

MASS VACCINATION FMD

PROPOSAL

13 January 2026



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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.



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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



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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



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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

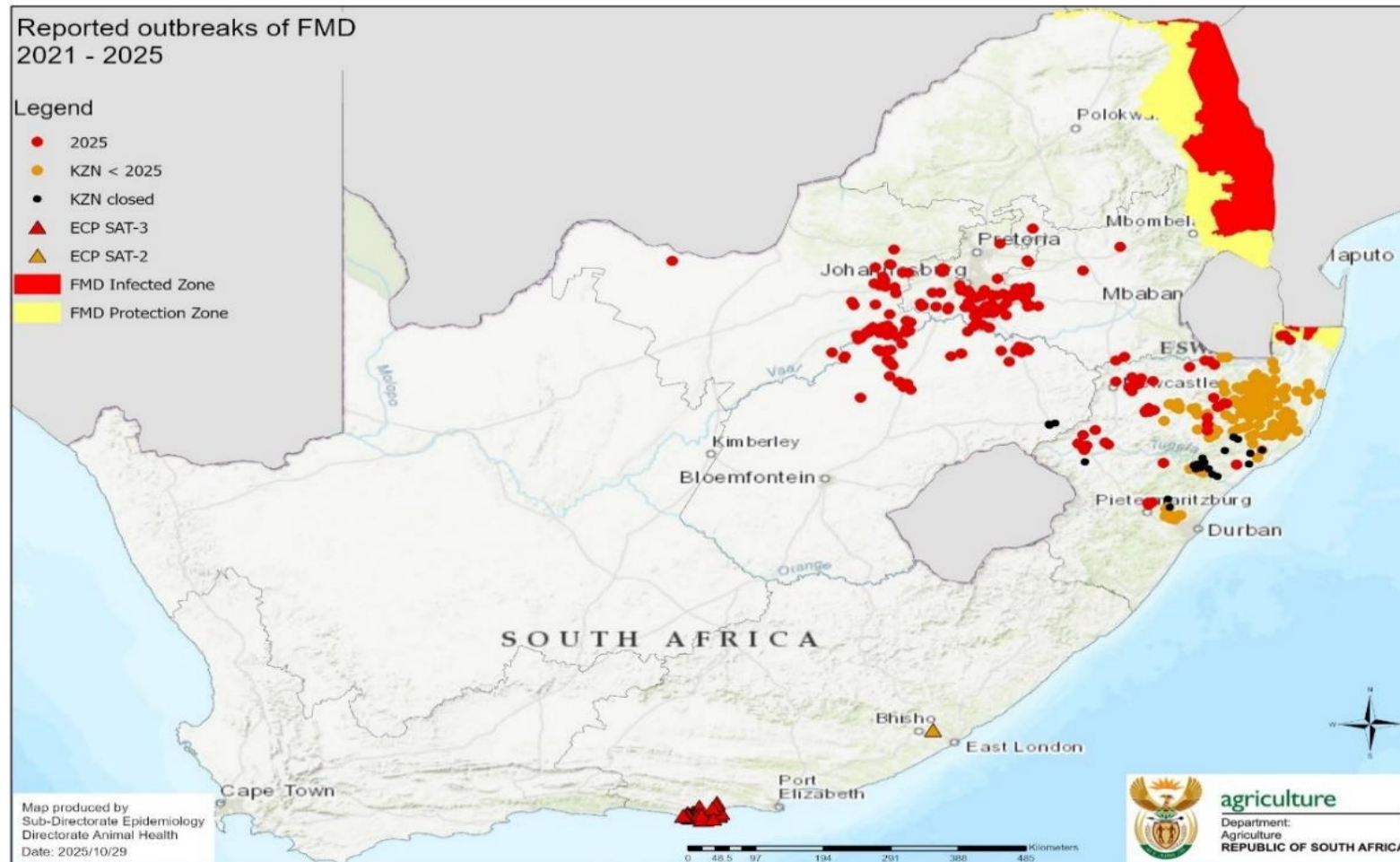


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PREVALENCE OF FMD IN SA



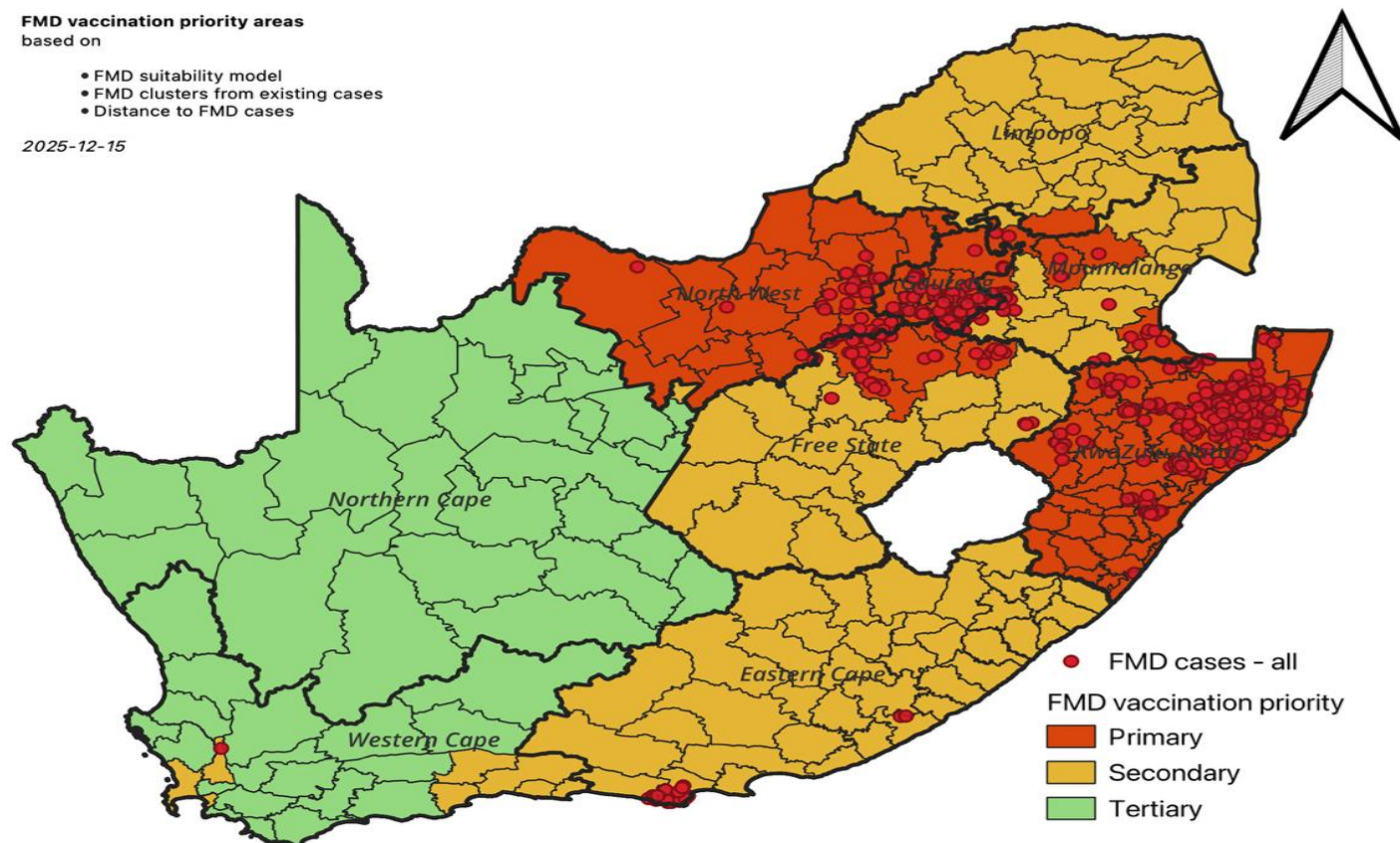
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FMD vaccination priority areas
based on

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

2025-12-15



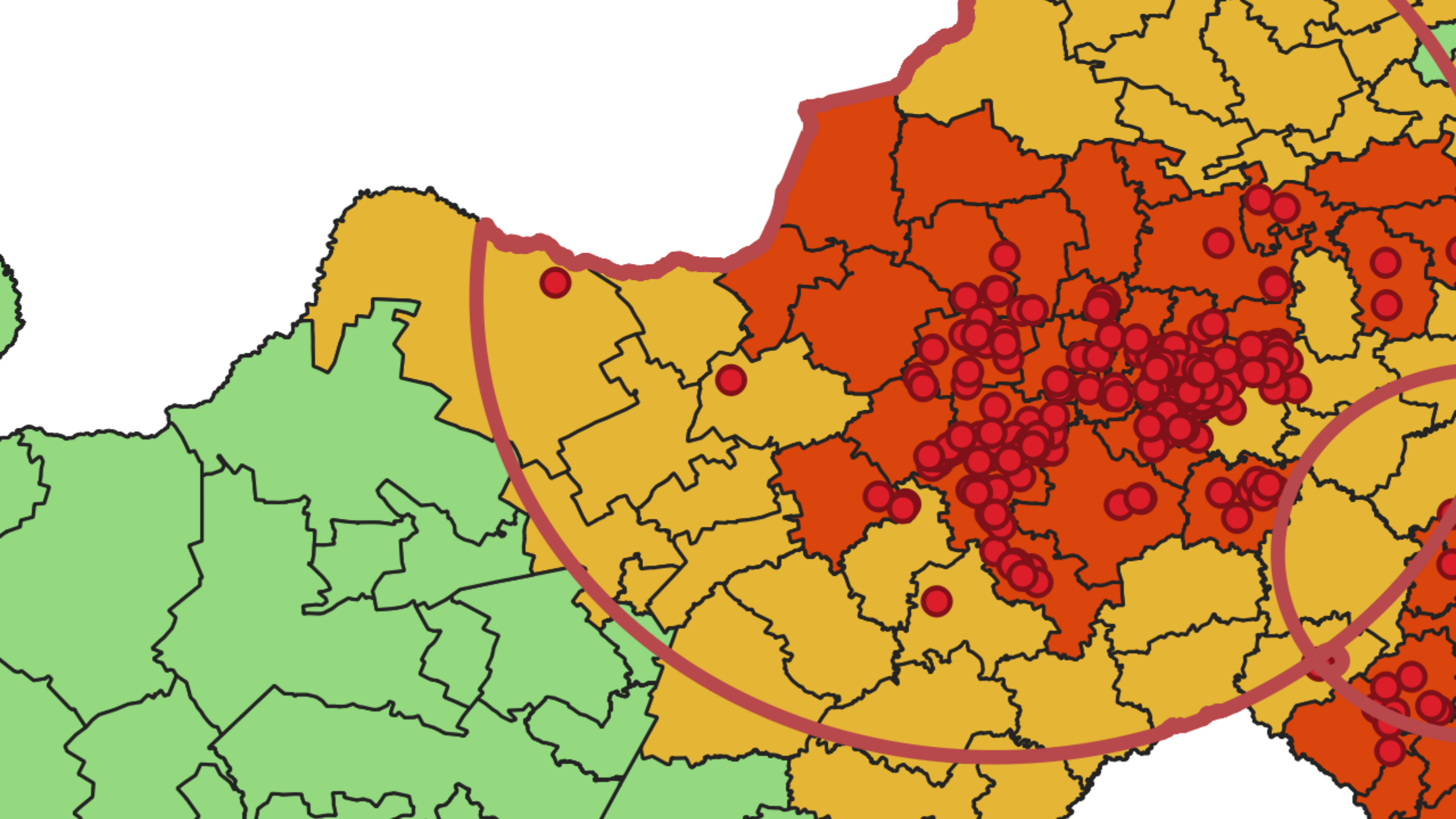
- FMD cases - all
- FMD vaccination priority
- Primary
 - Secondary
 - Tertiary



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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 WOAHP-recognised FMD freedom.



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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 WOAHP when evidence requirements are met.



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STRATEGY

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



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STRATEGY

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



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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.



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CRUCIAL FACTORS IN MANAGING FMD

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



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OPERATIONAL OBJECTIVES (12 MONTHS HORIZON)

(12-month horizon)

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



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Strategic Objective

- Reduce FMD incidence by $\geq 70\%$ in priority zones within 24 months.
- Achieve $\geq 80\%$ vaccination coverage in target populations; $\geq 90\%$ 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.



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Province Focus

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

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

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

- Biannual or triannual campaigns in border hotspots; cross-border coordination, Continue vaccinating in the protection zone
- Targets: communal clusters $\geq 80\%$; 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 $\geq 85\%$; commercial $\geq 90\%$.
- Joint wildlife surveillance and targeted vaccination near reserves.



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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.



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VACCINE PRODUCT MATCHING

- Vaccine selection to be based on TPP developed by the MTT
- Only use vaccines with **antigenic match** verified by WOAHA 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)



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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 $\geq 80\%$ 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)



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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 WOA 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



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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.



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MOVEMENT CONTROL

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



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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 • Accredited & expand lab screening role to approved provincial & private laboratories
Increased surveillance	
Policy reviews to address current emergency	



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

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



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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



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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.



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PROGRESS ON VACCINES

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



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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.



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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**



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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**.



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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



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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



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