LIVING MODIFIED ORGANISM (LMO)

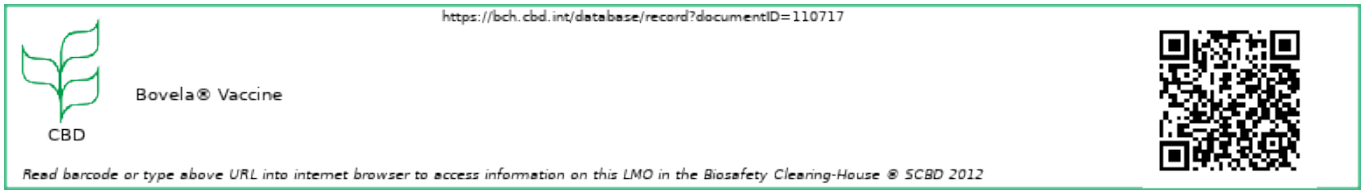
BCH-LMO-SCBD-110717-2

? Decisions on the LMO ? Risk Assessments

LAST UPDATED: 03 AUG 2016

Living Modified Organism identity

The image below identifies the LMO through its unique identifier, trade name and a link to this page of the BCH. Click on it to download a larger image on your computer. For help on how to use it go to the LMO quick-links page.



Name

Bovela® Vaccine	EN

Transformation event

Bovela

Developer(s)

- PERSON: DRA PATRÍCIA SCHWARZ | BCH-CON-SCBD-110716-2

PERSON

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RELATED ORGANIZATION

Description

Bovela is a vaccine developed to immunize bovines against the disease caused by the bovine viral diarrhea virus (BVDV) types 1 and 2, including the vaccination of cows and calves, in order to protect the fetus against transplacental BVDV infection.	EN

This virus is a single stranded positive-sense RNA pestivirus from the Flaviviridae family that replicates only in the cytoplasm. Its genetic material codes for the EMS and NPRO proteins, which in their native form inhibit the interferon dependent (IFN-gamma) immune response type Th1, therefore inhibiting the host immune response.

The absence of coding sequences for these viral genome proteins impairs the virus's ability to inhibit the production of interferon, therefore promoting the host immune system. The vaccine is adjuvant-free and targeted for the active immunization of pregnant cows and of animals after three months of age, in order to reduce the clinical symptoms of the disease, viremia and viral excretion.

Recipient Organism or Parental Organisms

The term “Recipient organism” refers to an organism (either already modified or non-modified) that was subjected to genetic modification, whereas “Parental organisms” refers to those that were involved in cross breeding or cell fusion.

BCH-ORGA-SCBD-110658-4 ORGANISM | PESTIVIRUS A (BVDV-1)

Viruses

BCH-ORGA-SCBD-110712-3 ORGANISM | PESTIVIRUS B (BVDV-2)

Viruses

Point of collection or acquisition of the recipient organism or parental organisms

Parental strains of the two viral types were isolated from animals infected in Germany (KE9, BVDV-1) and the United States (NY-93 and BVDV-2). EN

Characteristics of the modification process

Vector

pXIKE-B-NdN and pKANE99C EN

Techniques used for the modification

Virus-mediated gene transfer

Introduced or modified genetic element(s)

Some of these genetic elements may be present as fragments or truncated forms. Please see notes below, where applicable.

BCH-GENE-SCBD-110714-1 ERNS CODING SEQUENCE | (BVDV-1)

Protein coding sequence | Production of medical or pharmaceutical compounds (human or animal) (Vaccines)

BCH-GENE-SCBD-110715-1 NPRO CODING SEQUENCE | (BVDV-1)

Protein coding sequence | Production of medical or pharmaceutical compounds (human or animal) (Vaccines)

Notes regarding the genetic elements present in this LMO

Briefly, modified BVDV-1 and BVDV-2 RNA were transcribed in vitro from complete clones of cDNA pXYKE-B-NdN (corresponding to the modified BVDV-2) and pKANE99C (corresponding to the modified BVDV-1). Later on, the BVDV strains were propagated in MDBK-B2 cells lineage and the viral RNA was extracted to establish the cDNA standard library and to its extension EN

by polymerase (RT-PCR) chain reaction. The target living virus, modified and attenuated, were obtained by cDNA elaboration after in vitro transcription and RNA transfection of MDBK cells.

Sequencing of master virus seeds (MVS) to modified BVDVs were used to inoculation in MDBKB2 cells and, after 48 hours of incubation, the supernatant material was removed and cells were cleansed and lysed. Total RNA was extracted from cells, examined for integrity and later converted into cDNA for sequencing. Results of sequencing the established MVS confirmed the presence of introduced deletions in Npro and Erns. When compared, the MVS sequences and original isolated KE9 and NY93 showed the presence of just minor differences in nucleotides that were determined to have no influence over the attenuated phenotype.

PCR data obtained for MVS and WVS (MVS + 5) of strains in vaccines of modified BVDV have also confirmed the presence of the introduced Npro deletion. The in vitro data were also supported by PCR data obtained in BVDV (virus isolation method) positive samples which showed that the introduced Npro deletion remained stable for several in vitro passages. Jointly, the data show that BVDV genomes containing the inserted deletions are genetically stable in vitro and in vivo.

LMO characteristics

Modified traits

Production of medical or pharmaceutical compounds (human or animal)
Vaccines

Common use(s) of the LMO

Vaccine

Additional Information

Other relevant website addresses and/or attached documents

? Bovela® - Boehringer Ingelheim *(English)*

? Bovine Viral Diarrhea Virus: Prevention of Persistent Fetal Infection by a Combination of Two Mutations Affecting Erns RNase and Npro Protease *(English)*

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Further Information

Questions about the Cartagena Protocol on Biosafety or the operation of the Biosafety Clearing-House may be directed to the Secretariat of the Convention on Biological Diversity.

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