

**SEEPZ SPECIAL ECONOMIC ZONE
ANDHERI (EAST), MUMBAI.**

AGENDA FOR

**MEETING OF THE APPROVAL COMMITTEE FOR
SECTOR SPECIFIC SPECIAL ECONOMIC ZONE FOR
BIOTECHNOLOGY AT PUNE OF M/S. SEZ BIOTECH
SERVICES PVT LTD - SEZ.**

DATE : 15.10.2024

TIME : 11.00 A.M.

MEETING OF THE APPROVAL COMMITTEE FOR SECTOR SPECIFIC SPECIAL ECONOMIC ZONE FOR BIOTECHNOLOGY AT PUNE, UNDER THE CHAIRMANSHIP OF DEVELOPMENT COMMISSIONER, SEEPZ-SEZ ON 15.10.2024

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Agenda Item No.	Subject
Agenda Item No. 01 :-	Confirmation of the Minutes of the Meeting held on 27.06.2023
Agenda Item No. 02 :-	Action taken report for the Minutes of the meeting held on 27.06.2023
Agenda Item No. 03 :-	Application for Approval of list of materials for M/s SEZ Biotech Service Pvt Ltd. (Developer)
Agenda Item No. 04 :-	Monitoring Performance for M/s Serum Institute of India Pvt. Ltd., (PBP -I)

I/2324/2023

Minutes of the 29th Meeting of the Approval Committee meeting held under the Chairmanship of Development Commissioner SEEPZ-SEZ for Sector Specific Special Economic Zone for Bio-Pharma sector of M/s. SEZ Biotech Services Pvt. Ltd. - SEZ, held on 27.06.2023 via Video Conferencing.

1	Name of the SEZ	M/s. SEZ Biotech Services Pvt. Ltd. - SEZ
2	Sector	Bio-Pharma
3	Meeting No.	29th
4	Date	27.06.2023

Members present

Sr	Name and Designation (S/Shri.)	Department
1	Smt. Mital Hiremath Joint Development Commissioner	Pune Cluster SEZ, Pune
2	Smt. Pradnya R. Gholap, DCIT (TDS) Pune	Nominee of Income Tax, Pune
3	Dr. Dileeraj Dabhole, Deputy DGFT	Nominee of DGFT, Pune
4	Smt. Sunita Jagtap Superintendent	Nominee of Customs, Pune

Special Invitee

Sr	Name and Designation	Department
1	Shri B. Ajay Kumar Specified Officer	M/s. SEZ Biotech Services Pvt. Ltd. - SEZ

Agenda Item No.01: Confirmation of the Minutes of the 28th meeting held on 30.05.2023

After deliberation, the committee approved the minutes of the 27th UAC Meeting held on 26.08.2022

Agenda Item No.02: Application of M/s. SEZ Biotech Services Pvt. Ltd. (Developer) for approval of additional List of Material for authorized operations.

It was informed to the Committee that as per the instructions from the previous approval committee, the matter of importing a Battery-powered reduced-scale Electrical Vehicle (Aston Martin) Model DB5 Junior, along with accessories (2 nos), was referred to the Ministry of Commerce and Industry (MoCI) for clarification. MoCI has clarified that Rule 10 of SEZ rules grants the approval committee the authority to permit goods and services for authorized operations, and action should be taken accordingly, following Rule 10 of SEZ Rules.

The Committee took on record the essentialities raised by the Developer :

- (i) The essentiality of the vehicle is duly certified by the Chartered Engineer
- (ii) There is no limitation on the seating arrangement for any electric operated vehicles

I/2324/2023

- (iii) There are precedents and approval for electric operated mobility vehicles in the SEZs earlier under Rule 10

The Committee, however observed that in the case of M/s.Serum Institute they have foreign and Indian delegates visiting their manufacturing unit, whereas it would not be case with other developers who would not require the same specific niche requirement but can take precedent of the said decision and hence it was decided by the Committee to disallow the proposal with the suggestion to the Developer to take the proposal to the Ministry or Board of Approval for getting necessary clarification.

Meeting ended with a vote of thanks to the Chair.

(Shyam Jagannathan, IAS)
Chairman-cum- Development
Commissioner
E-Mail- dcseepz-mah@nic.in

ACTION TAKEN REPORT FOR THE APPROVAL COMMITTEE MEETING HELD ON 27.06.2023 IN RESPECT OF SEZ BIOTECH SERVICES PVT. LTD., - SEZ, Pune APPROVED ON 30.06.2023

Name of the unit	Subject	Action Taken
M/s. SEZ Biotech Services Pvt. Ltd., - SEZ	Application for approval of List of Material	Approval letter for approval of List of Material was issued to the unit on 03.07.2023

**GOVT.OF INDIA,
OFFICE OF THE ZONAL DEVELOPMENT COMMISSIONER,
SEEPZ-SEZ (PUNE CLUSTER)**

**AGENDA NOTE FOR CONSIDERATION OF THE APPROVAL
COMMITTEE**

a. Proposal: -

- Proposal dated 13.08.2024 submitted by M/s. SEZ Bio-Tech Services Pvt. Ltd., (Developer) located at SBSPL-SEZ, Manjari Budruk, Pune for approval of Additional list of material required for authorized operation in the processing area.

b. Specific Issue on which decision of Approval Committee is required: -

- Approval for Additional List of material required for authorized operation in the processing area totally valued at Rs. 68,85,00,000/-.

c. Relevant Provisions: -

As per Rule 12 (2) of SEZ Rules, 2006 " The Developer shall make an application, after obtaining approval for the authorized operation under rule 9, to the Development Commissioner, along with the list of goods and services, including machinery, equipments and construction material required for the authorized operations, duly certified by a Chartered Engineer for approval by the Approval Committee".

d. List of Materials for Authorized Operations :

Sr. No.	Additional List of materials required for the mentioned Authorized operations	Estimated value for Goods purchased from DTA (Amount in Rs.)	Estimated value for Goods purchased from Import (Amount in Rs.)	Estimated Total Value of Goods (Amount in Rs.)
1.	For authorized operation in the processing area	68,85,00,000/-	0.00	68,85,00,000/-

TOTAL	68,85,00,000/-	0.00	68,85,00,000/-
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Detail of Estimated Material cost which is as follows:

S. No	Description	HSN	Unit	Qty	Total Price	Duty forgone (%)	Amount
Sr. No. 3. Approval letter dated 27.09.2012.							
3 GENERATION AND DISTRIBUTION OF RAW WATER STEAM 45 TONS/HOUR.							
1	BOILER,PARTS & ACCESSORIES	84021990	Nos	02	45,00,00,000.00	18%	8,10,00,000.00
2	STEAM DISTRIBUTION PIPING.	73079190	Lump-sum	-	2,00,00,000.00	18%	36,00,000.00
3	PROCESSED BLACK STEAM/RAW STEAM	28539090	Ton	90	14,85,00,000.00	18%	2,67,30,000.00
Sr. No. 5 Approval letter dated 27.09.2013							
5 GENERATION & DISTRIBUTION OF COMPRESSED AIR (QUANTUM APPROVED - 2500 FEET/MIN.)							
4	AIR COOLED SCREW CHILLER WITH SPARES & ACCESSORIES	84184090	Nos.	03	2,50,00,000.00	18%	45,00,000.00
5	CENTRIFUGAL CHILLER WITH SPARES & ACCESSORIES	84186990	Nos.	02	4,50,00,000.00	18%	81,00,000.00
TOTAL					68,85,00,000.00		12,39,30,000.00
Rounding up of Duty Foregone							12,39,00,000.00

e. Other Information: -

- M/s. SEZ Bio-Tech Services Pvt. Ltd., (Developer) has been granted Letter of Approval No. F.1/18/2011-SEZ dated 27.03.2012, 17.12.2012, 10.011.2016, 16.04.2018.
- The Developer has submitted Additional List of Materials duly certified by the Chartered Engineer Shri Sadanand Purohit, (Registration No. M-9923257299) for authorized operation in the processing area.
- The total value of Additional list of material is Rs. 68,85,00,000/-
- The Developer has submitted the following documents with the application
 - (i) List of materials
 - (ii) Chartered Engineer's Certificate
 - (iii) Undertaking

- The Specified Officer has submitted verification report dated 06.09.2024 and informed that the Additional list of material submitted by the Developer has been verified and their request for approval of procurement of items totally valued at Rs. 68.85 Crores for carrying out authorized operations be considered. Bond Balance as on date is Rs.158.49 Crores which is sufficient for the procurement of Indigenous material of estimated value of Rs. 68.85 crores.
- The Developer has submitted the procurement and utilization statement Quarterly upto June, 2024.

f. ADC's Observation :

The Approval Committee may kindly consider the proposal of the Developer for approval of Additional list of material valued at Rs. 68.85 Crores for authorized operation in terms of Rule 12(2) of SEZ Rules, 2006.

**GOVT. OF INDIA,
OFFICE OF THE ZONAL DEVELOPMENT COMMISSIONER,
SEEPZ - SEZ (PUNE CLUSTER),**

**AGENDA NOTE FOR CONSIDERATION OF THE APPROVAL
COMMITTEE**

a. Proposal:

Monitoring of the performance of M/s. Serum Institute of India Pvt. Ltd Unit PBP - I, for 5 years of 1st Block (FY 2019-20 to FY 2023-24)

b. Specific Issue on which decision of UAC is required:

Monitoring of performance for the period 2019-20 to 2023-24 (5 years of 1st block period) under Rule 54 of SEZ Rules, 2006

The details of the export projections are as detailed below:

c. Approved export Projections for 1st Block Period: (Rs. in Crores)

Year	1	2	3	4	5	Total
FOB Value of Exports	-	50.00	2900.00	2525.00	950.00	6425.00
FE Outgo	268.05	127.85	2366.25	1974.40	338.90	4679.55
NFE achieved	(268.05)	(77.85)	533.75	550.60	611.10	1695.45

**d. Performance as compared to projections: FY 2019-20 to 2023-24
(Rs. In Crores)**

Year	Export		F.E. OUTGO				
	Projected	Actual	Raw Material (Goods/Services)		C.G. import		Other outflow
			Projected	Actual	Projected	Actual	Actual
2019-20	-	4.22	2897.50	14.99	924.60	420.10	8.85
2020-21	50.00	17.76		169.07		465.04	13.31
2021-22	2900.00	12836.01		3201.40		497.10	57.03
2022-23	2525.00	2087.95		1106.21		390.75	39.19
2023-24	950.00	1017.44		478.02		483.51	97.60
Total :	6425.00	15963.38	2897.50	4969.69	924.60	2256.50	215.98

Cumulative NFE achieved: FY 2019-20 to 2023-24 (Rs. in Crores)

Year	Cumulative NFE Achieved	Cumulative % NFE Achieved
2019-20	-62.15	-1472.29 %
2020-21	-251.63	-1145.01 %
2021-22	9360.08	72.80 %
2022-23	10244.60	68.54 %
2023-24	10486.73	65.69 %

Employment Achievement (Direct): FY 2019-20 to 2023-24 -

Employment	Male	Female	Total
Projected	200	25	225
Achieved	2253	12	2265

e. Other Information:

LOA No. & Date	LOA No SEEPZ/NEWSEZ/SIPL-SBSPL/03/15-16 DATED 10.03.2016.			
Location of Unit	Serum Bio-Pharma Park, Off Soli Poonawalla Road, 212/2, Hadapsar, Pune - 411028.			
Validity of LOA	17.10.2024			
Item(s) of manufacture/ Services	Manufacturing : Biosimilar Monoclonal Antibodies in single or multi dose or in bulk form doses litres grams, C-Tb 10.0 Million Doses, Dengue Monoclonol Antibody in single and Multi doses or in Bulk form - 3.5 Million Doses, Erythropotin EPO Injection Multi Strength 20 Lakh vials, Human Papilloma Virus HPV Vaccine in Single or Multi Dose or in Bulk form-50 Million doses etc.			
Date of commencement of production	18.10.2019			
Execution of BLUT	Rs. 35.00 Crores accepted date - 16.05.16. Rs. 15.00 Crores accepted date - 27.06.19. Rs. 500.00 Crores accepted date - 10.06.21. Total : 550.00 Crores.			
Total Duty Foregone on Goods & Services procured (Categorieswise BLUT value utilized separately for imported and indigenous goods & services). This should be based on BLUT worksheet which provides for	F.Y.	Goods Imp. & Ind.	Services	Total
	2020-21	208.62	15.37	223.99
	2021-22	969.21	34.43	1003.64

estimated value and duty foregone separately for each category of procurement.	2022-23	70.05	26.55	96.60
	2023-24	276.47	64.00	340.47
Outstanding Rent dues	NA			
Labour Dues	NA			
Validity of Lease Agreement				
Pending CRA Objection, if any	NA			
Pending Show Cause Notice/ Eviction Order/Recovery Notice/ Recovery Order issued, if any	NA			
a. No. of employees as on 31.03.2024	2265 (Male 2253, Female 12)			
Quantity and value of goods exported under Rule 34 (unutilized goods)	NA			
Value Addition during the monitoring period	NA			
Whether all the APRs being considered now has been filed well within the time limit, or otherwise. If no, details of the Year along with no of days delayed to be given.	Yes			

f. The Specified Officer has submitted a report vide letter **dated 16.11.202, 10.05.2023 received on 22.05.2023 & 07.10.2024**, in the prescribed format along with point-wise reply to the discrepancies as follows:-

i) Export

Details of year-wise export as per the prescribed format:

From the year 2019-2020 to 2023-2024

(Rs. In Crores)

Year/Period	Figures as per APR	Figures as per Softex/ SB / Customs Records	Difference if any	Reason for Difference/Remark
(1)	(2)	(3)	(4)	(5)
2019-20	4.22	7.45	(-)3.23	FOB Value of Free Sample Export not considered for NFE Calculation in APR.
2020-21	17.76	18.12	(-)0.37	Less FOB Value of Free Sample Export not considered for NFE Calculation in APR., Less - FOB Value of SB 400035 wrongly considered as Outright Sale instead of

				others, Add - SEZ TO EOU (Rule 53(j)(a) of SEZ Rules 2006) 2020-21.
2021-22	12836.02	1327.57	(+)11508.45	Add : Supply of goods made in India as per Rule 53A(d) of SEZ Rule 2006 - 11532.52 Less : FOB Value of material Sent for Repair not considered in NFE but appeared in NSDL - -3.30, Less : FOB Value of Free Sample Export not considered for NFE calculation in APR - -12.56 Less : FOB Value of Cancelled Shipping Bills but appeared in NSDL t=report 2020-21 - -8.21.
2022-23	2087.95	1550.90	537.05	1. Less - FOB Value of Shipping Bills pertaining to last F.Y. 2021-22=(-Rs. 0.15 Crore.) 2. Less - FOB Value of free sample export = (-Rs. 62.67 Crore) 3. Add Supply of manufactured goods to other units in SEZ/EOU(Rule 53(A)(J) of SEZ Rules, 2006) 2022-23 = +Rs. 674.06 Crore. 4. Less FOB value of cancelled Shipping Bill but appeared in NSDL Report 2022-23 = (- Rs. 74.19 Crore)
2023-24	1017.44	1795.26	-777.82	1. Add SEZ to EOU (Rule 53(A)(J) of SEZ Rules 2006) 2023-24 = +Rs. 0.04 Crore. 2. Less - FOB Value of free sample export = (- Rs. 769.76 Crore) 3. Less FOB value of cancelled Shipping Bill but appeared in NSDL Report 2023-24 = (- Rs. 8.10 Crore.)

ii) Import

(Capital Goods including procurement done on IUT (from SEZ, EOU, STPI, EHTP) basis.

(Rs. In Crores)

Year/Period	Figures as per APR (RM Imported)	Figures as per Customs Records / Bond Register	Difference if any	Reason for Difference/Remark
2019-20	442.32	375.25	67.07	<p>Add - Value of Non-Capital Goods procured under Zone to Zone transfer, Less - Value of Non-CG received from EOU, which they have considered in APR,</p> <p>Add - Value of Capital Goods procured under Zone to Zone transfer, Less - Import From EOU (Loan Basis), Less - Import from EOU, Less - Re-Import Cases not considered, Add - Value of Spare Procure under Zone to Zone transfer considered as Spare in APR 4B(ii)</p>
2020-21	683.15	609.87	73.28	<p>Less - Value of NON-CG received from EOU which they have considered in APR, Less - Value of Goods received declared as OTHERS instead of Other Than CG in NSDL, Less - Re-Import Cases not Considered, Add - Value of Non-CG procured under Zone to Zone transfer, Less - Re-import Cases not considered.</p>
2021-22	3651.58	3701.31	(-)49.73	<p>Less -BOE entries not meant for this year APR, mostly pf previous year -1.56, Less - Import from EOU -13.83, Less - CG Transferred to other Units -10.52, Add - Value of CG procured under Zone to Zone transfer 56.33, Less - Value of Goods received from EOU - - 0.06, Less - BOE entries not meant for this years APR, mostly of previous years - -1.16, Less - Re-Import cases not considered - 0.11, Less : SPR Transferred to other Units - -0.29, Add : Value of SPRs procured</p>

				under Zone to Zone transfer - 0.71
2022-23	1466.10	1493.09	-26.99	Reconciliation sheets submitted by the Unit are attached.
2023-24	1055.06	968.72	86.34	Reconciliation sheets submitted by the Unit are attached.

c. **BLUT**

(Rs. In Crores)

1	Value of BLUT Executed (Duty foregone) (including for CG / Raw Material / Services) Value of Additional BLUT executed TOTAL Duty value of BLUT Executed in Lakhs:	1. Rs. 35 Crores acceptance date ; 16.5.16 2. Rs. 15 Crores acceptance date : 27.6.19 3. Rs. 500 Crores acceptance date : 10.6.21 Total Value of BLUT - Rs. 550 Crores.																						
2	Total Duty Foregone on goods & services procured Category Wise: Year Wise	<table border="1"> <thead> <tr> <th rowspan="2">F.Y.</th> <th colspan="2">Goods</th> <th rowspan="2">Total</th> </tr> <tr> <th>Imp. & Ind.</th> <th>Services</th> </tr> </thead> <tbody> <tr> <td>2020-21</td> <td>208.62</td> <td>15.37</td> <td>223.99</td> </tr> <tr> <td>2021-22</td> <td>969.21</td> <td>34.43</td> <td>1003.64</td> </tr> <tr> <td>2022-23</td> <td>70.05</td> <td>26.55</td> <td>96.60</td> </tr> <tr> <td>2023-24</td> <td>276.47</td> <td>64.00</td> <td>340.47</td> </tr> </tbody> </table>	F.Y.	Goods		Total	Imp. & Ind.	Services	2020-21	208.62	15.37	223.99	2021-22	969.21	34.43	1003.64	2022-23	70.05	26.55	96.60	2023-24	276.47	64.00	340.47
F.Y.	Goods			Total																				
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2023-24	276.47	64.00	340.47																					
3	Has the Unit procured goods and or services without having sufficient balance in their BLUT. If yes, Month & Year when the BLUT was exhausted Details of the consignments and Total value of Goods procured without having sufficient or nil balance in BLUT	No																						

(d)	Employment made as on date- (as on end of block period / year up to which monitoring is being done)	2265
(e)	Details of pending Foreign Remittance beyond Permissible	NO.

	<p>period, if any (as on 31.03.2024)</p> <p>To cross-check the same and verify whether necessary permission from AD Bank / RBI has been obtained.</p>	
(f)	<p>Whether all softex has been filed for the said period. If no, details thereof.</p> <p>SO to also check whether unit has obtained Softex condonation from DC office / RBI and if approved, whether they have filed such pending Softex.</p>	NA.
(g)	<p>Whether all Softex has been certified, if so till which month has the same been certified. If not, provide details of the Softex and reasons for pendency.</p>	NA.
(h)	<p>Whether unit has filed any request for Cancellation of Softex</p>	NA
(i)	<p>Whether any Services provided in DTA / SEZ/EOU/STPI etc. against payment in INR in r/o IT/ITES Unit during the period.</p> <p>If yes, details thereof (year wise details to be provided)</p>	NA.
(j)	<p>SO to verify and certify whether the unit has updated the BLUT ledger Module in SEZ Online.</p>	Kept in abeyance as per Office Order No. F. No. SEEPZ/JDC PUNE/01/2022-23/2151 dated 16.03.2023.
(k)	<p>Has the unit cleared any Capital Goods procured duty free in DTA against payment of Duty, or otherwise.</p> <p>Full details to be provided along with value of assets and duty discharged</p>	Nil.
(l)	<p>Is the unit sharing any of their infrastructures with other units or are utilizing infrastructure of another unit in the same or other SEZ.</p>	NO.

	<p>If so, details thereof, including the details of the unit with whom the sharing is being made, and the payment terms</p> <p>If approval for sharing of common infrastructure has been obtained from UAC / DC office, the date of UAC / Approval letter to be indicated</p>	
(m)	Whether all DSPF for services procured during the said monitoring period under consideration has been filed by the unit and whether the same has been processed for approval by the SO Office.	They are filing DSPF for Services procured online (NSDL) from 1.11.2023.
(n)	Whether unit has filed all DTA procurement w.r.t. the goods procured by them during the monitoring period for the relevant period. If no, details thereof	They are filing DTA procurement online (NSDL) from 01.04.2024 onwards.
(o)	Details of the request IDs pending for OOC in respect of DTA procurement on the date of submission of monitoring report	NIL.
(o)	<p>Has the unit set up any cafeteria / canteen / food court in unit premises.</p> <p>If yes, whether permission from UAC / DC office has been issued, or otherwise office has been issued, or otherwise</p> <p>Whether unit has availed any duty paid goods / services for setting up such facility?</p> <p>If yes, whether unit has discharged such duty / tax benefit availed? details to be given including amount of duty / tax recovered or yet to be recovered</p>	Nil.
(p)	Whether any violation of any of the provision of law has been noticed/observed by Specified Officer during the period under monitoring.	Nil

g. Relevant provisions:

Rule 54 of SEZ Rules, 2006 *“Performance of the Unit shall be*

monitored by the Approval Committee as per the guidelines given in Annexure appended to these rules”

h. ADC’s observations:

- The Unit has achieved cumulative export revenue of Rs. **15963.38** Crores as against projected export of Rs. **6425.00** Crores and achieved cumulative NFE of 10486.73 Crores which is 65.69 % in 5 years of 1st Block Period i.e. during (FY 2019-20 to 2023-24)
- The unit has achieved Employment of 2265 employees (Men - 2253 & Women - 12) as on 31.03.2024.
- Approval Committee may like to monitor the performance of the Unit for FY 2019-20 to 2023-24 (5 years of 1st Block period).