

Compliance to Environmental Clearance (EC) Conditions

Compliance Status towards the conditions stipulated in the Environmental Clearance (EC) for the manufacture of formulation based products, drug & drug based intermediates, fermentation based products & custom synthesis products at Plot Nos. 276 & 277 of KIADB Harohalli Industrial Area Phase-II, Kanakapura Taluk, Ramanagar District. (EC No. SEIAA 15 IND 2013 dated 13th July 2015)

Sl No	EC stipulated Conditions	Compliance Status
1	National Emission Standards for Organic Chemicals Manufacturing Industry issued by ministry vide GSR 608 (E) dated 21 st July 2010 and amended time to time shall be followed by the unit.	National Emission standards issued by the ministry vide GSR 608 (E) dated 21 st July 2010 is being followed
2	The total effluent generated shall not exceed 360 KLD. The industrial effluent and domestic sewage shall be treated in the proposed ETP of capacity 200 KLD followed by MEE and STP of capacity 60 KLD respectively.	Currently, the effluent generated is limited to 150 KLD. Industrial effluent being treated in Effluent Treatment Plant of 155 KLD (upgradable upto 295 KLD) capacity, MEE and Solvent stripper of 60KLD and 25 KLD capacity respectively. Domestic sewage is treated in STP of 30KLD (Upgradable upto 60 KLD) capacity.
3	In proposed ETP, aeration lagoon to be replaced by a tank to prevent ground water contamination due to leakage from unlined lagoons. Also stripper has to be introduced before aeration tank.	As per suggestions from SEIAA, Aeration lagoons are not constructed in ETP. All tanks are of RCC with water proofing to prevent ground water contamination due to leakage. Stripper of 25 KLD has been constructed before Biological system. Log books have been maintained in the ETP and STP sections.
4	Total water requirement shall not exceed 360 KLD and shall be met from KIADB supply and recycled water and prior permission shall be obtained from concerned authority. No ground water shall be used.	Total water consumption is currently 200 KLD. The water requirement being met from KIADB and the recycled water. Permission is obtained from KIADB for supply of fresh water. Ground water is not being used.
5	The process emission from boiler shall be dispersed through a stack of adequate height as per KSPCB and CPCB standards. The gaseous emissions from the DG set shall be dispersed through stack height as per CPCB standard shall be provided. Acoustic enclosure shall be provided to the DG set to mitigate noise pollution.	Stack of adequate height (42.5 m) has been provided for the boiler for effective dispersion of process emission. 2 No's stack of adequate height (31.5 m) has been provided for DG's as per CPCB guidelines. DGs have been equipped with acoustic enclosures to mitigate noise pollution..

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6	Ambient air quality data shall be collected according to NAAQES notified by the ministry vide G.S.R. No 816 (E) dated 16th September 2009. The levels of PM ₁₀ , SO ₂ , NO _x , VOC and HCl shall be monitored in the ambient air and emissions from the stack and displayed at convenient locations near the main gate of the company and at important public places. The company shall upload the results of monitored data on its website and also update the same regularly. It shall simultaneously be sent to MoEF - Bangalore, SEIAA- Bangalore and respective zonal offices of KSPCB and CPCB.	Ambient air quality data being monitored according to NAAQ Standards notified by the ministry vide G.S.R. No 816 (E) dated 16 th September 2009. The level of PM ₁₀ , SO ₂ , NO _x , VOC being monitored in the ambient air and emission stack and displayed near the main gate of company.
7	The company shall upload the status of compliance of stipulated environmental clearance conditions, including results of monitored data on its website and shall update the same periodically. It shall simultaneously be sent to Regional Office - MoEF, SEIAA - Karnataka, respective zonal office of KSPCB and CPCB. The levels of SPM, RSPM, SO ₂ , NO _x and VOC and emissions from stacks shall be monitored and displayed at convenient location near the main gate and important public places.	Environmental Clearance compliance report has been submitted to RO- MoEF, SEIAA- Karnataka, zonal office of KSPCB and CPCB. The level of SPM, RSPM, SO ₂ , NO _x and VOC and emissions from stacks being monitored and displayed at a board near the main gate. The data is shared with KSPCB every month.
8	The company shall obtain authorization for collection storage and disposal of hazardous waste under Hazardous Waste (Management, Handling & Transboundary Movement) Rules, 2008, for management of hazardous waste and prior permission from KSPCB shall be obtained for disposal of solid / hazardous waste to the TSDF, The concerned company shall undertake measures for fire fighting facilities in case of emergency.	Hazardous waste Authorization obtained under Hazardous and other Waste (Management & Transboundary Movement) Rules 2016 from KSPCB for the collection, storage and disposal of hazardous wastes generation. The industry is equipped with advanced firefighting system such as Fire hydrants, fire extinguishers, Automatic sprinkler system to handle any emergency.

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9	In plant, control measures for checking fugitive emissions from all the vulnerable sources shall be provided. Fugitive emissions shall be controlled by providing closed storage, closed handling and conveyance of chemicals / materials, multicyclone separator and water sprinkling systems. Dust separation system including water sprinkling system shall be provided at loading and unloading areas to control dust emissions. Fugitive emissions in the work zone environment, product, raw materials storage area etc shall be regularly monitored. The emissions shall conform to the limits stipulated by KSPCB.	Industry has provided closed storage, closed handling & conveyance system for chemicals / materials handling. The industry has also provided dust collectors for operations where fugitive dusts are expected. The underground tanks in the tank farm have been provided with nitrogen inertization system with breather valves and flame arrestors. These engineering controls would help in minimizing fugitive emissions in the work zone.
10	Hazardous chemicals shall be stored in tanks in tank farms, drums, carboys etc. Flame arrestors shall be provided on tanks in tank farms. Solvent transfers shall be by pumps.	Hazardous chemicals are stored in leak proof tanks in tank farm, drums and carboys etc. Flame arrestors are provided on tanks in tank farms. Solvent transfer being done through pumps.
11	The company shall undertake the following waste minimization measures. 1. Metering and control of quantities of active ingredients to minimize waste. 2. Reuse of byproducts from the process as raw materials or as RM substitutes in other processes. 3. Use of automated filling to control spillage. 4. Use of closed feed system into batch reactors.	<ul style="list-style-type: none"> • All our manufacturing operations involve batch processing. Control of active ingredients are ensured by dispensing of the exact batch quantity by qualified technicians as detailed in the approved batch manufacturing records. • As ours is a small volume research based multi-product API manufacturing unit, it is not found feasible to use byproducts of a process as a substitute to raw materials for another process. However during process development we do ensure optimal use of raw materials by adopting QbD (Quality by Design) approach and using tools like DoE (Design of Experiments). • We use air operated double diaphragm pumps (AODD) for charging of solvents through the charging line in a closed system. Solids are charged using a hopper with a double valve system. Wherever viable, small pack sizes of raw materials are procured from vendors in order to

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	<p>5. Venting equipment through vapour recovery system</p> <p>6. Use of high pressure hoses for equipment clearing to reduce waste water generation.</p>	<p>enable ease of handling and to avoid dispensing thus eliminating the possibility of spillage.</p> <ul style="list-style-type: none"> We use air operated double diaphragm pumps (AODD) for charging of solvents through the charging line in a closed system. Solids are charged using a hopper with a double valve system Reactor vapor line is connected to the condenser and sub-cooler. Any escape of solvent vapors from the condenser is routed to the vent condenser to ensure minimum loss of solvent vapors. Towards continual improvement in conservation of water, high pressure jet pumps are used for cleaning of equipment's.
12	<p>Control measures for all fugitive emissions shall be provided.</p> <ol style="list-style-type: none"> Closed handling shall be provided for chemicals. Reflux condenser shall be provided over reactor. System of leak detection and repair of pump based on preventive maintenance Acid shall be taken from reactors to carboys through closed pipeline. Cathodic protection shall be provided to underground solvent storage tanks. 	<p>Following efforts are made to control fugitive emissions.</p> <ul style="list-style-type: none"> Closed handling is provided for the chemicals. Reflux condensers are provided over all reactors with sub-coolers. Refer photo 08 Preventive maintenance plan are made for repair of pumps and to detect leak in system. Acids are generally obtained from suppliers in carboys. Acids are transferred from carboys to the reactor in a closed system using AODD pumps. Refer Photo-06 The underground solvent storage tanks are of SS – 304
13	<p>Solvent management shall be as follows,</p> <ol style="list-style-type: none"> Solvent used in the process shall be completely recovered and reused. Efforts are to be made to recover inorganic salts. Reactor shall be connected to chilled brine condenser system Reactor and solvent handling system shall have mechanical seals to prevent leakage 	<p>Solvent management is as follows,</p> <ul style="list-style-type: none"> Solvent used in the process is completely recovered as part of process or at the ETP in stripper Multiple effect evaporator followed by ATFD is being installed for recovery of inorganic salts. Reactor vents are connected to chilled brine condenser system Refer photo-09 Reactor and solvent handling system is provided with mechanical seal for prevention of leakage and dry run

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	<p>5. The condensers shall be provided with sufficient HTA and residence time so as to achieve 95% recovery</p> <p>6. Solvents shall be stored in a separate space specified with all safety measures.</p> <p>7. Proper earthing shall be provided in all electrical equipments wherever solvent handling is done.</p> <p>8. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.</p> <p>9. Fugitive emissions in the work zone environment, product, raw materials storage area etc shall be regularly monitored. The emissions shall conform to the standards stipulated by KSPCB.</p>	<p>protection is provided.</p> <ul style="list-style-type: none"> • Condensers are provided with sufficient HTA and residence time to achieve more than 95% recovery. • Solvents are stored in dedicated underground tanks in tank farm and in non petroleum storage area. All the safety measures for fire hazard is taken care. • Earthing is provided to the electrical equipment where solvent handling is done. Earth rite system is installed to dissipate static charge accumulation from the unloading vehicles. All the electric motors are earthed and connected to dedicated earth pits. • Entire plant is flame proof. The underground solvent storage tanks are provided with breather valve to prevent losses.
14	No effluent shall be discharged outside the factory premises and zero discharge concept shall be adopted.	The industry assures Zero Liquid Discharge Company and Treated effluent is reused as cooling tower make up and boiler feed.
15	Multi-cyclone followed by bag filter shall be provided to the boilers to control particulate emission within 100 mg/Nm ³ . The gaseous emission shall be dispersed through stack of adequate height as per CPCB/KSPCB guidelines.	Furnace oil is used as fuel in the boiler. Particulate emission well below 100 mg/Nm ³ . Flue gas analysis report is attached as Annexure. Stack of adequate height (42.5 m) is provided as per CPCB/KSPCB guidelines.
16	Two stage chilled water/caustic scrubber shall be provided to process vents to control HCl. Two stage scrubber with caustic lye media solution shall be provided to process vents to control SO ₂ . The scrubbing media shall be sent to ETP for treatment. Efficiency of scrubber shall be monitored regularly and maintained properly. At no time, emission levels shall go beyond the prescribed standards.	Reactor vents are connected to well designed alkali scrubbing systems for control of HCl and SO ₂ vapours. These scrubbers are provided with heat exchangers with chilled water circulation for keeping the scrubbing media temperature low for effective scrubbing of flue gasses. Scrubbing media sent to ETP for treatment using stripper followed by MEE and ATFD. Efficiency of scrubbers being monitored regularly to ensure the emissions are not beyond prescribed standards. Scrubbers are monitored for acid mist and particulate matter on a regular basis

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		and reports of the same are submitted to KSPCB every month.
17	As proposed, spent carbon shall be sent to cement industries. ETP sludge, Process(inorganic and organic), evaporation salts shall be disposed off to TSDF for landfilling/incineration. The ash from boiler shall be sold to brick manufacturers	Spent carbon is sent to KSPCB authorized incinerators. ETP sludge, process (organic & inorganic) and evaporation salt is disposed off to TSDF. Currently, we are exploring co-processing as an option for the disposal of Hazardous waste. Towards this, application to include co-processing in the existing HWM authorization has been submitted through XGN Software.
18	Boiler ash shall be stored separately as per CPCB guidelines so that it shall not adversely effect the air quality, becoming air borne by wind or water regime during rainy season by flowing along with storm water. Direct exposure of workers to fly ash and dust shall be avoided.	There is no generation of boiler fly ash or dust from the boiler as industry uses Furnace Oil as fuel for boiler.
19	During transfer of materials, spillages shall be avoided and garland drains shall be constructed to avoid mixing of accidental spillages with domestic waste and storm drains	Industry has provided closed storage, closed handling & conveyance system for chemicals / materials handling to eliminate spillages. Industry has provided garland drains around all the buildings to collect the roof & surface run off conveying the same to rain water harvesting pits for ground water recharge. Industry has constructed a compound wall to prevent entry of discharge from other premises. A dedicated line has been provided for conveying the untreated effluent to the ETP. For using the treated rainwater for gardening a pipeline has been provided.
20	The company shall harvest surface as well as rain water from rooftop of buildings and storm water drains to recharge the ground water and use the same water for various activities of the project to conserve fresh water.	The company has installed roof top rain water harvesting shafts and sump. The same being used for ground water recharge and used for gardening purpose.

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21	The unit shall make arrangement for protection of possible fire hazards during manufacturing process in material handling. Firefighting shall be as per OISD 117 norms	Earthing and Bonding is practiced during charging of material into the reactor. Inertization is practiced for prevention of flammable atmosphere inside the reactor during manufacturing. Advanced Fire Fighting system is installed in the premises to protect against possible fire hazards during manufacturing process in material handling.
22	Training shall be imparted to all employees on safety and health aspects of chemical handling. Pre employment and routine periodical medical examination for all employees shall be undertaken on regular basis. Training to all employees on handling of chemicals shall be imparted.	Training is imparted to all employees on safety and health aspects of chemical handling. Photographs of training are enclosed. Pre-employment and annual health checkup for all employees are undertaken.
23	Usage of PPE's by all employees/workers shall be ensured.	Industry is continuously enforcing the employees/workers on the usage of PPE. Periodic training is imparted to all the employees on the usage of PPE's.
24	Occupational health surveillance of workers shall be done on a regular basis and records shall be maintained as per Factories act.	Occupational health surveillance for all the employees are undertaken on regular basis and the records are maintained.
25	Greenbelt shall be developed in atleast 33% of area with suitable species of the plants as per CPCB guidelines to mitigate the effects of fugitive emissions. Selection of plant species shall be as per CPCB guidelines.	Greenery is developed in 33% of area with suitable species.
26	The adequate financial provisions shall be made in the budget of the project for implementation of the above suggested environmental safeguards. Funds so earmarked shall not be diverted to any other purposes.	Adequate financial provisions are made in the budget for implementation of the environmental safeguards. Funds totaling to the tune of Rs 2.23 crore have been spent on implementation of environmental safeguards during the period Oct-2018 to March-2019.
27	The company shall abide by the recommendations made in the EIA/EMP/risk assessment reports. Risk assessment shall be included in the safety manual.	For all the activities carried out in the industry, a Hazard Identification and risk assessment (HIRA) identifying the significant environmental aspects and significant hazards is prepared on a periodic basis.
28	Provisions shall be made for the housing of construction labours with	Agreed and Complied

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	all the necessary infrastructure and facilities such as fuel for cooking, mobile toilet, mobile sewage treatment plant, safe drinking water, medical health care, creche etc. The housing may be in the form of temporary structure to be removed after the completion of the project. All the construction waste shall be managed so that there is non impact on the environment.	
29	Avoid bromination processes (wherever followed).	Noted
30	Recover Lithium salts in the effluent wherever lithium compounds are used in the reactions.	Currently, lithium based compounds are not used for the production of intermediates and final end products. However, if products requiring the use of lithium arise, efforts shall be made to recover lithium and the same will be documented.
31	Treatment of re-calcitrants to be documented and kept at all times.	Noted
32	Adopts Good Manufacturing Practices (GMP) and green chemistry.	Industry has adopted good manufacturing practices & green chemistry.
33	The proponent shall spend Rs 100 Lacs over a period of 10 years towards, healthcare, providing drinking water facilities and sanitation, promotiom of education etc to nearby villagers the Corporate Social commitment vide letter dated 24th June 2015 and report be submitted to the authority.	The CSR activities are conducted in a phase wise manner by Anthem Bio Sciences group of companies.
34	The project authorities shall also earmark atleast 5% of the project cost towards CSR and item-wise details along with timebound action plan shall be prepared and submitted to the authority.	
Additional Conditions		
1	The project authorities shall strictly adhere to the stipulations made by the KSPCB	Agreed and complied

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2	At no time, the emissions shall cross the prescribed limits. In the event of failure of any pollution control equipment, adopted by the unit, the unit shall immediately put it out of operation, and shall not be restarted until the desired efficiency has been achieved.	Agreed and industry assures to maintain the emissions to the prescribed limits
3	No further expansion/modification shall be made without prior permission of SEIAA / MoEF as the case may be. In case of alteration in the project from what is submitted, a fresh reference shall be made to SEIAA to assess the adequacy of conditions imposed.	Agreed.
4	The gaseous emissions including SO _x , NO _x , PM, RSPM shall conform to the limits imposed by concerned authorities. Emissions shall not cross prescribed limit at any time. In case of failure of Pollution Control equipments, the unit shall not be restarted until the control equipment is restarted.	Stack monitoring is carried out every month and reports are being submitted to KSPCB.
5	The project authorities shall strictly comply with the rules and regulations under Manufacture Storage and Import of Hazardous Chemicals Rule - 1989. All transport of Hazardous chemicals shall be as under Motor Vehicles Act. Authorization must be obtained from KSPCB for handling and storage of Hazardous Waste	We have obtained authorization from KSPCB for collection, treatment, storage and disposal of hazardous wastes. The rules as per MSIHC are being followed.
6	The project authorities must strictly comply with the rules and regulations with regard to the handling and disposal of Hazardous waste in accordance with the Hazardous Waste (Management, Handling) Rules 2003. Authorization must be obtained from KSPCB for handling, storage and disposal of Hazardous Waste.	Agreed. Authorization for handling and storage and disposal of Hazardous Wastes has been obtained from KSPCB.
7	Solar energy shall be used for lighting on roads etc. in addition to solar	65% of the monthly energy consumption in the industry is met from Solar power grid, Atria

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	water heating. A hybrid or fully solar lighting and heating shall be provided. Details regarding this shall be provided to SEIAA.	Solar power, Hiriyr. The industry shall use solar energy. We have installed motion sensors & energy efficient CFL &LED bulbs for lighting purpose.
8	Noise control measures shall be employed to maintain a level of 85 db(A). The ambient noise levels shall conform to EPA and db (A) day time and 70 db(A) night time	Noise control measures are employed to maintain level of 85db(A). Noise level conforms to EPA during day time and night time.
9	The project proponent shall ensure compliance to all environment safeguards as per the information provided.	Compliance will be ensured on all environment safeguards as per the information provided.
10	The implementation of the project with respect to environmental safeguards shall be monitored by MoEF, regional office at Bangalore, KSPCB / CPCB, Department of Environment and Ecology. A six monthly status report shall be submitted to monitoring agencies.	Compliance report is being submitted. to RO, MoEF/ SEIAA/CPCB
11	The proponent shall inform the public that EC has been accorded and clearance letter is available with KSPCB and on website of SEIAA. This shall be advertised within 7 days and in two prominent dailies, one of them in vernacular and copies of the same shall be sent to MoEF Regional office, Bangalore, KSPCB / CPCB, Department of Environment and Ecology.	Complied. Advertisement has been made in newspapers The Hindu and Udayavani on July 31st 2015.
12	The project authorities shall inform MoEF Regional office, Bangalore, KSPCB / CPCB, Department of Environment and Ecology, the date of financial closure and final approval of the project by concerned authorities and date of start of the project.	The EC issued by SEIAA was received in hand on 13 th July 2015 CFE issued by KSPCB was received in hand on 09 October 2015 The project started in month of 2015.
13	The SEIAA may suspend the clearance if compliance is not found to be satisfactory.	Noted.
14	The SEIAA has the right to impose additional conditions if necessary. The company in a timebound manner shall implement it.	Noted & accepted.

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15	The above conditions shall be enforced, among others the provisions of Water act, Air act, Environment (Protection) Act, Public Liability Act.	Noted & accepted.
16	The issue of Environment Clearance doesn't confer the Project proponent with any right to operate without clearances from other statutory authorities.	Noted & accepted.
16	Concealing factual data, submission of false data, failure to comply with any conditions, may result in cancellation of the clearance and may also attract actions under provisions of Environment (Protection) Act-1986	Noted & accepted.
17	Any appeal against the Environmental Clearance shall be with the National Green Tribunal preferably within 30 days as prescribed in Section 16 of the National Green Tribunal act	Noted
18	Officials from MoEF, Bangalore. Dept of Ecology and Environment who shall be monitoring the implementation of the environmental safeguards shall be given full co-operation, facilities, data etc by the project proponents during the time of inspection. A complete set of documents submitted to SEIAA/MoEF shall be forwarded to APCCF, Regional office of MoEF, Bangalore/Dept of Ecology and Environment, Bangalore/ Regional Officer, KSPCB Bangalore.	Documents were already submitted initially to the concerned authorities (Form-1 and Pre-Feasibility report)
19	In case of changes in the scope of the project, the project would require a fresh appraisal by the authority.	Noted & accepted.
20	The authority reserves the right to add additional safe-gaurds subsequently if found necessary, and to take action including revoking the EC under the provisions of the EPA to ensure implementation of adequate safe guards in a timebound and satisfactory manner.	Agreed

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21	All other statutory clearances such as approval for storage of diesel from chief controller of explosives, Fire Dept, Forest Conservation act, Civil aviation dept. and Wildlife (Protection) Act shall be obtained as applicable from competent authorities.	Agreed and complied. List of clearances obtained is enclosed as Annexure 01 of EIA report
22	These stipulations would be enforced among others under the provisions of Water Act, Air Act, Environment (Protection) Act, Public Liability Act and Environment Impact Assessment notification 2006.	Noted
23	Under the provisions of the EPA, legal action shall be initiated against the project proponent if it is found that the construction has been started without obtaining the Environment Clearance.	Agreed

To,

Date: 01-02-2019

The Additional Principal Chief Conservator of Forests,
Ministry of Environment and Forests,
Regional Office (Southern Zone),
Kendriya Sadan, 4th floor, E & F wings,
17th Main road, 2nd block, Koramangala,
Bangalore-560034, Karnataka

Respected Sir,

Sub: Request for issue of certified copy of EC compliance report w.r.t our project
"M/s Anthem Biosciences Private Limited" located at Plot Nos. 276 & 277 of KIADB
Harohalli Industrial Area Phase-II, Kanakapura Taluk, Ramanagar District – Reg.

Ref: Environmental Clearance Letter No: SEIAA 15 IND 2013 dated 13th July 2015

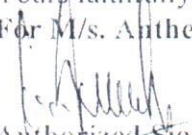
With reference to the above subject, we have obtained Environmental Clearance from KSEIAA for the manufacture of formulation based products, drug & drug based intermediates, fermentation based products & custom synthesis products at Plot Nos. 276 & 277 of KIADB Harohalli Industrial Area Phase-II, Kanakapura Taluk, Ramanagar District.

Now, the management is planning to undertake change in product mix within the existing premises and for which Revised Environmental Clearance has to be obtained from KSEIAA. Therefore, as per the office memorandum of MoEF, Govt. of India dated 30.05.2012, we request you to kindly issue the Certified Copy of the Compliance Report of Environmental Clearance for the above said project at an earliest for onward action. For your ready reference, a copy of latest compliance report is attached.

Thanking You.

Yours faithfully,

For M/s. Anthem Biosciences Private Limited


Authorized Signatory

Encl: Compliance to EC conditions along with Annexure


प्रपणकर्ता
DESPACTCHER
पर्यावरण वन एवं जलवायु परिवर्तन मंत्रालय
Ministry of Environment, Forests & Climate Change
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