging	Maintenance
20 01 38	wood other than that mentioned in 20 01 37	Warehouse
20 01 39	plastics	Office, canteen
20 03 04	septic tank sludge	All plant
20 01 08	biodegradable kitchen and canteen waste	Canteen
20 01 02	glass	Canteen
20 03 01	mixed municipal waste	Canteen, office, Toilet

Table 34 Characterise not dangerous waste.

The **Table 35** shows instead an estimate perhaps more changeable than the hazardous waste as it is closely linked to the ability of a correct execution of the collection by individual employees. All waste, except waste collection destined to landfill (EWC 200301) are intended for recovery of type R13[10].

European Waste Code	Yealy total amount (tonn)		
	First phase	Second phase	Third phase
15 01 02	1.0	2.0	3.0
15 01 01	1.0	3.0	5.0
15 01 04	1.0	2.0	3.0
15 01 07	0.5	1.5	2.0
15 01 06	0.15	0.3	0.5
15 01 03	1.0	2.5	3.5
20 01 38	0.2	0.7	1.0
20 01 39	0.01	0.015	0.02
20 03 04	1.5	4.0	5.0
20 01 08	2.0	3.5	5.0
20 01 02	0.3	0.6	0.8
20 03 01	2	3	5

Table 35 Quantify each not hazardous waste.

B.3.1.2 Measure of waste management, storage and handling

Waste management is an activity of public interest, specifically normed to ensure high environmental protection and effective controls. The recovery, re-use and disposal must be carried out without endangering the human health and the operators, and without using processes or methods which could harm the environment. The procedure for the internal waste management, that is, until the boundary of the HAL FAR plant, falls into the documentation of the system of integrated environmental, health and safety[11]. According to the environmental policy, waste management is carried out according to the principles of precaution, prevention, empowerment and cooperation between all parties involved in the production, distribution, use and consumption of goods which originate waste, as well as the "polluter pays" principle.

Waste management undertaken by the Sterling Chemical Malta Ltd reflects the one already existing in Italy, and in particular it must take place according to the following hierarchy:

1. Prevention;
2. Preparing for re-use;
3. Recycling;

[10] R13:is type of recovery or disposal operation for our waste into company arrive (Storage of wastes pending any of the operations R 1 to R12).
[11] MIOA_4.4.6-C “Waste management” included in annex B.2.1-A1

4. Recovery;
5. Disposal.

Finally, the management of waste must be carried out according to the principles of effectiveness, efficiency, economy, transparency, technical and economic feasibility, as well as in compliance with the existing rules of participation and access to environmental information. Below we try to summarize the management steps that will be adopted. To safeguard these main behavior and in accordance with the rules of Italian industry at the time of the initial training, each employee should be made aware of the following restrictions:

- For the non-hazardous waste it is required to limit the consumption, to recycle, to differentiate, and finally if it is not possible, to dispose in special containers of unsorted waste;
- It is forbidden to mix hazardous waste with different hazardous characteristics or hazardous with non-hazardous waste. Mixing shall include the dilution of hazardous substances;
- It is forbidden the abandonment and the uncontrolled storage of waste on land and soil as well as the placing of waste of any kind, solid or liquid, in the surface water and groundwater; the abandonment of waste is forbidden in areas not responsible for the collection;
- The containers for collection of waste must not be filled beyond 90% of their capacity, to prevent leakage of toxic material during transport;

The waste management goes through the following check, action and problem solving steps:

1. Staff training and awareness who constantly generates and manipulates waste, so as to immediately give all relevant information in order to better manage the generated waste;
2. Attribution of proper EWC code, both in the case of new waste and for a healthy periodic review of the list of codes already adopted and in force. This revision is in preparation for the possible search for new solutions for recovery, re-use or disposal of the waste. This activity will be accompanied by an annual analytical investigation or whenever the quality of the waste will obviously be changed (eg in case of new productions);
3. Indoor and outdoor collection planning. All over the plant are placed collectors of different colour, shape, characteristics and sizes in order to collect different waste in quality and quantity. For this reason it is necessary to devote an operator to the waste's collection and disposal, who on alternate days traces the temporary collection points in order to empty them and to bring the waste into the temporary storage area until they are removed by the authorized dealers. In addition, it is necessary to combine a weekly schedule for disposal waste so that each week the operator will be responsible for updating the register of waste storage MRA_4.4.6-

C1 in which the Manager may have useful information on the amount and type of waste in the company and submit a formal request to the company taking care of the external waste management (i.e. collection, filling the documents, shipping to the disposal or recovery area)

4. Checks and controls on proper waste management: making periodic audits in order to ensure that all information contained in the procedure of the integrated management system are observed;

B.3.1.2.1 General criteria for the chemical waste's management

In the collection operations of waste chemical it must be taken all the precautions that are normally put in place in the handling and storage of hazardous chemical agents: in particular, it is important, to pay attention to the respect of the compatibility criteria between the various substances. In particular, there will be considered chemically incompatible those substances which could:

- violently react;
- react producing a considerable amount of heat;
- react causing the formation of flammable products;
- react determining the formation of toxic products.

The "waste management" procedure has attached a table with an indication as example, of incompatible chemicals and to which reference is made.

The waste will be collected in a suitable containers according to the volume and type of waste. The containers must have the following general characteristics:

- Being made of material resistant to the action of refusal content;
- Ensure an adequate seal to prevent leakage of material or, anyway, of dangerous vapors;
- Being properly labeled with the symbol "R" black on a yellow field and an indication of the code, the composition of the waste and the main danger characteristics;
- The labels should be placed on the container prior to its use;

The bags containing solid waste (i.e., activated carbon, celite, plastic, gloves, polluted sand) shall be placed in suitable resistant containers to prevent damage and loss of contents in the workplace and outside. All containers must anyway be sealed and protected against water and humidity in case of substances which may dangerously react with water or otherwise decompose in the presence of moisture, giving rise to dangerous products.

B.3.1.2.2 Temporary waste storage

In front of the external flammable warehouse will be used as service area (there are no buildings) and, for the convenience of operators and while awaiting subsequent developments, skips have been placed to collect paper, plastic, glass, wet waste and undifferentiated waste, for this reason the term "temporary storage" is used. The dangerous waste instead is to be positioned in the external flammable warehouse where there are specific fixed containment basins. The project show in **annex B.1.4-A2 "External Flammable warehouse".**, and into annex B.1.2-A2 the general plant of company with particular of singular working area.

In phase II the service area will be used for waste to be sent for disposed too.

Those skips, will have different color and size in relation to the type of waste to be collected. All the skips will be adequately indicated by signage stating the EWC code and a brief description of the waste. In this area there will be positioned even the big-bag used for filter collections of production or plant (i.e. protective masks for the operators, or the activated carbon used for the abatement of volatile organic compounds within the fume process, or even the filters used in the air treatment unit for cleaning the air at the workplace). These big bags will be placed on movable containment tanks to prevent any releases of harmful substances on the soil, in the following table there is indicated the size of these movable tank collections. Also in the same area there will be allocated empty drums containing the raw materials used in the production process so that the operator can proceed to their packaging on a single or multiple pallets. All the drums must be packed through cellophane to be protected from the weather and then labelled according to their type. All waste will be anyway visually indicated, with an R label on yellow background.

The second part devoted to waste is included in a covered structure also to accommodate volumetrically more consistent raw materials, i.e. those who come in tanks and drums, tending to have flammable nature. The structure is below the surface level of the company and to access it there are two ramps of short length and 3% slope. This structural choice allowed to make the entire area as a single containment basin to accommodate a spill which evolving during the handling of the waste or raw material. The whole area is waterproof and is divided into fixed containment basins made of reinforced concrete and equipped with lanes of support for the pallet on which tanks are anchored. The property has three containment basins, only one is dedicated to the waste because we chose to dispose, as quick as possible, the produced waste.
The basin where the bulks will be placed, is again divided into three areas delimited by vertical walls, this will allow operators to locate the area of relevance for the EWC code to be allocated. The division was made according to the chemical compatibility of the waste thinking that an eventual spillage of multiple waste will not bring to a mixing of them.
The containment basins have no connection to the sewer system, but they have a slope towards closed drains having the task of collecting what may be spilled. The structure is

well ventilated because the access ways are always open and externally connected , this ensure an adequate and natural air exchange and a way out for any fumes that would develop as a result of fire.

In addition, there has been established various rules and standards that operators who will take care of waste management must observe, in particular

- ✓ hazardous waste is sent for recycling or disposal at least every 10 days regardless of the amount,
- ✓ the temporary storage complies with the requirements relating to the prohibition of mixing hazardous waste;
- ✓ The fixed or mobile containers or tanks must reserve a residual volume of safety equal to or greater than 10%;
- ✓ The fixed and mobile containers or tanks must be placed on the waterproofed floor and with the containment system of a capacity equal to the tank or, in case in the same basin there are several tanks, the capacity of the basin must be at least 30% of the total volume of the tanks;
- ✓ The containers must be grouped by type of homogeneous waste and arranged in a way to allow an easy inspection;
- ✓ All the containers must be properly labelled by providing the complete description of the waste (type, EWC code, weight, origin, date of manufacture).

Some type of waste can be stored in different locations than the external flammable warehouse. For example toners (EWC 080317*) are stored in the workshop using not palletized "eco-box" packaging type with lids and seal and capable of preventing the liquids and powders leakage , with a maximum size of 35 cm\35 cm\70 cm and a total weight (packaging and waste content) not exceeding 30 kg. The used cartridges must be stored in the packaging left empty by the new product and deposited into the container. Into the container It can also be inserted the toners for copiers but they must be enclosed in plastic bags to prevent ink or dust leakage inside the bag. The products collected are concerned in particular of the light and the excessive heat. The storage, therefore, must be carried out in a dry place, not exposed to the weather and not exposed to extreme temperature changes.
Same thing for the batteries or exhausted batteries container and other waste material coming from the processing of mechanical maintenance. And above all, the exhausted oils for which are used a double bottom tank and a level viewer visually allowing to understand the free capacity of the tank before it can be used.

In addition to the different types of closed containers (skip, tank, drum or box) and the fixed and mobile containment basins, there are scattered in different parts of the spill-kits containing different materials for the temporary containment and absorption of various pollutants released as liquid for example:

- Manhole cover: Plates designed, in emergency situations, to cover the entry of the ducts and prevent the escape of the liquid pollutants. The bottom, blue in color, is adhesive and seal the opening of the sewer's manholes opening. The upper part, resists to snags, tears and wear. Being flexible, they adapt to uneven surfaces. Made of polyurethane anti-UV treated, resistant to water, oils and many chemicals. Easy to clean with soap and water after each use.

- Oil absorbent non-slip granules or fine, to absorb and thoroughly clean contaminated surfaces;

- Barriers to use in case of large quantity spills of liquid, as their content, sufficiently heavy, prevents the displacement of the sleeve itself caused by the force of the liquid flows.

- Only oil sheets and sleeves with oleophilic and hydrophobic properties, ideal for outdoor use, in the rain or on watercourses and ponds.

- Universal sleeves and sheets suitable for liquids such as oil, coolants, adhesives, grease, water, solvents, acids, bases, etc..

- Universal sleeves and sheets for chemicals that can absorb aggressive liquids, toxic and caustic.

- Sheets and sleeves for spills of sulfuric acid from batteries and accumulators.

The positioning of spill-kit are shown in the plan in ***Annex B.3.1.-A1 Plan for spill kit location*** highlighted the geometry of the temporary storage of covered area of waste.
The tables below show the waste that can be produced within the Sterling plant, their storage mode and its location and the capacity of the containment measures required for their storage as well as the security safeguards.

EWC	European Waste name	Primary Packaging	Storage Area	Maximum storage capacity	Capacity of containment	Containment measures	Protective mesures
070701*	aqueous washing liquids and mother liquors	IBC and drums of capacity 200 L	External Flammable Warehouse	36 m^3	110% of the largest tank stored	Containment basin waterproof (110% of	Fire extinguisher, material anti spill and absorbent
070703*	organic halogenated solvents, washing liquids and mother liquors	IBC and drums of capacity 200 L	External Flammable Warehouse	36 m^3	110% of the largest tank stored	Containment basin waterproof	Fire extinguisher, material anti spill and absorbent
070704*	other organic solvents, washing liquids and mother liquors	IBC and drums of capacity 200 L	External Flammable Warehouse	36 m^3	110% of the largest tank stored	Containment basin waterproof	Fire extinguisher, material anti spill and absorbent
070709*	halogenated filter cakes and spent absorbents	in sealed plastic bags into jumbo bag	External Flammable Warehouse	1 m^3	110% of the largest tank stored	Mobile containment basin waterproof	Fire extinguisher
070710*	other filter cakes and spent absorbents	in sealed plastic bags into jumbo bag	External Flammable Warehouse	1 m^3	110% of the largest tank stored	Mobile containment basin waterproof	Fire extinguisher
080317*	waste printing toner containing dangerous substances	Bin	Maintenance	0,16 m^3	110% of the largest tank stored	cover and seal capable of preventing the dispersion of liquids and powders	Fire extinguisher
150110*	packaging containing residues of or contaminated by dangerous substances	Waterproof film	External Flammable Warehouse	20 m^2	110% of the largest tank stored	Cover manholes	Fire extinguisher
150202*	absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by dangerous substances. (are included cleaning wipes contaminated with organic solvent and any production residue).	in sealed plastic bags into jumbo bag	External Flammable Warehouse	2 m^3	110% of the largest tank stored	Mobile containment basin waterproof	Fire extinguisher
160508*	discarded organic chemicals consisting of or containing dangerous substances	Drum in HDPE	External Flammable Warehouse	200 litres	110% of the largest tank stored	Containment basin waterproof	Fire extinguisher, material anti spill and absorbent

160506*	laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals	Drum in HDPE[12]	External Flammable Warehouse	200 litres	110% of the largest tank stored	Containment basin waterproof	Fire extinguisher, material anti spill and absorbent
160807*	spent catalysts contaminated with dangerous substances	in sealed plastic bags into jumbo bag	External Flammable Warehouse	1	110% of the largest tank stored	Containment basin waterproof	Fire extinguisher
161001*	aqueous liquid wastes containing dangerous substances	IBC and drums of capacity 200 L	External Flammable Warehouse	36 m^3	110% of the largest tank stored	Containment basin waterproof	Fire extinguisher, material anti spill and absorbent
190110*	spent activated carbon from flue-gas treatment	in sealed plastic bags into jumbo bag	External Flammable Warehouse	1 m^3	110% of the largest tank stored	Mobile containment basin waterproof	Fire extinguisher
160602*	Ni-Cd batteries	Bin	Maintenance	30 litres	-	not required	Fire extinguisher material anti spill and absorbent
160213*	discarded equipment containing hazardous components other than those mentioned in 16 02 09 to 16 02 12	Tank	Maintenance	500 litrres	-	not required	Fire extinguisher
130205*	mineral-based non-chlorinated engine, gear and lubricating oils	tank	Maintenance	500 litres	-	not required	Fire extinguisher material anti spill and absorbent
15 01 02	plastic packaging	Skip	External Flammable Warehouse	20 m^2	-	not required	Fire extinguisher
15 01 01	paper and cardboard packaging	Skip	External Flammable Warehouse	20 m^2	-	not required	Fire extinguisher
15 01 04	metallic packaging	Skip	External Flammable Warehouse	20 m^2	-	not required	Fire extinguisher
15 01 07	glass packaging	Skip	External Flammable Warehouse	20 m^2	-	not required	Fire extinguisher
15 01 06	Mixed packaging	Skip	External Flammable Warehouse	20 m^2	-	not required	Fire extinguisher
15 01 03	wooden packaging	Skip	External Flammable Warehouse	20 m^2	-	not required	Fire extinguisher
20 01 39	plastics	Skip	External Flammable Warehouse	20 m^2	-	not required	Fire extinguisher

[12] HPDE: is a polyethylene little branched, thus high intermolecular forces and higher rigidity compared to low density polyethylene, is generally synthesized through polymerization for coordination with a system catalico of Ziegler-Natta type

20 01 08	biodegradable kitchen and canteen waste	Bin	External Flammable Warehouse	2,500 litres	-	not required	Fire extinguisher
20 03 01	mixed municipal waste	Skip	External Flammable Warehouse	20 m^2	-	not required	Fire extinguisher

Table 36 Storage location of waste

B.3.1.2.3 Describe of waste stream

For the wastes produced by Sterling, there are several possible scenarios for the waste management and it is related to the nature of the waste. The following table illustrates the principle management stream of waste:

Stream	*Operation step*	*European Waste code*
Stream 1	Reduction at the source	07073*,070704*,150110*,
	Re-use	
	Collection	
	Trasport	
	Recovery	
Stream 2	Reduction at the source	15 01 02, 150101, 150110*, 150104, 150107, 150106, 150103, 160602*
	Recycled	
	Collection	
	Trasport	
	Recovery	
Stream 3	Reduction at the source	130205*,190110*,160508*,160506*,070709 *, 070710*, 150202*
	Collection	
	Trasport	
	Disposal	
Stream 4	Collection	200301, 200108,
	Trasport	
	Material recovery station	
	Landfill	

Table 37 Waste stream

The following block diagram synthetically represents the waste management in the Sterling's work.

Stream 1

Reduction at the source means reducing the production of waste. As for the waste resulting from the chemical synthesis processes (both production and laboratory), to reduce waste means to reduce the demand for input raw materials and this is possible only through a study of resources optimization. It is one of the tasks of the research and development laboratory, which is the synthesis optimization that has the following objectives:

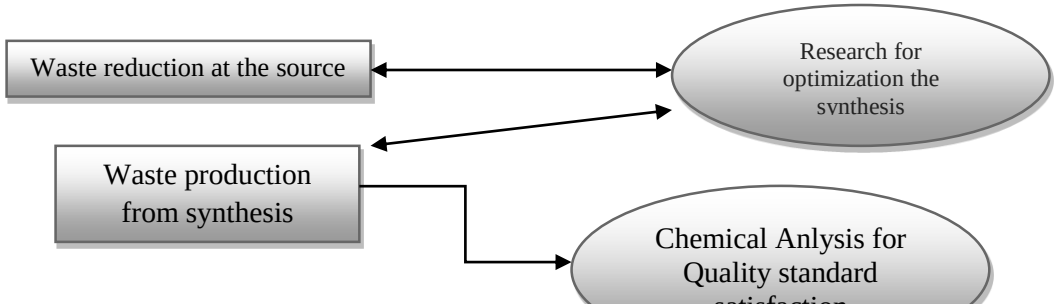
- Increasing in the synthesis yield and purity: not only implies a financial gain for the same time and human resources and materials, but also a reduction of the output waste because it has more potentially allocable product on the market;
- Reduction of working time;
- Reduction of the used raw materials: this aspect affects the nature of the used raw material (for example the replacement of solvent A with solvent B involves a smaller amount of solvent usable in the synthesis, consequently less expense, less rejection in output);

However, this is an operation that lasts over time and is still constant.
The second step is to evaluate the reusability of the produced waste. In particular, for the raw materials adopted for the synthesis it is already in place a policy of re-use of waste,

with particular reference to solvents such as acetone, methanol and dichloromethane, which play the main roles in the Sterling's production. In particular, the examination of the possibility of recovery and reuse of these solvents is always done, but it is not always possible to re-use within the production cycle, and this depends on the quality of the waste. In particular, once obtained, the waste is sampled and analyzed by the quality control laboratory which considers different parameters (such as purity, content of water) according to the specifications contained in the International Pharmacopoeia. Based on the results, the production manager and the quality department defines whether to address a waste to the reuse within the next synthesis or, for example, even to the simple plant cleaning. Another initiative in view of the last step of this assumed scenario it is the internal analysis of COD on some code EWC 070701 * waste, in fact, below or above a range of values it is possible to recover these mother liquors or to treat them and then dispose them. The analysis is therefore preventive and allows, in most cases to halve the hazardous waste liquids for disposal. The liquid waste code EWC 070704* and 070703* will always go to recover. Except in cases where (and this refers to the most non-halogenated organic solvents) the mixture of the solvent is extremely heterogeneous so as not to allow the destination plant an effective and economic recovery treatment.

The collection of special hazardous liquid waste is always in a cubic meter tanks that are emptied and returned so that they cannot constitute a rejection and not fall into the category of 150110*.

Hazardous wastes are always sent out of the island and the carrier takes also care of the waste management's documentary part. The operator chosen is GreenSkip Ltd. The transport takes place in different sizes van (depending on requirements), the bulks are initially stocked in the GreenSkip warehouse and subsequently placed in a container and shipped to Italy by sea, with docking at the port of Genoa. The following diagram shows the main stages of the first scenario.

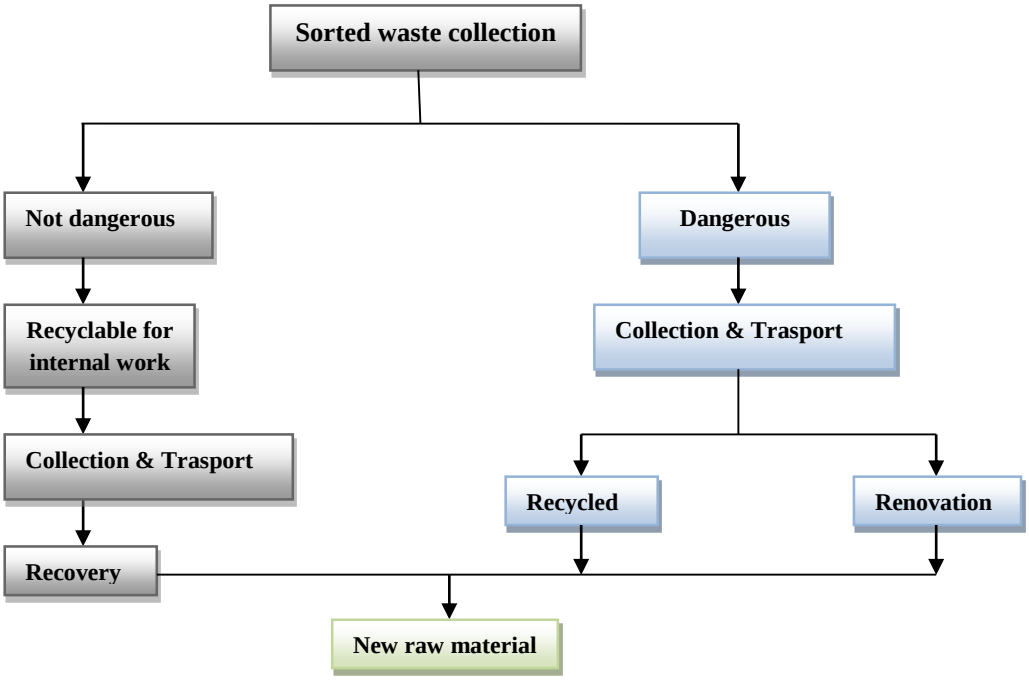


Flow Chart 9 Waste stream type one.

Stream 2

In this flow of waste management there are two categories, hazardous and non-hazardous waste. For both there is always the principle of the source reduction of the waste produced. For the category of non-hazardous waste the company policy is the awareness on the resource conservation issues that also means restriction of certain items such as paper, cardboard, plastic and glass sparingly following some basic rules of civility: With a little attention considerable savings can be achieved with no efforts. Enable all network printers and copiers for the front and back side makes us halving the consumptions. Reducing the margins and the font sizes allows to decrease the amount of the used paper, without losing the text in readability. Before printing, checking the preview helps not to waste a whole sheet just for a few lines. Where possible, it is always better to reuse. The sheets used may be useful to write on the back side, the folders can be retrieved folding them on the opposite side, the used but still in good condition envelopes can be used for internal communications: covering the old address with a label makes them look like new. Another trick: get rid of junk mail. Let's cancel any subscriptions to newspapers, newsletters and magazines that we do not read, or that we can easily consult online, and let's ask to receive our bills directly to our inbox. Second critical step in this direction is the education to recycling, being careful to remove all non-cellulosic materials such as staples and adhesive tape, so that it is ready to be recycled minimizing the separated waste. The organization provides specific bins for recyclable materials within any office or working area and then a larger collection skip placed outside. All the wastes that way recycled (listed in **Table 34**) will be addressed to the recycling. The principle is the same for e.g. with regard to toners or batteries and accumulators (strictly non-lead), the material collected will be addressed to a system that, depending on the quality of the waste, it decides whether to regenerate or recycle them. For example, concerning the toners, the collected cartridges regeneration is expected to be individually checked for its suitability

reuse. They are then completely disassembled and de-dusted for the recycle of the mechanical parts; all the elements subject to wear, will be eliminated. The suitable components for re-use are cleaned and inserted into the production line. The worn parts are replaced with new parts. The cartridges are filled with powder or corresponding ink and sealed. In case of recycling, the collected cartridges are classified and reduced to fragments. The so fragmented materials are divided into plastics, metals and residues of ink/toner, expanded foam and subsequently processed into raw materials for the manufacture of new products daily used. The remaining materials and the residual ink or toners are used to generate energy or disposed in an environmentally responsible manner.



Flow Chart 10 Waste stream type 2

Stream 3

The second stream of training covers the waste that cannot be recycled, but they will be addressed to activities of purification and subsequent disposal. Typically fall into this category the waste with code EWC 070701* either the water used to wash the plant or the mother liquors and such impossibility is due to the heterogeneous mixture created during the reaction, filtration and centrifugation operations. Therefore, it becomes essential, even in this case, the source reduction of the produced waste, which can be done in two ways, the first is always through the search for a better synthesis, the second one is to try to isolate as much as possible the processing steps as to increase the number of discharges. This second way is, however, not so used, because it implies a doubling of the processing time and related costs but also increases the risk of failure of the reaction and therefore it is often used in the cleaning plant manufacturing when there is the need to use multiple products in sequence.

Stream 4

The third stream of solid waste management concerns the separated waste for which it was required to the service provider a selection of the recoverable materials.

For the output waste streams from the production department there are also available the individual processes block diagrams for the active ingredient. This information have as input the incoming raw materials and as output the waste and gaseous effluents from the various chimneys. The block diagrams are available in ***Annex B.2.2-A2 "API's flow diagrams."***

B.3.2.1.3 Handling, collection and transportation of waste

Regarding the handling of waste produced the changes can occur in three ways:

1. With the forklift's help equipped with wheels and driven by three phase electric motors, also employed in the raw material's loading-unloading phase. This vehicle is used in order to move tanks and big bags. For security reasons, all operators have followed a training course leading to obtaining a driving license. The raw materials moving operations (even the short ones) are sensitive, for this reason it has been associated a moving operating instruction belonging to the management system of environmental integrated health and safety, certificated in Italy and also supplied to Malta with possible future certification. The forklift will typically be used outdoors or in the raw material warehouse or in the waste temporary storage;

2. With the help of a trans-pallet used for the handling with ground guide of tank also of reduced size. The use of trans-pallet is especially intended for confined spaces, such as the production departments. It is also used by the waste carriers for storing the waste tanks inside the trucks;

3. The hand carriage is implemented only for small loadings. It is typically the case of the raw materials supply within the laboratories, or the displacement of the bins for the collection of waste towards the collecting skips which are larger and placed outside.

The main directional waste lines are:

- From the production department to the covered and uncovered waste deposit;
- From the A1 to the A2 at the moment of the transfer to the hauler;
- From the laboratory to the areas A1 and A2 of the temporary waste storage.

Part of the route is on paved but discovered surface.

Once described the internal handling, the waste disposal is carried out with the assistance of a Sterling operator that with the forklift's help lifts up the bulks, the tanks and the big bags to the truck's level where the conveyor is awaiting and which by trans-pallet sort the pallets inside the van making sure that they are securely anchored to the wall by straps. As for the non-hazardous bulk waste, the recycled and undifferentiated,

collected in various sizes skips, the company providing Sterling these collectors for rent, on commission by the waste manager, will replace the full skip with an empty one. The recycling will still be subject to the screening in the waste collection station operator.

It is possible in the near future that Sterling will decide to change the mode of the waste delivery, especially hazardous waste, using containers and placing them on pallets to be disposed. In this case the carrier will only pick up the filled container.

The waste transportation for disposal outside the plant includes the following steps:

1. Road transport, on the Maltese territory going from the HAL FAR site to the temporary deposit of waste in case of transport without container;
2. Road transport on the Maltese territory from the storage broker site to the harbor, or in case of rental containers, from the Sterling site to the harbor;
3. Transport by sea with docking at the Genoa harbor;
4. Road transport to the disposal facility located in the city of Milan or Bologna in connection with the type of service selected.

All transportation will be in compliance with the requirements under ADR regulations, for this reason the operators monitoring the shipment of waste will be properly trained in accordance with the procedure MIOA_4.4.6-N1 "Dangerous Goods Management" and MIOA_4.4.6-N2 "Marking, labeling and packaging in accordance with the ADR regulations." These instructions are contained in the management system in ***Annex B.2.1-A2.***

The following table shows the operators chosen for the waste management and transport with an Internet address where to check the environmental permits ownership necessary for the execution of the commissionable works.

Kindly note that any recovery or disposal operation of waste outside the site will be carried out a either a local facility permitted by MEPA for such and activity or by an overseas facility permitted to carry out such an operation.
Any permit shall be obtained through the broker of reference that also runs the Waste Management. The operator is green skip. Sterling has already the Consignment permit for certain types of waste, while the CN number is assigned to the Green Skip operator that, at the time of taking charge of waste delivers to Sterling the Green Copy.
Also The cross-border movement of waste is entrusted to the Operator broker that takes care of the travels and authorizations in accordance with the already mentioned laws.

Any transboundary movement of waste shall be carried out in accordance with the following regulations, as amended from time to time:

(a) Regulation (EC) N° 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste

(b) Commission Regulation (EC) N° 1379/2007of 26 November 2007 amending Annexes IA, IB VII and VIII of Regulation (EC) N° 1013/2006 of the European Parliament

and of the Council of Shipments of waste, for the purposes of taking account of technical progress and changes agreed under the Basel Convention; and

(c) Commission Regulation (EC) N° 1418/2007 of 29 November 2007 concerning the export for recovery of certain waste listed in Annex III or IIIA to Regulation (EC) N° 1013/2006 of the European Parliament and of the Council to certain countries to which the OECD Decision on the control of transboundary movements of waste does not apply.

For any other waste which Sterling will produce and that is not included in this project description will ask permission to MEPA.

Operator	Role	Waste type (EWC)	Type service	Destination	More information
Green Skip Services Ltd	Broker/waste carriers in Malta	Hazardous and Non Hazardous waste collection	• Refuse collection & transportation; • Refuse containing • Refuse sorting • Refuse compacting • Waste disposal • Waste management service	Milan (Italy)	www.greenskipgroup.com
Ewr ambiente srl	Broker	Hazardous waste	• Technical, operational, legislative (administrative) during the whole execution of the work;	Bologna (Italy)	www.ewrambiente.it
Sullivan maritime	Waste carriers in Malta	Hazardous and Non Hazardous waste collection	• Export freight charges • Bunker adjustment factor • THC discharging port • IMO surchenge • Service document process • Handling charge • Pre-carriage	Hal FAR- La Valletta	www.sullivanmaritime.com.mt
Alfarec S.p.A.	Recovery/disposal plant in Italy	Hazardous waste	• Control of waste merchandise and analytical incoming and outgoing; • unpacking and repacking, sorting and selection of consignments mixing and grouping similar types of waste; • mixing and grouping similar types of waste	Bologna (Italy)	www.alfarec.it
Fratelli Rizzo Autotrasporti snc	Waste carriers in Italy	Hazardous waste	• Trasnsportation	Genova - Bologna	www.rizzoecologia.com
Grimaldi Lines	Waste carriers on sea	Hazardous and Non Hazardous waste collection	• Cross-border freight services	La Valletta – Genova (Italy)	www.grimaldi-lines.com
Ecosfera group srl	Recovery/disposal plant in Italy	Hazardous waste	• Technical, operational, legislative (administrative) during the whole execution of the work;	Milano (Italy)	www.ecosferagroup.it

Table 38 Waste operators

B.3.2 Emissions to groundwater

There are no emissions into groundwater. The facility will have a waste water reservoir which will handle process water to be shipped as hazardous waste. Sterling has commission the services of an independent warranted engineer so as to confirm that the proposed construction is in line with Schedule 1 Activity 43 of LN 106 of 2007. This warranted attachment in annex **B.3.5.A2**. Sterling confirm that there will be no seepage or dangerous leaks neither when emptying nor during the operation. In order to guarantee this, it is adopted a surveillance system controlling the tightness of the underground tank every two years.

B.3.3 Emissions to sewer

The water discharges into public sewers are those arising from the hygienic/sanitary and domestic activities of the complex and not by the specific industrial activity. In fact, the network of sewage, flows into the drains of the toilets, changing rooms, kitchen. In the layout of the sewer connection[13]they are shown in different colors:

- Sanitary drainage: water discharges from toilets and changing rooms;
- Water drainage: industrial waste water not coming from the kitchen.

Each line is equipped with:

- **Gully trap**: These traps are constructed outside the building to carry waste water discharge from washbasin, sinks, bathroom etc. and are connected to the nearest building drain/sewer so that foul gases from sewer do not come to the house. These are deep seal traps, the depth of water seal should be 50 mm minimum. It also prevents the entry of cockroach and other insects from sewer line to waste pipes carrying waste water.
- **Manhole**: is the top opening to an underground utility vault used to house an access point for making connections or performing maintenance on underground and buried public utility and other services including sewers, telephone, electricity, storm drains and gas;
- **Intercepter chamber**: The trap is a basic interceptor found on the outlet of a chamber with a rodding point fitted over the top to access the outgoing pipe work, in the collar end of this rodding shaft would be a clay ware cap or tea pot lid as they are known which would form a seal until access was required.

The pipelines will be built in rigid non-plastic PVC for drains with connecting sleeves and relative elastomeric seals complying with UNI EN 1401 - SN4 type with bar length of 6.00 m for gravity pipes. The pipelines will be laid on a bed of equally distributed sand, the thickness of which is not less than 10 cm, and should not contain inert material with a diameter greater than 5 mm. The tube will be supported for at least 20 cm per side, up to the diametral plane, and then covered with the same loose material for a thickness not less than 15 cm, measured on the upper generatrix. The next total filling of the excavation shall be done with sand or other suitable

[13] ***Annex B.2.7-A1 Lay out drainage***

material until the road container. All the conducted with covering less than 1.00 m, measured from the road surface to the extrados of the pipe shall be overseen by adequate concrete slab reinforced with Rck 250 mesh. The catchpits will be sealed with walls and prefabricated reinforced for heavy loads. The catchpits should be brought at level with additional elements in C.A.V. of the same thickness of the catchpit, perfectly plastered with cement mortar in the junctions. The connections to the public sewer manholes should be constructed of PVC pipes with the same characteristics for the main pipeline. The input portion will not be less than the extrados of the main pipe. The whole sewer structure will be built in the Sterling Chemical Malta Ltd private property, while there is a single point of connection to the public sewer.

The **Table 39** below illustrates some of the characteristics of the discharges, such as the section of origin and the physical - chemical characteristics that one could encounter.

Into annex B.3.3-A1 there is the sewer discharge permit by Water Service Corporation.

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final discharge [14]	Partial discharge [15]	Equipment, phase or group of phases of origin discharge	Discharge way		receptor	Average annual volume discharge				
			Type	Frequency [16]		Main flow rate (m^3/year)	Flow rate of peak (m^3/h)	Main flow rate (m^3/day)	Mounth of peak	Method assesment
1	1a	Laboratories'sToilets and dressing room	Water discharge	irregular	Public sewer	100	0,5	0,2	February	Estimate
	1b	Canteen and toilet of dressing room	Sanitary discherge	irregular	Public sewer	200	0,8	5,0	February	Estimate
	1c	Visitor WC	Water discharge	irregular	Public sewer	50	0,5	0,2	February	Estimate
	1d	Visitor WC	Sanitary discharge	irregular	Public sewer	50	0,5	0,2	February	Estimate
	1e	Disabled WC	Sanitary discharge	sporadic	Public sewer	5	0,3	0,0	February	Estimate
Second phase										
1	1a	Laboratories'sToilets and dressing room	Water discharge	irregular	Public sewer	200	0,5	0,5	February	Estimate
	1b	Canteen and toilet of dressing room	Sanitary discherge	irregular	Public sewer	300	0,8	10,0	February	Estimate
	1c	Visitor WC	Water discharge	irregular	Public sewer	100	0,5	0,5	February	Estimate
	1d	Visitor WC	Sanitary discharge	irregular	Public sewer	100	0,5	0,5	February	Estimate
	1e	Disabled WC	Sanitary discharge	sporadic	Public sewer	5	0,3	0,0	February	Estimate
Third phase										
1	1a	Laboratories'sToilets and dressing room	Water discharge	irregular	Public sewer	250	0,5	0,8	February	Estimate
	1b	Canteen and toilet of dressing room	Sanitary discherge	irregular	Public sewer	350	0,8	13,0	February	Estimate
	1c	Visitor WC	Water discharge	irregular	Public sewer	150	0,5	0,8	February	Estimate
	1d	Visitor WC	Sanitary discharge	irregular	Public sewer	150	0,5	0,8	February	Estimate
	1e	Disabled WC	Sanitary discharge	sporadic	Public sewer	5	0,3	0,0	February	Estimate

Table 39 Domestic sewage discharge.

[14] Final discharge: point of connection to the public sewer.
[15] Partial discharge: connection point to the internal sewerage system.
[16] Frequency: the frequency of discharge is irregular, continuous or sporadic

The type of wastewater that will be channeled into the public sewer system does not provide for the pollutants listed in Schedule A or B of LN 139 of 2002, also, the chosen pipe tipology (PVC) is used to ensure that there will be no release of heavy metals within the public sewer. Any other requirement under the above law is respected having:

- ✓ Separated water comparable to domestic water from rain and from the water used for washing the plant;
- ✓ Having identified the devices able to prevent the formation of unpleasant odors inside the workplace.
- ✓ By identifying a specific point for sampling the final effluent discharged into the public sewer;
- ✓ Identifying a series of catchpit useful for maintenance, cleaning and inspection of the Authorities in case of necessity;

In the following table are indicated possible pollutants and it is compared what expected in terms of concentration[17]

Analyte name	Units	Limited for Maltese low	Expected value
pH	n.2.	6÷10	7.8 ± 0.3
Temperature	°C	40	30÷35
Settleable solids:	ml/L	20	Not provided
Suspended solids	Mg/L	500	100 ± 15
Total Kjeldahl Nitrogen	mg/L as N	100	11.4±1
Sulphides and compounds releasing hydrogen sulphide on acidification:	mg/L as S	10	Not provided
Hydrocyanic acid and compounds releasing hydrocyanic acid on acidification	mg/L as CN	10	Not provided
Total Sulphates:	mg/L as SO4	1000	45±5
Free and emulsified grease	mg/L	200	0.8±0.1
Free chlorine	mg/L as CI	100	Not provided
chlorine	mg/L as CI	1000	180±20
Total Chromium	mg/L as Cr	5	Not provided
Total silver	mg/L as Ag	5	Not provided
Total Nickel	mg/L as Ni	5	Not provided
Total Copper	mg/L as Cu	5	Not provided
Total Lead	mg/L as Pb	1	Not provided
Total Zinc	mg/L as Zn	10	Not provided
Total non-ferrous material	mg/L	30	Not provided
Total soluble non-ferrous material	mg/L	10	Not provided
Total arsenic	mg/L as As	0.05	Not provided
Total fluoride	mg/L as F	10	Not provided
Total Boron	mg/L as B	2	Not provided

Table 40 Maximum Discharge Concentration Values expected.

[17] The estimate was made based on the experience in Italy, as the type and quality of the discharge is the same.

In Section B.3.10 it is described the plan also provided for monitoring and controlling the water discharges, and the management of them is entrusted to the procedure MPA_4.4.6-Management of supply and waste water.

B.3.4 Emissions to the sea

Not emmission to the sea.

B.3.5 Rainwater

The plants for rainwater recycling allow the reuse of the water from the downspouts of the buildings and from the surface run-off, ensuring a reserve ideal for the irrigation of green areas, for the fire fighting and emergency water supply (for example interruption of supply by the local water supply).

The rainwater management has also taken account of the origin of the same, as there are:

- Runoff, that is, the water falling on the forecourts for moving of the staff, the goods and the means of transport, representing, at least initially, a real water washing of the uncovered surfaces;
- Rainwater, ie the fall and the collection on the roofs and subsequently conveyed through gutters in the final destination place.

In order to use the rainwater within the green areas, in case of fire and for backup in case of shortage it has been adopted a system of qualification of the water that covers one-piece rectangular spillway used to limit the pollution and the depletion of groundwater resources, dealing with the first rain water and consisting of a parallelepiped block tank of high resistance reinforced concrete to ensure zero leakage and seepage into the ground, and completely covered with driveway and manhole inspection concrete. The system will consist of:

- Storage tank capacity of 600 m^3
- Pump room: a lifting system with its electrical panel;
- Inspection chamber: to allow maintenance of the tank and the pump room;
- Abutment and finishing: To ensure the access in the surface area, inside the tank is created a concrete load-bearing wall thickness of 60 cm dividing the tank into two areas, one of these is connected to the outlet pipe in which rainwater will channel in the event of overflow;
- Pipes and supply: Departing from the plant, two types of underground piping, those destined to power the fire service and those intended for the irrigation and road surface outside the production complex. The first are powered through the pump, the latter are activated only in case of overflow, which is in case the level of water collected overflows the limits of the container. All the pipes forming part of the rainwater drainage system are in PVC, with an internal diameter of 200 mm in a way that there is not the risk of contamination by heavy metals.
- Input pipes

All of the tub is waterproofed and the materials used are shown in the project contained in the ***Annex B.3.5-A1 "rainwater reservoir system."***

The whole system can be inspected because it has a crawl space. At least once a year it will be verified the integrity, the cleanliness and the stability of the tank. All the accessories should be checked and cleaned. The procedure is summarized as follows:

- To completely empty the tank;
- To remove the residual material;
- Clean the tank and the accessories with water, disposing of it as waste;

B.3.5.1 Water washing

The water used for the cleaning equipment or cleaning of laboratory equipment and plant (except the piping and reactor) is polluted (even if minimally) from raw materials that have transited into or that have been useful to clean the tools and therefore will be managed as a waste having a European code 070701*. The washing water will come from the production department (lines and finishing unit), laboratories and the temporary storage of indoor wastes.

- Washing water from the laboratories: The laboratories need to wash their own tools for this reason, under the hood. They have a washing area. The discharge of such sinks is connected directly to the underground tank located outside the building in the vicinity of the loading/unloading of goods. The effluent from the laboratories is made up of 80% water, 15% acetone and a small amount from traces of other pollutants on the used tool;

- Washing water production department: All production lines are fitted along the walls with gutters. The production lines paving is in fact leaning toward the side walls in a way that a possible loss of liquid can flow toward the raceways, be collected and conveyed to the underground tank of collection. In this duct will end up even waters used for the paving washing of the entire production area (weighing chamber, finishing unit and production lines);

- The washing water storage tank and the waste flammable raw materials: also in this case it is possible to collect the washing water of the flooring from accidentally spilled liquids. The gathering takes place on an underground tub different than the previous two.

To accommodate these waters there are two underground tanks containment, capable of receiving the production and laboratories water, with a capacity of 25 m^3 and a parallelepiped shape, the other can receive those from the temporary storage of waste and flammable raw materials with covered capacity of 2 m^3 able to receive the spills developed in response to a fall from a forklift or by containers of raw materials and waste. This area is usually not washed unless necessary for removal of the spilled raw material.

The tank is equipped with a larger interceptor chamber so as to prevent backflows into the room connected to the tub of unpleasant odors or harmful gas. In the tub there is a change of air with a ventilation allowing to maintain high oxygen content, and further it lowers the risk of accumulation of volatile organic compounds.

Both tanks are in resin so as to prevent the leakage of the accumulated liquid.

In ***Annex B.3.5-A2*** the technical design of the washing waters collection tanks and Warranted Engineer.

B.3.6 Emission to air

For emissions is intended the set of substances in the gaseous and solid state and/or liquid particles generated by combustion processes and/or processes of production, extraction, processing and utilization, considered in a time interval and in the position where the same are released into the atmosphere. In particular, in Sterling, two large families of emissions can occur:

- concentrated emissions generated through extremely small of exhaust sections, so that they can be considered puntiform such as, for example, the emission point's terminal sections, exhaust ducts in general;
- fugitive emissions that occur within limited environments and they come out through the exhaust sections having very extended surfaces such as, for example, windows and generic warehouses openings, or outside directly generated.

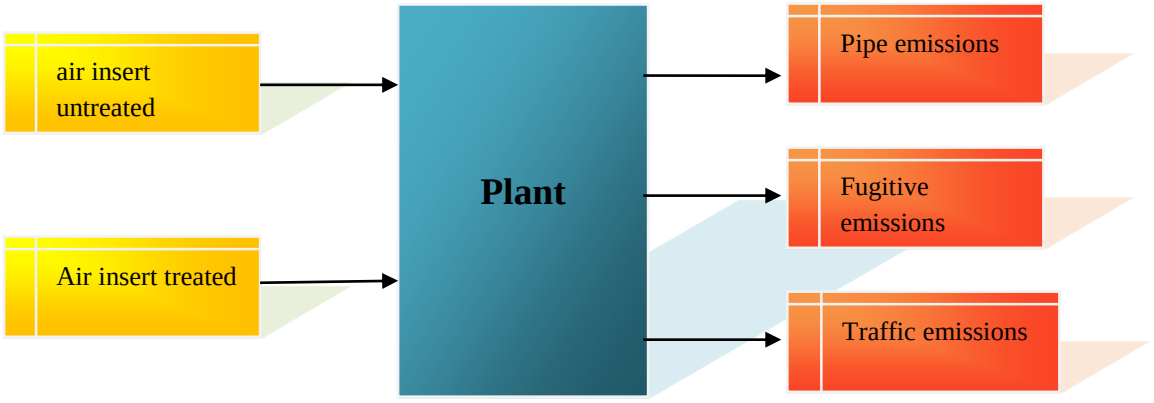
Where the concentrated emissions have waste gases released into the atmosphere through a duct characterizable in terms of size, geometry, and especially flow; they will be called as conveyed emissions and in this category are also conveyed emissions of a series of all-air Air Handling Unit whose purpose is to draw air from the outside by treating it according to the requests of temperature or relative humidity needed to create in the different working environments.

Fugitive emissions arise from a direct contact of volatile substances or light dusts with the environment, under normal operating conditions. These can be caused by:

- the intrinsic equipment characteristics (eg, filters, dryers, ...);
- the operating conditions (eg during the transfer of material from tankers);
- the type of operation (eg maintenance activities);
- gradual discharges in other environmental compartments (eg, cooling water or wastewater);
- opening of the doors at the entry/exit by the operators and raw materials/intermediates production/finished products.

Inside of the fugitive emissions there are also fugitive emissions into the environment that are resulting from a gradual loss of tightness of a part of the equipment designated to contain a fluid (gas or liquid), this is generally caused by a pressure difference and by the resulting loss. Examples of fugitive emissions include losses from a flange, a pump or a part of the equipment and losses from storage of gaseous or liquid products. Note that fugitive emissions are a subcategory of diffuse emissions.

The following diagram summarizes the flow of emissions.



Flow Chart 11 Air flows in input and output from the factory.

B.3.6.1 Piping emissions

The production plant have some channeled emissions resulting from the various activities taking place within them. Each issue will be identified by the related chimney before being expelled into the atmosphere and by an alphanumeric sequence code. In **Table 41** we summarize these emissions characterizing them according to place of origin and then to the individual assets that generate them and indicating the possible polluted that can be traced within the effluent and abatement systems chosen to capture the pollutants themselves.

Emission Code	Generation area	Process	Abatement system	Possible pollutants	Quantities of substances estimate
EM1	Production area	handling raw materials, distillation, extraction, filtration, centrifugation, dryer	Scrubber, active carbon filter, tube bundle heat exchanger, and the following filters: HEPA absolute filter H14 Rigid pocket filter EU 8 Syntetic Flat Filter EU3	Volatile Organic Compounds (VOC)	10 mg/Nm^3
	Weighing room	Handling raw materials, weighing raw materials		Powder	< 1 mg/m^3
	Finished goods area (clean rooms)	Handling raw materials, products and intermediate products		nitrogen oxide (NO_x)	50 µg/m^3
EM4	Laboratories	Handling raw materials, weighing raw materials	HEPA Filter EU13, Scrubber	Volatile Organic Compounds (VOC)	10 mg/Nm^3
				Powder	< 2 mg/m^3
				Benzene	1 µg/m^3
EM5	Steam generator	Vapour production	Not required	Particulate Matter $PM_{10}/PM_{2,5}$	10/12 µg/m^3
				Carbon monoxide	< 1 mg/m^3
				NO_x	90 µg/m^3
				CO_2	12,5 % in volume
EM6	Boiler	Hot water production	Not required	Sulfure dioxide	undetectable
				Particulate Matter $PM_{10}/PM_{2,5}$	10/12 µg/m^3
				Carbon monoxide	< 1 mg/m^3
				NO_x	90 µg/m^3
				CO_2	12,5 % in volume
EM7-EM8	Cooling tower	is a heat rejection device which rejects waste heat to the atmosphere through the cooling of a water stream to a lower temperature	Besides treating the circulating cooling water to minimize scaling and fouling, the water should be filtered to remove particulates, and also be dosed with biocides to prevent growths that could interfere with cleaning the tank every six months	Legionella	< 50 ufc/l

Table 41 Description of gaseous effluents

The main emissions point will be indicated with the alphanumeric abbreviation EM1 in which it will arrive the fumes of the process needed to accomplish the raw materials transformation to the finished wet product or to its relative intermediates. In particular, the flow lines determining the gaseous effluent's final quality are:

1. A series of catchment appendix, appropriately hooked up which forcibly aspire vapors or dusts from different strategic points of the different production lines such as loading zones in correspondence to the hatch of the various reactors or of the empty-drums pump for loading the liquid raw materials. In particular the flow lines become operational at the time of raw materials loading within the device (reactor, filter and spin). This load can be done through a dip tube connected to a fixed line through the empty- drums pump or, in the case of solid, through the hopper and the hatch opening;
2. Normal Vents of the plant i.e. valves allowing the venting of the reactors and other equipment also during the synthesis operations
3. the flow of a liquid ring vacuum pump 130 m^3 / h. The ring is made with liquid water in a closed cycle with heat exchanger cooling brine. The eventually polluted water is sent to destruction by specialized companies;
4. the delivery of a vane vacuum pump from 160 m^3 / h. This suction pump has a soda neutralizer for eventual acid vents and two traps cooled with brine at -15 ° C, to block traces of organic solvents;
5. the delivery of a piston vacuum pump 80 m^3 / h. The pump draws from a static dryer 1 m^3, and in the suction phase, it is provided with brine heat exchanger and storage tank to capture the vapors of organic solvents from the dryer.
6. Blow down system, in the event of excess of pressure inside the reactors the discs broke leaving the gas to get out and the accumulated vapors towards a collecting tank, here starts the first condensation of the material, all other vapors arrive, after the abatement system to the final emission point.

The system used is the scrubber through capturing mechanisms denominated "wet scrubber" capable of removing particles from the gas stream incorporating them in the drops of water which was subsequently separate the liquid phase from the gaseous one. The solid raw materials used are considered large and that's the reason they are easier to capture and so there is no need for any HEPA filter as for other emission points. The efficiency is very linked to the speed of the flow, but there is no clearance as happens for HEPA filters. It can be deduced only from experience. In Italy there is the same type of wet scrubber for which it is recorded an efficiency greater than 95%

The finishing area, completely sterilised because of the handling of the finished product and production intermediates, it is served by a system of emission and inputs of air. The outgoing air is conveyed to the EM1 emission point before passing to an appropriate abatement system. In that room the air is introduced from the outside, suitably filtered, thermostatically controlled at constant humidity, through fan 5500 m^3/h ensuring No. 30 air changes/h. The inlet and outlet air passes through a series of filters:

- Absolute Filter Efficiency Class 13 EU 99.99%

- Pockets Rigid Filter Class Efficiency EU 8 80/90%
- Piano Filter Class Efficiency EU 3 <60%

for the complete elimination of any dust. While as concerning the vapors, after the above mentioned filters, the gas passes from the scrubber, where Volatile Organic Compounds are captured.

The EM1 emission point conveys in the atmosphere the vapours and dust coming from extractor used in the weighing room, where are conducted raw material's sampling, weighing and fractionation operations for the production and the different laboratories.

The system consists of three levels of abatement. In the first level of abatement there will be used a pre-electrostatic dust filter having an efficiency > 95% on particles greater than 0.5 microns in diameter and 80 - 85% for smaller particles; the pre-filter installation choice will allow the cleaning of the pre-filter itself without necessarily having to intervene with other frequencies on the HEPA filter and the activated carbon filters. For finer solid particles it has been chosen an HEPA absolute filter class H14 * with ≥ 99.995% efficiency on particles with a diameter of up to 3 microns. The second level of abatement is represented by an absolute filter consisting of small folds in which the separation of the sheets is done by continuous thermoplastic yarns glued on the filtering septum. While as concerning the vapors, after the above mentioned filters, the gas passes from the scrubber, where Volatile Organic Compounds are captured.

The EM4 emission point conveys the aspirations from the hoods coming from the Quality Control and Research and Development laboratory. In this sense, it can be found in the exhaust fumes both the dust (because the weighing of solid raw materials to be analyzed occurs just below the hood) and volatile organic compounds (VOCs) through the classic operations of opening bottles containing liquids, or pouring in beckers or pipettes, chromatography map's surveys, that's why the intake system has been equipped of an absolute filter efficiency class EU13 99.9%.

The points emission EM5 and EM6 collect the fumes coming from the steam generator and from the boiler. The industrial combustion process providing power to the system is of stationary type and it consists of several sub-systems each of which is designed to optimize the energy production then the high efficiency transformation and the minimizing of the pollutants production resulting in limiting the environmental impact of the whole process. The block diagram below, outlines the operation in the pollution of the steam generator to install in Sterling. There is in fact a preparation section and a fuel supply system, a burner, a combustion chamber (the boiler) in which the thermal exchange occurs between the hot fumes and the water-vapor system that powers the turbine. These fumes are not treated, in the sense that it has been chosen to minimize the formation of traditional upstream pollutants from combustion through the choice of generator and last generation boilers able to limit the production of pollutants during the choice of fuel. In the combustion chamber and within the single burner employed. In fact:

- NOx FORMATION: In the combustion gases there are always present nitrogen oxides, mainly NO with a few percent of NO_2 even if, as components of the fuel, there are not appreciable quantities of nitrogen. Together with this presence there are three distinct mechanisms:
  - ✓ "Thermal" nitrogen production;

- ✓ Production of nitrogen fuel
- ✓ "Prompt NO" production

In the steam generator and boiler chosen the formation of these pollutants in the combustion chamber is contrasted and the success of this type of intervention is based on the ability to avoid excess air and high temperatures. For the realization of these conditions there have been used the multi-stage combustion technique (hence the double ring of fumes which characterizes both the boiler and the steam generator), which enables the recirculation of combustion gases. The technique does so in two ways: the temperature lowering in the NO thermal production area and the reduction of the partial oxygen pressure with effects on the formation of NO from fuel; in addition, the chosen burner allows to decrease the temperature of flame, adjust the inflow of oxygen and create zones within the reducing flame so as to contrast the formation of NOx from the moment of ignition of the burner itself

- FORMATION CO, PM10, PM2, COT resulting from incomplete combustion within the chamber. The high energy efficiency allows to complete the combustion that allows to have a stoichiometric ratio greater than 1;
- FORMATION CO_2: The carbon dioxide formation is closely related to the temperature and the excess of combustion air. Actually an excess of oxygen reduces the combustion quality and increases the carbon dioxide production. For this reason, it will be inserted a probe able to verify the proper supply of oxygen and prevent excess CO_2;
- BENZENE and IPA and SO_x: The first two are completely absent from the starting fuel which is the LPG, while it has a low sulfur content thus giving rise to insignificant emissions of sulphates

As noted for the steam generator is also true for the boiler and its EM6 emission point.

The point of emissions EM7 and EM8 collected on air the vapour from cooling tower allocated on roof top of the building.

The **Table 42** shows the technical characteristics of the individual geometric chimneys, bearing in mind that at the time of construction, for structural needings, some data (although not significant) can change in relation to the available space. It is anyway of minor changes that may be implemented and decided only at the time of their creation. The so identified chimneys should not change between the first and the third phase, except plant restructuring which of course will be promptly communicated at the Authority control. On the other hand, in the **Table 43** are reported in detail the technical data and pollution expected for the steam generator and the boiler, including the requirements MEPA on the form.

Code	High (m)	Sectional geometry	Diameter (mm)	Section area (m^2)	Flow rate (Nm^3/h)	Temperature max (°C)	Amount of time (h/day)
EM1	11.0	round	350	0.0961	6,000	25	24
EM4	10.0	round	500	0.196	5,000	25	12
EM5	10.0	round	300	0.07	3,600	95 ÷ 108	24
EM6	10.0	round	250	0.049	2,500	95 ÷ 108	24
EM7	10.0	round	1500	0.588	2,500	95 ÷ 108	24
EM 8	10.0	round	1500	0.588	2,500	95 ÷ 108	24

Table 42 emission point technical & geometric characteristics.

The location of all point emission shows in Annex B.3.6-A1

	Rated thermal input (kW)		Energy output		Date of manufacture (year)	Stack high (m)	Fuel type	Annual fuel consumption (Nm^3)			Energy efficiency	
	Max	Min	Max	Min				First phase	Second phase	Third phase	Max (%)	Min (%)
Steam generator	349	320	500 kg/h (vapour production)		2012	10.0	LPG	11.0	17.0	47.0	92.0	90.0
Boiler	348	318	332.7 kW	303.4 kW	2012	10.0	LPG	5.5	8.0	18.0	95.6	95.4

Table 43 Boiler and steam generator data shee

B.3.6.2 Spread out emissions

The fugitive emission's potential sources are detected in the production complex:

1. The material movement in the storage and weighing stages with outdoor rackings, and in this case the localization is limited to the only deposit; in this case the emission due to the storage phase is not only linked to the sealing of the tank/drum in which the raw materials arrive or in which are stored the industrial wastewater while for the weighing, it always occurs in the temporary storage of waste and outdoor warehouse for the flammable raw materials with racking but in a closed circuit so that the diffuse emission is limited to the opening of the empty tank/drum, at the insertion of the pump and its drive circuit which aspires and conveys in other vacuum tank/drum to be filled;

2. The material movement within the production plant: besides what already mentioned in the previous point (failing to keep proper containers) it is necessary to probe the aspect of the introduction into the reactors through the hatch of the solid raw materials, which may result in the dispersion of dust in the working environment even if small part because they are the active mobile hoods, the location of such potential fugitive emission is the plant;

3. The passage of the lifting equipment of fine particles, actually the transition takes place on the asphalt for which this item is considered negligible;

4. The maintenance work with the production of fine particles, but in the case of operations such as welding or cutting it is turned on the mobile suction able to suck those dust and trap them inside the filter

In order to limit fugitive emissions and keep them under control Sterling implements the solvent management plan (described in the next paragraph) that allows to monitor the annual emissions of VOCs including the fugitive.

B.3.9 Noise

The report on the noise is given in ***Annex B.3.9-A1*** by a competent technician.

Two types of study were performed. The first one concerns the noise produced towards the external environment (Noise survey) The second one concerns the protection of health and safety in the workplace, in this sense, an external professional has prepared a report with its sound level detection (HIA report-show in Annex B.5.1-A1). On the basis of these results it has been issued a document assessing the risk of exposure to workers in which the most noisy areas are identified as well as all the initiatives to eliminate or reduce the worker exposure.

After this initiative, Sterling has commissioned a new study (Noise & Vibration Report) that showed noise from the pump room. So, Sterling has removed two pumps and the Noise and the noise was reduced below the limit.

Currently the workers are equipped with noise devices when entering in the areas indicated by the HIA authors and into. “Document of noise risk assessment”. The specific instruction you can show in annex B.3.9-A1 at the project description consolidated.
The above-mentioned areas are shown in floor plans, and, in correspondence with the areas the PPE mode of use are also highlighted by instructions and photographs. Two of the three pumps that led to noise levels above the threshold limit have been replaced. The noise analysis, has shown that without these pumps the level has fallen below the threshold value (Noise and vibration monitoringreport –Annnex B.3.9-A1). Moreover the only room in which it was observed a high noise level does not provide for the workers presence. There will enter only in case of emergency due to the shutdown of one of the pumps. For the workers in neighboring areas, the noise monitoring has shown that there is no appreciable noise.
In annex B.3.9-A1 of the Project Description consolidated we have reporting this documents:

- The Last Noise& Vibration report, post HIA report
- The last noise report after remove the pump in external pump room
- The noise survey for external area
- Noise plant
- Noise risk assessment
- Operative instruction for the correct insertion of ear plug

B.3.10 Monitoring

This level of control and monitoring is inspired by what happens in Italy taking into accounts the main components of the environment with which interacts Sterling Chemical Ltd Malta. Below, divided by forms, the control areas:

1. Production
2. Consumption of auxiliary raw materials
3. Consumption of water resources;
4. Energy production and consumption;
5. Emissions into the water;
6. Waste production and management;
7. Emissions into the atmosphere;
8. Noise level;
9. Clearing the installation

FORM 1 Production

Each year the Sterling Chemical Malta Ltd will prepare a report on the production and will draw up a production program, in order to have the parameters on which relate the environmental impact of its activities. This is a pre-requisite form to the control activities also based on an index determining the environmental efficiency. For example, a following data is definitely the consumption of drinking water or from rain per kg of finished product or intermediate

production. This index will allow to figure out if an excess of water consumption is not expected to be attributable to the type of product, the nature of its synthesis or to the problems occurred during the processing (such as a double treatment or a double cleaning of a reactor). The following table shows the useful data that will be implemented for a comprehensive analysis of the health status of the work related to the environmental sustainability.

Product	Quantity (t)	Lot number	production time	Line production	Note

Monitoring Table 1 Production data.

FORM 2: Consumption auxiliary materials and chemicals raw material

In the Monitoring Table 2 are marked the amount of raw materials used in the production department, in the pilot plant and in the Quality Control and Research & Development laboratories. It is also marked:

- Quantity given in tonnes;
- Utilization phase;
- Storage method;
- Terms and frequency control

It also points out the following: The used measurement method is based on the warehouse's loads and discharges. In particular, all the raw materials used in the production cycle are weighed at the time of delivery to the various departments and re- weighed (rendered) at the time of taking over by the new warehouse.

Raw material	CAS Number	Type of use	Storage mode	Amount total (t)	Frequency control

Monitoring Table 2 Consumption auxiliary materials and chemicals raw material

The table will be monthly updated, to allow the leaking check if the raw materials are related to the product or to the actually generated intermediate.

FORM 3: Consumption of water resources;

The **Monitoring Table 3** has been filled out with water input and output data, taking into consideration the relevant types of flows:

- Wp - rain water;

- Wa - water withdrawn from the aqueduct and intended for exclusive industrial use (excluding water drawn from wells and/or water supply intended for domestic use, irrigation and any other non-industrial use);
- Wa, u - water withdrawn from the aqueduct and put to another non-industrial use;
- Wrin - wastewater of internal origin and recovered within the production cycle;
- W - waste discharged water;

For each of the above parameters are specified:

- The sampling point;
- The volume, in cubic meters;
- The use
- The determination method of the indicated data;
- The date of the checks
- Any notes.

The table will be weekly updated as required by the procedure on water supplies. Besides, each flow will be monitored by flowmeter. The weekly update along with the work and production program will allow to understand any losses or other destination not expected by the water flows.

Flow type	Amount total (m^3)	Type of use	Measurement methodology	Data Control	Note

Monitoring Table 3 consumption water resources.

FORM 4: Energy production and consumption;

Until the functioning of the solar panel which will replace only in a limited way the boiler for the production of the hot water, this form will take into consideration only the energy consumption developing in the site. In particular, we will identify:

- ET thermal energy consumption, in kWh;
- EE - consumption of electricity drawn from the grid, in kWh;

For each of the parameters there have been identified the following items:

- Quantity;
- Method of measurement;
- Use phase;
- Time reference;

- Recording reference;

The control frequency is weekly, while the measure is by meter reading.

Energy type	Energy consumption (kWh)	LPG consumption	Measurement methodology	Data Control	Note
ET from boiler					
ET from Steam generator					
EE					

Monitoring Table 4 Energy consumption

FORM 5: Emissions to water

The table shows the following information

- The researched pollutant
- The discharging number;
- The delivery of the final discharge;
- The sampling method
- The pollutant concentration
- The method of analysis

The plan includes an annual analysis of the water discharges into the public sewer and those overflows resulting from the washing of the roofs and yards.

The following table shows the analysis parameters to be analyzed.

Standard/parameter	Discharge point	Receptor discharge	Samples methodology	concentration of the pollutant	Measurement methodology	Data control
pH	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		APAT CNR IRSA 2060 Man 29 2003	
Conductivity	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		APAT CNR IRSA 2090 B Man 29 2003	
Total Suspende Solids	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		APAT CNR IRSA 4070 Man 29 2003	
Biological Oxygen Demand (BOD5)	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		APAT CNR IRSA 4070 Man 29 2003	
Chemical Oxygen Demand	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		APAT CNR IRSA 4070 Man 29 2003	
Total Nitrogen	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		APAT CNR IRSA 4070 Man 29 2003	
Ammoniacal Nitrogen	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		APAT CNR IRSA 4070 Man 29 2003	
Phosphorous	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		APAT CNR IRSA 4070 Man 29 2003	
Sulphite	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		APAT CNR IRSA 4070 Man 29 2003	
Total surfactants	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		MP 1403 rev 05 2005	
Aluminium	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		EPA6020A 2007	
Barium	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		EPA6020A 2007	
Borum	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		EPA6020A 2007	
Cadmium	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		EPA6020A 2007	
Chromium	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		EPA6020A 2007	

Chromium VI	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		APAT CNR IRSA 3150 C MAN 29 2003	
Ferrum	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		EPA6020A 2007	
Mercurium	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		EPA6020A 2007	
Nichel	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		EPA6020A 2007	
Copper	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		EPA6020A 2007	
Lead	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		EPA6020A 2007	
Zinc	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		EPA6020A 2007	
Total hydrocarbons	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		EPA50121A CNR IRSA 5160 A2 MAN 29 2003	
aromatic organic solvents	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		EPA50121A CNR IRSA 5160 A2 MAN 29 2003	
Escherichia coli	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		EPA50121A CNR IRSA 5160 A2 MAN 29 2003	
DAPHNIA MAGNA	Sd1, Sd2	Sewer	APAT IRSA CNR 1030		EPA50121A CNR IRSA 5160 A2 MAN 29 2003	

Monitoring Table 5 Water emissions

Form no. 6 Waste management

For every produced waste, the following information will be labeled:

- Description of the type of waste
- European Waste Code;
- Amount of waste given in tonnes;
- The processing phase in which they are produced;
- Location/storage area;
- The waste destination, in terms of re-use, recovery, recycling or disposal by landfill or treatment;

The sheet update will be monthly

Waste description	EWC	Total amount (kg)	Work phase production	Storage	Destination

Monitoring Table 6 Waste management

Form n° 7 Emissions on air

The following table shows the flow gas characterization data from the chimneys. The types of pollutants to be monitored are reported in **Table 41**

Emission point	Height stack (m)	Area (m^2)	Temperature flow (°C)	Speed flow (m^2/s)	Flow rate (Nm^3/h)	Concentration polluntant (mg/Nm^3)	Abatement measures

Monitoring Table 7 Emission on air

Form n°8 : Noise

It is proposed a two-year noise control on the external environment and within the workplace.

Measurament point	Description point	Categoria limite da verificare	Measurament method	Worker exposed	Measured value morning	Measured value night	Date monitoring

Monitoring Table 8 Noise description

Form n° 9: Clearing the installation

On annual basis, during the closure and stationary activity period, usually in August and/or December it will be made the cleaning of the system and the related auxiliary equipment In particular, in addition to the provisions of the maintenance plan there will be:

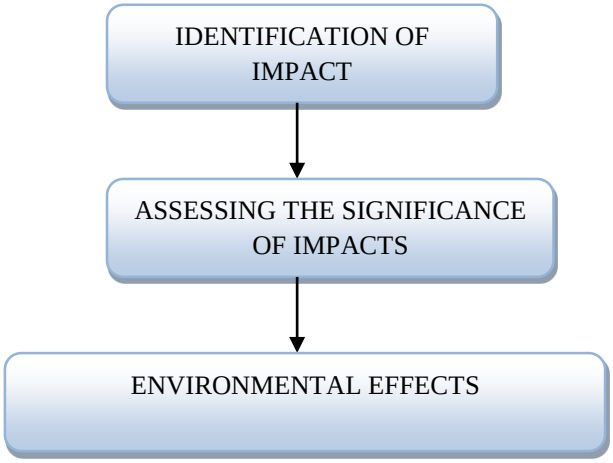
- ✓ Cleaning of underground tanks (either the ones accumulating rainwater, and those useful in the collection of the plant washing water)
- ✓ Monitoring the legionella in the points of possible development (cooling tower, air conditioning, climate control, boiler and steam generator);
- ✓ Boiler and steam generator maintenance according to the maintenance and control program and smoke test to verify the content of oxygen, carbon dioxide, etc..

B.3.11 Emissions & waste summary

Please You can see the summary description by block into **Annex B.3.11 "Emissions and Waste Summary".**

B.4 Impact on the environment

For the purposes of this text, for environmental impact, it will be considered all of the effects caused by an event, action or behavior on the environment as a whole, so not necessarily the impact has to take as a negative connotation, but even positive. The impacts arise from the activities interaction, services and products of the organization with the environment in which it is immersed and which wants to become an integral part. Here it will be examined the most significant environmental impacts that could be developed following the entry into operation of the chemical plant and the significance must be understood both in time and in space. In order to assess even semi-quantitatively these impacts, the integrated management system that the company will acquire, will have to include the MPA_4.3.1 procedure that defines the nature, the degree of the management and what really exercised at the evaluation time, what it has improved the management and finally the significance of the impact if it is manifested through the intersection of parameters such as frequency, probability of occurrence, extension and quantification of the event. Following, a schematic summary flow chart for the characterization of these interactions.



Flow Chart 12 Method of impact assessment.

B.4.1 Identification of impacts

One of the goals of this section is to identify the environmental aspects that may be associated with activities and/or products and/or services in the future of the Sterling Chemical Malta Ltd's organization, and on which it may exercise control or have some influence. Among all the environmental aspects[18] taken into consideration it will be identified on the basis of a significance criterion defined by the organization, the ones producing significant impacts on the environment, to whom it will be given the name of "significant environmental aspects".

[18] Environmental aspects: An environmental aspect is a feature or characteristic of an activity, product, or service that affects or can affect the environment

It should be emphasized that each environmental aspect associated with an activity, product or service of the organization is analyzed in three different operating conditions: in the "normal", "abnormal" and "emergency" defined as follows:

- Under normal conditions: the operation conditions of an organization scheme, or those that characterize most of the time the business, the production and the services of the organization;
- abnormal conditions: temporary conditions periodically occurring in the organization. For example, referring to a chemical plant, they are the starting conditions (start up) or maintenance shutdown; another situation involving an abnormal condition compared to the normal course of production is represented by the presence of internal yards, both in the construction and in the mechanical field;
- Emergency conditions: occurrence of not easily predictable or manageable events, even if their occurrence was simulated. For further explanation on this issue, see the procedure MPA_4.4.7.

The traced aspects were divided into direct and indirect, the direct ones are those in which the company exercises its control and management and they include:

1. emissions to air;
2. discharges into water;
3. waste reduction, recycling, reuse, transportation and disposal of solid waste and other, especially of hazardous waste;
4. use and contamination of land;
5. use of natural resources and raw materials (including energy, rainwater);
6. other local environmental changes (acustic climate, vibration, visual impact, construction sites, etc. ..);
7. issues related to the transport of goods by road and the employees;
8. risks of environmental accidents and impacts arising, or likely to result, accidents and potential emergency situations;
9. effects on biodiversity.

With regard to indirect environmental aspects, these are represented by those for whom the company does not have full management control, such as:

1. product related issues (transportation, use and recycling);
2. waste disposal delegated to third parties (including transport);
3. contractors, subcontractors and suppliers environmental behavior;
4. natural disasters (earthquakes, floods);
5. non-compliance with the health and safety standards of its employees or contractor's employees.

The following table specifies the environmental matrices of reference with the different environmental aspects to whom it is associated a numerical code, the first number defines the area of environmental reference (identified in numerical order), while the second gives a sequential order to the environmental aspect assessed for the same environmental reference area.

Serial number	Environmental matrix reference	Environmental aspect to be evaluated	Reference code
1	Air	Increase in greenhouse gas	1.1
		Increased amounts of fine dust	1.2
		Increase in gas harmful to the ozone layer and/or hazardous air pollutants	1.3
		Production of odors	1.4
		Fugitive emissions	1.5
2	Aquatic environment	Alteration of surface water quality	2.1
		Alteration quality groundwater bodies	2.2
		Water consumption	2.3
		Water discharges into sensitive receptors	2.4
		Alteration of surface and/or underground water balances	2.5
3	Soil and subsoil	Contamination for the fall of dust or other pollutants	3.1
		Soil use	3.2
		Alteration of the chemical / physical / biological properties of the soil	3.3
4	Flora and fauna	Flora and fauna alteration	4.1
		Interference with trails and wildlife migration routes	4.2
		Ecosystems and ecological networks interruption	4.3
5	Anthropic environment	Landscape impact	5.1
		Alteration of the historical / social / economic heritage	5.2
6	Acoustic climate and vibration	Changing the on site acoustic climate	6.1
		On site alteration in the vibration level	6.2
		Changing the acoustic climate in the workplace	6.3
		Alteration in the vibration level in the workplace	6.4
7	Energy resources	Electricity consumption	7.1
		Fuel consumption	7.2
		Thermal energy consumption	7.3
		On site light sources impact	7.4
8	Transport	Impact on road traffic	8.1
9	Wastes	Non-hazardous waste production	9.1
		Hhazardous waste production	9.2
10	Public health	On site ncreased acute/chronic worker's diseases	10.1
		Increased acute/chronic diseases of the surrounding areas population	10.2

Table 44 Environmental aspects of reference for Sterling installation.

The study of the interaction between the individual activities of the departments and the identified environmental aspects will create matrices or double entry tables in which there are put in relation the Sterling's operations (broken down by department) and the environmental components during the activity. At the intersection of the rows with the columns, there are the direct or indirect potential physical and socio-economic impacts, which will provide a basic information for the significance of the detected impacts or, where applicable, their negligible. On the following environmental matrices it will be also highlighted the impact conditions, ie the boundary

conditions of the system in which that particular impact may occur, therefore, these matrices have a qualitative value.

B.4.2 Assessing the significance of impacts

The importance of the environmental impacts of the Sterling Chemical Malta Ltd's various activities is evaluated by quality criteria.

Given the characteristics of the organization, the choice consists in the adoption of a semi-quantitative criterion built through matrices that define the importance of the impact through a special note with a number of benchmarks. It will adopted a methodology mainly based on the analysis of the risk that ultimately leads to the calculated estimate of the Index of Significance as the product between the Probability of occurrence (P) and the Index of Impact Effects (C), in case of studying an impact occurring in emergency conditions, otherwise the index of Significance (IS) will be given by the product of the frequency of occurrence (F) and the Index of Consequences (C).

The variable references are the following:

- the frequency of occurrence "F" (under "normal" or "abnormal" conditions) and/or the probability of occurrence "P" (under "emergency" conditions);
- the index of Effects "C";
- the environment sensitivity of the "SA" to the environmental aspect in consideration;
- the severity of the impacts "G" caused by the environmental aspect;
- the significance of the environmental aspects "S".

The first 4 parameters contribute to the definition of the environmental aspect significance.

The frequency rate (F) represents the number of times that a particular environmental aspect generated by an activity takes place over a certain time interval. In particular, the higher the frequency of environmental aspect occurrence the greater the weight with which this index will affect the significance of the environmental aspect analysed. The following table shows the weights classification associated to the different established study frequencies.

Frequency of occurrence (F) - (in Normal or Abnormal Conditions)	Less than once a year	At least once a year but less than once per month	At least once a month but less than once per week	At least once a week but less than once per day	At least once a day but less than once per hour	At least once an hour or continuously
Frequency weight assessment	0.1	0.2	0.4	0.6	0.8	1

Table 45 Frequency of impact

With regard to the index of probability, it represents the possibility that an impact can manifest itself in the future. This criterion will be adopted only in assessing the potential impacts that

would develop only in emergency conditions. In this case it is very important to refer to a limit level, possibly sets by a regulatory constraint, and therefore, the more the reference parameter qualitatively describing the impact is close to the limit set by the regulations, the higher the probability of occurrence is; below there's a table similar to the frequency one, with indication of weights in absolute associated value with the probability value and proximity to the level exceeded even of one parameter relating to that specific environmental aspect;

Proximity to the legal limit	61 %	41 ÷ 60 %	31 ÷ 40 %	21 ÷ 30	11 ÷20	≤10%
Probability of occurrence (P) - (in terms of Emergency)	Very unlikely	Unlikely but possible	Likely	Standard	Frequent	Expected and repeatable
Significance weight assessment	0.1	0.2	0.4	0.6	0.8	1

Table 46 Odds of impact

The second criterion evaluation phase of significance involves the estimation of gravity and sensitivity parameters of the surrounding environment. In particular, the measurement of the severity of a possible environmental impact assessment involves three aspects: the duration of the event that caused the impact, the space affected by the impact and the reversibility of environmental damage and the ability to handle the event by the operators. Evaluating the combination of these four elements it is possible to define the following severity scale

Numerical order	**Gravity description**	**Duration of impact**	**Reversibility of the damage**	**Impact area**	**Management capacity of the event**
1	Positive impact	Permanent		Standard	
2	The impacts caused do not have detectable effects on the environment	Immediate resolution	Yes	Radius ≤ 10 m	Very high
3	The impacts have detectable effects but insignificant and confined in space and time	≤ 10 min	Yes	Plant borders	High
4	The caused impacts have detectableand significant effects, but with limited consequences in time	≤ 1 hour	Yes	Radius ≤ 500 m	Medium
5	The caused impacts have significant effects on the environment with long-term consequences	More than one hour but less than 1 day	Yes	Radius ≤ 500 m	Medium-Low
6	The impact caused an irreversible impact on the surrounding environment	>24 h	No	Municipal borders	Low

Table 47 Seriousness index of impact

Regarding the sensitivity of the area concerning at the environmental/potential impact aspect, it will be referred to two parameters such as the spatial delimitation of the impact itself and the cumulation of the expected damage as reported in the following table.

Reference order	**Area description**	**Impact area**

1	The area surrounding the site is not man-made and has no particular need for environmental protection	Radius ≤ 10 m
2	A predominantly agricultural area with the presence of pastures and crops intended for human consumption	Plant borders
3	The area surrounding the site is man-made	Radius ≤ 500 m
4	Area with particular natural and environmental interest but not subject to any kind of constraints	Industrial area limits
5	Area subject to landscape and/or geological constraint Protected area, parks or natural reserves	Municipal borders

Table 48 District impact

Established the severity index (G) and the index of environmental sensitivity (Sa) we get the index of the consequences C defined as the product between the severity index and the environment sensitivity.

$$C = G * Sa$$

This index can also be deduced by the intersection of the reference index in the following two-dimensional matrix.

			Severity of the impacts (G)					
			Positive impact on the environment	The impacts caused do not have detectable effects on the environment	The impacts have detectable effects but insignificant and confined in space and time	The caused impacts have detectable and significant effects, but with limited consequences in time	The caused impacts have significant effects on the environment with long-term consequences	The impact caused an irreversible impact on the surrounding environment
			-1	**1**	**2**	**3**	**4**	**5**
Sensitivity of the environment (Sa)	The area surrounding the site is not man-made and has no particular need for environmental protection	**1**	-1	1	2	3	4	5
	A predominantly agricultural area with the presence of pastures and crops intended for human consumption	**2**	-2	2	4	6	8	10
	The area surrounding the site is man-made	**3**	-3	3	6	9	12	15
	Area with particular natural and environmental interest but not subject to any kind of constraints	**4**	-4	4	8	12	16	20
	Area subject to landscape and/or geological constraint Protected area, parks or natural reserves	**5**	-5	5	10	15	20	25

Table 49 Effect index of impact.

Each environmental aspect associated with the company activities is evaluated using the above criteria, in the three normal, abnormal and emergency conditions.

Estimated frequency rates (or probability depending if the impact refers to a usual routine or exceptional activity) and the consequences is it possible to estimate the index of environmental sensitivity and then judge whether an environmental aspect is significant or not. This index is given by the product of the frequency and consequences:

IS=F*C (for normal or abnormal conditions)

IS=P*C (for emergency conditions)

And to the found value corresponds a box of the color matrix of reference quoted below:

		F o P					
		0.1	0.2	0.4	0.6	0.8	1.0
C	-5	-0.5	-1	-2	-3	-4	-5
	-4	-0.4	-0.8	-1.6	-2.4	-3.2	-4
	-3	-0.3	-0.6	-1.2	-1.8	-2.4	-3
	-2	-0.2	-0.4	-0.8	-1.2	-1.6	-2
	-1	-0.1	-0.2	-0.4	-0.6	-0.8	-1
	1	0.1	0.2	0.4	0.6	0.8	1
	2	0.2	0.4	0.8	1.2	1.6	2
	3	0.3	0.6	1.2	1.8	2.4	3
	4	0.4	0.8	1.6	2.4	3.2	4
	5	0.5	1	2	3	4	5
	6	0.6	1.2	2.4	3,6	4.8	6
	8	0.8	1.6	3.2	4.8	6.4	8
	9	0.9	1.8	3.6	5.4	7.2	9
	10	1	2	4	6	8	10
	12	1.2	2.4	4.8	7.2	9.6	12
	15	1.5	3	6	9	12	15
	16	1.6	3.2	6.4	9.6	12.8	16
	20	2	4	8	12	16	20
	25	2.5	5	10	15	20	25

Table 50 Identity matrix of impact

This two-dimensional matrix provides values ranging from - 5.0 to 25.0 and at different ranges is associated a different color for assessing the significance of the impact according to the following legend:

S < 0	positive environmental impact
0 < S < 4	Non-significant environmental impact
4 ≤ S ≤ 10	significant environmental impact
S > 10	Severity environmental impact

Table 51 Severity of the impact.

The value of the index of significance (IS), will define whether the presumed impact will be positive, non-significant, significant or critical.

The table shows the final matrix. This matrix is only of estimates as it is based on the Italian experience, on the nature of abatement and treatment of emissions and water discharges. In addition, a more exhaustive environmental impacts are exhaustively treated in the EIS attached to the documentation.

Mark	Environmental sector	landmark	environmental aspect to be evaluated	Severity index	Comments
1	air	1.01	Increase in greenhouse gas	2.4	The production of heat using the LPG certainly cause the release into the air of an amount of CO2 equal to about , also even if the efficiency yield is very high there could be no trace in the flue gases of fireplaces E5 and E6 CO. The modest size of the boiler and the steam generator, their high combustion efficiency allow to consider this impact not relevant and in any case below the limits imposed by the legislation. A similar story for harmful gases such as NOx, SOx (almost absent for the type of fuel used) and VOCs, which should be added, however, especially in the category of VOC traces of pollutants from the flue and production laboratories (the main found solvents are acetone, methanol and toluene). However arising from the Italian experience, the VOCs from the production activity are an average of 10 mg / NMCS. The adopted abatement systems for this solvent retention, in Italy have guaranteed the maintenance of such emission limits for dust
		1.02	Increased amounts of fine dust	0.6	
		1.03	Increase in gas harmful to the ozone layer and/or hazardous air pollutants	2.4	
		1.04	Production of odors	0.6	
		1.05	Fugitive emissions	1.8	
2	Water	2.01	Alteration of surface water quality	-1	There are water discharges into surface waters or in the underground ones
		2.02	Alteration quality groundwater bodies	-1	
		2.03	Water consumption	1.2	The expected water consumption ranges from a minimum of approximately 850 cubic meters to a maximum (in the third stage) of about 3,000 cubic meters. This water cannot be derived from rainwater because it does not respond to the international standards of quality
		2.04	Water discharges into sensitive receptors	0.4	The discharge water for wastewaters similar to those urban and domestic, occurs in public sewers, on the road surface will instead be collettated overflow rainwater, ie those that exceed the capacity of the collection of the underground tank
		2.05	Alteration of surface and/or underground water balances	0.6	The company does not draw directly from groundwater resources and recovers where possible according to the law units of the rainwater. The alteration of the water balance for the water supply is not significant
		2.06	Contamination for the fall of dust or other pollutants	3.6	The fall of pollutants released into the air, if not controlled can cause an impact in the long run. It is the most significant value found in the table.
3	land	3.01	Soil use	0.6	The soil use, complies with the use intended by the Planning Authority
		3.02	Alteration of the chemical / physical / biological properties of the soil	3.6	The fall of pollutants released into the air if not controlled can cause an impact in the long run. It is the most significant value found in the table.
4	Flora and fauna	4.01	Flora and fauna alteration	0.1	The area does not have a particular interesting flora, while the fauna does not change its nature. The company is located in an already solid and advanced industrial context
		4.02	Interference with trails and wildlife migration routes	0.4	The company is located in an industrial area already indented in which it is already highlighted the existence of an ecological discontinuity caused by other company presence. In a developing industrial context and with strong connotations of industrial area the limited surface does not cause interference with the birds migration routes. For a more complete study see the EIS and related technical studies carried out by professionals.
		4.03	Ecosystems and ecological networks interruption	0.4	

5	anthropic environment	5.01	Landscape impact	0.4	The plant is located in an industrial area with significant aesthetic qualities. It is not considered a foreign environment
		5.02	Alteration of the historical / social / economic heritage	0.4	Please refer to the opinion expressed by the professional contacted for the EIS implementation
6	Noise	6.01	Changing the on site acoustic climate	0.4	Please refer to the acoustic technician analysis who has been entrusted with the compilation of the B.3.9 Noise paragraph
		6.02	On site alteration in the vibration level	0.4	
		6.03	Changing the acoustic climate in the workplace	0.4	
		6.04	Alteration in the vibration level in the workplace	0.4	
7	Energy	7.01	Electricity consumption	3.2	The energy consumption is essential for the activity. Sterling has decided to use a renewable source such as heat for hot water supply even and this allows a reduction of the minimum needs of the company.
		7.02	Fuel consumption	2.4	
		7.03	Thermal energy consumption	3.2	
		7.04	On site light sources impact	0.1	In the property it is encountered only three luminous spots consisting of external headlights to illuminate the external cargo handling place. This lighting is essential to ensure the safety of movement by operators working the second and third shift. Furthermore such lights project downwards the light beam.
8	Transport	8.01	Impact on road traffic	0.4	The impact on road traffic is extremely limited considering only 8 vehicles per day direct to the company. An extremely small rate if conceived for an activity in an industrial area
9	waste	9.02	Non-hazardous waste production	6	The waste aspect is certainly the most delicate and potentially impacting the environment. For the island certainly significant impact is given by the waste remaining on the island itself because directed to landfill or incineration, while all hazardous waste are exported to Italy and disposed in specially authorized companies
		9.01	Hazardous waste production	5	
10	Health	10.01	On site increased acute/chronic worker's diseases	1.8	The conditions for operators working in website comes from
		10.02	Increased acute/chronic diseases of the surrounding areas population	2.4	The acute and chronic diseases can develop only in case of a major accident (explosion and fire) with the release of air pollutants such as dioxins and furans. In Italy this has never happened and also the maximum in raw material's storage that can enter these elements in the air are below the thresholds established by the Seveso Law

Table 52 Matrix of synthetic evaluation of potential environmental impacts

B.4.3 Environmental effects

The possible impacts will be assessed for the various environmental areas (air, water, soil, energy, waste, etc. ..). The pollution effects are related both to the pollutant itself and to the environmental field initially hosting it. From the identification table and the significance qualitative assessment are mainly detected four episodes determining potential environmental impact. The first one occurs in abnormal operating conditions, the second under emergency conditions, the third one under abnormal conditions, the fourth under normal operating conditions.

- In case of uncontrolled losses, this can happen in case of lack of supervision, maintenance and cleaning of boilers or for clogging and abatement malfunction associated with the production plant; in this case, the pollution is limited to certain compounds:
  - ✓ Volatile Organic Compounds (methanol, acetone, toluene, tetrahydrofurane, dichloromethane);
  - ✓ Dust (either from particulate matter PM2 ePM10 and chemical elements);
  - ✓ NO_x;
  - ✓ Carbon Monoxide;
  - ✓ Benzene.

But most of all the interested sector is only the air one, except for dust whose quantities are extremely small and can fall back into the aquatic environment due to rain; those are the abnormal operating conditions.

- In case of fire or explosion within the plant production, in the boiler room or in the storage warehouses, in addition to volatile organic compounds there will be a release on the environment of other polluting elements, first of all dioxins with which refers to a group of 120 particularly stable and persistent polychlorinated aromatic compounds in the environment, toxic to humans, animals and the environment itself. The dioxins are semi-volatile substances, thermally stable, slightly polar, water-insoluble, highly soluble, highly resistant to chemical and biological degradation. In the soil they bind to the organic fraction and, once adsorbed (or "bound" and concentrated on a surface, represented, for example, from the solid phase of the soil), they remain relatively motionless: because of their insolubility in water they do not tend to migrate in depth. What exposed it would evidently show up as a result of an emergency condition;
- In case of accident at work, for example, the breaking of the raw materials or the waste during the transport. In this case it is also difficult to assess the extent of pollution because it is closely related to the amount of the spilled pollutant and especially where the accident occurred (for example, in the company, or during the transport of the product), and then the possible interested environmental matrices. This is an abnormal circumstance;

- The production of waste: this is clearly a constant activity over time both as regards the undifferentiated non-hazardous and hazardous waste. Even if, while the first environmental pollution is linked to an efficiency qualitative part of the destination place (or landfill disposal), the second case is linked both to an efficient recovering system and waste cleaning and to an emergency condition such as a road or maritime accident resulting in spillage of the load.

B.4.3.1 Pollution by work

From the summary table emerges how the most significant environmental impacts are related to the production of waste and emissions into the atmosphere, although in the latter case it is always contained within the legal limits

The release of pollutants into the air, beyond the limits established by national and European environmental effects may contribute to the following:

Photochemical pollution: The photochemical pollutionis constituted by a mixture of pollutants whose main component is the ozone formed in the lower atmosphere usually in the hot season. The formation of ozone and other pollutants composing the photochemical pollution occurs, thanks to the solar radiation, starting from the nitrogen oxidesand volatile organic compounds emitted from vehicular traffic from the heating (boiler + steam generator) and the plant manufacturing, and other sources as the pollutant cloud is transported by the wind, so that the affected areas may have dimensions of hundreds and even thousands of kilometres: the photochemical pollution can typically be a long-distance transboundary air pollution phenomenon.

Eutrophication: Eutrophication is the excessive enrichment of nutrients in the water and soil. The ground deposition of nitrogen promotes the growth of forests as nitrogen is a nutrient, but at the same time leads to the destruction of many ecosystems both on land and in the sea, with the result of depleting the biodiversity. In a freshwater environments eutrophication is almost always originated by the presence of phosphates, as the phosphorus is typically the organic substance which limits the growth of vegetable organisms in freshwater. On the ground and in the sea, however, in most cases, nitrogen is the limiting factor. Consequently, the deposition of nitrogen - which originates from the emissions of nitrogen oxides and ammonia - in these contexts acts as a fertilizer. All of this helps some plant species that can easily use nitrogen in excess, but generally happens at the expense of other species. The impoverishment of ecosystems due to nitrogen deposition is a very serious problem in much of Europe. Because of the damage due to eutrophication, which originate from the issue of air pollutants that often travel thousands of kilometres before being deposited on the ground or on the water, in Geneva in 1979, 34 countries and the European Community signed the Convention on long-range transboundary air Pollution.

Acidification: Since the 50s in Europe, there has been a gradual increase in acidity of precipitation, causing damage to the ecosystems in soil and water. The main cause of this phenomenon is the emission of sulfur oxides into the atmosphere. Along with other air pollutants in the atmosphere these contaminants can move up to several thousands of

kilometers before being deposited on the ground and damaging the environment. When the soil is acidified due to the acidifying pollutants deposition, easily loses the nutrients contained in it since these are more readily soluble in water and therefore tend to migrate into the deeper layers, where they are no longer useful for the nourishment of plants. In addition, the soil acidification helps the release of metals that can damage the microorganisms responsible for important and useful decomposition processes, as well as through the food chain may extend to the birds and mammals, including humans. The groups most sensitive to acidification are fish, lichens, mosses, some type of mushrooms and small aquatic organisms. Surveys conducted on forests in all Europe show that about a quarter of the trees examined is damaged. This damage to forests has many causes, but most experts agree that the acidification of soil and high concentrations of ozone in the air are important factors that contribute to the damage of forests.

The type of pollution (considered over extended periods of time) has a cross-border effects on those above mentioned .

In the **Table 53** are synthetically associated the environmental effects at the pollutant reported in the flue gas and for each pollutant and its potential effect on human health

Pollutant	Description	Source	Effects on the environment	Effects on human health
VOC	Volatile organic compounds (VOC) is a very large class of organic substances that includes both hydrocarbons (formed only from carbon atoms and hydrogen) and compounds containing oxygen, chlorine, and other elements. VOCs are emitted as a gas from solid or liquid products, and they include a large number of chemicals, some of which may have adverse effects on health.	Production line, laboratories, steam generator, boiler	Photochemical pollution:	Irritation of eyes, nose, throat, headache, loss of coordination, nausea, damage to liver, kidney and central nervous system. Some organic compounds can cause cancer in animals, and some are suspected of causing cancer in humans, and for certain it is certainty. The symptoms associated with exposure to VOCs include conjunctival irritation, nose and throat discomfort, allergic skin reactions, wheezing, vomiting, epistaxis, fatigue, dizziness. The ability of VOCs to cause adverse health effects varies a lot, from compounds that are highly toxic to those for which there is no known adverse effect. As with other pollutants, the extent and nature of the effect depends on a number of factors including the level and exposure time.
CO	is a colorless, odorless, flammable, and very toxic gas. It is formed during the combustion of the organic substances, when they are incomplete for lack of air (ie, lack of oxygen). The emission main cause is the complete lack of combustion inside the rooms of the steam generator or boiler.	Steam Generator, boiler, traffic	Negligibles	The environmental effects are considered negligible, while the effects on humans are particularly dangerous. Its danger is due to the formation with the hemoglobin of the blood of a physiologically inactive compound, the carboxyhemoglobin, which prevents tissue oxygenation. At low concentrations causes headaches, diffuse weakness, dizziness, at higher concentrations can result in lethal outcomes. The carbon monoxide must be considered primary pollutant because of its long residence time in the atmosphere, which can reach six months. The environmental effects are

				considered negligible, while the effects on humans are particularly dangerous. This pollutant, focusing on the ground, is a very serious threat to children as well as adults suffering from anemia, also threatens the development of the fetus and aggravates cardiovascular disease. The toxicity is proportional to the concentration and time of exposure.
NO_x;	For nitrogen oxides (NOx) generally includes a mixture of nitrogen oxide (NO, also called nitrogen monoxide) and nitrogen dioxide (NO2). Both these compounds are formed by gases originated and emitted into the atmosphere during combustion processes typically 90-95% of NOx emitted during a combustion process is constituted by NO, the remaining from NO2. The nitrogen monoxide (NO) is a colorless gas, on contact with the air turns into nitrogen dioxide. Nitrogen dioxide (NO2) is a reddish-brown gas smell irritating for which there are limits on concentrations in air to protect human health.	Production line, laboratories, steam generator, boiler	Acidification, eutrophication, photochemical pollution	With regard to the effects on human health, nitrogen oxides are potentially hazardous to the health. In particular, the nitrogen monoxide (NO), similarly to carbon monoxide, acts on hemoglobin, fixing at it with methaemoglobin and nitrosometaemoglobina formation This process interferes with the normal oxygenation of the tissues by the blood, but despite this, there have never been reports of deaths due to poisoning by NO. The nitrogen dioxide is more dangerous to human health, with a toxicity four times greater than the nitrogen monoxide. Strong oxidant and irritant, the nitrogen dioxide exerts its toxic effect mainly on the eyes, mucous membranes and lungs. In particular, this gas is responsible for specific respiratory system's diseases (bronchitis, allergies, irritation, pulmonary edema which may also lead to death). Those most at risk are those most sensitive to the toxic action, such as children and asthmatics. Nitrogen oxides can be considered among the most critical air pollutants, not only because nitrogen dioxide in particular has negative effects on health, but also because, in bright sunlight, provoke secondary photochemical reactions that

				create other pollutants ("photochemical pollution"): in particular, it is a precursor to ground-level ozone and fine particles of the abutment.
$PM_{2,5}$ PM_{10}	The particulate matter (PM) is constituted by a set of very small particles (solid or liquid) dispersed in the atmosphere. The particles are classified according to their characteristic size: fine particles, also known as PM10 includes all particles as small as 10 micrometers in diameter (1 micron is one-millionth of a meter) and PM2.5 includes all "fine" particles with a diameter up to 2.5 micrometers.	Production line, laboratories, steam generator, boiler	Eutrophication:	The long-term exposure, such as that suffered by those who live for many years in areas with high concentration of dust, it has been associated with effects such as respiratory function's reduction, the development of chronic bronchitis and even premature death. The short-term exposure (from few hours to a few days) it can cause pre-existing lung disorders, cause asthma attacks and worsen bronchitis and also there is an increased on the susceptibility of respiratory infections. In patients with heart disease, the short-term exposure to fine particles can cause arrhythmia or heart attack.

Table 53 Summary of the effects on human health of pollutants potentially released into air

As concerning the waste matter from the point of view of emission in the atmosphere of gases responsible for climate change, the landfills result hazardous if the waste is not pre-differentiated (as unfortunately it often happens). It is scientifically proven that the waste in landfills cause high emissions of CH_4 and CO_2, two very active greenhouse gases; a modern landfill is responsible for ensuring the presence of capturing systems of these gases (especially methane, which can be used rather than dispersed into the atmosphere). Another source of pollution, but this time for soil and water it is definitely made up of percolate formed as a result of contamination of rainwater with inert or urban waste. In this case, the toxic substances can move into the food chain. If the harmful chemicals released by the process of decomposition of the waste reaches the aquifer and this is under control, there should be no problems, because in that case it would be enough to block their use. The problem comes, however, when the water is not monitored because, the continous use, could spread various diseases: the bacterial-viral chemical intoxications. For this reason it has been given a higher weight in the production of inert or urban non-hazardous waste meaning those undifferentiated ones. The solution, in addition to the intensify of the recycling, it will consist on producing least wastes.

As for special hazardous waste they may seriously impact on the environment only in the event of an accident during the transport of hazardous waste abroad. In this case, the incident may concern:

- The soil and subsoil (including ground water) if the accident occurs during the transport by road;
- The sea, in the event that the incident occurs during the sea transport.

The resulting effect is of course closely linked to the type of poured pollutant. For this reason it is necessary to always refer to safety data sheets accompanying the goods.

B.4.3.2 Pollution by Fire

The main pollutants released into the environment following a fire, are dioxins and furans. In particular, in addition to those already specified it is necessary to remember that despite being poorly water-soluble, in water they find an excellent way to spread once adsorbed on the mineral and organic particles present in the suspension. The above mentioned physico-chemical characteristics, make these substances easily transportable by air currents, and, to a lesser extent, from the rivers and ocean currents, thus making possible the contamination of places far from the emission sources. Because of their ubiquitous presence in the environment, persistence and fat solubility, the dioxins tend, over time, to be accumulated in living organisms, which means they accumulate in the tissues and organs of humans and animals. In addition, rising in the food chain, the concentration of these substances may be increased (biomagnification[19]), leading to a higher risk exposing the top of the chain.

[19] Biological magnification often refers to the process whereby certain substances such as pesticides or heavy metals move up the food chain, work their way into rivers or lakes, and are eaten by aquatic organisms such as fish, which in turn are eaten by large birds, animals or humans. The substances become concentrated in tissues or internal organs as they move up the chain. Bioaccumulants are substances that increase in concentration in living organisms as they take in **contaminated air, water, or food** because the substances are very slowly metabolized or excreted.

On the basis of the so far available knowledge, the primary mechanism of entry of dioxins in the terrestrial food chain, would seem to be the atmospheric deposition in the vapor phase on the leaves of the plants and, partially on the ground and subsequently ingested by animals. Dioxins are substances accumulated in the organism's fatty tissues so if contaminated grass and soil are ingested by herbivores there is an accumulation of these substances in their meat fats and in milk fat products. The entry of dioxins in aquatic food chain occurs, especially, by the particulate matter (wet and dry deposition, erosion, drainage, etc..) transferred to the aquatic environment. The dioxin's lipophilic nature (similar to fat) and their low solubility in water means that they are adsorbed to organic compounds bioaccumulated in aquatic organisms with different modes of taking. The intake of dioxins by aquatic organisms occurs through the bioconcentration of the water and the transfer into trophic networks. The amount of dioxins bioaccumulated by these organisms strongly depends, besides the concentration of dioxins in the aquatic environment, to the percentage of fat content in the organism.

Sterling Chemical Malta Ltd can release dioxins into the atmosphere only in the event of fire and due to the presence during this fire of some raw materials containing chlorine. In the atmosphere they can be transported for long distances, but the consequences occur when these major pollutants leave the atmosphere and lay on the soil, vegetation and water through wet and dry deposition mechanisms. In the case of wet deposition, the dioxins may impact soil, water bodies and vegetation in two ways: either dissolving in precipitation or they are associated with particulate matter removed by precipitation. The wet deposition is the primary mechanism through which the small particulates is removed from the atmosphere. In conclusion the dioxins are physically removed from the atmosphere by:

- ✓ wet deposition (removal by precipitation);
- ✓ dry deposition of particulates (gravitational fall of the particles), and finally dry deposition of the vapor phase (absorption of these substances in the vapor phase by vegetation).

The terrestrial environment can receive environmental pollutants through different pathways, the most important are:

- ✓ atmospheric deposition;
- ✓ spreading sludge and compost;
- ✓ spreading of sediments from flooding;
- ✓ erosion from nearby contaminated areas.

Dioxin in the soil, for example, shows no significant mobility as it is adsorbed by the organic carbon of the soil itself; once adsorbed, it remains relatively immobile and because of the low solubility in water it shows no tendency to migrate in depth. The most likely way of escape on the surface of moist soil is the volatilization, while the adsorption may attenuate this process. The persistence of dioxin in the superficial layers of the soil is estimated with a half-life equal to 9-15 years, while the estimated half-life for the deeper layers is 25-100 years

(HSDB). The soils are, therefore, natural receptors for dioxins and, due to the limited removal and the long period of half-life, they represent a typical matrix buncher.

The aquatic environment can receive dioxins through:

- ✓ atmospheric deposition;
- ✓ introduction of industrial waste,
- ✓ wash-out of contaminated soils.

Once released into water bodies, dioxins can evaporate and then go back into the atmosphere, or it can be adsorbed to the sediments or bioaccumulated in the organisms. Dioxins are poorly water-soluble molecules, but they are excellent in water via diffusion once adsorbed on the mineral and organic particles that are suspended on it.

The absorption of organic compounds by plants is controlled by several factors:

- ✓ physico-chemical properties of the compound (water solubility, vapor pressure, octanol-water25, molecular weight);
- ✓ environmental factors (temperature, organic carbon content in the soil, water content in the soil);
- ✓ characteristics of the plants.

Plants may be contaminated by pollutants through three mechanisms:

- ✓ radical absorption (transfer of the pollutant from the soil to the high part of the plant through the absorption by the roots);
- ✓ volatilization from the soil;
- ✓ atmospheric deposition (directly on the leaves).

In regards to the effects on humans as the top of the food chain, it is exposed to the consequences arising from the presence of dioxins in the environment even in low or very low concentrations. Following, a summary of the most well-known effects of these contaminants on the body, highlighting that it is mainly matter of diseases resulting from acute exposures typical of accidents and/or occupational exposures. It should also be noted that, in some cases, the cause-effect relationship between exposure to contamination and effects on the body is not been fully established. Historically, the chloracne has been the first clinical and pathological expression linked to exposure to dioxins. It was reported as occasional illness among workers engaged in the production of pesticides in the early '30s, and between workers of the plant for the synthesis of polychlorinated biphenyls (PCBs). The disease shows up with rashes and pustules similar to those of juvenile acne, but with possible localization extended to the entire body surface and protracted manifestations, in severe cases for several years. Studies in animals and humans show the alterations in the immune system induced by dioxins even at doses much limitate. These changes consist in the reduction and damage of the lymphocytes population (cells that play an important role in the body's defenses and other infectious microorganisms). Other studies show how the dioxin's action can be especially harmful during

fetal development, at the time of the tissue differentiation of the immune system, resulting in the long term alterations, both in the immuno-suppressive sense and hyper-sensitization. Other important dioxin's effects are found at the level of the endocrine system; these contaminants are in fact classified as endocrine modulators, a term that means "an exogenous agent that interferes with the production, release, transport, metabolism, binding, action or elimination of natural hormones in the body responsible for maintaining homeostasis (a situation that allows you to keep in a state of dynamic biochemical balance the living conditions of the internal environment of the body) and the regulation of the reproductive processes and development. In the fetuses exposed to a concentrations of dioxins equal to or slightly higher than the basic values in utero, there have been found effects on the development of the nervous system and the neurobiology of the behavior, as well as effects on the thyroid hormone. In addition to the bio-accumulate, they were observed toxic effects, both chronic and acute, generally consisting of a reduction in fertility, growth defects, immunotoxicity and carcinogenicity in specimens of wild animals exposed to dioxins in their environment. However, outside the laboratory it is often impossible to demonstrate a clear cause/effect relationship between the exposure to the dioxins and the observed phenomena. Studies on the early life stages (eggs, embryos, larval stages) show that the majority of species are sensitive to dioxins, as these chemicals act on a number of systems which are important for growth and development, including the metabolism of vitamin A and the sex hormones.

The possibility that this may produce an impact of this kind is extremely limited, as it is testified by the fact that the company does not fall under the Seveso law, and therefore it is not considered at risk of a major accident.

Pollution and its effects have a transboundary nature.

B.4.3.3 Pollution incident by working

The accident at work is tied up to the spill into water or raw material's soil. In this case, the effects on the environment are related to the type and quantity of the spilled product, as well as the transboundary damage should be assessed in relation to the place where the incident has developed. For small accidents inside the company it is possible to exclude the cross-border nature of the impact concerning the small entities of raw material, more complex is what related to the transport of raw materials and waste from abroad to the island and from the island to Italy.

B.5 Environmental Statements

The Environmental Impact Statement is in **annex B.5.1.**

B.7 Planning Status

The Sterling Chemical Malta Ltd has the following permissions.

Sterling Chemical Malta Permission		
Authority	***Reference Document***	***Scope***
MEPA	PA/04236/08	Full Development Permission
MEPA	Minor Amendment to Permission PA/04236/08	Extension External Flammable Warehouse
MEPA	TRK: 148537	Preparation of an environmental impact statement
MEPA-Environment Protection Directorate	TRK 148537 (EA 00057/12)	Report on Environmental Impact Statement (EIS)
Water Corporation	DMU 6745	Public Sewer Discharge Permit
MEPA	PA/03033/12	Installation of LPG bulk storage in a facility/factory already covered by permit PA/04236/08
Malta Financial Services Authority	C3250B/6 date 9th Febbruary 2006	Certificate of Registration of a Limited Liability Company
Medicines Authority	MT/0119HM/2013	Certificate of GMP compliance of a manufacturer

Table 54 Planning status: all permit for development activity.

Copy of all permit shows in annex B.7.1-A1

B.8 Technically competent person

In Italy, the technically responsible person for the issuing of environmental permits is not attributed by regulations, as the permissions are managed and monitored by the appropriate department headed by a manager, while the IPPC authorization is issued to the company. However, Sterling is aligned to the international standards on the Good Manufacturing of the product and for this reason it is necessary a Technical Director who assumes, among other activities, the supervision of the entire production process in order to ensure the best hygiene conditions. The Technical Director then, has a competence not only in terms of Quality Assurance, Quality Control, but also in production processes and systems so as to obtain all the necessary information in order to ensure the production of active pharmaceutical ingredients in compliance with good manufacturing practice.

In order to try to align in a single figure what it is required, it is necessary an ad hoc training by the Italian head of each department as well as the Technical Director. It was decided, therefore, to propose the role of Technique Competent Person to the current Technical Director ad interim of the factory in Italy, thanks to its expertise in manufacturing processes, knowledge of the operation of the plant but also because in Italy he held the position of Head of Environmental Management System within the integrated Management System environment, Health and Safety and he is therefore informed about the administrative procedures pertaining to the Environment and Security interesting the Maltese plant.

During this period (6 months), the Technical Director will be responsible to train and coordinate the formation of a new resource that will assume the status of Technically Competent Person. Such person shall be hired from Sterling Chemical Malta Ltd, and will constantly remain in the company.

B.8.1 Relevant offences

Below is a list of management.

Tecnically competent person	
Full Name	Sara Farnesi
Position	Qualified Person
	Environmental Management Rapresentative
Date of employement	02/11/2004
Mobile Number	+393382951452

Soil Director	
Full Name	Simone Ferlin
Position	Soil Director
Date of employement	01/01/2000
Mobile Number	+393289096199

Company secretary	
Full Name	Olga Urazova
Position	Sales Manager
Date of employement	01/09/2003
Mobile Number	+393386003992

In annex **B.8.1-A1 Police conduct of relevant** persons and into annex **B.8.1-A2 their curriculum vitae.**

B.9 Expenditure plan

The Environmental Monitoring Plan includes a number of control activities on the various "environmental elements" aimed at verifying compliance operation of the system. This plan is based on a model of organization that emphasizes flexibility, so that it can be subject to changes both on the basis of specific instructions from the control of local authorities, and to face the potentially critical unpredictable situations.
The objectives of the environmental monitoring plan are:

- Acquiring data to document the evolution of the environmental situation in relation to the plant operation.
- To check the plant estimate impact during the year.

- Verify during the operating phase the effectiveness of abatement adopted in order to take action to settle any residual impacts.
- Ensure, during the operating phase, the control of the environmental situation in order to promptly detect any unforeseen situations and to provide the necessary corrective actions. Provide to MEPA all the necessary information in case of inspections, checks or complaints from neighbors or other exercises of the civilian population.

The following table pertains the nature of the monitoring (grouped by sector), the number of planned inspections, the points of monitored emission/discharge and the allocated costs for the environmental monitoring.

Type of monitoring	Monitored pollutant	Number of inspections per year	Checked items	Type of monitoring
Emission to air	CO, NO_x, SO_x, $PM_{2,5}$,PM_{10}, COV, CO_2	2	EM5, EM6	Emission to air
	NO_x $PM_{2,5}$,PM_{10}, COV	2	EM1 , EM4, EM7,EM8	
Ambient monitoring	COV, Acetone, Methanol, Dychloromethane	1	Production lines (3), finishing area (2) laboratories (2) warehouses (2)	Ambient monitoring
Sewer discharge	As from Monitoring Table 5 in the form B	2	Sd1, Sd2, cleaning drainage systems	Sewer discharge
Monitoring of water quality[20]	Legionella	1	Points for hot water	Monitoring of water quality21
Noise & Vibration[22]	Noise	0.5	Points of higher noise making	Noise & Vibration23
Clearing installation[24]	Cleanliness and efficiency	1	Cleanliness of supply pipelines of all utilities, underground-shine tubs, cleaning of boiler and steam generator	Clearing installation[25]

Table 55 Analisi dei costi del piano di monitoraggio ambientale

[20] The inspection points are the drinking water's points of supply (toilet, steam generator, boiler, cooling tower);
21 The inspection points are the drinking water's points of supply (toilet, steam generator, boiler, cooling tower);
[22] The noise will be measured in the most sensitive workplaces like the 3 production lines, the boiler room, the area in which there are placed chillers and laboratories.
23 The noise will be measured in the most sensitive workplaces like the 3 production lines, the boiler room, the area in which there are placed chillers and laboratories.

[24] For control points are intended all the underground tanks, boiler, steam generator, clean lines of the gas and steam supply, drinking water and the fire escape.
[25] For control points are intended all the underground tanks, boiler, steam generator, clean lines of the gas and steam supply, drinking water and the fire escape.

B.10 Glossary

Abbreviations	Meaning	paragraph reference of IPPC report
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road	B.3.2.1.3 Handling, collection and transportation of waste
PVC	Poly(vinyl chloride),is the third-most widely produced plastic, after polyethylene and polypropylene	B.3.3 Emissions to sewer and B.3.5 Rainwater
CAV	vibrated reinforced concrete elements.	B.3.3 Emissions to sewer
HEPA	High-efficiency particulate absorption, is a type of air filter	B.3.6.1 Piping emissions
VOC	Volatile organic compounds (VOCs) are organic chemicals that have a high vapor pressure at ordinary room temperature.	B.3.6.1 Piping emissions
NOx	NOx is a generic term for mono-nitrogen oxides NO and N_2O (nitric oxide and nitrogen dioxide). They are produced from the reaction of nitrogen and oxygen gases in the air during combustion, especially at high temperatures.	B.3.6.1 Piping emissions
CO_2	Carbon dioxide	B.3.6.1 Piping emissions
PM10, PM2.5	Particulate matter concentrations refer to fine suspended particulates less than 10 microns in diameter (PM10) and 2.5 microns in diameter	B.3.6.1 Piping emissions
HSDB	Hazardous Substances Data Bank: is a toxicology data file on the National Library of Medicine's (NLM) Toxicology Data Network (TOXNET®). It focuses on the toxicology of potentially hazardous chemicals.	B.4.3.2 Pollution by Fire
Seveso law	Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances (as amended) is a European Union law aimed at improving the safety of sites containing large quantities of dangerous substances. It is also known as the Seveso II Directive, after the Seveso disaster. It replaced the Seveso Directive and was in turn modified by the Seveso III directive (2012/18/EU)	B.4.3.2 Pollution by Fire
EWC	European Waste Code	B.3.1 Waste
R&D	Research and Development laboratory	B.1.4.3.1.2 Research & Development Cycle-Work
REI60	With the symbol REI (followed by a number n in minutes) identifies a structural element that must be kept for a certain time n the mechanical strength, resistance to flames and hot gases, thermal insulation;	B.1.4.3.1 Production cycle
ATEX	ATmosphères ed EXplosibles. Equipment and protective systems for potentially explosive atmosphere	B.1.4.3.1 Production cycle
PPE	Personal Protective Equipment.	B.1.4.3.1 Production cycle
GMP	Good manufacturing practices (GMP) refer to guidelines laid down by agencies which control authorization and licensing for manufacture and sale of food, drug products , and active pharmaceutical products. These guidelines are laid down with the intention of providing minimum requirements that a pharmaceutical or a food product manufacturer must meet while manufacturing drugs or food products ,which then assures that the products manufactured/produced are of high quality and do not pose any risk to the consumer or public.	B.1.4.3.1.1 Local production description
IBC	Intermediate Bulk Container is a reusable industrial container designed for the transport and storage of bulk liquid and granulate substances (e.g. chemicals, food ingredients, solvents, pharmaceuticals, etc).	B.1.4.3.1.4 Warehouse work cycle
ISO 14001	ISO14000 SERIES ENVIRONMENTAL MANAGEMENT SYSTEMS	B.2.1 Environmental Management System

P & ID	Pipe and instrumentantion diagram is a diagram in the process industry which shows the piping of the process flow together with the installed equipment and instrumentation.	B.2.2.1.1 Reaction Unit
AISI	American Iron and Steel Institute	B.2.2.1.2 Finishing Area
RTQ 3S r	Model of boiler	B.2.2.1.3 auxiliary units
HVAC	HVAC (heating, ventilation, and air conditioning) is the technology of indoor and vehicular environmental comfort. HVAC system design is a subdiscipline of mechanical engineering, based on the principles of thermodynamics, fluid mechanics, and heat transfer.	B.2.2.1.3 auxiliary units
ASHRAE	ASHRAE (Formerly the American Society of Heating, Refrigerating and Air Conditioning Engineers), founded in 1894, is a building technology society with more than 54,000 members worldwide. The Society and its members focus on building systems, energy efficiency, indoor air quality, refrigeration and sustainability within the industry.	B.2.2.1.3 auxiliary units
AHU	An air handler, or air handling unit (often abbreviated to AHU), is a device used to condition and circulate air as part of a heating, ventilating, and air-conditioning (HVAC) system	B.2.2.1.3 auxiliary units
BREF	the Best Available Techniques (BAT) reference documents, the so-called BREFs (as well as a few other reference documents) that have been adopted under both the IPPC Directive (2008/1/EC) and the IED.	B.2.2.4 Best Available Technology (BAT)
IUPAC	The International Union of Pure and Applied Chemistry (IUPAC) serves to advance the worldwide aspects of the chemical sciences and to contribute to the application of chemistry in the service of Humankind	B.2.3 Raw Materials
API	Active Pharmaceutical Ingredient refers to a substance or substance combination used in manufacturing a drug product. API also refers to the active or central ingredient in the product which causes the direct effect on the disease diagnosis, prevention, treatment or cure. While API is the active component of a drug, excipients are the inactive or inert substances present in a drug.	
MSDS	A material safety data sheet , safety data sheet (SDS),or product safety data sheet (PSDS) is an important component of product stewardship and occupational safety and health.	B.2.3 Raw Materials
LPG	Liquefied petroleum gas, also called LPG, GPL, LP Gas, liquid petroleum gas or simply propane or butane, is a flammable mixture of hydrocarbon gases used as a fuel in heating appliances and vehicles.	B.2.6 Energy
PED	Pressure Equipment Directive	B.2.6.1 Heat Energy
LED	A light-emitting diode (LED) is a semiconductor light source.[7] LEDs are used as indicator lamps in many devices and are increasingly used for general lighting.	B.2.6.2 Describe the proposed basic measures for improvement of energy efficiency
VRF	Variable refrigerant flow (VRF) is an HVAC technology uses refrigerant as the cooling and heating medium	B.2.6.2 Describe the proposed basic measures for improvement of energy efficiency
RAEE	The Waste Electrical and Electronic Equipment Directive (WEEE Directive) is the European Community directive 2002/96/EC on waste electrical and electronic equipment (WEEE) which, together with the RoHS Directive 2002/95/EC, became European Law in February 2003.	B.2.6.2 Describe the proposed basic measures for improvement of energy efficiency
HDPE	High-density polyethylene or polyethylene high-density (PEHD) is a polyethylene thermoplastic made from petroleum. Known for its large strength to density ratio, HDPE is commonly used in the production of plastic bottles, corrosion-resistant piping, geomembranes, and plastic lumber.	B.3.1.1.1 Hazardous waste production
R13	is type of recovery or disposal operation for our waste into company arrive (Storage of wastes pending any of the operations R 1 to R12).	B.3.1.2 Measure of waste management, storage and handling

COD	In environmental chemistry, the chemical oxygen demand test is commonly used to indirectly measure the amount of organic compounds in water. Most applications of COD determine the amount of organic pollutants found in surface water (e.g. lakes and rivers) or wastewater, making COD a useful measure of water quality. It is expressed in milligrams per liter (mg/L) also referred to as ppm (parts per million), which indicates the mass of oxygen consumed per liter of solution.	B.3.1.2.3 Describe of waste stream
Rck	Characteristic cubic compressive strength of concrete	B.3.3 Emissions to sewer
PPE	Polyphenylene Ether (PPE) - A thermoplastic, linear, noncrystalline polyether obtained by the oxidative polycondensation of 2,6-dimethylphenol in the presence of a copper-amine-complex catalyst. Polyphenylene ether, also called polyphenylene oxide, is usually blended with polystyrene to improve its toughness and processability. Polyphenylene ether has excellent electrical properties, unusual resistance to acids and bases, and is processable on conventional extrusion and injection molding equipment. PPE is easily attacked by some hydrocarbons, although it resists many chemicals. Polyphenylene ether possesses excellent dimensional stability, low moisture absorption, and high mechanical and dielectric strength	B.1.4.3.1 Production cycle
IR	Infrared spectroscopy (IR spectroscopy) is the spectroscopy that deals with the infrared region of the electromagnetic spectrum, that is light with a longer wavelength and lower frequency than visible light. It covers a range of techniques, mostly based on absorption spectroscopy. As with all spectroscopic techniques, it can be used to identify and study chemicals	B.1.4.3.1.2 Quality Control Cycle work
UV	Ultraviolet (UV) light is electromagnetic radiation with a wavelength shorter than that of visible light, but longer than X-rays, that is, in the range between 400 nm and 10 nm, corresponding to photon energies from 3 eV to 124 eV. It is so-named because the spectrum consists of electromagnetic waves with frequencies higher than those that humans identify as the color violet.	B.1.4.3.1.2 Quality Control Cycle work
WHO	WHO is the directing and coordinating authority for health within the United Nations system. Chemical Safety is achieved by undertaking all activities involving chemicals in such a way as to ensure the safety of human health and the environment. It covers all chemicals, natural and manufactured, and the full range of exposure situations from the natural presence of chemicals in the environment to their extraction or synthesis, industrial production, transport use and disposal.	B.1.4.3.1.2 Quality Control Cycle work

Table 56 Terms and acronyms contained in the report

B.11 Appendix

Reference code	Title	
B.1.2-A1	Lay out Factory	
		Level -1 (parking area)
		Level 0
		Level 1
		Level 2
		Level 3 (roof top)
B.1.2-A2	Lay out Factory – stage III	Level 0
B.1.4-A2	Lay out of external flammable warehouse	
		Minor Amendment to Permission PA0423608
		Ground floor plan
		Comparison Ground floor proposed and approved
		Elevation of External Flammable warehouse
B.1.4-A4	Lay out equipment	
		Level 0
		Level 2 and Level 3
B.2.1-A1	Environment Management System	
B.2.1-A2	Environment, Health & Safety Management system	
B.2.2-A1	Production Operation Manual	
B.2.2-A2	Block Plan – Production Process	
B.2.2-A3	Best Available Technologies	
B.2.2-A4	Lay out Factory – Alternative Solution Plan	
B.2.2-A5	Emergency Training and Reaction	
B.2.3-A1	Chemical List	
		API's List
		Raw Material's List
B.2.3-A2	Material Safety Data Sheet	
B.2.4-A1	Operational plan for control of technical gases	
B.2.5-A1	Maintenance Plan rev.05	
B.2.6-A1	List of equipment power consumption	
B.2.7-A1	Lay out drainage system	
		Drainage system of External Flammable Warehouse
		Lay out factory with drainage system
		Sanitary drainage system
B.2.8-A1	Risk Assessment	
B.2.8-A2	Emergency and Evacuation Plan	
B.2.8-A3	Environment Emergency Plan	
B.2.8-A4	Fire and Ventilation Report	
B.2.10-A1	Decommisioning & Cessation plan rev.01	
B.3.1-A1	Plan for spill kit location	
		Stage I&II
		Stage III
B.3.3-A1	Public sewer discharge permit	
B.3.5-A1	Rain water reservoir tank	
B.3.5-A2	Wash water tank	
		Warranted Perit
		Wash water reservoir details
		Wash water tank location
B.3.6-A1	Location of air point emissions	
B.3.9-A1	Noise act	
		Noise Risk Assessment

		Noise & vibration monitoring 1
		Noise plan
		Noise & Vibration monitoring 2
		Noise Survay
		instructions for the correct insertion of ear plug
B.3.11-A1	Emissions and Waste Summary	
B.5.1-A1	Environment Impact Statement	
		Health Impact Assessment (HIA)
B.7.1	Planning Status Permit	
		Malta Resource Authority Permit
		Certificate of GMP compliance of a manufacturer
		EU Decision of implementation
		Full development permit
		Installation of LPG tank
		Public Sewer Discharge permit
		Registration limited liability company
		Report on Environment impact statement
B.8.1-A1	Police conduct of Relevant offences	
		Company secretary
		Technically competent person
		Soil director
B.8.1-A2	Curriculae vitae of Relevant offence	
		Company secretary
		Technically competent person
		Soil director

Table 57 Annex list

Tecnically Competent Person

Sara Farnesi

Soil Director

Simone Ferlin

Sterling Chemical Malta Ltd

STERLING CHEMICAL MALTA LTD
HF51, HAL-FAR INDUSTRIAL ESTATE
BIRZEBBUGIA - BBG3000 MALTA
MT VAT 16941304

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Any personal information collected in this form will be used for establishing the aid which may be granted to the applicant. All information will be processed in accordance with the Data Protection Act, Cap 440 of the Laws of Malta and shall be treated in confidence. The information contained in this application form will be processed by Malta Environmental & Planning Authority (MEPA) and may be forwarded to third parties appointed by MEPA to evaluate, administer, implement, monitor, or audit any part of this incentive. You have the right to access, rectify, and, where applicable, the right to erase personal data concerning you. Malta Environment & Planning Authority guarantees fair processing in respect of your personal information.