

Luxembourg, 15 May 2025

Public

Environmental and Social Data Sheet¹

Overview

Project Name:	<i>BIOVET RDI PROGRAMME</i>
Project Number:	<i>2024-0557</i>
Country:	<i>Bulgaria, Regional – EU countries</i>
Project Description:	<i>RDI investments in Bulgaria and other EU countries in the sphere of feed additives, veterinary pharmaceutical products and vaccines.</i>
EIA required:	no
Invest EU sustainability proofing required	Yes
Project included in Carbon Footprint Exercise ² :	no

Environmental and Social Assessment

Environmental Assessment

The project includes R&D activities for the development of complex veterinary medicines, vaccines and feed additives. 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 be carried out in existing and authorised research facilities. The project activities are not specifically listed in Annexes I or II of the EU Directive 2011/92/EU as amended by the 2014/52/EU Directive, therefore they are not subject to an Environmental Impact Assessment procedure. The operating procedures in place are in line with best industry standards and are regularly audited externally.

The promoter utilises an environmental management system and safety programmes and is conducting its business in compliance with all applicable environmental laws and regulations.

It operates using Good Manufacturing Practices (GMPs), and its manufacturing facilities are designed and constructed according to EU and FDA (the US Food and Drug Administration) requirements. The promoter has the following certifications ISO 9001, ISO 14001, ISO 45001, ISO 22716, FSSC 220.

¹ The information contained in the document reflects the requirement related to the environmental, social and climate information to be provided to Investment Committee as required by the Invest EU Regulation and it represents the equivalent of the information required in the template of the InvestEU sustainability proofing summary

² Only projects that meet the scope of the Carbon Footprint Exercise, as defined in the EIB Carbon Footprint Methodologies, are included, provided estimated emissions exceed the methodology thresholds: 20,000 tonnes CO₂e/year absolute (gross) or 20,000 tonnes CO₂e/year relative (net) – both increases and savings.

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Other Environmental and Social Aspects

The promoter has implemented a comprehensive Health and Safety Management System, which includes primary and ongoing personnel training based on detailed written safety protocols. The promoter's facilities are constructed in full compliance with all relevant environmental, health, and safety regulations. Regular inspections of working conditions, such as artificial lighting levels, noise, temperature, humidity, and air velocity, are conducted by an accredited independent laboratory.

The promoter's production sites are designed as multi-product facilities with high-level segregation and operational flexibility. Strict separation of production areas for biological products is ensured, with dedicated Personal Air Locks for entry and exit, and fumigated Material Air Locks for material handling and waste disposal where necessary.

The biological agents utilized in the promoter's operations are classified under Biosafety Level 2 (BSL-2). Where appropriate, the promoter employs single-use technologies to enhance biosafety measures. BSL-2 zones feature dedicated HVAC systems providing 100% fresh air and equipped with HEPA filtration for exhaust air in areas handling live pathogens. Full decontamination processes are implemented within all BSL zones.

The promoter maintains advanced differential pressure controls and unidirectional personnel flow throughout classified and BSL areas, including a two-step de-gowning process upon exit. A dedicated decontamination area for solid waste ensures no live pathogens are released into the environment. Validated effluent decontamination systems are utilized, employing continuous heat treatment for liquid waste from drainage systems, alongside a general wastewater treatment plant to manage overall waste disposal.

The promoter's commitment to sustainability is reflected in strategic investments in renewable energy generation for its own operations. In 2023, the promoter successfully met approximately 25% of its electricity needs through renewable energy sources. Through continuous innovation in R&D projects and within production facilities, the promoter aims to further reduce energy consumption per unit of production, enhance energy efficiency, and explore additional initiatives to make manufacturing processes as environmentally sustainable as possible.

Social benefits are further amplified by the project's focus on sustainable animal health solutions, which address public health challenges such as reducing antibiotic resistance.

The promoter's commitment to gender equality and inclusive employment practices enhances the attractiveness of this project for the EIB and is evidenced by the fact that, in 2022, women, who represented 58% of the R&D workforce, accounted for 40% of top management.

Conclusions and Recommendations

In the light of the above, the proposed investments do not require any additional permits and fall within an already authorised scope. The project activities are not specifically listed in Annexes I or II of the EU Directive 2011/92/EU as amended by the 2014/52/EU Directive, therefore they are not subject to an Environmental Impact Assessment procedure. The promoter's strong governance and operational capabilities ensure the successful execution of the project, supported by their robust experience in advanced biopharmaceutical manufacturing processes.

The Project is carried out in compliance with applicable national and EU environmental and social legislation. Based on the environmental, climate and social information and based on the review of the likely significant environmental, climate and social risks and impacts and the mitigation measures and management systems in place, the Project is deemed to have low



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residual environmental, climate and social risks and impacts. No further sustainability proofing is therefore required.

Overall, the project not only meets EIB's public policy objectives but also delivers substantial economic, social, and environmental benefits. As such, the project is acceptable for financing in environmental and social terms.