EXPORT CREDIT GUARANTEES OF THE FEDERAL REPUBLIC OF GERMANY

Hermes Cover

QUESTIONNAIRE FOR PHARMACEUTICALS AND BIOTECHNOLOGY MANUFACTURING (SECTOR-RELATED QUESTIONS)

The completion of this questionnaire is voluntary. However, replying to the relevant questions as completely as possible will facilitate and speed up the assessment of the environmental, social and human rights impacts of the project for which the German export supplies or services offered for cover are intended. This – together with the questionnaire not related to a particular sector, the completion and submission of which should also be considered in order to speed up the assessment procedure – can replace the description of the environmental, social and human rights impacts in the memorandum.

The questionnaire provides guidance on what information may be important for this sector. It is based on the World Bank/IFC General Environmental Health and Safety (EHS) Guidelines and the IFC EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing. Additional information on the applicable standards can be found at AGA Portal.

This is a list of possible questions. Depending on the individual case only some of them, or perhaps also additional information, may become relevant in the course of the application procedure. Because of the specific features of each project further clarification may be required.

CONTENT

A. Pharmaceuticals and biotechnology manufacturing

A.1. Process and resources consumption

- What will be manufactured and what process will be used? Please give a technical description of the individual process steps. What fuels will be used?
- Does a production-related connection with other (planned) facilities exist (e.g. power generation, harbour facilities)?
- Does the project or any associated facilities (i.e. facilities which would not exist without the project and which are necessary for the project's existence) include bio-prospecting? If so, how is it guaranteed that the rights of local communities are respected and the biodiversity of affected habitats is not impaired?
- Does the project or any associated facilities (i.e. facilities which would not exist without the project and which are necessary for the project's existence) include research, production or trade of living modified organisms? If so, how is it guaranteed that the biodiversity is not impaired through the controlled or uncontrolled release of such organisms into the environment?
- Does the project or any associated facilities include activities that give rise to bioethical issues (e.g. development of genetically modified foods, gene therapy experiments, stem cell research, animal testing, clinical trials, handling of genetic information, sale of genetic and biological samples or transgenic animals)? If so, how is a responsible management of such activities guaranteed?
- How is the planned plant supplied with energy? What fuels are used?
- How is the planned plant supplied with raw materials?
- How are the finished goods transported away?

A.2. Air emissions

- Please state the maximum values of the parameters for any waste gases emitted in mg/Nm³ for all process steps, especially PM, active ingredients (each), total class A (in accordance with the PPAH of the World Bank for pharmaceuticals manufacture), class B (in accordance with the PPAH of the World Bank for pharmaceuticals manufacture), benzene, vinyl chloride, dichloroethane. Occasionally, not all pollutants listed in the table are emitted or others specific to the project have to be added. Please inform us if that is the case.

Air Emissions Levels for Pharmaceuticals and Biotechnology Manufacturing			
Pollutants	**Units**	**Guideline Value**	**Project Value**
Active Ingredient (each)	mg/Nm³	0,15	
Particulate Matter	mg/Nm³	20	
Total Organic Carbon	mg/Nm³	50	
Hazardous Air Pollutants	kg/year	900 – 1800[3]	
Total Class A [1]	mg/Nm³	20[4]	
Total Class B [2]	mg/Nm³	80[5]	
Benzene, Vinyl Chloride, Dichloroethane (each)	mg/Nm³	1	
VOC	mg/Nm³	20 – 150[6] 50[7]	
Bromides (as HBr)	mg/Sm³	3	
Chlorides (as HCl)	mg/Sm³	30	
Ammonia	mg/Sm³	30	
Arsenic	mg/Sm³	0,05	
Ethylene Oxide	mg/Sm³	0,5	
Mutagenic Substance	mg/Sm³	0,05	

Notes:
1. Class A compounds are those that may cause significant harm to human health and the environment. They include Montreal Protocol substances, as well as others identified in the EU Directive 1999/13/EC on the Limitation of Emissions of Volatile Organic Compounds due to the Use of Organic Solvents in Certain Activities and Installations. Example of Class A compounds include: acetaldehyde, acrylic acid, benzyl chloride, carbon tetrachloride, chlorofluorocarbons, ethyl acrylate, halons, maleic anhydride, 1,1,1 trichloroethane, trichloromethane, trichloroethylene, and trichlorotoluene.
2. Class B compounds are organic compounds of less environmental impact than Class A compounds. Examples include: toluene, acetone and propylene.
3. Process-based annual mass limit. 900: Actual HAP emissions from the sum of all process vents within a process; 1,800: Actual HAP emissions from the sum of all process vents within processes.
4. Applicable when total Class A compounds exceed 100 g/hr.
5. Applicable when total Class B compounds, expressed as toluene, exceed the lower of 5 t/year or 2 kg/hr.
6. EU Directive 1999/13/EC. Facilities with solvent consumption > 50 tonnes/year. Higher value (150) to be applied for waste gases from any technique which allows the reuse of the recovered solvent. Fugitive emission values (non including solvent sold as part of products and preparations in a sealed container): 5 percent of solvent input for new facilities and 15 percent for existing facilities. Total solvent emission limit values: 5 percent of solvent input for new facilities and 15 percent for existing facilities.
7. Waste gases from oxidation plants. As 15 minute mean for contained sources.

Source: IFC EHS Guidelines PHARMACEUTICALS AND BIOTECHNOLOGY MANUFACTURING, table 1, page 12

- Please also state the chlorocarbons contained in the individual exhaust air values achieved in ng/Nm³ (e.g. dioxins, furans).
- Please also state the (expected) emission values (in particular greenhouse gas emissions (CO_2eq), dust (PM), sulfur dioxide (SO_2) and nitrogen oxides (NO_x) in mg/Nm³) for any steam and power generation. In the case of plants with a capacity of more than 50 $MW_{thermic}$ please use the questionnaire *Conventional Energy* as guideline.
- Please describe what measures are taken to avoid/reduce emissions from the site.
- What limit values for ambient air quality are applicable in the buyer's country (please make a table available)? Please state the relevant expected emission levels. Please comment on any changes in the ambient air quality before and after the project implementation. If there are no national limit values, please use the table below.

WHO Ambient Air Quality Guidelines[1,2]

	Averaging Period	IFC Guideline Value [µg/m³]	Guideline Value Host country	Project Value (baseline status) [µg/m³]	Project Value (after implementation) [µg/m³]
Sulfur dioxide (SO_2)	24-hour	125 (Interim target-1) 50 (Interim target-2) 20 (guideline)			
	10 minute	500 (guideline)			
Nitrogen dioxide (NO_2)	1-year	40 (guideline)			
	1-hour	200 (guideline)			
Particulate Matter (PM_{10})	1-year	70 (Interim target-1) 50 (Interim target-2) 30 (Interim target-3) 20 (guideline)			
	24-hour	150 (Interim target-1) 100 (Interim target-2) 75 (Interim target-3) 50 (guideline)			

Particulate Matter ($PM_{2.5}$)	1-year	35 (Interim target-1) 25 (Interim target-2) 15 (Interim target-3) 10 (guideline)			
	24-hour	75 (Interim target-1) 50 (Interim target-2) 37.5 (Interim target-3) 25 (guideline)			
Ozone	8-hour daily maximum	160 (Interim target-1) 100 (guideline)			

Notes:
[1] World Health Organization (WHO). Air Quality Guidelines Global Update, 2005. PM 24-hour value is the 99th percentile.
[2] Interim targets are provided in recognition of the need for a staged approach to achieving the recommended guidelines.

Source: WORLD BANK/IFC GENERAL EHS GUIDELINES 2007, table 1.1.1, page 4

- Please describe the on-site monitoring of air emissions as well as ambient air quality levels.

A.3. Fresh water and effluents

- How much (fresh) water is used on site? Is the water recirculated?
- Where and how is the water withdrawn?
- What wastewater streams are generated?
- How are effluents treated on site? Please also state whether effluents are discharged into a public sewage treatment system or into surface water bodies (river, lake, sea). If there are discharges, please provide information on the quantities of the wastewater streams (e.g. m^3/h or l/s).
- Please state the maximum values of the effluent parameters in mg/l, especially for TSS, AOX, BOD, COD, oil and grease, phenol, hexavalent chromium, arsenic, cadmium, mercury, each active ingredient (AI). Occasionally, not all pollutants listed in the table are emitted or others specific to the project have to be added. Please inform us if that is the case.

Effluents Levels for Pharmaceuticals and Biotechnology Manufacturing			
Pollutants	**Units**	**Guideline Value**	**Project Value**
pH	S.U.	6 – 9	
BOD_5	mg/L	30	
COD	mg/L	150	
TSS	mg/L	10	
Oil and grease	mg/L	10	
AOX	mg/L	1	
Phenol	mg/L	0,5	
Arsenic	mg/L	0,1	
Cadmium	mg/L	0,1	
Chromium (hexavalent)	mg/L	0,1	

Mercury		mg/L	0,01	
Active ingredient (each)		mg/L	0,05	
Ammonia		mg/L	30	
Total nitrogen		mg/L	10	
Total phosphorus		mg/L	2	
Ketones (each)[(1)]		mg/L	0,2	
Acetonitrile		mg/L	10,2	
Acetates (each)[(2)]		mg/L	0,5	
Benzene		mg/L	0,02	
Chlorobenzene		mg/L	0,06	
Chloroform		mg/L	0,013	
o-Dichlorobenzene		mg/L	0,06	
1,2-Dichlorethane		mg/L	0,1	
Amines (each)[(3)]		mg/L	102	
Dimethyl sulfoxide		mg/L	37,5	
Methanol / ethanol (each)		mg/L	4,1	
n-Heptane		mg/L	0,02	
n-Hexane		mg/L	0,02	
Isobutyraldehyde		mg/L	0,5	
Isopropanol		mg/L	1,6	
Isopropyl ether		mg/L	2,6	
Methyl cellosolve		mg/L	40,6	
Methylene chloride		mg/L	0,3	
Tetrahydrofuran		mg/L	2,6	
Toluene		mg/L	0,02	
Xylenes		mg/L	0,01	
Bio-assays	Toxicity to *fish*	T.U.[(4)]	2	
	Toxicity to *Daphnia*		8	
	Toxicity to *algea*		16	
	Toxicity to *bacteria*		8	

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Notes: 1. Including Acetone, Methyl Isobutyl Ketone (MIBK). 2. n-Amyl Acetate, n-Butyl Acetate, Ethyl acetate, Isopropyl Acetate, Methyl Formate. 3. Including Diethylamine and Triethylamine. 4. TU = 100 / no effects dilution rate (%) of waste water. The "no effect dilution rate" should be monitored with standard toxicity tests (e.g. CEN, ISO or OECD acute toxicity testing standards.)
Source: IFC EHS Guidelines PHARMACEUTICALS AND BIOTECHNOLOGY MANUFACTURING, table 2, page 13

- Please describe the measures planned to avoid/reduce/treat wastewater.
- Please describe the on-site monitoring of the effluent values. Is biological testing performed at the outlet to determine the toxicity?
- How and where are the effluents discharged? Please explicitly comment on the pH value and the temperature rise at the point of discharge, describe possible effects of the discharge on the ecology of the water bodies and provide information on the condition and size of the water body (e.g. flow values, flow rate). Please give also details on protection measures.
- What national standards are applicable for the discharge of sanitary sewage? How is the sewage treated before it is discharged? Please state the expected maximum values of the pollution levels in the sewage. If there are no national limit values, please use the table below.

Indicative Values for Treated Sanitary Sewage Discharges[1]

Pollutants	Units	Guideline Value	Project Value
pH	pH	6-9	
BOD	mg/L	30	
COD	mg/L	125	
Total nitrogen	mg/L	10	
Total phosphorus	mg/L	2	
Oil and grease	mg/L	10	
TSS	mg/L	50	
Total coliform bacteria	MPN[2]/100 ml	400[1]	

Notes:
[1] Not applicable to centralized, municipal, wastewater treatment systems which are included in EHS Guidelines for Water and Sanitation.
[2] MPN = Most Probable Number

Source: WORLD BANK/IFC GENERAL EHS GUIDELINES 2007, table 1.3.1., page 30

A.4. Waste

- What relevant waste products are generated on site?
- What measures are taken to avoid, treat and dispose of the waste (solid/liquid) generated and where/how is it deposited?
- Please give also details on possible waste incineration processes (type and quantity of waste, incineration temperature, etc.).
- Do the wastes contain hazardous pollutants? If so, how are they disposed of?
- Is it necessary to treat the waste chemically or to sterilize it prior to disposal? If so, please explain.

A.5. Noise

- How far is the nearest residential area away?
- Are noise mitigation measures necessary or planned? If so, what measures?
- Please state the noise impact (existing background noise level and additional noise emissions of the project) on the nearest receptors (industrial estates and residential areas) in dB(A) for day and night after completion of the project in accordance with the table below.

Noise Level Guidelines[1]				
	One Hour LA_{eq} (dBA)			
Receptor	**Guideline Value Daytime (07:00-22:00)**	**Project Value Daytime (07:00-22:00)**	**Guideline Value Nighttime (22:00-07:00)**	**Project Value Nighttime (22:00-07:00)**
Residential; institutional; Educational[2]	55		45	
Industrial; commercial	70		70	
Notes: [1] Guidelines values are for noise levels measured out of doors. Source: Guidelines for Community Noise, WHO, 1999. [2] For acceptable indoor noise levels for residential, institutional, and educational settings refer to WHO (1999).				
Source: WORLD BANK/IFC GENERAL EHS GUIDELINES 2007, table 1.7.1, page 53				

- Do the project's noise emissions lead to an increase of the background noise level at the nearest receptors by more than 3 dB(A)?

A.6. Occupational health and safety

- How were the relevant occupational health and safety hazards identified and assessed (e.g. Hazard Identification Study – HAZID, Hazard and Operability Study – HAZOP or Quantitative Risk Assessment – QRA)?
- What safety measures and/or control systems are planned to prevent accidents from happening and to guarantee safety and health (in particular with regard to the handling of hazardous chemicals and pathogens as well as noise, heat, fire and explosions) at the workplace?
- What average and maximum noise exposure is to be expected at the workplaces? What safety measures are taken at workplaces where the noise exposure exceeds 85 dB(A)?
- How are subcontractors integrated into the health and safety measures on site?
- If the project consists in the modernisation or expansion of an existing plant, please make accident statistics for the past two years available to us.

A.7. Health and safety of the population

- What measures are taken to minimize impacts and possible risks for adjacent communities in particular with regard to the handling of hazardous materials, the prevention of leakages, fire and explosions, waste disposal, traffic management, emergency planning, cooperation with local rescue teams?

B. Additional information

Additional information on the **Common Approaches**, our **environmental, social and human rights due diligence** and the **applicable standards** can be found at:

https://agaportal.de/main-navigation/schnellzugriff-aga-konsortium/verantwortung

The **World Bank/IFC EHS Guidelines** can be found on the website:

http://www.ifc.org/wps/wcm/connect/topics_ext_content/ifc_external_corporate_site/ifc+sustainability/our+approach/risk+management/ehsguidelines.