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HOW BURDENSOME REGULATION OBSTRUCTS HUNGER RELIEF

by Krisztina Pusok
Project Director: Julian Morris
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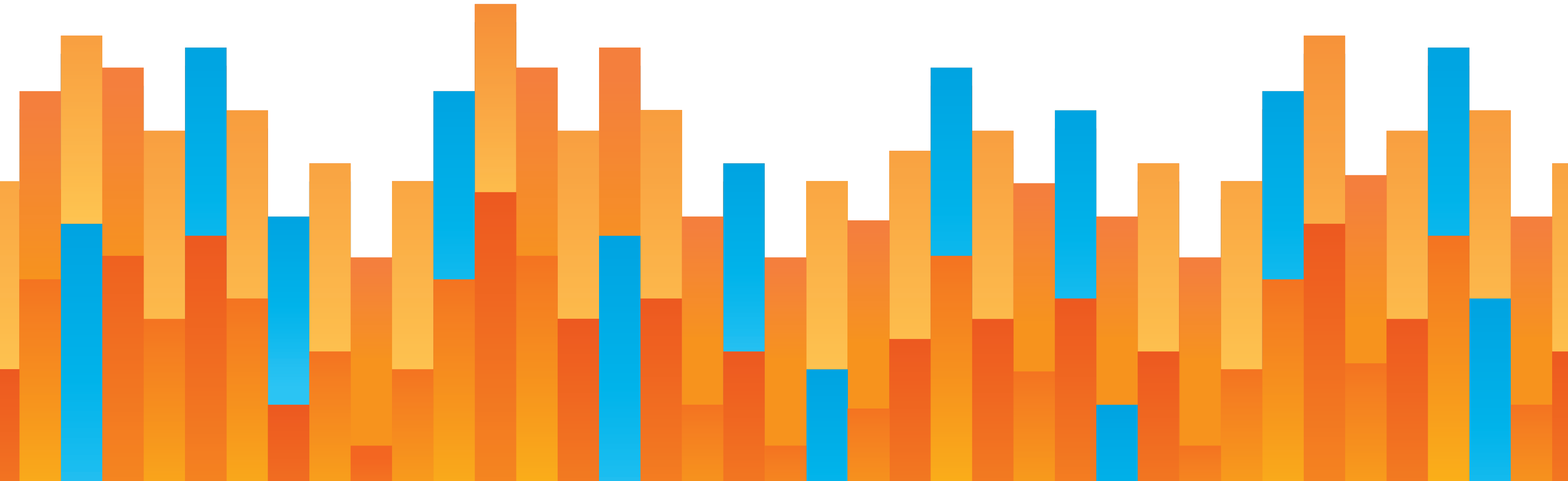

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PART 1

INTRODUCTION

Henry Kissinger proposed at the World Food Conference in 1974 that “within a decade, no child should go to bed hungry.” Since the 1970s, hunger in the developing world has been cut by more than half, with the rate going down from at least 35% to less than 15%. Despite decades of progress, current studies on the issue of hunger (e.g. IFPRI Global Food Policy Report) highlight its continuing prevalence worldwide: millions of people still experience chronic hunger.

Hunger in its various forms (e.g. malnutrition, famine) is a serious threat to human health:

> *People who are chronically hungry are undernourished. They don’t eat enough to get the energy they need to lead active lives. Their undernourishment makes it hard to study, work or otherwise perform physical activities. Undernourishment is particularly harmful for women and children. Undernourished children do not grow as quickly as healthy children. Mentally, they may develop more slowly. Constant hunger weakens the immune system and makes them more vulnerable to diseases and infections. Mothers living with constant hunger often give birth to underweight and weak babies, and are themselves facing increased risk of death.* [1]

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[1] UN Food and Agriculture Organization. “Debating World Hunger.” Web.<https://developmenteducation.ie/feature/exploring-the-shape-of-our-world-today/debating-world-hunger/> Accessed 20 June 2018.

It is often said that “hunger does not discriminate.” Yet, it does. This brief seeks to show how burdensome and excessive regulations block the potential benefits of breakthrough technological innovations from reaching vulnerable populations.

Parts 2 and 3 describe past and current trends in the prevalence of hunger worldwide. Part 4 discusses the role of technological innovations (the Green Revolution) in achieving progress on hunger in the past few decades. Part 5 addresses the promising benefits of several existing and emerging technologies, while Part 6 examines how the current regulatory environment erects costly barriers, keeping these technologies from reaching vulnerable populations.

Finally, this brief offers recommendations to help solve hunger by reforming current regulatory regimes[2] that block the diffusion of beneficial technologies.

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[2] Since the key focus of this paper is the role of technology on hunger and malnutrition, the paper restricts the discussion of challenges only to those pertaining to the adoption and diffusion of technology. Other challenges to hunger and malnutrition that are not included in this paper include challenges posed by conflict, poor market infrastructure, water and environment-related policies, and institutional constraints.

PART 2

TRENDS IN THE PAST CENTURIES

Current global statistics on hunger are more heartening than in previous decades. The share of the world's population suffering from hunger is shrinking. Despite population growth, the total number of undernourished persons is lower as well (see Figure 1). Today the majority of countries have hunger prevalence levels below 35%, with the highest prevalence across Sub-Saharan Africa (particularly in the East) and a number of countries across Asia. In 1991, only a select number of developing countries had undernourishment levels under 5%. In 2015, many countries achieved this, particularly across Latin America, the Middle East and North Africa. Even those who are food-deprived are less severely malnourished than in the past (see Figures 2 and 3). While humanity now produces more than enough food to theoretically feed everyone on Earth the recommended 2,000 calories per day[3] (see Figure 4), there is still a disproportionate distribution among regions.

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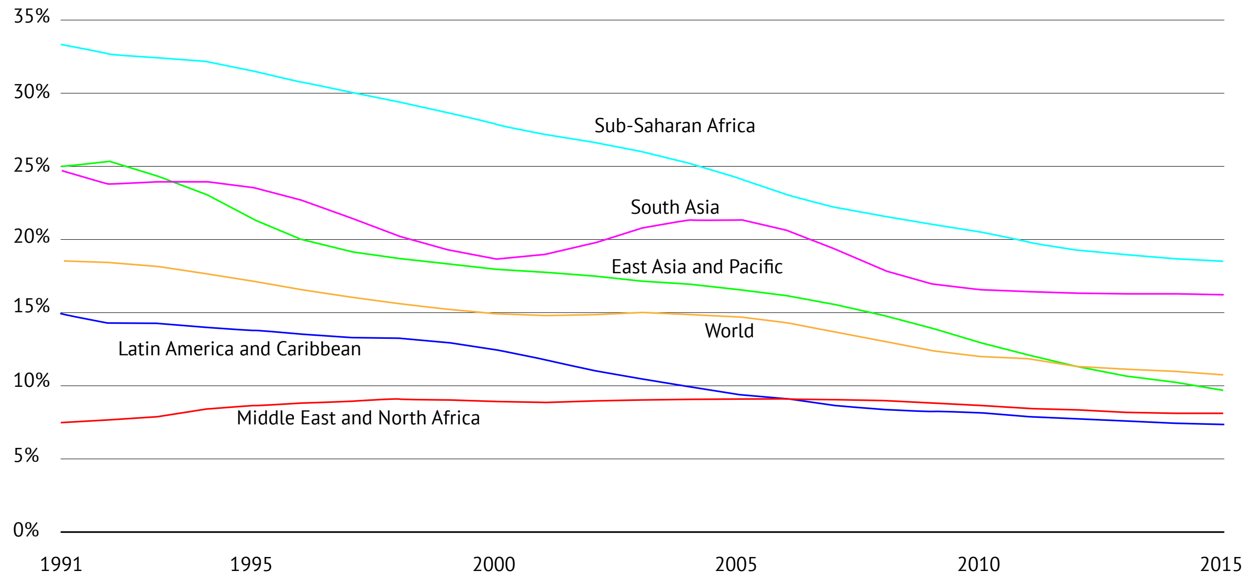
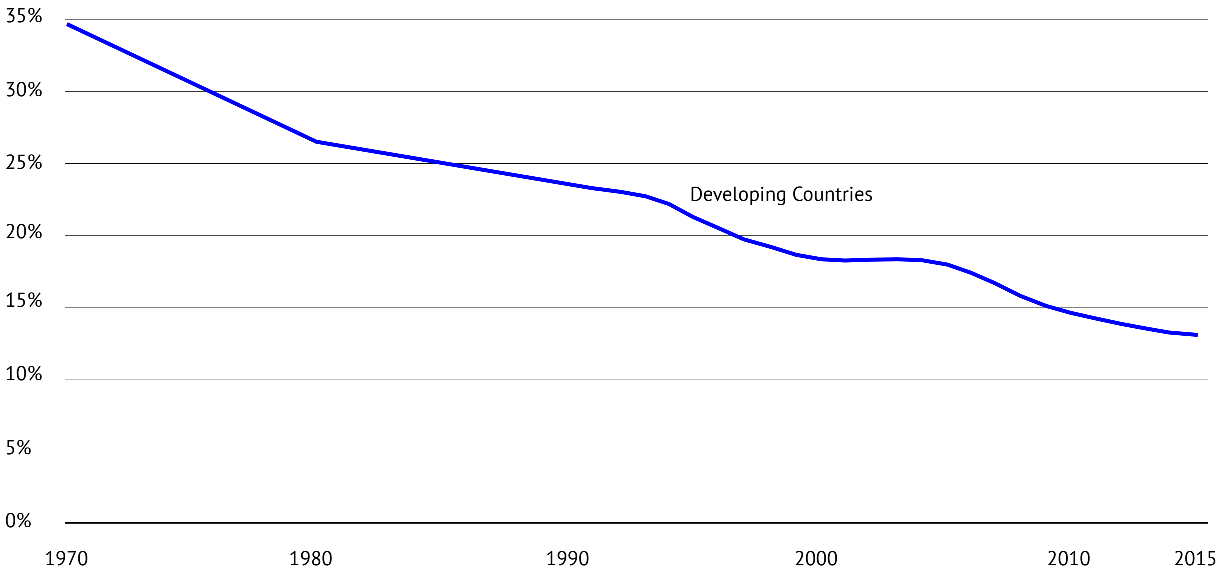
[3] U.S. Department of Health and Human Services. "Estimated Calorie Needs per Day, by Age, Sex, and Physical Activity Level." Appendix 2.
Web. https://health.gov/dietaryguidelines/2015/guidelines/appendix-2/ Accessed 20 Jun. 2018.

FIGURE 1: SHARE OF THE POPULATION THAT IS UNDERNOURISHED



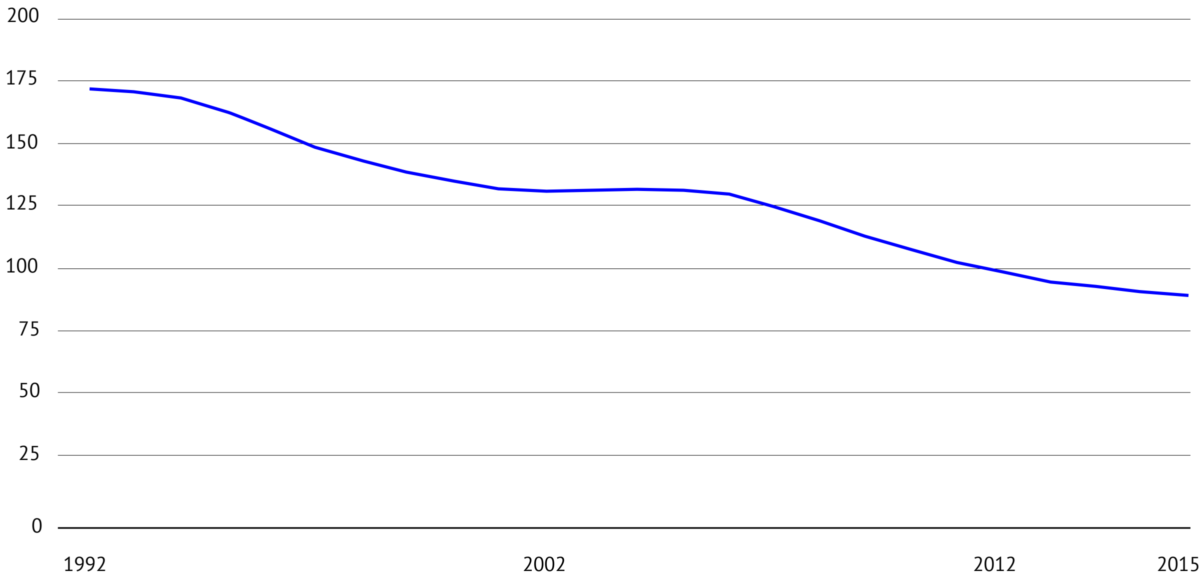
Source: UN Food and Agriculture Organization (FAO) FAOSTAT Online Dataset. Web. <www.fao.org/faostat/en/>

FIGURE 2: PREVALENCE OF UNDERNOURISHMENT (%) IN DEVELOPING COUNTRIES SINCE 1970



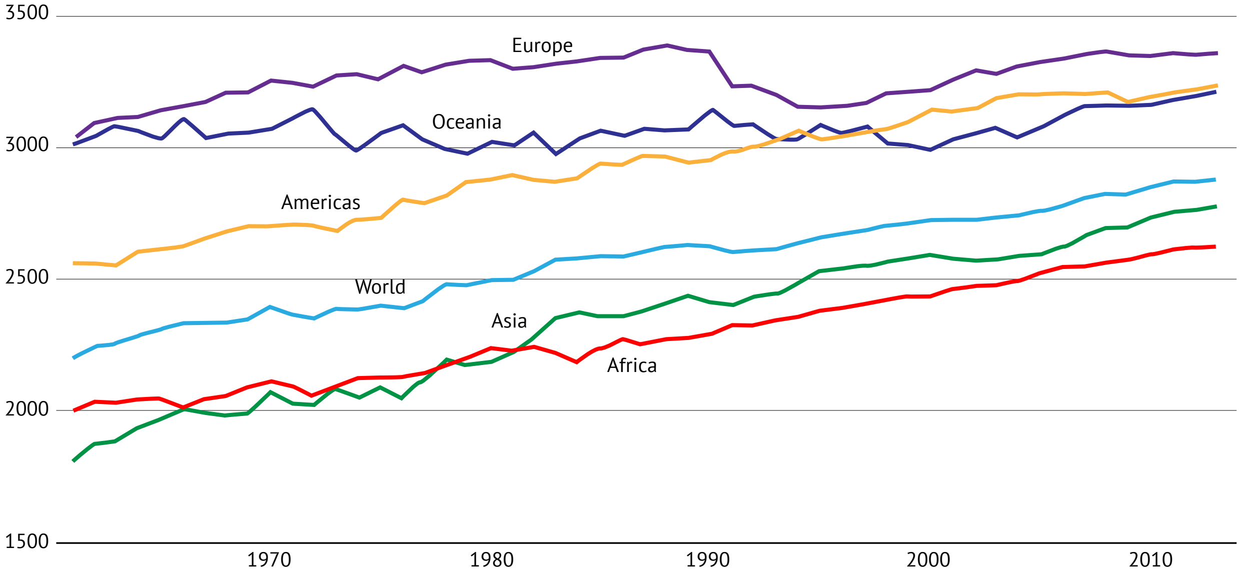
Source: UN Food and Agriculture Organization FAO Indicators. Web. <https://ourworldindata.org/hunger-and-undernourishment>

FIGURE 3: FOOD CONSUMPTION SHORTFALL AMONG FOOD-DEPRIVED PERSONS (CALORIES PER DAY, 1992-2016)



Source: The World Bank DataBank- World Development Indicators. Web. <http://databank.worldbank.org/data/reports.aspx?source=world-development-indicators>

FIGURE 4: FOOD AVAILABILITY (KCAL PER CAPITA PER DAY)



Source: UN Food and Agriculture Organization (FAO) FAOSTAT Online Dataset. Web. <www.fao.org/faostat/en/>

PART 3

CURRENT STATISTICS

According to the International Food Policy Research Institute (IFPRI), global hunger has increased after nearly a decade of prolonged decline. The number of undernourished people globally rose from 777 million in 2015 to 815 million in 2016.[4]

TABLE 1: GLOBAL UNDERNOURISHMENT COMPARISON, 2000, 2015 AND 2016

Indicator	Share of the reference population in 2000	Share of the reference population in 2015	Share of the reference population in 2016
Overall population that is undernourished	14.8 %	10.7 %	13.0 %
Children under 5 that are stunted	32.6 %	23.2 %	27.8 %
Children under 5 affected by wasting	N/A	N/A	7.7 %
The under-five mortality rate	77.5	42.2	40.8
Global Hunger Index (GHI) score	N/A	21.3	21.8

NOTE: There is no aggregate worldwide indicator for “children under 5 affected by wasting” for 2000 and 2015. The Global Hunger Index (GHI) originates in 2006.

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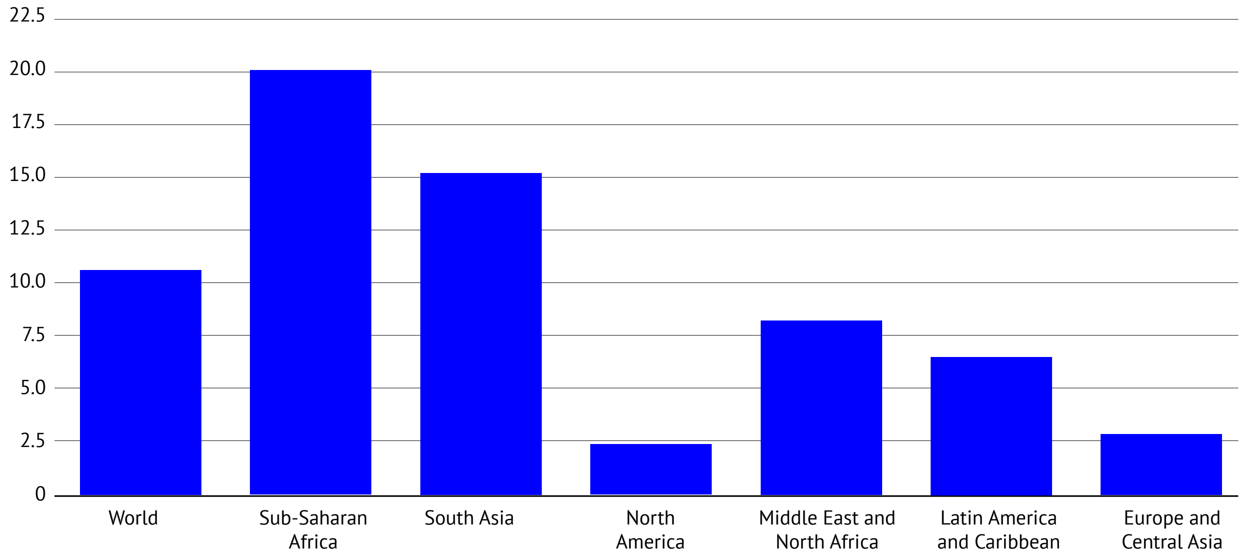
[4] International Food Policy Research Institute. “FAO Food Security Report shows a world hungrier for results and action.” Web. <http://www.ifpri.org/blog/fao-food-security-report-shows-world-hungrier-results-and-action> Accessed 20 June 2018.

The 2017 Global Hunger Index (GHI) indicates that worldwide levels of hunger and undernutrition have declined over the long term: At 21.8 on a scale of 100, the average GHI score for 2017 is 27% lower than the 2000 score (29.9). Of children under five, 27.8% are stunted, down from the 2000 rate of 37.7%, and the under-five mortality rate dropped from 8.2% in 2000 to 4.7%.

Some regions are more affected than others (see Figure 5). The regions of the world struggling most with hunger are South Asia and Sub-Saharan Africa, labelled by IFPRI as regions with *serious* hunger issues.[5] There is some significant variation within the regions as well. For example, about half of the countries in the East and Southeast Asia, whose average benefits from China's GHI score of 7.5, are in the serious range.[6] Similarly, given that three-quarters of South Asia's population resides in India, the *serious* situation in that country strongly negatively influences South Asia's regional score.

FIGURE 1: REGIONAL PREVALENCE OF HUNGER



Source: IFPRI 2017 Global Hunger Index

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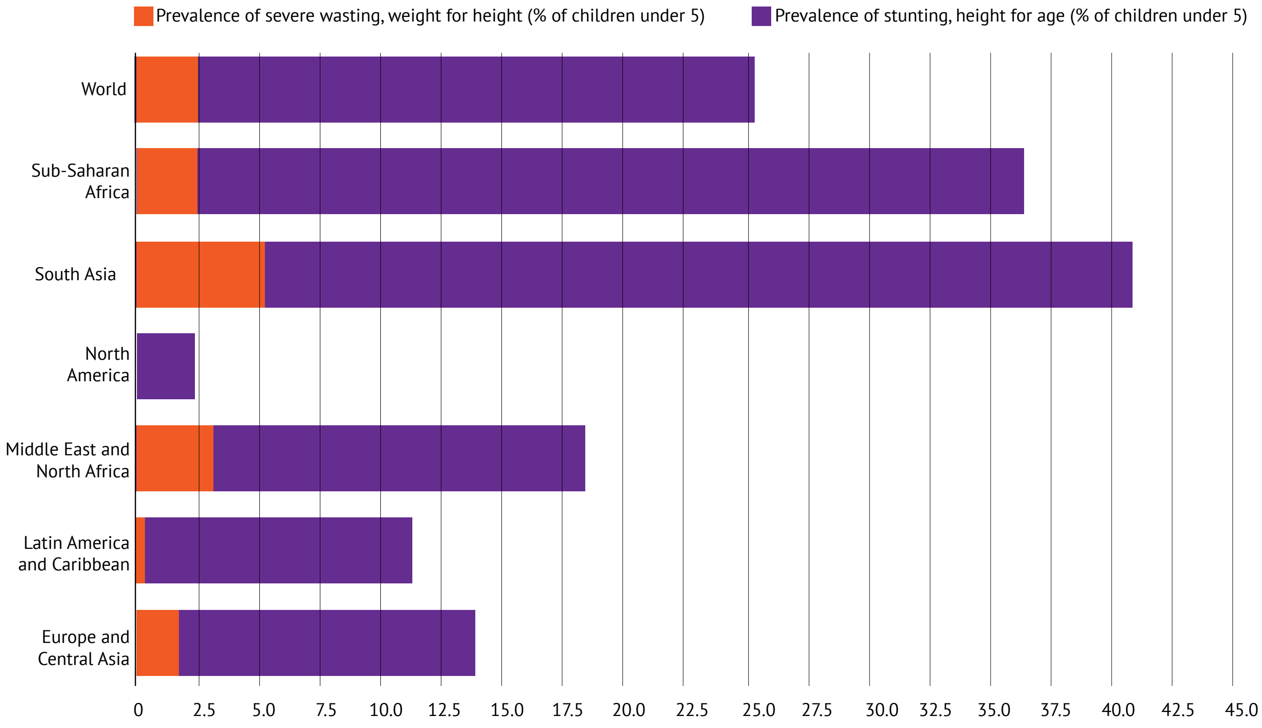
[5] Von Grebmer, K., et al. (2017). 2017 global hunger index: The inequalities of hunger. International Food Policy Research Institute. Web <http://ebrary.ifpri.org/cdm/ref/collection/p15738coll2/id/131422> 20 June 2018.

[6] Ibid.

Eight countries suffer from *extremely alarming* or *alarming* levels of hunger, according to IFPRI. Except for Yemen, all are in Sub-Saharan Africa: Central African Republic (CAR), Chad, Liberia, Madagascar, Sierra Leone, Sudan and Zambia. Several of these countries have experienced political crises or violent conflicts in the past several decades.

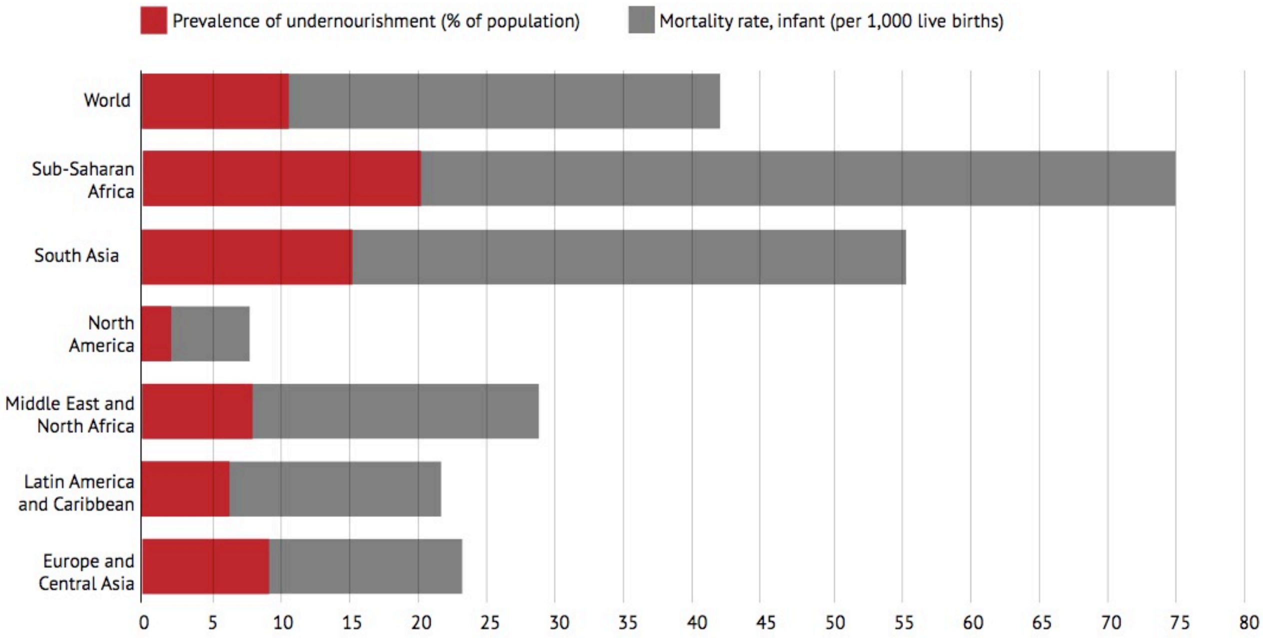
In the regions with the most hunger—South Asia and Sub-Saharan Africa—hunger takes different forms. In South Asia, for example, child undernutrition, as measured by child stunting and child wasting, is higher than in Sub-Saharan Africa. Meanwhile, Sub-Saharan Africa has a higher child mortality rate and struggles more with undernourishment, reflecting overall calorie deficiency for the population.

FIGURE 2: CHILD UNDERNUTRITION, REGIONAL PERSPECTIVE



Source: The World Bank DataBank—World Development Indicators. Web. <http://databank.worldbank.org/data/reports.aspx?source=world-development-indicators>

FIGURE 3: OVERALL CALORIE DEFICIENCY FOR THE POPULATION



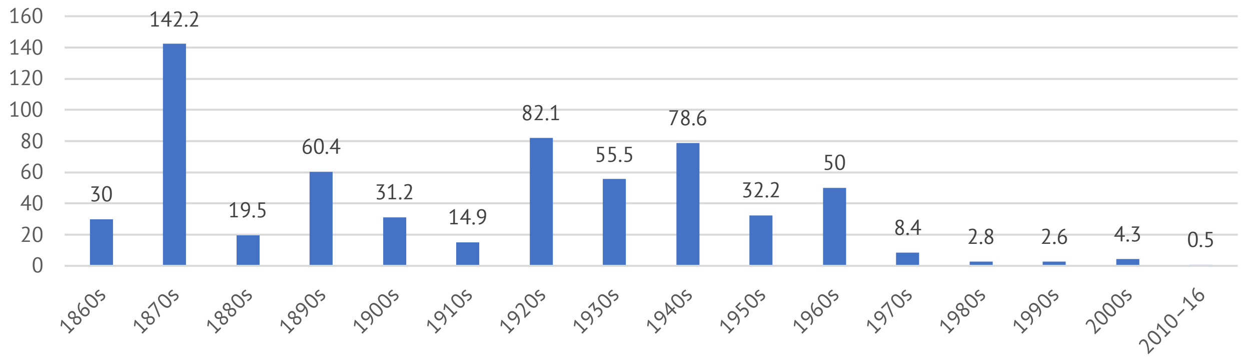
Source: The World Bank DataBank—World Development Indicators. Web. <http://databank.worldbank.org/data/reports.aspx?source=world-development-indicators>

PART 4

THE ROLE OF TECHNOLOGICAL INNOVATIONS

Less than a century ago, hunger was a near-universal experience. Then, something changed. Over the past century, famines that kill more than 100,000 people have become rarer and rarer, to the point where they are almost obsolete. In the 21st century, 600,000 people have been killed by great famines, a high number but nowhere near the 27 million who died from famines between 1900 and 1909.

FIGURE 8: GLOBAL ANNUAL DEATH RATE (PER 100,000) DUE TO FAMINE, PER DECADE



Source: OurWorldInData.org Web. <https://ourworldindata.org/famines#note-6>

Besides the exchange and specialization that helped bring down food prices, a burst of innovations called the Green Revolution led to higher agricultural productivity and decreased food prices even further. The various scientific technologies developed by Norman Borlaug, the central figure in the Green Revolution, include:[7]

- ***new farming irrigation methods*** (e.g. drip irrigation, sprinkler, center pivot, lateral move, and sub-irrigation) brought several advantages[8] to agricultural sustainability as it minimized weed growth and soil erosion while reducing energy costs;
- ***stronger and more resistant pesticides*** boosted crop production and improved both the quality and yield tremendously;
- ***the shift to inorganic and chemical-based fertilizers*** became a strategy for more effective agricultural production; and
- ***newly developed seeds*** for more proficient crop growth was a key and transformative technological innovation of the Green Revolution as advancements in bio-technology enabled seeds to absorb more water and fertilizer, expanding crop yields.

Current research shows that without such technological breakthroughs, countries around the world, such as India and Mexico, may not have had the ability to escape massive food shortages and famines.

Even as the world's population grew, the market ensured that the supply of food rose to meet growing demand. Between 1966 and 2000, the population of low-income countries almost doubled, while food production increased by 125%.[9] During the same period, world wheat production increased by 91%,[10] while average cereal yields have nearly tripled since 1961, from around 0.6 tons (metric tons)/hectare in 1961 to about 1.7 tons/acre in 2013.[11]

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[7] Kundra, Rajan. "An In-depth Introduction to Green Revolution Technologies." Web. <https://hnrs353.wordpress.com/science-section/technology-of-the-green-revolution/ > 20 June 2018.

[8] Kesavan, P. C. and M. S. Swaminathan. "Strategies and Models for Agricultural Sustainability in Developing Asian Countries." *Philosophical Transactions: Biological Sciences*, Vol. 363, No. 1492, *Sustainable Agriculture II* (Feb. 27, 2008): 877-891. Jstor.org. The Royal Society.

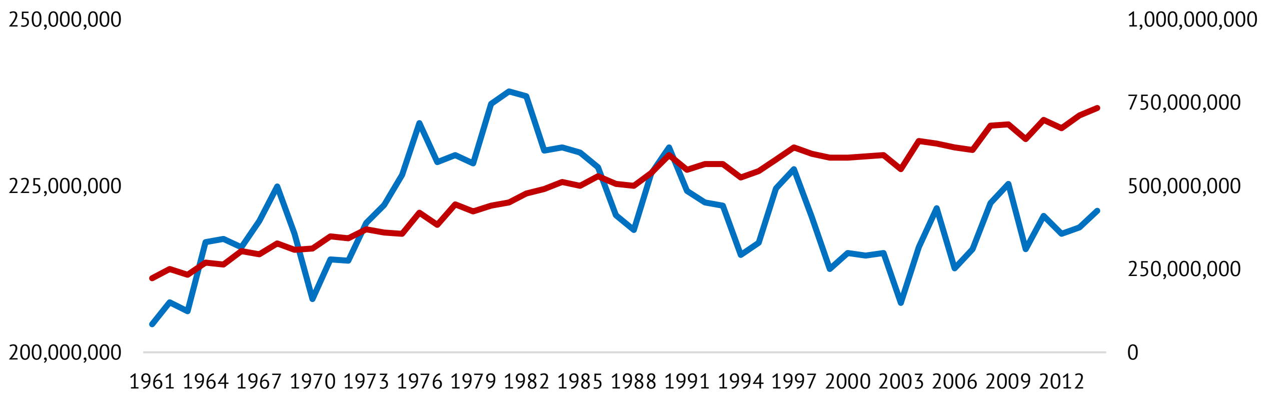
[9] Khush, Gurdev S. "Green revolution: the way forward." *Nature Reviews Genetics* 2.10 (2001): 815-822.

[10] Ibid.

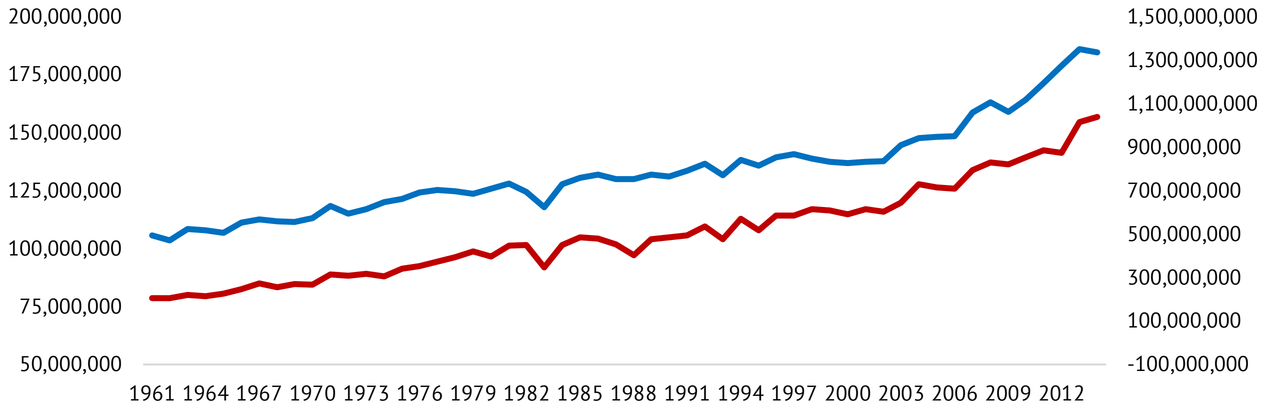
[11] See Morris, Julian. *The Paris Agreement: An Assessment.* Reason Foundation. Policy Brief No. 133, April 2016. Available at: http://reason.org/files/assessing_paris_agreement_climate_change.pdf

FIGURE 9: CROP PRODUCTION, 1961–2014

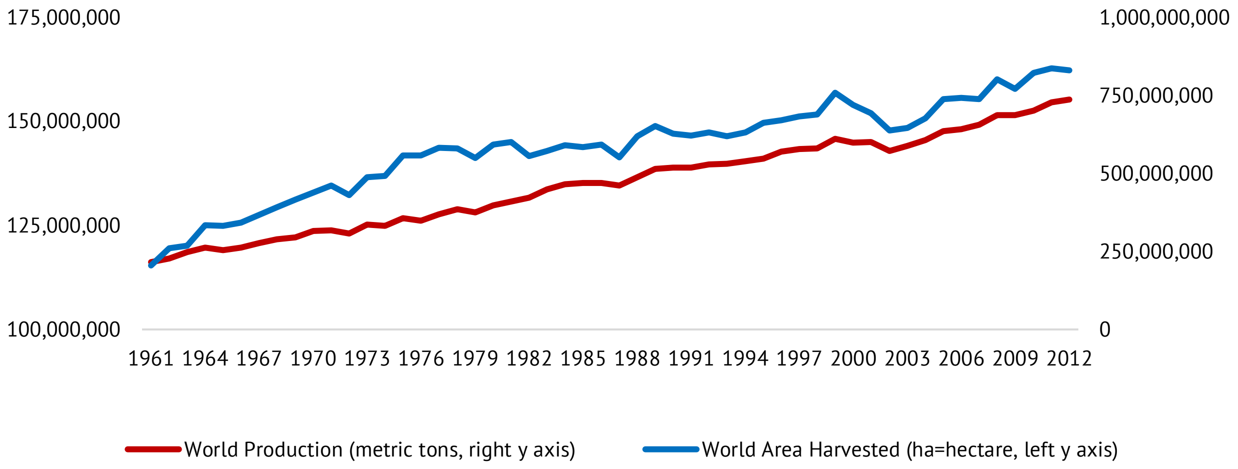
Wheat



Maize



Rice



Source: UN Food and Agriculture Organization (FAO) FAOSTAT Online Dataset Web.
http://www.fao.org/faostat/en/#data/QC/visuafiglize

Other several significant innovative accomplishments have also been achieved with other plants as well (e.g. papaya, tomato, potato), emphasizing the broad reach and the widespread impact of plant biotechnology. For example, potato yields in the U.K. doubled from 22 metric tons/ha in 1960 to 45 metric tons/ha in 2003.[12] This trend was experienced throughout different regions around the world. As a result, China is now the number one potato producer in the world (86 million metric tons) and India (45 million metric tons) is second.[13]

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[12] Bradshaw, John E. "Plant breeding: past, present and future." *Euphytica* 213.3 (2017): 60.

[13] Bradshaw, John E. "Scientific Breeding in the Twentieth Century and Future Goals." *Plant Breeding: Past, Present and Future*. Springer International Publishing, 2016. 39-71.

PART 5

A CURRENT LOOK AT HUNGER AND INNOVATIVE SOLUTIONS

Some have suggested that if it were not for the Green Revolution, a billion people might have died of famine.[14] Yet, not all countries faced success during the Green Revolution. In spite of these advances in food grain production, 800 million people—mostly in developing countries—go to bed hungry every day.[15] Some regions are more affected than others (see Figure 10).

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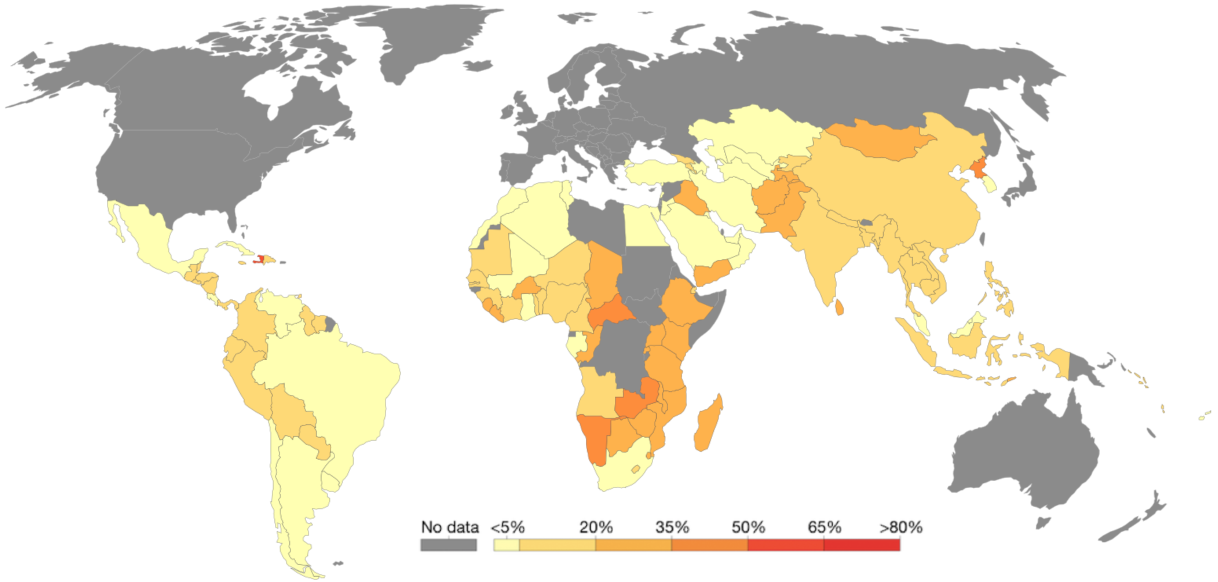
[14] Ndaba, Obadias. "Africa's Green Revolution Key to Feeding the World." The Huffington Post. March 1, 2017. Web. http://www.huffingtonpost.com/entry/africas-green-revolution-key-to-feeding-the-world_us_57a3c366e4b0ccb02371e7e7

[15] The World Economic Forum. "What is Hunger?" 16 Oct. 2015. Web. https://www.weforum.org/agenda/2015/10/what-is-hunger/ Accessed 20 June 2018.

FIGURE 10: SHARE OF THE POPULATION THAT IS UNDERNOURISHED, 2015

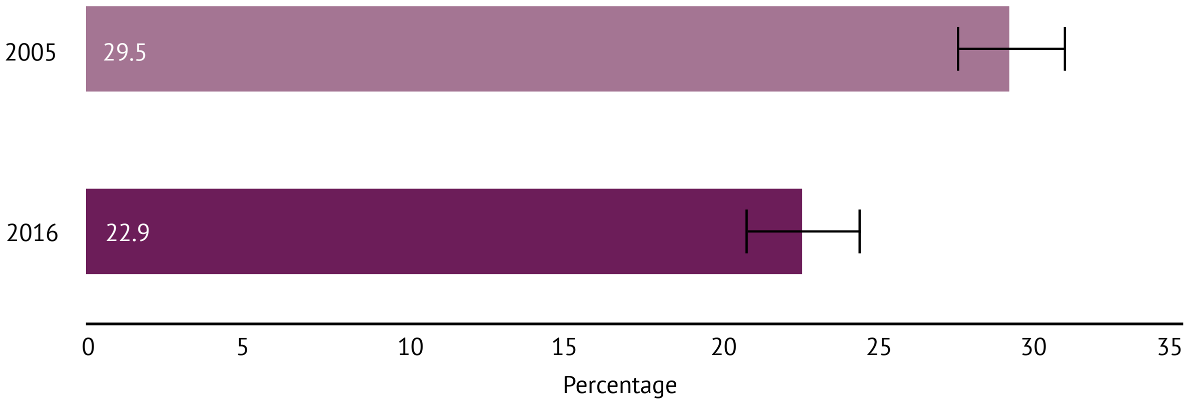


Source: UN Food and Agriculture Organization (FAO) FAOSTAT Online Dataset Web. http://www.fao.org/faostat/en/#data/QC/visualize

Malnutrition is still cause for concern worldwide. Evidence on various forms of malnutrition points to continuous decreases in the prevalence of stunting among children, as reflected in global and regional averages.

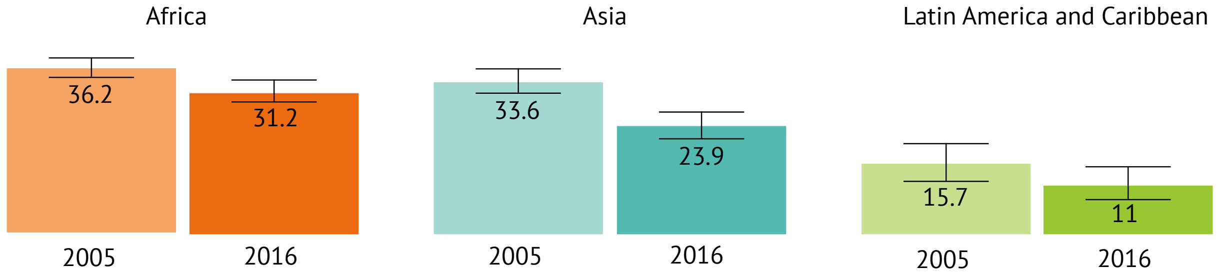
While child stunting rates seem to be decreasing for both global and regional averages, in 2016 155 million children under five years of age across the world suffered from stunted growth, increasing their risk of suffering impaired cognitive ability (see Figure 11). From 2005 to 2016 most regions achieved reductions in stunting, with the rate of improvement fastest in Asia and Latin America and the Caribbean. The prevalence of stunting also declined in all sub-regions in Africa, but at a much slower rate.

FIGURE 11: DECLINING GLOBAL RATES OF STUNTING AMONG CHILDREN



Source: UN Food and Agriculture Organization (FAO) Web. ***http://www.fao.org/state-of-food-security-nutrition/en/***

FIGURE 12: GLOBAL STUNTING RATES IN CHILDREN, 2005 AND 2016



Source: UN Food and Agriculture Organization (FAO) Web. ***http://www.fao.org/state-of-food-security-nutrition/en/***

While the international community is expected to face persistent threats to food security, especially malnutrition, technological advances continue to accelerate rapidly, providing opportunities for progress and the prospect of finding sustainable solutions for hunger and malnutrition.

Conventional plant breeding technologies are unlikely to meet increasing food demands and other environmental challenges.[16] A wide array of emerging technologies (e.g. GPS guidance systems, sensors, robotics, drones, autonomous vehicles, variable rate technology,

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[16] Gao, Caixia. "The future of CRISPR technologies in agriculture." Nature Reviews Molecular Cell Biology 39 (2018): 1-2.

GPS-based soil sampling, automated hardware, telematics, and software) could provide more accurate, precise farming techniques for planting and growing crops. While high-precision agriculture principles have been around for more than 25 years, it has only been over the past decade that they have become mainstream due to technological advancements and the adoption of other, broader technologies. The specific adoption of mobile devices, access to high-speed internet, low cost and reliable satellites for positioning and imagery, farm equipment that is optimized for precision agriculture by the manufacturer, and widespread consistent availability of electricity are some of the key technologies characterizing the trend for precision agriculture. It is estimated that more than 50% of today's farmers use at least one precision farming practice.[17]

Many such emerging innovative technologies in and outside the agriculture sector could be game changers for achieving progress on hunger and malnutrition. Such innovations include:[18]

- ***Next-generation DNA gene-sequencing technologies***: Recent advances in genome sequencing through next-generation sequencing (NGS) technologies provide new tools for evaluation of the grain quality,[19] and thus, opportunities to develop healthier and more productive crops and livestock. The applications of NGS in agriculture have shown progress in breeding, diagnosis, evolution, ecology, and basic functional genomics and hold the potential to dramatically improve crop yields. Examples of recent NGS applications that improve genetic diversity for crop improvement include rice, sugarcane and eucalyptus. NGS also supports the rapid domestication of new plant species and the efficient identification and capture of novel genetic variation from related species.
- ***Gene-editing technology***, like Clustered Regularly Interspaced Short Palindromic Repeat (CRISPR), has the potential to revive some of the early promise that genetic engineering has not fulfilled, such as making plants that are higher yielding, drought tolerant, disease resistant, more nutritious, or just better tasting. In addition, CRISPR

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[17] Schmaltz, Remi. "What is Precision Agriculture?" in AgFunder News 24 Apr. 2017 Web. https://agfundernews.com/what-is-precision-agriculture.html

[18] This is not a complete and exhaustive list of current and emerging technologies that could be used to achieve progress on hunger and malnutrition. The listed innovations seek to emphasize the enormous potential of emerging technologies to achieve progress on hunger and malnutrition.

[19] Edwards, M. A. and R. J. Henry. "DNA sequencing methods contributing to new directions in cereal research." *Journal of Cereal Science*. 2011. Volume 54, DOI 10.1016/j.jcs.2011.07.006.

can efficiently improve not just row crops such as corn but also fruits and vegetables, ornamentals, and staple crops such as cassava.[20]

- ***Biofortification*** involves the use of both conventional techniques of plant breeding as well as genetic modification of plant genomes to increase levels of key vitamins and essential minerals in crops.[21] Biofortification is used to enhance the micronutrient contents of major staple foods eaten widely by the poor (e.g. rice, wheat, corn, cassava, beans, sweet potato, and pearl millet), having the potential to offer sustainable solutions to malnutrition.
- ***Vertical farming***, the technique of producing food indoors, not out on a farm, in vertically stacked layers, can provide a solution to hunger especially in urban areas where farming areas are scarce. Successful forms of vertical farming have included hydroponics (plants are grown in a nutrient-rich basin of water), aeroponics (crops' roots are periodically sprayed with a mist containing water and nutrients), and aquaponics (involves breeding fish to help cultivate bacteria that's used for plant nutrients).
- ***Lab-grown or cultured meat*** is an alternative to farm-grown meat as a means of reducing livestock production and the use of antibiotics in meat production.[22]
- ***Digitized agriculture and the use of big data*** in agriculture seek to provide farmers with tailored insight on how to grow crops more efficiently. Although for now, using big data to improve agricultural productivity is largely centered in high-income regions, farmers in places such as sub-Saharan Africa and India are increasingly using mobile phones to exchange information about weather, disease and market prices.[23] These trends are only expected to grow as information technology spreads. Open access to knowledge, data and effective information networks can contribute to improving food production and nutrition. Other uses of digitized agriculture

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[20] Bomgardner, Melody. "CRISPR: A new toolbox for better crops." *Chemical and Engineering News* (2017): Volume 95 Issue 24, pp. 30-34. Web. https://cen.acs.org/articles/95/i24/CRISPR-new-toolbox-better-crops.html

[21] Combs Jr, Gerald F., and James P. McClung. "The vitamins: fundamental aspects in nutrition and health." Academic press, 2016.

[22] Woll, S., and I. Böhm. "In-vitro-meat: a solution for problems of meat production and consumption." Ernahrungs Umschau 65, no. 1 (2018): 12-21.

[23] Roach, John. "Can Data-Driven Agriculture Help Feed a Hungry World?" Yale environment360, March 2016. Web. <http://e360.yale.edu/feature/can_data-driven_agriculture_help_feed_a_hungry_world/2969/>

> include online platforms that can shorten the value chain by eliminating many middlemen, whose participation drives up prices for consumers and reduces farmers' profit margins.

Such emerging technologies show great promise for making food systems more interconnected, climate-resilient and efficient.

PART 6

BURDENSOME REGULATORY BARRIERS

6.1

THE HUMAN COST OF UNWARRANTED CAUTION

These emerging technologies are what make “precision agriculture” possible, bringing scientific rigor and efficiency to farming. Yet, excessive and unscientific regulations threaten the diffusion of such innovations and impede their reach to those who need them most.

Take the case of biotechnology.[24] Biotechnology holds tremendous possibilities to provide sustainable solutions for hunger, especially in low-income countries. The use of high-yielding, disease- and pest-resistant crops directly improve food security, alleviate poverty and conserve the environment.[25] Yet, biotechnology is one of the most regulated and underappreciated technologies. For the past two decades, regulators in the United States and many other countries have created regulatory policies that treated biotechnology as if it were inherently risky and in need of unique, intensive oversight and control. The burden

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[24] While this paper specifically discusses the example of biotechnology, evidence shows that the regulatory burden extends to the use of other technologies as well.

[25] Jamil, Kaiser. “Biotechnology—A Solution to Hunger?” UN Chronicle 46, no. 3 (2009): 70.

of this unfavorable and costly regulatory milieu is tremendous. The 20-year-long tortuous passage of the genetically modified salmon (AquAdvantage salmon) through the U.S. regulatory system provides a stark example of a lengthy and costly regulatory burden. The AquAdvantage salmon has been subjected to one of the most prolonged, if not exhaustive, regulatory assessments in history.[26] Without the hypervigilance that stood in the way, this nutritious and affordable salmon would have been on the market sooner.

The AquAdvantage salmon case describes the rule rather than the exception. Estimates suggest that between 1999 and 2003 the number of field trials in the United States involving gene-spliced crops plunges from 120 to 20.[27] That means many technological advancements could be used currently, but for obstructive and burdensome regulations.

Most of the burden weighs more heavily on those who need it the most. Golden Rice is one of the many cases illustrating the social loss from the heavy regulation of biotechnology. (See *The Case of Golden Rice* on next page.)

In the United States, regulation of agricultural biotechnology falls under the Coordinated Framework for the Regulation of Biotechnology.[28] However, the Food and Drug Administration (FDA), Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and other federal agencies included in the current Coordinated Framework do not have clear lines of authority over the potential applications of different biotechnologies (e.g. gene drive research).[29] For some potential applications of biotechnologies, regulatory jurisdiction may overlap, which suggests the need for a straightforward process to quickly determine which agency should coordinate governance of that specific technology, and avoid costly and unnecessary delays.

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[26] Van Eenennaam, Alison L., and William M. Muir. "Transgenic salmon: a final leap to the grocery shelf?" *Nature Biotechnology* 29, no. 8 (2011): 706.

[27] Miller, Henry I. and Gregory Conko. "Agricultural biotechnology: Overregulated and underappreciated." *Issues in Science and Technology* 21, no. 2 (2005): 76-80.

[28] In 2017, a revised CFRB was issued.

[29] "Committee on Gene Drive Research in Non-Human Organisms: Recommendations for Responsible Conduct (2018) Summary." *Journal of Responsible Innovation*, 5:sup1. S243-S254. DOI: 10.1080/23299460.2017.1415789

The Case of Golden Rice

Estimates suggest that since 2010, vitamin A deficiency killed more children than either HIV/Aids, tuberculosis, or malaria worldwide.[30] *To provide a sustainable solution to this type of malnutrition, Golden Rice was engineered to produce beta-carotene, a vitamin A precursor. Its promise was to mitigate vitamin A deficiency, which in extreme cases can cause blindness or death among poorly fed children. It was estimated that a bowl of cooked Golden Rice (approx. 50g) provides approximately 60% of the recommended intake of vitamin A for young children.*[31]

Unfortunately, Golden Rice remains a promise, given that it has not yet reached commercialization, and the seeds are not yet available to farmers for planting. Professor Ingo Potrykus, one of the co-inventors, believes that "the rice is not available yet because of the onerous regulations and, to a lesser extent, opposition to GM products by groups such as Greenpeace."[32] *Potrykus has been arguing for years to change the burdensome and scientifically unjustified regulations that control government approval of transgenic crops for planting and consumption.*[33]

The delayed introduction of Golden Rice for over a decade has been very costly both in monetary terms as well as social costs. Specifically, the delay has raised the social costs of regulation to a loss of lives far beyond one million in several countries with vitamin A deficiency problems and rice-dependent poor populations, such as The Philippines, Bangladesh, India, Vietnam, Indonesia, and China.[34] *Golden Rice could save in India alone approximately 40,000 lives per year.*[35]

While Golden Rice is a startling example of the human costs of delays in GM crop development and deployment, several other similarly useful crops that can benefit the environment and human health are also dangerously delayed.

Per recent research, Golden Rice will probably be released within the next five years.[36] *Until then, Golden Rice remains a controversial dream of a "humanitarian" GM crop,*[37] *and an unfortunate illustration of global social loss due to heavy regulation of GM technology.*

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[30] Dubock, Adrian. "The politics of golden rice." *GM crops & food* 5.3 (2014): 210-222.

[31] Francis, David, John J. Finer and Erich Grotewold. "Challenges and opportunities for improving food quality and nutrition through plant biotechnology." *Current Opinion in Biotechnology* 44 (2017): 124-129.

[32] Pritchard, Bill, Rodomiro Ortiz and Meera Shekar, eds. *Routledge Handbook of Food and Nutrition Security*. Routledge, 2016.

[33] Ibid.

[34] Potrykus, Ingo. "Lessons from the 'Humanitarian Golden Rice' project: Regulation prevents development of public good genetically engineered crop products." *New biotechnology* 27.5 (2010): 466-472.

[35] Ibid.

[36] Stone, Glenn Davis, and Dominic Glover. "Disembedding grain: Golden Rice, the Green Revolution, and heirloom seeds in the Philippines." *Agriculture and Human Values* 34, no. 1 (2017): 87-102.

[37] Francis, Finer and Grotewold. "Challenges and opportunities for improving food quality and nutrition through plant biotechnology."

Much of the current U.S. regulatory system is unnecessarily complicated and lacks clarity and predictability about the kinds of technologies/products that would actually be subject to regulation. A regulatory climate that fosters innovation in agricultural biotechnology will be an important component in meeting the challenges facing the future of farming and agriculture.

The most effective regulatory system should:

1) provide clear, risk-based criteria to identify organisms that are exempt from pre-market oversight and those needing further risk assessment, and
2) include mechanisms by which organisms within the initial risk-based scope can be efficiently assessed for risk and, if appropriate, determined to pose no plant pest risk.

Efforts to regulate the diffusion of biotechnology is not limited to domestic regulation. The wider adoption and diffusion of biotechnology applications could significantly improve human nutrition and reduce the amount of land, water and pesticides needed to produce food. Yet, these advances are being drastically limited by the unscientific, hugely burdensome, United Nations-based regulatory regimes.

6.2 THE BIOSAFETY PROTOCOL

The Biosafety Protocol is an international environmental treaty under the United Nations (UN) Convention on Biological Diversity that establishes rules and procedures for international trade in certain agricultural biotechnology products.

The Protocol came into effect in 2003 and was developed based on concerns initially expressed in the 1970s that biotechnology presented unusual risks to human health and the environment. The ideas, however, have comprehensively been proven wrong by scientific research.[38] The Protocol has nevertheless generated significant regulatory obstacles to the development of GM-crop technology at great social and economic costs (see the case for Golden Rice).

The Protocol's rules of trade allow importers to embargo imports on products of modern biotechnology virtually without constraint. This, in return, can inhibit investments in

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[38] See Dubock, Adrian. "The politics of golden rice." *GM crops & food* 5, no. 3 (2014): 210-222.

biotechnology suitable for developing countries,[39] which will obscure the potential benefits of the biotechnology. The Protocol provides a disguised instrument of protectionism, one that offers concentrated benefits to particular interest groups at the expense of the larger public. The ultimate bearers of this burden are the producers who will limit investments on banned products and face smaller markets, and consumers who will face fewer choices and higher prices.

Furthermore, recent research contends that the precautionary-principle-driven standards and regulations the UN defends actually harm the environment and public health, stifling the development of environmentally friendly innovations that can increase agricultural productivity, help clean up toxic wastes, conserve water, supplant agricultural chemicals, and reduce the contamination of grain by fungal toxins.[40]

For example, scientific evidence shows no risks to the environment and human health from biotechnology, any greater than there have been from any crop breeding technology for the last 60, or 70 or 10,000 years.[41] Scientists worldwide agree that biotechnology is merely a refinement, or improvement, over less-precise and predictable genetic techniques that have been used for centuries, an exquisite tool that can help to develop plants with higher yields and innovative traits.[42]

Apart from the direct costs on society and scientific progress, the Protocol has arguably obscured the potential benefits of the technology and fed unwarranted suspicion of a useful scientific development.

Many countries have developed or are now developing regulatory systems in response to the Protocol. Many such systems are based on a strong precautionary and nearly preventive

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[39] Holtby, Kareen L, William A. Kerr, and Jill E. Hobbs. *International Environmental Liability and Barriers to Trade: Market Access and Biodiversity in the Biosafety Protocol.* Cheltenham, UK: Edward Elgar, 2007. Print.

[40] For example, see Adler, Jonathan H. “More sorry than safe: Assessing the precautionary principle and the proposed international biosafety protocol.” Texas International Law Journal 35 (2000) 173.

[41] Dubock. “The politics of golden rice.”

[42] Miller, Henry I., and Gregory P. Conko. The Frankenfood myth: how protest and politics threaten the biotech revolution. Greenwood Publishing Group, 2004.

approach, which may further restrict biotechnology research and diffusion of useful and life-saving agricultural products.

As biotechnology is essential to feeding a growing world population while also protecting biodiversity, the Protocol makes this task much more difficult by causing delays in the testing of biotechnological products, increasing the potential for corruption and significantly inhibiting the diffusion of useful technologies in areas that need them the most.

6.3 THE FUTURE OF BIOTECHNOLOGY

The outlook for the new biotechnology, especially as it would benefit the population in need, would be far better if governments expended effort on disposing, or at the very least improving current models of unscientific and flawed regulatory policies. For example, a recent peer-reviewed study published in *Nature Biotechnology*, emphasizes that most of the regulatory regimes around the world, including those of the US EPA and USDA, are neither scientifically defensible nor justifiable in the sense that all too often, they lead to the plants of lowest risk being subject to the highest degree of scrutiny.[43] The result is a massive waste of limited resources, huge disincentives to innovation in a time of great need, and no increase in public or environmental safety.

The study offers an alternative regulatory approach that has previously been proposed by academics, known as the “Stanford Model.” In the 1990s, Stanford University developed the Stanford Model for risk-based regulation, which was widely applicable for the field-testing of any organism, regardless of the method or methods employed in its construction.[44]

The Stanford Model was mainly proposed as an alternative to the lack of proportion between risk and regulatory scrutiny. This model stratifies organisms according to risk in field trials, and is comparable to existing regulatory regimes, such as those for quarantine

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[43] Conko, Gregory, Drew L. Kershen, Henry I. Miller and Wayne Parrott. “A Risk-Based Approach to the Regulation of Genetically Engineered Plants.” *Nature Biotechnology*, Volume 34, Number 5. May 2016. Available at SSRN: https://ssrn.com/abstract=2971485 or http://dx.doi.org/10.2139/ssrn.2971485

[44] Tuteja, Narenda, Sarvajeet Singh Gill, and Renu Tuteja, eds. “Omics and plant abiotic stress tolerance.” Bentham Science Publishers, 2011.

regulations for plants or animal pests, and also to the U.S. government's approach to handling dangerous pathogens or other microorganisms in the laboratory.[45] This makes the model more quantitative and nuanced than the USDA's long-standing approach to "regulated articles" as plant pests or potential plant pests.[46] The advantage of the Stanford Model is that it is sufficiently flexible to accommodate differences in regulatory authorities' preferences for greater or lesser regulatory stringency, as long as the risk factor of each category is coupled with an appropriate and relative regulatory requirement.

This alternative implies a product-based protocol that is capable of assessing any new risks that might be associated with emerging biotechnologies (especially in genome editing).[47] Because the Model's procedures are based on risk assessment principles that are independent of organism and traits, they can be applied to virtually any trait in any organism. This model should serve as inspiration for the development of a more dynamic regulatory system that is flexible enough to accommodate any novel plant research and breeding techniques.

Non-governmental organizations could also play a more significant role. Non-governmental agencies already certify the quality of consumer products ranging from seeds to medical devices.[48] While direct government oversight may be appropriate for products with high-risk characteristics, governments need not position themselves into every aspect of biotechnology. A serious reevaluation of existing policies assessing innovations in biotechnology and digital agriculture is needed.

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[45] Sprink, Thorben, Dennis Eriksson, Joachim Schiemann, and Frank Hartung. "Regulatory hurdles for genome editing: process-vs. product-based approaches in different regulatory contexts." *Plant Cell Reports* 35, no. 7 (2016): 1493-1506.

[46] Conko, Gregory, Drew L. Kershen, Henry Miller, and Wayne A. Parrott. "A risk-based approach to the regulation of genetically engineered organisms." *Nature Biotechnology* 34, no. 5 (2016): 493.

[47] Conko et al. "A Risk-Based Approach to the Regulation of Genetically Engineered Plants."

[48] Miller, H., and G. Conko. 2005. "Agricultural Biotechnology: Overregulated and Underappreciated." *Issues in Science and Technology* 21(2): 76-81.

PART 7

CONCLUSION

In a 2005 peer-reviewed study, Henry Miller and Gregory Conko write: “the stunted growth of agricultural biotechnology worldwide stands as one of the great societal tragedies of the past quarter century.”[49] More than a decade later, we are witnessing the same tragedy. An overly burdensome regulatory environment is worrying, not only because of its direct effects on research and development, but also because it will keep beneficial technologies out of the hands of the resource-poor farmers in low-income countries who need them most.

Innovations in biotechnology and technologies to support integrated soil fertility management, integrated water management, high yielding varieties from conventional breeding and genetic modification all contributed to food security, and will continue to be critical for the progress on food security. Going forward, solutions must address the transfer of technology to users worldwide (especially focusing on small-scale farmers), the transparency of scientific solutions, a pro-business policy environment through the protection of intellectual property and reduced trade barriers, and an essential collaboration between the private and public sectors.[50]

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[49] Ibid.

[50] A.T. Kearney. *Innovation in Agriculture: The Path Forward*. Web. <https://www.atkearney.com/consumer-goods/article?/a/innovation-in-agriculture-the-path-forward>

The technologies and innovations discussed in this brief directly and indirectly affect the development of agriculture and the future of food security. Employing the best of scientific knowledge and technological breakthroughs will be crucial for ending hunger. This, however, is dependent on disposing of unscientific, excessive and stifling regulations, nationally and internationally, that remain barriers for breakthrough technologies to achieve their potential to bring greater food security to the poor.

ABOUT THE AUTHOR

Krisztina A. Pusok is the director of policy and research at the American Consumer Institute: Center for Citizen Research. Krisztina researches environment and energy policies, and the regulation of innovations and technologies in the agri-food sector.

Krisztina completed her Ph.D at the University of Missouri, where she conducted extensive research on public-private partnerships and voluntary industry standards. She has had responsibility for building partnerships with non-profit organizations, the private sector, and academic research institutions, as well as engaging students in finding sustainable solutions to hunger. Krisztina also has a master's degree in international security studies from University of St Andrews in the U.K. and a bachelor's degree in international relations and international business from Webster University in Austria.