XIX Seminar on Harmonization and Control for Veterinary Medicines
Americas Committee on Veterinary Medicines (CAMEVET)
Panama, Republic of Panama
September 24 - 27, 2013

Opening speeches

Professor Batista Gerardino, Deputy Minister of Agriculture, welcomed the participants, as Dr. Manuel Gonzalez Cano, OIE Delegate from Panama, Dr. Filiberto Frago Santamaria, OIE Sub-Regional Representative for Central America and the Caribbean, and Mr. Milson da Silva Pereira, SINDAN Executive Director.

Assumption of the Presidency

Dr. Marvin Yohan Vega Espinosa took the role as President of the Seminar.

Dr. Enrique Argento, CAMEVET Secretary, presented Ms. Ana Maria Sgammini, who has been hired to perform support tasks for the Secretariat.

Session I - Relations of CAMEVET and implementation of harmonized documents

Report of the 81st General Session of the OIE

Dr. Martin Minassian, Technical Assistant of the OIE Regional Representation for the Americas, presented the topics of relevance for the CAMEVET which were discussed at the 81st General Session of the OIE.

This included the presentation of the Technical topic I, entitled "Modern approaches and the use of new technologies for the control and eradication of aquatic and terrestrial animal diseases that fully consider animal welfare and minimize the impact on food security", as the Resolution No. 35 of the World Assembly of Delegates.

One of the conclusions of this study was that 75.9% of the countries responding to the survey support the use of DIVA strategies (Vaccines differentiating animals vaccinated from naturally infected) or high potency vaccines during an outbreak, and it is necessary for the OIE and countries to update their standards to the use of these and other new technologies.

Other topics presented dealt with the updating of the OIE list of antimicrobials of veterinary importance, and the OIE procedure for registration of diagnostic kits.

Finally, modifications adopted in the Terrestrial Animal Health Codewere presented. This included the adoption of definitions for "Good Manufacturing Practices" and "veterinary medicinal product", and also the update of Chapter 6.9, *Responsible and prudent use of antimicrobial agents in veterinary medicine.* He also reminded participants that Chapters 6.6, 6.7 and 6.10, also related to antimicrobial resistance, are under review. For that, it shall

be important to be aware about the distribution of the reports of the OIE Commissions in order to provide comments via the Delegates.

Moreover, he urged Focal Points to intervene more actively in issuing comments to the modifications proposed in the OIE Standards.

Participants expressed their satisfaction with the inclusion of these definitions in the Glossary and the content incorporated into Chapter 6.9 of the Terrestrial Code, as they include a direct reference to the measures required to combat illegal practices in the marketing of veterinary products, as well as the inclusion of criteria for the manufacture of medicated feeds.

Status of implementation of harmonized documents in member countries.

Dr. Enrique Argento presented the status of implementation of harmonized documents. He remarked that necessary that everycountry send the proper answer to this survey , as this information helps to measure and characterize the impact of the work of the Committee.

It was noted that, in many cases, harmonized documents are not incorporated in national regulations without any change, but are used as a technical guidance, or are applied without being formally included in the regulations, so it is important to have such information.

On this basis, the Secretariat will include these options in the upcoming consultations to countries.

CAMEVET Strategic Plan: Status of advancement

Dr. Carlos Francia, Member of the Executive Board, and on behalf of CAPROVE, made a report on the progress of the CAMEVET Strategic Plan for 2010-2015.

He commented that although the full implementation of harmonized documents was not met, the implementation of technically equivalent regulations is a significant advance.

He also highlighted the participation in the VICH Outreach Forum and the requirement made by the OIE Headquarters to review the quality of translations of three VICH guidelines into Spanish, and the opportunity to participate in the review of the VICH guideline for stability testing, in order to include the assays for products to be commercialized hot weather climatic areas, which are not covered by the current guideline.

On the other hand, noted that the diffusion of harmonized documents to all OIE member countries, as well as the incorporation to the OIE Standards as a pending task. In this regard, it was considered that the participation in VICH is a possible way to meet these goals.

Another point raised as pending is the low perception of the importance of the topics related to veterinary products by the Delegates of the Veterinary Services, for which the continuity in their invitation to participate in the Seminars was proposed.

The presence of the Mexican Delegate to the OIE Dr. Joaquin Braulio Alvarez Delgadillo was highlighted. He expressed the importance for his country to support the work of all National Focal Points, and also added that industry problems are also State problems, and responsibilities are always shared.

He expressed his congratulations to the participants by the results obtained in the forums linking the authorities and the industry in the Americas.

Proposal for the creation of the CAMEVET Training Committee.

The Executive Board informed the problem of the limited availability of specific training opportunities in the field of veterinary products was raised, for both public and industry sector staff.

Dr. Liliana Revolledo was convened to present the main problems in the registration of veterinary products from both the public and industry sector, which in many cases are based on the lack of personnel with sound knowledge in this topic

From that, she proposed the creation of an "ad-hoc" training commission in CAMEVET, in order to promote and develop training activities for public and private sectors. These will include both class room and virtual activities, using available communication tools. Moreover, these activities should be available in several languages, and include evaluation and certification systems. Moreover, these activities shall serve as an alternative source of funds for CAMEVET.

It was unanimously approved that the Executive Boards hall create a training committee, which shall develop its Terms of Reference, and begin planning training activities.

It was commented that the Veterinary Services in some countries provide training to private companies in order to reduce the frequency of errors, so it was proposed to integrate these activities in the planning.

Presentation of the results of the official sector meeting

Dr. Benigno Alpizar Montero presented the results of the meeting held by the representatives of the official sector, whose minutes are included as Annex.

Topics presented included the requirement of residue withdrawal studies, for which the relevance of performing such studies for each particular formulation was commented. Other topics regarding free sale certificates and the need for revision of the guidelines for Good Manufacturing Practices were also discussed.

The unavoidable responsibility for manufacturers to perform residue withdrawal studies was stated. However, it was emphasized that it is essential for producers to respect the withdrawal periods.

Participants from OIRSA member countries member countries indicated on the availability of diffusion materials to promote good practices in the use of veterinary products, included in the materials distributed.

Presentation of the results of the meeting of the industrial sector

Dr. Carlos Menendez presented the results of the meeting held by industry participants. Topics included issues regarding the prescription of veterinary products, as well as the difficulties encountered in applying the Central American Technical Regulation. Countries were urged to unify their forms for the registration and the Free Sale Certificate models harmonized by the Committee.

After the request of support raised by the FIFVETCA representative regarding the ongoing negotiations about the implementation of regulations on residue depletion studies in Central America with the official sector, the Secretary made clear that the interaction between the government and private sectors is one of the objectives of CAMEVET, urging participants to continue their efforts in coordinating common positions.

CAMEVET participation in the VICH Outreach Forum

Dr. Enrique Argento made a presentation on his participation on behalf of the Committee, reviewing the history of the meetings celebrated, and reporting that next meeting will be held in November 2013.

He highlighted the participation of representatives from the Americas in such meetings, as the participation of CAMEVET in the Working Group formed by VICH to develop training activities, through Dr. Nestor Guerrero, the review of Spanish translations by Drs. Carlos Francia and Margarita Pinto, and the participation of Dr. Laura Sbordi in the Experts Working Group on residues in honey.

As for the revision of the VICH guideline on stability of veterinary products, the CAMEVET harmonized document shall be provided, considering that covers tropical climate zones not included in such guideline.

Participation in the Drug Information Association meeting

Dr. Argento reported on the invitation received to participate in the meeting of the DIA, whose member countries participate in VICH with IFAH, to present an overview of the impact of veterinary products in livestock production in the region.

Report on the OIE Global Conference on the Responsible and Prudent Use of Antimicrobial Agents for Animals, "International solidarity to fight against antimicrobial resistance"

Dr. Gloria Alarcon made a presentation on the World Conference, held in Paris, France, between 13 and 15 March 2013[1].

She detailed the topics discussed at the Conference, and presented the adopted recommendations. One of the relevant topics referred to the need for improved communication, collaboration and existence of agreements between all parties involved.

Also, stressed that one of the recommendations for OIE member countries refers that they "*develop or update appropriate legislation and regulation on import, marketing authorisation, production, distribution (including transport and storage) and use of quality veterinary medicinal products in interaction with other relevant competent authorities and private interested parties, and to ensure their efficient implementation".*

Sesion II –Working documents

Dr. Argento reminded the participants to respect the deadlines allocated for the submission, as this causes delays in the circulation and approval of the working papers.

Registration for homeopathic veterinary products

Dr. Germán Sarmiento Parra, representing Dr. Nestor Guerrero Lozano, presented the progress of the working document, in Step III status.

Based on the comments made by several countries, which raised doubts as whether the submitted document included the final comments, as the comments received after the deadline, a final circulation of the document including all of the comments received was approved.

A lapse of 60 days after the closure of the Seminar was established for the circulation of the compiled document, with 60 additional days for the reception of comments and its final adoption.

Guideline for the registration of biotechnologically obtained subunit vaccines

Drs Emigdio Lemes Anaya and Jesus Mena Campos made a presentation on the progress in the working document, in Step III status, detailing the changes made by the countries which submitted comments.

He clarified that comments were received after the deadline, which were presented and accepted, stating that these changes were not included in the Portuguese version. The document was approved and included as Annex.

[1]Presentations and conclusions are available at http://www.oie.int/eng/A_AMR2013/presentations.htm

The proposal made by SINDAN providing the Portuguese translation, which shall be available within 60 days, was accepted.

Guidelines for the establishment of withdrawal periods for veterinary products

Dr. Carlos Francia presented the progress in the preparation of the working papers related to the *guideline for conducting residue studies*, the *guideline for the calculation of withdrawal periods*, and the *guideline for the validation of analytical methods*.

In this regard, he commented that the criteria applied in these guidelines is to consider as many scenarios as possible.

He noted that, although the basis for the preparation of these Guidelines have been the documents from VICH, the FDA and the EMA, they included new contents adapted to the reality of the continent, as in the case of the application of veterinary products through immersion.

According to the current procedure, the changeto the status of Step III was approved, and the drafts shall be circulated within a 90 days dead line fort he submission of comments.

Control of vaccines for infectious bovine rhinotracheitis (IBR)

Dr.Viviana Parreño presented the final document on potency testing for inactivated vaccines containing bovine herpesvirus (BoHV-1), in Step III status.

The document was approved unanimously, and is included as Annex

Guideline for potency tests in vaccines containing inactivated Bovine Parainfluenza 3 (PI-3) virus - guinea pig model

Dr. Viviana Parreño presented the progress in the working document, in Step III status, stating that no further comments were received to the final versions, and general comments provided too there related documents were used to improve their quality.

Dead lines for the submission shall be respected in order to provide comments.

Guideline for the registration of nutraceutical veterinary products/ dietary supplements

Dr. Jorge Dale, on behalf of the working group, presented the final version of the working document, in Step III status.

Existing problem was raised regarding the fact that in many cases theare as of registration of veterinary products have no concern in the document.

After the opinions of some participant sabout the need for a fur ther review by members of the Working Group regarding stability tests, it was agreed that they shall be included in a

new version of the document, with a final distribution with additional 60 days for the reception of comments.

Proposal for new working groups

Recommendations for the design of safety tests for the development and registration of inactivated vaccines for cattle.

Dr. Maria Marta Vena presented the proposal for a working paperon safety testing for bovine inactivated vaccines, especially viral vaccines for non-vesicular diseases, usually in combination with bacterins.

The propos alwas accepted. The Working Group will be coordinated by Dr. Maria Marta Vena, with the participation of representatives of the official sector from Chile, Mexico and Uruguay, as well as ADIPRAVE, CAPROVE and CEV.

Guideline for potency testing in vaccines containing inactivated bovine rotavirus.

Dr. Viviana Parreño made a presentation on the subject, on the basis of the importance of this virus associated with neonatal calf diarrhea.
The methodology fort he evaluation of potency in combined vaccines containing inactivated bovine rotavirus waspresented, using a guinea pig experimental model, which greatly optimizes the evaluation.

The propos alwas accepted. The Working Group shall be formed by the same members of the Parainfluenza-3 Working Group.

Veterinary products and aquaculture

The proposal to include issues related to the field of aquaculture was accepted, for which a working group was formed, coordinated by Canada, including Chile, Costa Rica, Mexico, Peru and the Cuban Center for Genetic Engineering and Biotechnology, representatives from ANVET, ALANAC, CAPROVE, FENALCO and SINDAN.

This working group will define the content and propose draft papers for the Committee, and also identify experts.

Minorspecies

Alter the discussion regarding the need for documents for that topic, a working group wasformed, under the coordination by SINDAN, with the participation of there presentatives from Chile, Cuba, Ecuador and Uruguay, as well as industry representatives from ADIPRAVE, ALANAC, CEV, CLAMEVET and FENALCO.

Growth promoters

SINDAN shall convene a speaker for the next seminar, and coordinate a working group composed by representatives from Ecuador, the Cuban Center for Genetic Engineering and Biotechnology, and industry representatives from ADIPRAVE, ALANAC, ANVET, AVISA, CEV, CLAMEVET, and the Chamber of Agricultural Products of Costa Rica.

Bioequivalence Working Group

The group will be coordinated by CAPROVE, and will aim to prepare a technical guideline for the design of trials. The groups hall include representatives from Chile, Mexico, Peru and Uruguay, as well as ADIPRAVE, ALANAC, CEV, CLAMEVET, FENALCO and SINDAN.

Instruction guides for completing the harmonized CAMEVET forms for pharmaceutical and biological products

Dr Federico Luna, in representation of Argentina, proposed him self for the coordination of the Working Group, with the participation of Ecuador, and representatives of CAPROVE, CLAMEVET, SINDAN, and of Dr. Liliana Revolledo.

Labeling

Dr. Carlos Francia expressed the need for a document compiling the difficulties faced by the industry in terms of the different labeling requirements, which shall serve as a basis for assessing the need fort here vision of the harmonized document.

For that purpose, the Secretaria twill require the submission of the regulation spertaining to the labeling of veterinary products to the countries.

This document will be distributed 120 days before the celebration of the next seminar, only for information and with out requiring comments.

The Working Groups hall be coordinatedby CAPROVE and be formedby ALANAC, ANVET, AVISA, INFARVET/CANIFARMA, CLAMEVET, FENALCO and SINDAN.

Roundtable discussion: The present and future CAMEVET

Dr. Ofelia Flores, official representative of Mexico, stressed that the interest in CAMEVET is evident, given the continued and growing involvement of industry and the public sector in the annual meetings.

Dr. Carlos Francia mentioned that one of the needs for further progress in the Committee is to continue to develop the current and future strategic plans.

The formation of a Working Group with the role of drafting the CAMEVET Strategic Plan for the period 2015-2020 was proposed and approved. It shall comprise the official representatives of Argentina, Canada, Jamaica, Mexico, Paraguay and Uruguay, as well as representatives from ADIPRAVE, ALANAC, CEV and CLAMEVET.

The Working Group will make available a trilingual first draft within 180 days, which will be circulated for comments. In addition, the Secretariat will support the Working Group by asking each country to identify the three most important topics to be included in the Strategic Plan, with a deadline of 60 days for the submission of proposals.

It was commented that in some countries the register of veterinary products is under Health Ministry control for that reason, this kind of products moot be included in one Health concept.

Moreover, Dr. Argento added that the Committee's participation in international forums and the consideration of the opinions of the Committee are a sign of its increased visibility

The continuity in the participation in the activities of VICH was unanimously decided.

It was stated that technical documents are essentially guidelines, and the implementation is a decision of each country, so that each country must properly assess the risks, through the dialogue between the public sector and its industries, keeping the objective of raising the quality of our products to reach more markets.

Special emphasis was placed on activities to promote the creation and strengthening of networks among the sectors involved, maintaining common goals.

Another accepted proposal refers that future Seminars shall include the reports of meetings where CAMEVET members participate, and promoting the participation on behalf of the Committee.It was also requested that efforts be made in order to include the reference to the actions and achievements of CAMEVET in the presentation made by the OIE at the Codex Alimentarius meetings.

Communications

The improvement in communications from the Secretariat was highlighted, being a pending task the update of the contents of the website, hosted under the OIE Regional Representation for the Americas.

In this regard, Dr. Minassian made the clarifications, being resolved that a partial solution shall be the use of a public folder hosting the documents, so that interested parties can access them. The Secretariat shall communicate the way to access such folder, after its creation.

The need for a directory of contacts was raised, and the representatives of the Associations were required to communicate any updates in their authorities and contact details to the Secretariat.

Expenses report, financial state and 2012/2013budget

Resources available to September 24, 2013	40.690,00 USD
Income	
- Seminar registration XIX	30.000,00 USD

(USD 300 / participant)

Resources available at the end of the Seminar	70.690,00 USD	ARG 50,000.00

Budget for the financial year 2013 / 2014

Expenditures

Fixed expenses	8.400,00 USD
Variable expenses	
- Support Fund for Focal Points	3.000,00 USD
- Participation at meetings of the VICH	3.500,00 USD
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Composition of the Executive Board

According to the CAMEVET Rules, Dr. Glen Gifford shall take office as Chair of the Committee by the end of the current Seminar, being current office until the end of next Seminar. Moreover, Dr. Marvin Yohan Espinosa Vega shall take the position of Honorary member from the official sector, in terms of being able to capitalize on his experience and participate in the organization aspects of the next Seminar.

Venue for the next meeting

The proposal to hold the next seminar in Ottawa, Canada, between August 27 and 29, 2014, following the Workshop for OIE National Focal Points for Veterinary Products is accepted.

The register mode will include an obligatory on line phase.
This registration will be used to send the invitations on time to let the needed official waivers and the Canadian VISA

Secretary wills verity the assistants confirmation 60 days before the seminar, in order to inform the assistants number to the organization committee.
The “on line” assistants will have a differential fee. The people inscription out of time will pay a higher fee.

In addition, it was accepted the Guatemala proposal to organize 2015 Seminar

Annex:

1. Minute of the official sector meeting
2. Minute of the industry sector meeting
3. Harmonized Documents : Guideline for the registration of biotechnologically obtained veterinary products
4. Harmonized Documents: Control of vaccines for infectious bovine rhinotracheitis (IBR)
5. List of participants

Annex 1

Acta Sector Oficial

Países participantes:
Argentina, Belice, Bolivia, Canadá, Costa Rica, Cuba, Chile, El Salvador, Estados Unidos, Guatemala, México, Nicaragua, Panamá, Paraguay, Perú, Uruguay, Venezuela
El Dr. Marvin Vega da la bienvenida a los oficiales participantes.

Temas tratados

Períodos de restricción y ensayos de depleción de residuos
El representante de Costa Rica expuso las dificultades en Centroamérica para la implementación de normativas y otras regulaciones relativas a los ensayos de depleción de residuos para la comprobación de períodos de retiro, que el sector privado considera más exigentes que lo establecido por organismos como la Administración de Drogas y Alimentos de Estados Unidos de América (FDA) y la Comisión del Codex Alimentarius.
Al respecto, solicitó la opinión de expertos en el foro del CAMEVET para presentar las correspondientes aclaraciones respecto a la necesidad ineludible de realizar estudios de eliminación de residuos para cada producto en particular, y la imposibilidad de extrapolar estos resultados a partir de la información publicada para los principios activos. Asimismo, correspondería incluir en dicha aclaración el hecho que la Comisión del Codex Alimentarius no establece períodos de restricción, y que tanto la FDA como la Agencia Europea de Medicamentos (EMEA) sólo publican los períodos de restricción para las formulaciones registradas bajo su autoridad. Asimismo, ninguno de estos organismos reconocidos avala el establecimiento de períodos de restricción para principios activos sin relación a las formulaciones.
El representante de Cuba avaló lo comentado, indicando que estos ensayos deben realizarse para cada producto comercial.
Por otra parte, la representante de Guatemala indicó que el establecimiento de los períodos de restricción se realiza por molécula, utilizando la información provista por la FDA.

Guías de Buenas Prácticas de Manufactura (BPM)
Los representantes de Cuba, Paraguay, Perú,y Uruguay solicitaron que se plantee al foro la actualización de las guías de Buenas Prácticas de Manufactura para medicamentos veterinarios,armonizada en CAMEVET y que se trabaje en una guía para productos biológicos que tome en cuenta el Informe 32 de la OMS.
El representante de Cuba aclaró que en el CAMEVET ya se han armonizado dos documentos relativos a Buenas Prácticas de Manufactura, tanto para fármacos como para biológicos.
La representante de Argentina indicó con respecto a las BPM que se está exigiendo el uso de laboratorios certificados a las empresas con certificación, y que se está solicitando la realización de nuevos estudios de estabilidad para los productos en el caso de cambios en las plantas de fabricación. Por otra parte, apoyó la revisión y actualización de las Guías de BPM., en particular para polvos de administración oral. Asimismo, propuso que se trabajara en una guía de inspección para productos veterinarios ectoparasiticidas.

Certificados de Libre Venta

Expuso que debido a los actuales cambios administrativos se está llevando a cabo una revisión de los productos registrados, por lo quesolicitó conocer las reglamentaciones sobre los Certificados de Libre Venta.
Argentina comentó que correspondería que utilizaran el Certificado de Libre Venta armonizado en el CAMEVET, aclarando que existen disparidades a la hora de su aplicación.

Otros temas tratados
La representante de México propuso que las conclusiones de los Seminarios del CAMEVET sean propuestas para su inclusión en las reuniones del VICH.

Se concluyó que es importante conocer y aportar sobre la implementación e internalización de los documentos armonizados en el CAMEVETen los diferentes países.

Annex 2

Acta de la Reunión de la Industria Veterinaria

Se hace sentir una fuerte preocupación ante la exigencia del expendio de vacunas (biológicos) con receta, pues esto está ocasionando que las recetas sean vendidas lo que sumado al valor del producto como tal, desincentiva la compra de los mismos y por ende la aplicación, desfavoreciendo a los pequeños productores, quienes ante esta situación dejaran de hacerlo, lo que traerá como consecuencia el repunte de enfermedades. Se considera que esta figura de expendio de biológicos con receta, aplica para lo que es la clínica de animales de compañía, no así para los animales de producción, pues en este último caso se habla de poblaciones de animales en números grandes (hatos, parvadas etc.)

La industria Veterinaria solicita a CAMEVET recomiende sea revisada la aplicación del Reglamento Técnico Centro Americano (RTCA) de medicamentos veterinarios, pues al no haber criterios comunes entre las autoridades regulatorias, se está evidenciando una marcada discrecionalidad en la aplicación de este instrumentos, principalmente en lo que respecta al numeral (6I) cuyo uso se transforma e interpreta en obstáculo técnico al comercio (OTC-OMC). Sobre todo en el tema de las renovaciones, mismas que de acuerdo al reglamento vigente (RTCA) solo deben cumplirse determinados y muy puntuales requisitos, mas sin embargo renovar un producto debidamente registrado está llevando demasiado tiempo y los requisitos son los mismos que los que se solicitan para un producto nuevo. Esta situación está vulnerando la comercialización, desabastecimiento de mercados y atentando con el posible despido de personas y cierre de empresas.

Se solicita al CAMEVET, como ente integrado por el sector oficial y la industria, haga un llamado a los involucrados a propiciar el diálogo en aras de revisar los criterios normativos actualmente aplicados y generar conjuntamente nuevos que conlleven a la corrección de los artículos contenidos en el RTCA de medicamentos veterinarios que están causando las distorsiones.

Se hace hincapié que solamente a través del dialogo respetuosos entre las partes integrantes (sector oficial y privado) será posible llevar a buen término las actualizaciones necesarias en la normativa y por ende en la calidad de los productos.

La gradualidad y la correcta priorización en la aplicación de los nuevos requisitos es imprescindible para que el proceso sea viable dada la inexistencia de infraestructura y otros recursos necesarios para el complimiento de lo establecido.
Se solicita que el modelo CAMEVET de Dossier, sea aceptado en todos los países de la región, pues se ha evidenciado que en algunos, hay rechazos por su presentación, hay que considerar que el mismo ya fue debidamente aprobado en el seno del CAMEVET.

Nuevamente ROTULADO, esta es una situación que está causando graves problemas en los registros y renovaciones, pues se continúa con la discrecionalidad y la arbitrariedad de los funcionarios oficiales, consideramos que debe existir respecto a lo armonizado.

Es imprescindible que la OIE trabaje en la página Web de la oficina regional, para que todos podamos tener acceso a la misma, debido a que es una herramienta de vital importancia para llevar a cabo consultas tanto para el sector oficial como privado.

Se inste a un foro de información en Nicaragua, tendiente a desmitificar a las ivermectinas las mismas han demostrado ser una herramienta de mucha eficacia para el control de las parasitosis en la especies de destino, no obstante se han mitificado debido al mal uso que a las mismas les han dado los productores, con el consecuente castigo de su prohibición en Nicaragua y la probable misma tendencia en otros países.

Se quiere dejar constancia que la industria veterinaria, produce medicamentos de calidad terapéutica, lamentablemente el mal uso de las diversas especialidades por parte de los productores, ha provocado que de una forma muy directa se castigue a los laboratorios fabricantes, cuando verdaderamente es culpa de los productores al hacer mal uso de las herramientas terapéuticas y de control que se les brinda.

Annex 3

CAMEVET
Code:
PROCEDURE
Effective date

REGISTRATIONOF VETERINARY PRODUCTS

REGISTRATIONFORM FOR SUBUNIT IMMUNOGENS OBTAINED THROUGH BIOTECHNOLOGICAL PROCESSES

INTRODUCTION:

Subunit vaccines composed of semi-pure or purified proteins have been commercially available since the early1980s, with subunit components produced by recombinant DNA technology available since the 1990s (Cohen,1993; Rhodes et al., 1994; Ulmer et al., 1993; 1995). The latter have attracted growing interest and activity since that time. Subunit vaccines do not include live recombinant vector technologies, which provide the delivery ofrecombinant proteins in vivo. The field of genomics and related areas has revolutionized the manner in whichmicrobial antigens are identified. Since the first bacterial genome was sequenced in 1995, there has been a hugeincrease in the number of bacterial, viral, and parasite genomes for which genome sequences are available.

Indeed, virtually all pathogens of animals are represented and those pathogens that are not can readily beobtained in less than a day. More importantly, the development of the bioinformatics resources and tools that arerequired to analyze these genomes has proceeded in parallel and it is now relatively easy to identify surfaceexposedantigens, specific B- and T-cell epitopes, etc. There is no requirement to have the ability to grow theorganism in culture.

The production of subunit antigens can be achieved by both conventional biochemical or recombinant DNAtechnologies. The latter involves a range of prokaryotic and eukaryotic expression systems including yeast, insectcell and plants (Chichester&Yusibov, 2007) by means of a variety of integrated or transient expressionstrategies. Biochemical techniques remain useful in some cases where recombinant expression is not appropriate,such as antigens requiring complex assembly (e.g. fimbriae), or when post-translational modification is necessary.

Subunit vaccines could have some advantages over live attenuated and inactivated vaccines, including the abilityto induce strong humoral and cell-mediated immune response. The vaccines furthermore have an excellent safetyprofile, and can be used in combination with other subunit vaccines.One of the biggest advantages of subunit vaccines is that they are generally compatible with DIVA(Differentiating Infected from Vaccinated Animals) strategies aslong as the antigen is not being used as a marker.

The current guideline aims at enabling the registration process of subunit immunogens, obtained through biotechnological processes, for CAMEVET countries.

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REGISTRATION FORM FOR SUBUNIT IMMUNOGENS OBTAINED THROUGHBIOTECHNOLOGICAL PROCESSES
DATE:

1. - PRODUCT COMMERCIAL NAME

2. – CLASSIFICATION - GENERIC NAME(Exclusive official use)

3.-APPLICANT BUSINESS ESTABLISHMENT: PROPRIETOR/ LEGAL REPRESENTATIVE

3.1.Name:
3.2. Commercial domicile(Street – City– Country):
3.3. Official filling out authorization Nº:
3.4. Technical person in charge:
3.4.1 Profession:
3.4.2 Professional identification Nº (Registration number or Record):

4. – MANUFACTURING ESTABLISHMENT(for products processed in the country)

4.1 Name:
4.2 Commercial domicile(Street – City – Country):
4.3 Officialfilling out authorizationNº:
4.4 Technical person in charge:
4.4.1 Profession:
4.4.2 Professional identification Nº (Registration number or Record):

In case several manufacturers are involved in the manufacture of the immunogen, all of themshall be listedwith the same piece of information and the main manufacturer shall be declared.(defined by the contract between the manufacturers or the holder who submit the product for registration).

5. - ORIGINMANUFACTURING ESTABLISHMENT (for importedproducts)

5.1 Name:
5.2 Commercial domicile(Street – City – Country):
5.3 Official filling out authorization Nº:
5.4 Technical person in charge:
5.4.1 Profession:
5.4.2 Professional identification Nº (Registration number or Record):

In case several manufacturers are involved in the manufacture of the immunogen, all of themshall be listedwith the same piece of information and the main manufacturer shall be declared.(defined by the contract between the manufacturers or the holder who submit the product for registration).

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6.-LEGAL DOCUMENTS

6.1 Manufacture Agreement/s.
6.2 Manufacturer Representation Agreement in origin.
6.3 Certificate of Authorization of the Manufacturing Establishment.
6.3.1. Habilitation Certificates from other manufacturers of the product (where applicable).
6.4 For imported products: Certificate of Registration and Free Sale (CAMEVET form) or equivalent documentation, sent by the authorities in the country of origin or in their default Manufacture Authorization (Export Certificate)and explanation of the reasons why it is not commercialized in that country.
6.5 Trademark Registration Certificate in the country of origin for products that are not generic or common international denomination. (In accordance to the regulations established in each country)

7. - BIOLOGICAL LINE DEFINITION

7.1 Chemical and/or biological designationof the active principles.

8. –PHARMACEUTICAL FORM

9.-QUALITATIVE-QUANTITATIVE FORMULA - BIOLOGICAL AND CHEMICAL CONSTITUTION

9.1 Formula of representative batch by dose: Active Pharmaceutical Ingredient (s), adjuvants,excipients, diluents, others.

10. –SPECIFICATIONS AND CONTROL METHODS OF THE COMPONENTS OF THE FORMULA

10.1Active principle.

10.1.1 General information.

10.1.1.1 Physical form.

10.1.1.2 Structural formula. (Sequence)

Inclusion in the case of proteins the conformational structure data.

10.1.1. 3Relative molecular mass.

10.1.1.4 pH.
10.1.1.5Structural evidences of the active ingredient.
Include comparison data with the natural or reference form whenever possible.
10.1.1.6 Biological, immunologic, and physical - chemical characterization.
10.1.1.7Expression of the potency or Biological Activity.
In case the potency is shown in units, the unit shall be defined.

10.1.2 Genetic development.
10.1.2.1 Gene of interest: Name, origin, strategy of isolation, construction, sequence,rationality for the selection of the gene.

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10.1.2.2 Description of the origin strain or cellular line: Name, origin, history,

Identification characteristics andextraneous agents testing

10.1.2.2.1Preparation of the production strain (or cellular line).

10.1.2.2.2Construction of the expression vector: Name and origin.

10.1.2.2.3Description of the production strain and/or cellular line.

Biological properties of the elements found in the final formulation.

10.1.2.2.4 Genetic stability during the storage and conservation and during production.

10.1.3Cell Bank Systems.

10.1.3.1Preparation and description of the Master Cell Bank (MCB).

Identification of the MCB. Indicate details of the number of vials, volume and estimated duration of the MCB, as well as storage conditions.

10.1.3.2 Preparation of the subsequent Work Cell Bank (WCB) from the MCB (Acceptance criteria).

Identification of the WCB. Indicate details of the number of vials, volume and estimated duration of the WCB, as well as storage conditions.

10.1.3.3 Routine control methods of the MCB and of the WCB.

Tests carried out for the quality control of the cell banks. Expected results. Frequencyof testing.Justification of the quality control methods in the case of mammalian cells.

11. METHODS OF PRODUCT MANUFACTURE

11.1 Active principle(s).

11.1.1 Description of the process of obtaining of the active principle(s), Fermentation and harvest (expression in bacteria, yeasts) culture cells, animals or plants asbioreactors.

11.1.1.1 Name of the production site(s). Refer to all the sites where all active ingredients are produced.

11.1.1.2Definition of the production batch. (Include details of the production scale: minimum volume, maximum volume, average volume)

11.1.1.3 Flowchart. (Process description)

11.1.1.4 Storage and conservation of the intermediate harvests.

11.1.1.5 Process controls including the acceptance criteria of every harvest.

11.1.2 Purification.

11.1.2.1 Name of the site(s) of purification.

11.1.2.2 Definition of a batch (Include details of the production scale: minimum volume, maximum volume, average volume).

11.1.2.3 Flowchart.

11.1.2.4 Storage of the intermediate products.
Conditions and duration.

11.1.2.5 Process controls.

11.1.2.6 Reprocessing criteria.

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(Reprocessing criteria of every purification step)
11.1.2.7Control of the materials used in the process.
11.1.2.8 Control of the critical points and intermediate products.

11.1.3 Impurities and/or contaminants.
11.1.3.1 Detection andidentificationof impurities (Quality control methods, quantification and specification limit).
11.1.3.2 Other considerations (Inactivation methods and determination ofnonviability).

11.1.4 Quality Controlsof the Active Principle.
11.1.4.1 Specification.
11.1.4.2 Analytical procedures.
11.1.4.2.1 Validation of the analytical procedures.
11.1.4 3 Analyses of the batches. Production consistency.
11.1.4.4 Reference Materials.
11.1.4.4.1 Primary Reference Material.
11.1.4.4.2 Working Reference Materials.
11.1.5 Characteristics of thepacking materials.
11.1.6 Stability.
11.1.6.1 Accelerated stability studies.
11.1.6.2 Real-time stability studies.
11.1.7 Proposal of storage conditions and retest periods.
11.2 Final Product.
11.2.1 Name of the site(s) of production(includes all the manufacturers of the Final Product).
11.2.2 Productive process. Description.
11.2.2.1 Preparation of the formulation system.
11.2.2.2Formulation. Composition by size of the formulation batch. (Maximum batch size, minimum batch size, average batch size)
11.2.2.3 Filling.
11.2.2.4 Labeling and packaging.
11.2.2.5 Process description. Flowchart.
11.2.2.6 Controls during the process.
11.2.2.7 Quality Control of Excipients.
11.2.2.7.1 Specifications.
11.2.2.7.2 Analytical procedures and their validation.
11.3 Risks in product manufacturing process.
11.3.1 Describe the procedures used to eliminate possible risk factors for human/animal health and the environment during the product manufacturing process.

12. - CONTROL METHODS OF THE FINISHED PRODUCT

12.1Specifications.
12.2 Analytical procedures.

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12.2.1 General physical-chemical and microbiological requirements.
12.2.2 Safety. Innocuousness control.
12.2.2.1 Type of test and species.
12.2.3 Control of immunologicaleffectiveness and potency.
12.2.3.1 Type of method and species.
12.2.4 Validation.
12.2.5 Analysis of the batches. Production consistency.

13- WAY OF PRESENTATION AND CONTENT

(General descriptions of multi-pack boxes, clamshell packaging, etcetera)

14. - SPECIFICATION AND CONTROL OF PACKAGES

14.1 Characteristics of the package.
14.2 Packaging security. Tamper-proof features.
14.3 Quality control of packages.
14.4 Description of the batch key.

15.- STABILITY STUDIES

Enclose the stability and galenicdevelopment studies of the product that justify the declared period of validity.

16.-PERIOD OF VALIDITY (Expiration)

16.1 Period of validity of the final product.
16.2 In case ofmultidoseproducts, period of validity once the package has been opened.
16.3 For products administered in drinking water, stability, compatibility and the period of time of its effectiveness in the solution shall be indicated.
16.4The maximum use timeshall be indicated after their preparation or reconstitution.Attach the stability and clinical studies of product development to support the stated expiration date.

17. –SAFETY AND EFFICACY TESTS

17.1 Animal safety studies in the target species.
17.2 Efficacy studies.
17.2.1 Efficacy in the animal model.
17.2.2 Studies for determination of the doses.
17.2.3 Optimum dose studies.
17.2.4 Challenge studies.
17.3 Clinical field studies (Phase III)
17.3.1 Clinical Studies Reports.
17.4 Additional studies to establish the efficacy.
17.5 Pharmacovigilance data (Reportsonphases I, II and III).

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18. - INDICATIONS FOR USAGEAND COMMERCIALIZATION CATEGORY

18.1. Main and/or complementary indications(if applicable).
18.2. Target animal species.

19. - ROUTE OF ADMINISTRATION andUSE OF THE PRODUCT

Parenteral, oral, dermal, pulverization, scarification, ocular, nasal or others.

20. - DOSAGE

20.1 Dose of the product in preventive or curative application bybody weight according to species and age.
20.2 Recommended application schedule.
20.3 Necessary time to onset of immunity and its duration.

21.- POSSIBLE ADVERSEEFFECTS (Local and/or general), INCOMPATIBILITIES AND ANTAGONISMS

21.1 Contraindications and use limitations (cases in which its administration could give place to harmful effects).
21.2 Precautions that must be adopted before, during or after its administration.
21.3 Warnings.

22. –WITHDRAWAL PERIOD

Provide details in case of meat, milk, and eggs, when appropriate.

23. - GENERAL PRECAUTIONS

23.1 Maximum and minimum temperature limit for its correct conservation.
23.2 Describe the suitable way of storage, transportation and destruction of the product, as well as the method of elimination of the packages that constitute a risk factor for the public health, animal health and the environment.
23.3 Precautions for technicians, trained personnel, and veterinarians when administering theimmunogen.

24. – LABELSAND LEAFLETS - GRAPHICLETTERING PROJECT

25. - SCIENTIFIC WORKS AND/OR MONOGRAPHS

The scientific works and/or monographs related to the product should be enclosed.
The translation of the abstract and the conclusions of the above-mentioned works in the corresponding official language should be included.

26. - OBSERVATIONS

27. - AUTHORIZED SIGNATURESAND DATE

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Annex 4

C A M E V E T
Cod: 000
TRÁMITE III

DATE: September 27th, 2013

POTENCY for bovine vaccines containing bovineherpesvirus 1 (BoHV-1) causal agent of the InfectiousBovineRhinotracheitis (IBR)

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POTENCY for bovine inactivated vaccines containing Bovine herpesvirus 1 (BoHV-1) causal agent of the Infectious Bovine Rhinotracheitis (IBR)

1. INTRODUCTION

Bovine herpesvirus 1 (BoHV-1) is the etiological agent of the infectious bovine rhinotracheitis/ infectious pustularvulvovaginitis (IBR/IPV), disease of the domestic and wild cattle that causes a wide range of clinical signs including rhinotracheitis, vulvovaginitis, infectious pustularbalanoposthitis, conjunctivitis, abortion, enteritis and encephalitis (1, 2, 3).

After respiratory and genital infections, BoHV-1 becomes latent in the neural ganglia. Stress can induce reactivation of the latent infection and virus may be shed intermittently (1, 3).

Infection elicits an antibody response and a cell-mediated immune response within 7-10 days. Neutralizing antibodies may persist 5 years after infection, but re-stimulations (reactivation or vaccination) are needed to keep titers at detectable levels by viral neutralization technique. On the contrary, total antibodies, evaluated by ELISA, remain detectable for life (24).

In general, vaccines prevent the development of severe clinical symptoms and reduce the shedding of virus after infection, but they do not prevent infection. Several eradication campaigns with and without vaccination (mandatory and/or voluntary) are being carried out in Europe. Norway, Finland, Sweden, Austria, Denmark, Switzerland and various regions of Italy and Germany had eradicated the infection (1,7). In the rest of the world, infection is endemic and with high prevalence (8, 9, 10, 11).

Various attenuated and inactivated BoHV-1 vaccines are currently available in the region.In Argentina and Uruguay, the only authorized vaccines are inactivated ones.Vaccines contain strains of the virus, generally replicated during multiple passages in cell culture.Inactivated vaccines contain high levels of inactivated virus or portions of the virus particle (glycoproteins) supplemented with an adjuvant to stimulate an adequate immune response.Inactivated vaccines are administered intramuscularly or subcutaneously. Marker or DIVA (Differentiating Infected from Vaccinated Animals) vaccines are now available in various countries.These marker vaccines are based on deletion mutants or in a subunit of the virion, for example, glycoprotein E (12). This type of vaccines is used in Europe in countries that carry out eradication programs with vaccination campaigns (1,7). In endemic countries, intensive vaccination programs may reduce prevalence of infected animals (1).

For the approval of vaccines containing IBR, international control organisms (APHIS, USA; EMEA-CVMP, UE; OIE; VICH) (1, 2, 13, 14) require potency and efficacy assays in the target species, which imply vaccination and challenge of susceptible and seronegative bovines. Once the product is approved, the quality of each batch to be released must be controlled by a potency test that determines product immunogenicity in bovines or other laboratory animal model (*in vivo* test). Some agencies, for example the CVB, USDA allow*in vitro* potency tests using a parallel line assay and a validated reference vaccine [Title 9, Code

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of Federal Regulations (9 CFR) 113.8(a)(3)(ii)]. The *in vitro* potency test must be statistically validated and show an acceptable agreement when compared to the potency test in the target species. It is also strongly desirable that the model be validated as a predictive tool of the degree of protection that the vaccine will provide against the viral shed in seronegative bovines. Due to the unavailability of seronegative bovines and the high cost of immunogenicity tests in the natural host, this potency and efficacy test cannot be carried out routinely in the target species. Therefore, it was decided to develop and validate a standardized test in laboratory animals (guinea pigs) that can assess potency of each vaccine batch, guaranteeing the presence of standardized and efficient products in the marketplace.

Regarding animal health, international organisms encourage the development of *in vitro* tests, to avoid and reduce to the minimum the use of animals for experimental control tests.In the particular case of these vaccines, simple or combined and inactivated, the application of these techniques is possible and it is worth exploring them. However, given the disadvantage that each formulation (group of inactivated antigens and adjuvant, vaccines in subunits and DNA vaccines) needs to be standardized, an *in vivo* test is still considered inevitable to assess potency of these products (17).

2. POTENCY CONTROL IN GUINEA PIGS: AIMS

In the guinea pig model, though it´s an *in vivo* assay, the number of animals employed (n= 6 per vaccine and 4 witnesses/placebos) and the amount of blood extractions is reduced to the minimum.Guinea pigs, unlike other laboratory animals such as rats, have the advantage of being bigger in size, thus allowing paired serum sampling without risking their lives. Furthermore, with the volume of sample obtained, the quality of all viral antigens contained in polyvalent vaccines can be assessed. In some cases, such vaccines can contain 4 strains of these 5 agents: Bovine herpesvirus, bovine viral diarrhea virus, respiratory syncytial virus, parainfluenza virus type 3, bovine rotavirus.Some vaccines to prevent bovine neonatal diarrheas also include bovine coronavirus in their formulation.

Finally, serological evaluation is independent from the type of adjuvant (oil or water) and from the amount and quality of inactivated viruses contained in the formulation.

Guinea pig model: background

The trial assay for viral vaccines in guinea pig is based on the immunization of 6 guinea pigs in two doses of vaccine (with a 21 day interval), applied subcutaneously, of a volume equal to 1/5 the bovine dose.Animals are also kept under study during a minimum of 30 days.Serum samples are taken at the time of the first vaccine dose (0 days post-vaccination) and 9 days post-revaccination.Together with the assessment of unknown vaccine(s) (n=6), two groups of guinea pigs are included, one vaccinated with the reference vaccine of known potency (n=6) and the unvaccinated control group.Thirty days after the beginning of control, vaccinated animals are bled and a serological control by ELISA and viral neutralization is performed.It is worth mentioning that guinea pigs are a BoHV-1 free

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species, so they are naturally seronegative to antibodies (Ab) against this viral agent.

Based on the results obtained since 2008, where all guinea pig serums obtained at the beginning of the test were negative, we can recommend annual control of the reproductive animals of the colony, eliminating likewise initial sampling of the animals, sampling the vaccinated and control groups only at the end of the test (30 dpv).

Validation of the guinea pig model for IBR strain, based on a linear regression analysis of the Ab titers determined by ELISA and viral neutralization (VN), indicated a dose-response relationship to the BoHV-1 antigen concentration in the vaccine in bovines and guinea pigs (dose-response assay).The guinea pig model was able to discriminate between vaccines containing 1 $\log_{10}$ difference in its Ag concentration, both by ELISA and VN.Based on the results obtained in the dose-response curve, cut-offs or ranges of Ab titers anti-BoHV were estimated. These allow vaccines to be differentiated by the immunogenicity induced in guinea pigs and bovines. Two cut offs and three categories were established by ELISA (Table 1) and VN (Table 2). Finally, representative vaccines of each category were assessed in an experimental challenge test with IBR in seronegative bovines and the relation between Ab titer in guinea pigs and bovines and the degree of protection against infection was established (18).

SPECIES	VACCINE POTENCY ELISA		
	NON SATISFACTORY	SATISFACTORY	VERY SATISFACTORY
GUINEA PIG	$\bar{y} < 1.93$	$1.93 \leq \bar{y} < 3.02$	$3.02 \leq \bar{y}$
BOVINE	$\bar{Y} < 1.69$	$1.69 \leq \bar{Y} < 2.72$	$2.72 \leq \bar{Y}$

Table 1. Cut offs determined by ELISA expressed as the log10 of the reciprocal of the analyzed serum dilution that results positive in the assay. Mean Ab titer of groups of 5 guinea pigs, evaluated 30 days post vaccination (dpv) and groups of 5 seronegative bovines evaluated 60 dpv. Bovines receive two doses of vaccine with a 30-day interval ,following vaccine manufacter´s recommendations,and are sampled at 0 and 60 dpv. This latter point corresponded to the peak or plateau of Ab titers reached by aqueous or oil vaccines, respectively.Guinea pigs receive two doses of vaccine (1/5 the volume of the bovine dose) with a 21-days interval and are sampled at 0 and 30 dpv. The two dose regimen chosen in the lab animal model allow detecting the immune response induced by vaccines of low potency. The 21 interval between doses was adopted in order to obtain a curve of Ab kinetic response similar to that obtained in bovines, but in a shorter period of time providing a faster alternative method for vaccine potency testing than the one conducted in bovines.

Ab titers determined by ELISA as higher than 3.02 in guinea pigs and 2.72 in bovines were associated to very satisfactory potency vaccines. Vaccines inducing Ab titers between 3.02 – 1.93 in guinea pigs and 2.72 – 1.69 in bovines resulted satisfactory (18).Whereas, vaccines which induced Ab titers lower than 1.93 in guinea pigs and 1.69 in bovines were considered non satisfactory for commercialization.

SPECIES	VACCINES POTENCY viral neutralization (VN)		
	NON SATISFACTORY	SATISFACTORY	VERY SATISFACTORY

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GUINEA PIG	$\bar{y} < 1.31$	$1.31 \leq \bar{y} < 2.05$	$2.05 \leq \bar{y}$
BOVINE	$\bar{Y} < 1.27$	$1.27 \leq \bar{Y} < 1.96$	$1.96 \leq \bar{Y}$

Table 2. Cut offs determined by VN expressed as Ab neutralizing titers calculated by the Reed and Muench method.Mean Ab titer of groups of 5 guinea pigs, evaluated 30 days post vaccination (dpv) and groups of 5 seronegative bovines evaluated 60 dpv. Bovines receive two doses of vaccine with a 30-day interval, and are sampled at 0 and 60 dpv.Guinea pigs receive two doses of vaccine (1/5 the volume of the bovine dose) with a 21-days interval and are sampled at 0 and 30 dpv.

Neutralizing Ab titers higher than 2.05 in guinea pigs and 1.96 in bovines were associated to very satisfactory potency vaccines.Vaccines inducing Ab titers between 2.05 – 1.31 in guinea pigs and 1.96 – 1.27 in bovines resulted satisfactory.Whereas, vaccines which induced Ab titers lower than 1.31 in guinea pigs and 1.27 in bovines were considered non satisfactory and therefore unsuitable for commercialization.

Either by ELISA or VN, vaccines classified as very satisfactory or satisfactory comply with the requirements established by the American 9.CFR, USA and the OIE Manual of diagnostic tests and vaccines of terrestrial animals for approval. Regarding protection against infection, a reduction of 1/100 or higher of the titer of infectious virus shed by vaccinated animals as compared to the titer shed by unvaccinated controls is requested. In the challenge assay performed with representative vaccines of the very satisfactory and satisfactory categories, in animals vaccinated with both vaccines, the amount of virus shed is significantly reduced when compared to control.Furthermore, virus shed by animals vaccinated with a very satisfactory vaccine was significantly lower than the one shed by the group receiving the satisfactory vaccine. In relation to the duration of clinical signs, the OIE demands a reduction of at least three or more days, with respect to the duration of the disease in controls. This requirement was only fulfilled by the very satisfactory vaccine.However, when more appropriate measurements are used to assess the disease, such as the area under the curve which considers severity and duration of clinical symptoms, both vaccine categories significantly reduce the signs of the disease.

Following this criterion, in order to evaluate agreement between bovines and the guinea pig model, 63 parallel trials were carried out in both species which included the calibration vaccines used in the dose-response assay, groups inoculated with placebo, unvaccinated groups and 22 commercial vaccines of unknown quality. Concordance was estimated by the kappa coefficient and results were (K)=0.894; ASE = 0.041; 95% CI 0.813–0.974; $p < 0.0001$, for Ab determined by ELISA and K=0.876, ASE = 0.050; 95%CI 0.777–0.971; $p < 0.0001$, for neutralizing Ab.This indicates a very good agreement between the potency estimated for the guinea pig model and the one obtained in the target species (19).

The guinea pig model succeeded in adequately predicting not only vaccines immunogenicity, but also the efficacy grade when experimentally challenged in bovines. The proposed test does not need complex technology nor infrastructure, just an animal facility with guinea pigs and common serological techniques (ELISA, VN) of routine use in virology laboratories, appropriately harmonized with international norms (9CFR, OIE, EMEA) and preferably validated following norms ISO-IEC 17025 (20, 21, 22, 23).

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Validation criterion for guinea pig testing

Potency testing in guinea pigs is considered valid when the mean Ab titer obtained from animals vaccinated with a reference vaccine results to be the expected value (24), and unvaccinated control animals (controls) remain seronegative for Ab against BoHV-1 throughout the experience.

Vaccine approval criterion by potency testing in guinea pigs.**a) ELISA**

All serums of animals immunized with a control vaccine will be evaluated. FIVE (5) serums with the highest titers obtained will be selected and an average will be calculated on that basis.For the **APPROVAL** of the vaccine submitted to control, mean Ab titers at 30 dpv must be higher or the same as **1.93** for ELISA technique for BoHV-1.

b) VIRAL NEUTRALIZATION

All serums of guinea pigs immunized with the vaccine submitted to control will be evaluated.FIVE (5) serums with the highest titers obtained will be selected and an average will be calculated on that basis.For **APPROVAL** of the vaccine submitted to control, mean Ab titers at 30 dpv must be higher or the same as **1.31** for VN technique for BoHV-1.

Harmonization of assays for the region

A positive and negative control serum panel and reference vaccines will be elaborated and made available for regional users to harmonize the results obtained for each assay laboratory adopting the control method. Local reference serums (from guinea pigs and bovines) will be traceable in the described techniques to European reference bovine serums (EU1, EU2 y EU3) provided by OIE Reference Laboratories.

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POTENCY TESTING FOR IBR IN GUINEA PIGS **Guinea pig conditions.** Animals must be more than 30 days old and weight 400 grams ± 50 grams. For each batch under control, at least SIX (6) GUINEA PIGS will be vaccinated. Males and females may be used but each group must contain animals of the same sex.

Animal quarantine. Animals will have an adaptation period of SEVEN (7) days, at least, after entering the inoculation room.

Vaccine inoculation. A vaccine of 1/5 the volume of the bovine dose is applied subcutaneously.

Blood extraction to obtain serum samples. It can be collected by cardiac puncture, jugular vein or auricular vein, without anticoagulant. Samples are clarified by centrifugation, fractioned in 500 ul aliquots and stored at -20ºC until analysis. Sample identification: label with date, protocol number, vaccine ID, guinea pig number, DPV time.

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SEROLOGICAL CONTROLS FOR POTENCY TEST IN GUINEA PIGS *ELISA ASSAY FOR THE DETECTION OF ANTIBODIES AGAINST IBR*

A validated indirect ELISA is used to detect antibodies anti-BoHV-1 (20). Briefly, plates are sensitized with BoHV-1 virus, obtained from infected MDBK cells (positive well) or MDBK cells as negative control of infection (negative well). Optical density of virus and uninfected cells to sensitize plates is determined by crossed titration for each batch produced and it is constant for all the plate. Serums are assayed in both wells (+ and -) in 6 serial 4 fold dilutions starting from a minimum dilution of 1/40. The assay is developed using an Ab anti IgG (H+L) from guinea pig marked with peroxide as detection antibody. H_2O_2/ABTS is used as chromogen substrate system and reading is performed by an ELISA reader at 405 nm.

REAGENTS

- **Plates sensitization buffer (carbonate/bicarbonate) pH 9.6.**

Na_2CO_3 0.159 g.
$NaHCO_3$ 0.293 g. Distilled water q.s. 100 ml.
Adjust pH with NaOH/ HCl 1 N Store at 4º C (1-8º C).

- **Citric Acid Buffer pH 5.0**

Citric acid monohydrate 0.960 grs.
NaOH1N aprox. 10 ml to reach pH 5.0
Distilled water q.s. 100 ml.
Adjust pH to: 5.0 ±0.5 with Na(OH) or HCl 1N. Store at 4º C (1-8º C).

- **ABTS mother solution**

ABTS 0.22 g.
Citric acid buffer 10 ml.
Aliquote 1 ml. in plastic tubes.
Store at –20 ± 5º C.

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- **Revealing solution ABTS**

ABTS mother solution 300 ul.
Citric acid buffer pH5 10 ml.
Hydrogenperoxide 30 volume (H_2O_2) 10 ul.

- **Stop solution: SDS** (sodium dodecyl sulfate/ sodium laurilsulfate) in 5% water.Store at room temperature.

- **Wash buffer** (PBS, pH 7.4- $Tween_{20}$ 0.05%)

PBS pH 7.4 1000 ml.
$Tween_{20}$ 500 iL.

- **Blocking Buffer and diluent**.PBS/Tween20 0.05%/OVA 1%, pH 7.4

$Tween_{20}$ 500 ul.
PBS 1X 1000 ml.
Ovalbumin 10 g.
Aliquote 50 ml in plastic tubes.Store at –20 ± 5º C.

REAGENTS FOR SENSITIZATION

Positive capture control – Antigen: Preparation based on MDBK cell cultures infected with BoHV-1 reference strain.
Negative capture control:Preparation based on MDBK cell cultures.

Conjugated detection antibody Anti-IgG conjugate marked with peroxidase. The following can be used:Affinity purified goat anti- Guinea Pig Ig G (H+L) peroxidase labeled, KPL, cat.# 14-17-06.Peroxidase- conjugated affiniPure Goat anti-guinea pig IgG (H+L), Jackson, cat. # 106-035-003Note:Conjugates from other suppliers or produced in-house previously verified/ validated as optimal for ELISA assay can be used after corresponding titration with reference serums.

CONTROLS
Guinea pig positive control: Serum pool of 5 guinea pigs vaccinated with two doses of vaccine containing 10^7 $DICT_{50}$/ml of BoHV-1 in oil adjuvant (Reference Vaccine). Assays will be accepted when positive controls fall within the mean value ± 1 standard deviation (SD).

Mean value of corrected absorbance ± 1 SD = 0.520 ≤ 0.740 ≤ 0.960

The given serum, analyzed by seroneutralization must show an anti BoHV-1 neutralizing antibodies titer between 2.4 and 3.0 (Titer expressed using the Reed and Muench method). ***Guinea pig negative control:*** Guinea pig serum whose corrected absorbance in the dilution used results minor to technique cut off (40% corrected absorbance of positive control).
Reagent blank:PBS.For each control, 4 wells are used (two positive captures and its two corresponding negative captures)Also, it is advisable to include in each assay a positive sample of known titer and another negative sample (internal standard serums). These samples are randomly set in different places in at least two assay plates and run in all assays.

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ELISA PROCEDURE:

Plates coating

2. **Perform the dilution used for the antigen and its negative capture control in coating buffer, pH 9.6.Use 96-wells ELISA plates "immulon 1b type". Place 50øl of antigen in rows B-D-F-H and 50øl of negative capture in rows A-C-E-G. Incubate during 17 hours ±2 h., between 4º C and 8º C.**
3. **Discard the content of the plate. Wash 3 times with wash buffer (PBS/Tween$_{20}$ 0.05 %, pH 7.4)**
4. **Add 100 ul/well of blocking buffer (PBS Tween$_{20}$ 0.05%/OVA 10%, pH 7.4).Incubate in humid chamber for 1 hour, at 37º C.**
5. **Next, discard blocking buffer, wash 3 times and either proceed with the assay or save the plate at -20ºC, for 30 days maximum.**

Dilution and setting of samples **For the dilution of samples, the use of 96-wells culture plates is recommended.Place 195 ul of blocking buffer in column 1 and 7 and 150 ul in the remaining columns. Add 5 ul of serums to be analyzed and place them in pairs of wells 1 AB, 1 CD, 1 EF, 1 GH, 7 CD, 7 EF, 7 Gh (initial serum dilution 1/40). 7 samples fit per plate.Wells 7-12 AB are to assay controls. Carry out 4 fold dilutions transferring 50 ul from 1-6; discard tips. Using new tips carry out dilutions of 7-12.**

9. **Transfer 50 ul of each dilution performed to the reaction plate starting with the most diluted dilution to the most concentrated one.**

Dilution and setting of controls

10. **ELISA kit will be provided with standardized controls prepared in the following way: Place 200 ul of diluent (PBS Tween$_{20}$ Ova 10% pH 7.4) in two tubes and 4ul of positive control serum in one of the tubes and 4ul of negative control serum in the other. Homogenize.**
11. **Add 50 ul of the positive control dilution in wells A7 B7 A8 and B8 and 50 ul of negative control dilution in wells A9 B9 A10 and B10 and add 50 ul of PBS Tween20 Ova 10% pH 7.4 in wells A11 B11 A12 and B12 (Reagent blank). Incubate in humid chamber during 1 h. at 37º C .**
12. **Discard content of the plate.Wash 4 times.Dry.**
13. **In a tube containing 5000 ul of diluent add the corresponding quantity of conjugated antibody following the dilution used. Add 50 ul per well in all the plate.Incubate in humid chamber during 1 hour, at 37º C.**

14. **Discard the content of the plate. Wash 5 times. Dry.**

Development, Reading and Interpretation

15. **Prepare 5 ml of developing solution.Add 50 ul of developing solution in each well and wait between 10 and 15 minutes with the plate in darkness.Read the assay at 405 nm to control that the positive control reaches the optical density expected in the established time range.**

16. **Stop reaction adding 50 ul of stop solution (SDS 5%) in all plate wells and read. Transferreading data to a calculationsheet.**

17. **Substract each absorbance of the negative captures from their respective positive captures.(Example:H1 minus G1= ODc (Corrected optical densities).**

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18. **Calculate the mean of ODc of the positive control (100% PP).**

19. **Calculate the PP% of each sample in each dilution [PP = (ODc sample / ODc Positive Control)*100]**

20. **Calculate the mean of the replicates of the negative control and its PP%.**

ASSAY ACCEPTANCE (CONFORMITY)

The following described criteria will be applied individually to each plate.

- **An assay plate is accepted when ODc of the positive control is within the established range: 0.520 - 0.960. Negative control and reagents blank show PP% lower to assay cut-off (40%PP). Positive reference serum titer results in the expected value +/- a 4 fold dilution (error of the method).**

- **Antibodies titer of a sample is established as the reciprocal of the maximum dilution, whose PP% is higher or the same as the assay cut-off (40%PP).**

RESULTS REPORT OF IMMUNOGENIC QUALITY OF IBR VACCINES TESTED IN GUINEA PIGS AND SERUMS EVALUATED BY ELISA.

Results can be interpreted and used to classify a vaccine in the guinea pig model by ELISA only if the ELISA assay has been accepted and you count with a minimum of 5 animals with results to estimate the mean Ab titer induced by the vaccine.

To validate the assay, serums of guinea pigs immunized with the reference vaccine must result in a mean titer within the established range determined by a control chart which shows the mean value ± 2 standard deviations obtained from a minimum of 5 tests.

For the vaccine under evaluation, the mean antibody titer anti-BoHV-1 detected by ELISA as the average of the titers of 5 animals is informed (log10 of the reciprocal of the maximum dilution whose percentage of positivity is higher or the same as the assay cut off, established as higher or the same as 40% of the positive control). Negative samples in the minimum serum dilution assayed (1/40) are expressed as an arbitrary titer of 0.3 for calculation purposes.

VIRAL NEUTRALIZATION ASSAY TO DETERMINE AB FOR IBR

REAGENTS

Virus used: BoHV-1 Los Angeles (LA) reference strain or native BoHV-1 virus strain.Diluted so as to contain 100 tissue culture infectious dose 50% ($DICT_{50}$).

Controls: ***Guinea pig positive control:*** Serum pool of 5 guinea pigs vaccinated with two doses of vaccine formulated with 10^7 $DICT_{50}$/ml of BoHV-1 in oil adjuvant (Reference Vaccine) with a neutralizing Ab titer of 2.4-3.0.

Guinea pig negative control:Normal guinea pig serum pool (pre-immunized guinea pig serums or unvaccinated controls).

Positive standard:Immunized guinea pig serum, with known VN Abtiter.***Negative standard:*** Normal guinea pig serum.

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Cell suspension: A cell suspension of MDBK line containing 200.000-250.000 cel/ml is used.

Samples inactivation: Before being used in a VN assay, serum samples, including assay controls, must be heat at water bath at 56 ± 3º C, during 30 ± 5 minutes, to inactivate the complement.

Preparation of working medium: MEM-E supplemented with 1% antibiotic solution (0.5 gentamicin sulfate, 0.7% streptomycin sulfate, 0.2% penicillin G sodium) and 2% of bovine fetal serum (BFS).

VIRAL NEUTRALIZATION ASSAY PROCEDURE WITH FIXED VIRUS- VARIABLE SERUM:

1. 96-wells culture plates are used. Place 75ìl/well of medium in all plates to be used.
2. **Design of plate for serums tested:** Add 25ìl of the sample being tested, in quadruplicate. Start with a minimum dilution of 1/4 which summed to the volume of virus and cells results in an initial dilution of 1/8. Include standards of known titer at random among the samples to be analized.
3. **Design of control plate:** Positive and negative control serums are placed in the same way as the samples. To perform the cell control, add 150ìl of working medium per quadruplicate in four rows (16 wells in total). For the control of the 100 $DICT_{50}$ of virus, three 10 fold dilutions are carried out based on the work dilution. 75ìl of the 4 folded dilutions prepared are set in quadruplicate (Pure, 1/10; 1/100 and 1/1000) and 75ul of medium is added.
4. Carry out 4 fold serial dilutions, transferring 25ìl, for all samples and control serums.
5. A toxicity control is carried out for each sample, adding 75ìl of medium in another plate.
6. Prepare the dilution of the work virus (100 $DICT_{50}$) in the work medium. Add 75ìl of the dilution of work virus in all plates, except for the plate of toxicity controls, in the cells control and in the 100 $DICT_{50}$ control.
7. Carry out three 10 fold dilutions of the work virus (pure, 1/10; 1/100; 1/1000) set 4 replicates of each dilution in a separate plate.
   Incubate the plates (serum-virus blend) during 1 hour at 37 º C in an atmosphere containing 5% CO_2.
8. Add 100ìl of the cell suspension containing 200.000-250.000 cel./ml per well to the seum-virus blend, in all plates. Incubate plates at 37 ± 1º C in an atmosphere containing 5 ± 1 % CO_2 during 48-72 h.

Reading and interpretation

After 48-72 h., reading is performed by inspection of monolayers in an optical microscope. Reading is by observation of viral cytopathic effect (CPE) typical of bovine herpes virus. Wells presenting a CPE typical of BoHV-1 are considered positive. In toxicity controls, monolayer must be observed the same as the cells controls, free of CPE and free of toxic effect. The neutralizing titer of the analized serum is obtained by the quantity of protected replicates in the serial dilutions based on the Reed and Muench interpolation method. If a certain serum presents toxicity in the analized dilutions, the neutralizing antibodies titer won´t be determined by this technique.

ASSAY ACCEPTANCE (CONFORMITY)

The assay is accepted when:

- Monolayers of cell controls are in good conditions (confluent monolayers, light-refracting cells, with no morphological alterations, with no signs of contamination and with no BoHV-1 CPE).
- Viral suspension titer contains 100 $DICT_{50}$, with an admitted range of 50-200 $DICT_{50}$.
- Positive control shows the expected titer ± 1 well.
- Negative control results negative. An arbitrary value 0.3 is assigned for calculation purposes.

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REPORT OF RESULTS OF IMMUNOGENETIC QUALITY OF IBR VACCINES TRIED/ TESTED IN GUINEA PIGS AND SERUMS EVALUATED BY VN

Results can be interpreted and used to classify a vaccine in the guinea pig model by VN only if the viral neutralization assay has been accepted and you count with a minimum of 5 animals with results to obtain the mean Ab titer induced by the vaccine. To validate the assay, serums of guinea pigs immunized with the reference vaccine must show a mean titer within the range established by a control chart which shows the mean value ± two standard deviations obtained from a minimum of 5 samples.

For the vaccine under evaluation, mean neutralizing Ab titer anti-BoHV-1 obtained by the Reed and Muench method of the 5 immunized guinea pigs must be informed. Negative samples in the minimum serum dilution assayed (1/8) are expressed as an arbitrary titer of 0.3 for calculation purposes.

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Annex 5

XIX Seminario sobre Armonización del Registro y Control de Medicamentos Veterinarios
Comité Medicamentos Veterinarios de las Américas (CAMEVET)

XIX Seminar on Harmonization of Registration and Control of Veterinary Medicines
Americas Committee of Veterinary Medicines (CAMEVET)

Panamá, Republic of Panama September 24-27, 2013

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List of acronyms used in the document

ADIPRAVE: Industries Association of Agrochemicals Products and Veterinary (Uruguay)
ALANAC: National Association of Pharmaceutical Laboratories (Brasil)
ANVET: National Association of Veterinary Laboratories (Chile)
APROVET: National Association of Laboratories for Veterinary Products (Colombia)
AVISA: Venezuelan Association of Animal Health Industry

CANIFARMA: National Chamber of the Pharmaceutical Industry (México)
CAMEVET: Americas Committee on Veterinary Medicines
CAPROVE: Argentine Chamber of Veterinary Products Manufacturers
CEV: Chamber of Veterinary Specialties (Uruguay)
CLAMEVET: Argentine Chamber of Veterinary Medicinal Laboratories
EMA: European Medicines Agency
FDA: U S Food and Drug Administration
FENALCO: National Federation of merchants (Colombia)
FIFVETCA: Federation Central American of Industry Veterinary Pharmaceutical
ICA: Colombian Agricultural Institute
INFARVET: Veterinary Pharmaceutical Industry – Canifarma (México)
OIE: World Organisation for Animal Health
OIRSA: International Regional Organization for Plant and Animal Health
SENASA: National Agrifood Health and Quality Service (Argentina)
SINDAN: National Union of Industry Products for Animal Health (Brasil)
VICH: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

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