

Appendix A - Determination Letter



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REFERENCE NUMBER: 16/3/3/6/1/A7/20/3138/25
DATE OF ISSUE: 28 AUGUST 2025

The Director
The Biologicals and Vaccines Institute of Southern Africa (Pty) Ltd trading as "The Biovac Institute"
Private Bag X3
PINELANDS
7430

For Attention: Mr. M. Mac Naughton

Tel: (021) 514 5000
Email: markm@biovac.co.za

Dear Sir

ACKNOWLEDGEMENT OF RECEIPT OF THE CHECKLIST AND CONFIRMATION OF THE APPLICABILITY OF THE NEMA EIA REGULATIONS, 2014 (AS AMENDED) WITH RESPECT TO THE PROPOSED DEVELOPMENT OF A VACCINE PRODUCTION FACILITY AND ASSOCIATED INFRASTRUCTURE ON UNREGISTERED ERF 183467, A PORTION OF THE REMAINDER OF ERVEN 118296, 103659 AND 24176 AND ERF 1056, PINELANDS.

1. The checklist for the determination of the applicability of the NEMA EIA Regulations, 2014 (as amended) dated 29 July 2025 and received by this Department via electronic mail correspondence on 31 July 2025, this Directorate's electronic mail correspondence dated 27 August 2025 and your electronic mail dated 27 August 2025, refer.
2. This letter serves as an acknowledgement of receipt of the afore-mentioned checklist received by this Directorate and to confirm the applicability of the NEMA EIA Regulations, 2014 (as amended).
3. Based on the information provided by you, this Directorate notes the following:
 - 3.1. The proposed development entails the development of a new commercial vaccine production facility and associated infrastructure on unregistered Erf 183467, a portion of the Remainder of Erven 118296, 103659 and 24176 and Erf 1056, Pinelands. The proposed development will include laboratories, production and packaging facilities. The proposed development will comprise of the following:
 - 3.1.1. A manufacturing building for the manufacturing, filling and packaging of vaccines.
 - 3.1.2. A utilities building.
 - 3.1.3. Associated municipal service infrastructure.
 - 3.1.4. The proposed development will have a development footprint of approximately 14000m².
 - 3.2. The proposed site is located within an urban area on properties zoned as Utility, Transport 2 and General Industrial 2. The proposed site is currently vacant and is located inside an urban area.

- 3.3. Based on the Terrestrial Plant Species and Terrestrial Biodiversity Compliance Statement (compiled by Bergwind Botanical Surveys and Tours CC and dated 15 October 2023), this Directorate notes the following:
 - 3.3.1. The proposed site would have historically contained the Cape Flats Sand Fynbos vegetation type, which is classified as a Critically Endangered ecosystem in terms of the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004) – The Revised National List of Ecosystems that are Threatened and in Need of Protection, 2022.
 - 3.3.2. However, the proposed site no longer contains the Cape Flats Sand Fynbos vegetation type and constituent plant species are not present.
- 3.4. No watercourses or wetlands are located on the proposed site. The closest watercourse is approximately 700m away from the proposed site.
- 3.5. No dangerous goods will be stored on the proposed site.
- 3.6. According to the process flow diagram, no heating or treatment is included in the manufacturing process.
4. Based on the information contained in the aforementioned checklist, please note the following:
 - 4.1. Although the checklist indicates that no dangerous goods will be stored on the proposed site, according to the raw materials list, some raw materials are deemed to be hazardous, which may be listed in terms of the South African National Standard No. 10234, supplement 2008 1.00: designated "List of classification and labelling of chemicals in accordance with the Globally Harmonized Systems (GHS)".
 - 4.1.1. Please note that the NEMA EIA Regulations, 2014 (as amended) defines "dangerous goods" as *"goods containing any of the substances as contemplated in South African National Standard No. 10234, supplement 2008 1.00: designated "List of classification and labelling of chemicals in accordance with the Globally Harmonized Systems (GHS)" published by Standards South Africa, and where the presence of such goods, regardless of quantity, in a blend or mixture, causes such blend or mixture to have one or more of the characteristics listed in the Hazard Statements in section 4.2.3, namely physical hazards, health hazards or environmental hazards;"*
 - 4.2. Although the process flow diagram indicates that no heating or treatment is included in the manufacturing process, written confirmation from the licensing authority (in this instance the City of Cape Town) to confirm whether the proposed development will require an Atmospheric Emissions Licence in terms of the National Environmental Management: Air Quality Act, 2004 (Act No. 39 of 2004) has not been provided.
5. In light of the above, please note the following:
 - 5.1. Should the proposed development include the storage of dangerous goods, where the storage and handling of dangerous goods occur in containers with a combined capacity of 80m³ or more, the proposed development will trigger Activity 14 of Listing Notice 1 of the NEMA EIA Regulations, 2014 (as amended).
 - 5.1.1. Should the aforementioned listed activity be triggered by the proposed development, written Environmental Authorisation would be required from the competent authority (in this instance this Directorate) prior to the undertaking of the said development on unregistered Erf 183467, a portion of the Remainder of Erven 118296, 103659 and 24176 and Erf 1056, Pinelands.
 - 5.1.2. You are hereby advised that only those activities applied for will be considered for authorisation.

5.2. Should the proposed development not require the storage of dangerous goods, where the storage and handling of dangerous goods will not occur in containers with a combined capacity of 80m³ or more, the proposed development will not trigger Activity 14 of Listing Notice 1 of the NEMA EIA Regulations, 2014 (as amended).

5.2.1. Written environmental authorisation would therefore not be required from the competent authority (in this instance this Directorate) prior to the undertaking of the said development on unregistered Erf 183467, a portion of the Remainder of Erven 118296, 103659 and 24176 and Erf 1056, Pinelands.

5.3. Should the proposed development require an Atmospheric Emissions Licence in terms of the National Environmental Management: Air Quality Act, 2004 (Act No. 39 of 2004), the proposed development will trigger Activity 6 of Listing Notice 2 of the NEMA EIA Regulations, 2014 (as amended).

5.3.1. Should the aforementioned listed activity be triggered by the proposed development, written Environmental Authorisation would be required from the competent authority (in this instance this Directorate) prior to the undertaking of the said development on unregistered Erf 183467, a portion of the Remainder of Erven 118296, 103659 and 24176 and Erf 1056, Pinelands.

5.3.2. You are hereby advised that only those activities applied for will be considered for authorisation.

6. Should any revision of the proposed development comprise any activities that constitute a listed activity as defined in Listing Notice 1, 2 and 3 of NEMA EIA Regulations, 2014 (as amended), an application for environmental authorisation must be submitted to the competent authority and authorisation obtained before such activity(ies) may commence.

7. You are reminded of your general duty of care and the remediation of environmental damage, Section 28(1) of NEMA specifically states that –

"Every person who causes, has caused or may cause significant pollution or degradation of the environment must take reasonable measures to prevent such pollution or degradation from occurring, continuing or recurring, or, in so far as such harm to the environment is authorised by law or cannot reasonably be avoided or stopped, to minimise and rectify such pollution or degradation of the environment".

This Department reserves the right to revise or withdraw comments or request further information based on any information received.

Your interest in the future of our environment is greatly appreciated.

Yours faithfully

Keagan-Leigh

Digitally signed by
Keagan-Leigh Adriaanse

Adriaanse

Date: 2025.08.28

09:34:56 +02'00'

p.p.

MR. ZAAHIR TOEFY

DIRECTOR: DEVELOPMENT MANAGEMENT (REGION 1)

Copies to: (1) [REDACTED] Environmental Consulting Services (Pty) Ltd]
(2) Ms. M. Stewart (City of Cape Town: ERM)
(3) Mr. I. Gildenhuys (City of Cape Town: Air Quality)
(4) Mr. E. Roux (DEA&DP-Directorate: Air Quality)

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