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ONTARIO VETERINARY COLLEGE
DEPARTMENT OF PATHOBIOLOGY

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Expert Statement Regarding Concerns About Modified RNA Vaccines in Food Production Animals

Dear Honourable Andrew Bridgen, Member of the British Parliament,

I am an Associate Professor of Viral Immunology who specializes in the subdiscipline of vaccinology. I was asked to provide an expert statement about concerns regarding using modified RNA (modRNA) vaccines in food production animals. This is to facilitate discussions in your parliament, and beyond, about farming-related issues. Please find attached a copy of my professional curriculum vitae so you can assess my expertise.

I publicly raised concerns about using modRNA vaccines in food production animals based on scientific concerns including, but not limited to, 1. The systemic biodistribution of lipid nanoparticles that are used as a vehicle to deliver modRNAs to cells throughout the body; 2. Shedding of modRNA vaccines and/or components/derivatives thereof. These scientific principles mean there is the potential for the transfer of modRNA vaccines, their components, or their derivatives (*i.e.*, target proteins) to people via food products from agricultural animal and plant species. This raises issues related to human and animal health and welfare, as well as regulatory concerns.

Please find attached a more detailed summary of these concerns based on my expert assessment of where the overall weight of the primary scientific evidence lies.

Sincerely,

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The Elegant Concept of Vaccines

The purpose of a vaccine is to simulate infection with a pathogen so a person can mount a protective immune response without having to be exposed to the risks associated with the disease caused by the pathogen. Naturally acquired immunity represents the gold standard that vaccinologists try to achieve with their immunization technologies. Naturally acquired immunity is usually broadly reactive to minimize risk of immunoevasion, confers long-lasting protection against acquisition of the disease and prevents transmission of the causative pathogen to others. In principle, the concept of an ideal vaccine is sound. In practice, scientists have much to learn about natural immune responses and some vaccines come closer than others to achieving the gold standard of naturally induced immunity.

Lipid Nanoparticles and Modified RNA Vaccine Technology

Messenger RNA is a naturally occurring genetic blueprint that cells use to manufacture proteins. Messenger RNA is only useful inside cells. Natural messenger RNAs are extremely fragile; so much so that they do not survive long enough in the body to be used as effective components of vaccines. A solution to this problem has been the manufacturing of synthetic, also known as 'modified', RNAs (modRNAs). To help get modRNAs into cells, they get packaged into tiny bubbles made of fat, called lipid nanoparticles (LNPs). When LNPs contact the fat layer that surrounds cells, which is called the cell membrane, they fuse and release the modRNAs into the cells where they can serve as a blueprint for manufacturing the protein that they encode. Modified RNAs encode proteins that the immune system can target on pathogens.

LNPs were originally designed with the goal of delivering drugs throughout the body, including into the brain to treat things like Alzheimer's disease, brain cancers, and Parkinson's disease[1,2,3]. They were also being tested for widespread delivery of genetic blueprints to try to correct genes associated with diseases; a strategy known as gene therapy[4]. However, one of the major roadblocks to using LNPs for these purposes was that multiple administrations resulted in excessive toxicities, in part due to activation of inflammatory mechanisms of the immune system[5]. Consequently, companies strategically decided to re-purpose LNP-encapsulated modRNAs for use as vaccines. The rationale was two-fold:

1. The immune system needs to detect something as being dangerous before it responds to it. LNPs containing modRNAs are highly 'reactogenic' and, therefore, perceived as being dangerous

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[1] Khan NH, Mir M, Ngowi EE, Zafar U, Khakwani MMAK, Khattak S, Zhai YK, Jiang ES, Zheng M, Duan SF, Wei JS, Wu DD, Ji XY. Nanomedicine: A Promising Way to Manage Alzheimer's Disease. Front Bioeng Biotechnol. 2021 Apr 9;9:630055. doi: 10.3389/fbioe.2021.630055. PMID: 33996777; PMCID: PMC8120897.

[2] Nsairat H, Khater D, Odeh F, Al-Adaileh F, Al-Taher S, Jaber AM, Alshaer W, Al Bawab A, Mubarak MS. Lipid nanostructures for targeting brain cancer. Heliyon. 2021 Sep 16;7(9):e07994. doi: 10.1016/j.heliyon.2021.e07994. PMID: 34632135; PMCID: PMC8488847.

[3] Jagaran K, Singh M. Lipid Nanoparticles: Promising Treatment Approach for Parkinson's Disease. Int J Mol Sci. 2022 Aug 19;23(16):9361. doi: 10.3390/ijms23169361. PMID: 36012619; PMCID: PMC9408920.

[4] Yi Zhao, Leaf Huang, Chapter Two - Lipid Nanoparticles for Gene Delivery, Editor(s): Leaf Huang, Dexi Liu, Ernst Wagner, Advances in Genetics, Academic Press, Volume 88, 2014, Pages 13-36, ISSN 0065-2660, ISBN 9780128001486, https://doi.org/10.1016/B978-0-12-800148-6.00002-X.

[5] Lv H, Zhang S, Wang B, Cui S, Yan J. Toxicity of cationic lipids and cationic polymers in gene delivery. J Control Release. 2006 Aug 10;114(1):100-9. doi: 10.1016/j.jconrel.2006.04.014. Epub 2006 May 13. PMID: 16831482.

to the body[6]. By virtue of being reactogenic, this technology induces inflammation, which is the foundation for any immune response.

2. "An ideal vaccine is… effective in providing lifelong protection against disease after a single dose".[7] As such, companies working with LNPs that are toxic when administered multiple times, latched onto the concept of using LNP-encapsulated mRNAs as vaccines in adults, where they would theoretically only have to be administered once.

Therefore, companies like Pfizer/BioNTech and Moderna made LNPs containing the modRNAs that encode the spike protein from severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2), which is the causative agent of the novel coronavirus disease that was first identified in 2019 (COVID-19). These products were tested to assess their potential to be used as vaccines. Remember, an "ideal vaccine" is one that **safely** provides protection against acquisition of a disease and transmission of the causative agent to others **after administration of a single dose**[8]. Now, think about the remarkably short duration of immune responses induced by COVID-19 vaccines for which some people have now taken more than ten doses. Clearly, it was inappropriate to convey the message that these were excellent vaccines when the reality is that they are so far from meeting the official definition of an ideal vaccine as to make it difficult to keep them under the umbrella term of 'vaccine'.

Importantly, most people do not realize that the LNP delivery system for modRNAs was switched away from trying to administer drugs and gene therapies precisely because of the definition of an ideal vaccine. Specifically, it was well recognized that multiple doses of LNPs were dangerous and toxic. So much so, that the concepts of LNP-vectored administration of drug and gene therapies had to be largely abandoned. The original hypothesis that drove the use of LNPs as a vaccine delivery technology was that as little as **a single dose** would be needed if they qualified as "ideal vaccines".

In demonstration of this, consider the following quotation from a journalist that interviewed the Chief Executive Officer of Moderna in 2016: "*Delivery – actually getting RNA into cells – has long bedeviled the whole field. On their own,* ***RNA molecules*** *have a hard time reaching their targets. They* ***work better if they're wrapped up in a delivery mechanism, such as nanoparticles made of lipids. But those nanoparticles can lead to dangerous side effects, especially if a patient has to take repeated doses over months or years. Novartis abandoned the related realm of RNA interference over concerns about toxicity, as did Merck and Roche.***"[9]

Also: "*In nature, mRNA molecules function like recipe books, directing cellular machinery to make specific proteins. Moderna believes it can play that system to its advantage by using synthetic mRNA to compel cells to produce whichever proteins it chooses. In effect, the mRNA would turn cells into*

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[6] Chapin-Bardales J, Gee J, Myers T. Reactogenicity Following Receipt of mRNA-Based COVID-19 Vaccines. JAMA. 2021 Jun 1;325(21):2201-2202. doi: 10.1001/jama.2021.5374. PMID: 33818592.

[7] https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information/page-14-basic-immunology-vaccinology.html (accessed March 1, 2024)

[8] https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information/page-14-basic-immunology-vaccinology.html (accessed March 1, 2024)

[9] https://www.statnews.com/2016/09/13/moderna-therapeutics-biotech-mrna/ (accessed March 1, 2024)

tiny drug factories. ***It's highly risky.*** *Big pharma companies had tried similar work and abandoned it because* ***it's exceedingly hard to get RNA into cells without triggering nasty side effects.***"

Then consider this quotation in the article from Dr. Katalin Karikó who recently received the Nobel prize for developing the synthetic modified RNA technology: "*I would say that* ***mRNA is better suited for*** *diseases where* ***treatment for short duration*** *is sufficiently curative,* ***so the toxicities caused by delivery materials are less likely to occur***". Of concern, it was discovered after awarding the Nobel prize that modRNA gets mis-read by the protein manufacturing machinery in cells, causing the unanticipated production of unpredicted foreign proteins that represent a "high level of impurity".[10,11]

Finally, please note this quotation: "*Moderna's most advanced competitors, CureVac and BioNTech, have acknowledged the* ***same challenge with mRNA. Each is principally focused on vaccines for infectious disease*** *and cancer,* ***which the companies believe can be attacked with just a few doses of mRNA***." [12]

Now, consider the promotion of "*repeated doses over months or years*" of COVID-19 modRNA vaccines, alongside the growing number of modRNA vaccines in the pipeline to target other diseases, as well as for use in farming. When people hear these concerns from the CEO of Moderna, other pharmaceutical companies, and the Nobel prize-winning scientist in which they placed their trust for the health of themselves and their family, they are left wondering why such serious concerns of toxicity due to multi-dosing was not rigorously disclosed to the public. And this is but one of an ever-growing number of problems with modRNA vaccine technology that have been identified in the peer-reviewed scientific literature.

modRNA 'Vaccines' Failed to Meet Expectations

Unfortunately, the modRNA vaccines against COVID-19 failed to come close to meeting the definition of an ideal vaccine. First, they fail to protect against infection and acquisition of disease. And, with many people around the world up to and even beyond ten doses within a three-year timespan, they don't come close to being effective with a single dose. Alarmingly, this means the entire premise of using them as vaccines to avoid multi-dose-associated toxicities has been lost. In the end, the public are expected to make their own informed decisions about vaccines. Yet their general perceptions tend to match the classical textbook definition of a vaccine, which is something that induces an immune response that protects a person from getting the disease and prevents them from transmitting the causative agent to others. As such, the public needs to be aware of how far the modRNA products are from being ideal vaccines.

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[10] Mulroney TE, Pöyry T, Yam-Puc JC, Rust M, Harvey RF, Kalmar L, Horner E, Booth L, Ferreira AP, Stoneley M, Sawarkar R, Mentzer AJ, Lilley KS, Smales CM, von der Haar T, Turtle L, Dunachie S, Klenerman P, Thaventhiran JED, Willis AE. N^1-methylpseudouridylation of mRNA causes +1 ribosomal frameshifting. Nature. 2024 Jan;625(7993):189-194. doi: 10.1038/s41586-023-06800-3. Epub 2023 Dec 6. PMID: 38057663; PMCID: PMC10764286.

[11] https://www.theepochtimes.com/world/exclusive-health-canada-official-deleted-scientists-note-saying-mrna-shots-have-high-level-of-impurity-internal-emails-5593451

[12] https://www.statnews.com/2016/09/13/moderna-therapeutics-biotech-mrna/ (accessed March 1, 2024)

The COVID-19 Vaccine Rollout Has Revealed Troubling Features of LNP-Encapsulated modRNAs

1. ModRNA vaccines against SARS-CoV-2 induce immune responses but fail to confer immunity, which means they cannot prevent infection, nor transmission.

2. A wide array of side-effects that were missed in the rush to get modRNA products to market were discovered only after the global public rollout. In some cases, these adverse events have the potential to be lethal. These include, but are not limited to, blood clots, myocarditis, pericarditis, and anaphylactic shock. The underlying mechanism of action of modRNA vaccines is cause for concern. Getting cells to express proteins from a pathogenic virus means, by definition, that those cells will be killed by the ensuing immune response, especially if immunological effector mechanism are pre-existing, as would be the case with a booster dose or vaccinating an individual that naturally cleared a prior infection. The degree of this self-destruction and whether it can spill over into long-term autoimmune diseases remains understudied and actively debated within the scientific community. By relying on passive monitoring systems during the public rollout of modRNAs, side-effects have likely been underestimated. The reality is that modRNA vaccines are unsafe and even lethal for at least some recipients. The degree to which this is an issue is the subject of ongoing debates.

3. Modified RNA vaccines that are injected into muscles get distributed throughout the body, seeding a wide array of organs and tissues[13,14], and these vaccines can be shed from the body. For example, there is definitive scientific evidence that modRNA COVID-19 vaccines get into the breastmilk of nursing mothers[15,16]. There is no reason to think the same would not occur in other species, including the mild of cows and goats, for example.

SPECIFIC CONCERNS ABOUT THE USE OF ModRNA VACCINES IN FARMING

Veterinary modRNA Vaccines Are Being Fast-Tracked for Rollouts

One Health: Vaccinating Animals to Protect the Health of People

The concept of 'one health' is that the health of people, animals, and the environment are interlinked and interdependent. The health of one can potentially impact the health of the other two. For example, the most potentially dangerous forms of the 'flu' occur when human influenza viruses exchange chunks of genetic material with influenza viruses that infect pigs and birds. This can result in

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[13] Cosentino M, Marino F. Understanding the Pharmacology of COVID-19 mRNA Vaccines: Playing Dice with the Spike? Int J Mol Sci. 2022 Sep 17;23(18):10881. doi: 10.3390/ijms231810881. PMID: 36142792; PMCID: PMC9502275.

[14] Trougakos IP, Terpos E, Alexopoulos H, Politou M, Paraskevis D, Scorilas A, Kastritis E, Andreakos E, Dimopoulos MA. Adverse effects of COVID-19 mRNA vaccines: the spike hypothesis. Trends Mol Med. 2022 Jul;28(7):542-554. doi: 10.1016/j.molmed.2022.04.007. Epub 2022 Apr 21. PMID: 35537987; PMCID: PMC9021367.

[15] Hanna N, De Mejia CM, Heffes-Doon A, Lin X, Botros B, Gurzenda E, Clauss-Pascarelli C, Nayak A. Biodistribution of mRNA COVID-19 vaccines in human breast milk. EBioMedicine. 2023 Oct;96:104800. doi: 10.1016/j.ebiom.2023.104800. Epub 2023 Sep 19. PMID: 37734205; PMCID: PMC10514401.

[16] Hanna N, Heffes-Doon A, Lin X, Manzano De Mejia C, Botros B, Gurzenda E, Nayak A. Detection of Messenger RNA COVID-19 Vaccines in Human Breast Milk. JAMA Pediatr. 2022 Dec 1;176(12):1268-1270. doi: 10.1001/jamapediatrics.2022.3581. Erratum in: JAMA Pediatr. 2022 Nov 1;176(11):1154. PMID: 36156636; PMCID: PMC9513706.

outbreaks in the human population of swine and avian flus. There are many other zoonotic pathogens that can be transmitted from animals to people. As such, there is growing interest in promoting global human health through the mass vaccination of animals of agricultural interest. The rationale is that if animals can't get a disease and transmit the causative agent to people, this could avoid outbreaks in the human population.

One Health: Fast-Tracking of Veterinary modRNA Vaccines

Many modRNA vaccines are being developed with the goal of administering these to food-producing animals. Historically, the first clinical testing of a mRNA vaccine was in cattle, preceding the rollout of COVID-19 modRNA vaccines into people. Australia is currently an example of a country in which new modRNA vaccines against Foot and Mouth Disease and Lumpy Skin Disease are being fast-tracked to address the economic impact of these diseases on their livestock industry[17]. The same is occurring for a wide array of other pathogens, including influenza viruses in poultry and swine[18].

Why Should People Care About modRNA Vaccines for Farm Use?

There are at least six reasons:

1. If veterinary modRNA vaccines targeting pathogens that can infect people are as far from meeting the definition of an ideal vaccine as the COVID-19 vaccines were, then massive numbers of animals will be conferred with far from sterilizing immunity. This, in turn, could produce massive reservoirs of animals around the world that can promote the emergence of unique and potentially immuno-evasive variants of zoonotic pathogens that could then infect people. Global regulators should be compelled to insist, without compromise, that veterinary modRNA vaccines for zoonotic pathogens confer immunity, which the modRNA vaccines that are currently available for people fail to confer. This means that animals receiving vaccines should be rendered unsusceptible to the target disease, and they should be unable to transmit the causative agent to others, especially humans. Unlike COVID-19 modRNA vaccines, veterinary modRNA vaccines should be required to undergo formal transmission testing as part of any approval process.

2. COVID-19 modRNA 'vaccines' are injected into muscles, then they distribute throughout the body, and can leave the body as evidenced by their secretion in breastmilk. This means there is the potential for modRNA vaccines to get into edible tissues of food animals. It would not be safe, nor medically approved, for people to consume veterinary modRNA vaccines in milk, eggs, and meat. Careful testing needs to be done to determine where modRNAs and other components or derivatives from modRNA vaccines go in the bodies of animals and how long they last in veterinary species. This would determine, in part, the 'wash-out' period, which is

[17] https://www.abc.net.au/news/rural/2022-08-22/foot-mouth-vaccine-development-fast-tracked-nsw-biosecurity/101356300 (accessed March 2, 2024)

[18] Rcheulishvili N, Papukashvili D, Liu C, Ji Y, He Y, Wang PG. Promising strategy for developing mRNA-based universal influenza virus vaccine for human population, poultry, and pigs- focus on the bigger picture. Front Immunol. 2022 Oct 17;13:1025884. doi: 10.3389/fimmu.2022.1025884. PMID: 36325349; PMCID: PMC9618703.

how long one needs to wait before obtaining food from agricultural species to ensure humans are not exposed to the medical product.

3. Wherever modRNA can be found in an animal's body, one would also expect there to be the protein that it encodes. This represents a major concern for modRNA vaccines for farming. The potential problem here is a phenomenon known as 'oral tolerance'[19]. Immune systems are designed to interpret things that are eaten as being non-dangerous. This is to avoid harmful chronic inflammation in the gastrointestinal tract (stomach and intestines), as well as food allergies. It also prevents suffering chronic inflammation against the massive number of bacteria and viruses that live in the gastrointestinal tract. When people eat something, their immune systems become unable to respond to it[20]. The goal of using modRNA vaccines in food animals to try to stop zoonotic pathogens before they can infect people could backfire badly if the proteins from pathogens get into animal-derived food products. Inducing oral tolerance against pathogen-derived proteins could cripple a person's ability to protect themselves against the pathogen being targeted.

4. The concept of 'GMO foods' (GMO = genetically modified organism) is already a substantial hurdle in the agricultural industry for many consumers. Use of modRNA vaccines would render animals at least transiently genetically modified (assuming the synthetic RNAs are eventually cleared). But, until scientifically proven otherwise, there even remains the possibility of permanent genetic modification of animals. This could occur should any modRNA get reverse transcribed into DNA and integrated into an animal's chromosomes. Alternatively, there is the consistent contamination of COVID-19 modRNA vaccines with bacterial DNA used to manufacture the modRNA. With genetic components like the SV40 promoter in the DNA contaminating Pfizer/BioNTech's modRNA vaccine, there exists an alternative potential mechanism whereby there could be permanent integration into the chromosomes of cells. Any of these possibilities could add a novel wrinkle to the concept of GMO foods and needs to be closely evaluated through research, with the goal of adopting suitable regulatory policies.

5. Ther is also the well-being of farm animals that needs to be considered, especially if an array of different modRNA vaccines end up being administered, with the potential for each of them requiring repeated dosing. Modified RNA vaccines are not entirely safe in people, especially if more than one dose is administered, and this may apply to animals as well. Care must be taken to ensure that animal welfare is preserved, along with their ability to reproduce efficiently. Research in animals represents an ideal scenario to conduct extensive and careful studies into the safety of modRNA vaccine technologies, including addressing the numerous legitimate, well-rationalized safety questions that have been raised but largely ignored during the rollout into humans.

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[19] Rezende RM, Weiner HL. Oral tolerance: an updated review. Immunol Lett. 2022 May;245:29-37. doi: 10.1016/j.imlet.2022.03.007. Epub 2022 Apr 5. PMID: 35395272.

[20] Yoshida T, Hachimura S, Kaminogawa S. The oral administration of low-dose antigen induces activation followed by tolerization, while high-dose antigen induces tolerance without activation. Clin Immunol Immunopathol. 1997 Mar;82(3):207-15. doi: 10.1006/clin.1996.4319. PMID: 9073543.

6. Research is being conducted to get plant-based foods to produce modRNAs for consumption by people. For example, there is a project at the National Science Foundation, California, United States of America, in which lettuce and spinach are being engineered to express proteins from pathogens by giving these plants modRNA genetic blueprints.[21] The idea is that people will eat these plants, and this will induce an immune response that, in theory, could protect them from a targeted disease. Here are key quotes from the report:

    a) "*Ideally, a single plant would produce enough mRNA to vaccinate a single person*"

    b) "*We are testing this approach with spinach and lettuce and have long-term goals of people growing it in their own gardens*"

    c) "*Farmers could also eventually grow entire fields of it.*"

    Again, this would represent a novel form of GMO food. The risk of modRNA vaccines or their components/derivatives getting into food derived from agricultural animals would likely be an unintended harm by those trying to protect animal and human health. But turning edible plants into modRNA vaccine factories is intended to get people to consume the proteins encoded by the modRNA genetic blueprints. This concept of food-packaged pathogenic proteins converts the theoretical risk of consumption with food animals into a blunt reality. Once again, this raises the potential for unintended oral induction of immunological tolerance against pathogens. Indeed, scientists have been using this precise strategy of expressing target proteins in plants to harness the power of oral tolerance to cripple the immune system in a way that would prevent it from causing "autoimmune, allergic and inflammatory diseases"[22]. This means that eating parts of pathogens in the context of food products could backfire. The intention would be to induce protective immune responses. However, the overall weight of the scientific literature suggests that the most logical hypothesis is that it will render the immune system less able to respond to pathogens. Further, controlling dosing with these kinds of vaccines would be impossible, especially if people were to grow them in their gardens. First, the amount of target protein that is manufactured from modRNAs is already inherently unpredictable; it depends on the metabolic activity of the cells that randomly acquire the modRNAs. Further, people could consume as much modRNA as they wish should it be grown in edible plants. There would be no ability for health professionals to provide oversight for the consumption of such vaccines. The ability to regulate the administration of vaccines would be lost. Also, the messaging with COVID-19 modRNA vaccines was that 'more is better'. For some people, this approach could drive massive consumption home grown modRNA vaccines. Some people don't understand that 'more' does not equal 'better protection' when it comes to vaccines; and overdosing could be harmful. A vaccine requires a target protein(s) plus an adjuvant, which provides a danger signal to the immune system, so it knows to respond to the target. It is unknown how lettuce and spinach, which people consume regularly, would be perceived as dangerous by the immune system. One of the two main ingredients in the recipe for an ideal vaccine seems to be missing.

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[21] https://www.universityofcalifornia.edu/news/grow-and-eat-your-own-vaccines (accessed March 2, 2024)

[22] Ma S, Liao YC, Jevnikar AM. Induction of Oral Tolerance with Transgenic Plants Expressing Antigens for Prevention/Treatment of Autoimmune, Allergic and Inflammatory Diseases. Curr Pharm Biotechnol. 2015;16(11):1002-11. doi: 10.2174/1389201016666150826121334. PMID: 26306744.

If foodborne pathogen-derived proteins were somehow able to induce an aggressive immune response against a pathogen, one must wonder if there could be a risk of this breaking tolerance to other protein components of the food. If this was to occur, it could lead to the induction of food allergies. Projects like this raise the concern of whether they are being conducted merely to push technological boundaries in the absence of involvement of immunologists trained in vaccinology. Technological innovations do not automatically translate into good for the world. In my expert opinion, getting people to eat food expressing proteins from pathogens could be a recipe for rendering large numbers of people more susceptible to the very diseases that researchers would be aiming to protect against.

The Precautionary Principle

The precautionary principle is that novel medical products should never be implemented into practice until high standards of safety and efficacy have been proven. The onus is not on the end user of modRNA vaccine technology to prove a potential for net harm. Instead, the onus is on anyone promoting a novel medical intervention to provide transparent primary scientific evidence to prove that benefits exceed risks. In this context, hearsay reputational evidence is unacceptable. This would include deferrals to statements made by organizations that have not undergone the rigorous scientific peer-review and publication process, and for which authorship, disclosure of conflicts of interest, methods, and raw data have not been provided. Instead, one needs to establish where the overall weight of the primary scientific evidence lies. And when it comes to the safety of modRNA vaccines for farming, this would include addressing all well-rationalized scientific concerns, including the many that were deemed inappropriate to raise during the rollout of modRNA vaccines into humans.

Scholarly Debate and Informed Consent

There needs to be a return to good scientific practice. This should include rigorous, respectful, public debates of the science underpinning modRNA vaccines before they are licensed for routine use in farming applications. No scientific topic should be off-limits for respectful discussions. The issues raised in this report should be critically assessed to either affirm or allay these concerns. After all, robust, uncensored scholarly debate represents the best way to ensure the safety of the public when it comes to novel medical technologies, including making sure they are fully informed when making their own decisions about how to use it.

Research

Governments need to recognize the potential for modRNA vaccine technologies to not only have positive global impacts on health, but also the possibility of substantial negative outcomes. Modified RNA vaccines and substantial funding for research need to be made readily available to objective third-party investigators to run critical experiments to address questions like, but not limited to the following:

a) Do modRNA vaccines for agricultural applications induce immune responses that protect against infection?
b) Do they protect against transmission of the causative agent of the disease?

c) Do veterinary mRNA vaccines or any of their components, including the proteins they encode, get into milk, meat, eggs, and/or other food products (*e.g.*, livers, etc.)?
d) If so, how long are they present?
e) Can consumption of proteins from zoonotic pathogens potentiate oral induction of immunological tolerance that would render a person more susceptible to the disease being targeted?
f) What are the consequences to the health of people that inadvertently consume modRNA vaccines or their components/derivatives?
g) Can modRNA vaccines impact health or fertility of farm animals or the long-term physiological development or health of their offspring?
h) What is the environmental impact of potential shedding of modRNA vaccines or their components/derivatives from farmed animals and plants?

A Call for a Moratorium

Until concerns raised in this report and those identified by other experts are definitively addressed, it is my expert opinion that no modRNA vaccine intended for agricultural applications (nor any for human use, for that matter) should be licensed by any regulatory body. This is for the sake of ensuring the protection of both human and animal health. Overly rapid deployment of this technology anywhere in the world has the potential to cause public health problems elsewhere on the globe. After all, pathogens do not respect boundaries.