Appropriate Assessment Screening Report

Celebrating 40 Years in Business
Alexion
Fill Finish Facility Athlone
IE0311213-22-RP-0001, Issue: A

Issue date: 22 January 2014
Document Sign Off

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Alexion
Fill Finish Facility Athlone
IE0311213-22-RP-0001, Issue A

File No: IE0311213.22.130

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1 Introduction

PM Group has been appointed by Alexion Pharmaceuticals Inc. to conduct an Appropriate Assessment (AA) Screening on the subject property (the site) which is one section of the existing Alkermes Monksland site, which lies to the west of Athlone, Co. Roscommon and immediately north of the M6 motorway. The subject site is owned by Alkermes.

This report has been prepared by PM Group and contains information required for the competent authority to undertake a screening exercise for Appropriate Assessment (AA). The report provides information on and assesses the potential for the proposed development to impact on Natura 2000 sites.

The information in this report forms part of, and should be read in conjunction with the planning application documentation being submitted to Roscommon County Council in connection with the proposed upgrade.

It is necessary that the proposal has regard to Article 6 of the European Commission Habitats Directive (EC/92/43) (as amended) (herein referred to as the Habitats Directive). This is transposed into Irish Law by the European Communities (Birds and Natural Habitats) Regulations, 2011 (SI 477 of 2011) (herein referred to as the Habitats Regulations).

It is the responsibility of the competent authority, in this instance Roscommon County Council, to make a decision as to whether or not the proposed development is likely to have significant effects, either individually or in a combination with other plans or projects, upon Natura 2000 sites. If likely significant effects cannot be ruled out then it would be necessary for Roscommon County Council to undertake an AA of the implications of the proposed upgrade on Natura 2000 sites in view of their conservative objectives.

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1 Natura 2000 sites are part of an EU-wide network of nature protection areas established under the EU Habitats Directive. The aim of the network is to aid the long-term survival of Europe’s most valuable and threatened species and habitats. It is comprised of Special Areas of Conservation (SAC) designated by member states under the Habitats Directive, and also incorporates Special Protection Areas (SPA) designated under the EU Birds Directive.
2 Methodology

The first stage of AA is referred to as screening. This stage identifies the likely impacts on a Natura 2000 site, which would arise from a proposed development either alone or in combination with other plans and projects, and further considers whether these impacts are likely to adversely affect the integrity of any Natura 2000 sites.

If conclusions at the end of the screening exercise are that there is no likelihood of significant impacts occurring on any Natura 2000 sites, as a result of the proposed development either alone or in combination with other plans and projects, then there is no requirement to proceed to subsequent stages of AA.

However, even if the screening exercise makes a finding of no significant impacts, and therefore concludes that further stages of the AA process are not required, these findings must be clearly documented in a "Screening Report for Appropriate Assessment" in order to provide transparency of decision-making.

Screening for Appropriate Assessment involves the following:
1. Determining whether a project or plan is directly connected with or necessary to the conservation management of any Natura 2000 sites;
2. Describing the details of the project / plan proposals and other cumulative plans or projects that may affect any Natura 2000 sites (see Section 3);
3. Describing the characteristics of relevant Natura 2000 sites and identifying the potential for effects on any Natura 2000 sites undertaken on the basis of available information as a desk study or field survey or primary research as necessary (see Table 3.1); and
4. Assessing the likelihood and significance of any likely effects on any Natura 2000 sites (see Table 3.1).

This screening exercise was based on a desktop study. Sources of information relied upon include the following:
- Ordnance Survey of Ireland mapping and aerial photography available from www.osi.ie
- Online data available on Natura 2000 sites as held by the National Parks and Wildlife Service (NPWS) from www.npws.ie
- Information on water quality in the area available from www.epa.ie
- Information on soils, geology and hydrogeology in the area available from www.gsi.ie
- Information on the location, nature and design of the proposed development supplied by the design team
3 Screening Assessment

3.1 Brief Site Description

The subject site is located in the existing Alkermes Monksland site, which lies to the west of Athlone, Co. Roscommon and immediately north of the M6 motorway. The site includes the Fill Finish Building and the Administration & Laboratory Building which lie at the southern end of the Alkermes site. The proposed site 6.02 hectares and the footprint of the existing buildings, the Fill Finish Building and the Admin and Lab Building, together come to approximately 2,600m².

The subject site is zoned as for industrial development and is owned by Alkermes. It is in the process of being purchased by Alexion.

The main site features are two buildings:

The Fill Finish Building was completed in 2006 and is biopharmaceutical sterile fill finish facility. The building was moth-balled in 2009 but the HVAC system has been kept operational and the facility is regularly cleaned. There is currently limited access to the building with one or two individuals entering the building per week to complete the relevant checks and cleaning.

The Admin and Lab Building is a single storey concrete building which was built in the 1980s. Most of the equipment and facilities within the building have been removed. The building is kept locked and there is no general access.

Additional features on the subject site include a car park, generators, and a contractors compound with substation and transformer.

The proposed site has been developed and it is made-ground. The bedrock is a locally important aquifer whereby the water quality is considered to be of high vulnerability. Land is relatively flat with a slight increase north of the site and a slight decline south of the site towards the River.

The Alkermes Fill Finish Building and the Admin and Lab Building are fit for the filling, laboratory and office activities intended by Alexion. The site infrastructure and services can be separated from the Alkermes operations to establish a fully independent site. A number of new buildings will be required to be built on the site including a CUB (Central Utilities Building), Electrical Substation and Fire Water Pump-house. A number of changes to the internal hardstandings will also be required.

3.2 Features of the Surrounding Environment

The proposed site is bounded on all sides and at the southern end of the existing Alkermes operational site. It is zoned for Industrial Development. The land use in the surrounding area is primarily agricultural to the west and south west. The other main industrial / infrastructure installations in the vicinity are Roscommon County Council Waste Water Treatment Plant, Arran Chemicals and Carty Meats to the west, and ESB substation to the south east and the M6 motorway to the south. Other industrial and commercial activities border the Alkermes site to the north of the R362.

3.2.1 Natura 2000 Sites in Vicinity of Proposed Development

The proposed development site is not located within either a Special Area of Conservation (SAC) or a Special Protection Area (SPA). However there are a total of 12 designated sites within 15km of the proposed site. The Natura 2000 designated sites located within 1km, 5km and 15km of the proposed upgrades works are illustrated in Figure 3.1 and are listed below:

- River Shannon Callows SAC (000216)
- Middle Shannon Callows SPA (004096)
- Lough Funshinagh SAC (000611)
- Lough Ree SAC (000440)
- Lough Ree SPA (004064)
- Carn Park Bog SAC (002336)
- Crosswood Bog SAC (002337)
- Mongan Bog SPA (004017)
- Mongan Bog SAC (000580)
- Fin Lough (Offaly) SAC (000576)
- Castlesampson Esker SAC (001625)
- Ballynamona Bog and Corkip Lough SAC (002339)

Figure 3.1: Natura 2000 Sites within 1km, 5km and 15km of the Proposed Site

3.3 Description of Proposed Development

The purpose of the modification of Alkermes Fill Finish Building, the upgrade of the Admin and Lab Building and the construction of a CUB, Electrical Substation and Fire Water Pump-house, is to meet a portion of Alexion's planned Drug Product filling requirements going forward. In addition to the building conversions, the project includes the development of a site infrastructure and utilities to support the independent operation of the Fill Finish facility as a secure, safe and regulatory compliant facility.

3.4 Other Development nearby which may lead to Cumulative Impacts

The proposed site is bounded on all sides and at the southern end of the existing Alkermes operational site. The main features of the Alkermes site are as follows:

To the north of the subject site are the main Alkermes manufacturing buildings, labs, administration, tank farms, car parks etc. The subject site is separated from this area by an internal site road that runs east / west. Immediately adjacent to the subject site on the western side is the Alkermes thermal oxidiser, waste management area, effluent treatment plant and firewater retention pond. To the east of the subject site there are some additional Alkermes engineering and office buildings. There is also an ESB substation on the Alkermes site to the south of the subject site.

The land use in the surrounding area (adjacent to the overall Alkermes site) is primarily agricultural to the west and south west. Other industrial and commercial activities border the site to the west and north of the R362. The Roscommon County Council Waste Water Treatment Plant (WWTP), Arran Chemicals and Carty Meats are located to the West of the site. The nearest surface water body is the River Cross which is approximately 200m south of the facility. The River Cross enters the Shannon approximately 5 kilometres downstream of the site. Surface water is collected through the storm water drain network around the subject site from building roofs, roads and all hard standing areas. A new surface water pipe will be installed to connect up a number of existing surface water sewer at a location downstream of the firewater pond. The existing outfall from the Admin and Lab Building and the connection point to the shared sewer will remain in place with an inspection chamber / sampling point to be installed prior to the connection point with continuous electronic monitoring. This will ensure surface water will not be contaminated entering the River Cross.

Process Discharge will be treated within the Fill Finish Building (pH treatment is only required). A new manhole will be constructed at the point where existing process sewer crosses local authority foul sewer and will be tapped into foul sewer. A trade discharge licence will be required by the Roscommon County Council. This will require that adequate sampling locations shall be provided to ensure that a representative sample of the process effluent can be obtained. There may be a requirement for 24 hour composite sampling to be conducted. Process drainage from the Admin and Lab Building will be diverted to connect directly to the local authority foul sewer and pass via a sampling point for pH detection. A new polypropylene collector drain is proposed which is sufficient for dilute and slightly acidic / basic solutions at room temperature and low concentrations. Discharge with a pH of 6-8.5 can discharge to the local authority sewer. Stronger concentrated acids and bases will be collected separately for specialist disposal.

The foul discharge from the Fill Finish Building currently has direct connection to the local authority foul sewer in the car park. The foul connection from the Admin and Lab Building also has a direct connection to the local authority foul sewer. All domestic discharge such as toilets, sinks, etc. will discharge to this sewer. Information on the quality of Monksland’s WWTP final effluent is available in the treatment plant's Annual Environmental Report (AER) from 2009 to 2012 on the EPA website (www.epa.ie). During this period, there have been 50 samples of the effluent analysed. In relation to Biochemical Oxygen Demand (BOD) of the effluent, there have only been four exceedances of the plant’s 25mg/l limit, none of which have occurred from 2011 onwards. During the years 2011 and 2012, the plant has operated with a final BOD of consistently less than 10mg/l. There have
been 10 exceedences of the plant’s Chemical Oxygen Demand (COD) between 2009 and 2012, while the plant has exceeded its Total Suspended Solids limit 7 times during the same time period. However, none of these exceedences have occurred from 2011 onwards. In addition, the WWTP has met its Total Phosphate limits in all samples taken between 2009 and 2012. The orthophosphate limit of 0.5mg/l has been breached regularly from 2009 to 2012. The treated final effluent is discharged to the Cross River. The current population equivalent (PE) capacity of the treatment plant is 14,381. It is not expected that this capacity will be exceeded in the next three years, as there is currently a spare capacity of 4,264 PE.

There is a history of PCE and TCE contamination on the subject site. The source of PCE contamination is currently unknown as the history of the PCE contamination issue is unclear. It is understood however that the sources of both TCE and PCE are not on the subject site and the subject site is on the pathway to the receptor i.e. Cross River. Arran Chemicals and Alkermes (north of the subject site) have a monitoring programme in place and will continue to monitor for levels of TCE and PCE on the subject land. Therefore, Alexion will have to provide access to the monitoring points. Alexion will ensure that any excavated soil from the subject site will be done in accordance with the appropriate standards.

There will be no potential air impact from the proposed modification of the Fill Finish Building, the upgrade of the Admin and Lab Building and the construction of the CUB, Electrical Substation and Fire Water pump-house. There is only very minor air emissions from the Fill Finish Building and the boiler proposed for the CUB which will not generate significant air emissions. Therefore, there will be no air impact on SACs or SPAs within 15km of the site.

The project’s AA, legislation (both EU and national) and environmental policies of each plan will ensure that the interactions between other plans and projects and this proposed development are reduced minimising the risk of adverse effects on the integrity of the surrounding Natura 2000 sites.
### 3.5 Potential Impacts from Proposed Development on Natura 2000 Sites

**Table 3.1: Identification of Natura 2000 Sites and their Relevance to the Proposed Development**

<table>
<thead>
<tr>
<th>Site Code and Name</th>
<th>Distance from Development</th>
<th>Do any potential source-pathway-receptor links exist between the proposed development and the Natura 2000 site?</th>
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</thead>
<tbody>
<tr>
<td>River Shannon Callows SAC  (000216)</td>
<td>2.5 – 3 km East</td>
<td>No. There is the potential for surface water run-off during both the modification, construction and operational phases which could carry sediments or pollutants downstream into the SAC via the tributaries of the River Shannon running within and immediately adjacent to the proposed development site. However, with the control measures discussed above for the treatment of water, this is highly unlikely. The necessary mitigation measures will be taken into account during the project to ensure that no contaminated surface water reaches the SAC.</td>
</tr>
<tr>
<td>Middle Shannon Callows SPA (004096)</td>
<td>2.5 – 3km East</td>
<td>No. The Shannon Callows continues to hold approximately 40% of the Irish population of Corncrake, a species of global conservation concern that is also listed on Annex I of the EU Birds Directive. A good variety of other bird species are attracted to this site. It is not deemed that any significant impact on this SPA would arise, due to the fact that these species are mobile and that there is ample similar quality agricultural grassland habitat in the area available to these species. The necessary mitigation measures will be taken into account during the project to ensure that no contaminated surface water reaches the SPA. Alexion will ensure that all construction works shall be in accordance with any planning and environmental stipulations.</td>
</tr>
<tr>
<td>Lough Ree SAC (000440)</td>
<td>4km to the North</td>
<td>No. There is the potential for surface water run-off during both the modification, construction and operational phases could carry sediments or pollutants downstream into the SAC via the tributaries of the River Shannon running within and immediately adjacent to the proposed development site. However, with the control measures discussed above for the treatment of water, this is highly unlikely. The necessary mitigation measures will be taken into account during the project to ensure that no contaminated surface water reaches the SAC.</td>
</tr>
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### Site Code and Name | Distance from Development | Do any potential source-pathway-receptor links exist between the proposed development and the Natura 2000 site?
--- | --- | ---
Lough Funshinagh SAC (000611) | 12km to the North | No

Due to the distance between the proposed development and this SAC the potential for water pollution via a hydrological pathway is considered to be insignificant due to the large separation distance between the source and the receptor, over which significant mixing and dispersion of potential pollutants would occur.

Lough Ree SPA (004064) | 4km to the North | No

Lough Ree is of high ornithological importance for both wintering and breeding birds. It supports nationally important populations of seven wintering waterfowl species, as well as other important species including Whooper Swan and Greenland Whitefronted Goose (both of which are listed on Annex I of E.U. Birds Directive). The site has a range of breeding waterfowl, notably nationally important populations of Common Scoter, Great Crested Grebe and Tufted Duck. It also has a colony of Common Tern, another species listed on Annex I of the E.U. Birds Directive.

It is not deemed that any significant impact on this SPA would arise, due to the fact that these species are mobile and that there is ample similar quality agricultural grassland habitat in the area available to these species. The necessary mitigation measures will be taken into account during the project to ensure that no contaminated surface water reaches the SPA. Alexion will ensure that all construction works shall be in accordance with any planning and environmental stipulations.

Carn Park Bog SAC (002336) | 11km to the East | No

Carn Park Bog is a site of considerable conservation significance comprising as it does a raised bog, a rare habitat in the E.U. and one that is becoming increasingly scarce and under threat in Ireland. This site supports a good diversity of raised bog microhabitats, including hummock/hollow complexes, pools and Sphagnum lawns, as well as the rare species Sphagnum pulchrum.

As the proposed development is 11km from the SAC there will be no impact on the SAC.
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<td>Crosswood Bog SAC (002337)</td>
<td>9km to the East</td>
<td>No. Crosswood Bog is a site of considerable conservation significance comprising as it does a raised bog, a rare habitat in the E.U. and one that is becoming increasingly scarce and under threat in Ireland. This site supports a good diversity of raised bog microhabitats, including hummock/hollow complexes, pools and wooded flushes. Furthermore, it supports a population of the rare bog moss Sphagnum pulchrum. As the proposed development is 9km from the SAC there will be no impact on the SAC.</td>
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<td>Mongan Bog SPA (004017)</td>
<td>12km to the South</td>
<td>No. Mongan Bog is an important example of a relatively intact midland raised bog. It has been used as a feeding and roost site by part of the River Suck population of Anser flavirostris albinrons. However, it appears to be seldom used nowadays. It also supports breeding Gallinago gallinago and probably Numenius arquata. Mongan Bog is an important site for invertebrates, with several rare species recorded. As the proposed development is 12km from the SPA there will be no impact on the SPA.</td>
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<tr>
<td>Fin Lough (Offaly) SAC (000576)</td>
<td>12km to the South</td>
<td>No. Fin Lough is a shallow limestone lake surrounded by a complex of wetland habitats. The lake and its surroundings include open water, reedswamp, tall sedge, alkaline fen, fen-bog transition, swamp woodland and bog. The alkaline fen, which is a habitat listed on Annex I of the EU Habitats Directive, is species-rich with characteristic plants including Black Bog-rush (Schoenus nigricans) and the sedge species, Carex flacca, C. lepidocarpa and C. panicea. The total flora of the Fin Lough wetland is remarkably rich: 210 species of vascular plants and 29 species of bryophytes have been identified to date. In addition, the site supports an extensive invertebrate fauna. As the proposed development is 12km from the SAC there will be no impact on the SAC.</td>
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<tr>
<td>Site Code and Name</td>
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| Castlesampson Esker SAC (001625) | 6km to the West           | No.  
Castlesampson Esker is largely intact and fairly undisturbed. The vegetation of most of the esker is of dry grassland, with small amounts of scrub scattered throughout. Improved grassland in the site is found mainly at the base of the esker. Dry grassland on the site is quite species-rich and supports several species not usually seen on eskers. The importance of the site lies in its almost intact structure, something that is very rare in Irish eskers, in its relatively undisturbed state and in the presence of good quality, species-rich dry calcareous grassland of a type listed, with priority status, on Annex I of the EU Habitats Directive.  
As the proposed development is 6km from the SAC there will be no impact on the SAC. |
| Ballynamona Bog and Corkip Lough SAC (002339) | 8km to the West | No.  
Ballynamona Bog and Corkip Lough is a diverse site with an excellent diversity of bog and wetland habitats. The site and surrounding land overlies limestone bedrock and the soils present are derived from limestone drift. Much of the site is surrounded by low esker ridges which contain areas of species-rich calcareous grassland and scrub. Corkip Lough fluctuates markedly throughout the year and during the summer the water level drops revealing a species-rich wetland flora. The quality of the habitats occurring at this SAC is very good with the areas of bog woodland and turlough being of particularly high ecological value. A number of relatively rare plant and animal species occur, these include the rare aquatic invertebrate Eury cercus glacialis and the wetland plant Teucrium scordium.  
As the proposed development is 8km from the SAC there will be no impact on the SAC. |
4 Conclusion

The proposed development which will involve modification to the existing Fill Finish Building, upgrade to the Admin and Lab Building and the construction of a CUB, Electrical Substation and Fire Water Pump-house, in Monksland, Athlone, Co.Roscommon.

Nine SACs and three SPAs were identified within 15km of the proposed development site. As can be seen in Table 3.1 above, there is not considered to be any source-pathway-receptor links between the proposed development and these Natura 2000 sites, and the need for AA of these sites can therefore be ruled out.