









RSC 12

France: experience with poultry HPAI vaccination

- Speaker: Olivier DEBAERE, Crisis Director HPAI/ASF
- ► Country or institution: France Ministry of agriculture
- 12th March 2025

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WHY?

1. CONTEXT

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



HPAI poultry outbreaks per season in FRANCE (August N to July N+1)









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



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

Excessive burden on public finances

Early 2021:

we need to vaccinate

July 2022: an approved Roadmap

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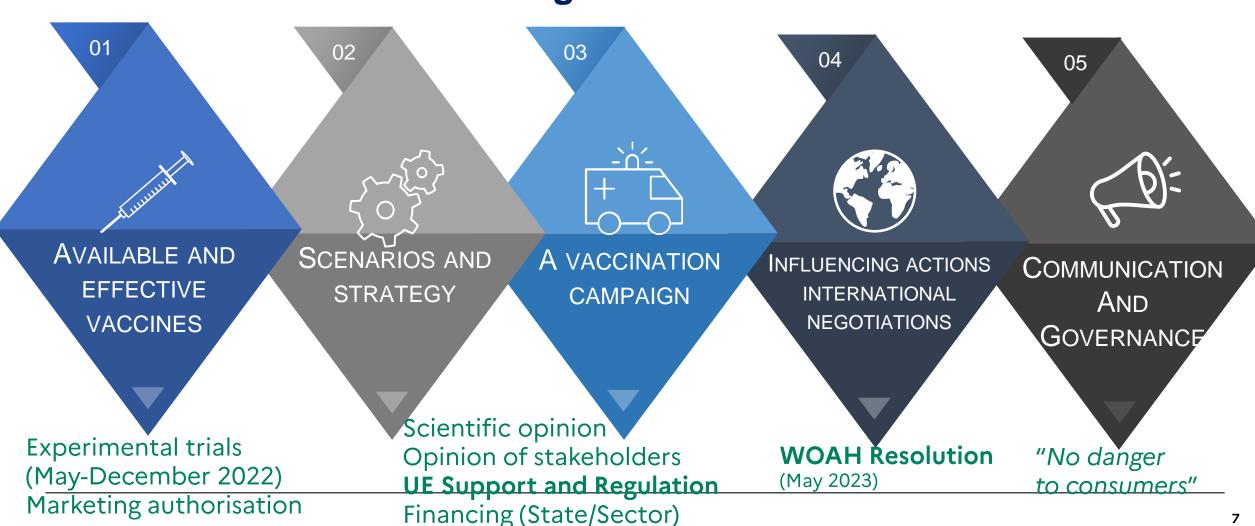
HOW?

2. CHALLENGES

DEFINING A VACCINATION STRATEGY HPAI VACCINATION ACTION PLAN



Objective: To define a strategy and a plan for vaccination in France 5 main challenges and areas of work





VACCINES



The used vaccine should:

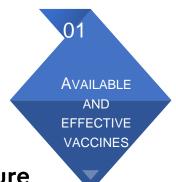
- Be effective on the HPAI clade 2.3.4.4.b strain
- Have the capacity for a DIVA strategy using the NP ELISA serology
- Have an authorisation for use, issued by the ANMV (The National Veterinary Medicines Agency)
- = > https://www.anses.fr/fr/content/médicaments

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,	_ SC	+5°C	Yes	_ Yes
BOERHINGER INGELHEIM	Muskovy ducks	_		Non	_
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 by the Ministry of agriculture
 - 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 :

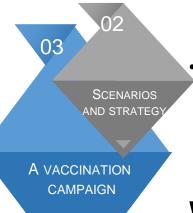
VOLVAC BEST since October 2023

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

CEVA RESPONS since May 2024

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





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)

WOAH Support

Terrestrial code, chapter 10.4:

The use of vaccination against avian influenza may be recommended under specific conditions. Any vaccine used should comply with the standards described in the Terrestrial Manual. Vaccination will not affect the high pathogenicity avian influenza status of a free country or zone if surveillance supports the absence of infection, in accordance with Article 10.4.28., in particular point 2

- 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 prevent the spread of the virus and complements control measures to achieve eradication.

Modalities

- <u>Preventive</u> vaccination is the only feasible option at this stage.
- Vaccination should be accompanied by a strict <u>surveillance</u> 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

- <u>Biosecurity</u> 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





• 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	



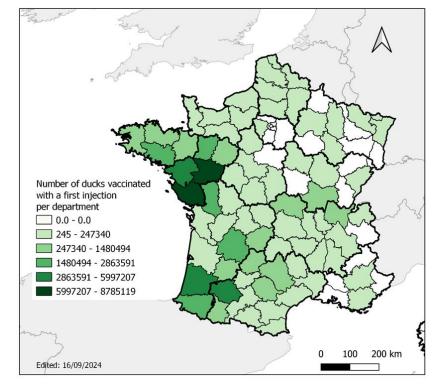
Vaccination follow-up report

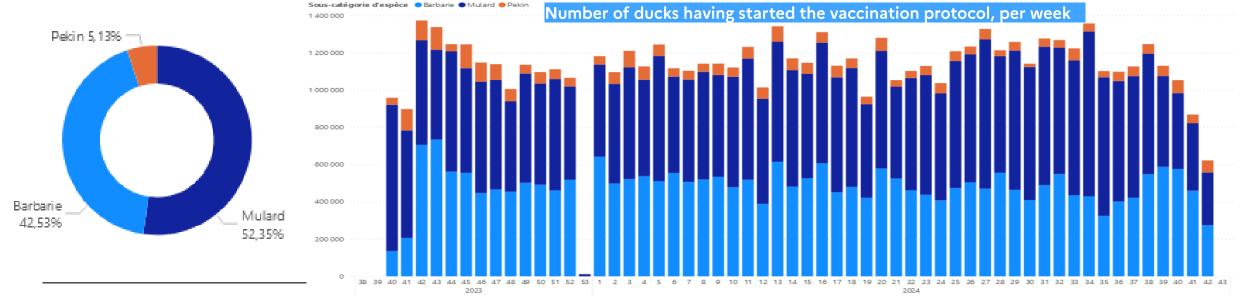
Period of the 1st vaccination campaign from 1st October 2023 to 30th September 2024



2317

Number of establishments







REINFORCED POST-VACCINATION SURVEILLANCE



	5 : 6	A ative assessible and		
Conditions	Reinforced passive surveillance	Active surveillance		
Where?	Epidemiological Unit	Epidemiological Unit		
By who?	Breeder or Technician	Official veterinarian		
Eroguanay2	Weekly	Every 30 days:		
Frequency?	vveekiy	clinical visit + virological analysis		
How?	Swabs (tracheal or oropharyngeal swabs) on 5 cadavers Since April 2024: in case 5 deaths didn't occur during the week, the number of samples can be completed on morbid ducks, up until 5 samples get collected	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



Passive post vaccination monitoring

- Weekly monitoring of up to 5 dead animals in establishments holding vaccinated ducks (PCR analysis)
- Over the period 1st October 2023 30th September 2024 :
 - Number of RT-PCR analysis (1 pool = up to 5 swabs): 21 282

Active post-vaccination monitoring

- Monthly clinical surveillance of establishments holding vaccinated ducks with sampling of 60 vaccinated ducks (PCR analysis)
- Over the period 1st October 2023 30th September 2024 :
 - Number of analysis RT-PCR (1 pool = 5 swabs): 206 223

⇒ No positive HPAI virological results related to the vaccination monitoring







	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



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 (General Directorate for Food/DGAL)

Participants: Agricultural professionals, veterinarians, ANSES (risk assessment), ENVT (veterinary

school), SIMV (vaccines producers)

Consisting of:

Regional Campaign Monitoring Cells

- Leader: DRAAF
- Participants:
 Agricultural
 professionals,
 veterinarians
- Role: Anticipate labor and logistics issues

Data Valuation and Analysis Cell

- Leader: DGAL
- Tool Evaluation:
 Movement database managers, Calypso,
 Cartogip, SIGAL
- Scientific Evaluation: ANSES, ENVT

Sanitary Diplomacy Cell

- Leader: DGAL
- Participants:
 Interprofessional organizations

Cost Observatory

 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



2023 Semester 1: TOWARDS A VACCINATION STRATEGY

February 2023

EU regulatory framework:

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

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

June

Vaccines: Autorisation delivered by ANMV

Expertise:

ANSES' opinion on vaccination scenarios

March

Communication to Member States and third countries

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

May



2023 Semester 2: 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

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

Official vaccination plan:

Published on Ministry's website

August

Launch of the vaccination campaign

Traceability / Information system

October

Communication to Member States and third countries



2024 Semester 1: COURSE OF THE 1st VACCINATION CAMPAIGN

Liberté Égalité Fraternité

January – February 2024

Vaccination of breeding flocks: further research

Hatchery vaccination: preparatory work

EC working group 14 February

April – May 2024

EC working group 23 April

WOAH SG

Referral to ANSES for the next campaign

Vaccines: launch of a 2nd call for tenders

December 2023 Vaccines: results of the 2nd call for tender

March 2024

ANSES epidemiological assessment at 6 months

June – July 2024

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

A SUCCESSFUL 1ST CAMPAIGN



1st vaccination campaign started 1st October 2023











10
2023/
2024

81	488	0	492	1377	402	10
August 2015/ July 2016	2016/ 2017	2017/2020 3 seasons	2020/2021	2021/2022	2022/2023	2023/ 2024 included 2 vaccinated



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:

- COLLECTIVE SUCCESS OF THE 1ST CAMPAIGN
- 2ND VACCINATION CAMPAIGN = CONTINUATION OF THE 1ST CAMPAIGN

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4. CONCLUSION AND OPPORTUNITY

- COLLECTIVE SUCCESS OF THE 1ST CAMPAIGN
- 2ND VACCINATION CAMPAIGN = CONTINUATION OF THE 1ST CAMPAIGN



At a glance: HPAI outbreaks in France

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- Zoonotic risk
- Moral distress of breeders
- Exhaustion of veterinary services
- No societal acceptance of mass killings
- Excessive burden on public finances

Early 2021 = we need to vaccinate!

October 2023 = 1st vaccination campaign

Season 2023/2024 = only 10 outbreaks

Season 2024/2025 (24/02/2025) = only 19 outbreaks, free-

status on December, free status on February



Actions in 2024: preparation of the 2nd campaign

Liberté Égalité Fraternité

August

Financing decision for the vaccination campaign and breakdown of costs

October

Start of the 2nd HPAI vaccination campaign

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

June / July

French regulatory framework:

Publication of updated implementation guidelines for local veterinary services

On the field:

Updated operational sheets for field actors prepared by SNGTV

September

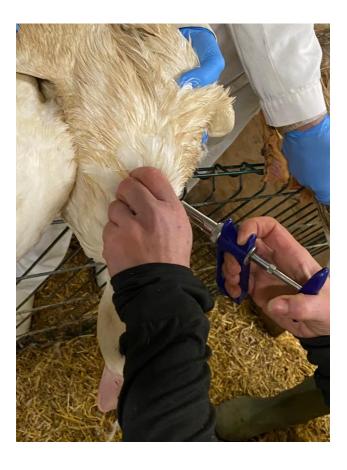
Anses opinion to adapt HPAI management measures :
Conclusion = to continue

December

Communication campaigns aimed at Member States and third countries



Few pictures of the vaccination campaign







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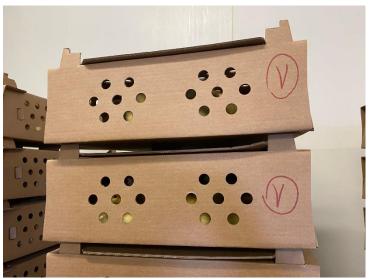


Day-old ducks Vaccination at the hatchery











French Ministry of Agriculture website

Everything about the HPAI vaccination action plan in France (updated and available in English)

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



