Luxembourg, 14 March 2019

Public

Environmental and Social Data Sheet

Overview

Project Name:	SKIN HEALTH R&D
Project Number:	2018-0686
Country:	Spain
Project Description:	Financing of R&D in skin health of the promoter for the period 2019-2022.

EIA required: no

Project included in Carbon Footprint Exercise[1]: no

(details for projects included are provided in section: "EIB Carbon Footprint Exercise")

Environmental and Social Assessment

Environmental Assessment

The project's R&D activities are a central part of the promoter's operations and will be embedded in the existing organisational and management structure. The project will not result in any significant environmental impact as it will be carried out in existing and authorised research facilities. The operating procedures in place are in line with best industry standards and are regularly audited externally.

The research activities undertaken in the project are aimed to result in new and improved medical treatments with a positive impact on healthcare quality. Therefore, the project, if successful, is expected to bring positive social impact.

Other Environmental and Social Aspects

The promoter is certified according to environmental management system ISO14001:2015 and safety programmes and is conducting its business in compliance with all applicable environmental laws and regulations, notably:

- Directive 2009/41/CE of the European Parlament and of the Council 6th May, relative to the contained use of genetically modified organisms.
- Real Decreto 664/1997 del 12 de Mayo relativo a la protección de trabajadores frente a los riesgos relacionados con la exposición a agentes biológicos en el lugar de trabajo. BOE nº 124 del 24 de Mayo.

[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.

- Guía Técnica para la evaluación y prevención de los riesgos asociados con la exposición a agentes biológicos. Instituto Nacional de Seguridad e Higiene en el Trabajo.
- Ley 9/2003, de 25 de abril, por la que se establece el régimen jurídico de la utilización confinada, liberación voluntaria y comercialización de organismos modificados genéticamente.
- Real Decreto 178/2004, de 30 de enero, por el que se aprueba el Reglamento general para el desarrollo y ejecución de la Ley 9/2003, de 25 de abril, por la que se establece el régimen jurídico de la utilización confinada, liberación voluntaria y comercialización de organismos modificados genéticamente.
- DECRET 62/2015, de 28 d'abril, pel qual s'estableixen mesures per a l'exercici de les competències de la Generalitat de Catalunya en matèria dels organismes modificats genèticament.
- Laboratory Biosafety Manual, 3rd edition, World Health Organization 2004.
- Biosafety in Microbiological and biomedical laboratories, 5th edition CDC-NIH.
- Procedimiento Medioambiental ITMA(CI)/600/03 (PRC-0002121): Control y gestión interna de residuos en los centros de investigación (19 January 2011)

The promoter's sites in Spain and in Germany are certified according to ISO 14001:2015 international standard for environment management, covering R&D activities, manufacture of active pharmaceutical ingredients, and manufacture and wholesale of drug products. In addition, as part of its integrated health, safety and environmental policy, the promoter has implemented an energy management system, certified according to ISO 50001:2014 and an occupational health and safety management system certified according to OHSAS 18001:2007.

Animal testing

The promoter has a strict Animal testing policy, according to which it is highly committed to their responsible use and their welfare.

The promoter strictly adheres to the European (Directive 2010/63/EU), Spanish (Real Decreto 53/2013) and Catalan (Decret 214/1977) regulations related to the care and use of animals for research.

The promoter follows the principles of Replacement, Reduction and Refinement (the "3Rs" of Russell and Burch), which means:

- Animals shall not be used if there is an alternative non-animal method (*in vitro, in silico*…) able to provide the promoter with the same scientific results that would have been expected in vivo.
- If animals have to be used, the promoter shall use the minimum number to achieve the scientific results.
- When animals have to be used, the promoter shall apply all its knowledge and skills to alleviate or minimise pain, suffering or distress, and to enhance animal welfare.

Every procedure or project with animals is carefully reviewed and approved by an internal Ethics Committee and, in addition, by the relevant authorities. This Committee is a regulated body which ensures ethical compliance and adherence to the laws, and is formed by the

Luxembourg, 14 March 2019

Specialist in Animal Welfare, who is responsible on site for the supervision of the welfare and care of the animals in the facilities, and by expert scientist members.

Conclusions and Recommendations

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 by EIA Directive 2014/52/EU amending Directive 2011/92/EU. The Promoter has an integrated health, safety and environment management system and effective operating procedures in place which are in line with best industry standards.

Considering the above, the project is acceptable for Bank financing in environmental and social terms.