REGULATORY CONSIDERATIONS FOR THE REGISTRATION OF AVIAN INFLUENZA VACCINES, INCLUDING EMERGENCY AUTHORIZATIONS

AGRICULTURA
SECRETARÍA DE AGRICULTURA Y DESARROLLO RURAL

SENASICA
SERVICIO NACIONAL DE SANIDAD, INOCUIDAD Y CALIDAD AGROALIMENTARIA

2023 AÑO DE Francisco VILLA
EL REVOLUCIONARIO DEL PUEBLO

April 2023

REGISTRATION DOSSIER SENASICA PROCEDURE 01-024

SENASICA
SERVICIO NACIONAL DE SANIDAD, INOCUIDAD Y CALIDAD AGROALIMENTARIA

- Registration Card format
- Label and packaging text project
- Analytical Report
- Product Specifications
- Primary and secondary packaging description
- Certificate of origin If national, the vaccine strain is provided by Senasica.
- Immunizing agent used
- Analytical technique
- Manufacturing protocol
- National Verification (Official laboratories)
- Master seed and production characteristics If national, it is provided by Senasica.
- Biological control test results
- Batch quality control test procedures, results and interpretation of results
- Test: Sterility, Purity, Strength and Immunogenicity, safety or innocuousness.
- Sterility test methodology
- Warnings, toxicity and antidote
- Uses, doses, routes of administration
- Field tests in case of imported product

*Documents that comprise the file (Art. 153, 154, 155 section V and 156 of the RLFSA).

PRODUCTORA NACIONAL DE BIOLÓGICOS VETERINARIOS

Support the maintenance of master seed for marketing to establishments interested in its registration **H5N2**

REGISTRATION OF PRODUCTS AT SADER SENASICA PROCEDURE 01-024

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AGREEMENT by which the exotic and endemic animal diseases and pests of compulsory notification in the United Mexican States are listed (11/29/2018 DOF).

AGREEMENT by which the campaign and the animal health measures that must be applied for the diagnosis, prevention, control and eradication of Notifiable Avian Influenza are made known, in the areas of the territory of the United Mexican States in which this disease is present . (06/21/2011 DOF)

Guide for the preparation of documents for the registration of biological products for use in animals.

https://www.gob.mx/senasica/documentos/guias-regulacion-de-productos-veterinarios

Reception of SENASICA Dossier

*National or imported product

Information analysis

*If necessary, additional information is requested from the owner

Preliminary results are obtained from the official laboratory.

Compliance

Approval Registration No.

B-0000-000

EMERGING VACCINE ASSESSMENT AND SELECTION

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- **Invitation to the Pharmaceutical Industry** that produces regulated vaccines for its application in Mexico against AI type A, to present their proposals

- **The sequences obtained from the H5N1 strain corresponding to case CPA-19638-22 are sent** to the laboratories, which are available in the database of the National Center For Biotechnology Information (NCBI):

  OP691321.1 ; OP691322.1 ; OP691323.1 ; OP691324.1 ; OP691325.1 ; OP691327.1 ; OP691328.1

- **Questionnaire request** to know the production capacity and characteristics of the proposed vaccine

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EMERGING VACCINE ASSESSMENT AND SELECTION

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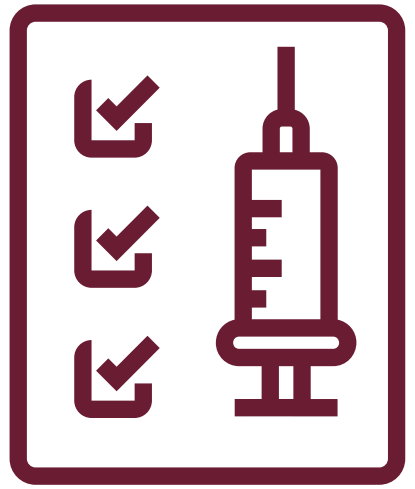
Questionnaire:

- What genetically engineered vaccines do you produce against Avian Influenza?

Indicate, if applicable, the challenge tests and against which strains of VIAAP the biological produced by you has been submitted. Cite the relevant references



- What is the current production capacity of your company for the mentioned biologics?
- Do you have current records from SADER or another government of the vaccine(s) mentioned? Provide the name(s) of the registered vaccine and its registration number.
- Do you have antigens and antisera for the vaccine(s) you produce?
- Do you market to other countries vaccine(s) against AI, produced in Mexico? (But)
- What vaccination schedule do you recommend for the vaccine(s) you produce?

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EMERGING VACCINE ASSESSMENT AND SELECTION

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Selection:

- **Documentary review** of the information sent by the laboratories, which was evaluated by technical experts from Senasica.

- **Selection of emergency vaccines** taking into account risk, information from references of studies against the H5N1 strain in other countries.

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EMERGING VACCINE ASSESSMENT AND SELECTION

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Selection:

3 Vaccines regulated in Mexico are authorized

- Registration No. B-0171-003.

Made in Mexico, currently registered for export purposes only.
Inactivated vaccine derived from genetic engineering.

- Registration No. B-0258-131.

Currently registered for export purposes only.
It is an inactivated vaccine derived from genetic engineering.

- Registration No. B-7378-113.

Registered for sale in Mexico Genetically active virus

Vaccination:

- According to the vaccination protocol established in the **National Animal Health Emergency Device "DINESA".**

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EMERGING VACCINE ASSESSMENT AND SELECTION

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Selection:

- **Assessment,** verification and challenge tests **are performed** at the official CENASA laboratory.

Physicochemicals	In vitro	In vivo
Physical inspection	Sterility	Security
Vacuum	Identity	**Strength**
Humidity	Pollutants	Coexistence
Determination of inactivate	Immunogenicity	
pH	Qualification	

- Tests to be included in the quality control certificate

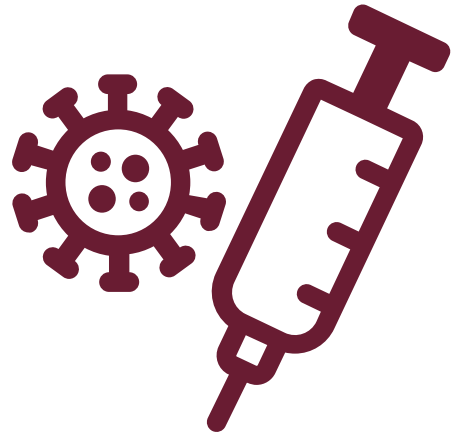
- **Results are obtained** and a **decision is made whether to maintain or suspend approval of the provisional candidate vaccine** for use during the emergency.

EMERGING VACCINE ASSESSMENT AND SELECTION

Vaccines with satisfactory results in the potency tets:

- Registration No. B-0171-003.
- Registration No. B-0258-131.

Which continued with the authorization for the emergency



The authorization as an emergency vaccine for, Registration No. B-7378-113, **was canceled due to unsatisfactory results.**

EMERGENCY AUTHORIZATION

Determining to conclude with the vaccination by Senasica

Cancellation of Authorization as an emergency vaccine

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THANK YOU!

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