Environmental and Social Data Sheet

Overview

Project Name: SARTORIUS R&D Project Number: 2013-0544

Country: Germany, France, Finland

Project Description: The promoter is a laboratory and process technology

company, covering the segments of Bioprocess Solutions, Lab Products & Services and Industrial Technologies. The project which mainly consists of R&D expenditures related to the development of new products will also include vocational training expenditures. The activities included in the project will be located at the promoter's existing facilities in Germany with some R&D activities taking place in other

European countries.

EIA required: no

Project included in Carbon Footprint Exercise¹: no

Summary of Environmental and Social Assessment, including key issues and overall conclusion and recommendation

The Research and Development activities included in the project are not listed in the EIA directive. Furthermore, the project concerns investments in research and development that will be carried out in existing facilities without changing their already authorised scope. An Environmental Impact Assessment (EIA) is therefore not required under Directive 2011/92/EU.

The project per se does not have any impact on the environment; however an important part of the project R&D activities targets the development of innovative single-use products that will help the single-use technology penetration of the biopharmaceutical industry and will subsequently contribute to increased environmental and social sustainability because of the lower energy and water consumption of this technology compared to conventional - "stainless steel based" – bioprocessing technology. The project is therefore considered acceptable for Bank financing.

Environmental and Social Assessment

Environmental Assessment

The R&D activities of the project will be managed and carried out by the promoter's existing R&D staff in Germany (Goettingen, Guxhagen) and also in France (Aubagne) and Finland (Helsinki). All these sites are ISO 9001 certified. In addition all the promoter's major manufacturing sites worldwide are certified ISO 14001. The project's R&D activities are a central part of the promoter's operations and, as such, will be embedded in the existing organisational and management structure. The operating procedures in place are in line with best industry standards.

An important part of the project focuses on the development of single-use products that are used in modern biopharmaceutical production plants to replace conventional "stainless steel based" manufacturing systems. On the contrary to conventional technology, the single-use approach allows the suppression of resource-intensive cleaning processes (using ultrapure water, clean steam and chemicals) and associated waste-water processing. For example, a

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.

typical industrial manufacturing process for monoclonal antibodies using predominantly single-use solutions requires around 87% less water and 30% less energy than the equivalent process using predominantly reusable solutions. Other publications also establish that the energy consumption associated with sterilization, cleaning and materials in processes based on single-use is around half that of conventional processes.

Although single-use products have clear environmental benefits in terms of energy and water consumption, their use also generates more waste, but as the waste materials are contaminated they have to be destroyed through incineration, therefore they can be used as fuel source for heat and/or power generation (ultrapure plastics used for single-used products contain around 80% to 90% of the energy of pure crude).

Globally, the single-use technology has a clear positive impact on the environment.

Other Environmental and Social Aspects

The promoter has a strong focus on energy saving. A new energy management system, in line with ISO 50001, was recently introduced at the single-use manufacturing plant in Goettingen; this will be setting the standard for the promoter's sites worldwide. The promoter is also continuously putting a lot of effort to reduce water consumption and to recycle materials and chemicals that are necessary for membrane manufacturing.

In addition, the promoter has a strong safety culture and good operating and HSE (Health, Safety and Environment) procedures in place. Sartorius HSE management system is in line with the requirements and guidance from the German Occupational Health and Safety Agency. A respectable Total Recordable Injuries (TRI: number of total recordable injuries per million hours) of 7.8 was achieved in 2013.

Sartorius is in full compliance with the Global Product Strategy initiative of the European Community Regulation on Chemicals (Reach).

The vocational training component of the project contributes to support youth employment in Germany.