Veille citoyenne d'information sur les OGM et les semences

Self-amplifying messenger RNA “vaccine”: after the human, the duck

Par Annick BOSSU

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A year and a half ago, France made it compulsory to vaccinate farmed ducks against the avian influenza virus, in order to protect its meat and foie gras industries. To date, France is the only country to have taken this vaccination route. One of the two vaccines used, the self-amplifying messenger RNA (mRNA) vaccine, raises questions.



In a November 2024 publication from the French Ministry of Agriculture[i], we learn that since October 1, 2023, France has made it compulsory to vaccinate farmed ducks against highly pathogenic avian influenza (HPAI). This obligation applies to all farms with more than 250 birds, with the exception of breeding duck farms whose production (day-old birds or hatching eggs) is destined for the European market or for export[ii]. Between October 1, 2023 and September 30, 2024, 61 million ducks were vaccinated against HPAI. On October 1, 2024, this campaign was repeated with two different vaccines, including one of a new type: the self-amplifying mRNA

vaccine (which had not been chosen for October 1, 2023 because of its low-temperature transport conditions).

Inf'OGM has already taken an interest in the self-amplifying mRNA "*vaccine*" against Covid in humans and its potential dangers for human health[iii]. In the case of veterinary vaccines against avian influenza, the Ministry claims that "*the consumption of products from vaccinated animals does not entail any danger. The vaccines are authorized by the French Veterinary Medicines Agency (ANMV), which guarantees their safety*"[iv]. But is this really true?

Emergency management of the avian influenza epizootic

Since the early 2000s, the avian influenza epizootic has spread from Asian to European countries via the industrial breeding system and accelerated communication channels. The virus responsible for this epizootic is an RNA virus, known by the acronym A(H5N1), where A stands for avian, H for hemagglutinin (the surface protein that enables the virus to attach itself to the cell it infects) and N for neuraminidase (the enzyme that enables the virus to leave the cell once replicated)[v]. This virus mutates and recombines extensively. As a result, there are many different subtypes. Data sheet 1[vi] published by the French Ministry of Agriculture specifies that the most widely circulating virus belongs to clade 2.3.4.4b.

In justifying the need to vaccinate ducks, the same sheet explains that this epizootic is causing major economic losses and poses a permanent threat to wild birds and mammals, including humans.

The Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (Anses) states that "*the highly pathogenic avian influenza virus (HPAI) subtype H5N1 has been circulating intensively worldwide for several years, mainly in wild birds (such as ducks and geese) and domestic poultry (chickens, ducks, turkeys). It is also capable of infecting numerous species of wild mammals (foxes, seals, sea lions, etc.) and domestic animals (cats, dogs, pigs). The virus has also been detected for the first time in dairy cows in the USA. The virus can occasionally be transmitted to humans, in which case it is known as avian flu. The international situation, particularly in the United States, is cause for concern, but no human-to-human transmission has been observed to date. In France, no human case of avian flu has yet been detected*"[vii].

In May 2023, the World Organisation for Animal Health (WOAH) opened the way for vaccination against the influenza virus in ducks, considering that conventional control measures "*of biosecurity, stamping out and movement restrictions*" were no longer sufficient[viii].

However, with regard to this vaccination, the Anses had previously (on March 30, 2023) issued an opinion following a referral from the DGAL (Direction générale de l'alimentation)[ix]. This opinion was extremely cautious. Indeed, on numerous occasions, it is noted that the expert opinion is "*based on hypotheses that will have to be verified*".

The mRNA injection used on French ducks

To be marketed in France, any industrially-produced drug or vaccine must have received a marketing authorization (MA) from the European Medicines Agency[x] (EMA) or, failing this, a temporary authorization for use (ATU in French). For veterinary vaccines, the ATU is issued by the Agence nationale du médicament vétérinaire, which is the case for the two vaccines used against the avian influenza virus. The two ATUs concerned can be found on the Anses website[xi].

The first vaccine, VOLVAC B.E.S.T. AI + ND, is not a "*genetic*" vaccine, *i.e.* an RNA or DNA vaccine. It is a recombinant protein vaccine (or viral subunit vaccine: in this case, the modified H5 hemagglutinin of the avian influenza virus). It was used in the first vaccination campaign, from October 2023 to September 2024, and is being renewed for the vaccination campaign starting on October 1, 2024.

The second vaccine, with self-amplifying mRNA, named CEVA RESPONS A1 H5, has been in use since October 1, 2024. On the Anses website, under the heading ATU, we read that "*(In view of a health situation requiring emergency vaccination), the present temporary authorization for use (ATU) was granted taking into account a benefit-risk balance judged to be positive for the vaccine in view of the elements provided, but with a limited level of evidence concerning the information available*". In addition, the validity date of this ATU is April 1, 2025, whereas vaccination with this product began on October 1, 2024 for a one-year period.

Inf'OGM has requested clarification from Anses. With regard to the assessment, we asked about the risk assessment carried out, which led to the conclusion that the benefit/risk balance was positive. *Inf'OGM* has asked Anses for the opinion setting out these conclusions. No reply has yet been received at the time of publication of this article.

As for the benefits, the efficacy of vaccination has been the subject of a joint study by Anses and the Toulouse National Veterinary School[xii]. This efficacy is relative: digestive and respiratory excretion of the virus by vaccinated animals is only reduced compared to that of non-vaccinated animals. It is not eliminated. As a result, transmission of the virus between vaccinated ducks is possible: collective immunity has not been established. Further work is required.

The ATU for the self-amplifying mRNA vaccine has been issued to the French company CEVA Santé Animale[xiii]. Its "*vaccine*" contains a long molecule of artificial mRNA encoding the antigenic H protein against the virus, but it also contains other sequences coding for replicases (enzymes). These replicases will dramatically increase the amount of artificial mRNA produced, and hence of antigenic protein[xiv], without it being known whether or how this replication is likely to stop.

These risks of self-amplification of modified mRNA in the body of the animal (hen and various duck subspecies) are likely to be the same as in humans[xv]. But as this mRNA is destined here for an animal that has to be slaughtered to be eaten, its health does not seem to be a problem, if it allows the ducks to survive until slaughter.

The vaccine also contains excipients: iron oxide in the form of nanoparticles coating the mRNA, and squalene, whose safety has not been proven. But then again, the health of the vaccinated animal is irrelevant if it survives to slaughter.

Another problem: immunology has shown that vaccines can exert selection pressure on circulating viral strains. Strains not targeted by the vaccine are favored and, among them, a variant with increased pathogenicity potential may emerge. This is one of the major risks of vaccines, both for the species vaccinated and for other species, including humans[xvi].

What are the risks for human health?

In an organism vaccinated with mRNA, it is excreted from the cells that synthesized it, then distributed throughout the body's tissues. This has been demonstrated in the case of mRNA injections against Covid in humans[xvii].

In the case of the CEVA RESPONS A1 H5 “*vaccine*”, self-amplification will also increase this distribution of modified mRNA (encapsulated or naked) in the organs, as well as that of the synthesized H antigenic protein. Muscles and liver will be affected. The question then arises: have pre-clinical studies assessed the possibility of transmitting self-amplifying mRNA to humans when they eat duck meat and fatty liver? Especially since duck is often eaten half-cooked.

It is said that the “*vaccination*” is stopped, as with other vaccines, a few weeks before the ducks are slaughtered. Is this sufficient in this case? Is the residual presence of self-amplifying mRNA carefully and systematically checked after slaughter?

Can we also guarantee that the vaccine's excipients will not be transmitted to humans via the consumption of meat or foie gras? It should be remembered that the safety of squalene in the vaccines used against the human H1N1 influenza epidemic in 2009 has been called into question, and that no assessment of nanoparticles has been carried out[xviii].

None of these considerations are mentioned in the temporary authorization form for this “*vaccine*”. Only the accidental danger of the vaccine for the person performing the injection is considered. In the same file, ATU n° 90053, the special precautions concerning environmental protection are not mentioned.

The Anses website[xix] states that: “*Vaccines intended for livestock species are unique in that they are used on animals whose products (milk, eggs, meat, offal, etc.) are consumed by humans. A further step in the assessment is added with an in-depth evaluation to guarantee the safety of the vaccine for people consuming these products. This means that every component of the vaccine, whether the active ingredient or any adjuvants and excipients, is carefully checked to ensure that it poses no risk when an animal product is consumed*”.

Where can we find the details of all this painstaking verification work? And, in particular, where is the scientific evidence that “*when a product from a vaccinated animal is consumed [by humans], any residual mRNA is destroyed in the stomach by digestive enzymes and acidic conditions*”[xx] ? In the case of Covid, vaccine RNA has been found in all human organs, without exception[xxi]. Admittedly in small quantities, but what will happen in ducks with the self-amplification of the messenger RNA replication process?

In the absence of data on the food and environmental safety of these self-amplifying mRNA vaccines, shouldn't we apply the precautionary principle and lift the requirement for this type of duck vaccination in France, or even ban these “*vaccines*”?

In any case, we urgently need to think about simple strategies for combating avian influenza: maintain the genetic diversity of ducks on farms, whereas they are currently all bred from a very small number of lines; reduce the size and density of farms, which is precisely what the ENVT[xxii] suggests, as small (and open-air) farms are much better able to resist avian influenza[xxiii]. Several small structures are more resilient than one large one.

Behind these questions of vaccines for animals, it's industrial agriculture that we need to question.

i French ministry of Agriculture and Food Sovereignty, « Avian Influenza : the French vaccination action plan », 13 November 2024.

ii Ministère de l’Agriculture et de la souveraineté alimentaire, « 10 informations à retenir concernant la vaccination contre l’IAHP », October 2024 (in french).

iii Annick Bossu, « Une deuxième vague de vaccins à ARNm arrive sur le marché », *Inf'OGM*, 5 November 2024 (in french).

iv Ministère de l'Agriculture et de la souveraineté alimentaire, « 10 informations à retenir concernant la vaccination contre l'IAHP », October 2024 (in french).

v Isabelle do O'Gomes, « Qu'est-ce que la grippe aviaire ? », *Sciences et avenir*, 20 June 2022 (in french).

vi French ministry of Agriculture and Food Sovereignty, Direction Générale de l'Alimentation, « Data sheet 1 – the grounds for vaccination », October 2024.

vii Anses, « Virus Influenza aviaire hautement pathogène (IAHP) : les autorités sanitaires françaises poursuivent leurs actions et renforcent leur coopération face au risque de circulation d'un virus adapté à l'Homme », 6 February 2025 (in french).

viii WOAH, « Resolution n°28 – Strategic challenges in the global control of high pathogenicity avian influenza », May 2023.

ix Anses, « AVIS de l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail relatif à « l'élaboration d'une stratégie nationale de vaccination au regard de l'influenza aviaire hautement pathogène en France métropolitaine » », 30 March 2023 (in french).

x French ministry of Agriculture and Food Sovereignty, Direction Générale de l'Alimentation, « Fiche 4 – Presentation of the authorised vaccine », October 2024.

xi Anses, « Annexe à l'ATU n° 90055 » (in french).
Anses, « Annexe à l'ATU n° 90053 » (in french).

xii Anses et ENVT, « Expérimentation de vaccination des canards mulards en élevage contre un virus influenza aviaire hautement pathogène A(H5N1) clade 2.3.4.4b – Rapport intermédiaire : « Évaluation expérimentale de la protection clinique et de l'excrétion virale » », 7 April 2023 (in french).

xiii First French company of animal health, fifth at the worldwide level, Ceva Santé animale has 7,000 employees in 47 countries. Its historic headquarters are based in Libourne (33). Its sales in 2024: 1.77 billion euros.
Valérie Deymes, « Ceva Santé animale inaugure un laboratoire génomique pour les crises sanitaires de demain », *Sud Ouest*, 9 February 2025 (in french).

xiv Annick Bossu, « A second wave of mRNA vaccine coming to the market », *Inf'OGM*, 5 November 2024 (in french).

xv Ibid.

xvi Iwami S, Suzuki T, Takeuchi Y., « Paradox of vaccination: is vaccination really effective against avian flu epidemics? », *PLoS One*, 2009.

xvii Annick Bossu, « Biotechnologies médicales à ARN : nouveau Graal ? », *Inf'OGM*, 30 March 2023 (in french).

xviii Mathilde DETCHEVERRY, « Nanotechnologies in the field: nothing new in twenty years? », *Inf'OGM*, 28 février 2025.

xix Anses, « Update on the assessment and authorisation of veterinary vaccines », 29 January 2025.

xx Ibid.

xxi Annick Bossu, « Une deuxième vague de vaccins à ARNm arrive sur le marché », *Inf'OGM*, 5 November 2024 (in french).

xxiiENVT, « Avian influenza: need to rethink management strategies in livestock farming », 22 October 2024.

xxiii GRAIN, « Bird flu: a bonanza for 'Big Chicken' », 5 April 2007.

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