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GF-TADs
GLOBAL FRAMEWORK FOR THE PROGRESSIVE CONTROL OF TRANSBOUNDARY ANIMAL DISEASES

Food and Agriculture Organization of the United Nations

World Organisation for Animal Health
Founded as OIE

Standing Group of Experts on High Pathogenicity Avian Influenza in Europe under the GF-TADs umbrella

BEST PRACTICES IN FRANCE

EXPERIENCE WITH POULTRY VACCINATION, CHALLENGES AND OPPORTUNITIES

SAMARKAND (UZBEKISTAN)
30/09/2024

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WHY ?

1. CONTEXT :

THE NEED FOR A COMPLEMENTARY TOOL TO BIOSECURITY, CULLING AND ZONING

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HPAI poultry outbreaks per season in FRANCE

(August N to July N+1)





81	488	0	492	1377	402
2015/ 2016	2016/2017	2017/2020 3 seasons	2020/2021	2021/2022	2022/2023

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Excessive burden on public finances

Season	2015/2016	2016/2017	2020/2021	**2021/2022**	2022/2023	**TOTAL**
Outbreaks poultry	81	488	492	**1377**	402	**2840**
Million of Poultry killed (included preventive killing)	0,35	4,5 (2,5)	3,3 (2,2)	**22** (6)	10 (3,5)	**40,15 million poultry killed**
State/UE compensation for livestock farmers (million €)	136	175	158	**621**	552	**1 642 million euros**

Zoonotic risk
Moral distress of breeders
Exhaustion of veterinary services
No societal acceptance of mass killings

Early 2021 :

we need to vaccinate

July 2022 : **an approved Roadmap**

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HOW ?

2. CHALLENGES :

DEFINING A VACCINATION STRATEGY
HPAI VACCINATION ACTION PLAN

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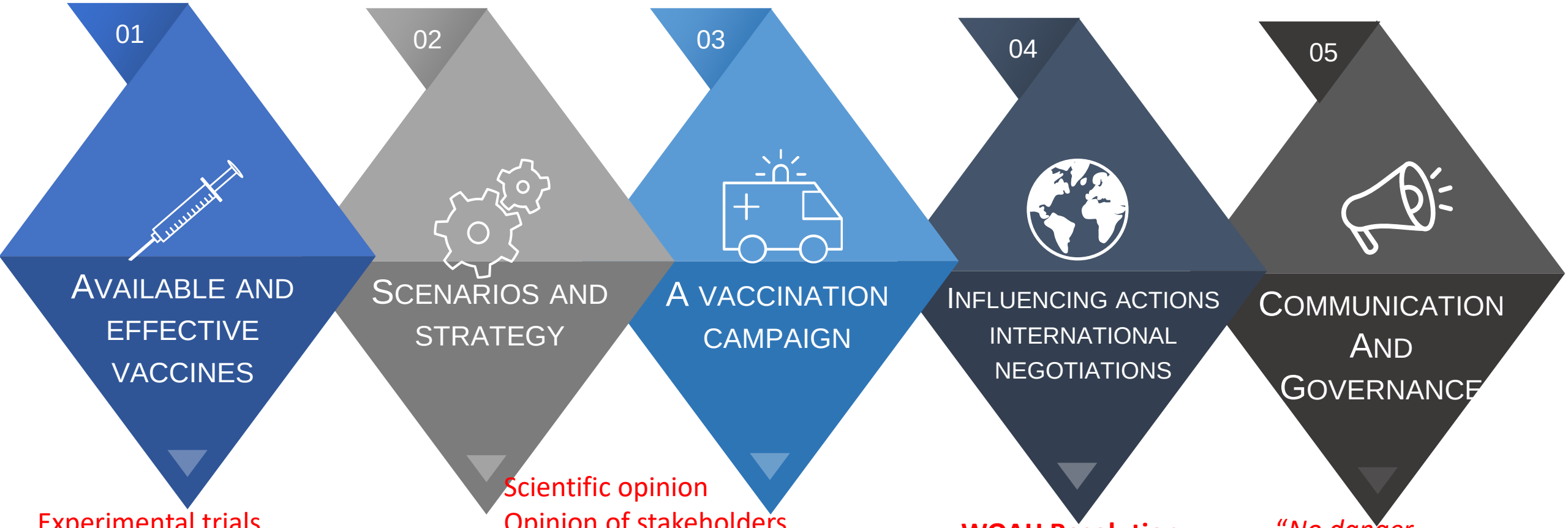
Objective: To define a strategy and a plan for vaccination in France

5 main challenges and areas of work



Experimental trials
(May-December 2022)
Marketing authorisation

Scientific opinion
Opinion of stakeholders
UE Support and Regulation
Financing (State/Sector)

WOAH Resolution
(May 2023)

"No danger to consumers"

VACCINES

- **The used vaccine should:**
  - Be effective on the HPAI clade 2.3.4.4.b strain
  - Have the capacity for a DIVA strategy using the NP ELISA serology
  - Have an authorisation for use, issued by the ANMV (The National Veterinary Medicines Agency)

  = > https://www.anses.fr/fr/content/médicaments

Two vaccines on the market meet these criteria

Vaccine and fabricant	Species	Administration route	Conservation	Vaccination at 1 day of age	DIVA ELISA NP serology
Volvac BEST AI+ND BOERHINGER INGELHEIM	Pékin ducks, Mulard ducks, Muskovy ducks	SC	+5°C	Yes Non	Yes
Vaccin CEVA Respons H5 Ceva Santé Animale	Mulard ducks, Pékin ducks, Muscovy ducks	IM	• 24 months ≤-60°C • 28 days ≤-20°C • 74 hours at 2-8°C	Yes	Yes

The 2 used vaccines

- **Call for tenders (April 2023) : 141 million doses purchased**
  - **First batch : 80 million doses**
    - 80 000 000 doses of VOLVAC BEST BI vaccine
  - **Second batch (December 2023) : 61 million doses**
    - 34,188,300 doses of VOLVAC BEST BI vaccine
    - 26,811,700 doses of Ceva Respons vaccine

- **2 vaccines used :**

VOLVAC BEST

https://www.anses.fr/fr/system/files/90055_ATU_M_ANNEXE.pdf

CEVA RESPONS

https://www.anses.fr/fr/system/files/90053_ATU_M_ANNEXE.pdf

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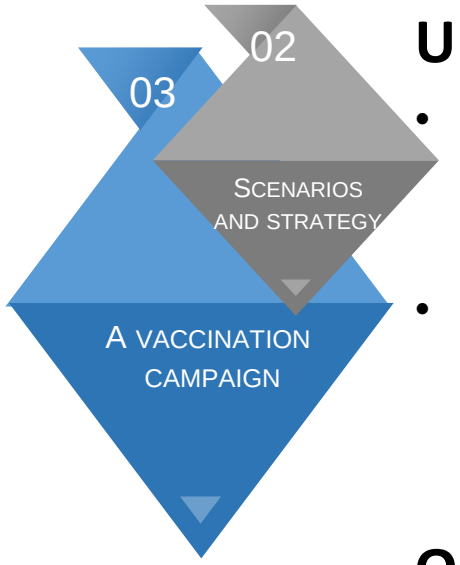
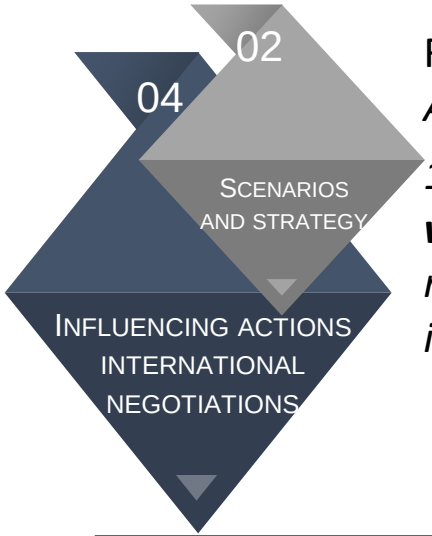


UE Support

- COUNCIL of the EU (13 May 2022) : Conclusions on highly pathogenic avian influenza (HPAI): a strategic approach for the development of vaccination as a complementary tool for prevention and control

- COMMISSION DELEGATED REGULATION (EU) 2023/361 of 28 November 2022 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards rules for the use of certain veterinary medicinal products for the purpose of prevention and control of certain listed diseases (Annex XIII)



OMSA Support

Resolution N°28 (90th General Session May 2023) on Strategic challenges in the global control of HPAI. *« The Assembly recommends that :*

10. Members respect and implement the adopted WOAH standards and ***recognise compliant use of vaccination without negative consequences on trade****, when the vaccination programme is supported by vaccination monitoring and disease surveillance systems that can demonstrate the effectiveness of vaccination and absence of infection."*

GUIDING PRINCIPLES FOR DEFINING VACCINATION STRATEGY

Objective

- Vaccination helps **to slow the spread** of the virus and complements control measures to achieve eradication.

Modalities

- **Preventive vaccination** is the only feasible option at this stage.
- Vaccination should be accompanied by a **strict surveillance system**.
- The vaccines selected will allow the implementation of a **DIVA strategy**.
- The implementation of a strategy will have to be preceded by **coordinated work towards trading partners** at European and international level.

Conditions

- **Biosecurity** is the cornerstone of HPAI control.
- Vaccination, from the moment it is required, must be made **compulsory** except in special cases.
- Vaccination **does not dispense with the elimination of outbreaks**, even when vaccinated.

THE MAIN OBJECTIVES AND TARGETS OF THE VACCINATION STRATEGY

Strategy	• **Preventive** vaccination
Species	• Ducks (Muskovy, Pekin and Mulard)
Zone	• All of mainland France (excluding Corsica)
Period	• All year, starting the first of October 2023

VACCINATION WITHIN A REGULATORY FRAMEWORK in accordance with EU REGULATION

Species	Production ducks	Breeding ducks
Ducks	Mandatory vaccination for farms with at least 250 ducks	Vaccination prohibited for breeding ducks whose products (ie hatching eggs and day-old ducklings) are exported to another Member State and third countries.
Gallus	Prohibited vaccination	Prohibited vaccination
Other species	Prohibited vaccination	Prohibited vaccination

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Vaccination follow-up report

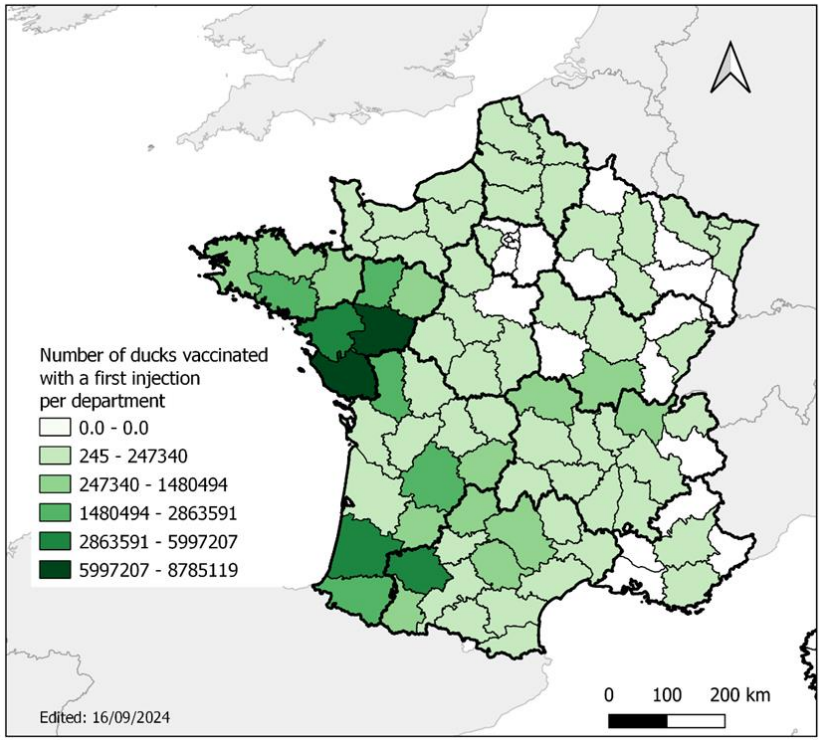
Period : from 1st October 2023 to 26th September 2024

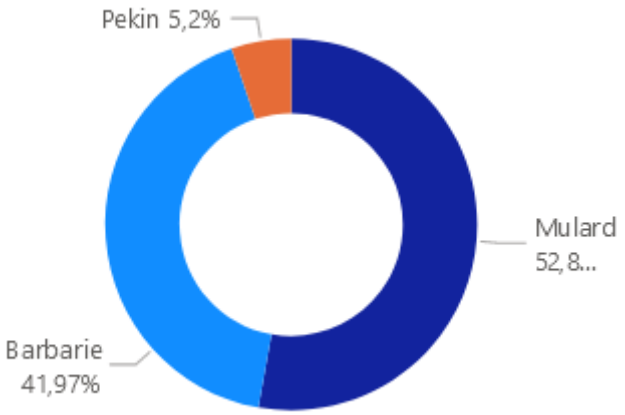
60 million

Number of vaccinated ducks

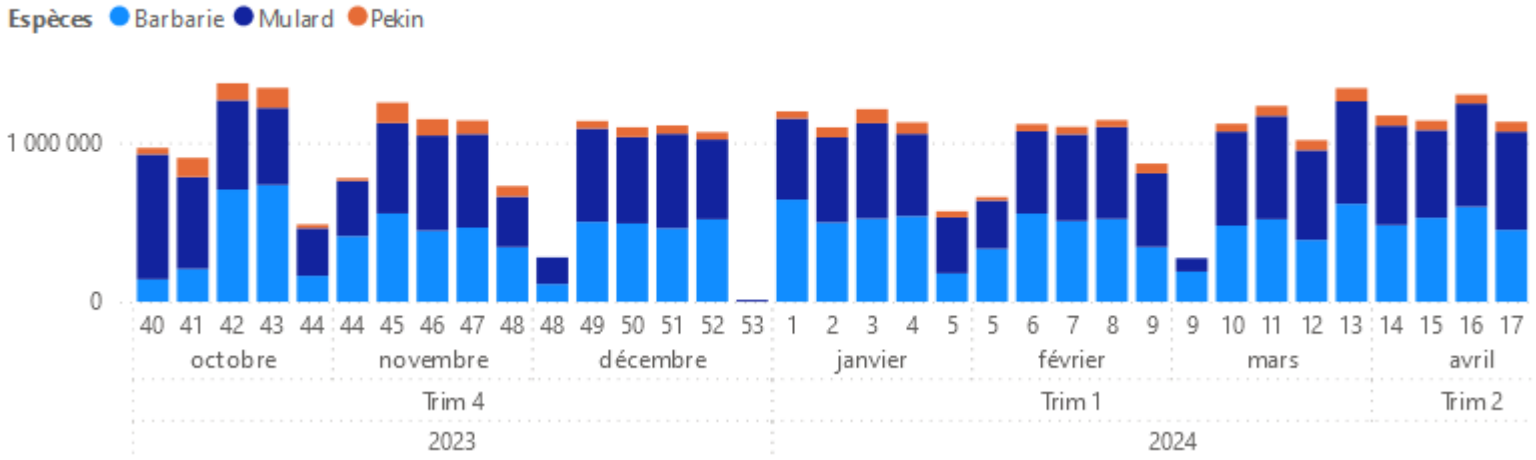
2100

Number of establishments





Number of ducks having started the vaccination protocol, per week



REINFORCED POST-VACCINATION SURVEILLANCE

Conditions	Reinforced passive surveillance	Active surveillance
Where?	Epidemiological Unit	Epidemiological Unit
By who?	Breeder or Technician	Official veterinarian
Frequency?	Weekly	Every 30 days: clinical visit + virological analysis
How?	Swabs (tracheal or oropharyngeal swabs) on 5 cadavers	Swabs on 60 vaccinated ducks (tracheal or oropharyngeal swabs)
Analysis?	RT-PCR gene M virology If the result was positive ➔ screening H5/H7	RT-PCR gene M virology (If the result was positive ➔ screening H5/H7)
Laboratoty type?	Recognised laboratory	Approved laboratory

Results : Post vaccination monitoring
(October 2023-August 2024)

Passive post vaccination monitoring

- Weekly monitoring of up to 5 dead animals in establishments holding vaccinated ducks (PCR analysis)
- Over the period October 2023 – August 2024 :
  - **Number of samples taken for PCR analysis: 32.371**

Active post-vaccination monitoring

- Monthly clinical surveillance of establishments holding vaccinated ducks with sampling of 60 vaccinated ducks (PCR analysis)
- Over the period October 2023 – August 2024 :
  - **Number of samples taken for PCR analysis: 822.654**

=> No positive HPAI virological results

Financing : 2023-2024 campaign

	Budget share	Paid by
Buying the vaccine	24%	State
Vaccine storage and transport	4%	State
Supervision of vaccination (by official veterinarians)	18%	State
Vaccination operations (by farmer, special teams or veterinarians)	27%	State/Farmers
Monthly visits for active surveillance (by official veterinarians)	8%	State
Active surveillance analyses (approved labs)	17%	State
Passive surveillance analyses (recognized labs)	2%	Farmers
	Around 100 million €	85% State 15% Farmers

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GOVERNANCE BODIES OF THE VACCINATION ACTION PLAN

Based on two bodies:

- **Strategic:** the Steering Committee (COPIL), including representatives of :
  - Poultry sector (producers associations)
  - Veterinarians
  - Scientific bodies
  - Vaccines producers
  - Regional services (local administrative unit)
- **Operational:** an internal committee, including representatives of the divisions (animal health, international, budget, …) of the Directorate general for food

The progress of the plan is regularly presented to the farmers' organizations.

CAMPAIGN MONITORING COMMITTEE

Role: Monitoring the campaign, evaluating its effectiveness, identifying solutions in case of difficulties
Leader: Ministry of agriculture (DGAL)
Participants: Agricultural professionals, veterinarians, ANSES, ENVT, SIMV

Consisting of:

Regional Campaign Monitoring Cells	Data Valuation and Analysis Cell	Sanitary Diplomacy Cell	Cost Observatory
• Leader: DRAAF • Participants: Agricultural professionals, veterinarians • Role: Anticipate labor and logistics issues	• Leader: DGAL • Tool Evaluation: Movement database managers, Calypso, Cartogip, SIGAL • Scientific Evaluation: ANSES, ENVT	• Leader: DGAL • Participants: Interprofessional organizations	• Leader: Interprofessional organizations

WORKING GROUPS

Several working groups where created during and after the start of the vaccination in order to better prepare and organize the campaign:

- Third countries communication working group
- Post-vaccination surveillance working group
- Tractability working group
- Vaccination of breeding ducks working group
- Vaccination at the hatchery working group

DATA RECORDING SYSTEM

CALYPSO

- To collect data on vaccination carried out by the **VETERINARIAN** or under his supervision: **vaccination and monthly visit for active surveillance.**

SIGAL

- To collect surveillance data: **LABORATORY analysis results**

CARTOGIP

- To combine the movement data declared by the operator and the vaccination data from Calypso and thus ensure the **TRACEABILITY OF THE VACCINATED ANIMALS.**

Marc Fesneau, former French minister of agriculture

1st October 2023 = official launch of vaccination

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EXPERIENCE IN DETAIL :

KEY MILESTONES IN THE IMPLEMENTATION OF THE 1ST VACCINATION CAMPAIGN 2023-2024

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S1 2023 : TOWARDS A VACCINATION STRATEGY

February 2023

EU regulatory framework :
Publication of the Delegated Regulation (EU) 2023/361 (OJEU 20/02/2023)

March

Expertise :
ANSES' opinion on vaccination scenarios

Communication to Member States and third countries

April

Expertise :
Technical and economic study by SNGTV of 3 scenarios selected by the Steering Committee

Vaccines :
Publication of a first call for tenders for the purchase of vaccines

May

Vaccination trial on Mulard ducks : Publication of results

Steering Committee : : consensus on a Scenario : Mandatory vaccination for « commercial duck, whole France, whole year »

WOAH general session:
- Adoption of a resolution on the strategic challenges of global HPAI control
- Bilateral meetings with third countries : presentation of the French vaccination strategy

June

Vaccines : Autorisation delivered by ANMV

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S2 2023 : TOWARDS THE VACCINATION CAMPAIGN

July

Vaccines : final attribution for the first call for tenders

Decision by the **Minister** to implement the vaccination strategy

Communication with third countries: CVO letters

August

Official vaccination plan:
Published on Ministry's website

September

French regulatory framework :
Publication of national decrees and implementation guidelines for local veterinary services

On the field :
Operational sheets for field actors prepared by SNGTV
Communication campaign

October

Launch of the vaccination campaign

Traceability / Information system

Communication to Member States and third countries

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Actions in 2024: Follow up, deepen, evaluate

December 2023

Vaccines: launch of a 2nd call for tenders

January – February 2024

Vaccination of breeding flocks: further research

Hatchery vaccination: preparatory work

EC working group 14 February

March 2024

Vaccines: results of the 2nd call for tender

April – May 2024

EC working group 23 April

WOAH SG

Referral to ANSES for the next campaign

June – July 2024

ANSES epidemiological assessment at 6 months

Communication campaigns aimed at Member States and third countries

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3. HPAI SEASON 2023/2024

NUMBER OF OUTBREAKS AND EFFECT OF DUCK VACCINATION

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1st vaccination campaign started 1st October 2023

"From storms to a quieter sea"






81	488	0	492	1377	402	10
2015/ 2016	2016/2017	2017/2020 3 seasons	2020/2021	2021/2022	2022/2023	2023/ 2024

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and if we had not vaccinated ?

Article : ***Promising effects of duck vaccination against highly pathogenic avian influenza, France***

Preprint : 28 August 2024

"*France recently adopted a preventive vaccination strategy, vaccinating domestic ducks with inactivated and mRNA vaccines. This study evaluates the impact of this campaign on reducing HPAI H5 outbreaks. Using predictive modelling based on previous outbreak data,* ***the expected number of outbreaks in 2023-2024 without vaccination was significantly higher than the observed cases, indicating a 95.9% reduction attributable to vaccination.*** *These findings suggest that vaccination effectively mitigated the HPAI H5 outbreak in France.*

The expected number of outbreaks in France in 2023-2024 was estimated at 487 *(95% prediction interval (PI): 273 – 701), significantly higher than the observed number (n=10)"*

Reference : https://www.biorxiv.org/content/10.1101/2024.08.28.609837v1.full.pdf

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4. CONCLUSION AND OPPORTUNITY :

2ND VACCINATION CAMPAIGN = CONTINUATION OF THE 1ST CAMPAIGN

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Actions in 2024: preparing the next campaign

June / July

Steering committee opinion on the key points for campaign 2024-2025 : consensus to repeat the same strategy

Vaccines: Order for 67.75 million doses of vaccines

August

Financing decision for the vaccination campaign and breakdown of costs

September

French regulatory framework :
Publication of updated implementation guidelines for local veterinary services

On the field :
Updated operational sheets for field actors prepared by SNGTV

October

Start of the **new HPAI vaccination campaign**

December

Anses opinion to adapt HPAI management measures

Communication campaigns aimed at Member States and third countries

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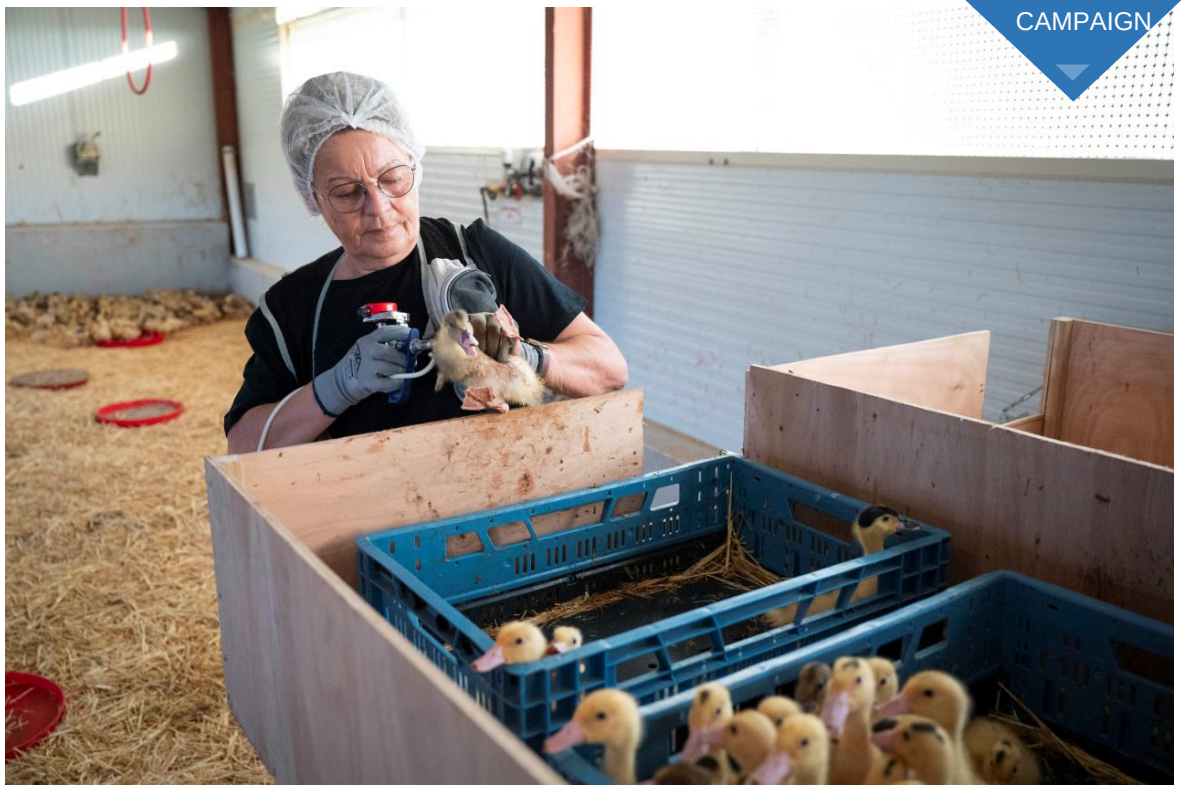
French Ministry of Agriculture website

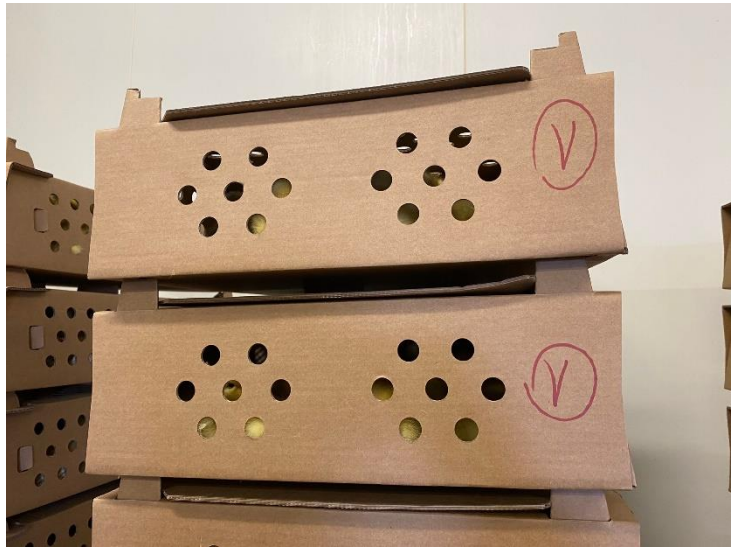
Everything about the HPAI vaccination action plan in France

(available in English)

https://agriculture.gouv.fr/tout-ce-quil-faut-savoir-sur-le-plan-daction-vaccination-iahp-en-france



Day-old ducks Vaccination at the hatchery



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