

NON-TECHNICAL SUMMARY

This is a summary, in non-technical language, of the findings of the Environmental Impact Statement (EIS). It is presented under the same chapter headings as the main EIS.

Introduction

Centocor Inc., a global leader in biopharmaceuticals, plans to invest in a major Biomedicines Manufacturing Facility at a 50 hectare (ha) greenfield site in Barnahely, Ringaskiddy, Co. Cork (Figure NTS 1 – Site Location Map). The €500m project will employ an estimated 330 people when fully operational. Centocor Inc. is a wholly owned subsidiary of Johnson & Johnson.

Project Management Ltd. (PM) has been commissioned by Centocor's Irish operating company Centocor Biologics (Ireland) Ltd., to coordinate the Environmental Impact Assessment for the project to be submitted to Cork County Council in support of a planning application for the proposed development.

The Fifth Schedule of the Planning & Development Regulations, 2001 (S.I. No. 600 of 2001) sets out a comprehensive list of project types and development thresholds that are subject to Environmental Impact Assessment. The proposed development comes under the following category of development outlined in Part II of the Fifth Schedule, which applies to:

“6.(e).....the production of basic pharmaceutical products using a chemical or biological process”

As the proposed development will involve the production of basic pharmaceutical products using a biological process, an Environmental Impact Statement is required.

Centocor's products, developed primarily through monoclonal antibody technology (or Biotechnology), help physicians deliver innovative treatments to improve human health and restore patients' quality of life. Demand for the development and manufacture of biopharmaceutical solutions to treat illnesses and conditions is accelerating at a rapid pace. It is Centocor's priority to address this need and to have increased manufacturing capacity available to grow its biopharmaceutical (or biomedicines) business. The proposed new facility in Ringaskiddy will be capable of manufacturing a range of Centocor products including:

- ☐ CNTO 148 – The next generation of Centocor's primary product Remicade. Remicade is a drug for the treatment of Rheumatoid Arthritis, Crohn's Disease and Psoriasis
- ☐ CNTO 1275 – For the treatment of Psoriasis and Multiple Sclerosis
- ☐ A number of other products for Oncology and Auto-immune diseases, which are at the early stages of development

This EIS has been prepared in accordance with the requirements of EC Directives and Irish Regulations regarding Environmental Impact Assessment and the “Guidelines on the Information to be contained in Environmental Impact Statements” (EPA, 2002) and the “Advice Notes on Current Practice in the Preparation of Environmental Impact Statements” (EPA, 2002).

Submissions regarding the proposed development were formally invited from interested parties. Consultation meetings with local communities, Cork County Council and local industries were initiated in addition to the circulation of a four-page newsletter to representative groups in the region. Comments received throughout the consultation process were considered as part of the EIA process and were addressed in this EIS where appropriate.

The facility will require an Integrated Pollution Prevention & Control (IPPC) licence, which will be sought from the EPA in advance of the facility becoming operational. Centocor Biologics (Ireland) Ltd will be making a notification to the EPA under the requirements of the Genetically Modified Organisms (Contained Use) Regulations, as a Class 1 (lowest risk) activity. The facility will also require a Greenhouse Gas Permit under the EU Emissions Trading Directive. The development does not come under the terms of the Seveso II Regulations (S.I. No. 476 of 2000).

Description of the Project

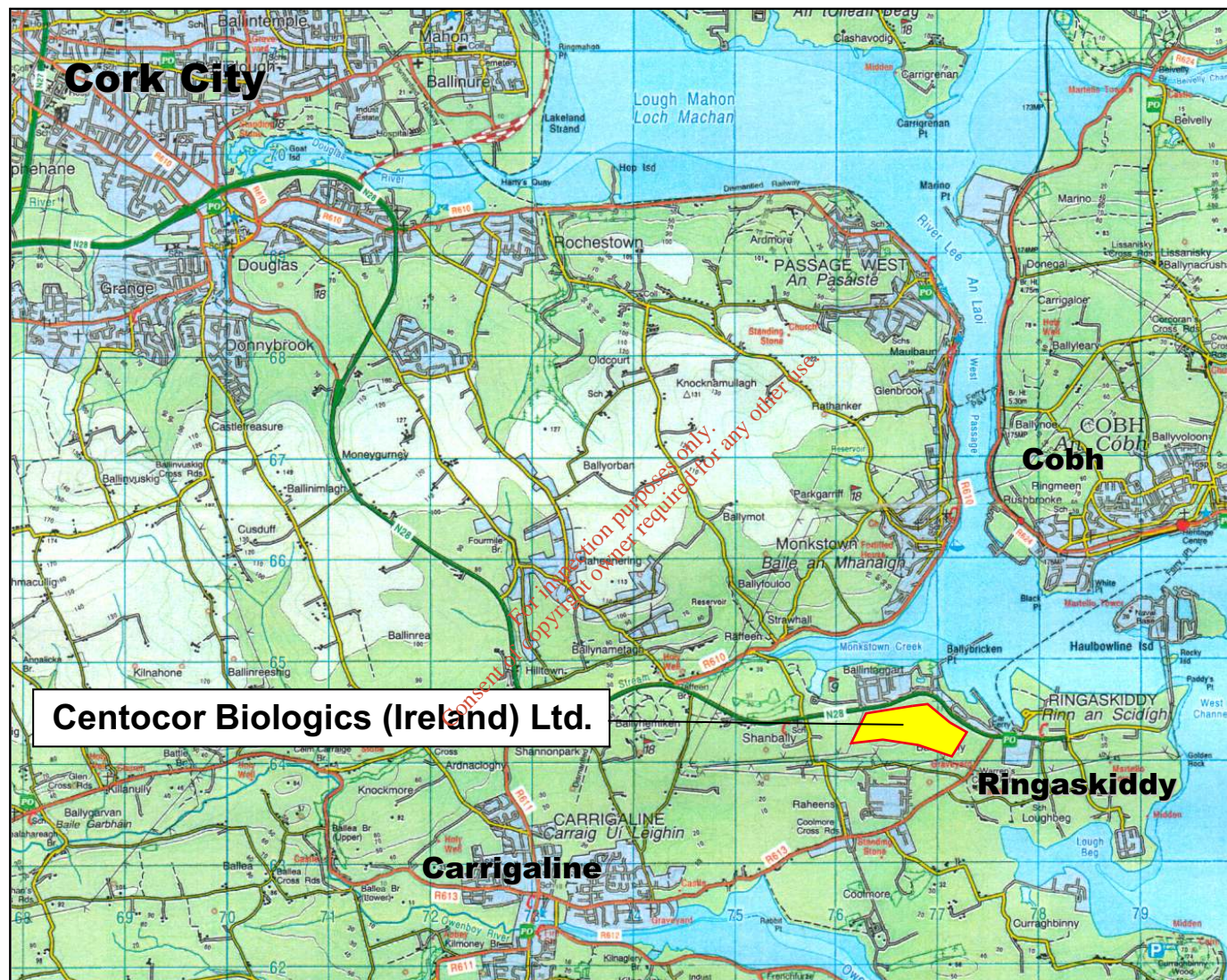
The objective of this project is to develop Centocor's new state-of the-art Biomedicines Manufacturing Facility to be located at Barnahely, Ringaskiddy, Co Cork. The Centocor Biomedicines Facility is being designed to manufacture antibodies and/or therapeutic proteins derived from mammalian cell cultures. Two biological-derived bulk products, referred to as CNTO 1275 and CNTO 148, will be produced as well as a number of other products which are in the early stages of development.

As shown in Figure NTS 2, the actual development area to accommodate the Biomedicines Facility is a 12 ha zone located in the southeast corner of the overall 50 ha site, adjacent to the primary site access road and services (i.e., water supply, trunk sewers, natural gas supply, and electricity). The facility will include four main buildings as identified in Figure NTS 3:

- ❑ Production Building – this building will consist of 2 floors for production, each 9m high and a top floor to serve as the mechanical plant room which will be approximately 9m including parapet.
- ❑ Central Utilities Plant (CUP) – this plant will house primary utilities (steam, chilled water, electrical power, compressed air, gases) and clean utility generation (e.g., purified water, water-for-injection, clean steam) for the facility.
- ❑ Administration and Laboratory Building – this is a four storey building, with offices, administration and cafeteria on the first and second floor, QA and QC laboratories on the third floor and a mechanical plant room on the fourth floor.
- ❑ Warehouse – a central warehouse is located south of the CUP which is designed to hold approximately 800 ambient pallet storage spaces stacked 5 pallets high. Three loadings docks and a central covered-in waste sorting, recycling and storage area are located on the west side of the warehouse.

Supporting site infrastructure includes a utility yard, wastewater treatment plant (WWTP), roads and car parking. The site requirements for heat and power will be provided by a combination of a CHP (combined heat and power) system, natural gas steam boilers, grid power and emergency diesel standby generators.

Figure NTS 4 shows ground level views of the proposed facility from the north, south, east and west directions.



Centocor Biologics (Ireland) Ltd.

Ringaskiddy

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Figure NTS 1 - Site Location Map

Centocor Biologics - Environmental Impact Statement - Non-Technical Summary

Project No: **101050**

Document No: **101050-22-RP-0001**

Date: **April 2005**

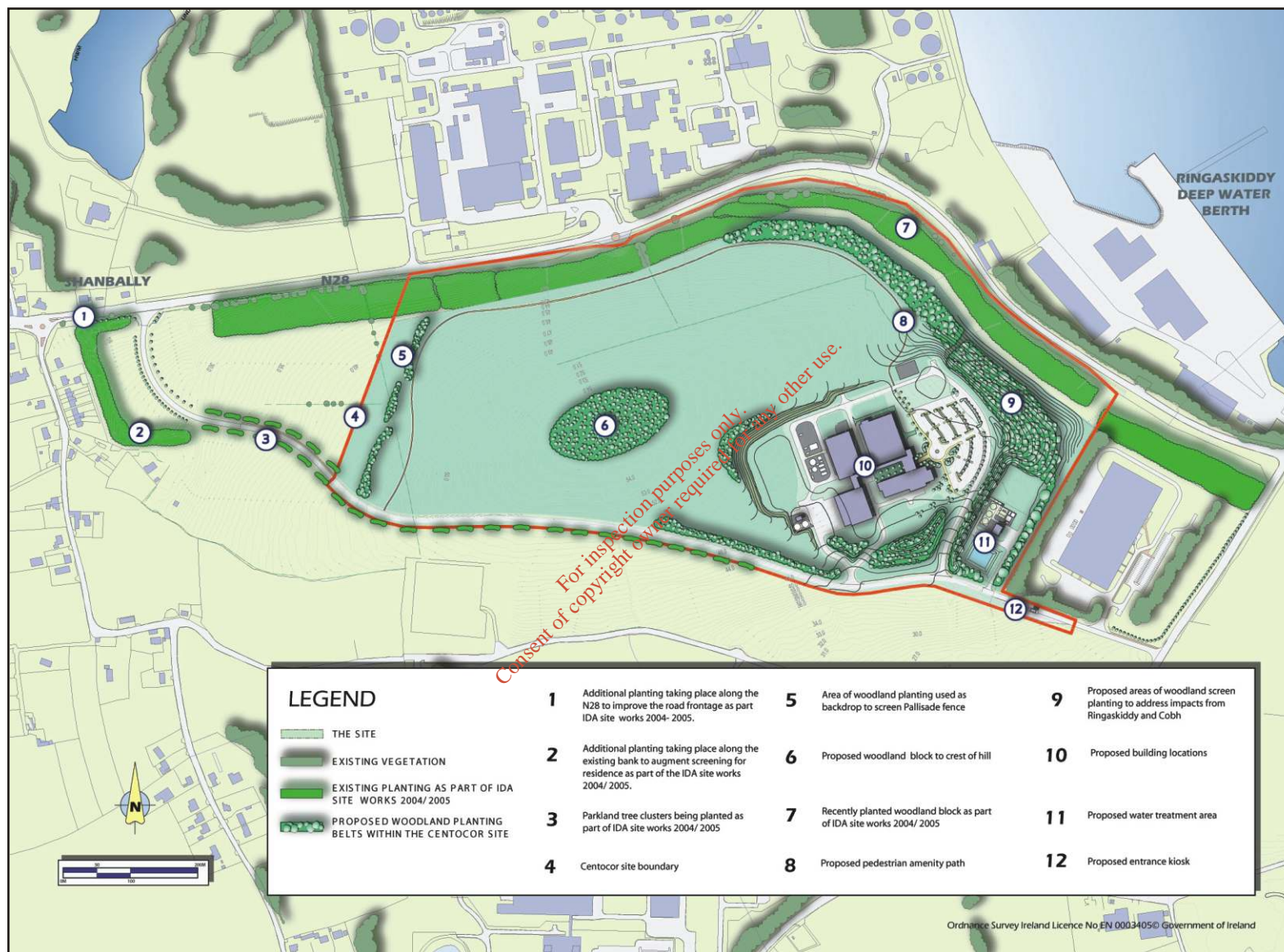


Figure NTS 2 - Site Plan

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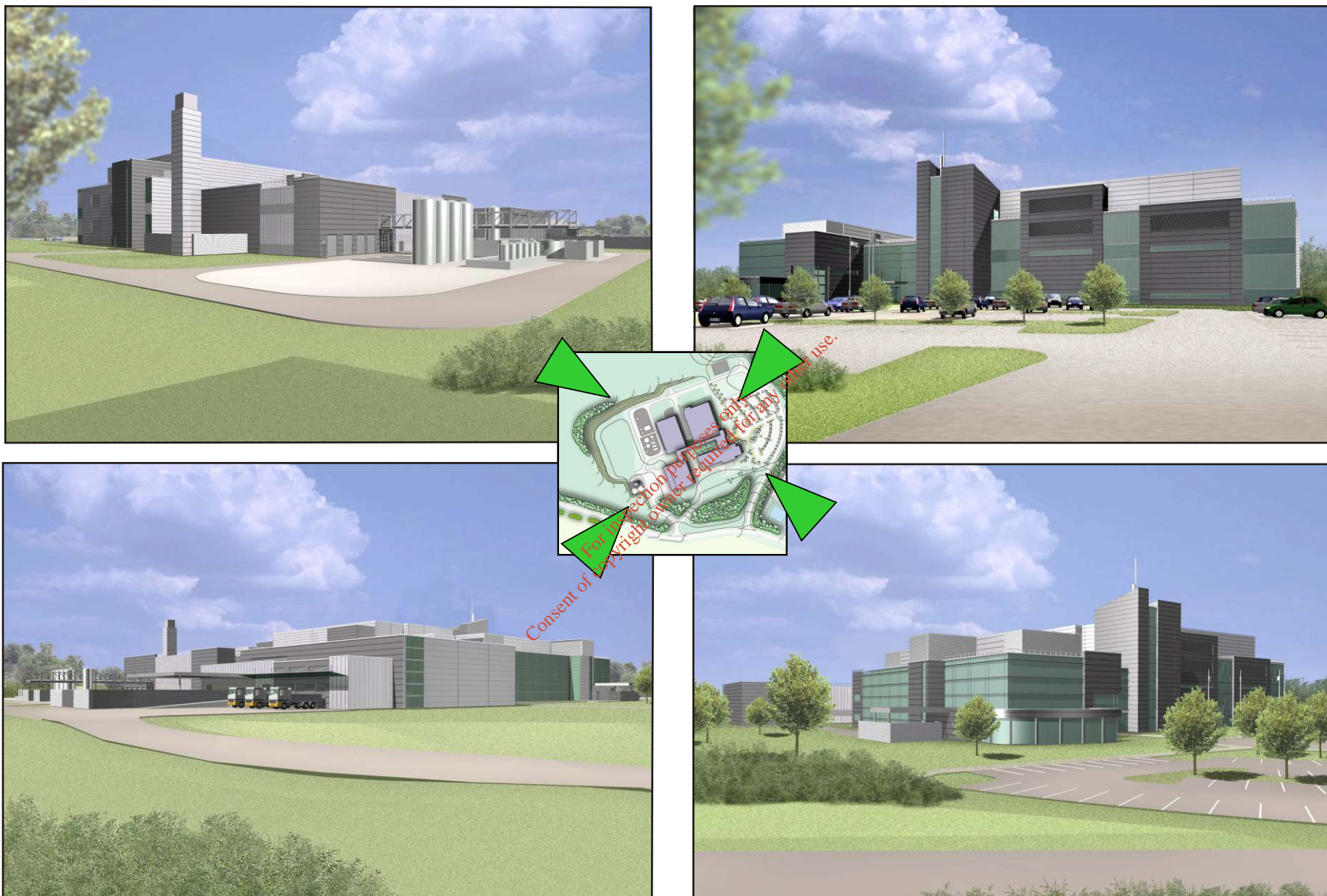
Figure NTS 3 - Facility Layout Plan

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A storm water drainage system will serve the entire site connecting to the existing IDA surface water sewer which discharges to Cork Harbour at Loughbeg. An emergency Retention Pond will be provided on the surface water drainage system to capture and retain surface water run-off in the unlikely event of an emergency situation such as a fire. A foul drainage system will be provided for the complete site and will be routed to the WWTP. A process drainage system (double contained) will be provided from each of the buildings and will travel underground to the WWTP. The WWTP will use state-of-the art technology and be designed to achieve a high quality treated effluent prior to discharge to the local IDA / Council sewer and marine outfall to Cork Harbour. The entire WWTP will be covered enclosed and extracted air will be treated to control any potential odours.

The production area of the facility is designed to process material from a working cell bank through to Formulated Bulk Product operating 7 days/week, 24 hours/day in all plant areas. The total annual Formulated Bulk output will be approximately 180 kg based on manufacturing a single product.

The facility will be designed to satisfy US and European regulatory agencies for multi-product facilities under current good manufacturing practices (cGMP) taking into account FDA (Food and Drug Administration), EMEA (European Medicines Agency), and Johnson & Johnson Corporate Guidelines.

The construction of the facility will consist of two distinct stages, namely:

- ❑ Site Development Works – Excavation works are required on the south eastern quadrant of the site to reduce the existing ground levels to the required formation levels (platform area of approximately 3.5 ha) for the buildings. The bulk of the excavated material will be reused on-site. Subject to Planning Permission, site development work is scheduled to be carried out during the first 13 weeks of the construction programme, during summer/autumn 2005.
- ❑ Building Construction Works – Following completion of initial site development works, pad foundations will be provided for each building, bearing on the underlying weathered shale, approximately 2m below the ground level. The building structures will be structural steel with concrete floors on metal decks. The building walls will be cladded and the roofs flat with 1.1m high parapets. Subject to Planning Permission, the main building construction works will commence in Autumn 2005, with a scheduled duration of approximately 2 years.

All site services will be installed underground and site roads will be constructed to base course asphalt as early as possible with a view to minimizing dust and maintaining a clean orderly site.

The construction phase of the project will be followed by a period of approximately two and a half years for plant commissioning, qualification and approvals before going into full production.

Alternatives Considered

It is a fundamental requirement of the EIA process that viable alternatives to the key project decisions have been evaluated in the context of environmental impact, and that the project as proposed represents the most appropriate solution in meeting the objectives of the development.

The key project decisions relating to the Centocor Biomedicines Facility have been:

- ❑ Why build this facility?

- ❑ Selection of the preferred site
- ❑ Selection of the preferred manufacturing process
- ❑ Selection of the preferred location for the proposed Biomedicines Facility within the Barnahely site
- ❑ Selection of the preferred arrangement of the proposed buildings
- ❑ Selection of the preferred site masterplan

A detailed evaluation of alternatives under each of these headings has been conducted by Centocor prior to selecting the preferred approach. In each case, minimisation of impacts on the receiving environment has been foremost in the evaluation and selection process. Details of the full range of alternatives considered are set out in Chapter 3 of the EIS.

Human Beings

Ringaskiddy is an established industrial / enterprise location and is designated a strategic industrial zone in the Cork County Development Plan (CDP) 2003 and the Cork Area Strategic Plan (CASP).

The proposed development is fully compatible with and facilitates the objectives of the Cork CDP 2003 in relation to planning and development within the Ringaskiddy Development Boundary.

In accordance with the Cork CDP 2003 planning objectives, the site is zoned for industrial use as follows:

“Suitable for large stand alone industry with suitable provision for landscaping and access points.”

The Barnahely site as acquired by Centocor is within one of 15 areas currently reserved for industrial development in Ringaskiddy. The site is surrounded by industries immediately to the north, south and east.

The proposed development is predicted to have no significant adverse impacts with respect to human health, socio-economic factors, landuse or the amenity value and tourism potential of the area.

The proposed project will result in a significant positive socio-economic impact providing both direct and indirect employment which in turn will boost the local economy. The construction phase (2005 to 2007) of the proposed project will result in the creation of up to 700 skilled and unskilled construction jobs directly, generating over €70 million in total wages and salaries. It is anticipated that expenditure on goods and services will be in the region of €65 million over the duration of the construction phase.

It is envisaged that operation of the proposed Biomedicines Manufacturing Facility scheduled to commence in January 2010, will entail a workforce of 330 persons. It is estimated that for every one full-time position created by the facility a second spin-off job will be created through the services industry or other.

The construction works will be visible from a number of locations due to the topography of the site. Overall, it has been concluded that the construction phase will have a temporary minor negative impact in terms of amenity views.

The production buildings associated with the proposed Biomedicines Facility will be visible from a number of amenities in the area. However, there are numerous industrial facilities within the industrial area of Ringaskiddy and the construction of this facility will not alter the character of the area.

It is considered that the construction and operational phases of the proposed development will not impact on the health and safety of residents in Ringaskiddy or the greater surrounding area.

Significant positive impacts are anticipated in terms of employment and economic activity and therefore no mitigation measures are required in respect of socio-economics. Mitigation measures associated with noise, dust, visual impact and traffic are outlined in the respective chapters of the EIS.

In summary, the residual impact of the proposed development on human beings will have a significant positive economic and employment effect, contributing to the local economy.

Landscape and Visual Impact

A detailed visual assessment of the site was carried out between January and March 2005. The methodology used for the landscape assessment entailed:

- ❑ A desktop study of the site in relation to its overall context both locally and regionally.
- ❑ Visiting the site and its environs to assess the following;
 - Quality and type of views in the area
 - The extent of the visual envelope, i.e. the potential area of visibility of the site in the surrounding landscape.
- ❑ Preparation of twenty photomontages (computer generated images of how the proposed facility will appear in the landscape from various viewing points)

Potential visual impacts of the Centocor facility have been fully assessed in the context of potential impacts on Designated Scenic Landscape Areas, Scenic Routes and Overall Landscape Character. This process was aided by the production of twenty computer generated photomontages with the proposed development superimposed on the site. The photomontage views were taken at both local and remote locations throughout the harbour area, including; Ringaskiddy Village, Castlewarren, Shanbally Village, Monkstown (upper and lower), Cobh/Rushbrooke, Whitegate, Curraghbinny, and Frenchfurze.

The visual impact assessment was used to determine the most appropriate measures, in terms of architectural design and landscaping, to be used to achieve the following mitigation objectives:

- ❑ Minimise negative impacts on the character and views from nearby residential properties, roads and other public areas.
- ❑ Assist the visual integration of the proposed development on the site into the surrounds through sensitive architectural design and an appropriate scale of planting.

A summary of the mitigation measures being employed is as follows:

- ❑ Under an existing contract being implemented by IDA Ireland, approximately 25,500 trees (6.5 ha approx.) of woodland have recently been planted along the northern boundary of the site, as well as the augmentation of existing planting along the western boundary, and upgrades to the existing entrances and road frontages through additional landscape works.
- ❑ Under this planning application, Centocor propose to plant an additional 6.1 hectares of native woodland around the site. Within 7-10 years, this planting will form a 5 – 10m high dense cover.
- ❑ The architectural design of the Centocor Biomedicines Facility calls for a series of four connected buildings each with its own architectural interest based on a common theme. This is a key mitigation measure which exploits the opportunity presented by a facility that can be viewed in the round. Since the facility can be seen from almost 360 degrees, the orientation of the four blocks of varying height and massing creates a strong visual interest.

Following implementation of these mitigation measures, residual moderate negative visual impacts due to the development may remain on limited views from lower parts of Monkstown. This impact will continue to reduce over time as the landscape planting continues to mature. All other views are considered to be slight negative or neutral.

Sample photomontage views (as existing and proposed) from locations in Ringaskiddy Village and Monkstown are shown in Figures NTS 5 and 6.

Roads and Traffic

A Traffic Impact Assessment on the surrounding road network of the proposed development was prepared by Atkins Ltd. in January 2005. The purpose was to determine the impacts that construction and operational generated traffic may have on the surrounding road network. The main findings of the assessment are summarised as follows:

Traffic on roads leading to the proposed development is already very busy during commuting hours with much of this traffic generated by people working in local industries. The NRA (National Roads Authority) has recognised this as a problem and is actively planning to construct a new N28 immediately south of the development site which would take the bulk of industry generated traffic off the existing local network. The preferred route for the new N28 has been selected, design is scheduled to be complete by year-end 2005, and plans call for Compulsory Purchase to begin in 2006 and construction to begin some time in 2008.

During the site development works for the proposed development, the traffic impact will be slight and temporary for a period of approximately 13 weeks. During peak hours this work would contribute modestly to traffic in the area and to the current queuing at the Shanbally Roundabout.

During the main construction period, a work force averaging 370 will need access to the site for a period of approximately 2 years with a maximum of 700 workers a day during the peak period of 4-6 months. Without mitigation, this additional flow could have a significant impact on traffic entering the area in the morning and leaving in the evening.

In order to minimise the impact during the main construction period, the contractor will operate incentive programs to reduce the number of cars coming into the area by rewarding those who have 3 or more people in their car. This approach has been used effectively in the past and is projected to reduce the number of cars entering the area for construction workers to approximately 400 per day at peak construction. The site will also operate an



Figure NTS 5 - Existing & Proposed Views from Ringaskiddy

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Figure NTS 6 - Existing & Proposed Views from Monkstown

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early start time to get a significant majority of the workers off the local roads prior to the existing peak traffic period. This will further reduce the number of construction related car trips during peak hours to approximately 100. While these measures will reduce the potential impact, there will still be a residual increase in traffic in the area leading to moderate additional queuing in Shanbally eastbound in the morning and westbound in the evening for the duration of the construction.

During operation, a workforce of 330 is planned for the site. Of that number, 128 will be working on a four cycle shift basis (32 workers each shift). Shift changes for these personnel will be at 7:30 a.m. and 7:30 p.m., entering and leaving the area outside of peak traffic times. The remaining 202 people will be allowed to work flexible hours starting from 7:30 to 9:30 a.m. and ending work from 4:30 to 6:30 p.m. Prior to construction of the new N28, it is projected that at least 40% these workers will elect to travel outside peak traffic times to avoid delays getting to and from work. With an average occupancy of 1.3 per car, this will lead to approximately 100 cars added to the local road system during peak travel times. This will increase traffic in the area and lead to additional queuing in Shanbally eastbound in the morning and westbound in the evening. However it is expected that this impact would be short term in duration, or may not arise at all, depending on the expected completion of the new N28. The selected preferred route for the new N28 includes an interchange for traffic to and from the West at the R613 (Ringaskiddy to Carrigaline Road). This will allow workers arriving from that direction to by-pass the local road network and will effectively eliminate the impact of the development on the existing local network.

Soils, Geology & Hydrogeology

A site investigation and desktop study to assess the soils, geology and hydrogeology that underlay the proposed Centocor site was carried out January 2005. From the assessment, it is concluded that the site is underlain by fractured siltstone and mudstone (shale). Soil thickness across the site varies and ranges from less than 1m thick in the north of the site to approximately 19m thick in the southwest corner of the site. Soil thickness is generally less than 2.5m across most of the site.

Groundwater is confined in fractures at depth (generally from 18m to 23m below ground level in the bedrock, however, some shallow groundwater was encountered during site investigations. Groundwater at the site is considered to be highly vulnerable to contamination due to the generally thin soil cover. The underlying aquifer is classed as locally important, however groundwater in the area is not used for potable water supply purposes.

The construction phase of the proposed development will involve a cut and fill operation which will involve the excavation of approximately 150,000m³ of material, of which 125,000m³ will be reused on site.

The key predicted impacts of the cut and fill operation are as follows:

- ❑ Alteration of site topography and removal of soil cover.
- ❑ Formation of spring lines along cut slopes.
- ❑ Infiltration of surface water run-off into the underlying bedrock aquifer.

The primary mitigation measures which will be put in place in response to the impacts identified above are as follows:

- ❑ The site will be graded to promote run-off and minimise surface water ponding.
- ❑ French drains will be installed at the toe of cut slopes to capture and redirect clean run-off from the slopes and from spring lines.
- ❑ Potential leaks from fuel storage and uncontrolled surface water run-off from soil stockpiles will be prevented through the use of bunds.

With the employment of the above mitigation measures, it is considered that the impacts on soils, geology and hydrogeology by the proposed development construction works will be minor.

Once the facility is operational it is unlikely to have any adverse impacts on the local soils, geology and hydrogeology due to the low volume of aqueous-based production, the high level of secondary containment of material storage and production areas, underground effluent pipelines and fuel storage areas and the high degree of liquid effluent processing on-site.

Flora and Fauna

An ecological assessment of the proposed development site was carried out in January 2005. The site, which is presently used for agriculture, overlooks the Monkstown area of Cork Harbour. Several sites designated for conservation occur in the vicinity but none is adjacent to the study area.

The following habitat categories were identified within the overall 50 ha site: Improved Agricultural Grassland; Hedgerows; Treelines; Scrub; Stone Walls and an Artificial Pond. Two of the hedgerows and the three treelines within the site are rated as of 'moderate local' ecological value. All of the other habitats are rated as of 'low local' ecological value. There are no rare, protected or threatened species of flora known from the site. The mammal species associated with the study area are commonly occurring species of the countryside and no species is of particular conservation importance. The potential for some of the trees in the survey area to support roosting bats is noted as all bat species are legally protected. The birds associated with the site are species that are commonly found in similar habitats elsewhere and none is of conservation importance. Some wintering wader species (mainly curlew and oystercatcher) from Cork Harbour visit the grassland fields for feeding and/or roosting purposes.

Approximately 12 ha of the site will be developed. The remainder will remain undeveloped though parts may be disturbed by construction traffic. All habitats in the construction site will be lost. However, as all of these habitats are rated as of 'low local' ecological value, the impact by loss of habitats is rated as 'minor negative'. Possible disturbance to habitats in the remainder of the site is unlikely to be significant as, with care, the habitats which are of some interest (essentially the hedgerows and treelines) can be avoided.

It is considered that the proposed development will not have any significant impacts on mammal species, as all the species which occur in the site area are widespread species and none is dependent on the site for their continued survival in the area. The 12 ha development area does not include any trees suitable for roosting bats. Some of the habitats which will be lost are likely to be used by nesting birds but all of these are widespread and common species and the loss of small amounts of potential nesting habitats is not of concern. Wintering wading birds are likely to continue to use the northern fields within the overall site and the loss of a relatively small amount of grassland habitat in the development area is not considered of significance.

No specific mitigation measures are required for the existing habitats in the development area due to their low conservation value. Landscaping within the site will compensate for the loss of the trees and shrubs in the hedgerow that will be removed. Native tree and shrub species will form part of the landscaping and a list of species which would be beneficial for local wildlife is given. Outside of the development area, care will be taken to avoid damage from construction vehicles to specified hedgerows and to the treelines. Mitigation measures are outlined for nesting birds and, if relevant, for both bats and badgers.

Owing to the existing low ecological interests at this site, and providing the mitigation measures outlined are followed, it is considered that the impacts on ecology by the proposed development will be, at most, minor negative. In the medium to long term, minor positive impacts are likely to be associated with the landscaping of the site.

Noise and Vibration

No requirement for either blasting or pile driving is anticipated during the construction of the Centocor Facility. As such, vibration will not be an issue with respect to the proposed development.

A baseline noise survey was undertaken at the site with measurements taken at the nearest noise sensitive and site boundary locations. The aim of this survey was to establish the existing (baseline) noise environment so that potential impacts over and above current levels could be predicted and assessed. Modelling of noise emissions from the principal external noise sources was also carried out to predict noise levels at noise sensitive locations when the facility becomes operational. Existing ambient day and night-time noise levels at the site are influenced by traffic noise and existing industrial sources.

The construction phase of the Centocor development will contribute to ambient noise levels for the duration of the construction works but measures will be taken to minimise as much as practicable any impact on ambient noise levels at the nearest noise sensitive receptors in the vicinity (i.e., residential dwellings at Marian Terrace, Shanbally and Warrens Court, Ringaskiddy). It has been established that natural attenuation due to distance, building screening and topography will ensure that recognised limits for day time and night-time noise will not be exceeded during the construction phase at these locations.

The major noise sources within the proposed facility when operational will include cooling towers, air handling units, CHP plant and the wastewater treatment plant. The EPA's Guidance Note for Noise in relation to Scheduled Activities recommends levels of 55dBA during the day and 45 dBA at night, measured at the nearest noise sensitive receptors to the development. Potential noise impacts will be mitigated by best installation and operational practice. A detailed noise modelling study has been carried out and this has demonstrated that there will be no negative impact on the receiving environment, as predicted at the nearest residences to the site.

Monitoring to confirm the modelling results will be undertaken upon commissioning of the site and an ongoing compliance programme will be implemented as part of the IPPC licence.

Water and Effluent

It is proposed that all effluent from the facility will be treated on-site and will be discharged via the existing Cork County Council / IDA marine outfall pipe to Cork Lower Harbour. This outfall terminates in the deepwater channel at Dognose Bank and is used as the outfall location for many industries situated in the Ringaskiddy Peninsula as well as effluent from

Carrigaline Town and Shanbally Village. Uncontaminated surface water from the site will be discharged to Loughbeg, a tidal inlet on the Ringaskiddy Peninsula in the Cork Lower Harbour area.

There are no watercourses or drainage ditches within or adjacent to the proposed site with the exception of a small artificial pond in the eastern portion of the site. Of poor water quality and low conservation value the removal of this pond as part of the development proposals was determined not to be significant.

To accommodate the workforce associated with the construction phase, it is proposed to install a temporary biological wastewater treatment plant as part of the early site development work. Consisting of a fully contained "package" type system, the plant will be capable of achieving a consistent effluent quality standard comparable with the levels specified in the EU Urban Wastewater Treatment Directive. The treated effluent will be discharged to the local public sewer which connects to the marine outfall. The package plant will remain on in operation until such time as the proposed permanent on-site wastewater treatment plant is commissioned and available.

A permanent on-site wastewater treatment plant will be installed at part of the Centocor development.

Wastewater will arise from all four buildings within the site, but primarily from the Production and CUP blocks. The proposed WWTP will be designed to treat both the process and sanitary effluent arising from the site.

The plant will use state-of-the-art technology and be designed to effectively and consistently achieve the emission limit values that will be prescribed in the site IPPC licence and as may presently be anticipated through the BATNEEC guidance notes for the industry sector.

Although a risk assessment concludes that on-site emergency retention is not technically required, Centocor propose to provide an emergency firewater/ stormwater retention pond to retain aqueous releases within the site in the event of an emergency situation such as a fire.

The additional treated effluent load from the Centocor development will have no significant impact on the capacity of the marine outfall to Cork Harbour. There is more than adequate capacity in the pipeline to accommodate both the Centocor development and the future Lower Harbour WWTP as proposed by Cork County Council. The physical and chemical characteristics of the treated effluent discharge will be such that they will not cause any problems in the operation, structural integrity or ease of maintenance of the off-site CCC sewerage system and marine outfall.

The anticipated impact of the emission from the Centocor WWTP on receiving water quality is expected to be insignificant in terms of the main water quality indicator concentrations namely BOD, Dissolved Oxygen and nutrients (nitrogen and phosphorus).

Air Quality & Climate

A survey of existing air quality was conducted during February and March 2005 to determine the current levels of nitrous oxides (NO_x), sulphur dioxide (SO₂), particulates (PM₁₀) and BTEX compounds in the ambient air. The concentrations of the various parameters recorded during the survey were within all relevant Air Quality Standards and guidelines. The results of the survey are well within the expected concentration ranges for either a rural or urban environment. The air quality on site with respect to all parameters is therefore described as good.

The initial site development phase of the Centocor project will involve significant earthworks works taking place over a 12 hectare development area for a period of 13 weeks approximately. This work will involve excavation and earth moving on a large scale, which could give rise to dust during dry conditions. Vehicle movements on temporary roads also have the potential to create occasional dust emissions, particularly during dry weather. Appropriate site management procedures will be implemented to minimise potential dust emissions. These will include, early paving of trafficked roads, vehicle wheel washing, spray dampening of roads, strict speed restrictions and strategic berming and early planting. With these mitigation measures in place, together with continuous monitoring, the residual impact of dust due to construction activities will be low.

Emissions to atmosphere from the operating facility will arise from:

- ☐ Combined Heat and Power (CHP) plant, boiler and emergency generator emissions
- ☐ Volatile organic compounds (VOC) emissions
- ☐ Miscellaneous emissions (such as Cooling towers and the WWTP).

The site requirements for heat and power will be provided by a combination of a gas-powered CHP system, steam boilers, standby generators, and power from the national grid. In common with all combustion or engine fuel usage, the turbine will produce some emissions. There will be nitrogen oxides (NO_x) when operating on natural gas. The natural gas fuel is virtually sulphur free. The level of nitrogen oxides produced will be similar to the levels found with normal direct-fired boilers, and special abatement systems will not be required.

Air dispersion modelling has been used to predict the maximum ground level concentrations of oxides of nitrogen likely to occur as a result of emissions from the CHP plant and boilers. The results of the modelling show that the predicted environmental concentrations are well within the applicable air quality standard limit values. These limit value standards have been developed for the protection of human health and the environment and as such the CHP / boiler emissions from the proposed development are not predicted to have any significant adverse impacts on ambient air quality.

Organic solvents will only be used in relatively small quantities on the Centocor site and will give rise to low level fugitive emissions only. No quantifiable off-site impact will arise.

A total of six cooling towers will be installed at the site. The air leaving the towers will be saturated with water vapour, which under certain weather conditions may form a visible plume. The plumes will, to a large extent, be shielded from view of the nearest residential areas to east of the site by the Production Building and to the west of the site by the natural topography of the Barnahely hill.

As with any wastewater treatment system there is some potential for odour. At the Centocor WWTP all tanks will be covered, and will be vented to a dedicated odour abatement package. The preferred odour treatment option will be to use a biofilter (peat based or similar). This system will ensure that all surface air that could potentially give rise to odour will be fully treated prior to being released to atmosphere through a vent which will discharge at a height of 10 metres above ground level.

The only minor impact on climate will be the emission of carbon dioxide, a greenhouse gas, from the operation of the CHP system and boilers.

Waste Management

Both the construction and operational phases of the proposed development will result in the generation of wastes.

The construction phase will involve initial site development to include large-scale cut and fill works. This will be followed by the construction of the facility itself. Waste will be managed as part of an overall Environment Plan for the Construction Phase. The plan will include specific detail on waste segregation and disposal as described in Chapter 12 – Waste Management of the main EIS.

The construction works will include large-scale cut and fill operations producing anticipated volumes of excavated material of 150,000m³. The majority of this material will be reused on site to construct embankments, as fill for the car park area and to fill other areas of the site. The excess material (estimated at 25,000m³) is anticipated to be taken off site for beneficial reuse on other infrastructural or related projects in the locality. In the event that suitable beneficial re-use options are not available at the time of the earthworks contract, the excess spoil will be disposed of in a responsible manner to a licensed landfill. Operators transporting the waste will be required to hold Waste Movement Permits and an appropriate waste licence must be held at the waste disposal facility.

Other wastes will be generated over the 27-month construction period and will typically include rubble, steel, timber, plastics, packaging, office and canteen waste and small quantities of hazardous waste (e.g. adhesives and paint containers). A system of segregation will be implemented on site with separate skips for timber, metal, plastic, rubble, canteen waste, paper/cardboard, paint/chemical containers and oils and greases. Where possible this material will be re-used or recycled while the remaining wastes shall be disposed of by licensed waste contractors to an approved landfill and in accordance with the relevant national and EU waste legislation. All subcontractors and site staff will be obliged to comply with the site Waste Management Plan.

The operation of the facility will result in the generation of a range of waste. These will include both hazardous and non-hazardous wastes. Wastes produced on site will be segregated at source.

Anticipated non-hazardous wastes will include packaging waste, office waste, WWTP sludge, canteen and kitchen waste, empty containers and autoclaved production bags, tubing, filters, GMP gowns etc. Where possible these wastes will be sent off site for re-use, recycling or recovery. Materials unsuitable for recycling and recovery will be sent off site for disposal to licensed landfill.

Hazardous wastes generated will include laboratory wastes, off-spec raw materials in addition to miscellaneous sources such as waste oils, UV and fluorescent tubes. Again, segregation will be carried out at source with wastes sent for recovery or recycling under

licensed contract where possible e.g. fluorescent tubes, batteries and waste oils. Some residual hazardous wastes that cannot be recycled will go for disposal under licensed contract. One of the advantages of using biotechnological processes for the production of pharmaceutical compounds is the relatively small quantity of hazardous waste produced when compared to facilities using synthetic chemical processes. The latter can produce many thousands of tonnes per annum whereas it is expected that the Centocor facility will produce hazardous waste in the order of 10 tonnes per annum.

As discussed, production and associated activities at the Centocor facility will unavoidably generate waste. As part of the Johnson & Johnson group of companies, Centocor Worldwide operate and maintain a well developed waste management, minimisation and auditing strategy which will also be implemented at the Ringaskiddy site.

The Centocor facility will also be licensed by the EPA under the IPPC licensing system and as such will be subject to a number of principles and conditions including Best Available Techniques (BAT), the IPPC licence waste conditions themselves and the requirement to establish and maintain an Environmental Management System (EMS) and Environmental Management Programme (EMP). All of these will ensure that waste will be managed in an environmentally responsible and proactive manner.

Material Assets

Material assets comprise physical resources in the environment, which may be of human or natural origin. The objective of the material asset assessment is to ensure that these assets are used in a sustainable manner with respect to the proposed Centocor development. Several material assets were identified as being relevant to the Centocor development. These include geological resources, land resources and public utilities. Other important material assets identified are discussed in other chapters namely natural amenities (Chapter 4 – Human Beings), designated areas (Chapter 5 – Landscape), scenic routes (Chapter 5 – Landscape), transport infrastructure (Chapter 6 – Roads and Traffic) and recreational facilities/ amenities (Chapter 4 – Human Beings).

It is anticipated that both the construction and operational elements of the proposed development will not have any significant impacts on the geological resources of the area. However, to reduce/avoid any potential impacts on previously unidentified geological features, excavation works will be closely monitored during site development works. The impact on both the public utilities and undeveloped land resource has been quantified and is considered to be neutral. Reference should be made to the respective chapters for anticipated impacts and proposed mitigation measures associated with the other identified material assets listed above.

Archaeology, Architecture and Cultural Heritage

For a project of the nature proposed, Cultural Heritage is typically addressed under the headings of Archaeological Heritage and Architectural Heritage. As this is a Greenfield development, Cultural Heritage impacts are largely confined to considerations of Archaeological Heritage.

The proposed development at Barnahely was the subject of a desk-top study and inspection during field studies. No known sites recorded in the Cork County Archaeological Inventory exist on the site and no new archaeological sites were detected in the field. The landscape however has been altered through agricultural practice by ploughing and the removal of field

boundaries. Given the site location adjacent to the coast and the genial climate, this area was an attractive settlement site for prehistoric peoples and sites including settlement and burial may have no surface expression. There is therefore a possibility of unearthing previously unknown sites.

A series of mitigation strategies is presented to avoid any accidental damage to buried archaeological material during construction works. This includes archaeological test excavation and the monitoring of any ground works by a qualified archaeologist under licence from The Heritage Service (Department of the Environment, Heritage and Local Government). No residual impacts on the archaeological or cultural heritage landscape are envisaged for this project.

Sustainability

The Planning and Development Act, 2000 requires that development must be consistent with “proper planning and sustainable development”. According to the Brundtland Report (1987)¹, sustainable development is defined as: *“Development which meets the needs of the present without compromising the ability of future generations to meet their own needs”*.

As part of the Johnson & Johnson group of companies, Centocor define sustainable growth as achieving economic vitality while promoting social equity and environmental protection. The Johnson & Johnson and Centocor Credo (philosophy) aligns closely with the principles of sustainable growth namely people, planet and profits.

J&J CREDO RESPONSIBILITIES	SUSTAINABLE GROWTH
To customers and employees	Social equity
To community and environment	Environmental responsibility
To stockholders	Economic vitality

It is recognised that buildings can have considerable sustainability related environmental impact e.g. through operational energy requirements; transportation of people between them; raw material consumption and land use requirements. They also perform important social and economic functions and make a significant contribution to our quality of life.

Many aspects of the design of the Centocor Biomedicines Facility are focused on sustainability. At corporate level, Centocor are striving to minimise carbon dioxide emissions associated with all their operations. For this project in Cork, provision has been made to install a gas fired Combined Heat and Power (CHP) plant on the site. This initiative will contribute to reducing carbon dioxide emissions from the site by up to 22% annually. CHP is recognised as being one of the key technology responses to Ireland’s achievement of its Kyoto protocol commitments. Reducing the energy that will be consumed during the life of the buildings has also been a focus of the design strategy for the development. The plant and equipment that will be used in the proposed development will all be modern and energy efficient.

In terms of local community, it is anticipated that the Centocor development will have a positive effect on community sustainability within Ringaskiddy and the surrounding area. The

¹ World Commission on Environment and Development (1997). “Our Common Future”.

nature and scale of the development is such that there will be a demand for locally provided services in the areas of retail, food and accommodation.

It is Centocor's policy to establish direct community dialogue with neighbours near their operating sites, both as part of the pre-planning process, and right through the construction and operating phases. This dialogue is seen by Centocor as vital to achieving a mutual understanding of how Centocor and the people living in the vicinity of the operation can jointly enhance the local social community.

Interaction of Impacts and Cumulative Effects

An important aspect of assessing the environmental impacts associated with an industrial development of the nature and scale proposed, is to consider how impacts identified under each of the subject headings might interact. Similarly, consideration must also be given to the cumulative effects arising from the interaction of the proposed project with impacts arising from existing and known future developments in the area.

This assessment has confirmed that no additional adverse impacts or worsening of effects are predicted to arise due to interactions or cumulative effects with the existing environment.

Assessment of cumulative impacts due to future construction projects in Ringaskiddy considered the planned construction of the proposed N28 from Bloomfield Interchange to Ringaskiddy. Should this project proceed during the course of the construction of the Centocor Facility, cumulative adverse impacts relating to traffic, dust and noise would be expected to arise. However, because the new N28 is unlikely to commence construction before late 2007, it is improbable that the construction phase will overlap with that of the Centocor Biomedicines Facility which is scheduled for construction completion during 2007.

The fact that significant land areas are zoned for industry in the Ringaskiddy area means that there is potential for new industrial development projects in the future. This prospect, and the potential for cumulative effects with the Centocor development, has been considered in all chapters in the EIS where deemed relevant. This is evidenced as follows:

Traffic – The traffic impact assessment for the development has been based on the use of the Cork Strategic Transport Model (CSTM) which includes conservative allowance for future traffic forecasts associated with industrial development in the area.

Air Quality – Air dispersion modelling has been used to predict the resultant maximum ground level concentrations of oxides of nitrogen due to the proposed facility, considered cumulatively with the existing baseline levels in the area (Chapter 11). It has been established that the impact on air quality due to the proposed Centocor development does not significantly reduce local air quality and does not impose restriction on future development in the area due to limited air quality capacity.

Water Quality – Assessment of the assimilative capacity of the receiving waters in Lower Cork Harbour has shown that the effect of the anticipated Centocor treated effluent discharge will be almost negligible (Chapter 10). Similarly, the quantity and quality of the Centocor treated effluent discharge will not compromise the capacity of the sewer and outfall to accommodate future industrial development in the area.