

Environmental and Social Data Sheet

Overview

Project Name:	BAVARIAN NORDIC FILL & FINISH PRODUCTION SITE
Project Number:	2016-0330
Country:	Denmark
Project Description:	Financing Bavarian Nordic's investments into a new fill & finish manufacturing facility
EIA required:	no
Project included in Carbon Footprint Exercise ¹ :	no

Environmental and Social Assessment

Environmental Assessment

The project will cover Bavarian Nordic's expenses to construct, furnish and implement a fill and finish facility on their existing production site, together with associated laboratory and manufacturing equipment. The facility will add approximately 1200m² to the total production area.

The new facility will be built adjacent to the company's current manufacturing plant situated in Kvistgård, Denmark for the fill and finish of aseptic liquid, lyophilised and live biological products. Bavarian Nordic has an integrated environmental management policy and effective operating procedures in place which are in line with best industry practice.

The fill and finish facility falls under the annex II of the EIA directive (2014/52/EU), referring to the manufacture of pharmaceutical products. The Danish Environmental Protection Agency ruled in July 2016 that the project will not have a significant impact on the environment, and has therefore been screened out and there is no Environmental Impact Assessment required. The production process of medicinal products has limited environmental impact and the products are also subject to environmental risk assessments under directive 2001/83/EC as deemed necessary, in order to complete the relevant marketing authorisation application. The project is located in an area reserved for industrial use with no impact on Natura 2000 sites. The project will be carried out according to state-of-the-art technology and will take into consideration environmentally friendly, low energy-and-resource consuming technologies.

Other Environmental and Social Aspects

Bavarian Nordic is audited, certified and authorised by the relevant Danish authorities for the manufacturing and release of human medicinal products. Furthermore, its quality control laboratory is qualified by the Competent National Authority as well as relevant international bodies. The promoter has a robust quality management system and effective operating procedures which have been duly audited by the Competent Authorities and are in-line with ICH and cGMP standards. The new facility will comply with the aforementioned standards.

¹ Only projects that meet the scope of the Pilot Exercise, as defined in the EIB draft Carbon Footprint Methodologies, are included, provided estimated emissions exceed the methodology thresholds: above 100,000 tons CO₂e/year absolute (gross) or 20,000 tons CO₂e/year relative (net) – both increases and savings.



Luxembourg, 7 May 2018

Bavarian Nordic will supply the Bank with copies of all the applicable and relevant authorisation documents during the due-diligence procedure.

Conclusions and Recommendations

The project will not result in any significant additional negative environmental and social impacts. It is therefore considered acceptable for the Bank financing in environmental and social terms.