SHOULD FOODS BE GENETICALLY ENGINEERED TO PRODUCE VACCINES OR OTHER PHARMACEUTICALS?

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Table of Contents

- I. Introduction
 - A. History of traditional vaccines
 - B. Advantages to a vaccine that does not need to be injected
 - 1. Badgers containing tuberculosis
 - 2. Stomach flu in pigs
- II. History of edible vaccines
 - A. Traditional vaccines were too costly to transport
 - 1. Charles J. Arntzen and Dominic Man-Kit Lam
 - B. Experimentation
 - 1. Plants
 - 2. Animals
 - a) Zebrafish
- III. Where will edible vaccines be useful?
 - A. 3rd world countries
 - B. Livestock & wildlife industry
 - C. Everyday people

IV.	Pros of Edible Vaccines		
	A.	Cost effectiveness	
		1.	Transportation
		2.	Produced indefinitely
	B.	Easier to administer	
	C. Less waste		vaste
		1.	No syringes
V.	7. Cons of Edible Vaccines		
	A.	Vacci	ne dosage
		1.	Tests on humans
	B. Edible vaccines mixed with food		e vaccines mixed with food
		1.	Raw foods
	C. Feeding animals edible vaccines		ng animals edible vaccines
		1.	Vaccine specific
	D.	Regulation	
		1.	Traditional GMO
VI.	Conclusion		
	A.	Compare pros and cons	
	B.	Should foods be genetically engineered to produce vaccines or other	
	pharmaceuticals?		

Conditions

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Edible Vaccines

All around the world and throughout human history, there have been many infectious, harmful, and even deadly diseases and viruses that have caused extreme chaos. Scientists fought this with the invention of vaccines which have performed near miracles in the fight against infectious diseases (Langridge). Back in 1796, Edward Jenner was the first person to create and use a vaccine to eradicate smallpox; after years of perfecting and innovating the creation and administration of vaccines, science eventually created today's modern-day procedures ("All Timelines Overview"). The next innovation, some scientists believe, is the use of edible vaccines to keep humans and animals safe from past and future infectious diseases. The edible vaccines are very simple to use, an individual would simply eat a food instead of being injected with a needle or syringe.

There are many advantages to having a vaccine that does not need to be injected. For example, there is currently a problem in England and Wales involving badgers containing tuberculosis. Their current solution for this is to trap the badger and inject the vaccine; this process is tricky and relatively time consuming which is why they are looking for a more efficient solution. One of the solutions to this problem would be to create an edible vaccine that the badgers could eat in their own habitat. This would be cost effective and widespread, making this solution very efficient (Gowtage, Sonya, et al). Another example of how edible vaccines would be beneficial has to do with the "protection against the common transmissible

gastrointestinal virus in pigs" (Savoie). By using the edible vaccine method, the vaccine could be given to the pigs in a pellet or ground meal form, which would make administering the vaccine very simple and cost effective (Savoie).

The simple use and cost effectiveness of edible vaccines are only a byproduct of the innovative idea. In the late 1980s, it was reported that about 20 percent of infants were not receiving basic vaccines to live a healthy life. The "diphtheria, pertussis (whooping cough), polio, measles, tetanus and tuberculosis" vaccines were too costly to transport to underdeveloped nations (Langridge). Mixing unvaccinated infants with harsh living environments resulted in about two million infant deaths (Langridge). This situation caught the eyes of Charles J. Arntzen and Dominic Man-Kit Lam who, at the time, were attending Texas A&M University. In 1992, they proposed the idea of genetically altering plants to produce vaccines as a response to the World Health Organization who were trying to find an "[...] inexpensive, oral vaccines that needed no refrigeration [...]" (Vermij; Langridge).

This began the birth of the edible vaccine idea. After years of development, scientists have been able to create plants and animals containing vaccines. In fact, here in the United States, some "several acres of crops, most of them still experimental, are planted each year. Researchers have thus far produced more than 45 different antigens in a wide range of plants" (Vermij). Some of these edible vaccines have been fed to animals for testing. The results that were reported seem promising; however, the edible vaccines need help to be effective. "Many in the field say that, at least in animals, plant-based oral vaccines have been proven to be safe and effective. For instance, corn loaded with proteins from a gastroenteritis virus is effective, at least when used as a booster, in protecting pigs against the disease" (Vermij).

The zebrafish has also been used as a delivery vehicle for vaccines. Zebrafish in Singapore have been genetically modified to contain the hepatitis B vaccine. These modifications were done by researchers from the National University of Singapore; they state that there are 27g of vaccine per kg of fish ("Edible flu vaccines"). "It has also been suggested that this technology could also be adapted to other, more common fish, such as salmon" ("Edible flu vaccines"). This could also lead to the idea that vaccines can be genetically added to livestock for human consumption, further expanding the foods containing vaccines. However, researchers say that "plant-based vaccines would be safer than those produced in animal tissues because the chances of unknown human pathogens hitching a ride would be extremely small" (Vermij). Because of the successful trials done on plants and animals, a group of volunteers were brought in to consume some of the edible vaccines. The article explaining this test states:

In humans, several vaccines have passed safety trials. Arntzen's group at Arizona State University tried vaccines produced in genetically modified potatoes and corn against enterotoxic *Escherichia coli* and Norwalk virus. Koprowski's group fed volunteers spinach containing a rabies booster vaccine. Both groups have tested oral hepatitis B vaccines, either as primary or booster vaccine, in lettuce, spinach and potatoes. Although small phase 1 trials like these can't prove protection, volunteers in the studies showed an "appropriate," though not always strong, immune response, Arntzen says (Vermij).

This statement also suggests that trials and tests will continue to move forward and process until perfect.

If edible vaccines are proven to be just as safe and effective as traditional vaccines, then their will most likely be a very high demand for them in the coming years of its release (Savoie).

The most proper use of the edible vaccines would be to fulfill its original goal and help the infants and even adults in 3rd world countries. One of the major difficulties of transferring vaccines to 3rd world countries is the refrigeration needed for safe transport ("Vaccine Storage Guide"). However, with the introduction of edible vaccines, "during transport and storage, vaccine-containing seeds or dried leaves would not need refrigeration, a significant advantage in developing countries. Oral vaccines especially, administered as juices or tablets to circumvent dose variability, would pave the way for mass vaccinations in those countries" (Vermij). Using the advantages of edible vaccines growing from plants one step further, "the plants could be grown locally, and cheaply, using the standard growing methods of a given region" (Langridge). Producing vaccines like this, in their own country, would also avoid the economic hurdle that comes with producing and transporting vaccines the traditional way (Langridge).

Another place where edible vaccines will be in very high demand is in the livestock and wildlife industry. This is just like the previously mentioned examples of vaccinating badgers for tuberculosis in a widespread and effective manner, and the example of corn containing the gastroenteritis vaccine to protect pigs against the disease (Gowtage; Vermij). This could also be given to the animals in many different ways. One way would be to mix it within their food, they animals will most likely have no idea or will not care. Another method would be to simply feed them a pellet or plant of some sort, this could prove to be a more difficult task, but ensures that the animal is getting the correct amount of the vaccine.

In addition to using edible vaccines to distribute to animals, there is a good chance that it can be sustainable for human consumption. Just as human trails have begun in some labs around the world, there is a high chance that once fully successful and effective, that it could be sold and

distrusted to hospitals and healthcare centers around the world. The technology would be much more simple and efficient to use for the distribution of basic vaccines.

The three applications that were listed are just some of the pros that came with edible vaccine technology. Because of the design of these vaccines, they are very easily distributed. No refrigeration means that it can be distributed all over the world without special and high transportation costs. In fact, the whole system is very cost effective. As previously stated, the crops might have the potential to be grown locally, completely eliminating the cost of transportation. There is also the possibility that these crops will be able to regrow. "Because many food plants can be regenerated readily, the crops could potentially be produced indefinitely without the growers having to purchase more seeds or plants year after year" (Langridge). This eliminates the need to keep genetically modifying plants in order to keep production moving. However, until it is proven that each plant will be an exact copy and not differ in vaccine chemistry from seed to seed, this will only be a possibility and not a guarantee. These edible vaccines are also much easier to administer; in fact, it almost completely eliminates one of the jobs given to a health care professional because all the patient has to do is eat the given vaccine. They, of course, will still need to be present during the serving of the edible vaccines because they would need to calculate out the correct dosage that is needed for each individual. Because the vaccine only needs to be eaten and not injected, this eliminates the need of syringes which also eliminates the possibility of infections if the needle becomes contaminated (Langridge).

Not needing syringes will not only beneficial to people, but it will also be beneficial to the environment. According to the World Health Organization, there is an estimated 16 billion injections that take place worldwide over one year. It is also estimated that the United States accounts for 800,000,000 of those needles in a single year ("How Many Needles Do Hospitals

Use and How Do They Dispose of Them"). These needles are eventually sterilized by heating up and killing all microbial life in a device or structure called an autoclave ("Where Does Biohazardous Waste Go"). "Much of the waste treated by autoclaving and shredding ends up at the sanitary landfill" ("Where Does Biohazardous Waste Go"). By using edible vaccines, there will be a decrease in the need for syringes which will in turn cause a decrease in the amount of unnatural material being dumped into the ground.

However, until we get to the point where edible vaccines are used all around the world, there are hurdles, some of them being very big, that scientists need to solve or adapt to in order for this technology to be effective. One of those hurdles is making sure that each edible vaccine and those who come after are containing the same exact amount of vaccine. If not, then their becomes the risk of giving the patient too much or too little of the vaccine, putting the patient into immediate or future harm. Currently, the tests on humans are successful but not perfect, the edible vaccines do not create a strong enough immune response (Vermij). Additionally, a challenge appears when edible vaccines are mixed with food:

Before they can be approved, Plotkin says, plant-based vaccines will have to consistently generate stronger immune responses, which would need to be studied carefully for every crop. "If vaccines are intimately presented together with food, the gut's immune system faces a conundrum," he notes. The gut is designed not to react to antigens in food, but must produce a useful response against the vaccine. Instead of being immunized, patients could even end up being 'tolerized,' meaning an immune response against future invaders would be weakened, not intensified.

This creates a huge hurdle in the edible vaccine idea because the stomach may have to be completely empty in order for the vaccine to take full effect.

During the zebrafish experiment, it was reported that the amount of fish that needed to be consumed was quite small in size; however, "[...] due to the nature of the vaccine, the fish would have to be consumed raw in order to prevent the vaccine from being denatured" ("Edible flu vaccines"). This may also suggest that everything containing a vaccine must be consumed raw, which, depending on what it is the individual has to consume, may be anywhere from fine to unpleasant.

Another hurdle, pertaining to feeding animals edible vaccines, is that not all animals and vaccines are compatible. "[...] a bait-vaccine carrier developed for wild boar (Sus scrofa) was also attractive to badgers in Spain, but of 150 baits consumed by badgers, 87% had the vaccine carriers (plastic capsules) rejected and of these, 99% were separated from the bait intact with the payload of water still inside" (Gowtage). This suggests that every vaccine has to be tailor made for each specific species (Gowtage). Because there are hundreds or wildlife species living among other species, it could lead to waisted vaccines and sick animals. It is unknown what happens when one animal eats a different animal's specified vaccine; further tests must be done before coming to a conclusion and labeling it completely save.

The other, most important hurdle, is ensuring that edible vaccines are completely safe for humans, animals, and the environment. This is such a big hurdle that "[...] even Arntzen now says his original idea of distributing vaccine-bearing fruit was naive, because regulatory agencies will not approve vaccines with variable dosing" (Vermij). There must be specific safety boards added for the sale and distribution of these edible vaccines. This is what happened in the recent and current GMO debate. "John Krebs, chair designate of the new UK Food Standards Agency,

has called for the creation of an international advisory panel to address all sides of the GM food debate, including the safety and regulation of exports, economic development, and environmental and ethical questions" (Savoie). With this bored put in place, it is said that "every major scientific organization in the world has concluded that the genetically engineered crops currently on the market are safe to eat and that the process of genetic engineering is no more risky than older methods of genetic alteration" and that "These are precisely the same organizations that most of us trust when it comes to other important scientific issues such as global climate change and the safety of vaccines" (Ronald). The same actions need to be done for edible vaccines to ensure that it is complexly safe for humans, animals, and the environment. Tests still need to be done to prove that it is environmentally friendly and does not affect other natural foods. This brings up the question of the safely and safeguarding of these genetically altered plants and their seeds. If one of the plants seeds are misplaced and released into the wild, then plants containing vaccines will freely grow. This becomes a major problem when some unaware child or adult eats one of these wild plants (ex. fruits) and becomes ill.

The idea that vaccines can be genetically modified into common foods would be a useful solution for making vaccines easier to distribute to 3rd world countries, making vaccines easier and cheaper to manufacture, and creating vaccines that have no waste (such as syringes) leftover for the environment. Comparing the pros and cons is one of the only fair ways to determine if the edible vaccine idea is a safe, effective, and reliable method to replace current vaccines. After looking at both the pros and the cons of edible vaccines, foods should be genetically engineered to produce vaccines and other pharmaceuticals if, and only if, the future tests regarding safely to people, animals, and the environment show that it has no effect and is 100% safe. There should also be mandatory rules that ensure there is no contact between naturally grown food and foods

containing vaccines at any time. Everything from the growing, to the production, to the shipping and distributing should stay completely separate from naturally grown foods to ensure that there is no possible way to mix up the two foods and risk a national, or worldwide, emergency.

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