Recombinant canine parvovirus (CPV) strain 630a

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Note: This submission is based on published, peer-reviewed, and regulatory sources available as at March 2026. No claims are made beyond the evidence cited. Where data gaps or regulatory ambiguities are identified, they are flagged as such. This submission does not oppose the registration of Nobivac DP Plus. It identifies regulatory intersections that are relevant to the APVMA's statutory mandate and that warrant cross-agency attention. The product addresses a genuine and critical animal welfare need. The EMA EPAR for Nobivac DP Plus is publicly available at https://www.ema.europa.eu/en/medicines/veterinary/EPAR/nobivac-dp-plus.

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Mechanism of action and immunology

Recombinant canine parvovirus component (strain 630a)

Strain 630a is a second-generation recombinant canine parvovirus vaccine strain constructed using recombinant DNA technology. It combines the genetic backbone—including the inverted terminal repeats (ITRs) and non-structural protein genes—of MSD's established CPV-2 vaccine strain 154 (used in existing Nobivac DHPPi, DHP, and Parvo-C vaccines) with a capsid (VP2 structural protein) sequence derived from a CPV type 2c field isolate (Pearce et al., *Vaccines*, 2023; MSD Animal Health, Nobivac DP Plus Product Information).

This construction was specifically designed to improve the vaccine strain's ability to overcome maternally derived antibody (MDA) interference while retaining the safety record of the 154 backbone. MSD has stated that strain 630a "was made using recombinant technology to directly put specific attenuating changes into the virus capsid" and that "it behaves in a similar manner to a field virus, except for the fact that it doesn't cause disease" (MSD Animal Health Hub, *Nobivac DP Plus Q&A*).

Critically, strain 630a is a live, replicating gene-technology organism. Unlike the non-replicative canarypox vectors used in other recombinant veterinary vaccines (e.g., the Recombitek product line), strain 630a is designed to replicate in the vaccinated animal. It infects and replicates in the bloodstream and intestinal mucosa, causes viraemia, and is shed in the faeces of vaccinated dogs. This replication is integral to the vaccine's mechanism of action—it is what produces the strong, rapid immune response that enables MDA breakthrough from 4 weeks of age.

MSD describes the enhanced replicative fitness as follows: "it is likely that 630a is able to grow better inside the dog, meaning that it is likely it can efficiently infect and replicate without being inactivated as easily by maternal antibody" (MSD Animal Health Hub, *Nobivac DP Plus Q&A*).

Conventional distemper component (strain Onderstepoort)

The CDV component uses the established Onderstepoort attenuated live distemper virus strain, which has been used in canine vaccines for decades. It is not a gene-technology organism. It is included at a higher minimum titre ($10^{5.1}$ TCID50) than in other Nobivac products ($10^{4.0}$ in Nobivac DHP/DHPPi) to improve MDA breakthrough for distemper. The CDV Onderstepoort strain is not shed by vaccinated puppies (EMA EPAR, Nobivac DP Plus; EC Product Annex).

Potential for good (therapeutic benefit)

Efficacy

Canine parvovirus remains one of the most significant viral pathogens in dogs in Australia and worldwide, with high morbidity and mortality in unvaccinated puppies. MDA interference with conventional CPV vaccines creates a "window of susceptibility"—a period during which puppies are too old for passive maternal protection but too young for effective active immunisation. An estimated 40% of parvovirus cases occur in puppies less than 11 weeks of age (MSD Animal Health Hub, *Nobivac DP Plus*).

Nobivac DP Plus is the first vaccine demonstrated to overcome this gap. In published studies:

- All puppies vaccinated with Nobivac DP Plus seroconverted, including those with MDA titres up to 1664 HAI units—levels at which conventional MLV parvovirus vaccines uniformly fail (Pearce et al., *Vaccines*, 2023; comparative study in *Vaccines*, 2025).
- Onset of immunity is 3 days for canine parvovirus and 7 days for canine distemper virus (EMA product information).
- In challenge studies, strain 630a induced sterilising immunity in naïve animals within 3 days of vaccination (Pearce et al., 2023).

Animal welfare benefit

This product addresses a genuine and critical animal welfare gap. Closing the MDA interference window has the potential to prevent fatal parvovirus infection in the most vulnerable age group. The distemper component at higher titre provides improved protection against a disease that causes severe neurological and systemic disease with high mortality. Core vaccination of puppies is the single most effective veterinary intervention for preventing fatal infectious disease in dogs, and is recommended by the WSAVA, AAHA, and AVA.

Potential for harm

Harm to treated animals (dogs)

The EMA EPAR and product information report the following:

- A small, non-painful swelling at the injection site (maximum 1 cm) is very commonly observed within the first week, resolving within a few days
- Reduced activity may occur within 4 days of vaccination
- In very rare cases, hypersensitivity reactions including anaphylaxis (sometimes fatal) may occur

No treatment-related systemic adverse effects beyond these standard vaccine responses have been reported. The safety profile is consistent with established live parvovirus and distemper vaccines. Overdose safety studies in dogs and cats have been conducted (Pearce et al., 2023).

Harm to humans (user safety)

In case of accidental self-injection, medical attention should be sought. Standard APVMA labelling requirements for injectable live vaccines apply.

Harm to non-target animals

This is the section that distinguishes Nobivac DP Plus from both conventional MLV vaccines and from non-replicating recombinant vaccines.

Faecal shedding of recombinant parvovirus strain 630a

The EMA product information states: "In some puppies, the canine parvovirus vaccine strain may be found in faeces for up to 8 days after vaccination. Occasionally this virus can spread to other dogs or cats, but without causing clinical signs of disease" (EC Product Annex, Nobivac DP Plus).

Published studies provide more detail:

- In the comparative MDA study, **all puppies vaccinated with Nobivac DP Plus shed vaccine virus**, and **all but one of the unvaccinated sentinel puppies seroconverted** from environmental exposure to the shed virus alone (Vaccines, 2025). This confirms that shed strain 630a is not only viable but sufficiently abundant to immunise in-contact animals through environmental transmission.
- For conventional MLV CPV-2 vaccines (strain 154 and others), the broader literature demonstrates faecal shedding of vaccine-strain parvovirus DNA for up to 28 days post-vaccination, with 23% of healthy adult dogs shedding CPV DNA and infectious virus successfully isolated in cell culture (Freisl et al., *Vet J*, 2017; Decaro et al., *Vaccine*, 2014).

- Strain 630a is specifically engineered for enhanced replicative fitness relative to conventional vaccine strains (MSD Animal Health Hub, *Q&A*). The comparative study demonstrated that vaccine virus shed from other vaccine strains (Versican Plus P, Eurican Primo P) was unable to immunise sentinel puppies, whereas strain 630a shed virus immunised all but one sentinel (Vaccines, 2025). This indicates a higher shed viral load and/or greater biological activity of shed strain 630a compared to conventional vaccine strains.

Cross-species transmission

The EMA product information confirms that strain 630a can spread to cats. In cats, the virus may be shed for up to 5 days and spread to other cats without causing clinical signs (EC Product Annex). CPV is closely related to feline panleukopenia virus (FPV).

Wildlife implications

The susceptibility of Australian native wildlife—including dingoes (*Canis lupus dingo*), quolls (*Dasyurus* spp.), and Tasmanian devils (*Sarcophilus harrisii*)—to vaccine-strain parvovirus, and specifically to recombinant strain 630a, is not characterised. Dingoes are known to be susceptible to canine parvovirus. Whether a recombinant parvovirus strain engineered for enhanced replicative fitness presents different ecological implications from conventional attenuated strains is unknown.

Harm to the environment, waterways and aquatic ecosystems

Canine parvovirus—including vaccine strains—is one of the most environmentally persistent viruses known. CPV can remain viable in soil and on fomites for months to years, is resistant to many common disinfectants, and is stable across a wide pH and temperature range (reviewed in Decaro & Buonavoglia, *Vet Microbiol*, 2012; University of Florida Shelter Medicine, 2021).

Strain 630a is a replicating, faecally shed, environmentally persistent **gene-technology organism**. Once deposited on soil via the faeces of a vaccinated puppy, the virus is expected to persist in the environment for a period consistent with the known environmental resilience of canine parvovirus generally. The specific environmental persistence and fate of recombinant strain 630a—including whether its engineered capsid modifications affect environmental stability, host range, or ecological behaviour relative to conventional vaccine strains—**has not been studied or published**.

The EMA environmental risk assessment for Nobivac DP Plus, as documented in the EPAR (EMA/565735/2020), would have been conducted under the VICH GL6/GL38 framework. For veterinary vaccines containing gene-technology, the EMA requires an environmental risk assessment that includes evaluation of the gene-technology organism itself—but as with companion animal pharmaceuticals generally, the Phase I exposure assessment typically concludes that environmental concentrations from companion animal use are below trigger values.

Harm to biodiversity, coastline and ocean

No direct risk to aquatic or marine ecosystems is expected. The principal concern relates to terrestrial biodiversity: the deposition of a viable, environmentally persistent, genetically modified parvovirus on

Australian agricultural and natural landscapes via the faeces of vaccinated companion animals. This concern is addressed in Section 8.

4. Comparison with existing alternatives

Parameter	**Nobivac DP Plus** (630a + Onderstepoort)	**Conventional MLV CPV + CDV** (e.g., Nobivac DHP, Vanguard, Protech)	**Recombitek class** (canarypox CDV + MLV CPV)
Parvovirus component	Recombinant (GMO)—strain 630a	Conventional MLV (non-GMO)	Conventional MLV (non-GMO)
Distemper component	Conventional MLV Onderstepoort (non-GMO)	Conventional MLV (non-GMO)	Recombinant canarypox vector (GMO)
Which component is the GMO?	Parvovirus	Neither	Distemper
GMO component replicates in dog?	Yes	N/A	No (canarypox is non-replicative)
GMO component shed in faeces?	Yes (up to 8 days per EMA; potentially longer per general CPV shedding literature)	N/A	No
Shed GMO immunises contacts?	Yes (demonstrated in sentinel study)	N/A	N/A
Environmental persistence of shed GMO?	High (parvovirus persists months–years)	N/A	N/A
MDA breakthrough from 4 weeks?	Yes (parvovirus); partial (distemper)	No	Partial (distemper only)
OGTR licensing required	Yes	No	Yes
Organic certification: GMO prohibition engaged?	Yes—for the shed, replicating, environmentally persistent component	No	Yes—but for the non-shed, non-replicating component

Assessment

Nobivac DP Plus offers a genuine and significant clinical advance—it is the only vaccine demonstrated to close the MDA interference gap for parvovirus from 4 weeks of age. This benefit is substantial. However, it is also the only commercially available canine vaccine in which the gene-technology component is the shedding, replicating, environmentally persistent element. In the Recombitek class, the gene-technology component (canarypox vector) does not replicate or shed; the shedding component (MLV parvovirus) is not a gene-technology organism. Nobivac DP Plus collapses these into a single component: strain 630a is simultaneously a gene-technology organism, a replicating virus, a faecally shed biological agent, and a member of the most environmentally persistent virus genus in veterinary medicine.

Key data gaps and concerns

Environmental fate of recombinant CPV strain 630a in soil

The environmental persistence and viability of strain 630a specifically—as distinct from conventional CPV strains—has not been studied. Whether the engineered capsid modifications affect environmental stability, host range in non-target species, or ecological behaviour is unknown.

Duration and extent of faecal shedding of strain 630a

The EMA product information states shedding "for up to 8 days." However, the published comparative study demonstrated that shed virus from Nobivac DP Plus-vaccinated puppies immunised unvaccinated sentinel animals (Vaccines, 2025), indicating biologically significant shed viral loads. The broader CPV shedding literature documents faecal shedding of conventional MLV CPV strains for up to 28 days (Decaro et al., 2014; Freisl et al., 2017). Whether strain 630a's enhanced replicative fitness results in higher or more prolonged shedding than conventional strains warrants investigation.

Cross-species transmission of recombinant strain 630a to Australian wildlife

The EMA confirms transmission to cats. Whether dingoes, quolls, or other Australian native species are susceptible to strain 630a is not characterised.

Interaction between recombinant CPV strain 630a and organic certification systems

See *Gene technology, organic certification, sustainability disclosure, and environmental externalities: the convergence in a single component*.

Absence of labelling guidance for organic property contexts or GMO status disclosure

Current product labelling does not alert veterinarians or animal owners that the parvovirus component is a gene-technology organism.

Overall assessment

Potential for good

High. This product addresses a critical, well-documented gap in puppy protection. Closing the MDA interference window for parvovirus from 4 weeks of age is a genuine pharmacological and clinical advance. The distemper component at higher titre provides additional benefit.

Potential for harm to animals

Low. The safety profile is consistent with established live parvovirus vaccines. The Onderstepoort distemper strain has decades of safety data. Overdose safety data for strain 630a have been generated.

Potential for harm to humans

Very low. Standard precautions for injectable live veterinary vaccines apply.

Potential for harm to the environment

Low to moderate, with significant unquantified dimensions. Strain 630a is a live, replicating, faecally shed GMO belonging to the most environmentally persistent virus genus in veterinary medicine. It is engineered for enhanced replicative fitness relative to conventional vaccine strains. It has been demonstrated to transmit to in-contact animals via environmental exposure (sentinel study). The specific environmental fate, persistence, and ecological behaviour of this recombinant strain in Australian soils and ecosystems has not been studied. The environmental risk assessment conducted under VICH/EMA frameworks was not designed to address these questions in the context of organic certification or native wildlife ecology.

Existence of lower-risk alternatives

Yes, but with trade-offs. Conventional MLV CPV vaccines (e.g., Nobivac DHP, Vanguard) do not contain a GMO parvovirus component and thus avoid the GMO/organic certification intersection, but they cannot overcome high MDA levels and leave the susceptibility gap open. Titre testing in adults reduces vaccination frequency but does not apply to primary puppy vaccination. No alternative product matches Nobivac DP Plus's ability to close the MDA window from 4 weeks of age.

Recommendations for APVMA consideration

1. **Registration should proceed** on the basis of the product's demonstrated safety, efficacy, and critical animal welfare benefit. The MDA breakthrough capability addresses a genuine unmet clinical need.
2. **Require mandatory post-market pharmacovigilance** with reporting intervals of 6 and 12 months, with specific monitoring for adverse events in target and non-target species and any reports of strain 630a detection in wildlife or non-target domestic animals.
3. **Confirm OGTR licensing** is in place or will be a condition of registration before marketing.
4. **Confirm DAFF Biosecurity** have evaluated the biological material component for import.
5. **Request, as a post-approval commitment, environmental fate data** for strain 630a in representative Australian soil types, including persistence, viability, and any host-range studies relevant to Australian native wildlife. This is justified by the unique combination of properties this product presents: a replicating, shed, environmentally persistent gene-technology organism.
6. **Ensure labelling includes:** clear identification of the parvovirus component as a gene-technology organism constructed using recombinant DNA technology; a statement that vaccinated animals will shed recombinant vaccine-strain parvovirus in faeces; standard safety warnings; and environmental disposal instructions.
7. **Include a labelling advisory** that the product contains a live recombinant gene-technology organism that is shed in the faeces of vaccinated animals, and that this may be relevant where animals reside on certified organic, biodiversity, or biosecurity-sensitive properties or areas.

Gene technology, organic certification, sustainability disclosure, and environmental externalities: the convergence in a single component

Why Nobivac DP Plus presents a unique regulatory question

The regulatory intersection identified in this section differs from that posed by any other commercially available companion animal vaccine. In other products, the gene-technology organism concern and the environmental shedding concern attach to different components of the same vaccine. For example, in the Recombitek product line (Boehringer Ingelheim), the gene-technology organism is the non-replicating, non-shedding canarypox distemper vector, while the shedding component is the conventional (non-gene technology) MLV parvovirus. The two concerns are analytically separable.

In Nobivac DP Plus, **all three concerns converge in a single component—recombinant CPV strain 630a**:

Regulatory concern	Engaged by strain 630a?
Gene Technology Act 2000—live gene-technology organism requiring OGTR licence	Yes
Organic standards—explicit prohibition on genetic engineering	Yes
DAFF contamination guideline—gene-technology materials on certified organic land	Yes
Live virus replication in the vaccinated animal	Yes
Faecal shedding of viable virus	Yes (EMA confirmed; sentinel study demonstrated biological activity of shed virus)
Environmental persistence (months to years for parvovirus)	Yes (genus-level characteristic)
Engineered for enhanced replicative fitness	Yes (MSD describes 630a as designed to "grow better inside the dog")
Demonstrated transmission to in-contact animals via shed virus	Yes (sentinel study: all but one unvaccinated sentinel seroconverted)
Cross-species transmission confirmed	Yes (EMA: spreads to cats; may be shed by cats for up to 5 days)

This means that a puppy vaccinated with Nobivac DP Plus on a certified organic property is shedding a **live, replicating, gene-technology engineered, environmentally persistent virus**—one demonstrated to be biologically active in shed form—directly onto certified organic land via its faeces. No other companion animal vaccine currently on the market presents this specific combination of properties.

Australian regulatory framework

The regulatory framework for this product involves the same government departments and oversight bodies identified for gene technology veterinary products generally:

Office of the Gene Technology Regulator (OGTR): Strain 630a is a live gene-technology organism under the Gene Technology Act 2000 (Cth). The OGTR must licence all dealings with the organism, and the APVMA must consult the Gene Technology Regulator before making registration decisions (Agricultural and Veterinary Chemicals Administration Act 1992, s. 8A).

APVMA: Registers the vaccine product and evaluates efficacy, safety, and environmental risk. The APVMA guideline for new veterinary vaccines requires that vaccines containing gene-technology organisms undergo OGTR evaluation and environmental assessment.

DAFF: Responsible for the National Standard for Organic and Bio-Dynamic Produce (the export standard) and the organic export regulatory framework. DAFF's *Guideline for Responding to Contamination by Prohibited Substances or Materials in the Organic Export Supply Chain* (Organic Notice 2018-01) addresses "the presence of genetically modified materials and organisms" on certified organic production systems.

DAFF: Biosecurity team responsible for assessing biological material for importation to Australia.

Department of Climate Change, Energy, the Environment and Water (DCCEEW): Assesses the environmental safety of biological products regulated by the APVMA.

Standards Australia: Responsible for the voluntary domestic standard Australian Standard 6000:2015 Organic and Bio-Dynamic Products and certification requirements to that standard, as well as describing responses by organic operators to contamination events.

ACCC: Recognises AS 6000-2015 as the benchmark voluntary domestic standard for evaluating organic claims under Australian Consumer Law.

The organic certification collision

Under both of Australia's organic standards:

National Standard for Organic and Bio-Dynamic Produce (Edition 3.8, DAFF): "The use of products comprised of or derived from genetic engineering is prohibited." Additionally, only inputs listed in the Standard are permitted, and the use of pesticides produced from synthetic chemicals is prohibited.

AS 6000-2015 (Standards Australia): Contains equivalent prohibitions and input specifications on genetic engineering: "2.3.2.1 Genetically modified organisms or their derivatives shall not be used."

Australian organic livestock vaccination provisions

Under the National Standard and AS 6000:2015, vaccines used on organic livestock must not contain genetically modified ingredients or by-products (NS Section 1.3.1; AS 6000:2015 Section 2.3.2.1).

These prohibitions apply to organic production systems. Companion animals on certified organic properties are not themselves "organic livestock" under either standard (see Sections 8.1 and 8.3 of the atinvicitinib submission). However, Nobivac DP Plus presents a scenario that goes beyond the ambiguities identified for small-molecule pharmaceuticals or non-replicating gene-technology vaccines:

A working dog or companion animal vaccinated with Nobivac DP Plus on a certified organic property is depositing a **live gene-technology organism** onto certified organic land—not just chemical metabolites, not just a non-replicating gene-technology organism fragment, but a viable, replicating, gene-technology engineered virus demonstrated to transmit to in-contact animals via environmental exposure. This virus belongs to the most environmentally persistent genus in veterinary medicine and has been specifically engineered for enhanced replicative fitness.

The DAFF export standard contamination guideline (Organic Notice 2018-01) addresses contamination by "prohibited substances or materials, including the presence of genetically modified materials and organisms." Its scope extends to the entire "organic production system," defined as "all activities relating to an operator's approved production unit, off production unit processes and produce." Sanctions are graduated based on the nature of the contamination:

- **Unnecessary intentional use:** The deliberate use of prohibited substances in a manner inconsistent with the National Standard and not required by law
- **Negligent introduction:** Where the presence could have been reasonably avoided
- **Accidental introduction:** Where the presence could not have been reasonably avoided
- **Necessary intentional use:** Use inconsistent with the Standard but required by law

Vaccination of a companion dog is not "required by law" in Australia for most diseases (rabies vaccination is not mandatory for domestic dogs in most jurisdictions). The operator consents to and usually initiates the vaccination. The faecal shedding of the recombinant virus onto certified land is a known and documented consequence of the vaccination. This scenario does not fit neatly into any of the guideline's four categories, nor the AS 6000:2015 general prohibition or contamination management pathways, and it is unclear what response—if any—a certifying body would be required to take after consultation with the relevant Standard-managing entity.

The working dog context

As identified for other vaccine products, the concern is most acute for working dogs on organic properties. Livestock guardian dogs and herding dogs are integral to organic livestock operations,

have continuous access to certified organic pasture, and are routinely vaccinated as puppies. If vaccinated with Nobivac DP Plus at 4 weeks of age, a puppy will be shedding recombinant strain 630a onto certified organic pasture during the very period of its early life when it is establishing its presence on the property.

The published sentinel study demonstrates that shed strain 630a is sufficiently biologically active to immunise unvaccinated in-contact animals through environmental exposure alone (Vaccines, 2025). On a diversified organic property, this raises the theoretical possibility that organic production livestock (sheep, cattle, goats, pigs, poultry, other) or companion animal cats could be exposed to a gene-technology biological agent deposited via the companion animal's faeces—an exposure that the organic operator may not be aware of and that the organic standards were not designed to address.

Sustainability risk disclosure

Australia's mandatory climate-related financial disclosure regime (AASB S2, under the ASRS) is designed to expand beyond climate to additional sustainability topics over time (AASB, *Overview of AASB S1 and AASB S2*, April 2025). Gene technology contamination of organic production systems is a recognised market access risk, domestically and internationally. Altering the definition of gene-technology organisms or deregulating gene editing techniques threatens international equivalency, noting risks to exports to the USA (33% of organic exports), the EU, and other markets.

For companies operating in the organic supply chain, the introduction of a faecally shed recombinant gene-technology organism—via a routine companion animal vaccination—as a potential contaminant on certified organic land represents a novel risk that is not currently addressed by any disclosure framework but could become material as sustainability reporting expands.

International comparison

Under the USDA NOP, genetic modification is an "excluded method" generally prohibited in organic production, with a narrow and contested exception for vaccines at §205.105(e) that requires placement on the National List (USDA AMS, *Vaccines Made from Excluded Methods*, 2011). This exception applies to organic production livestock vaccines; it does not address companion animal vaccination on organic land. The NOSB has not evaluated recombinant parvovirus vaccines specifically.

Under the EU organic regulation (2018/848), gene-technology organisms are prohibited. The treatment of gene-technology vaccines in organic livestock production has been subject to interpretation at certifier level. The extension to companion animals on certified organic properties has not been addressed.

Under IFOAM norms, "the deliberate use or negligent introduction of genetically engineered organisms or their derivatives is prohibited." The question of environmental deposition of a gene-technology organism via companion animal faeces is novel and unaddressed.

Recommendations specific to this section

1. **That the APVMA acknowledge the unique regulatory position of Nobivac DP Plus** as the only commercially available companion animal vaccine in which the gene-technology component is simultaneously the replicating, faecally shed, environmentally persistent element. This distinguishes it from both conventional MLV vaccines (no gene technology) and non-replicating recombinant vaccines (gene-technology organisms but no shedding).

2. **That the APVMA, OGTR, DAFF and DCCEEW consider establishing cross-agency guidance** addressing the specific scenario of a live, replicating, shed gene-technology organism deposited on certified organic land by a vaccinated companion animal. This guidance should:

    - Clarify whether such deposition constitutes a contamination event under Organic Notice 2018-01 and in respect of AS 6000:2015 provisions
    - Clarify the obligations (if any) of organic operators, certifying bodies, and prescribing veterinarians
    - Affirm that core vaccination of companion and working animals is an essential welfare practice that must not be deterred by organic certification uncertainty

3. **That the APVMA consider requesting, as a post-approval commitment**:

    - Environmental fate data for strain 630a in representative Australian soil types (persistence, viability)
    - Host-range data for Australian native wildlife species (particularly dingoes and quolls)
    - Characterisation of the duration and extent of faecal shedding of strain 630a compared to conventional CPV vaccine strains

4. **That product labelling clearly identify the parvovirus component as a gene-technology engineered organism** and include a statement that recombinant vaccine virus is shed in the faeces of vaccinated animals. An advisory noting relevance for animals residing on certified organic properties should be considered.

5. **That this question be drawn to the attention of the National Organic Standard Advisory Committee (NOSAC)** for consideration in any future revision of the National Standard, to the Organic Policy Division of DAFF, as well as Standards Australia as owner of the domestic organic standard AS 6000:2015.

Sources

Product-specific

EMA, EPAR—Public Assessment Report for Nobivac DP Plus (EMA/565735/2020)

EMA, CVMP Summary of Positive Opinion for Nobivac DP Plus (EMA/CVMP/500514/2020)

EC Product Annex—Nobivac DP Plus Summary of Product Characteristics (EU/2/20/265)

MSD Animal Health Hub, *Nobivac DP Plus Q&A*, https://www.msd-animal-health-hub.co.uk/ahp/ca-faq-DP-PLUS

MSD Animal Health Hub, *Nobivac DP Plus Product Page*, https://www.msd-animal-health-hub.co.uk/products/Nobivac-DP-PLUS

MSD Animal Health South Africa, *Nobivac Puppy DP Plus Product Information*

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MSD Animal Health, *Nobivac Puppy DP Plus Launch Presentation* (South Africa)

Gene technology legislation and regulatory

Gene Technology Act 2000 (Cth)

Gene Technology Regulations 2001 (Cth)

Agricultural and Veterinary Chemicals Code Act 1994 (Cth), s. 5A

Agricultural and Veterinary Chemicals Administration Act 1992 (Cth), s. 8A

APVMA, *Guideline for the Registration of New Veterinary Vaccines*

APVMA, *Veterinary Medicines Technical Report Guidance*

APVMA, *Environment (Part 7) Data Guidelines*

OGTR, *Gene Technology and Animal Health*

DAFF, *Regulatory Framework in Australia*

Organic standards and policy

DAFF, National Standard for Organic and Bio-Dynamic Produce, Edition 3.8

Standards Australia, AS 6000-2015 Organic and Biodynamic Products

ACCC, *Organic Claims* (2023)

DAFF, *Guideline for Responding to Contamination by Prohibited Substances or Materials in the Organic Export Supply Chain* (Organic Notice 2018-01)

NSW DPI Primefact 760, *Use of Vaccinations and Other Veterinary Treatments in Organic Livestock Farming*(2008)

Senate Rural and Regional Affairs and Transport Legislation Committee, *National Organic Standard Bill 2024—Progress Report* (2025)

International organic standards and GMO vaccines

USDA NOP, 7 CFR §205.105(e); §205.603(a)(4)

USDA AMS, *Vaccines Made from Excluded Methods: Technical Report* (2011)

NOSB Livestock Committee, *National List Proposal: GMO Vaccines* (2012)

OrganicEye, *USDA Challenged on Illegal GMO Use in Organics* (2023)

IFOAM Norms for Organic Production and Processing

EU Regulation 2018/848

Parvovirus shedding and environmental persistence

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