

## Environmental and Social Data Sheet

*(Further guidance is contained in the Environmental and Social Practices Handbook)*

### Overview

Project Name:	Merck Pharma R&D
Project Number:	2012-0005
Country:	Germany
Project Description:	The project concerns the clinical trials related to the development of "Stimuvax <sup>®</sup> based" innovative vaccines for various cancers.
EIA required:	NO
Project included in Carbon Footprint Exercise <sup>1</sup> :	NO

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

The R&D activities encompassed within this project will not materially change current R&D practices and will be carried out within existing facilities. Thus, an Environmental Impact Assessment (EIA) according to the Directive 2011/92/EU is not required.

### Environmental and Social Assessment

#### Environmental Assessment

As a group, Merck is ISO 14001 certified, meaning that all manufacturing sites are ISO 14001 certified. The R&D headquarter in Europe is also ISO 14001 certified.

Merck has a sound environmental policy including regular audits and reporting. R&D facilities and practices are in compliance with national and EU relevant regulation and the promoter maintains adequate internal procedures and management practices.

#### EIB Carbon Footprint Exercise

Project is not included - the EIB draft Carbon Footprint Methodologies only include emissions from Investment Loans, and large allocations under Framework Loans, above the methodology thresholds.

#### Social Assessment, where applicable

The clinical trials which are included in the project are performed under regulated and strictly controlled conditions, in existing specialised facilities which are regularly inspected by competent authorities - EMEA in Europe and/or national equivalent bodies in the rest of the World (FDA, PMDA, SFDA,...). The recruitment of patients is performed in accordance with the European directive (2001/20/EC) and/or equivalent international regulations in case of clinical trials performed outside Europe.

#### Other Environmental and Social Aspects

Merck actively participates in associations and initiatives to promote scientific best practices and develop alternative research methods following the "3R" concept, in order to Reduce, Refine and Replace animal experimentation in pre-clinical development.

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<sup>1</sup> 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 CO<sub>2</sub>e/year absolute (gross) or 20,000 tons CO<sub>2</sub>e/year relative (net) – both increases and savings.