CT BRASIL, MINISTÉRIO DA CIÊNCIA E TECNOLOGIA
[Ministry of Science and Technology] and
CTNBio, Comissão Técnica Nacional de Biossegurança
[National Technical Biosafety Committee – CTNBio]

MINISTRY OF SCIENCE AND TECHNOLOGY
NATIONAL TECHNICAL BIOSAFETY COMMITTEE – CTNBio
EXECUTIVE SECRETARIAT

PRELIMINARY CONCLUSIVE TECHNICAL APPROACH
No. 0102/2004

Process No: º: 01200.001033/2004-15

01200.001033/2004-15

Applicant: Merial Saúde Animal Ltda.

Merial Saúde Animal Ltda.

CNPJ [National Register of Legal Entities]: 57.600.249/0017-12

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Address: Fazenda São Francisco s/nº - Caixa Postal: 242 - PAULINIA - SP - 13140970

Fazenda São Francisco s/nº - Caixa Postal: 242 - PAULINIA - SP - 13140970

Subject: Application of Preliminary Conclusive Technical Opinion for the import of anti-tick vaccine.

Application of Preliminary Conclusive Technical Opinion for the import of anti-tick vaccine.

Previous Abstract: 104/2004 published in D.O.U [Federal Official Gazette] No. 60 of March 29, 2004.

Meeting: 77 Ordinary Meeting held on May 12, 2004

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Decision: GRANTED

GRANTED

CTNBio, after assessing the process concerning the application of Conclusive Technical Opinion for the import of anti-tick vaccine, has concluded by the GRANT.

At the extent of the provided for in Article 1 D, Law 8974/95, the Committee has concluded that the application meets the CTNBio guidelines as well as the relevant legislation that seeks to assure the biosafety of the environment, agriculture, and human and animal health.

PRELIMINARY CONCLUSIVE TECHNICAL OPINION OF CTNBio

1) Technical Background:

It was requested an import authorization for GMO's derivative to be used as experimental vaccine against bovine tick. The vaccine is produced from a combination of a purified protein subunit, from tick's salivary cement, and a vaccine adjuvant.

This protein subunit, from tick's salivary cement, is produced in an *Escherichia coli* strain modified using a recombinant plasmid containing the gene of this protein under the control of a prokaryotic promoter of the plasmid. Following the induction of expression of tick salivary cement protein in *E. coli*, the bacterium is lysed and this bacterial lysate is processed for purification. The protein purification is accomplished by affinity-column chromatography resulting in the finished antigenic product, i.e. highly purified Trp5 protein free from GMO.

2) Biosafety measures described in the process

Although not describing the measures, the process refers to the import of GMO-purified finished derivative, whose laboratory handling, differently of the viable GMO, does not represent risks to biosafety.

3) There are no restrictions to the GMO Derivative use in analysis and the project does not require considerations of ethical nature involving genetic manipulation.

It is a purified antigenic protein that induces antibodies without risk to the health of animals and people and whose objective is to minimize/inhibit the tick infestation in animals.

Once met the biosafety recommendations and measures included in the process, this activity does not cause a potentially significant environmental degradation nor it is harmful to the human health.

Jorge Almeida Guimarães
President of CTNBio