MASS VACCINATION
FMD

PROPOSAL

13 January 2026

agriculture
Department:
Agriculture
REPUBLIC OF SOUTH AFRICA

2030 NDP

FMD

- FMD is a highly contagious disease of all cloven hoofed animals.
- FMD SAT serotypes, (SAT 1, SAT 2, SAT3)often cause mild diseases or sub-clinical infection that cannot be detected by physical inspection alone.
- Dairy cattle develop severe lesions.
- South Africa lost its FMD freedom status in 2019
- The current outbreak started in 2021-22 when animals moved from Phalaborwa to Kwa – Zulu Natal.

FMD

- South Africa has a population of buffaloes in our game reserves. Buffaloes are carriers of FMD, they don't develop clinical signs.
- From there, the disease spread to other Provinces, we now have 5 Provinces which are severely affected
- Eastern Cape got infected and now the disease is under control..
- Western Cape reported an infected farm on the 1st of November.
- Northern Cape never reported an outbreak of FMD.
- Department declared disease management areas (DMA), Some provinces the DMA did not work

BACKGROUND

The details of the outbreaks

- SAT2 FMD outbreak event in KwaZulu Natal, Mpumalanga, North West, Gauteng and Free State Provinces
- SAT1 FMD outbreak event in KwaZulu Natal Province
- SAT3 FMD outbreak event in the Eastern Cape Province
- SAT2 FMD outbreak event in the Eastern Cape Province

BACKGROUND

Western Cape Province

- The Western Cape Province reported one outbreak
- there is a targeted Active Surveillance which commenced in May 2025

Limpopo Province

- Limpopo Province had SAT3 FMD outbreaks on 8 properties in 2021.
- Recently they had 3 outbreaks

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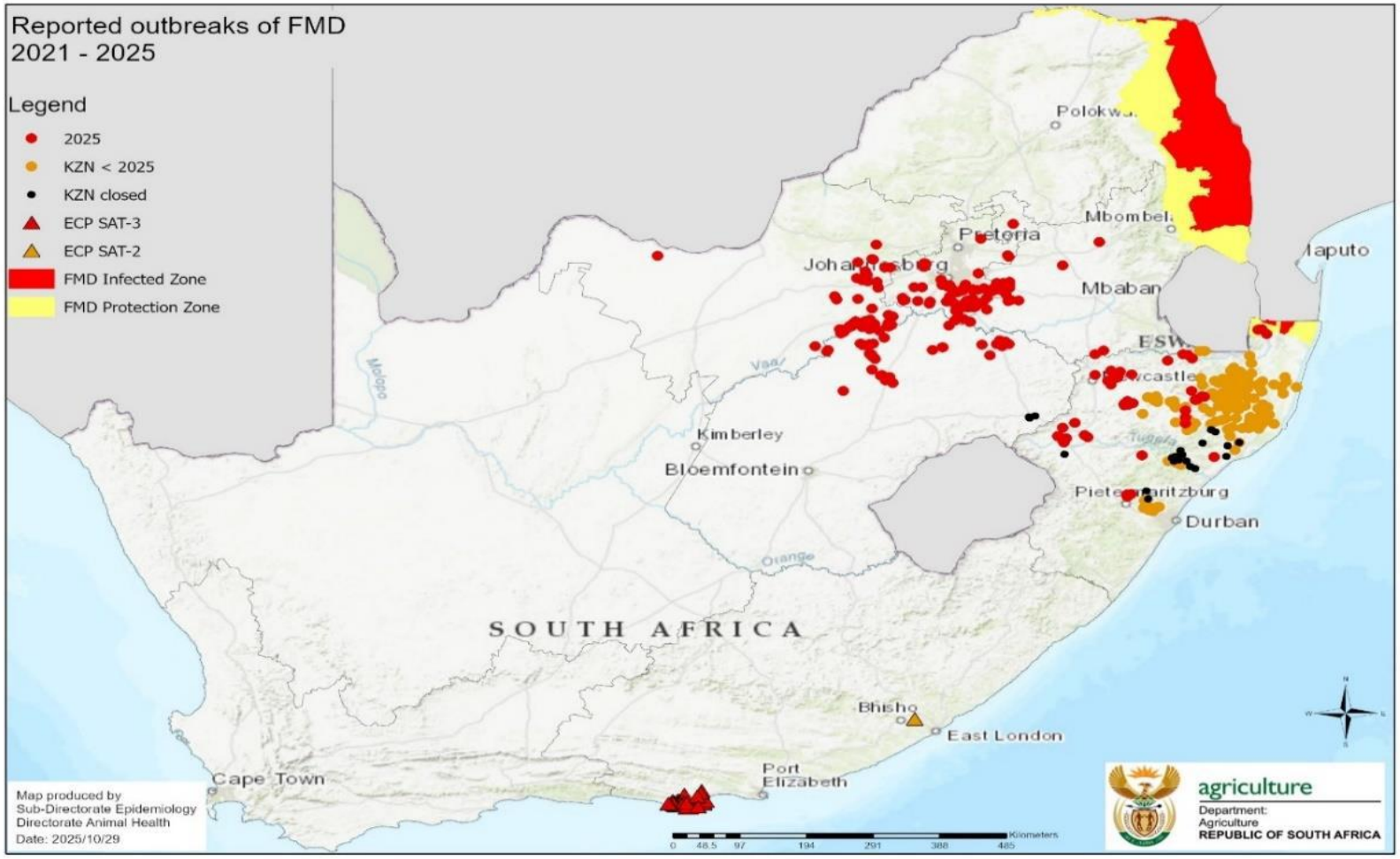
PREVALENCE OF FMD IN SA



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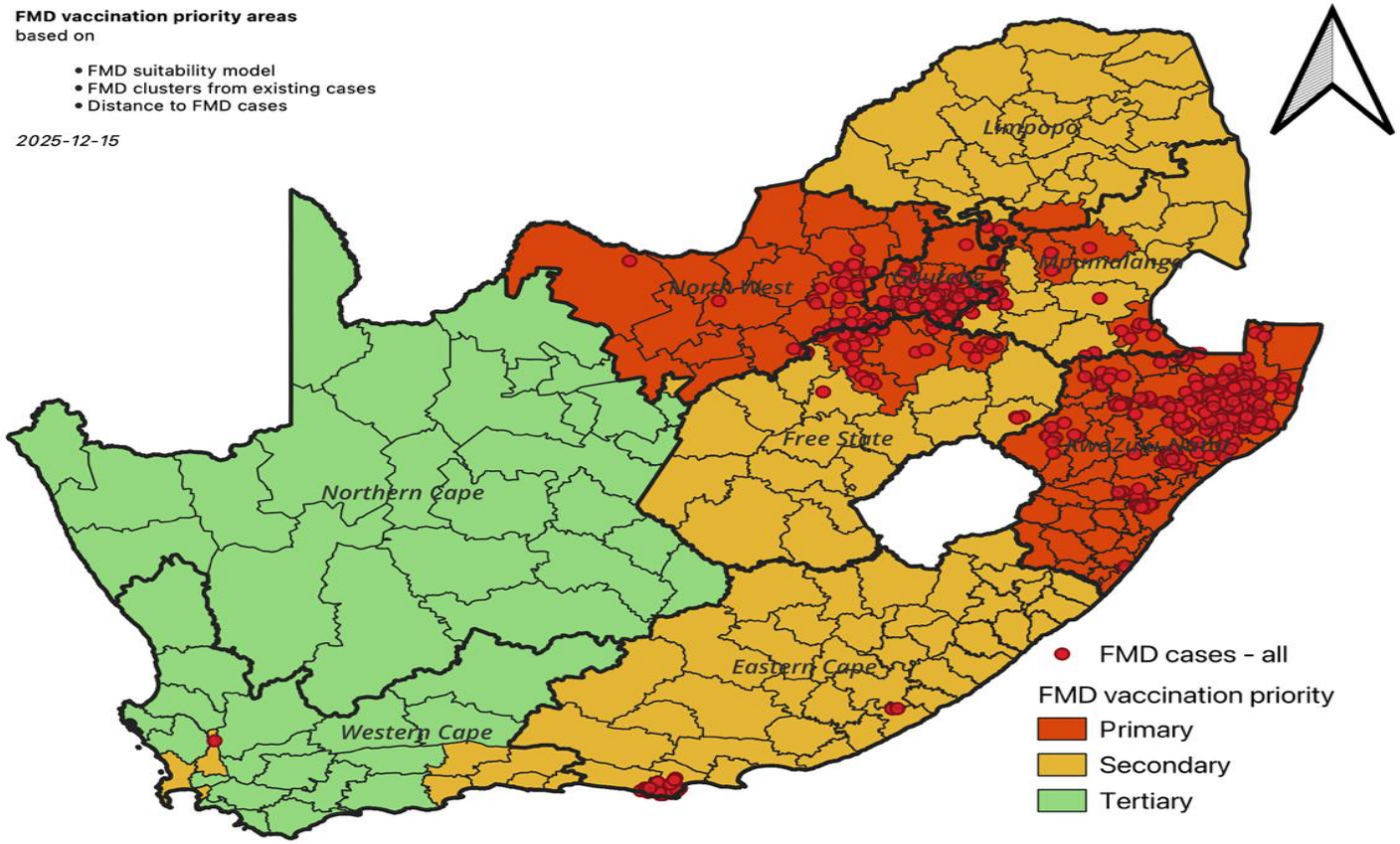
FMD vaccination priority areas
based on

- FMD suitability model
- FMD clusters from existing cases
- Distance to FMD cases

2025-12-15



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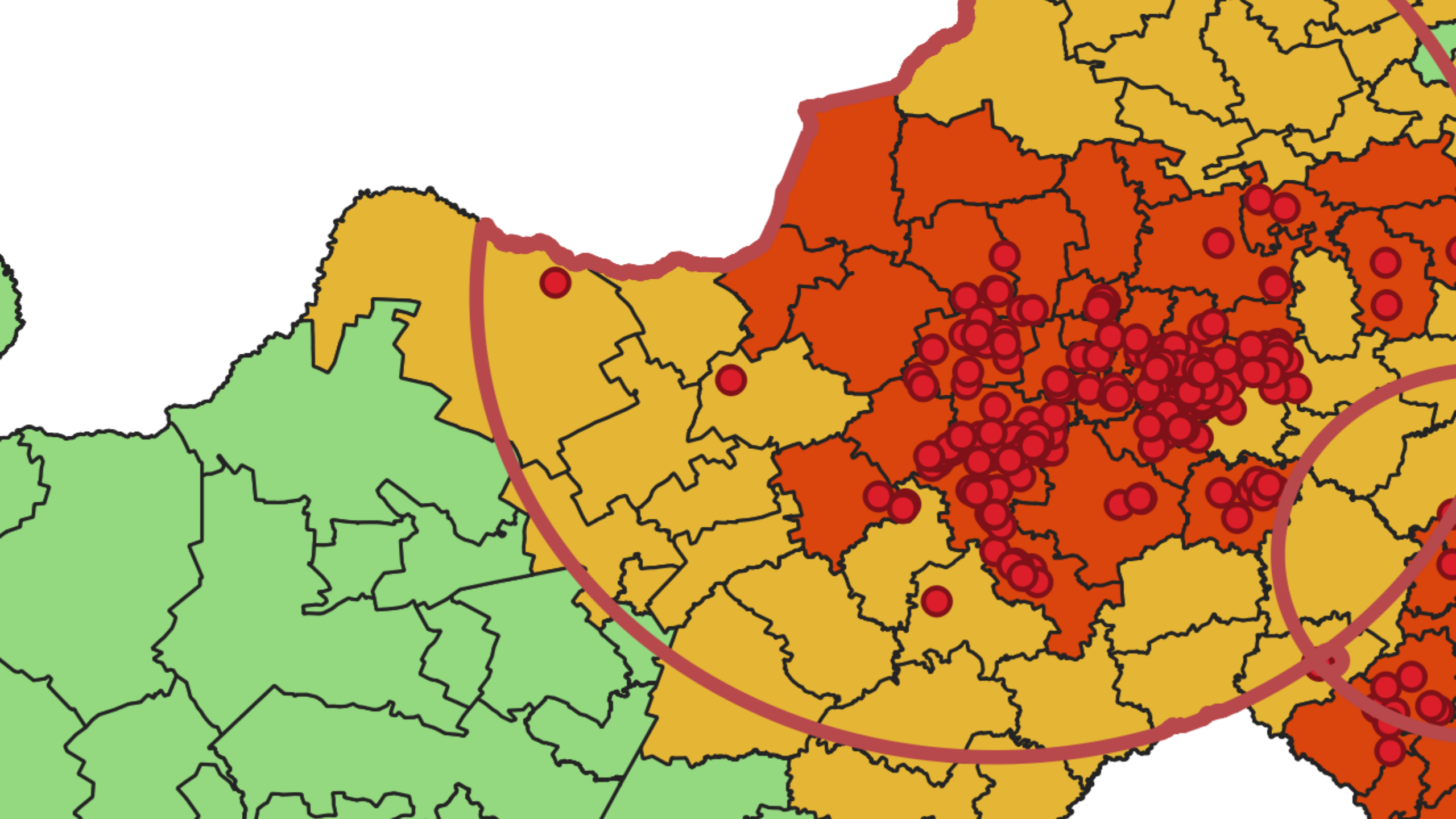

LIVESTOCK STATISTICS

Province	FMD vaccination priority classification	Estimated cattle (FAO dataset)	Associated count of municipalities
Eastern Cape	secondary	4595393	39
Free State	primary	632203	4
	secondary	2429481	16
Gauteng	primary	474928	10
KwaZulu-Natal	primary	4327475	51
Limpopo	primary	102261	1
	secondary	1496654	24
Mpumalanga	primary	522777	5
	secondary	1346143	13
North West	primary	2196694	19
Northern Cape	secondary	24649	1
	tertiary	679948	26
Western Cape	secondary	169782	7
	tertiary	557929	18
ALL	ALL	19556317	234
	Primary	8256338	90
	Secondary	10062102	100
	Tertiary	1237877	44

MASS VACCINATION

- The current FMD crisis in South Africa calls for an expanded, integrated national FMD control and eradication strategy.
- Progressive Control Pathway for FMD (PCP-FMD). The focus should be:
  - A risk-based **vaccination strategy**;
  - Strengthening of the **diagnostic and laboratory network**;
  - A comprehensive **surveillance strategy**;
  - **Movement control measures** appropriate to zone-specific risk;
  - **Trade-support mechanisms for communal systems**; and
  - A **progressive zoning and compartmentalisation framework** supporting the recovery of WOAH-recognised FMD freedom.

STRATEGY

- **Strategic aim and guiding principles**

- Interrupt virus transmission,
- reduce incidence to very low levels in 2–3 years,
- create certified FMD-free zones with vaccination and
- Pilot compartments for trade, then transition selected zones to FMD-free without vaccination and apply to WOAH when evidence requirements are met.

STRATEGY

- **Phase 1 (Years 1–2): Stabilisation**
  - Intensive vaccination
  - Strengthened surveillance
  - Enhanced movement control
  - Laboratory capacity reinforcement

STRATEGY

- **Phase 2 (Years 2–4): Consolidation**
  - Establish buffer zones and compartments
  - Improved communal trade systems
  - Application for freedom with vaccination for selected zones

STRATEGY

- **Phase 3 (Years 4–7): Vaccination Withdrawal in Free Zones**
- Evidence-based cessation of vaccination
- NSP-based proof of freedom

The success of this strategy will strongly rely on urgent review of the legislative framework, that has to be adapted to the current emergency situation.

CRUCIAL FACTORS IN MANAGING FMD

- **Phase 4 (Years 7–10): National Freedom**
- National cessation of vaccination
- WOAH recognition of FMD-free status

OPERATIONAL OBJECTIVES (12 MONTHS HORIZON)

(12-month horizon)

- **Reduce outbreak incidence by ≥70%** in high-risk provinces through systematic vaccination.
- **Reach ≥80% vaccination coverage** of targeted cattle populations in priority districts.
- Achieve **measurable seroconversion in vaccinated herds: ≥70%** protective VNT titres.
- **Integrate vaccination with diagnostics** → vaccine matching, NSP monitoring, outbreak mapping.
- Preserve FMD-free provinces through buffer vaccination and strict movement controls.

Strategic Objective

- Reduce FMD incidence by ≥70% in priority zones within 24 months.
- Achieve ≥80% vaccination coverage in target populations; ≥90% in feedlots/dairies.
- Establish certified compartments and progressive zones (with then without vaccination).

Policy Principles

- Risk-based targeting (epicentre → endemic → at-risk → free zones).
- Mandatory vaccine-matching before approval for use.
- Combine vaccination with post-vaccination monitoring, surveillance, movement control, traceability.

Province Focus

Kwazulu-Natal, Gauteng, North West -**Epicenter - Primary**

- Immediate mass vaccination across affected districts; repeat within 3 months.
- Targets: feedlots 100%, commercial ≥90%, communal ≥80%.
- Mandatory on-arrival feedlot vaccination; quarantine 7–14 days; rapid ring teams.

High-risk, recurring infection. And border interface) Parts of Fee State, Mpumalanga and Limpopo

- Biannual or triannual campaigns in border hotspots; cross-border coordination, Continue vaccinating in the protection zone
- Targets: communal clusters ≥80%; commercial/export 100%.
- Mobile teams to reach remote dip tanks; NSP buffer surveys.

Mpumalanga (Wildlife & corridor risks)

- Biannual campaigns in Nkomazi and Bushbuckridge; market node vaccination.
- Targets: communal wards ≥85%; commercial ≥90%.
- Joint wildlife surveillance and targeted vaccination near reserves.

Province Focus

Eastern Cape (Moderate–High risk)

- Ward-level risk stratification: Hotspot wards, Market Node wards, Low-risk wards.
- Hotspots: biannual vaccination; Market Nodes: targeted vaccination on arrival.
- Low-risk wards: no routine vaccination; intensified testing surveillance for freedom proofs.
- Consider establishment of the protection zone in the Eastern Cape

Gauteng, Free State, North West (At-risk nodes)

- Targeted vaccination: communal areas, feedlots, collection centres, high-throughput markets.
- Pre-movement vaccination ≥14 days prior for animals entering nodes.
- Market and slaughterhouse surveillance; digital movement permits enforced.

Western & Northern Cape (Protection zones)

- No routine vaccination — reserve vaccines for emergency rings only.
- Intensify surveillance (passive + active) and rapid response capacity (<48h).
- Maintain documentation to preserve export eligibility.

VACCINE PRODUCT MATCHING

- Vaccine selection to be based on TPP developed by the MTT
- Only use vaccines with **antigenic match** verified by WOAH FMD Reference lab (r1/VNT) and sequencing. Switch antigen composition if a mismatch is found.
- Use high-potency formulations for emergency/suppressive vaccination. Maintain access to regional/OIE vaccine banks for surge supply.
- So far we have:
  - **BVI** vaccine
  - **Dollvet** (application submitted)
  - **Biogenesis Bago** (Still to apply)

OPERATIONAL OBJECTIVES (12 MONTHS HORIZON)

- **Priority 1**: feedlots (all incoming cattle), large commercial dairy herds, export-oriented feedlots/abattoirs, communal grazing areas and smallholder cattle in high-movement zones.
- **Entry (feedlot) protocol**: vaccinate **on arrival (day 0)** + booster at manufacturer interval (commonly 21–28 days), quarantine intake pens for 7–14 days and sample for surveillance. For long-stay animals, revaccinate at 6–12 months depending on product.
- **Mass preventive campaigns** in high-risk districts: plan 2 rounds/year (6 months apart) for provinces with active circulation, aim ≥80% coverage of susceptible animals in target populations.
- **Emergency rule**: if a confirmed case is within defined epidemiological distance (e.g., linked supplier or within X km), implement ring vaccination of feedlot or area and immediate suppliers within 48–72 hours.

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  - **Biogenesis Bago** (Commenced discussion}

DIAGNOSTIC AND LABORATORY NETWORK

- There is an urgent need to strengthen diagnostic capacity in the country and broadening the diagnostic function beyond just OVR.
  - **National Reference Laboratory (NRL) — ARC-OVR**
- **Core responsibilities**: confirmatory testing (RT-PCR, antigen ELISA), serotyping, virus isolation, sequencing, r1/VNT vaccine-matching, NSP serology, proficiency testing and international reporting. All suspected outbreaks must have samples routed to NRL for rapid confirmatory results and vaccine-match within the shortest possible turn-around (target <72 hours for initial RT-PCR; 4–7 days for vaccine-match).
- **There is a strong need for the OVR to work hand in hand with the WOAH World FMD reference laboratory at Pirbright** - UK
  - **Regional & provincial labs**
- Regional labs perform rapid antigen/RT-PCR screening and forward positive/critical specimens to NRL. Equip regional labs with cold-chain sample kits, SOPs and secure courier links.
  - **Field sampling & chain of custody**

DIAGNOSTIC AND LABORATORY NETWORK

- Standardise sample sets (epithelial/vesicle fluid + serum), use electronic submission forms, and ensure cold-chain to NRL.
- Train district vets and private practitioners in sampling, packaging and biosecurity.
  - **Diagnostics to inform vaccination**
- NRL vaccine-matching results must feed directly into the vaccination operational cell to:
  - confirm whether current vaccine is appropriate,
  - recommend antigen changes or emergency vaccination expansion, and
  - decide on withdrawal timing for candidate “without vaccination” zones.
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SURVEILLANCE STRATEGY (detect, monitor, demonstrate absence)

- **Passive reporting** (mandatory notification + incentives/compensation where stamping-out applies).
- **Active targeted surveillance**: sentinel herds in markets, abattoirs, feedlots, border buffer zones, and communal grazing nodes. Use NSP + VNT panels.
- **Post-Vaccination Monitoring (PVM)**: sample representative animals 21–30 days after booster to estimate seroconversion and protective titres; include NSP testing to detect breakthrough infection.
- **Participatory & market surveillance**: engage state vets, dip-tank committees, and industry to report anomalies.

MOVEMENT CONTROL

- The objectives of movement control should be:
  - Reduce virus spread during outbreaks
  - Protect free and buffer zones
  - Enable safe livestock trade
  - Support WOAH zoning applications
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MOVEMENT CONTROL

During Outbreaks

- **Standstill orders** for 14–30 days within 10–20 km radius
- Temporary checkpoints on major transport routes
- Digital movement permits (QR-coded)

At Auction Markets

- Only animals from free zones or tested negative
- Work with the SAPS and Defence

Critical Success factors

Movement control & Permits	• Digital QR-coded movement permits integrated with LITS & vaccination records. • High-risk → protection zone: inspection ≤48h, vaccination certificate required. • Outbreak standstill 14–30 days and checkpoints on strategic routes.
Availability of matching vaccine	• Compliance to established TPP
Support for trade in communal areas	• Community electronic ID & tagging; micro-compartments for compliant village groups. • FMD-safe markets: enclosed, pre-inspected, certified markets for communal sales. • Incentives: transport subsidies, trader training, preferential buying from certified herds.
Increased diagnostic capacity	• Strengthen OVR capacity as National reference lab • Accredit & expand lab screening role to approved provincial & private laboratories
Increased surveillance	
Policy reviews to address current emergency	

REVIEWS –Legislative (Who 0Directorate Animal Health and MTT)

- F branding
- Lifting of the DMA
- Lifting of the quarantine measures

BIOGENESIS BAGO

- Based in Argentina
- Agent in South Africa is Martin Krog
- Met with Biogenesis Bago representative from Argentina through the Argentina Embassy
- Agent and OBP will apply for section 21 and import permit.
- Vaccine contains SAT 1 and 2, SAT 3 antigen available
- It is oil based
- No VNT has been conducted
- We will require 6PD50
- Antigen immediately available

REVIEWS –Legislative

- Approve drafting of targeted amendments to the Animal Diseases Act to:
  - (i) create explicit **Animal Health Emergency** powers;
  - (ii) authorise emergency vaccination modalities (ring/protective/suppressive) and emergency procurement;
- Approve amendments to the Animal Identification Act (or Regulations) to enable phased **mandatory electronic identification (eID)** in priority sectors and to require reporting to the national LITS.
- Authorise Regulations to: (i) implement a **national digital movement-permit system** (QR-enabled) integrated with LITS and vaccination records; (ii) define **compartment and FMD-safe market** certification standards; and (iii) fast-track emergency vaccine import/conditional authorisation and pharmacovigilance.
- Approve emergency funding (seed and contingency) and instruct SARS/Treasury/DPSA coordination to fast-track transfers and procurement for the first 90 days.

PROGRESS ON VACCINES

- Discussed 3 Vaccines
  - Biogenesis Bago form Argentina
  - DollVet
  - BVI vaccines

Progress on Biogenesis Bago

- Biogénesis Bagó is a global biotechnology company specialized in the development and production of animal health products.
- The BIOAFTOGEN FMD vaccine is registered in 35 countries world wide with 300 million doses of the vaccine produced annually.
- Antigen and vaccine banks allows Biogénesis Bagó to provide FMD vaccines at short notice in case of emergencies.

BIOAFTOGEN FMD vaccine

- BIOAFTOGEN FMD vaccine is formulated as a high potency vaccine (PD50 > 32) and is suitable for use cattle, goats sheep and **pigs**.
- It confers protection against FMDV from **7 days post-vaccination** that last more than 6 months.
- It has **broad cross-protection** against circulating FMD viruses.
- The vaccine as a exceptional track record and was widely used in South America as part of the continental FMD eradication programme.
- Biogénesis Bagó is willing to offer a **guarantee of the efficacy** of the BIOAFTOGEN FMD vaccine under South African conditions. Written confirmation of the guarantee is expected to be received by **14 January 2026**

BIOAFTOGEN FMD vaccine for South Af

- Biogénesis Bagó agreed to formulate a vaccine specifically for South Africa.
- The trivalent vaccine will contain antigens for SAT 1, 2 and 3.
- We are currently preparing the application go SAHPRA for authorisation to use a unregistered medicine under Section 21 of Act 101. Application is expected to be filed by **19 January 2026**.
- Biogénesis Bagó is ready to formulate **1 million doses** of the trivalent vaccine (SAT 1, 2 and 3). The vaccine will be delivered within **40 days** following confirmation of the order.
- An additional **5 million doses** of the trivalent vaccine will be available by **March 2026**
- Post-vaccination sera will be imported and submitted to the ARC-OVR for vaccine matching. Confirmatory testing also be done at the World Reference Laboratory at the Pirbright Institute.
- **Results of the vaccine matching** is expected to be completed by **13 February 2026**.

Dollvet vaccine

- Mother company is based in Turkeye
- Agent is Dr Berger from a Registered South Africa company called Dunevax
- Current status
- Applied for import permit (fron Act 35) and Section 21 permit (from Act 101)
- Section 21 already issued by Act 101.
- Import permit – will be issued
- Dollvet composition has SAT 1,2.3.
- Oil based
- VNT has been conducted and found unprotective for SAT 2 and 3
- We will require 6PD50

RECOMMENDATION

- Dollvat process already done However it will take almost two months to get the vaccine.
- Biogenesis process to be initiated but can deliver earlier