# AUTOGENOUS VACCINE: USE AND REGULATION (FRANCE)

16 November 2021- Introduction and sequence 1

29 November 2021- Sequence 2

13 December 2021- Sequence 3

3 January 2022 - Sequence 4


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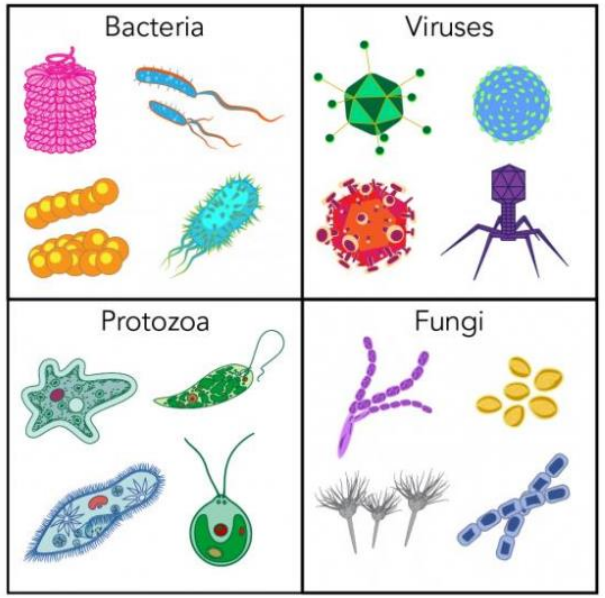
Definition:




Authorised vaccines:

Includes **all products** designed to **stimulate active immunization** of animals **against disease**, without regard to the type of microorganism or microbial component or toxin from which they may be derived or that they contain.

Autogenous vaccines:

**Inactivated immunological** veterinary medicinal products which are manufactured from **pathogens and antigens obtained from an animal** or animals in an epidemiological unit and **used for the treatment of that animal** or those animals in the same epidemiological unit or for the treatment of an animal or animals in a unit **having a confirmed epidemiological link**.

General definition as adopted from EU

# AUTHORISED VACCINES VS AUTOGENOUS VACCINES

## Authorised vaccines

### Full application

- Master seed :
  - Bacteria, viruses, live or inactivated
- *Quality :*
  - control, batch release
- *Safety :*
  - Analytical test
  - Extraneous agents
- *Efficacy :*
  - Field trial, onset and duration of immunity

## Autogenous vaccines

### No full dossier

- Inactivated
- Bacteria / Virus
- No test on safety
- No test on efficacy

## Surveillance and control

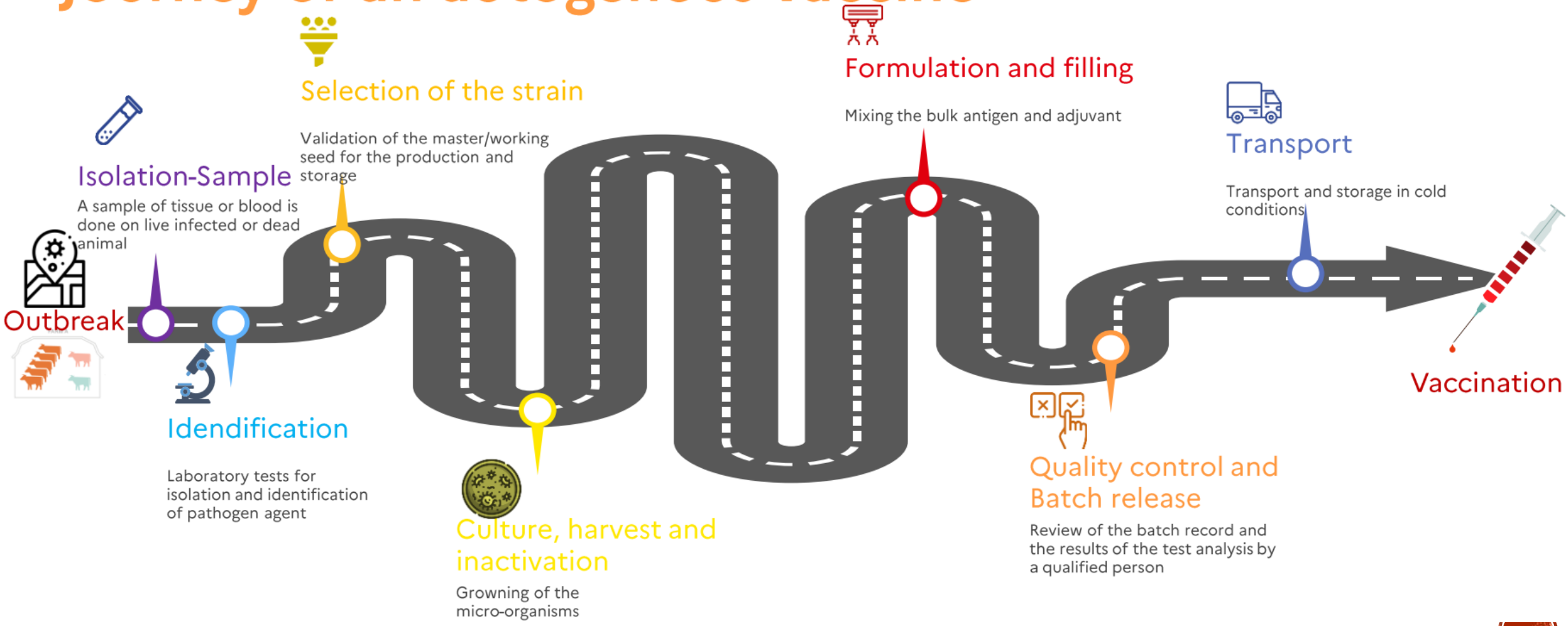
- Pharmacovigilance
- GMP certificate

# Different type of autogenous vaccines:
## Antigen type

| Type of vaccine | Licensed vaccines using this technology | First introduced |
|---|---|---|
| **Live attenuated (weakened or inactivated)** | Measles, mumps, rubella, yellow fever, influenza, oral polio, typhoid, Japanese encephalitis, rotavirus, BCG, varicella zoster | 1798 (smallpox) |
| **Killed whole organism** Autogenous vaccines | Whole-cell pertussis, polio, influenza, Japanese encephalitis, hepatitis A, rabies | 1896 (typhoid) |
| **Toxoid** | Diphtheria, tetanus | 1923 (diphtheria) |
| **Subunit (purified protein, recombinant protein, polysaccharide, peptide)** | Pertussis, influenza, hepatitis B, meningococcal, pneumococcal, typhoid, hepatitis A | 1970 (anthrax) |
| **Virus-like particle** | Human papillomavirus | 1986 (hepatitis B) |
| **Outer membrane vesicle** Pathogen antigen — Gram-negative bacterial outer membrane | Group B meningococcal | 1987 (group B meningococcal) |

| Type of vaccine | Licensed vaccines using this technology | First introduced |
|---|---|---|
| **Protein–polysaccharide conjugate** Polysaccharide — Carrier protein | *Haemophilus influenzae* type B, pneumococcal, meningococcal, typhoid | 1987 (*H. influenzae* type b) |
| **Viral vectored** Viral vector — Pathogen gene — Viral vector genes | Ebola | 2019 (Ebola) |
| **Nucleic acid vaccine** DNA — RNA — Lipid coat | SARS-CoV-2 | 2020 (SARS-CoV-2) |
| **Bacterial vectored** Pathogen gene — Bacterial vector | Experimental | – |
| **Antigen-presenting cell** Pathogen antigen — MHC | Experimental | – |

# Journey of an autogenous vaccine

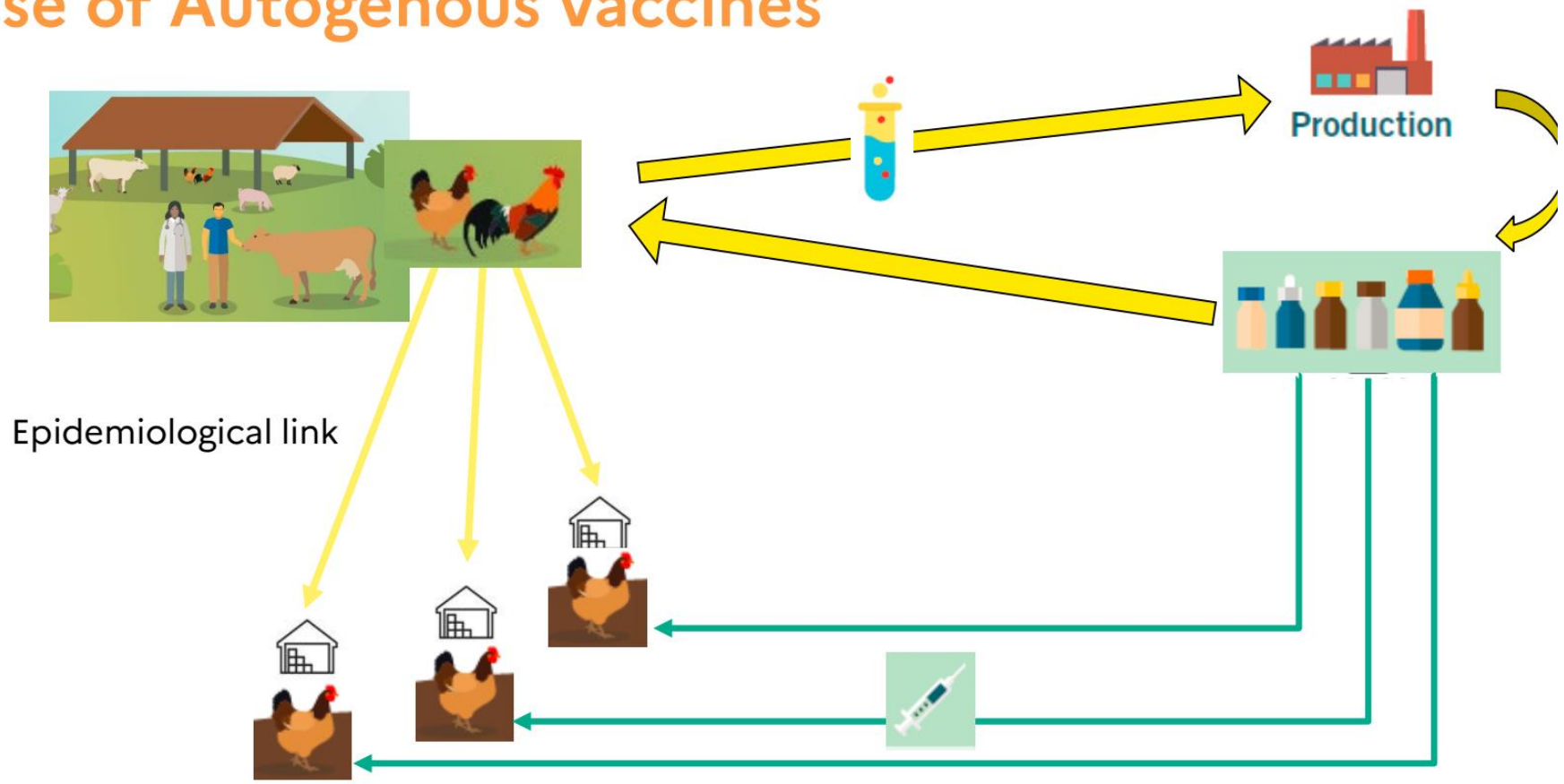


To fit with current practices and integrated concepts of breeding/rearing/production :

- Same epidemiological unit : same and single rearing site / same farm where the pathogen is present or multiple rearing site/farm having an epidemiological link

- Epidemiological link : groups of animals having a link when one of them is to be put in contact with pathogens never met before but present in the other group of animals raised in another rearing site/farm. The movement of animals between, rearing sites/farms should be considered when establishing the epidemiological link

# Use of Autogenous vaccines



# AUTOGENOUS VACCINE

**Alternative medecine to be used in particular and justified circumstances :**

. Absence of authorised vaccines :

- minor species, minor diseases
- shortages
- particular use, route of administration

. New / Emergent disease, antigenic shift

. Alternative to antibiotics

# Risk identified with regard to the use of autogenous vaccines

For livestock animals,

Main risks

- risk of transmission of disease
  - if inactivation (of the bacteria or the viruse) is not complete
  - if the viral isolate is not fully controled and purified ( presence of extraneous agents)

- risk of infection
  - can result from the contamination of raw materials, specifically samples taken at the farm, or from the autogenous vaccine when it is being prepared.

# Risk identified with regard to the use of autogenous vaccines

For livestock animals,

Other risks

- risk inherent in the use of adjuvants :
  - local and/or general reactions →Choosing of adjuvants suitable for the target species

- risk of hypersensibility :
  - since used in contaminated situation (G- bacteria) + other materials (risk increased due to absence of purification)

- other risks as toxic reaction (antigens, impurities)

As any other vaccines

# Risk identified with regard to the use of autogenous vaccines

For livestock animals,

- risk of lack of efficacy

  - Due to :
    - choice of composition, quality (stability …)
    - choice of administration route, pharmaceutical form
    - administration conditions, animals
    - many other reasons

Other risk

Vet responsability

# Risk identified with regard to the use of autogenous vaccines

For the user : risk is negligible, limited to accidental injection (importance of the adjuvant and of the vet responsibility at time of administration)

As any other vaccines

For the consumer : no risk, only adjuvants with MRL

# FRENCH LEGAL FRAMEWORK MANAGEMENT OF RISKS

# French legal framework – Manufacturing licence

« obligation of means and no obligation of results »

### Location

licence is granted for 1 preparation site (establishment)

*Technical dossier and inspection of the site*

### A qualified person

Preparation must be performed by a qualified person (veterinarian or pharmacist) mentioned in the autorisation

### Only bacteria – no Virus

### Positive list of bacteria and animal species

Listed in the appendix of the licence

### Positive list of adjuvants

In compliance with MRL regulation

# All risks

## Requirements for isolation of the antigen :

- Collection by the vet
- No GMO or notifiable disease
- Importance of traceability
- Isolation and identification by a competent authorised site

## Requirements for preparation and formulation :

- under GMP, validation of critical operations like inactivation

## Requirements for controls :

- Sterility
- Complete inactivation
- Endotoxin (bacterial)
- Absence of extraneous agents (viral)

## Requirements for stability :

- 6-12 months

## Requirements for labelling

# Conclusion

- Autogenous vaccines are useful VMPs but less secure than an authorised vaccines with full dossier
- Authorised vaccines shall be used as 1st choice
- Only Restricted Use for autogenous vaccines : administration to the animal of the same location or with epidemiological link
- Only inactivated bacterial vaccines
- Only prepared in a licenced premises under GMP conditions
- Efficacy depends on the choice of the pathogen
  - By the vet
  - through a diagnostic approach
- Need for flexibility, need for quick answer
- Use in the frame of limited market (economically driven)
- Limited volumes, specific distribution channels

# THANK YOU