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The Costs of Overregulating Animal and Plant Biotechnology: Lessons from COVID-19

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Modern molecular biology offers tools for precisely altering traits of crops and livestock. Similar tools have been used to develop vaccines and treatments for COVID-19. Genetically engineered (GE) crops have been used to produce animal feed and fiber, but rarely approved for human consumption. We estimate that hundreds of thousands of children have died from malnutrition due to delays in the regulatory approval of Golden Rice, and tens of billions of dollars have been lost due to excessive regulations of GE livestock. In light of societal responses to the pandemic, we suggest a reconsideration of current GE regulations given their high cost in lives and treasure.

Societies throughout the world have taken drastic steps to limit the carnage of COVID-19. In addition to costly social distancing and other public health measures, governments have accelerated the normal regulatory procedures to fast-track approval of both vaccines and medical treatments for COVID-19. These swift and aggressive responses to COVID-19 stand in

stark contrast to the heavy regulatory burdens and the limited introduction of plant and animal biotechnology solutions to address age-old problems of malnutrition and food insecurity, despite the evidence that these technologies are as safe as traditional food technologies.

The discovery of DNA in the 1950s opened new avenues for both medical treatments and crop and animal breeding strategies. Detailed knowledge of genetic mechanisms and genome sequences has enabled the development of genetic technologies to more precisely treat or prevent diseases and has dramatically increased the rate of genetic selection for production traits. While new tools of genetic engineering have been adopted wholeheartedly in medicine, they still have only limited practical applications in commercial crop breeding and almost no applications in animal breeding.

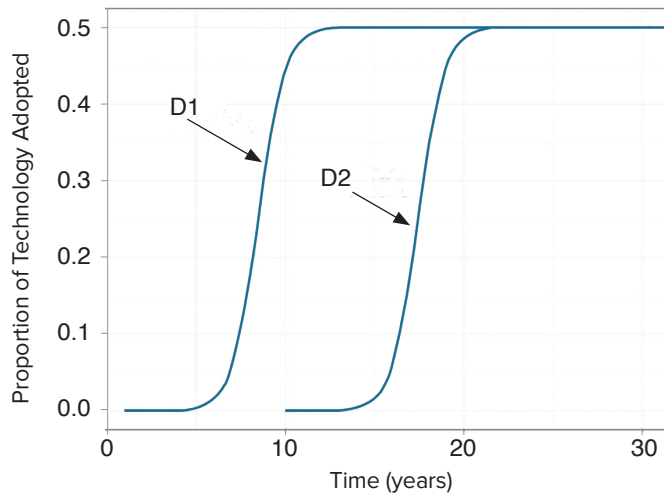
Humans have selectively bred crops and livestock for millennia, improving production traits or disease resistance. Traditional breeding relies on the randomness generated by nature, limiting its precision. By identifying the functions of specific genes, scientists

can increase the speed and precision of selective breeding, enabling them to obtain traits and address challenges that have eluded traditional breeding methodology. Research suggests that genetic engineering technologies are, in principle, as safe as traditional breeding, and their use is supported by multiple scientific bodies. However, regulatory constraints, reflecting political economic considerations, have limited the application of genetic engineering to improve the efficiency of crop and animal production. In this paper, we argue that the regulation of agricultural biotechnology is too strict and too costly in terms of lives and treasure lost. Society's response to COVID-19 provides further perspective on these regulations.

Costs of Delaying the Introduction of GE Plant Technologies

Several genetically engineered (GE) plant varieties have been commercialized, mostly for production of fiber, such as cotton, and animal feed, such as corn and soybeans. Studies consistently show that the adoption of GE varieties tends to increase yield, reduce toxic chemical use, and reduce agricultural

Figure 1. Effect of a 10-Year Regulatory Delay on the Adoption of a New Technology



Note: D1=Diffusion without delays; D2=Diffusion with delays

land use and greenhouse gas emissions. Furthermore, the introduction of GE varieties reduced the price of cotton and soybeans by an estimated 20% and the price of corn by 10%. The Americas have seen extensive adoption of GE technology, while the production of GE varieties is practically banned in Europe. African countries likely stand to gain the most from employing GE technologies, but their adoption in Africa has been limited. GE cotton has been adopted heavily in India and China, but few other GE varieties are produced in Asian countries.

The introduction of many crop biotechnologies has been blocked in multiple countries. In most cases, regulators decide to delay their decision, and in some cases, the delays continue to the present.

Our analysis of the costs of regulatory delays takes into account that the adoption of new crop varieties is a gradual process. Every year of delay reduces the immediate benefit of the new variety and, by slowing the adoption process, reduces the benefits in future years. In assessing the costs of a delay, a reasonable assumption is that several years are needed for regulatory evaluation before the process of diffusion can commence. We also assume that diffusion takes place over a finite

period. A standard regulatory process typically takes no more than 10 years. If the regulatory process takes longer, we call the excess time a regulatory delay. Groups that oppose the technology, pressure for regulatory delays by citing concerns about the potential for environmental harm and other unforeseen consequences that require more time to be understood.

The cost of a regulatory delay is the difference in the expected net benefit (gains from consumption minus production costs) without delays minus the expected net benefit with delays. Figure 1 illustrates the diffusion curve without regulatory delays (D1) starting 10 years after discovery, compared to diffusion (D2) that begins 20 years after discovery. The difference between the curves reflects the lower diffusion rate every year because of the regulatory delays, and summing the discounted extra losses over the planning horizon will yield delay costs.

There are several cases where adoption of GE crops has been approved by technical agencies but delayed for political reasons. One case is the adoption of Golden Rice, a variety of rice fortified with vitamin A. Each year, more than 600,000 children die and even more lose their eyesight due to vitamin A deficiency (VAD). Golden

Rice was developed to address this problem, but its adoption has been delayed by regulations. It was first introduced in 1992. Even when allowing extra time for technical improvements, it could have been approved by 2010. If Golden Rice adoption saved 10% of the lives lost due to VAD in the last 10 years, it would have saved 600,000 lives. Our studies suggest that each year of delay costs over \$1 billion in Bangladesh alone. Failing to approve GE varieties of major food commodities (wheat and rice throughout the world and corn in Europe, Asia, and Africa) has resulted in economic losses of \$136 billion to \$1.3 trillion, depending on the length of the planning horizon, interest rate, and the assumed yield effect of the GE technology. Much of the cost is borne by consumers.

Animal Breeding

While GE crops have been adopted to a limited degree, genetic engineering in livestock has seen only minimal use, even though traditional methods of animal breeding have been used to improve agricultural productivity and address food security challenges. About 50% of the calories supplied by crops are directly consumed by humans, and about 40% are used as animal feed. Thus, improvements in livestock's input-use efficiency of grains will reduce the amount of land and other inputs needed to produce animal products. For example, animal breeders have tripled the feed efficiency (pound of meat per pound of feed) of broiler chickens (chickens raised for meat) over the last century. These productivity improvements have made chicken affordable for billions of people around the world, improving food security and reducing the environmental footprint of animal protein production compared to alternative animal proteins.

Similarly, genetic improvements have helped increase dairy productivity. Milk production per cow in the U.S. has more than quadrupled over the

last 75 years, allowing farmers to meet growing demand without a proportional increase in farm inputs. In fact, the U.S. dairy cattle herd has declined by more than half, from 25 million cows in 1944 to 9 million today, even as milk production has increased by 60%. As a result, the carbon footprint of a glass of milk today is one-third of what it was in 1944.

Similar trends can be seen in the swine sector and other animal food products. However, animal agriculture remains a major source of greenhouse gases, both because of its inputs and as a result of animal waste products. Furthermore, overfishing threatens the sustainability of fisheries, and aquaculture and mariculture are among the fastest growing agricultural sectors in both developed and developing countries, though these sectors are challenged to increase efficiency and reduce pollution.

With population growth and rising incomes, reducing the environmental footprint of agriculture will require continued improvements in the efficiency of animal agriculture. Developments in biotechnology provide tools to enhance animal productivity and control animal diseases. The genomes of numerous animals have been sequenced, and CRISPR CAS9 (gene editing) and other technologies have been used to develop beneficial traits in animals. However, the utilization of these technologies has thus far been heavily constrained by regulations in the U.S. and globally. As we will show later, the costs of these regulations are very high.

Application to Fish Aquaculture

The major producers of Atlantic salmon are Canada, Chile, Norway, Scotland, and the U.S., and annual U.S. exports exceed \$3 billion. Much of the salmon we eat is farmed Atlantic salmon, which, if raised in floating sea cages where the fish may escape, can be devastated by diseases carried by wild

salmon. As an alternative, studies suggest that land-based salmon farming is less vulnerable to diseases and less polluting, emitting just half the greenhouse gases associated with growing fish in conventional fish farms.

Canadian scientists have developed a fast-growing Atlantic salmon variety, AquAdvantage, through genetic engineering. AquAdvantage salmon grow 40% faster than non-transgenic salmon and require 25% less feed to produce the same biomass. The first paper describing AquAdvantage salmon was published in 1992 and this fish could have become available in 2002 after a 10-year regulatory process. However, political objections, stemming from unproven environmental concerns, have continued to delay its introduction in the U.S. through 2020.

We computed the costs of delay from 2002 through 2020, in 2020 USD. Various assumptions are needed to calculate these costs, such as a 4% interest rate and estimates of demand and supply parameters. Furthermore, we assume salmon output is 30% higher for farms using transgenic salmon, so total production is 15% higher when 50% of farms adopt transgenic varieties. Under these assumptions, the estimated costs of regulatory delays ranged from \$18 to \$37 billion; our preferred estimate was \$26 billion. These extra costs are paid by consumers (through higher prices) and producers (through higher production costs).

The social costs of this regulatory delay extend well beyond the costs to current salmon consumers and farmers. Fast-growing salmon allows inland salmon production and, if adopted globally, could enable salmon production in developing regions far from coastal areas and with limited access to fish. Furthermore, adoption of this technology would provide additional incentives for the use of genetic engineering to improve the productivity of salmon and other fish, which could

provide a valuable and affordable source of protein.

Application to Swine

Porcine reproductive and respiratory syndrome (PRRS) is a major viral swine disease with a global annual cost of about \$4.5 billion a year. Scientists have used gene editing to develop PRRS-resistant pigs by knocking out a single gene. This technique is not transgenic (no genes are introduced) and, without extra regulatory requirements, it is reasonable to assume its adoption could have commenced in 2020. But again, regulatory barriers presented delays. Assuming a 50% final adoption in the U.S. and EU, a 5-year regulatory delay would cost \$4 billion and a 10-year delay \$7.5 billion. If the final rate of adoption is 100%, a 5-year delay would cost \$7.5 billion, and with 10 years of delay it would cost \$14 billion in the U.S. and Europe. China has close to 50% of the global supply of pigs. So, adjusting for China-specific considerations, the cost of a 10-year delay due to regulatory delays when the final adoption is 100% is estimated to be around \$13.5 billion.

The swine sector is afflicted by another deadly disease, the African swine fever (ASF), which decimated 40% of China's pork production and doubled the price of pork in 2019. The disease is now spreading throughout the world. Higher pork prices will likely increase the demand for other types of meat, including game and wildlife, which may lead to the spread of zoonotic diseases. Gene editing and other genetic engineering technologies offer a promising approach to control ASF infections in the global pig population. Hopefully, if a genetic solution to this problem becomes available, it will be utilized as soon as possible without excessive and costly regulatory delays.

Discussions and Lessons From the Pandemic

New biotechnologies enhance the capabilities of medical and agricultural researchers and have the potential to

improve human health, save human lives, enhance food security, and reduce environmental footprints. While applications of molecular technology, and in particular genetic engineering, have been widespread in developing new medical treatments, its applications in agriculture, both for crops and especially for livestock, have been limited. The recent pandemic has taught us three lessons about the use of genetic engineering.

First, molecular technologies can develop more effective and faster solutions to controlling the spread of diseases. The pandemic showed the limitations and costs of relying on cultural practices like social distancing and protective equipment alone. Controlling the pandemic requires the use of modern technologies to quickly develop vaccines and to keep the vaccines current for whatever mutations COVID-19 may undergo. Historically, the development of effective vaccines has taken multiple years, but modern molecular technologies have accelerated both the development time and vaccine effectiveness compared with traditional vaccine development. Similarly, the desire to avoid modern inputs and rely on organic methods in agriculture has its limitations. Taking advantage of new advances in molecular technologies in a responsible manner can solve major food and environmental challenges.

Second, one of the major barriers to the introduction of GE products in agriculture has been precautionary. Delaying the introduction of technologies like Golden Rice or genetically engineered bananas was justified by concerns about uncertain social and ecological costs, even though genetic engineering has been used extensively without any major incidents or significant loss of life. Golden Rice was introduced in 1992, and even assuming slow development, its adoption could have started in 2010. The numbers of lives that could have been saved by the adoption of Golden Rice in India, Bangladesh, the Philippines, and African

countries is at least as great as the number of lives lost to COVID-19.

Societies have taken drastic and costly measures to address the pandemic and now apply cures that were developed using methods similar to the ones used to produce Golden Rice. The response to the pandemic has shown that society is willing to incur significant costs to adjust to a health crisis and save lives, which suggests that we should also reconsider some of the rigid regulations that have prevented the use of biotechnology tools in food and agriculture.

Third, the pandemic has shown the importance of resilience, preparation, and adaptability in the presence of shocks. Our society is facing shocks that endanger our lives and pose risks to our food and health supplies. Having technologies that are capable of swiftly addressing emerging challenges can effectively improve our capacity to deal with a crisis. The U.S. was not well prepared to face the pandemic, but our medical researchers swiftly developed effective vaccines, highlighting the value of investment in research.

Similarly, our food system was able to cope with social distancing and restriction of movement by quickly adopting e-commerce tools that enabled retailers to provide food to homes, thereby increasing accessibility to food. Similarly, business activities were able to continue as people worked from home and adopted the use of conferencing software. Continued development of solutions based on modern biotechnologies is essential in order to enhance our capacity to address shocks to our health and food systems. We need to develop regulatory frameworks that allow and incentivize the introduction of new capabilities when they are most needed.

Our analysis shows that, while modern biotechnologies have significantly contributed to improving our quality of life and economic well-being, they have been significantly underutilized

in crop production and drastically underutilized in animal production. The pandemic shows that we are ready to take real risks, adopt new technologies, and change our practices in order to save lives. Virtually all national academies of science suggest that modern biotechnology tools are as safe as traditional agricultural technologies, but we overregulate many of them because of hypothetical risks. Adopting more reasonable and flexible regulatory frameworks that would allow us to utilize the power of modern biology can improve the food system and the environment and enhance our resilience to future shocks to our global society.

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For additional information, the authors recommend:

Van Eenennaam, Alison L., F. De Figueiredo Silva, J.F. Trott, and D. Zilberman. 2021. "Genetic Engineering of Livestock: The Opportunity Cost of Regulatory Delay." *Annual Review of Animal Biosciences*. Vol. 9.