

TRK 148537 (EA 00057/12)

INSTALLATION OF MANUFACTURING PLANT AND OBTAINING AN OPERATIONS PERMIT FOR THE PRODUCTION OF ACTIVE PHARMACEUTICAL INGREDIENTS (API), AND THE INSTALLATION OF LPG STORAGE TANKS IN A FACILITY/FACTORY ALREADY COVERED BY PERMIT PA 04236/08.

SITE AT FACTORY HF 51, QASAM INDUSTRIJALI, ĦAL FAR, BIRŻEBBUĠA, MALTA.

1. INTRODUCTION AND DESCRIPTION OF THE PROPOSED DEVELOPMENT

The Malta Environment and Planning Authority (MEPA) requested the submission of an Environmental Impact Statement (EIS) for development application TRK 148537 (*Installation of manufacturing plant and obtaining an operations permit for the production of active pharmaceutical ingredients (API), and the installation of LPG storage tanks in a facility/factory already covered by permit PA 04236/08*) at Factory HF 51, Qasam Industrijali, Ħal Far, Birżebbuġa. The application required the submission of an Environmental Impact Statement (EIS) in accordance with Schedule IA, Category I, Section 8.3.1.1 (v) of the Environmental Impact Assessment (EIA) Regulations, 2007 (Legal Notice 114 of 2007, as amended). The EIS was coordinated by Dr. Paul Gauci for ERSI Ltd.

1.1 DESCRIPTION OF THE PROPOSED DEVELOPMENT

The EIS assessed a proposal for the construction of an additional floor to existing management area, an extension of the production area, and the installation of (i) a manufacturing plant for the production of active pharmaceutical ingredients (APIs), and (ii) storage tanks for liquid petroleum gas (LPG). The proposal covers a total area of about 3,295 sqm and the site is already developed for such use (industrial) through previous approved permit PA 04236/08 (*Factory at Ħal Far for Sterling Chemicals Ltd. This excludes the installation of a plant and operation as an API for manufacturing which is subject to a separate permit*). The proposed development is located within HF 51 at the Ħal Far Industrial Zone in the south of Malta and within the Birżebbuġa Local Council Boundary. The factory is operated by Sterling Chemicals Malta Limited (SCM), which is a subsidiary of Sterling SpA, a company which is a hormone and steroid specialist involved in all the phases of the API product cycle.

The proposed plant will focus on export business for products ingredients with high added value and innovative content. It will involve the following dimensions:

1. Research and Development (R&D): Sterling process innovations tend to reduce the consumption of raw material and to maximise the development in terms of yield of APIs. The setting up of Sterling Chemicals Malta Limited would make possible for Sterling to research new products [in addition to processes];
2. The transfer of what R&D laboratories synthesize for production at the maximum possible capacity of the plant; and
3. The transfer of the knowledge generated through R&D to the development of the Maltese pharmaceutical sector. The new research centre at the Ħal Far plant is expected to ensure continuous development and innovation of products and processes in synergy with the research centres of the parent company [in Italy] and in collaboration with other research institutes and universities [including the University of Malta].

The intention of the company is to phase the production of the facilities according to the factory activating/building new departments following a plan of 3 stages. The operations connected with these stages are phased as follows:

- Phase 1: Stage I production which would involve pilot production for research and development (R&D);
- Phase 2: Stage II commercial production; and
- Phase 3: Stage III extension to the production area and increased commercial production.

Presently, SCM is permitted to carry out Stage I production. Details of the proposed additional floor and extension to the production area are illustrated in Figures 1-1 and 1-2 (pages 31-32) of the EIS Coordinated Assessment. The production process would involve the following nine stages:

1. receipt and verification of raw materials;
2. weighing of raw materials;
3. upload of reactors;
4. reactions;
5. extraction, separation, and transfer of the reaction mass to a new reactor;
6. distillation of the mixture;
7. filtration or centrifugation which would separate liquids from solids, which process would end with the unloading of intermediates or final products;
8. drying of the intermediates or final products; and
9. packaging, storage, and shipment.

A detailed production process is indicated in Figure 1-3 (page 38) of the EIS Coordinated Assessment.

The production process involves the use of raw materials which may be flammable and hazardous, produces emissions, liquid and solid wastes which are similarly potentially harmful to human beings and other biota, in this case, the flora and fauna that occur in the protected area located a few metres south of the site HF 51 site. The wastes will be separated at source (i.e. within the factory where they would be produced) in accordance with the European Waste Catalogue (EWC) code (European Commission, 2001). The Sterling waste management plan indicates that:

- waste would in general be transported away from the factory, for disposal or recycling when quantity in the storage facility reaches 10m³;
- non-hazardous waste would be separated into paper, plastics, and metals and transported in away from the factory at most every two months, or as needed, depending on the volume of waste generating activities taking place in the factory;
- hazardous wastes would be stored in sealed containers. Used oil and batteries would be transported away for recycling or disposal at most every two months, regardless of the amount collected.

The detailed waste management strategy that will be adopted by the proposed development can be found in Section 1.2.6 (page 76-92) of the EIS Coordinated Assessment.

Factory HF 51 is located in the Ħal Far Industrial Zone within the territory covered by the Marsaxlokk Bay Local Plan (MBLP). The corresponding policies are MBLP – MH01 to MH14, which seek to establish a balance between the leisure uses for which Ħal Far was, for many years known, and the industrial uses which commenced when the Ħal Far airport was transformed into an industrial zone in the early-1980s, which was to be allocated for export-oriented manufacturing. The industrial area is already developed, and a number of other companies manufacturing active pharmaceutical ingredients and finished pharmaceuticals are already present in close proximity to the site.

The proposal is a few meters away from: (i) an Area of Ecological Importance (AEI) – Rdum miċ-Ċirkewwa sa Bengħajsa (scheduled through Government Notice 400 of 1996); (ii) Rdumijiet ta' Malta Special Area of Conservation (SAC) of International Importance (as per Legal Notice 311 of 2006 and Government Notice 851 of 2010); (iii) an Area of High Landscape Value (AHLV) – Coastal/Ciffs (scheduled through Government Notice 400 of 1996); (iv) Natura 2000 site as per Habitats Directive (92/43/EEC); and (v) Special Protection Area (SPA) – Rdumijiet ta' Malta: Wied Moqbol sal-Ponta ta' Bengħajsa as per Wild Birds Directive (79/409/EEC).

A detailed overview of the planning policies and legislative framework which relate to the proposed development is provided in each relevant section within the EIS Coordinated Assessment.

1.2 ALTERNATIVES CONSIDERED

No alternatives vis-à-vis location and layouts were considered as part of this EIS given that the proposal is an extension of an already approved development (factory). Furthermore, the Ħal Far Industrial Zone has been designated the preferred location for the pharma sector for at least 14 years. The technology chosen is in accordance with the pollution prevention and control principles as established the Industrial Emissions Directive (IED) and conform to the Best Available Techniques Reference documents (BREFs) issued by the European IPPC Bureau (EIPPCB-JRC, 2014). The zero option would result that no commercial pharmaceutical production takes place within the factory.

2. EIA CONSULTATION

2.1 EIA SCOPING

During the scoping stage, the Project Description Statement (PDS) was circulated to the following consultees and was made available for public consultation from 30 October 2012 to 21 November 2012:

- Birżebbuġa Local Council;
- Malta Resources Authority;
- Transport Malta;
- Environmental Health Directorate;
- Superintendence of Cultural Heritage;
- Environmental NGOs: Din l-Art Helewa, Kummissjoni Ambjent, Birdlife Malta, Nature Trust Malta, Ramblers Association of Malta, Flimkien għal Ambjent Aħjar, Friends of the Earth Malta, Żminijietna, Fondazzjoni Wirt Artna, GAIA Foundation, Light Pollution Awareness Group, Moviment Graffiti, Malta Organic and Agriculture Movement, Malta Water Association, Youth for the Environment, Noise Abatement Society of Malta, Federazzjoni Birżebbuġa, Birżebbuġa Environmental Action Group.

The PDS was also circulated for internal review within MEPA.

Comments were received from Transport Malta (e-mail dated 5 November 2012), Ramblers Association of Malta (e-mail dated 8 November 2012), Birżebbuġa Local Council (e-mail dated 19 November 2012), Birżebbuġa Environmental Action Group (e-mail dated 20 November 2012), Environmental Health Directorate (e-mail dated 21 November 2012), and Superintendence of Cultural Heritage (e-mail dated 25 November 2012). A scoping meeting with the Birżebbuġa Local Council, government entities and environmental NGOs was also held on 16 November 2012. A copy of the submitted comments and minutes of the scoping meeting are being included as Appendix I and II, respectively to this report.

The final Terms of Reference were issued on 17 June 2013 following various discussions with applicant and architect.

2.2 EIA REVIEW

The draft EIS was submitted to MEPA on 28 May 2014 and was circulated for review to the same consultees consulted during the scoping stage (see Section 2.1 above) as well as the Civil Protection Department. The EIS was also circulated for internal review within MEPA.

The consultation period spanned between 29 May 2014 and 30 June 2014. Within the stipulated consultation period, comments were received via e-mail from: the Civil Protection Department (e-mail dated 3 June 2014), the Light Pollution Awareness Group (e-mail dated 20 June 2014), the Superintendence of Cultural Heritage (e-mail dated 27 June 2014), the Environmental Health Directorate (e-mail dated 1 July 2014), Birżebbuġa Local Council (e-mail dated 1 July 2014), and Birżebbuġa Environmental Action Group (e-mail dated 1 July 2014).

Comments made by MEPA and its consultees during the review stage were forwarded to the EIA Coordinator, the developer and the architect on 7 July 2014. These comments were addressed by the EIA Coordinator and responses were submitted to MEPA, all of which are included in Annex 01 (Hal Far EIS Comments and Responses) of the EIS Coordinated Assessment Report. Comments received during the consultation period are inserted in Appendix III to this Report.

2.3 EIA CERTIFICATION

The EIS was certified on 4 September 2014 and was published for a three-week public consultation period, with a deadline for submissions being 2 October 2014. A public hearing was held on 2 December 2014, with a deadline for comments by 9 December 2014, extended till 12 December 2014 (Appendix IV and respective annexes). Minutes of the meeting are also included as Appendix V. Comments were received from the Birżebbuġa Environmental Action Group (e-mail dated 12 December 2014).

3. EIA FINDINGS

The characteristics of the site, assessment of impacts and mitigation measures were identified in the EIS (summary found in Volume 4 of the EIS Coordinated Assessment), as follows:

3.1 LAND USE AND ANCILLARY CONSIDERATIONS

The proposed site is located within Factory HF 51, situated within the Hal Far Industrial Zone, and covered by the Marsaxlokk Bay Local Plan (MBLP). Given its location, the major land use is manufacturing (refer to Figure 3-4, page 100, of the EIS Coordinated Assessment) although entities active in construction, repair, waste management and storage facilities are located within or just outside the industrial zone. Table 3-1 (page 101-102) of the EIS Coordinated Assessment identifies the list of plants and respective activities within the Hal Far Industrial Zone.

3.1.1 IMPACTS ON LANDUSE

The factory within HF 51 site has already been mostly constructed through development permission PA04236/08 and is already operating for 'pilot production for Product & Development' in the pharmaceuticals sector, more specifically in the steroids API sub-sector. The proposal seeks the addition of the following components:

- an extra floor in the area within the factory allocated for the management;
- the installation of equipment in the existing factory building and their use for Phase II operations, namely 'commercial production; and
- the construction of a small extension for the equipment which would increase commercial production, in what would be Phase III of the operations.

The EIS identified the following impacts arising from the proposal (significance criteria are detailed in Section 4.1.1.8, pages 166-169, of the EIS Coordinated Assessment):

- Changes to the existing land use arrangements and land take-up within the HF 51 Site – General disturbances during construction works, including the escape of particulates – *Insignificant*; and
- Changes to the existing land use arrangements and land take-up within the Hal Far Industrial Zone – General disturbances during construction works, including the escape of particulates – *Insignificant*.
- Changes to the existing land use arrangements and land take-up within the HF 51 site – Escape or particulates and gases during operations which may contaminate the operations of taking place within HF 51 – *Insignificant*; and
- Changes to the existing land use arrangements and land take-up within the Hal Far Industrial Zone – Escape or particulates and gases during operations which may contaminate the operations of neighbouring manufacturing operations – *Insignificant*.

3.1.2 PROPOSED MITIGATION MEASURES

Construction

- Implementation of good construction management practices identified in Chapter 5 of the EIS Coordinated Assessment including well-maintained equipment, noise-proofing of equipment with excessive noise levels, proper storage and management of hazardous waste, and the implementation of an Environmental Risk Assessment.

Operation

- Adoption of appropriate mitigation measures identified in Chapter 1 of the EIS Coordinated Assessment including the installation of spill kits, the use of exhaust abatement systems and the installation of cryogenic condensation, emergency shutdown procedures, and regular maintenance of equipment.

3.1.3 RESIDUAL IMPACTS

Given that the EIS has identified that the land use impact from the proposed development is insignificant, no residual impacts are envisaged.

3.2 WATER BODIES

This assessment took into consideration the Geo-Environmental Baseline Survey and Report prepared by Dr. Saviour Scerri in 2005¹. The geological map presented in Figure 3-5 (page 105) of the EIS Coordinated Assessment identifies that the predominant exposed geological strata in the area are the Il-Mara and Attard members of the Lower Coralline Limestone Formation. There are four geomorphologic units that surround the proposal:

- High coastline - imposing sheer limestone cliffs that rise almost vertically to about 60m above sea level;
- Hal Far plain - the bedding plane at the top of Il-Mara member which is marked by a hard ground;
- Wied Żnuber - a deep gorge which has a maximum depth of about 60m; and
- Limestone pavement - solution features, which highly enhance the permeability of limestone and range from shallow rock pools and narrow conduits to large solution features such as caverns.

Beneath the proposed site, there is no perched aquifer and the only aquifer is the mean sea level aquifer (MSLA), which lies some 60m below. Given that the site is only about 320m away from the coastline, the aquifer would be thinly developed or non-existent. Figure 3-6 (page 107) of the EIS Coordinated Assessment indicates the water catchment of Wied Żnuber which covers an area of circa 1.78 km² and the proposal lies within. The nearest WSC borehole is located circa 1km away from the proposed site, and is therefore outside the area of influence of the site.

3.2.1 IMPACTS ON WATER BODIES

The EIS identifies six general processes during both construction and operation which as a result of the proposed development may have an impact on the surrounding water bodies (in particular, Wied Żnuber watercourse and the sea during rainfalls):

- Effects of fine particulates (from construction debris, rubble, soil, and construction material) on aquatic environments during construction (*insignificant impact if the appropriate mitigation measures are taken*);
- Degradation of aquatic environments due to spills or leakages of fuel, transported materials and fallout from exhaust streams during construction (*insignificant impact if the appropriate mitigation measures are taken*);
- Effects of fine particulates (production line, laboratories, steam generator and boiler) on aquatic environments during operation (*low to moderate adverse significant impact*);
- Effects of waterborne pollutants on habitats and biota, which may reach Wied Żnuber as a result of a spillage or overflow from the underground wash water storage facility (*probably moderate adverse significant impact*); and
- Degradation of aquatic environments due to spillages or leakages of hazardous waste during operation including use, transfer operations, misuse, accident or abatement malfunction (*may be moderate adverse significant impact along the path of any spills*).

3.2.2 PROPOSED MITIGATION MEASURES

The EIS proposes the following mitigation measures:

Construction phase:

- implementation of good construction management practices including as well-maintained equipment and proper handling and storage of dust-laden and hazardous materials;
- the control of water borne PMs during rainfalls and sprinkling/spraying of dust laden materials; and
- a good and effective contingency plan to clean up spills.

Operation phase:

- The re-use of harvested run-off water on-site;
- Monitoring and treatment of runoff water prior to harvesting into rain-water reservoir;
- Particulate-abatement measures to reduce the volume of emitted particulates;

¹ Scerri, S. (2005). Medichem Manufacturing (Malta) Limited: Geo-Environmental Baseline Survey and Report. In P. Gauci, *Environmental Impact Statement: Installation of a Manufacturing Plant for the Production of Active Pharmaceutical Ingredients at Hal Far* (p. 20). Msida, Malta: EKOplan.

- Bunding of the storage facilities;
- Channelling of contaminated waters and hazardous liquids to underground chambers;
- Secure storage of potential pollutants with secondary containment and fire-prevention systems;
- Storage of minimum quantities required and good operational practice to reduce the potential for accidents;
- A contingency plan to clean up spills; and
- Monitoring of all systems which prevent or control environmental pollution and ensure a proper contingency plan.

3.2.3 RESIDUAL IMPACTS

The EIS notes that the residual impacts resulting from the construction and operations of the development on the nearby water bodies (particularly the Wied Żnuber watercourse) is expected to range from none (specifically where impacts are temporary) to ones of low significance subject that all mitigation measures proposed are adhered to. Furthermore, it is being suggested that given its location (within an industrial zone), the whole area is to be compartmentalised vis-à-vis the Wied Żnuber area in order to safeguard the integrity of the SAC/SPA.

Environment Protection Directorate note: The Environment Protection Directorate is concerned on the capacity of the underground facility for wash waters, given that, as concluded in the Water Bodies environmental survey report, may not cope with the volumes of discharge and therefore there is the risk that a proportion of such waters end up in the Wied Żnuber watercourse. The EIA Coordinator stated that any liquid in the warehouse basins would be analysed before discharge. However, such a connection cannot be allowed in view of the potential for the accidental release due to human error or valve/seal malfunction. The connection is to be rerouted to the discharge point for process effluent. EPD recommends that the mitigation measures listed in the EIS, including monitoring, are included as development permit conditions and the IPPC permit conditions.

3.3 ECOLOGY

The Ecological Assessment was divided into: (i) terrestrial ecology; and (ii) a vertebrates assessment.

Terrestrial Ecology

Drawing 3-14 (page 119) in the EIS Coordinated Assessment illustrates the area of influence of the terrestrial ecological study. The area of influence incorporates the valley bed and sides of Wied Żnuber valley which is bounded by: (i) the Ħal Far Industrial Zone (from north-west to east); (ii) agricultural land (west, south-west and south-east); and (iii) the sea (south).

The area has been subject to significant anthropogenic influence (mostly agricultural uses), and traces of original vegetational communities persist in patches with limited accessibility (undergoing secondary ecological succession). Trees are also present along agricultural margins. Along the undisturbed valley sides, mostly are colonised by shrub formations, broadly characteristic of maritime steppe/garrigue, and, more specifically, by elements of the Maltese Rđum Community. Derelict areas which were subject to large amplitude disturbance were noted within the boundary of the Ħal Far Industrial Zone and are colonised by ruderal species. Figure 3-15 (page 122) illustrates a biotope/vegetation map indicating the general distribution of plant communities within the Area of Study. The vegetation assemblages identified in the EIS include:

- Valley Bed;
- Valley Sides;
- Overcliff Area; and
- Disturbed Area.

The following are a few of the species found within the Area of Studies:

Species	Vernacular	L.N. 311/2006	Trees & Woodlands	RDB status
<i>Valley Bed</i>				
<i>Ceratonia siliqua</i>	Carob		Schedule II	
<i>Darniella melitensis</i>	Maltese Salt-Tree	Regl. 26		Endemic
<i>Valley Sides</i>				
<i>Atriplex lanfrancoi</i>	Maltese Cliff-Orache	Schedule II(b)		Endemic, R,

		Schedule V(b); Habitats Directive: Annex II		Rest (MI)
Cheirolophus crassifolius	Maltese Rock-Centaury	Schedule II(b) Schedule V(b) Habitats Directive: Annex II		Endemic, R, Rest (MI)
Daucus rupestris	Cliff Carrot			Rest (MED+MI)
Thymbra capitata	Mediterranean Thyme	Schedule III(b)		GN 85 (1932)
<i>Overcliff Areas</i>				
Anacamptis pyramidalis	Pyramidal Orchid	Schedule VIII(b)		
Chiliadenus bocconeii	Maltese Fleabane	Schedule X(b)		Endemic
Limonium melitense	Maltese Sea-Lavender	Schedule III(b)		Endemic
<i>Disturbed Areas</i>				
Drimia maritima	Sea Squill	Schedule VIII (b) Schedule X (b)		Rest (MED)
Pistacia lentiscus	Lentisk		Schedule II	

Vertebrata

Drawing 3-13 (page 127) in the EIS Coordinated Assessment illustrates the area of study of the vertebrate study carried out. The area of influence was further divided into three sub-areas (A, B, and C), with HF 51 located in sub-area B.

A number of mammals, reptiles and amphibians within the area of study are indicated in Figures 3-17 to 3-28 (pages 140 to 149) of the EIS Coordinated Assessment. Some of the vertebrates identified within the Area of Study include: Wild Rabbit (*Oryctolagus cuniculus*), Painted Frog (*Discoglossus pictus*), Maltese Wall Lizard (*Podarcis filfolensis*), Algerian Hedgehog (*Atelerix algirus*), Lesser Horseshoe Bat (*Rhinolophus hipposideros*), and Soprano Pipistrelle (*Pipistrellus pygamaeus*).

The location is a recorded known breeding ground for a number of avian species especially along the cliffs and inside Wied Żnuber including Scopoli's Shearwater (*Calonectris diomedea*), Yelkouan Shearwaters (*Puffinus yelkouan*), Barn Swallow (*Hirundo rustica*), and Zitting Cisticola (*Cisticola juncidis*). An annotation of all the birds recorded within the area of study is indicated in pages 134 to 138 (Section 3.3.4/D) of the EIS Coordinated Assessment.

3.3.1 IMPACTS ON ECOLOGY

The EIS indicates that the: (i) effects of windblown limestone dust on habitats and biota; and (ii) degradation of biological communities due to leakages; both during construction phase may occur. These may lead to an *insignificant* impact (subject to appropriate mitigation measures). Furthermore, the following are the impacts envisaged on the terrestrial ecology as a result of the proposed development during operation:

- Effects of fine particulate on habitats and biota (*low to moderate adverse significant impact*);
- Effects of gaseous emissions on habitats and biota (*low to moderate adverse significant impact*);
- Effects of waterborne pollutants on habitats and biota, which may reach Wied Żnuber as a result of a spillage or overflow from the underground wash water storage facility (*probably moderate adverse significant impact*); and
- Degradation of biological communities due to spillages or leakages (*may be moderate adverse significant impact along the path of any spills*).

The EIS also identified the following impacts envisaged on vertebrates as a result of the proposed development:

- Light pollution from unshielded lights inside and around building during both construction and operation (*highly adverse significant impact*);
- Sound pollution from inside and around building during operation (*significant adverse significant impact*); and

- Chemical residues/run-off into Wied Žnuber during both construction and operation (*highly adverse significant impact*).

3.3.2 PROPOSED MITIGATION MEASURES

Implementation of good construction management practices that include:

- Implementation of a Construction Management Plan;
- Proper handling, storage, transport, and use of dust-laden materials;
- Minimisation of gaseous and particulates pollution caused by equipment and vehicles;
- Limitation of the period during the working day when the noise generating equipment is used;
- A contingency plan to clean up spills; and
- Minimisation of on-site servicing of vehicles and machinery.

Other measures include:

- Minimise light sources and proper shielding of luminaries;
- Regulate sound emissions from area;
- Line storage facility with non-absorbent material to contain any possible spill;
- Use of filters which are envisaged to reduce the volume of emitted particulates by 80% to 99.995%, dependent on the size of the particulate;
- Use of efficient combustion processes and retention of solvents;
- Bunding of the storage facilities and the channelling of contaminated waters and hazardous liquids to underground chambers;
- Secure storage of potential pollutants with secondary containment and fire-prevention systems;
- A contingency plan in case of emergency; and
- A Monitoring plan which includes monitoring of all systems which prevent or control environmental pollution and take corrective action if and when monitoring results identify an issue of concern.

3.3.3 RESIDUAL IMPACTS

Residual impacts on terrestrial ecology and vertebrates are expected to be of low significance on the assumption that: (i) particulate emissions and liquid discharges from the plant are precluded from making it to the Wied Žnuber area; and (ii) light and noise pollution would be controlled.

Environment Protection Directorate note: *The Directorate is in general agreement with the identification of impacts and mitigation measures being proposed. Previous EPD note is being reiterated.*

3.4 CULTURAL HERITAGE

The cultural heritage study involved a surface survey covering a 120 metre radius area from the proposed site. The findings were complemented by a desktop research which considered a 500 meter radius area (Figure 3-29, page 152, of the EIS Coordinated Assessment). The study concluded that Wied Žnuber and Hal Far have had a number of uses over time, varying from burial in prehistoric and Classical times, military in the Early Modern and Modern Period and agricultural. An exhaustive list of the cultural heritage assets found within the area are listed in Table 3-9 (pages 159-160) of the EIS Coordinated Assessment and these include:

Location	Category	Description	Protection actual or proposed
Wied Žnuber, Hal Far, Biržebbuğa	Vernacular	Rock-cut caves and holes	Grade 3
Wied Žnuber, Hal Far, Biržebbuğa	Archaeological	Dolmen	Class A (GN 1082/2009)
Wied Žnuber, Hal Far, Biržebbuğa	Military	Entrenchments	Grade 2
Wied Žnuber, Hal Far, Biržebbuğa	Military	Military structures	Grade 3
Ic-Čnus, Hal Far, Biržebbuğa	Archaeological	Megaliths within a rubble wall	Grade 2
Wied Žnuber, Hal Far, Biržebbuğa	Rock-cut	Cave	Grade 3

Rubble walls and dry walls found within Wied Žnuber were also recorded and assessed according to their grading. The condition of the rubble walls recorded in the survey are summarised in Table 3-10 (page 160) and Figure 3-32 (page 161) of the EIS Coordinated Assessment.

3.4.1 PREDICTED IMPACTS

The study identified that the footprint of the proposed development lies 78 meters from the nearest cultural features and about 180 meters from Wied Žnuber Dolmen (HLF13/006). Therefore, the EIS concludes that no cultural heritage features will be directly affected from the proposed development since the road separating the industrial area from the valley acts as a buffer. Furthermore, the cultural landscape has already been altered first with the construction of the Hal Far aerodrome and followed by its transformation into an industrial zone.

3.4.2 MITIGATION MEASURES

- No mitigation measures are being proposed.

3.4.3 RESIDUAL IMPACTS

Given that the EIS has identified that the cultural heritage impact from the proposed development is insignificant, no residual impacts are envisaged.

3.5 CLIMATE CHANGE

A study was carried out by the project building services engineer as part of the EIS and identified the greenhouse gases (GHGs) emissions from the proposed development. It was identified that during operation, the proposed plant will generate CO₂, NO_x and Methane and HFC from the material and fuel gas used. Given that HFCs are associated mostly with non-combustion sources such as refrigeration and industrial sources, HFCs were not analysed. Emissions of GHGs related to the proposed project can be divided into two: on-site and off-site emissions. Direct and indirect operation emissions are detailed below:

- Non-road construction engines (indirect impact);
- On-road vehicles (indirect impact);
- Electricity use (direct impact);
- Construction material for use (indirect impact); and
- Fugitive emissions associated with gas compression, piping and venting (direct impact).

The EIS estimates that the amount of CO₂ equivalent (CO₂e) emissions from the proposed development is 10,473 tonnes. The assessment also identifies a number of measures to reduce the carbon intensity from the proposed development including: (i) the use of clean power; (ii) reduction of construction activity emissions; and (iii) the use of building materials with low carbon intensity.

3.6 ENVIRONMENTAL RISK ASSESSMENT

An environmental risk assessment (Appendix Two C of the EIS Document) was carried out as part of the EIS in order to identify and assess any risks, possible major accidents, and the consequences that can occur within the proposed plant or the surrounding environment. The index method identified two production processes which resulted into a very high general risk index: (i) Production area (L1 + L2) with key substance: Methanol; and (ii) Loading/unloading and storage, LPG Tanks in LPG area, with key substance: Propane. The hazard and operability analysis (HAZOP), which results are found in Appendix Two C: Annex 1 of the EIS Coordinated Assessment, classified 23 Top (accident prone) events. The third assessment carried out, the fault tree and probabilistic calculation, took into consideration the top events that emerged from the analysis of the operability and established that the following six top events are to be addressed:

- Uncontrolled spill out of the containment basin (Top Event No. 1);
- Uncontrolled liquid spill out of the containment basin (Top Event No. 2);
- Vapours escaping (Top Event No. 6);
- Opening of the safety rupture disk (Top Event No. 14);
- Minor pollution abatement (Top Event No. 18); and
- Vapours escaping/spillage (Top Event No. 23).

Possible accident scenarios from the top events analysed were identified through the events tree assessment such as: pool fire, release of gas and vapours in air, emission in soil, and UVCE. The consequences pertaining to the results of the events tree assessments were studied through the assessment of consequences.

As a result of the assessments mentioned above, the EIS concluded the following consequences of the major events:

- **ZONE 1** - The area in which it can be reached or exceeded the threshold values of high lethality is always contained within the plant. High mortality effects due to radiation (stationary thermal radiation) are limited in close proximity of the release point;
- **ZONE 2** - The area in which are foreseen effects of a certain severity (non-fatal) on the exposed subjects and in which damages of a certain size on the structures or equipment are expected, is generally contained within the company perimeter. The radiation effects are always contained in the plant area and may reach maximum distances of approximately 20 metres from the release point; and
- **ZONE 3** - The focus area with minor and/or reversible effects, in which are predictable effects of radiation, are always contained within the plant. The effects are not responsible for domino effects.

3.7 HUMAN POPULATIONS

The assessment of health impacts on human populations carried out as part of the EIS takes note of the emissions and discharges of the proposed plant. The EIS identifies five major pollutants which are: (i) Air pollution; (ii) Particulate Matter; (iii) Noise pollution; (iv) Pollution of aquatic environments; and (v) Waste.

(i) Air pollution

The proposed development includes six emission points, some of which include abatement systems through which the following substances would be passing:

- VOCs;
- Nitrogen dioxide;
- Ozone;
- Carbon monoxide;
- Carbon dioxide; and
- Particulate matter.

The abatement systems that are to be installed in the emission systems are indicated in Table 1-23 (on page 70) of the EIS Coordinated Assessment.

(ii) Particulate Matter

Particulate matter is well known to cause adverse health effects even of the most serious nature (e.g. lung cancer, cardiac arrest) and mitigation of emissions is highly recommended, especially since the particles emitted from a pharmaceutical plant would be more likely to have an adverse health affect due to the activities at the plant.

(iii) Noise pollution

A noise impact study of the operation on external areas resulted that the noise levels are within those recommended for Industrial and Commercial sites in the Environmental, Health, and Safety Guidelines (70dB). However, the assessment stated that dB levels of 55 and above can still be considered harmful in the long-term.

(iv) Pollution of aquatic environments

There is the risk that any contaminants from the site could, in the event of severe flooding, drain into the valley and into the sea. This could potentially be a danger not only to the fragile ecology of the area, but also to humans as any dangerous chemicals could enter the food chain. Mitigation measure being proposed in this regards (excess rainwater would drain into the sewer system) would mitigate the risk of contaminated rainwater seeping directly into the valley system, but could potentially spill over unwanted chemicals into the sewer systems, with unknown but potentially harmful consequences. The proposed two underground reservoirs for rainwater are to have appropriate filters installed at all entry points that are intended to absorb most possible contaminants that might be a result of spillage, or emissions from various points around the premises. Wastewater collected after production, including water from the scrubbers used to clean the air chutes and water from the labs, is collected in an especially assigned wastewater reservoir and disposed of as wash water with European Waste Code 070701.

- (v) Waste.

Given the nature of the proposal, it is expected that during operation both hazardous (potentially toxic and in significant amounts) and non-hazardous waste is expected to be generated. Therefore it is being suggested that a comprehensive waste management strategy and scrutiny is applied on site to mitigate potential impacts on the public health and health of workers within the plant.

4. EPD COMMENTS AND CONCLUSIONS

The Environment Protection Directorate notes that this project is situated within the Hal Far Industrial Zone, an industrial area which is already mostly developed. This industrial park accommodates various industrial developments, including a number of other pharmaceutical companies. Furthermore, the site proposed to accommodate this proposal, is already constructed upon and although such practice is not encouraged by EPD since it may result in the fragmentation of development, it establishes a commitment for such use (industrial) through a previous approved permit application on site.

As discussed in the above sections, the EIS has predicted a number of potential impacts on the environment as a result of the proposed development, mostly being low to moderate adverse significance. Highly adverse significant impacts, namely light and sound pollution on the surrounding breeding grounds may also result. However, such impact may be adequately mitigated through the minimisation of light sources, proper shielding of luminaries and controlled sound emissions from the proposed plant. Overall, the significance of the residual impacts is subject to the implementation of appropriate mitigation measures during both construction and operation of the proposed plant.

EPD is concerned with the impact of release of fine particulate, gaseous emissions, and waterborne pollutants on the surrounding aquatic environment, habitats and biota, and human population. This may also result into a cumulative impact given the increase in the number of the pharmaceutical companies in the area. The Directorate acknowledges that the proposed development shall only be contributing by a fraction to the baseline situation in the area in proportion to the whole area context and location, and that the issue in question needs to be approached holistically (e.g. at local planning or policy-making level) rather than on an ad hoc project-by-project basis. This consideration also takes into account the cumulative contribution of other approved developments which are equally responsible of the exacerbation of the current (baseline) and potential future environmental impacts in the area. Furthermore, mitigation measures with regards to any potential measures may be sufficiently tackled through the IPPC process.

Mitigation measures as proposed in the EIS are to be implemented together with monitoring during operation to minimise any potential impact on the surrounding environment. The Environment Protection Directorate is concerned on the capacity of the underground facility for wash waters, given that, as concluded in the Water Bodies environmental survey report, may not cope with the volumes of discharge. In this instance, there is the risk that a proportion of such waters may end up in the Wied Żnuber watercourse. The EIA Coordinator stated that any liquid in the warehouse basins would be analysed before discharge. However, the Directorate is against such a connection in view of the potential risk for accidental releases due to human error or valve/seal malfunction. The connection should therefore be rerouted to the discharge point for process effluent. Updated plans may be sufficiently addressed directly through the mainstream development consent mechanism and the IPPC permit. With regards to the impact of the proposed plant on the human population, it is being suggested that the recommendations of the Health Impact Assessment (pages 30, 31 and 32 of the Health Impact Assessment) are implemented.

Apart from the mitigation measures emerging from the EIS, which are being recommended to be included as part of the development permit application, the Environment Protection Directorate is also including additional recommendations in terms of environmental monitoring during operation. All monitoring of emissions and regular reporting of activities should be submitted to both environmental and health authorities so as to ensure transparency of operations on the site. A comprehensive construction management plan (CMP) is also being requested to address the issues relevant to the construction-phase works.

In light of the above, the Environment Protection Directorate is in agreement with the main conclusions of the EIS and is of the opinion that the necessary mitigation measures need to be integrated into the project; including amendments to the design which are also being recommended accordingly.

Appendix I: Comments received through EIS Scoping stage (30 October and 21 November 2012).

A. Transport Malta (e-mail dated 5 November 2012),

Comments	EPD Comments
<p>Transport Malta would wish to see the following items (which are missing from the PDS) included in the TOR for the EIS:</p> <ul style="list-style-type: none"> Number of operational and servicing vehicles likely to access the site on a typical working day. Expected total number of daily vehicle movements (to include employee's vehicles) into and out of the site and the times of the busiest hours. Whether there will be any regular weekly or seasonal 'peaks' when vehicle movements are significantly higher than the usual. Whether such trip generation will have a significant impact on the road network and if so, what would be the recommended mitigation measures. 	Noted; no further comments.

B. Ramblers Association of Malta (e-mail dated 8 November 2012),

Comments	EPD Comments
We thank you for your invitation and inform you that the project does not fall within our scope of interest, and we have no person who can advise on this.	Noted; no further comments.

C. Birżebbuġa Local Council (e-mail dated 19 November 2012),

Comments	EPD Comments
<p>With reference to the email hereunder, please note that the Birżebbuġa Local Council would like the following issues to be included in the EIA:</p> <ol style="list-style-type: none"> Emissions, including how these will impact the locality of Birżebbuġa (including Benisgha area) as a result of the wind direction and speed. Waste, both liquid and solid Safety Measures Impact on surrounding valleys - Wied il-Buni and Wied il-Klima The impact of transport on Birżebbuġa Rain water harvesting Generation of alternative energy 	Noted; no further comments.

D. Birżebbuġa Environmental Action Group (e-mail dated 20 November 2012),

Comments	EPD Comments
<p>Item One</p> <p>The Project Description Statement failed to list the chemicals, acids and solvents used in the production of Hormone and Steroid active ingredients.</p> <p>We request that the list is made public together with the MSDS and Risk Factors for each. Experts conducting the EIA must know these to evaluate the risk to the environment. Later in the PDS, the applicant refers to (see 8.1.1.) dangerous and inflammable substances. Are we a third world country in referring to chemicals as dangerous without naming them? How are we to know if any of the chemicals used are banned in the EU or by WHO? We will not settle for a simple guarantee the substances used are dangerous and inflammable. Some might explode if they come in contact with other substances. Simple solution is to name the substances and amounts used in Stage One and in full production after stage three.</p> <p>Item Two</p> <p>We have noticed that the factory was connected to the main sewers recently. Are we to understand that the liquid waste is also being flushed down the main sewers. The applicant refers to Liquid waste storage. The EIA must specify way of treating liquid waste with maximum recovery of solvents and others before discharge to the main sewers. EIA must establish the amount of sewage, one can see besides the perimeter or rather the factory front and back garden. The amount of sewage has been accumulating for years. Factory foundations are saturated in sewage water. Besides</p>	Noted; no further comments.

what will the customers say when they see such accumulation of sewage.

Item Three

Research and Development is an ongoing concern, therefore we suggest that the EIA will consider annual inspection during the completion of stage two and three and in particular when in full production. The inspections will consider the risk factor to ambient air, neighboring factories, residential areas with a radius of one kilometer and finally the valley below (Wied Znuber) Odours are also to be considered

Item Four

EIA is to establish that no Insecticides, Pesticides and Fertilizers are manufactured from any by-products.

Item Five

Quality Control - It is stated that finished products must be stored for up to one year after closure of the stability program. EIA is to establish condition of safe storage, monitor regularly condition of packaging and release of contaminants to ambient air. What if, after one year the product is found to be unusable. The EIA is to establish maximum amount of solid waste which can be stored on site. If hazardous waste is produced and Malta has no facilities to accommodate such waste then the applicant is to seek export permit naming waste carrier

Item Six

Please identify, - Isolation, characterization and syntheses of impurities

Item Seven

Please identify intermediates in the following,- to develop, optimize, synthesize and purify active pharmaceutical ingredients and intermediates

Item Eight

4.3 of the PDS - R&D Pilot plant. If new products are produced then the applicant must apply to modify permit of Hormone & Steroid. With this I indicate that before the experimental stage a permit is to be obtained. EIA is to assess the risk factor should new products are in the experimental stage and in the production stage.

Item Nine

Consider the fire risk factor of storing raw materials stored shelves at up to six levels. See 4.6.1 Raw Material indoor warehouse

Item Ten

Until such time as the list of raw materials is made public one cannot determine what produces odours and noxious vapors. Request risk assessment on scrubbers and filters, before release to ambient air.

Item Eleven

It is stated that flammable products are stored in outdoor storage area. EIA is to establish adequate fire fitting equipment such as the Argonite System using oxygen depleting material such as argon and nitrogen, gases normally found in atmosphere. These inert gasses have negative impact with atmosphere. This system is operated automatically with detection and alarm devices. This system is installed at Mater Dei Hospital. Oxygen reducing compounds which are man handled can be dangerous to the operators.

IEA is to establish that adequate fire hydrants are installed to protect factory employees, road users, neighboring factory employees and property. This in the case that fire started at Sterling...

Item Twelve

<p>EIA is to establish that the system for storing hazardous and flammable liquid and solid wastes is up to and in line with Local, EU and International</p> <p>Item Thirteen</p> <p>EIA is to establish relative annual amounts in kilos and liters of imported raw material. MEPA is to be informed of all imports and dispatch of hazardous wastes.</p> <p>Item Forteen</p> <p>Please identify UTA (ref 8.1.4) of the PDS</p> <p>Item Fifteen</p> <p>EIA is to auto rise MEPA expert employees to inspect factory facilities contrary to (8.1.5)</p> <p>Item Sixteen</p> <p>Please identify RE1120 (8.1.9)</p> <p>Item Seventeen</p> <p>Fugitive gasses or vapors were not considered in the PDS, EIA is to establish sources and action that can be taken. Prevailing winds can affect neighboring factories. Arrow Farm had an accidental release of material which contaminated neighboring Medichem where employees ended with overdose in hospital. Beside the prevailing winds 2012 has a record amount of days where North East wind prevailed for days on end. This can have negative effect on Birzebbuga and Benghajsa.</p> <p>EIA is to establish if employees are given appropriate training in the Mother Factory or local administration.</p> <p>Finally the production of Hormones and Steroids make use of toxic and dangerous raw materials if quantities are released into the atmosphere, it can have fatal consequences.</p> <p>EIA is to establish Contingency and Environment plans.</p> <p>We suggest that in future active ingredients production is not accepted in Hal Far Industrial Estate.</p> <p>Local Council and BEAG are to be considered to attend all scoping meetings and make suggestions.</p>	
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E. Environmental Health Directorate (e-mail dated 21 November 2012),

Comments	EPD Comments
<p>With reference to your e-mail dated 30 October 2012 regarding subject indicated in caption and following review of the Project Description Statement, please be informed that we would like to have the following issues related to public health included in the terms of reference for this proposed development :</p> <ol style="list-style-type: none"> 1. Air pollution impacts especially from particulate matter during the construction stage, fine dusts, greenhouse gases, other harmful gases and emissions of hazardous air pollutants during the operation stage and their effects on on-site workers, sensitive receptors in the surrounding area, the general public and on the environment. This should include details of the ventilation system to avoid dispersion of dangerous substances in production area and external contaminations by emissions into the atmosphere. 2. Adverse impacts caused by unsafe, inadequate storage and improper handling, including potential accidental spillage, of raw materials on site. 3. Waste management and disposal issues of all generated waste streams including adverse impacts from storage of hazardous and flammable wastes. 4. Noise and vibration impacts. 5. Mitigation measures regarding odours and noxious vapours especially during sampling/weighing operations. 6. Traffic management and related problems and access arrangements. 7. Mitigation measures regarding aquatic sources in terms of water quality 	<p>Noted; no further comments.</p>

<p>(especially related to ground water pollution) including runoff management.</p> <p>8. Description of the potential adverse public health impacts and hazards associated with the development. These should include prevention, safety and emergency measures which would need to be taken on site in case of an emergency.</p> <p>9. Assessment of the overall cumulative impacts of the development on on-site workers, receptors in the area and on the general public</p> <p>Applicant is also requested to liaise with the Environmental Health Directorate regarding the proposed cooling towers which are to be duly registered with the Superintendent of Public Health and any other facilities in view of specific regulations under the Food Safety Act and the Public Health Act.</p> <p>The EPS should also include a detailed description of the measures envisaged to prevent, minimize and where possible offset any significant adverse health effects on on-site workers, sensitive receptors in the Area of Influence and on the general public. This should include details of monitoring programmes that may be proposed. The EPS should also identify, describe and discuss in detail the possible health effects of any residual impacts that cannot be mitigated.</p>	
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F. Superintendence of Cultural Heritage (e-mail dated 25 November 2012).

Comments	EPD Comments
<p>In response to your e-mails of the 4th October 2012, please find Terms of Reference for a Cultural Heritage Assessment i.c.w. the Environmental Planning Statement (EPS).</p> <p>1.0 Preamble</p> <p>The proposed project would involve a change of use and further works within an existing factory. Potential impacts may occur within the footprint of the project, in the immediate environs, and along access routes in the course of works. Potential impacts may include direct and immediate material impacts, as well as subsequent impacts that might arise from the modification of the existing situation and future operation of the factory. The site is in the immediate vicinity of Wied Znuber and approximately 120 metres from a dolmen that is an important archaeological monument.</p> <p>2.0 Scope and Definitions of the EIS</p> <p>For the purposes of this document, cultural heritage is defined by Article 2 of the Cultural Heritage Act (2002). This includes movable or immovable objects of artistic, architectural, historical, archaeological, ethnographic, palaeontological and geological importance.</p> <p>2.1 The study area will include:</p> <p>a) The total footprint of the proposed project. b) A 120 metre radius around the footprint. c) A 500 metre radius around the footprint.</p> <p>2.2 In the context of this particular application, cultural heritage considerations may include:</p> <ul style="list-style-type: none"> • Features of archaeological value and potential. • Military or civil architecture from the Knights period to British period. • Vernacular structures. • Distinguished buildings or gardens. • Field systems and agricultural features such as irrigation systems. <p>The above cultural heritage definitions and considerations are not to be considered as exhaustive. The EIS must consider all other forms of cultural heritage, both known and unknown.</p> <p>2.3 The Environmental Planning Statement will:</p> <ul style="list-style-type: none"> • Describe the Cultural Heritage assets within the study area • Analyse the cultural heritage features within the context of the cultural landscape • Assess the physical, spatial and visual impacts of the proposed development on the cultural heritage assets • Propose corrective measures for the protection of the cultural resources. 	<p>Noted; no further comments.</p>

<p>3.0 Methodology</p> <p>In quantifying the cultural heritage assets within the study area, and assessing the impacts of the proposed development, the EIA will undertake:</p> <p>3.1 Description and assessment of the property.</p> <p>3.2 Desktop and archival research to the 500 metre radius;</p> <p>3.3 Fieldwork and research, including “field walking”, topographic survey and remote sensing as may be necessary to the 120 metre radius. All fieldwork has to be authorised by the Superintendence of Cultural Heritage as defined below under point 4;</p> <p>3.4 Consultations with any relevant bodies, including the Superintendence of Cultural Heritage, Heritage Malta, the University of Malta, NGOs and Local Councils.</p> <p>3.5 Compilation of an inventory of the cultural heritage assets identified within the study area. The features of cultural heritage are to be described and plotted with grid references, on Data Capture Sheets, the design of which should be approved in advance by the Superintendence of Cultural Heritage. The Data Capture Sheets will be presented as an appendix to the EIS. The analysis of the features will be included in the main report.</p> <p>3.6 A cultural heritage Risk Assessment Map examining the various impacts of the proposed project is to be included in the EIS.</p> <p>4.0 Authorisation by the Superintendence of Cultural Heritage</p> <p>As per Cultural Heritage Act 2002, any form of investigation or prospection required for the identification of cultural heritage (including excavation, field walking, topographic survey and remote sensing) may only be undertaken by the Superintendence of Cultural Heritage or with its written approval.</p>	
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Appendix II: Minutes of EIS scoping meeting dated 16 November 2012

Meeting	Scoping Meeting: TRK 148537 - Installation of manufacturing plant and obtaining an operations permit for the production of active pharmaceutical ingredients (API), and the installation of LPG storage tanks in a facility/factory already covered by permit PA 04236/08.
Date	16.11.2012
Duration	Circa: 14.10 – 15.30
Location	DCS Boardroom
Present	Daniele Cavallaro (Sterling), Roberto Volpi (Sterling), Giuseppe Sgro' (Sterling), Perit Wallace Farrugia (Wallace Farrugia & Associates), Vincent Gauci (Malta Water Association), Carmel Caccopardo (Birżebbuġa Local Council), Mark Anthony Mifsud (Superintendence for Cultural Heritage).
MEPA	Charlene Smith (EPD – Environment Protection Officer); Mark Sultana (EPD – Assistant Environment Protection Officer)
Minutes taken by	Charmaine Zerafa (MEPA, EPD)

Charlene Smith (MEPA) opened the meeting by explaining the agenda and scope of the meeting, namely that the architect will be delivering a short presentation and that attendees are welcome to discuss and raise questions in view of the drafting of the terms of reference for the preparation of the Environmental Impact Statement (EIS).

Daniele Cavallaro (applicant) delivered a presentation on behalf of Sterling Chemicals Malta Ltd., explaining the aims and objectives of this project.

Following this presentation, the floor was opened for comments.

Vincent Gauci (Malta Water Association)

Mr. Gauci explained that there are two main areas of concern for the MWA: 1) Water usage and 2) Waste. With regards to water usage, he pointed out that Sterling Chemicals Malta Ltd. should consider using surface runoff water (through the collection of rainwater) as water is a very scarce resource in Malta. The construction of a reservoir for the collection of surface runoff water is believed to be of mutual benefit for both the development and the sensitive receptors.

The MWA is concerned vis-à-vis the generation of hazardous waste is expected to be of a high volume and one has to keep in mind that in Malta there aren't any facilities to treat such waste. Considerations of how to manage and minimize hazardous waste should be taken on board.

A deadline should be stipulated by when the certifications (such as ISO 14001 and EMAS) are obtained by the project proponent.

Perit Wallace Farrugia (Wallace Farrugia & Associates)

One should keep in mind that this project is already covered by a permit which allows the already built factory to be used for research and development (R&D). Roof water is already being collected in a reservoir to be used for irrigation and fire fighting in cause of emergencies.

Daniele Cavallaro (Sterling Chemicals Malta Ltd.)

It is being envisaged that certificates are obtained within 2 years that is by the end of 2014.

To consider using rainwater, tests have to be carried out and this is not feasible during Stage 1 (R&D) as a very small amount of water is used during this process. It would be more feasible to run these tests when Stage 2 (APIs manufacturing for commercial use) and Stage 3 (new production plant to expand production area) are underway.

Mark Anthony Mifsud (Superintendence of Cultural Heritage)

Is this application for a change of use of an existing factory?

Perit Wallace Farrugia (Wallace Farrugia & Associates)

The land in question was originally greenfield land, earmarked for this type of use. The proposal under this application is introducing a new use in an already approved and built factory area.

Carmel Caccopardo (Birżebbuġa Local Council)

The Birżebbuġa Local Council is requesting that: 1) the Environment Management System (EMS) is part of the permit conditions, 2) Sterling Chemicals Malta Ltd. would be in a position to commit itself to become eligible for EMAS certification instead of ISO 14001, 3) there is a structured dialogue between the company and the community as part of the environmental permit; and 4) A formal structure is stipulated through which MEPA and the community can monitor the company as to how it is adhering to conditions.

With regards to the amount of waste accumulated on site, is there a maximum volume or amount of days prior to export?

Will this project have a negative effect on the valleys present in the vicinity and what will happen in the case of spillage?

Daniele Cavallaro (Sterling Chemicals Malta Ltd.)

In Italy we are already considering obtaining the EMAS certification and this will also be our aim for the Malta site. The community is welcome at our factory and to contact us freely in order for us to answer any questions and explain our project. It is in our interest to safe guard the community and the environment.

With regards to waste we will stipulate both a maximum volume and number of days to minimize the amount of hazardous waste kept on site.

Charlene Smith (EPD) closed meeting by thanking the participants and confirming that the issues raised during the meeting will be factored into the formulation of TORs. Any comments can be sent via email to: eiamalta@mepa.org.mt or by post to the attention of The EIA Team, Environment Protection Directorate, St Francis Ravelin, Floriana by not later than Friday 23rd November 2012.

APPENDIX III: Comments received during EIA Review (29 May 2014 and the 30 June 2014)

A. Civil Protection Department (Email dated 3 June 2014)

Comments	Responses	EPD Comments
<p>With reference to the proposed installation of LPG Tank, the Civil Protection Department request proposal to be within the MRA regulations and LPG Code of practice.</p> <p>The Civil Protection Department requires that the area proposed for the installation of the LPG tank must be;</p> <ol style="list-style-type: none"> 1. Free of any combustible material, including the parking of vehicles; 2. Free from any kind of ignition sources; 3. Protected from any traffic accident by means of bollards and/or crash barriers. <p>The applicant must present the above Compliance Certificate, after completion of works.</p>	<p>The Applicant has been informed</p>	<p>Noted; no further comments from an EPD point of view.</p>

B. Light Pollution Awareness Group (Email dated 20 June 2014)

Comments	Responses	EPD Comments
<p>Reference is made to the EIS hereunder. Our comment relates to point 5.1.2.16 on the issue of external lighting. The EIS states that "It would evidently be pointless for SCM (Sterling Chemicals Malta) to be asked to make sure that external security lighting is acceptable to the International Dark-sky Association (IDA, 2000/2002; IDA, 2013)."</p> <p>Rather than being pointless we are of the opinion that the EIS itself makes it evidently clear that instead it should be mandatory that all exterior lighting be full cutoff having 0% ULOR (upward light output ratio). Industrial areas should have strict regulations on exterior lighting, owing to the high wattage light fittings and floodlighting which is normally installed in such locations.</p> <p>To-date there seems to be no policy on exterior lighting in industrial areas and this should not be used by applicants as an excuse for inadequate lighting schemes. There are no additional costs involved as nowadays all lighting manufacturers produce high quality full cutoff light fittings.</p> <p>We also suggest that the EIS wording be changed so that instead of referring to the IDA website (which refers mainly to US products), it should specify a technical requirement for all exterior light fittings to be procured and installed such that they are full cutoff exterior lighting with 0% ULOR.</p>	<p>This EIA Coordinator agrees completely that all external lights in the Hal Far Industrial Zone must be acceptable to the IDA.</p> <p>In his opinion however, the installation of the required luminaires should at least have been carried out by MIP, a Government agency, soon after the coastal cliffs were identified by the Government as candidates for protection under the Habitats and Birds directives (in 2003).</p> <p>This EIA Coordinator also agrees with the LPAG suggestion in the last paragraph.</p>	<p>Noted; no further comments from an EPD point of view.</p>

C. Superintendence of Cultural Heritage (Email dated 27 June 2014)

Comments	Responses	EPD Comments
<p>We refer to your Letter of Consultation dated 29 May 2014 and the submitted Environmental Impact Statement of 6 May 2014.</p> <p><i>Proposed development</i></p> <p>The application proposes:</p> <ul style="list-style-type: none"> - the installation of a manufacturing plant - the installations of LPG storage tanks in a facility/factory already covered by permit PA 04236/08. <p><i>Heritage Assessment</i></p> <p>The property lies within the Industrial Estate of Hal Far</p>	<p>1: The rock cutting that was needed for the underground facilities of the factory was carried out under a previous development permission, before this EIS was commission. The current proposal does not include rock cutting.</p> <p>2: No waters are expected to end up in the valley.</p>	<p>Noted; no further comments from an EPD point of view.</p>

<p>and the buffer for Site of Archaeological Interest related to the Wied Znuber Dolmen. This monument is scheduled at Class A.</p> <p>The area of the proposed development is full of archaeological remains including entrenchment walls, rubble walls, and tombs.</p> <p><i>Request for further information</i></p> <p>The following information is required from the applicant so that the Superintendence may conclude its response to the letter of consultation dated 29 May 2014.</p> <p>1. Will the proposed development require rock-cutting works? Kindly specify depths for rock-cutting.</p> <p>2. How will the development increase run water in Wied Znuber? Will the run water damage the rubble walls in the area?</p>		
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D. Environmental Heath Directorate (Email dated 1 July 2014)

Comments	Responses	EPD Comments
With reference to your e-mail dated 29th May 2014 regarding subject indicated in caption, please be informed that following review of the EIS submitted this Directorate would like to submit the following comments/recommendations regarding this proposal:	Thanks	Noted; no further comments from an EPD point of view.
Regarding the HIA, although this operation is within a designated industrial zone and no residents reported in HIA within 500m, the distance from the operation to nearest human habitations and settlements, including vulnerable populations such as centres for migrants should be submitted. The identification and description of nearby populations, with particular reference to any health factors that may be affected by the proposed development, will provide a baseline against which possible health impacts can be assessed.	Noted. There are no settlements, including centres for migrants with 500m of HF16. All settlements in the area at least a 1.2km away, as the crow flies.	Noted; no further comments from an EPD point of view.
The EHD is concerned on the potential effects on water bodies due to generation and handling of hazardous waste and potential leaks or spillages of hazardous fluids which may end up in nearby water course including the discharge of pollutants dissolved or suspended in water. Especially of concern is the Grech ESR that indicates a concern that the underground facility for wash waters may not cope with the volumes of discharge and the likelihood that a proportion of such waters end up in the Wied Žnuber watercourse. Grech states that the probability that such an impact occurs is 'likely'.	There was a misunderstanding regarding the capacities of the water storage facilities. These are clarified in the response in Row 19 above.	Noted; no further comments from an EPD point of view.
Regular monitoring of construction and operation outcomes including emissions to air, ambient monitoring, sewer discharge, water quality, noise & vibration and cleanliness of utilities should be carried out and appropriate records kept.	Agreed	Noted; no further comments from an EPD point of view.
Appropriate mitigation measures during both construction and operations including those recommended by consultants and those recommended in the CMP and EMS should be strictly adhered to. A management strategy for dealing with accidental release of chemicals including VOCs, dioxin and other POPs to surrounding areas should be provided. It is pertinent that a rigorous environmental management system be adopted during the construction works. Monitoring of all systems which prevent or control environmental pollution including the taking of immediate corrective action when necessary should also be implemented during the operation phase.	This information has been submitted to the MEPA as part of the application for the IPPC permit.	Noted; no further comments from an EPD point of view.

Comments	Responses	EPD Comments
The Pollution Incident Control Plan should also include mechanisms of handling complaints from surrounding activities, local councils and general public.	This information has been submitted to the MEPA as part of the application for the IPPC permit.	Noted; no further comments from an EPD point of view.
Adequate measures should be taken so as to prevent adverse impacts caused by unsafe, inadequate storage and improper handling of raw materials on site and from potential accidental spillage of hazardous fluids, fuel and lubricants which are to be well managed and adequately stored.	This information has been submitted to the MEPA as part of the application for the IPPC permit.	Noted; no further comments from an EPD point of view.
A waste management strategy should be adopted and strictly implemented so that all generated waste streams will be contained, separated and disposed of safely through the appropriate facilities and according to the necessary permits/licences. With regards to removal and disposal of any hazardous waste, adherence to regulatory codes and procedures and due diligence is important in view of any adverse impacts on sensitive receptors.	This information has been submitted to the MEPA as part of the application for the IPPC permit.	Noted; no further comments from an EPD point of view.
Generated wastes, cleaning chemicals, etc from any temporary sanitary facilities for on-site workers should be properly disposed of. Moreover all water for human consumption and personal use at said facilities is to be adequate and potable and preferably from the Water Utility Supply i.e. Water Services Corporation.	Agreed and the Applicant has been informed	Noted; no further comments from an EPD point of view.
It is also pertinent that storm water runoff be carefully managed and properly channelled and that adequate measures are taken to ensure that no water used from water dousing regimes, from wheel wash facilities and any general cleaning runs off the site.	Agreed and the Applicant has been informed	Noted; no further comments from an EPD point of view.
Reservoir-harvested rain water proposed to be collected/stored in same should not be used for human consumption and/or personal use.	Agreed and the Applicant has been informed	Noted; no further comments from an EPD point of view.
Any cooling tower installed as part of the auxiliary unit should be duly registered with the Superintendent of Public Health in accordance with the Registration of Cooling Towers and Evaporative Condensers Regulations, 2006 (L.N. 6 of 2006) and should conform to the requirements of the Control of Legionella Regulations, 2006 (L.N. 5 of 2006) as amended by L.N. 262 of 2006.	Noted	Noted; no further comments from an EPD point of view.
Any conditions imposed by MRA, the Competent Authority, regarding the proposed installation of the LPG storage tanks are to be adhered to.	Definitely	Noted; no further comments from an EPD point of view.
The canteen should be duly registered with the Food safety Commission in terms of the Registration of Food Premises Regulations L. N.180 of 2001, as amended by L.N. 136 of 2007.	The Applicant has been informed of this requirement	Noted; no further comments from an EPD point of view.
All recommended mitigation measures regarding adverse impacts arising during construction and operation phase are to be strictly implemented by applicant to mitigate significant adverse health effects and nuisances on sensitive receptors.	Agreed	Noted; no further comments from an EPD point of view.
The possible health effects of any residual impacts that cannot be mitigated should also be taken into consideration.	Agreed and the Applicant has been informed	Noted; no further comments from an EPD point of view.
Moreover any other unpredicted impacts and nuisances which may arise and that may have a significant adverse effect on public health are to be immediately addressed by the applicant and the necessary mitigation measures taken.	Agreed and the Applicant has been informed	Noted; no further comments from an EPD point of view.

Comments	Responses	EPD Comments
Complaints lodged by the public regarding any adverse impacts/nuisances should be immediately addressed by the applicant. All complaints lodged and actions taken are to be recorded and such records are to be readily available to the Competent Authorities when requested.	Agreed and the Applicant has been informed	Noted; no further comments from an EPD point of view.

E. Birżebbuġa Local Council (Email dated 1 July 2014)

Comments	Responses	EPD Comments
Coordinated Assessment Vol 4. Waste management Plan is to be adjourned every year.	Noted and the Applicant has been informed	Noted; no further comments from an EPD point of view.
1.4 It is stated that that raw materials MAY be Flammable and Hazardous, producing Emissions liquid and solids wastes, potentially harmful to human beings and flora. Question: to what extend can these harmful by products of the raw material can travel in strong winds? Will it travel as far as the Birzennuga or Benghajsa? Comment: It is said that it may be flammable and hazardous, would it be better to state that raw materials are flammable and harmful.	All emissions to air are to pass through filters and scrubbers as is explained in the document. In other words, harmful materials are not expected to travel to the mentioned settlements.	Noted; no further comments from an EPD point of view.
1.5. It is said that the permit will be issued under the Industrial Emissions framework regulations Are there other elements under which the permit will be issued. Question: What about the disposal of hazardous wastes being it liquid and solids? Reading further into the documents provided, hazardous waste is mixed with other hazardous waste in the underground reservoir. It is being proposed that all liquid waste will be disposed off in Italy Question: How can one believe this statement when in the summery of impacts (Coordinated assessment Vol 3)Effects of waterborne pollution on habitat at Wied Znuber as a result of spillage or overflow from the underground waste water storage facility. Probability of impact is unlikely if mitigation measures are adhered to. Yet, Grech ESR expressed concern that the probability is likely. We, also express concern heavy rains can also over fill the reservoir causing hazardous contaminated waste water into the valley. It can also become in contact with the underground aquifer sweet water, should it reaches the sea. Effects can be reversible if not a catastrophic output. Remarks This catastrophe is not clearly defined although it appears almost in all pages of this document. We propose that the byproduct of clean water required for production be stored in an isolated storage tank which, after testing, can be disposed at sea. RO b product is so disposed off at sea.	There was a misunderstanding regarding the capacities of the water storage facilities. These are clarified in the response in Row 19 above.	Noted; no further comments from an EPD point of view.
4.1.1 Green house gasses: The joke in this paragraph is the use of solar power. The amount of panels required to produce super heated steam is enormous. Super heated steam can only be produced used fossil fuel or powerful electric supply. Solar power can reduce the electric power need to run offices, canteen and other low power needed to run. Night time reliability on solar power is nil. Green house gases were discussed the HEI.	Manufacturing plants tend to be heavy users of electricity. However, this does not mean that the mangers of such plants should not try to reduce consumption.	Noted; no further comments from an EPD point of view.

Comments	Responses	EPD Comments
<p>5.1 SCM proposed a monitoring program and environment management.</p> <p>We suggest that MEPA alone will be responsible for the mentoring programme, better still MEPA should insist that an automatic Air, Noise, water and Lighting pollution monitor gives real time results and that this monitoring apparatus will be installed on site. Real time reading must be accessible to on line. Also, MEPA should be the only authorized authority to take samples for testing locally. WSC should also be involved in such sampling. The real time monitoring and sampling together with environment management procedure should be a condition of the IPPC permit. All expense to be incurred by SCM.</p> <p>Note: Medichem, just a stone throw away had to go under the Opra Regime monitoring at the expense of MEPA, being first time introduction.</p>	Noted	Noted; no further comments from an EPD point of view.
<p>Supporting Documents</p> <p>Appendix 2B</p> <p>Dangerous Categories of risk assessment as per Italian Laws.</p> <p>Question: How do Italian Laws compete with British standards or EU regulations? Although the Company is of Italian origin, production in Malta falls under MEPA and other local authorities. We were informed that Italian Laws are more relaxed then other standers mentioned above.</p> <p>Table 3.1.Fire index, explosion index, air pollution index, TOXIC Index and General risk Index can be alarming as very high, serious and very serious. Therefore production, storage of raw materials fall under the SEVESO DIRECTIVE. (see page 39)</p> <p>Table 3.2. Note General risk index: Raw material and hazardous waste storage rates High as per EU waste code 070701* Production rates very high.</p> <p>Question Do we really need such industry, that employs 20 works only at full swing mostly foreigners with the possibility that security, labour, office staff and cleaners will be Maltese nationals? They are not doing us any favours by building and operating this chemical factory, releasing harmful toxins. We see it as the Italians are treating Malta as an europium third world country. Shame on the MIP for introducing another pharmaceutical factory producing a cocktail of harmful emissions. This procedure of introducing more pharmaceutical factories must stop once and for all, we DO NOT need these unless the work force in high for Maltese workers. So far this is the most hazardous installation.</p> <p>2 Health Impact Assessment:</p> <p>By its' own admission, Sterling Chemicals Ltd provided data to Ersli Consultants Limited regarding Air Emissions, Water Effluent and Waste generated in the production of active pharmaceutical ingredients. One is wrong to say that the factory is already operational. The factory at the moment is in pilot stage according to the permit issued.</p> <p>The PDS is so important for one to know exactly the intensions of the Manufacturer. The PDS was criticized by Ersli Consultants. for failure to inform on monitoring, strategic and management .</p>	<p>Italian laws concerning EIA and IPPC refer to the same directives as the Maltese and the British ones.</p> <p>This project does not fall under the Seveso.</p> <p>Re the comment concerning the need for investment of the type in question: This comment should be addressed to the MEPA.</p>	Noted; no further comments from an EPD point of view.

Comments	Responses	EPD Comments
<p>3.1- Air Pollution:</p> <p>Air emissions from Five chimneys E1 to E5 releases air pollution from active carbon, tube bundle heat exchanger and scrubbers are VOC, Powder and Nitrogen Oxide at production level.</p> <p>From scrubbers active Carbon filters and Hepa Filter at Finished goods area are VOC and Powder.</p> <p>From HEPA Filters at the Laboratories pollutants are VOC, Powder and Benzene</p> <p>At the Steam generator facilities we have PM 2.5 and PM10, Carbon Monoxide, NOx and CO2</p> <p>From Boiler the released air pollution are Sulfur Dioxide, PM 2.5 and PM10, Carbon Monoxide NOs and CO2.</p> <p>VOC is an organic compounds including chemicals harmful to human health, which are highly volatile and easily spread.</p> <p>Every One comment on the prevailing winds but what about other winds that can be just as strong.</p> <p>Conclusion:</p>	Noted and the Applicant is informed	Noted; no further comments from an EPD point of view.
<p>MEPA is at fault for allowing long time before the EIA was concluded, since then the factory main structure is finished and production. This makes it hard to refuse permit after such investment.</p> <p>It is now for MEPA to monitor all the harmful air and water released. Noise and the environment, light pollution are also to be monitored.</p> <p>We hope that our recommendation for real time monitoring accessible to all on line is taken in the name of the environment.</p> <p>Had it been for use to grant the IPPC permit, we will vote against the release of the permit.</p> <p>All incidents are to be reported to MEPA within 24 hours from occurrence and included in the annual Environment Report giving details of all accidents.</p> <p>Our main concern is the release into the atmosphere of Hormones and steroids apart from all other releases mentioned above.</p> <p>We seek a hefty planning gain with the sole beneficiary being the Birzebbuga Local Council.</p> <p>We have an annual environment report of a similar factory in Zejtun. In its report they gave an explosion resulting in the collapse of the reservoir roof . In this report we are concerned with the small print quote "Sampling was carried out by this factory and is therefore not covered by laboratory accreditation. For this reason we are insisting that local Authorities carry out all sampling at a cost covered by the manufacturer.</p>	This comment should be addressed to the MEPA.	Noted; no further comments from an EPD point of view.
<p>Finally MEPA must insist on a bankers guarantee in case of catastrophe which may occur and people are hurt.</p> <p>This report is accredited to the University students, Hospital personnel and waste experts.</p> <p>We reserve the right to introduce other comments at the MEPA Board when discussing the IPPC Permit.</p>	This comment should be addressed to the MEPA.	Noted; no further comments from an EPD point of view.

F. Birzebbuga Environmental Action Group (Email dated 1 July 2014)


Comments	Responses	EPD Comments
Birzebbuga Local Council is of the opinion that an eventual IPPC permit sets up a tripartite Monitoring	This comment should be addressed to the MEPA.	Noted; no further comments from an


Committee to monitor closely the implementation of the permit conditions. It will also serve as a vehicle for stakeholder involvement, in particular for ensuring that the operations under consideration will not impact negatively the residential community of Birzebbuga.		EPD point of view.
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APPENDIX IV: Comments post-certification (3rd January 2014 – 24th January 2014)


Birżebbuġa Environmental Action Group (e-mail dated 12 December 2014).

Comments submitted by the public	Responses submitted by the EIA Coordinator	EPD Comments
Unlike other pharmaceutical factories in the area, Sterling Chemicals Malta Ltd is a company that is directly concerned in all the phases of the Active Pharmaceutical Ingredients (API) product cycle, from research to commercial production; Sterling, however, specializes in hormones, steroids and cytotoxic products.	<p>The statement that Sterling Chemical Malta Limited (SCM) is the first of its type to be located in the Hal Far Industrial Zone, is incorrect.</p> <p>In 2004/2005, this EIA Coordinator coordinated the preparation of an EIS concerning an API production plant which was to be located in the Hal Far Industrial Zone (in a site that is less than 250m, as the crow flies, away from plot HF51 where the SCM plant is located), and which was to provide the space for R&D, pilot production, and commercial production of APIs. The development permission for this plant was issued in 2005 and, to date, it is operational.</p>	Noted; no further comments.
It is already covered by a limited MEPA Permit (PA 4236/08) – “permitted to carry out pilot production for research purposes”; which permit, however, appears to have been overshot in that the factory building and finishes, and the new manufacturing and production plant are presently complete and fully operational.	<p>The reader should note that the phasing of the development of the SCM plant was planned to be realised as follows:</p> <p>Phase 1: Pilot Production, which is a component of the R&D function of the proposed plant</p> <p>Phase 2: Commercial Production</p> <p>Phase 3: further Commercial Production</p> <p>The BEAG comment regarding the current plant is also incorrect. It fails to note that development permission PA/04236/08) covers the following aspects:</p> <ul style="list-style-type: none"> • all construction works which were planned for all above-mentioned the three phases of the development of the plant, and • pilot production (Phase 1 only). <p>No commercial production (Phases 2 or 3) is taking place in HF51.</p> <p>A subsequent permission (ref: PA/04236/08) later issued in order to enable SCM install three LPG storage tanks.</p> <p>It should also be noted that in 2008, it was logical and imperative for SCM to apply for development permissions for a factory which houses all the three phases of the SCM-plant development. Certain facilities such as weighing, storage, the plant room, and water-heating and steam production facilities (using LPG) are common for all the three phases.</p> <p>Furthermore, the issue of permissions PA/04236/08 and PA/04236/08 would reduce substantially the time required for the processing of applications (such as the one under consideration in this EIS) for the installation of new equipment for commercial production, and, perhaps more importantly, reduce the need for construction works while API R&D and production works are taking place</p> <p>SCM also submit that the recent and current output of Pilot Production at their Hal Far plant is typical of R&D activity in the APIs field. Since R&D is essentially an activity which involves substantial experimentation, an experienced scientist should expect outputs to be relatively unpredictable. It is therefore impossible for one to make concrete forecasts of outputs, given that the primary function of R&D activity is the attainment of the best possible chemical syntheses, rather than pre-established production levels based on tried and tested formulae or procedures. This is one consideration which makes Pilot Production different to Commercial Production.</p> <p>Currently, SCM are running several studies, which evidently imply both the need for raw materials and the generation of wastes. The quantities of both raw materials and wastes would vary from study to study and from experiment to experiment. If, for example, the results of particular studies indicate that more research needs to be carried out in order for better results to be attained, experiments need to be carried out again and new ones tried out. This would, in turn, mean more raw materials and wastes.</p> <p>Indeed, in the Project Description Statement (PDS), which was issued three years ago, the declared amount of generated waste was half of the current average, and the figure was subsequently corrected in the EIS, as shown in Table 1-27 (on page 79 of the Coordinated Assessment Volume One) and reiterated in the Project Description prepared for the application of the IPPC permit (hereinafter referred to as the IPPC Project Description), specifically in paragraph B-7 table 38.</p> <p>The IPPC Project Description was submitted to the MEPA in May of 2014.</p>	<p>Noted; no further comments.</p> <p>Noted; no further comments.</p>
Unfortunately, the factory was planned and built by the mother company; and is now fully operational, without having the prior sanctioning of MEPA and other local health and environmental authorities, including, but not restricted to, Health, Safety, Water and Wastewater, and environmental protection. We have no evidence that this particular factory is presently adhering to the EU maximum emission values, and that it is not already contaminating the highly delicate environment in the immediate vicinity through its liquid and solid wastes. Therefore we seek reports of their current disposal of waste during the experimental period or rather, from the time the initial permit was granted.	<p>As is noted in the previous response, BEAG’s contentions in this comment are incorrect. The operations of the plant are still at the Phase 1 stage, and the MEPA is well informed about this.</p> <p>All the information that was submitted (i) to this EIA Coordinator for inclusion in this EIS, and (ii) in the IPPC Project Description has been copied to the BEAG.</p> <p>This information was to be examined by MEPA officials before the applications for the development permission in question and for the IPPC permit can be determined by the MEPA. The EIA process, and the public consultation which forms part of this process, are meant to provide the MEPA with information on the basis of which an informed decision can be made when the application for the said development permission is determined.</p> <p>The EIS (in the Coordinated Assessment Volume One and in the Comments and Responses documents) and the IPPC Project Description provide substantial information regarding waste and its management.</p> <p>Furthermore, SCM have indicated to this EIA Consultant that they have no problem in providing all the relevant documentation which was/is needed in order to ensure the proper treatment/disposal of waste. SCM is also in possession of all the necessary permits required for the transfer of waste. The quantities of produced and disposed wastes are available from both Green Skip Limited (the licenced Waste Broker appointed by SCM) and SCM themselves. Such documentation was provided to the Water Service Corporation (WSC) during their most recent inspection of the quality of the discharge from the SCM factory into the public sewerage system.</p> <p>The waste management procedure adopted by Sterling is presented in Annex 1.1 to Annex B.</p>	Noted; no further comments.

Comments submitted by the public	Responses submitted by the EIA Coordinator	EPD Comments
	<p>It should be noted that Sterling SpA (the mother company) has for long [since 1976] operated within the framework of the regulatory regime [used in EU Member States], which was adopted in Malta upon its EU accession.</p> <p>This experience has, among other things, enabled Sterling to obtain both the OHSAS 18001 and ISO 14001 certifications, both of which will be attained once commercial production commences at the SCM Hal Far Plant.</p> <p>Furthermore, the Sterling operations in both Italy and Malta involve the adoption of BAT as was/is required in the IPPC Directive and more recently in the Industrial Emissions Directive.</p> <p>Both the EIS and the IPPC Project Description include information regarding the BAT that have been and are to be adopted.</p>	Noted; no further comments.
<p>It results to the writer that it has already installed highly irregular wastewater drains and valves that are presently grossly contaminating the Maltese sewers with highly hazardous hormones, steroids, and other cytotoxic wastes. Moreover, it was reported in the EIS that any and all rainwater run-off would be contaminating the immediate Wied Znuber, and the area aquifer.</p>	<p>Reference should be made to the part of the previous response regarding the recent WSC inspection.</p> <p>Secondly, the EIS discusses the possible contamination of the valley in the event that the system designed to preclude such contamination are not designed, installed, and/or used correctly. This is normal practice in EIS report writing.</p> <p>The EIS does not speak of any contamination that is already taking place in the area, so the author of the comment should have included solid substantiations to support the serious allegations [in the comment]. In the absence of such substantiations the comment is invalid in as far as this EIA Coordinator is concerned.</p> <p>SCM reiterate that their waste management system consists of the following aspects:</p> <ul style="list-style-type: none"> • All hazardous waste has to be stored in the External Flammable Warehouse. The containers would be placed on impermeable basins, which are designed to contain any spills or leaks. This makes it impossible for any hazardous liquid to be discharged or to escape into the public sewerage disposal or rain-water harvesting/disposal systems. The corresponding details are shown clearly in the Coordinated Assessment (both Volumes One and Two) and in the IPPC Project Description. • In the case of a spill, while containers are placed on the fixed containment basins, inside the External Flammable Warehouse, the spilled liquid would be collected in a closed 2m3 chamber, the floor and walls of which are impermeable. SCM have informed this EIA Coordinator that they are willing to fund the regular inspection of this chamber by impartial experts. This EIA Coordinator notes that such issues are discussed in detail during the process leading to the issue of the IPPC permit. • Non-hazardous wastes would be kept in closed containers in front of the External Flammable Warehouse. <p>The above descriptions and the corresponding drawings are presented in both the EIS and the IPPC Project Description</p> <p>During the handling of hazardous waste containers, SCM will install in the forecourt [of the External Flammable Warehouse] a demountable spill-containment deck of the type shown in Figure 1 and Figure 2 (below), which would act as a secondary container in case of an accidental spill outside the impermeable basins in the External Flammable Warehouse.</p> <p>Furthermore, the environmental management system of the operations would include a requirement that tanks and hazardous waste containers would be moved from their containment basins only on the day of arrival of the truck that will transport them away from HF51. The appointed Waste Broker would be required to collect waste frequently in order to ensure flexible storage arrangements. Such arrangement would be particularly useful during heavy rains when it would not be advisable for hazardous liquid containers to be handled.</p>	Noted; no further comments.
		
	<p>Figure 1: example of a heavy-duty demountable spill-containment deck</p>	

Comments submitted by the public	Responses submitted by the EIA Coordinator	EPD Comments
		
	Figure 2: example of a heavy-duty demountable spill-containment deck showing the basic components of the system	
<p>From a factory meeting with high Sterling Officials on the 29th June, 2014, it results that the amount of highly hazardous liquid waste produced presently by Sterling Malta is twenty metric Tonnes per month; or twice the amount declared in the PDS and EIS to be eventually produced by Sterling</p>	<p>As is noted in the response to comment number Error! Reference source not found. (Error! Bookmark not defined.), the recent and current output of Pilot Production at the SCM plant [in Hal Far] is typical of R&D activity in the APIs field. Since R&D is essentially an activity which involves substantial experimentation, its outputs vary. It is therefore not possible for one to make concrete forecasts of outputs, given that the primary function of R&D activity is the attainment of the best chemical synthesis.</p> <p>Currently SCM are running several studies, which evidently imply both the need for raw materials and the generation of waste vary from study to study and the results of the studies. If, for example, the results of particular studies indicate that more research needs to be carried out in order for better results to be attained, experiments need to be carried out again and new ones tried out. This would, in turn, mean more raw materials and wastes.</p> <p>Indeed, in the Project Description Statement (PDS), which was issued three years ago, the declared amount of generated waste was half of the current average, and the figure was subsequently corrected in the EIS, as shown in Table 1-27 (on page 79 of the Coordinated Assessment Volume One) and reiterated in the Project Description prepared for the application of the IPPC permit (hereinafter referred to as IPPC Project Description), specifically in paragraph B-7 table 38.</p> <p>The IPPC Project Description was submitted to the MEPA in May of 2014.</p>	<p>Noted; no further comments.</p>
<p>Moreover, this hazardous waste was confirmed to be stored presently at the factory basements, to the potential further contamination of the delicate area aquifer, and the area potable water (borehole).</p>	<p>SCM maintain that waste is not stored in the factory basement. All wastes (liquid and solid hazardous) will be stored as indicated in the EIA, the IPPC Project Description, and above.</p>	<p>Noted; no further comments.</p>
<p>The authors of the “Health Impact Assessment” (Supporting Documents Appendix Two B – Other Reports) reported (3.) a “lack of other pollution mitigation measures”, noted potential health and safety hazards, and went so far as to report that Sterling “failed to provide information on monitoring and strategic management that should be addressed”.</p>	<p>The pollution abatement systems are well discussed in the EIS and are presently being subjected to the assessment of the MEPA through the process leading to the issue of the IPPC permit.</p> <p>More information is provided in other parts of this document.</p> <p>This EIA Coordinator confirms that a Waste Management Plan and a Monitoring Plan were submitted to the EIA Team. These plans also formed part of the IPPC project Description.</p> <p>As noted above, the MEPA is in possession all the details of the proposed pollution abatement measures and of the HIA, and it is in a position to make informed decisions when it determines the applications for the development permission and the IPPC permit.</p>	<p>Noted; no further comments.</p>

Comments submitted by the public	Responses submitted by the EIA Coordinator	EPD Comments
<p>It is, moreover, grossly evident that Sterling presently has a negative 'laissez faire' attitude in correcting exceeding environmental noise pollution and VOC emissions (3.1.1. and 3.2.2.); this needs to be addressed and corrected by independent monitoring and reporting in a good number of environmental fields, together with the direct involvement of both the environmental and health authorities. (5.,).</p>	<p>The 'noise' issue indicated in the HIA is not strictly speaking a concern of the EIS because the 'noisy' environment that is referred is located within the factory building and does not affect neighbours or visitors to the industrial zone. The impact of the internally-generated noise is not felt outside the factory building, as is confirmed in the noise assessment report prepared by Christian Calleja, which is included in the EIS (Appendix Two B). Calleja's assessment has also been included in the IPPC Project Description.</p> <p>The HIA identifies the pump room as the area which was excessively noisy. SCM have informed this EIA Coordinator that the pumps in this room are used for emergencies only, and would only be activated in the event of fire, in order to pump the water collected in the rain water reservoir. This area would only be accessed during fire drills or in case of a real fire. The activation of the pumps is automatic and the operator would only need to enter to turn the pumps off. This action would be circa 1 minute long.</p> <p>In response to the points raised in the HIA, SCM note that they are providing the following in both the pump room and plant room:</p> <ul style="list-style-type: none"> • Signs indicating where Personal Protective Equipment (PPE) had to be used; • The supply of the required PPE. <p>SCM also commissioned ad hoc noise monitoring by Maltese professionals who provided all the certifications of the instruments used. On the basis of the monitoring results SCM carried out the following actions:</p> <ul style="list-style-type: none"> • The preparation of a plan with identifies different levels of noise in the factory. • The preparation of a of noise risk assessment, on the basis of which protective measures have been identified. • The replacement of two of the three pumps in the pump room. <p>SCM then carried out further noise monitoring in order to check the working ordinary conditions.</p> <p>SCM submits that the monitoring reports were prepared in accordance with the criteria laid out in Maltese Occupational; Health and Safety Law.</p> <p>Once commercial production commences, all the required noise monitoring would be carried out by independent OH&S consultants.</p> <p>Annex 1.2 to Annex B describes the investigations and the adopted precautionary measures .</p> <p>The reference in the HIA 'amine-like smell outside the building' (from a possible VOC emission point), was investigated and it was discovered that such odours were being emitted from the vacant corner site located adjacent to HF51. The smell could be caused by water that ends up in this site (see Figure 3 on page 30).</p> <p>The drainage layout demonstrates that there is no possibility that the responsibility falls on Sterling Chemical Malta Ltd (see Annex 1.3 to Annex B)</p>	<p>Noted; no further comments.</p>

Comments submitted by the public	Responses submitted by the EIA Coordinator	EPD Comments
	 <p>Party wall separating HF51 and the corner site</p>	
<p>“The site lies at the edge of a valley system leading straight to the sea.....Theoretically, any contaminants from the site could, in the event of severe flooding, drain into the valley and into the sea.</p> <p>This could be a potential danger not only to the fragile ecology of the area, but also to humans (especially, the Birzebbuga residents) as any dangerous chemicals could enter the food chain. This is especially so given that hormones that are processed and produced on the site, and these could well affect both terrestrial and marine ecosystems” (Supporting Documents Appendix Two B, Other Reports, Health Impact Assessment para 3.3.1.).</p>	<p>Figure 3: water which has accumulated in the corner site adjacent to HF51.</p> <p>As is noted above, adverse impacts on the mentioned environmental resources would occur in case the required abatement measures concerning water management and hazardous substances are not designed, installed, or used as planned.</p>	<p>Noted; no further comments.</p>
<p>“Both Wied Znuber and the cliffs are scheduled under article 81 of the Environment and Development Planning Act and identified as a site of community importance (SCI) under the Habitats Directive and a special protected area (SPA) under the Birds Directive..... It is of particular hydrogeological importance as it's pores and fissures host the mean sea level aquifer (MSLA) below the site. The hydrogeological and hydrological features close to the site are:</p> <ul style="list-style-type: none"> • The mean sea level aquifer • Ephemeral watercourse of Wied Znuber • Catchment of Wied Znuber • Catchment of the site • Water boreholes administered by the Water Services Corporation (Coordinated Assessment, Volume Four, Non-Technical Summaries, Para 3.1., 3.2.). 	<p>Noted</p>	

Comments submitted by the public	Responses submitted by the EIA Coordinator	EPD Comments
<p>The area in question is also protected by the Natura 2000.</p> <p>The Summary of Impacts – HF51 (i.e. Sterling Malta Ltd) on Wied Zhuber presented by Philip B. Grech in his EIS study on Water Bodies is highly disconcerting to the residents of Birzebbugia.</p> <p>Inevitable and likely incident probability, with cumulative, long term, irreversible, high impact through rainwater, sanitary sewage and process wastewater were reported. EIS, (Supporting Documents, Appendix Two A, Environmental Survey Reports – Water Bodies). All these need to be addressed with urgency, together with continual independent monitoring, testing, reporting and trouble shooting, as and when required throughout the Sterling Malta Ltd operations.</p> <p>The above was confirmed again in the Ecological Report (Vertebrates), Summary of Impacts 3, where the low standard of HF51 storage facilities leading to chemical residues and run-off into Wied Zhuber, could further add to the long term, high and irreversible impacts, unless mitigation measures are immediately undertaken, once again, together with independent, regular monitoring. The conclusions and recommendations of the same report, one other amongst a long list of similar ones, should be followed by both the Planning and Environmental Authorities, and included in the relative permit conditions, where relevant.</p> <p>EIS, Supporting Documents, Appendix Two A, Environmental Survey Reports, Ecological Reports – Vertebrata.</p>	<p>Perit Philip Grech expresses some disagreements with respect to the proposed water management systems. However this does not mean that the systems as proposed by the SCM services engineer are not viable.</p> <p>As is noted above, the transport of hazardous wastes away from the factory will be taking place frequently, which means that the hazardous liquids storage facility will not be functioning at its limits.</p> <p>SCM submit that in the wash water reservoir a level switch would be used in order to warn of potential overflows. The threshold level is set to 70% of the capacity of the reservoir. The reservoir floor and walls are impermeable and it is not connected with any pipe or underground pipeline, other than the input pipe. SCM proposes a two-yearly assessment of the resistance, the mechanical efficiency of the pipes, and the permeability of the tank by an independent entity appointed by the MEPA.</p> <p>This EIA Coordinator is informed that on 03 December, 2014 the WSC carried out a check on the of the water discharged into its sewerage system and decided to renew the discharge permit. SCM has submitted to this EIA Coordinator that they would not object to their being required to monitoring their water management system (see Annex 2.1 to Annex B)</p>	Noted; no further comments.
<p>A good number of other suggested and “highly recommended” mitigating measures relative to ‘Water’, including “Rainwater Harvesting”, “Rainwater: in the event of flooding”, “Wastewater (Water washing)” and “Wastewater Disposal Audit are included in the Health Impact Assessment (Supporting Documents, Appendix Two B, Other Reports, Para 4.3. Water). The same study includes other important mitigation measures, including the Monitoring by an external entity together with and Regularity of Monitoring (Para 4.6 – 4.6.1-2).</p> <p>In like manner, MEPA permitting should pay particular attention to Chapter 5, “Recommendations” of the Health Impact Assessment (Page 30), and to Table 6: Summary of Recommendations (Page 31-32), AND INCLUDE ALL, WITHOUT EXCEPTIONS, IN ANY NEW PERMITTING, INCLUDING THAT RELATIVE TO THE IPPC.</p>	<p>The rainwater reservoir tank receives runoff from the roof, the open area between the factory and the External Flammable Warehouse (i.e. the above-mentioned forecourt of the warehouse), the area used for the solid waste stock, and for any rain water which would end up inside the External Flammable Warehouse.</p> <p>SCM note that the following issues should be taken into consideration:</p> <ul style="list-style-type: none"> • The forecourt is not used for the storage of raw materials or waste. Full or empty tanks may be placed in this area temporarily, as it is a transit zone for forklift trucks, pallet trucks, or trucks for loading and unloading goods/wastes. The operators are trained and the operational procedures emphasise that hazardous material cannot be stored in that area. In order to ensure that the forecourt is not contaminated, the heavy-duty demountable spill-containment deck shown in Figure 1 and Figure 2 (on page 27) would be set up whenever goods and wastes containers need to be moved. • The zone in which solid waste will be stored will be covered and the connection with the public sewerage system will be closed. 	Noted; no further comments.
<p>In view of the potential contamination risks to the aquatic environment, including aquifers, potable water, and wastewaters, as arising from the Sterling Malta Ltd Operations at HF 51, Hal Far Industrial Estate, as amplified in the relative Environmental Impact Statement, it is strongly recommended that all the relative documentation be referred to the Chief Executive of the Water Services Corporation, and the Chief Executive of the Malta Resources Authority for full compliance with the EU Water Framework, as transposed locally, including, but not limited to, the Sewer Discharge Control Regulations, Legal Notice 139 of 2002, as amended by LN 378 of 2005.</p> <p>Moreover, MEPA should nominate an independent qualified person, at the expense of Sterling Malta Ltd:</p> <ol style="list-style-type: none"> 1. to supervise and report on the implementation of a number of mitigating measures as recommended in the relative EIS, prior to the award of any further permitting, in order to mitigate or eliminate a number of potential risks and health hazards as arising directly from the Sterling Malta Ltd operations, with special reference to the water, wastewater, hazardous material storage, liquid hazardous wastes and their management, and the immediate HF51 environs, internally and externally, as presently managed. 2. To monitor, test and report for a period of three years (renewable throughout Sterling lifetime), at six monthly intervals, on the facilities and operations, storage and management of all liquid materials, including water, wastewaters; liquid and solid hazardous materials; liquid and solid hazardous and non hazardous wastes and their disposal. 	<p>As is noted in previous responses SCM does not object to have its systems monitored by independent consultants appointed by the MEPA.</p>	Noted; no further comments.
<p>One is astonished when reading that “it is important to note the authors of this HIA have been provided with some data on air emissions, water effluents and waste products that are produced at the Active Pharmaceutical Ingredients Plant being investigated. This is provided, presumably by specialists engaged by the owners of the factory....”(Health Impact Assessment {HIA} – Chapter 2.1- para 4).</p>	<p>The reason for the astonishment on the part of the author of the comment is not clearly established.</p>	Noted; no further comments.
<p>There is no reference to any method statements, or accreditation behind these reported values. Moreover, there is no reference in the EIS to any comparisons with established MEPA values for Air Quality in the South of Malta, or with statutorily accepted maximum emission limit values.</p>	<p>Given that the concentrations of air pollutants to be emitted into the atmosphere was not expected to be of significance, such information was not requested in the Terms of Reference of the EIS.</p>	Noted; no further comments.

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<p>One notes that Sterling Malta Ltd does have in place a number of emissions' abatement systems (scrubbers and HEPA/Carbon filters) in the production and finished products areas. However, the steam generator and Boiler were excluded from these systems, even through noxious gases (viz. NOx, CO, SO2) and hazardous Particulate Matter (PM10/PM2.5) are generated in these areas.</p> <p>We regret to point out that there is no particular abatement systems in place at the storage facilities for the legion of highly hazardous materials used by Sterling (see list of MSDSs provided), or for the temporary storage of hazardous liquids wastes or other hazardous solid wastes (20 IBCs per month stored at Basement Level as reported to representatives of the Birzebbuga Environmental Action Group {BEAG} by Daniele Cavallaro, Quality Assurance.</p> <p>Manager for Sterling on 29 June, 2014), Even the HIA -Chap 3, para1 noted a lack of pollution mitigation in some aspects, and some potential health and safety hazards.</p>	<p>In the case of air pollution abatement, SCM adopted a strategy based on the upstream blocking of potential pollutants.</p> <p>In the case of emission points E5 and E6, one would expect NOx, and to a substantially lesser extent, SOx (LPG contains traces of sulphur ~ less than 30 ppm), which would be produced by the steam generator and the boiler. In order to reduce the production of these compounds SCM have come up with the following mitigating measures:</p> <ul style="list-style-type: none"> • The combustion efficiency of the generator must always be above 95% as well as the rest is for the Steam Generator and the Water Heater. This would minimise the emission of NOx • The fuel used for the heating of water had to be of the low sulphur type, hence the use of LPG. <p>As is explained in detail in both the EIS and in the IPPC Project Description, emission points E1 to E4 are preceded by HEPA filters for particulates, and Active Carbon filters, the Scrubber, and the shell and tube condensers for organic chemicals.</p> <p>As is noted above (see response to comment Error! Reference source not found., Error! Bookmark not defined.), SCM submit that the reported amounts, especially in output, are typical of R&D activity in the APIs sector, and, being in an experimental field, the output forecasts can be variable as related to attempts to process that always constitute a cardinal principle of the research and development activity, aimed to the research of the best chemical synthesis.</p> <p>Currently, SCM are running several studies, which evidently imply both the need for raw materials and the generation of wastes. The quantities of both raw materials and wastes would vary from study to study and from experiment to experiment. If, for example, the results of particular studies indicate that more research needs to be carried out in order for better results to be attained, experiments need to be carried out again and new ones tried out. This would, in turn, mean more raw materials and wastes.</p>	Noted; no further comments.																					
<p>We note that it was our group that insisted on a list of products and their MSDS (omitted in the EIS reports). It is our concern that such amount of products is to be used in the manufacturing stages.</p> <p>Therefore we seek in advance annual amounts of all products to be used in the production of the finished active ingredient. MEPA is to keep a close watch on these chemicals, acids, solvents and gases. MEPA must insist that the list be reduced to not more than 80 imported hazardous, flammable, explosive goods. We recommend that the permit be based on these 80 products as a condition to the permit. Should any supplies be reduced and replaced by others, MEPA will discuss the issue to grant or refuse any changes. This also we recommend that will be a condition of the permit. Other similar factory, Medichem used 41 different chemicals acids and solvents to produce their active ingredients We are recommending twice as much to Sterling Pharmaceutical Ltd.</p>	<p>Had the MSDSs been requested in the Terms of Reference they would have been submitted in the EIS. Indeed, SCM had informed the EIA Coordinator about their availability and submitted as digitised copy of these documents to him. They were included in the IPPC Project Description. In other words, MEPA have been supplied with the information that is normally provided in MSDSs. The public would have been informed of these MSDSs through the public consultation pertaining to the process leading to the determination of the application for the IPPC permission.</p> <p>The other points in the comment are noted.</p>	Noted; no further comments.																					
<p>"Harmful VOCs are usually not acutely toxic. However in the long term, their effects can be quite severe, depending on the nature of the chemical (see list of MSDSs provided by Sterling, most of which are highly toxic to humans and the environment (flora and fauna) have highly hazardous properties, including, but not restricted to, carcinogenic, mutagenic, teratogenic, even at exposures of parts per million (ppm). Effects vary from increased susceptibility to asthma to increased risks of cancer. Additionally VOCs react in sunlight with nitrous oxides such as Nitrogen Dioxide to form Ozone, which is harmful to the respiratory system"</p> <p>"An additional problem with VOCs is that they are highly dispersible, and travel long distances from the point source. This could pose a problem as the site is approximately 1.2 km from the closest residential area in Birzebbugia. However with Malta's prevailing winds being most from a NW direction, the VOCs can be expected to be blown, on most days, over the sea and away from Malta. Should the wind be favorable for VOCs reaching residential areas, it is most likely that they will be highly dispersed by that time. At low concentrations upon air inhalation, their harmful affect would not be quantifiable, although there may be a harmful effect, especially in the long term." (HIA para 3.1.1.)</p> <p>As already pointed out, VOCs do not arise solely in the production and finished goods areas (covered by scrubbers and active carbon filters); the weighing room and laboratories are also directly concerned.</p> <p>Moreover, the HIA experts noted the release of VOCs on repeated HF 51 inspections, including areas such as the loading/unloading area, and the waste collection area (with VOCs directly arising from one of the irregular chimney vent), and the production lab. (HIA Para 3.1.1).</p> <p>It is strongly recommended that these constraints are remedied with priority, possibly by additional venting through existing scrubbers.</p>	<p>SCM submit that the long-term and short-term impacts of VOCs are known and also highlighted in the IPPC Project Description, which, as is noted earlier, has been submitted to support the SCM application for the IPPC permit.</p> <p>SCM have submitted the following table in order to provide a more detailed account of the emission system than that submitted to this EIA Coordinator and in the IPPC Project Description.</p> <table border="1"> <tr> <th>Emission point</th><th>Abatement system</th><th>Location in factory</th></tr> <tr> <td>E 1</td><td>Scrubber, carbon filter, tube bundle heat exchange, blow-down system</td><td>Production area</td></tr> <tr> <td>E 2</td><td>Scrubber, carbon filter, dust filter Absolute filter class efficiency 13 EU 99.99% Pockets rigid filter class efficiency EU 8 80/90% Pockets rigid filter class efficiency EU 3 80/60%</td><td>Finished goods area</td></tr> <tr> <td>E 3</td><td>Scrubber, carbon filter, HEPA filter that divided into two level For finer solid particles a 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.</td><td>Weighing room</td></tr> <tr> <td>E 4</td><td>See above</td><td>Laboratory</td></tr> <tr> <td>E 5</td><td>Multi-stage combustion technique, which enables the recirculation of combustion</td><td>Steam generator</td></tr> <tr> <td>E 6</td><td>gases.</td><td>Boiler</td></tr> </table>	Emission point	Abatement system	Location in factory	E 1	Scrubber, carbon filter, tube bundle heat exchange, blow-down system	Production area	E 2	Scrubber, carbon filter, dust filter Absolute filter class efficiency 13 EU 99.99% Pockets rigid filter class efficiency EU 8 80/90% Pockets rigid filter class efficiency EU 3 80/60%	Finished goods area	E 3	Scrubber, carbon filter, HEPA filter that divided into two level For finer solid particles a 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.	Weighing room	E 4	See above	Laboratory	E 5	Multi-stage combustion technique, which enables the recirculation of combustion	Steam generator	E 6	gases.	Boiler	Noted; no further comments.
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<p>“Nitrogen oxides, mainly NO2, are gaseous air pollutants ... which typically form when fossil fuels are burnt at high temperatures.</p> <p>Nitrogen oxides are known to be emitted from Pharmaceutical plants, and this has been acknowledged in the IPPC document provided. NO2 also mixes with outdoor air to form particulate pollution and ozone, especially in the present of sunlight. It is one of several widespread air pollutants that have national air quality standards to limit them in outdoor air”</p> <p>“Nitrous oxides can have quite a range of health effects on the lungs, namely</p> <ul style="list-style-type: none">• Increased inflammation of the airways• Worsened coughing and wheezing• Deterioration in lung function• Increased asthma attacks• Increased hospital admissions• Increased susceptibility o respiratory infection, such as influenza” <p>The HIA reports that no mitigation strategy is being offered by Sterling, who have only suggested “some monitoring of emissions”.</p> <p>The HIA points out additionally that Chimney E5 and E6 , which collect fumes coming from the steam generator and boiler, and which are confirmed to be the source of these noxious gases (HIA Table 1); and recommends (HIA 4.1.2.) that emissions from chimneys 5 and 6 should be “carefully monitored” so that in the event of an increase in emissions of this harmful gas, interventions would be undertaken to find the cause of increased emissions. Additionally, if possible, cleaner fuels should be obtained to minimize Nitrogen Dioxide as much as possible.</p>	<p>The reader is referred to the response to comment Error! Reference source not found. (Error! Bookmark not defined.).</p> <p>The E5 and E6 emission points are not connected to an abatement system because they extract the exhaust of a Hot-water Boiler and a Steam Generator. The latter has an energy efficiency of over 90% and a working system which inhibits the formation of the classical pollutants produced by these types of sources, such as SOx, NOx, CO and O3.</p> <p>The formation of pollutants is therefore blocked upstream of the emission.</p> <p>The major problem of conventional boilers is connected with incomplete combustion of fuels, which generates pollutants such as NOx and CO. Being aware of this SCM opted for a generator is of the double-pass type for which the residence of the flue gas and the fuel in the chamber is double and this ensures a higher yield in the combustion.</p> <p>Moreover, before exiting into the atmosphere, the fumes pass through an economiser which is an additional heat exchanger which allow a further reduction of traces of any remaining CO. This is because it maintains a high flue gas temperature to the end. The following is a summary of the abatement solutions proposed by SCM engineers with respect to the exhausts emitted through points E5 and E6</p> <table><tr><th>System for steam generator (E5)</th><th>System for boiler (E6)</th></tr><tr><td><ul style="list-style-type: none">- immersion in water of the combustion chamber- two smoke ring- degasser- economizer- combustion efficiency minimum guaranteed of 90%</td><td><ul style="list-style-type: none">- horizontal combustion chamber with flame inversion and battery smoke concentric pipes, it is a high yield hot water generator;- insulated boiler body- pre-mixer with modulating power for heating and electric ignition without a pilot flame- low-NOx burner with efficiency above 93%</td></tr></table> <p>Emissions containing the benzene, SOx and IPA depend greatly on the fuel in use. As is established in the EIS and in the IPPC Project Description, the combustion required for Water Heating and Steam Generation is and shall be fuelled by LPG. SCM indicate that the LPG supplier has guaranteed the supply of LPG in which sulphur content would less than 30 ppm. LPG does not contain benzene or IPA.</p>	System for steam generator (E5)	System for boiler (E6)	<ul style="list-style-type: none">- immersion in water of the combustion chamber- two smoke ring- degasser- economizer- combustion efficiency minimum guaranteed of 90%	<ul style="list-style-type: none">- horizontal combustion chamber with flame inversion and battery smoke concentric pipes, it is a high yield hot water generator;- insulated boiler body- pre-mixer with modulating power for heating and electric ignition without a pilot flame- low-NOx burner with efficiency above 93%	<p>Noted; no further comments.</p>
System for steam generator (E5)	System for boiler (E6)					
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<p>Ozone</p> <p>“This odourless gas is formed from NOx (Nirogen Oxides) and VOCs, both of which are emitted from the API plant at Hal Far... At abnormally high concentrations, usually brought about by human activities (largely by the combustion of fossil fuel), it is a pollutant and a constituent of smog... At ground level, ozone has a harmful effect on the lungs and irritates the respiratory system. Exposure to ozone and the pollutants that it produces (due to its oxidative reaction with other chemicals in the atmosphere) has been linked to asthma, bronchitis, heart attacks, premature death and other cardio-respiratory problems.”</p> <p>“The IPPC document (PD) provided did not include monitoring of Ozone within the facility or at emission points... and it is therefore highly recommended that monitoring of this gas be carried out. This is especially important since the facility emits both VOCs and Nitrogen oxides, that react together to form ozone. Should elevated measurement of this</p> <p>gas be detected, measures such as inspection of emission points or re-evaluation of activities on site should be carried out, as the effects... could be very harmful both in the short and long term”.</p>	<p>Both the EIS and the IPPC Project Description (see section B.2.4) discuss "Ozone Depleting Substances and fluorinated greenhouse gases".</p> <p>The document MIO_4.4.6-D3 procedure "Operational plan for control of technical gases" was submitted as part of the EIS following a request made by the MEPA after the EIS was assessed [by the MEPA] (see Annex 3.c.1 to Annex B)</p>	<p>Noted; no further comments.</p>				
<p>“Particulate matter is well known to cause adverse effects even of the most serious nature (eg. Lung cancer, cardiac arrest) and mitigation of emissions is highly recommended especially since the particles emitted from a pharmaceutical plant would be more likely to have an adverse health affect due to the activities at the plant.”</p> <p>Particles are expected to be emitted from the site from various sources, including the handling of raw materials which can be potentially harmful. It is therefore highly recommended that air filters on site (HEPA filters 13 and 14) are regularly changed to ensure that mitigation functions as expected... Once again for PM, monitoring should be implemented regularly.</p>	<p>All HEPA filters are regularly changed and replaced as determined by the maintenance plan that was delivered to the MEPA with the IPPC Project Description (in annex B.2.5-A1) (see Annex 3.d.1 to Annex B)</p>	<p>Noted; no further comments.</p>				

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<p>Hazards, Monitoring, Independent Audits, Mitigation Measures</p> <p>We are to point out that the reported (HIA PARA 3.1.1.) prevailing wind (NW) would be affecting directly and continually the residents of the scattered hamlet areas of Benghisa, Wied Znuberl/o Birzebbugia, a few metres off the HF 51 Sterling Factory site.</p> <p>The long term adverse health effects do not arise solely from the VOCs released, but hold also for emissions from Ozone, NOx, Hydrocarbons such as Benzene, Dichloromethane, non- halogenated solvents, and Particulate Matter. (see Table 1, Para 3.1. Air Pollution, of the HIA, see also additional info below) .</p> <p>On the other hand, the South West winds (LBIC), one other arising, fairly common wind, immediately blows the arising noxious gases and particulate matter over the Birzebbugia residents that live only 1.2. km away, including il-Brolli and Tal-Papa residential areas (in Brizebbugia), with the reported, arising, long list of negative long term effects on our health. This is NOT ACCEPTABLE, and we expect MEPA to take all the necessary precautionary and mitigating measures to safeguard the interests of the B'Bugia residents and our environment</p> <p>One expects that any and ALL recommendations, specifically made in the EIS are included, without fail, in any eventual further permitting/operating conditions/IPPC, and that subsequently further independent monitoring be maintained throughout the lifetime of the Sterling HF 51 operations. The EIS has stressed repeatedly phrases like “highly recommend”, follow up correction measures, as required, and “independent continual monitoring and audits”</p>	<p>The Risk Assessment which is discussed in the Coordinated Assessment (Volume One) and included as an Appendix to the EIS, highlights the relationship between the possible pollutants and prevailing winds.</p> <p>It is evident that SCM will have to comply with any conditions, limits, and thresholds which MEPA establish in order to protect the residents of Birzebbuġa and Bengħajsa.</p> <p>Also the attainment of ISO 14001 and OHSAS 18001 certifications involves, among other things, that the SCM operations will be subjected to environmental and health & safety audits. The IPPC permit will also involve such commitments.</p> <p>As for the ozone O3, a monitoring plan has, as is noted above, been submitted as a component of the supporting material for the application for the IPPC permit (see Annex 3.c.1 to Annex B).</p>	Noted; no further comments.
<p>The list of highly hazardous materials used by Sterling at HF 51 is to long to be included here; and their adverse effects on our health and environment was repeatedly stressed in the EIS. A review of the MSDS provided (somewhat belatedly by Sterling) confirms that the properties of the materials earmarked to be used are extremely hazardous, and include, amongst other, “oxidising”, “corrosive”, “irritants”, “toxic”, “ecotoxic” “carcinogenic”, “toxic for reproduction” and others that may induce hereditary genetic defects or increase their incidence.</p> <p>Most of these materials, in gaseous, liquid or solid forms, are extremely hazardous, even at very small concentrations, such as parts per million (ppm). What is even more disconcerting is that the mixture of these materials (compounds), the end products, and the resulting end waste are even more hazardous than the original.</p>	<p>As SCM note in their submission (Annex B to this document), the manufacture of pharmaceuticals involve the use of hazardous materials. This requires the adoption of techniques based on risk assessments regarding the likely impacts on the environment and public health, and the adoption of internationally recognised Good Manufacturing Practices, such as, but not limited to the ones issued in Volume 4 of the ‘The rules governing medicinal products in the European Union’ (as formulated in Directives 91/356/EEC and 91/412/EEC), which is entitled ‘Good manufacturing practice (GMP) Guidelines’.</p>	Noted; no further comments.
<p>One strongly recommended the MEPA enforced installation of the ‘Computer Assisted’, multi sensor, environmental control equipment, known as “Supervisory Control and Data Accession (SCADA). Duly calibrated and annually certified, this would provide real time assessment of most hazardous gaseous emissions, together with the operational reporting of the scrubbers, chimneys and other highly sensitive Sterling HF 51 operations. This equipment is NOT COST PROHIBITIVE, is in current use in Malta, and is widely enforced by other European Environmental Agencies, in such hazardous and highly compromising concerns. This would provide both MEPA and any other independent person or body entrusted with continual, real time, monitoring of Sterling Malta, and enable to resort to immediate corrective or remedial measures, as and when necessary. (see also Health Impact Assessment Chapter 4.6 – Mitigation: para 4.6.1. (Monitoring by external entity) and para 4.6.1.(Regularity of Monitoring)</p>	<p>A response this comment would be outside the remit of this EIA Coordinator.</p>	Noted; no further comments.
<p>The EU Seveso Directive and locally transposed IPPC legislation, demand strict monitoring and control measures to prevent repeat national disasters. The Birzebbugia residents hope that MEPA rises to the occasion by resorting to all the recommended mitigation and independent control measures, and any others necessary to safeguard their environment and health.</p>	<p>The proposed development does not fall within the framework of the SEVESO Directive.</p> <p>Evidently, this does not mean that SCM would not be required to monitor specific aspects of its operations. The monitoring requirement will be issued within the framework of the Industrial Emissions Directive, under which IPPC permits are issued.</p>	Noted; no further comments.

Comments submitted by the public	Responses submitted by the EIA Coordinator	EPD Comments
<p>The Sterling PD included a list of 15 highly hazardous waste CHEMICAL CLASSES, which cause a LEGION OF ADVERSE HEALTH and ENVIRONMENTAL EFFECTS, including, amongst others, those that cause cancer and harm to unborn children (Chap 3.4.1 – para 5). In theory Sterling are claiming in the PD that they will be following a number of rules (HIA 3.4.3.), most of which arise from locally transposed EU Directives.</p> <p>However, apart from telling us that Sterling would be primarily occupied with the “Active Pharmaceutical Ingredients (API)”, and that they specialize in the production of steroids, hormones and other cancer therapeutic products. One has just to imagine the myriad of complex, highly toxic, hazardous chemicals that would be arising at HF51 from the admixture of over 100 primary compounds, most of which are already hazardous in nature, as is confirmed from their MSDSs which, unfortunately, were only furnished at the last minute before the relative public hearing.</p> <p>The Waste Storage and Containment details, as amplified in the PD and Para 3.4.5. (table 5) DO NOT HIGHLIGHT THE FACT THAT MOST OF THE ARISING HAZARDOUS SOLID AND LIQUID HAZARDOUS WASTES WOULD BE STORED AT BASEMENT LEVEL OF THE Sterling HF51 Hal Far premises, as was even confirmed in para 4.4.2. of the HIA. One questions if MEPA, the HEALTH OR THE MALTA RESOURCES AUTHORITIES ever sanctioned such a highly QUESTIONABLE storage facility for different hazardous wastes, especially when one considers that the HF51 site already falls in a water catchment area that even have WSC potable water boreholes. (Coordinated Assessment, Volume Four, Non-Technical Summaries, Para 3.1., 3.2.). In an special “MITIGATION” Chapter (4.6.), the HEALTH IMPACT ASSESSMENT (EIS) STRESSED on the IMPERATIVE NEEDS TO ENFORCE on Sterling Malta Ltd</p> <p>(a) 4.6.1. Monitoring by external Entity, and (b) 4.6.2. Regularity of Monitoring</p> <p>One adds that such recommendations should be carried out, without fail , during the lifetime operations of Sterling Malta Ltd at HF51, Hal Far Industrial Estate.</p> <p>“As outlined in the PD document (Section 3.1.2.) audits will be performed regularly to ensure the highest safety standards are maintained. We strongly recommend that these audits be carried out by an external entity, as the hazardous material produced on site should be monitored from an unbiased perspective. The audit should also include handling of the waste during transport. Additionally no information was provided on how the waste is treated upon reaching the port of Genoa, and given that this waste can be a significant to human health we feel such information should be provided, and the appropriate authorities in Malta and abroad should be informed to ensure the highest standard of practice.” (Health Impact Assessment para 4.4.2.)</p>	<p>It should be noted that the MSDSs were forwarded to BEAG about three weeks before the 03 December 2014 public hearing. It appears that there were some technical problems connected with the recipient's computer that precluded BEAG from downloading the information.</p> <p>SCM submit that:</p> <p>Sterling could use about 300 commodities. Currently under research and development does not come to 50 raw materials. We must clarify that research and development means that not everything can be fixed in front of a computer and, for this reason in the list of the raw materials have been included all those currently employed in Italy (or who have been), and that could be used in Malta. The research phase means that we proceed with attempts to achieve a perfect synthesis and getting to optimize the final product. For this reason our analysts start from a bibliographical study followed by a practical approach that involves the purchase and the use of raw materials. The list is extensive but definitely Sterling cannot guarantee that it is exhaustive, as the needs of the internal testing, as well as the demands of the market, research and development of other synthesis for actual or future customers may change over the years. Moreover those who know the law of the waste are well aware that the relationship between the European Waste Code (EWC) and the nomenclature CLP-REACH on chemicals is very different and has no equal relationship 1: 1. It so happens that many raw materials can be disposed of with the same EWC code. Also, and this is considerably stressed, Sterling is already subject to a control check by Green Skip that is authorized by MEPA as manager and broker of waste. In case it is produced a new waste, Sterling will necessarily inform MEPA for the authorization. This standard also prescribes the procedure for the inside waste management where it is underlined how the waste will be mandatorily stored in containment basins.</p>	<p>Noted; no further comments.</p>
<p>A STRONG RECOMMENDATION FOR THE DIRECT INVOLVEMENT AND INTERVENTION OF THE HEALTH AND ENVIRONMENTAL AUTHORITIES</p> <p>“There are various assumptions that have been taken, such as the assumption that the monitoring outlines in the project description, as well as the operations described pertaining to dealing with waste, water usage and air emissions are correct. However, we feel, as concluded in section 4.6.2. that all MONITORING OF EMISSIONS AND REGULAR REPORTING OF ACTIVITIES SHOULD BE SUBMITTED TO BOTH ENVIRONMENTAL AND HEALTH AUTHORITIES SO AS TO ENSURE TRANSPARENCY OF OPERATIONS ON SITE. We also feel it is in the interest of the environmental authorities that they install their own monitors on site, so as to have a clear and unbiased reporting of the emissions reported in the environmental impact assessment. This would benefit the site as it would ensure reputable and high standard of operations on the site”*.</p> <p>“Additionally the report, under section 3, has outlined the health consequences of operations of the plant, and what can be done to mitigate such negative impacts. It is in the interest of both the workers on site, the public as a whole and the reputation of the company operating the site that such measures be taken to ensure good conduct from a public health perspective* (Health Impact Assessment Chapter 5 para 2)*</p> <p>Table 6 (HIA Chapter 5 pp 31-32) provides a Summery of Recommendations and interventions recommended in the Health Impact Assessment.</p> <p>The PICTURE presented in the “EIS – Coordinated Assessment, Volume 3, Summery of Impacts” IS HIGHLY DISCONCERTING through the IMPACTS ON “Land Use”, “The Water Bodies” and the “Ecology”(in and around the immediate area of the Sterling HF 51). The Operational Impacts are mostly adverse, severe, permanent and irreversible. The “proposed mitigation measures” and “Other Requirements” should invariably form part an integral part of mostly “strongly recommended” continual, regular monitoring and control measures that MEPA should enforce continual environmental monitoring and control measures on Sterling Malta Ltd, directly and through other External Entities, that should invariably include the Health and Environmental Authorities</p>	<p>The reader is referred to Annex B to this document for the position taken by SCM with respect to this comment. This EIA Coordinator has no comment to make regarding this comment, except that, as is noted above, the likely impacts that are described in the Coordinated Assessment would materialise in case the mitigation measures proposed in the SCM proposal are not designed, installed, or implemented as planned.</p>	<p>Noted; no further comments.</p>

Comments submitted by the public	Responses submitted by the EIA Coordinator	EPD Comments
<p>Unfortunately, Sterling Malta Ltd were given a free hand during the Construction Phase, and it results that Sterling has constructed and finished a number of irregularities, especially, but not exclusively, those relating to water, wastewater, and other liquid hazardous wastes. In this instance, we strongly recommend that the Malta Resources Authority be informed so as to inspect site in detail and report back to MEPA, with immediate remedial measures in mind.</p> <p>The writer, on behalf of the Birzebbuga Environmental Action Group (BEAG) expects MEPA to rise to the occasion and take in consideration and enforce these and all the other recommendations specifically made throughout the EIS in order to safeguard against the health and environmental hazards created by the operations of HF51, Sterling Malta Ltd.</p> <p>Our recommendation is that Sterling Malta Ltd will be imposed a bank guarantee of no less than 500,000 Euros to cover any catastrophic incidents to the environment and the residents of Benghajsa, Birzebbuga, Tal-Papa Estates and Qajjenza.</p>	<p>It is outside the remit of this EIA Coordinator to respond to this comment.</p>	<p>Noted; no further comments.</p>

APPENDIX V: Public Hearing of the EIS Minutes (2 December 2014)

Meeting	EIA Public Consultation for EIS in relation to the following development permit application: - PA 04236/08: Factory at Hal Far for Sterling Chemicals Ltd. This excludes the installation of a plant and operation as an API for manufacturing which is subject to a separate permit. Site at Factory HF 51, Qasam Industrijali, Hal Far.
Date	02 nd December 2014
Duration	Circa: 17.15 – 18.35 hrs
Location	Skola Primarja, Kullegġ San Benedittu, Birżebbuġia
EPD representatives	Perit Vincent Cassar (Chairperson)
Minutes taken by	Charmaine Zerafa (EPD)

Perit Vincent Cassar opened the meeting giving details about the proposed developments which are currently subject to the EIS (PA 04236/08: Factory at Hal Far for Sterling Chemicals Ltd. This excludes the installation of a plant and operation as an API for manufacturing which is subject to a separate permit. Site at Factory HF 51, Qasam Industrijali, Hal Far.).

Dr Paul Gauci (ERSLI Consultants Ltd.) delivered a presentation explaining the studies carried out as part of the EIS.

Perit Vincent Cassar opened the floor for comments after the presentation.

Mr. John Grech on behalf of Birżebbuġia Environmental Action Group, questioned whether the public hearing will also cover discussions with regards to the IPPC permit.

Dr. Paul Gauci and Mr. Anthony Aquilina (representative of the Environmental Permitting Unit within the Malta Environment and Planning Authority) explained that this public hearing is being carried out in terms of the EIA process and does not cover the IPPC process. Said process is still underway and consultations will be carried out at a later stage.

Mr. Grech enquired with regards to the type of material used for the reactors and the thickness of such material. He also questioned whether said reactors are already in place and installed.

Mr. Simone Ferlin Chairman of Sterling Chemicals Ltd. explained that some of the reactors will be in stainless steel while others will be in glass lined material. He stated that although the reactors are certified for higher levels of pressure, the company will limit the pressure to 0.49, to avoid having higher risks. Information with regards to the thickness of the material used and copies of certifications can be provided upon request.

Mr. John Grech made reference to the four production lines mentioned in the EIS and asked the location of said production lines.

Dr. Paul Gauci informed attendees that the mentioned production lines are found inside the production system; meaning that four different products can be produced at once.

Mr. Edwin Ebejer (Birżebbuġia Environmental Action group representative) pointed out that in the vicinity of the area proposed for this development, there are other industries producing different chemicals. He enquired with regards to the cumulative impact such industries will pose on human beings. Mr. Ebejer continued by asking about the consequences should there be a gas leakage or a contaminated water leakage and questioned about the probabilities for such accidents to take place.

Mr. John Grech pointed out that according to the EIS some accidents are listed as probably to happen once in three years and also as once a year. These are considered to be regular, and the effects of a leakage of contaminated water to sea will be substantial.

Dr. Gauci replied that the mentioned probabilities will mainly depend on the materials used, the design and the management system. One has to note that this company will be subject to the ISO 14001.

Mr. John Grech suggested that the system 'SCADA' is adopted by Sterling company. This system enables real time monitoring and immediate shut down in case of accident. He recommended that this system should be imposed by the Malta Environment and Planning Authority (MEPA) as a permit conditions. Mr. Grech requested the list of labelling codes that will be utilised by the company for the importation of hazardous goods. Further details should be provided on the type of outdoor lighting that will be used and to the effects of such lighting on migrating birds.

Dr. Gauci clarified that no outdoor lighting will be used on site other than the existing street lighting. Thus this is not the responsibility of Sterling Company but the responsibility of Malta Industrial Parks (MIP).

Mr. John Grech addressed those present by referring to a site visit carried out at the mentioned factory and pointed out that only few Maltese were employed with the company. He further asked who will be doing the monitoring once the company is up and running and whether the said monitors will be independent professionals.

Mr. Simone Ferlin explained that this project was initiated by two new graduates from the University of Malta. These graduates were offered an internship in Italy in order to provide them with the necessary know how with respect to the company and its functions. He confirmed that they are also employing foreign professionals giving that the company is not finding the necessary skilled human resources in Malta.

With regards to adopting the 'SCADA' system, one has to note that this system can be easily used with one solvent in use, however in the case of Sterling, the company will make use of three hundred solvents and therefore such is far more complicated. Another option would be to target one particular solvent. The company's Research and Development Team will look further into this matter and explore such option. Routine monitoring will be carried out by internally appointed officers but the actual monitoring and certification will be done by independent professionals.

Mr. John Grech made reference to the 'OPRA regime' system currently adopted by Medichem and suggested that Sterling company should consider using same process. He also suggested that MEPA imposes the use of such system as one of the permit conditions.

Perit Cassar closed the meeting by confirming that the points raised have been recorded and noted. He also thanked the participants and invited them to send any further comments, preferably by email to eamalta@mepa.org.mt, or by post to 'The Director, Environment Protection Directorate, MEPA Head Offices, St Francis Ravelin, Floriana', by 9th December 2014.
