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The Economic Impacts of Regulatory Delays on Trade and Innovation

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A nation's regulatory apparatus and decisions can have effects that reach far beyond its borders. We examine how regulatory decisions and their timing, as transmitted through trade relationships, can affect innovation. By changing the temporal path of biotechnology innovations and their adoption, regulatory asynchronies can have profound effects on social welfare. We use a global partial equilibrium model of world agricultural markets to examine the trade and welfare effects of delayed adoption of new biotech crop varieties due to the timing of regulatory decisions. We find that a three-year delay in the adoption of new biotech crop varieties significantly decreases overall welfare in agricultural markets and also results in a substantial redistribution of economic surplus from consumers to producers. We additionally find that consumers in major importing countries, where the regulatory decisions in question characteristically originate, pay a particularly high price in terms of foregone benefits.

1 INTRODUCTION

Innovation and trade are the twin pillars of a healthy economy and they stand in close relationship to one another. Innovation can spur trade by providing goods suited to new markets. Trade can advance innovation with the prospect of a wider market for new products as well as knowledge spillovers and technology transfer.¹ Conversely, trade restrictions can put a damper on innovation by increasing uncertainty regarding the future prospects of new goods and restricting market access and thus profit potential. For classes of products subject to government regulation, differing national regulatory systems can complicate trade. National governments vary in their capability to design and implement regulatory structures. International bodies meant to coordinate and harmonize national systems necessarily move slowly due to their consensus-based decision making

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¹ Kamal Saggi, *Trade, Foreign Direct Investment, and International Technology Transfer: A Survey*, 17 The World Bank Research Observer (2002).

procedures. As a result, at any one point in time different countries may have different criteria and procedures for assessing and approving new regulated products and may take significantly different amounts of time to do so.² In this article we examine the effects of asynchronous regulatory approvals on the global trade of biotech agricultural products. We find that these regulatory asynchronies, as transmitted through trade relationships, can have significant consequences on innovation and social welfare.

Crops developed through biotechnology must undergo regulatory approval to ensure their environmental, food, and feed safety before they are commercially introduced in the marketplace. This regulatory process necessarily lengthens the time required to bring such new crops to market. Insofar as this delay is necessary to ensure their safety, it is regarded as worthwhile. Efficiency is crucial, though; there are many possible ways that the regulatory review process can be structured. If the approval process goes on longer than necessary to ensure safety with reasonable scientific certainty, the opportunity cost of missing out on innovation can mount.³

A variety of opportunity costs exist, and their magnitude could be considerable when viewed within the scope of global agriculture. Timely introduction of new biotech crops can contribute to improving food security and overall standard of living. First generation biotech crops enabled farmers to have increased production at lower cost, with the twin benefits of increased producer income and lower consumer cost. Lower food costs amount to an increase in real income for consumers. As consumers spend less on food, additional income is available for savings or other consumer expenditures. The benefits of the additional wealth spread throughout the economy. Second generation biotech crops can also benefit consumers through higher nutritional quality. These characteristics combine to make biotech crops a cost-effective means of improving food security.⁴ This is especially true for biotech cultivars grown as subsistence, rather than cash, crops. Also, since a large portion of biotech crop production, in particular soybeans and maize, go into livestock feed, these benefits flow into downstream markets. As livestock production input costs decrease, higher quality animal protein becomes a more available and reliable food source for more people,

² Stuart Smyth et al., *Global Governance Quandaries Regarding Transformative Technologies for Bioproducts, Crops, and Foods*, 43 J. World Trade (2009).

³ Kent J Bradford et al., *Regulating Transgenic Crops Sensibly: Lessons from Plant Breeding, Biotechnology and Genomics*, 23 Nature Biotechnology (2005); Alison L Van Eenennaam, *GMOs in Animal Agriculture: Time to Consider Both Costs and Benefits in Regulatory Evaluations*, 4 J. Animal Sci. & Biotechnology (2013).

⁴ Judit Berman et al., *Can the World Afford to Ignore Biotechnology Solutions that Address Food Insecurity?*, 83 Plant Molecular Biology (2013).

further increasing food security.⁵ Trade disruptions or delays in innovation due to delayed approval of new biotech crops could impede progress in food security in developing countries.

Timely approvals of new biotech traits might also be important for just replenishing and sustaining the existing biotech product line-up. One of the more successful biotech innovations in the last twenty years has been Herbicide Tolerant (HT) crop varieties. These allow the use of broad-spectrum herbicides, such as glyphosate and glufosinate, over the top of crops, leading to better weed management at a lower cost and reduced environmental impact. In the continuing battle between farmers and weeds, constant innovation is necessary to stay ahead of weed adaptation and prevent widespread herbicide resistance in weed species. In the absence of new and effective crop-herbicide combinations, producers may fall back to more labour and machinery intensive methods of weed control, some of which may imply higher soil erosion and fossil fuel consumption.⁶

Perhaps more significantly, regulatory delays have the potential to slow down the biotechnology innovation process in general. In the short run, such delays mean that innovations ready to be marketed to agricultural producers are sitting idle. During this time, the welfare of both producers and consumers is reduced. Operating costs and market prices are higher than they would be without such innovations on the market.⁷ In the long run, excessive regulation may exert an overall dampening effect on the innovation process. The high cost of pursuing approval in jurisdictions where the process is longer and more expensive as well as the loss of revenue for technology developers tend to discourage innovation in general.⁸ These long run costs are as certain as they are difficult to measure. The costs take the form of research programmes never embarked upon, innovations never developed, firms never started, jobs never created, and products that never reach the hands of producers or consumers.⁹

A few studies have empirically examined the opportunity costs of regulatory delays in agricultural biotechnology. Pray et al. investigated the impact of partial

⁵ The State of Food Insecurity in the World 2014. Strengthening the enabling environment for food security and nutrition. (2014).

⁶ Stephen B. Powles, *Evolved Glyphosate-Resistant Weeds around the World: Lessons to Be Learnt*, 64 Pest Mgt. Sci. (2008); Jerry M. Green, *The Benefits of Herbicide-Resistant Crops*, 68 Pest Mgt. Sci. (2012); Leonard P. Gianessi & Nathan P. Reigner, *The Value of Herbicides in US Crop Production*, 21 Weed Tech. (2007).

⁷ China's agricultural biotechnology regulations-export and import considerations. (2011).

⁸ Ronald R. Braeutigam, *The Effect of Uncertainty in Regulatory Delay on the Rate of Innovation*, 43 L. & Contemp. Probs (1979); Matin Qaim, *The Economics of Genetically Modified Crops*, 1 Annual Rev. Resource Econ. (2009); Knut Blind, *The Influence of Regulations on Innovation: A Quantitative Assessment for OECD Countries*, 41 Res. Policy (2012).

⁹ Frederic Bastiat, *That Which is Seen, and That Which is Not Seen*, in *The Bastiat Collection* (Mark Thornton ed., 2007).

regulatory delays on the introduction of certain Bt cotton varieties in India. In this context, they examined the indirect opportunity costs of lost income to both farmers and seed companies and found that total income for Indian cotton farmers in the 2004/05 crop year would have been some USD 70 million greater if the specific Bt cotton varieties had been approved in a timely fashion.¹⁰ Bayer et al. estimated that each year of regulatory delay in the Philippines decreased the net present value of future farm income from biotech crops by 12%–36%, depending on the specific crop.¹¹ Kikulwe et al. calculated total foregone benefits of USD 179 million – USD 365 million for each year of regulatory delay of adoption of biotech bananas in Uganda. Most of this cost was borne by farmers in the form of lost income.¹² Wesseler et al. calculated a potential increase of EUR 87/ha – EUR 135/ha in annual gross profit for farmers in France had Bt maize been approved there. They estimated that France experienced total foregone net benefits of EUR 310 million over a five-year period as a result of not approving this crop for cultivation.¹³ Demont et al. estimated that not approving biotech sugar beets has cost EU farmers EUR 199/ha annually in lost income, and that the EU as a whole has foregone total benefits of EUR 169 million each year.¹⁴ Finally, Wesseler and Zilberman estimated that India had lost out on benefits of at least USD 199 million per year in improvements in health by not approving beta-carotene containing Golden Rice in 2002.¹⁵ The primary conclusions drawn from these studies are that foregone benefits due to delayed innovation can often be substantial, ongoing, and that developers, producers and consumers all lose from regulatory delays.

In this paper, we estimate the foregone economic benefits to world markets because of delayed adoption of new biotech soybean varieties that can occur, for instance, due to regulatory delays in importing countries and stated policies of seed producers not to introduce new varieties for production until they are approved in major export markets.¹⁶ Such occurrences have become commonplace in recent

¹⁰ Carl E. Pray et al., *The Cost of Biosafety Regulations: The Indian Experience*, 44 Q. J. Intl. Agriculture (2005).

¹¹ Jessica C. Bayer et al., *Cost of Compliance with Biotechnology Regulation in the Philippines: Implications for Developing Countries*, 13 AgBioForum (2010).

¹² Kikulwe et al., *Introducing a Genetically Modified Banana in Uganda: Social Benefits, Costs, and Consumer Perceptions*, IFPRI Discussion Paper 767 (2008).

¹³ Justus Wesseler et al., *The Maximum Incremental Social Tolerable Irreversible Costs (MISTICs) and other Benefits and Costs of Introducing Transgenic Maize in the EU-15*, 51 Pedobiologia (2007).

¹⁴ Matty Demont et al., *Biodiversity versus Transgenic Sugar Beet: The One Euro Question*, 31 Eur. Rev. Agric. Econ. (2004).

¹⁵ Justus Wesseler & David Zilberman, *The Economic Power of the Golden Rice Opposition*, 19 Envt. & Dev. Econ. (2014).

¹⁶ Crop Life International, *Product Launch Stewardship* (2015), available at <https://croplife.org/plant-biotechnology/stewardship-2/product-launch-stewardship/>.

years and imply that adoption of new biotechnologies has taken place later than it could have.

We focus our analysis on new HT soybean varieties already in the biotechnology development pipeline and the economic implications of a potential delay in their market introduction. As we discuss in detail below, first generation HT biotechnologies, especially glyphosate tolerance, have lost some of their effectiveness after twenty years of intensive use. As a result, producers in some parts of the world are currently experiencing increased weed control costs. The new HT soybean varieties can provide alternatives for cost-effective weed control. In this context, we examine the economic implications of making these new HT soybean varieties available to farmers later rather than sooner and we do so by estimating the impact of the timing of these market changes on supply, demand, prices, and overall welfare.

The rest of the study is organized as follows: in the next section we outline the benefits that have resulted from the first generation of biotech soybeans, then go on to describe the new varieties in the biotech pipeline and their potential benefits. In the following section, we examine in some detail the issue of asynchronous regulatory approvals of new biotechnology traits and its potential effects on innovation and adoption, in general. After discussing the conceptual basis for our model, we describe the construction of our scenarios and the model in detail. Following this, we present our empirical results and concluding remarks.

2 BENEFITS FROM FIRST GENERATION BIOTECH SOYBEANS

Soybeans are one of the oldest crops known to mankind, having been cultivated in China as early as 3000 BC. While soybeans were introduced to North America at the beginning of the nineteenth century, it was not until the early twentieth century that American farmers and agricultural scientists began to fully appreciate their potential as a source of vegetable protein and oil. After World War II, soybeans very quickly became one of the major agricultural commodities traded on world markets.¹⁷

The history of the soybean entered a new era in 1996 with the commercialization of the first biotech trait. The introduction of Roundup Ready™ (RR) soybeans, tolerant of the herbicide Roundup™ (glyphosate), prompted dramatic, swift, and worldwide changes in soybean production. With RR soybeans,

¹⁷ USSEC, Chapter One: The Soybean, Its History, and Its Opportunities (Accessed 15 Jan. 2015 2015).

one or two applications of the broad-spectrum glyphosate replaced multiple applications of more selective herbicides. In this way, RR soybeans and the expanded use of glyphosate, an inexpensive, less toxic, and more readily degradable herbicide, helped farmers achieve effective weed control at lower cost and shortened their production cycle, while facilitating low- and no-till farming practices.¹⁸

The impact of this innovation, coupled with a parallel strong expansion of global soybean demand, has been significant. Among the leading soybean producing countries, area devoted to soybean production increased by one-third in the United States while roughly tripling in both Argentina and Brazil. Modelling indicates that world soybean prices are 2%–5% lower than they would have been in the absence of the RR technology, due to the increased supply brought on by lower production costs.¹⁹

Producers have captured a large share of the benefits of RR soybeans, though consumers have benefitted significantly as well. The total world economic surplus created by this innovation from 1996 to 2009 has been calculated at almost USD 50 billion, of which more than 85% went to producers and consumers and 14% to the innovators. Most of the surplus came as a result of decreased production costs. On average, adoption of RR soybeans has allowed producers in the US to save USD 28.70/ha per year, in Argentina USD 22.70/ha per year, and in Brazil USD 32.40/ha per year.²⁰

Overall, the introduction of RR technology in the 1990s has had no appreciable impact on average soybean yields per unit area, since conventional methods of weed control (use of multiple herbicides and tillage) could achieve effective weed control, albeit at higher monetary cost and soil loss. Increases in production have therefore been primarily a result of expanding soybean area.²¹ However, in areas where weed control was difficult through conventional methods, RR soybeans have led to significant improvements in yield as well. For

¹⁸ The ability to use a more effective, broad spectrum herbicide has lessened the need for weed control through cultivation, so no-till practices has become more prevalent in many leading soybean areas. This also makes for a shorter growing season so much so that some South American farmers have been able to double crop soybeans after wheat, leading to increases in annual farm income of over USD 200/ha (Brookes and Barfoot, 2014).

¹⁹ Julian M. Alston et al., *The Size and Distribution of the Benefits from the Adoption of Biotech Soybean varieties*, in *Handbook on Agriculture, Biotechnology, and Development* (Stuart J. Smyth et al., eds, 2014).

²⁰ Julian M. Alston et al., *The Size and Distribution of the Benefits from the Adoption of Biotech Soybean Varieties*, in *Handbook on Agriculture, Biotechnology, and Development* 742 (Stuart J. Smyth et al. eds, 2014).

²¹ Srinivasa Konduru et al., *The Global Economic Impacts of Roundup Ready Soybeans*, in *Genetics and Genomics of Soybean* (Gary Stacey ed., 2008).

instance, Romanian farmers saw a 31% increase in soybean yield between 1999 and 2006.²²

Livestock producers using soymeal as feed have benefited from both lower prices and expanding supplies. As a result, livestock industries in many countries have experienced fast growth in the last twenty years. For instance, China's dairy production has quadrupled since 2000 while pork and poultry production have also increased by almost 50% over the same period.²³ In the end, people around the world benefitted from the decrease in world soybean prices to the tune of USD 15 billion from 1996–2009. Consumer surplus in both producing and importing countries experienced substantial increases.²⁴ In the European Union, the second largest importer of soybean products, RR soybeans added USD 1.5 billion to consumer surplus in 1996–2009. In China, the world's largest soybean importer, RR soybeans added almost USD 3 billion to consumer surplus over the same period.²⁵

3 THE BIOTECHNOLOGY PIPELINE IN SOYBEANS

Research and development of new biotech traits in soybeans but also in other crops has increased substantially in recent years. In 2008 there were some thirty commercialized biotech events in all crops, and as recently as 2009 the RR trait was still the only commercialized biotech soybean event. Pipeline forecasts at that time held the potential for seventeen individual soybean traits to be commercialized by 2015 and possibly as many as 120 new traits across all crops.²⁶ While some of these forecasts have not always materialized, trait development has continued apace in the intervening years. At present, there are 181 individual biotech events in 26 crops,²⁷ including 23 in soybeans that have undergone regulatory review and approval.²⁸ New traits in soybeans seek to remedy yield losses from diseases and insect pests, expand crop tolerance to an expanded

²² Graham Brookes et al., *The Production and Price Impact of Biotech Corn, Canola, and Soybean Crops*, 13 AgBioForum (2010).

²³ USDA, <http://apps.fas.usda.gov/psdonline/> (2015).

²⁴ Consumer surplus is a measure of economic benefit enjoyed by consumers when they purchase goods and services at market prices lower than those they would have been willing to pay. When innovation leads to lower market prices, therefore, the resultant change in consumer surplus indicates the economic benefits from the innovation that accrue to the consumers.

²⁵ Alston et al., *The Size and Distribution of the Benefits from the Adoption of Biotech Soybean Varieties*, 2014.

²⁶ Alexander J. Stein & Emilio Rodríguez-Cerezo, *International Trade and the Global Pipeline of New GM Crops*, 28 *Nature Biotechnology* (2010); *The Global Pipeline of New GM crops: Implications of Asynchronous Approval for International Trade* (2009).

²⁷ It is worth noting here that some of the product offerings going through regulatory review are stacked trait combinations which are regulated as separate entities in many jurisdictions.

²⁸ ISAAA, <http://www.isaaa.org/gmapprovaldatabase/default.asp> (2015).

portfolio of herbicides and improve oil composition and other soybean qualities. Table 1 summarizes recently approved biotech soybean varieties as well as those expected to be submitted for approval in the near future.

Table 1 Soybean Biotechnology Pipeline

<i>Type of Trait</i>	<i>Recently Approved*</i>	<i>In the Pipeline</i>
<i>Multiple Herbicide Resistance</i>	Dow Enlist TM – glufosinate and 2,4-D Dow Enlist TM E3 – glyphosate, glufosinate, and 2,4-D Bayer Balance TM – glyphosate and isoxaflutole Monsanto Genuity RR2 Xtend – glyphosate and dicamba Bayer and Syngenta – mesotrione and glufosinate	Bayer and Syngenta – mesotrione, glufosinate, and isoxaflutole Bayer and Syngenta – glyphosate, glufosinate, and HPPD
<i>Healthy Oils</i>	DuPont/Pioneer Plenish TM Monsanto Vistive Gold TM	Monsanto SDA Omega-3
<i>Disease Resistance</i>		BASF – fungal resistance Bayer – nematode resistance DuPont – Asian soybean rust, nematode resistance Syngenta – nematode resistance
<i>Insect Resistance</i>	Monsanto Intacta TM RR2 Pro – Bt and glyphosate resistance	Syngenta – Bt DuPont – resistance to Hemiptera and Lepidoptera

* Products are considered here ‘recently approved’ when they have received approval for cultivation in main producing countries and for importation in many key countries. Some may still lack import approvals in a few key import markets and as such they may not be yet commercially marketed.

Viral, fungal, bacterial, and nematode infections accounted for crop losses of over 11 million metric tons in the US alone in 2013, a value of USD 5.2 billion.²⁹ Several new soybean varieties developed to offer resistance to these diseases are in

²⁹ Carl Bradley & Tom Allen, *Estimates of Soybean Yield Reductions Caused by Diseases in the United States* (2015), available at http://extension.crops.illinois.edu/fieldcrops/diseases/yield_reductions.php.

the pipeline and expected to be ready for release in the next five years.³⁰ While insect pests have not generally been a problem in North American soybean fields, they can be a significant issue in tropical regions, especially South America. An estimated 8.8% of the world soybean crop is lost to insects each year.³¹ This would have amounted to over 23 million metric tons in 2012, valued at nearly USD 11 billion.³² As in other crops, most Insect Resistant (IR) soybean varieties contain the Bt (*Bacillus thuringiensis*) trait. Several additional IR products are expected to be commercialized in the next five to ten years.³³

New biotech soybeans with modified oil profile and other qualities also offer significant economic opportunity and the potential for improved human and livestock nutrition. A significant amount of research and development has been devoted to tailoring the oil content of soybean varieties in order to meet consumer demand for healthier food options.³⁴ As a result, in recent years there has been increased understanding that trans-fatty acids may increase serum cholesterol and change the proportions of the components of serum cholesterol in ways that could diminish heart health. Similarly, there has been improved understanding that cis-fatty acids, like oleic acid, can have the opposite effect, pushing the cholesterol profile in a healthier direction. Soybeans are showing increasing promise as a plentiful source for these healthier fats.³⁵ Two versions of High Oleic acid Soybeans (HOS) are already grown in the US under segregated conditions.³⁶ China has approved one high oleic soybean product for import, while the EU has not yet approved any.³⁷

³⁰ BASF is developing a fungal disease resistant cultivar that will be tailored for South American producers. DuPont is working on a strain resistant to Asian soybean rust. Syngenta, Bayer, and DuPont are each developing varieties resistant to a broad range of nematode infection (Context Network, 2014).

³¹ E-C Oerke, *Crop Losses to Pests*, 144 J. Agric. Sci. (2006).

³² USDA, <http://apps.fas.usda.gov/psdonline/>. 2015.

³³ Monsanto and Dow AgroSciences have both gained recent approval for current versions of IR (Bt) soybeans. Monsanto has also developed its Intacta RR2 Pro™ cultivar, which combines the Bt trait with glyphosate resistance and was tailored for South American producers. A second generation upgrade of Intacta is currently in development and will offer more modes of action and improved insect resistance. Syngenta has an IR soybean in development, and DuPont is developing a soybean line with resistance to insects of order Hemiptera (aphids, stink bugs) in addition to Lepidopterans. (Context Network, 2014).

³⁴ Kym Anderson, *Economic Impacts of Policies Affecting Crop Biotechnology and Trade*, 27 New Biotechnology (2010); Berman et al., *Plant Molecular Biology* (2013).

³⁵ Ronald P. Mensink & Martijn B. Katan, *Effect of Dietary Trans Fatty Acids on High-Density and Low-Density Lipoprotein Cholesterol Levels in Healthy Subjects*, 323 New Eng. J. Med. (1990); Brent D. Flickinger & Peter J. Huth, *Dietary Fats and Oils: Technologies for Improving Cardiovascular Health*, 6 Current Atherosclerosis Rpts. (2004).

³⁶ Plenish™ soybeans, developed by DuPont/Pioneer, was approved for cultivation in the US and Canada in 2009 and has since been approved for use in ten other countries, including China. The Plenish™ plus HR product is approved for cultivation in Canada and for use in six other countries, including China. (ISAAA, 2015).

³⁷ ISAAA, <http://www.isaaa.org/gmapprovaldatabase/default.asp>. 2015.

The benefits of omega-3 fatty acids to heart health are also well established. Consumption of omega-3 fats not only helps improve individuals' cholesterol profile, but has also been shown to decrease the incidence of heart disease and risk of sudden death from heart attack and stroke.³⁸ The primary source of omega-3 fats has been oily fish, such as tuna, salmon, trout, and sardines. Now there is a soybean variety in the pipeline with significant levels of omega-3 fat which is expected to be commercialized in the next three years.³⁹ It is anticipated that after their full commercialization, soybean varieties with modified oil profile will occupy an important position in the global soybean market.

Perhaps the most economically significant introduction of new biotech traits in soybean production, at least in the short run, may be the expanded line-up of traits that provide tolerance to different herbicides. Almost twenty years after the introduction of RR soybeans, the value of this herbicide tolerance has begun to diminish in some parts of the world due to the gradually increasing presence of weed biotypes resistant to glyphosate. Herbicide resistant weeds are not a new phenomenon; plant scientists have been grappling with this issue for some time.⁴⁰ At last count, 443 species of weeds have biotypes that have become resistant to members of twenty-two different herbicide groups. Glyphosate has fared better than some; to date glyphosate-resistant biotypes have been reported in thirty-one species worldwide.⁴¹ Weed resistance to glyphosate, however, is a significant problem due to glyphosate's status as the most widely used herbicide in the world, and one that does not have a ready replacement that is as effective, economical, and safe.⁴²

In the US, farmers have noticed a decline in the effectiveness of glyphosate due to weed resistance on 44% of the planted area. On those fields where weed resistance exists, expenditures on agricultural chemicals have increased by nearly USD 48/ha as farmers attempt to effectively control weeds and minimize yield losses.⁴³ Costs in other producing countries are comparable. Although detailed numbers on the share of acres are not readily available, herbicide resistant weeds

³⁸ Artemis P. Simopoulos, *Omega-3 Fatty Acids in Health and Disease and in Growth and Development*, 54 Am. J. Clin. Nutrition (1991); Penny M, Kris-Etherton et al., *Fish Consumption, Fish Oil, Omega-3 Fatty Acids, and Cardiovascular Disease*, 106 Circulation (2002).

³⁹ Monsanto's SDA Omega-3 variety is in stage 4 of the R&D pipeline. Biotech Traits Commercialized. (2014); Monsanto, *Stearidonic Acid (SDA) Omega-3 Soybeans* (2015), available at <http://www.monsanto.com/products/pages/sda-omega-3-soybeans.aspx>.

⁴⁰ E. James Retzinger & Carol Mallory-Smith, *Classification of Herbicides by Site of Action for Weed Resistance Management Strategies*, 11 Weed Tech. (1997).

⁴¹ Ian Heap, *The International Survey of Herbicide Resistant Weeds* (2015), available at <http://www.weedscience.com/summary/home.aspx>.

⁴² Stephen O. Duke & Stephen B. Powles, *Glyphosate-Resistant Crops and Weeds: Now and in the Future*, 12 AgBioForum (2009).

⁴³ NASS, Agricultural Resource Management Survey: U.S. Soybean Industry (USDA National Agricultural Statistics Service 2012).

have been found in all areas of Argentina. For fields with resistant weeds, increases in herbicide expenditures have been estimated to range from USD 18/ha to USD 121/ha as compared to fields without resistant weeds. Gross profits on farms with resistant weeds were, on average, USD 81/ha lower than those without, while growers in some areas registered net economic losses due to increased weed control costs.⁴⁴ In the case of Brazil, it has been estimated that in the Rio Grande do Sul region some 50% of the soybean area had populations of *Conyza* spp. and *Lolium multiflorum* resistant to glyphosate.⁴⁵ Some earlier estimates found that in 2010 4.3, 1.4, and 0.1 million soybean hectares across the country had populations of glyphosate resistance *Conyza* spp., *Lolium multiflorum*, and *Digitaria insularis*, respectively.⁴⁶ Potential yield losses are estimated at up to 44%,⁴⁷ and farmers have reported average increased costs of USD 35/ha for weed control.⁴⁸

New soybean traits that provide expanded herbicide tolerance are expected to be important for managing weed resistance in the future. Glyphosate resistance developed primarily where intensive and exclusive use of glyphosate has been the norm for growers.⁴⁹ Studies suggest that the key to managing resistance and preserving glyphosate as a viable weed control alternative in the future lies in restoring diversity to farmers' weed management strategies.⁵⁰ Diversity could expand by using multiple herbicides with different modes of action, preventing weeds from becoming resistant to any one of them.⁵¹ Using multiple herbicides, especially if they are applied post-emergence, could be facilitated by crops that are resistant to multiple herbicidal modes of action.

The bulk of the new biotech soybean products that have been recently released or are in the pipeline feature stacked events, combinations of both

⁴⁴ Similar incremental costs have been estimated in 'Economic Impact of Weed Resistance in Argentina'. Ing. Sebastián Senesi, Food and Agribusiness Program. UBA. FAUBA where the total incremental cost of weed control has been calculated at USD 1.3 billion. Cost Increases Caused by Resistant and Tolerant Weeds. (2014).

⁴⁵ (Vargas et al., 2012).

⁴⁶ Kleffmann Group, *Agricultural Marketing Information System (AMIS)* (2010), available at <https://www.kleffmann.com/en/products--services/amis-farmer-panel-research>.

⁴⁷ Antonio L. Cerdeira et al., *Agricultural Impacts of Glyphosate-Resistant Soybean Cultivation in South America*, 59 J. Agric. & Food Chemistry (2010).

⁴⁸ (Vargas et al., 2012).

⁴⁹ Chuck Foresman & Les Glasgow, *US Grower Perceptions and Experiences with Glyphosate-Resistant Weeds*, 64 Pest Mgt. Sci. (2008); Stephen B. Powles, *Evolved Glyphosate-Resistant Weeds around the World: Lessons to Be Learnt*, see *ibid.*, at 1020.

⁵⁰ Duke & Powles, *AgBioForum* (2009); Micheal D.K. Owen, *Weed Resistance Development and Management in Herbicide-Tolerant Crops: Experiences from the USA*, 6 Journal Für Verbraucherschutz Und Lebensmittelsicherheit (2011).

⁵¹ Gerald M. Dill et al., *Glyphosate-Resistant Crops: Adoption, Use and Future Considerations*, 64 Pest Mgt. Sci. (2008); Micheal D.K. Owen, *Weed Species Shifts in Glyphosate-Resistant Crops*, 64 Pest Mgt. Sci. (2008); Stephen B. Powles, *Evolved Glyphosate-Resistant weeds around the World: Lessons to Be Learnt*, see *ibid.* at 1019; Hugh J. Beckie, *Herbicide-Resistant Weed Management: Focus on Glyphosate*, 67 Pest Mgt. Sci. (2011).

established and newly developed herbicide tolerance traits. Since 2013, nine new events have been approved for production in the US and Canada and for use in a variety of other countries; six of these are stacked herbicide tolerance traits. None of these traits have yet been approved in China (some have not been submitted yet due to China's approval policies, described below) and only one has been approved for import into the EU.⁵² Several more stacked HT trait varieties are in the pipeline and expected to be ready for approval in the next five to ten years.⁵³ It is broadly anticipated that stacked HT traits with multiple modes of action will be an important ingredient in integrated weed management systems in the coming years. Even if some portion of a local weed population contains genes conferring resistance to a particular herbicide, these genes cannot be passed on to future generations if the plants are killed by another mode of action herbicide. Crops with stacked HT traits allow farmers to use a suite of herbicides to attain better weed control. More complete weed suppression is an important tool in limiting the development of resistant weeds by limiting the breeding population.

4 REGULATORY APPROVAL, ASYNCHRONY, AND POTENTIAL INNOVATION SLOW-DOWN

In order for these new soybean biotech traits to enter the market they must first gain regulatory approval in countries where they might be produced or marketed. This approval process can slow down commercialization.

Regulatory approval decisions for new biotech crops are made separately in different countries, are costly,⁵⁴ and can take some time to secure. Regulatory approvals for new biotech events took an average of 13.6 months in the US in the mid-2000s⁵⁵ but in the EU and some other countries approvals can take much longer and are by no means assured, even for events already approved elsewhere. In

⁵² Dow AgroSciences has received cultivation approval for its EnlistTM soybeans, resistant to glufosinate and 2,4-D, and also Enlist E3TM soybeans, developed in cooperation with MS Technologies, resistant to glyphosate, glufosinate, and 2,4-D. Bayer CropScience, is similarly in the process of commercializing its BalanceTM GT soybeans, resistant to glyphosate and isoxaflutole. Monsanto has gained North American approvals for its Genuity RR2 XtendTM trait, resistant to glyphosate and dicamba. Finally, Bayer CropScience and Syngenta is releasing a soybean variety resistant to mesotrione and glufosinate (ISAAA, 2015).

⁵³ A new soybean variety from Bayer CropScience and Syngenta, resistant to mesotrione, glufosinate, and isoxaflutole, is currently undergoing regulatory review in the US, Canada, and the EU. These two firms are also developing a cultivar resistant to glyphosate, glufosinate, and HPPD (4-Hydroxyphenyl Pyruvate Dioxygenase) inhibitors. BASF is developing an imidazoline tolerant form of its Cultivance soybean in cooperation with Brazilian researchers. (Context Network, 2014).

⁵⁴ Nicholas Kalaitzandonakes et al., *Compliance Costs for Regulatory Approval of New Biotech Crops*, in *Regulating Agricultural Biotechnology: Economics and Policy* (David Zilberman et al., eds, 2006).

⁵⁵ Greg Jaffe, *Withering on the Vine*, Center for Science in the Public Interest (2005).

the EU, for example, twenty-nine approvals have been issued since the beginning of 2010.⁵⁶ The bulk of these, however, have been renewals of previously approved events and approvals of combinations of previously approved events; the European Commission has approved only nine new biotech events over that time.⁵⁷ The backlog of applications in the EU has been steadily growing. There are now eighteen events awaiting approval, with an average pendency of over six years. Twelve of these are in need only of a final approval vote by the Commission.⁵⁸ Such delays not only slow down new product introductions in the global markets but also affect the flow of biotech innovations submitted for consideration to the EU regulatory authorities. The decision of BASF to withdraw three varieties of GM potatoes from the EU approval process in 2013, one of which was in the final stages, is but one example. The company cited expense and uncertainty as the reasons for the decision.⁵⁹

Regulatory requirements can and do vary from country to country and in some cases specific requirements can build in additional delays. China, for example, requires that proof of approval for use and sale in the exporting country be submitted with the application for import approval in China. The ensuing approval process involves several government agencies at both the federal and provincial level, and requires further field tests and animal feeding studies. The process has traditionally taken around two years, but has become significantly slower recently.⁶⁰ As a result of such policies, China significantly extends to total time required for the approval of new biotech traits. More recently, it has also begun to lag behind other countries in total approvals. In all, China has approved a total of fifty-five events, fewer, for instance, than the US (171) or Canada (155).⁶¹

Because of slower or asynchronous national approvals, some new biotech crops may be produced in exporting countries before they are approved for use in all importing countries. This situation, especially when combined with a zero-tolerance policy for unapproved events, has the potential to cause international trade disruptions. If soybean product shipments to the EU from major exporting countries were blocked due to unapproved biotech events, resulting price increases of various commodities in large markets like the EU

⁵⁶ EuropaBio, *Time for the Commission to Authorize Safe GMO Imports* (2015), available at <http://www.europabio.org/positions/time-commission-authorize-safe-gmo-imports>.

⁵⁷ ISAAA, <http://www.isaaa.org/gmapprovaldatabase/default.asp>. 2015.

⁵⁸ EU-28 Agricultural Biotechnology Annual Report (2014); EuropaBio, *Time for the Commission to Authorize Safe GMO Imports*. 2015.

⁵⁹ Global Status of Commercialized Biotech/GM Crops: 2013 (2013).

⁶⁰ China Agricultural Biotechnology Annual Report (2014).

⁶¹ These numbers include approvals of stacked trait events already individually approved. Global Status of Commercialized Biotech/GM Crops: 2014 (Executive Summary). (2014).

could be significant – up to 200%.⁶² Even smaller regional trade networks could experience noticeable price increases due to trade disruptions. Models suggest that the effects of trade disruptions between major Latin American importers and one or two of their major suppliers in the maize market in North and South America could be large. Even though alternative suppliers are available within the Americas, importing countries could still experience price increases of up to 20%.⁶³

These are not just theoretical possibilities. In 2007, low levels of Herculex maize, approved in the US but not the EU, were found in the commodity maize supply chain in spite of segregation efforts by producers and importers. As a result, EU imports of US maize gluten feed and distiller's dried grains dropped to nearly zero and stayed there for an extended time.⁶⁴ This incident may have cost EU livestock producers as much as EUR 1.6 billion in 2007/2008.⁶⁵ In July of 2009 traces of a biotech maize event, MON88017, again approved in the US but not in the EU, were found in a shipment of soybean meal being delivered to the EU. The shipments were delayed until the end of October of that year when MON88017 was finally approved by the European Commission.⁶⁶ In 2014, China rejected over 1 million tons of maize and maize products due to detection of the biotech event MIR162, approved in the US in 2010 but not in China until December of 2014. Industry analysts estimated the losses from this trade disruption in the hundreds of millions of dollars.⁶⁷ Economic impacts from market disruptions in soybean trade with China could be even more dramatic given China's much larger role in world soy markets.

Disruptions in international trade can be minimized by delaying commercialization of new biotech traits until regulatory approval has been secured in all major markets of key agricultural commodities. Along these lines, biotech firms have self-regulated by adopting a policy to not release a new biotech trait to farmers until it has been approved for use in major markets with functioning

⁶² Martin Henseler et al., *On the Asynchronous Approvals of GM Crops: Potential Market Impacts of a Trade Disruption of EU Soy Imports*, 41 Food Policy (2013); Nicholas Kalaitzandonakes et al., *Potential Economic Impacts of Zero Thresholds for Unapproved GMOs: The EU Case*, 45 Food Policy (2014).

⁶³ Nicholas Kalaitzandonakes et al., *Economic Impact Analysis of Potential Trade Restrictions on Biotech Maize in Latin American Countries*, in *Modeling, Dynamics, Optimization and Bioeconomics I* (Alberto Adrego Pinto & David Zilberman eds, 2014).

⁶⁴ The Economic Impacts of Asynchronous Authorizations and Low Level Presence: An Overview (2011).

⁶⁵ Alexander J. Stein & Emilio Rodríguez-Cerezo, *Low-Level Presence of New GM Crops: An Issue on the Rise for Countries Where they Lack Approval*, 13 AgBioForum (2010).

⁶⁶ T. Demeke & D.J. Perry, *Low Level Presence of Unapproved Biotech Materials: Current Status and Capability of DNA-Based Detection Methods*, 94 Can. J. Plant Sci. (2014).

⁶⁷ USDA, China Agricultural Biotechnology Annual Report, 2014.

regulatory systems.⁶⁸ However, questions on what constitutes a ‘major market’ as country imports can change from year to year and how slow a regulatory system might be before it is characterized ‘non-functional’ are still a matter of debate among affected stakeholders.

5 ESTIMATING THE COST OF DELAYED ADOPTION DUE TO ASYNCHRONOUS APPROVALS

The societal economic benefits from innovation can be measured as the increase in consumer and producer surpluses generated in the market, compared to what was the next best alternative before the innovation was introduced. As innovations decrease production costs or increase product quality, supply and demand relationships change. Such changes are manifested in the market as differences in the quantities sold and the market prices paid. Producers who adopt the new technologies benefit as lower costs and increasing supplies can lead to increased income. Consumers benefit as they get more for their money when price decreases and/or quality increases.⁶⁹ Regulatory delays mean that both groups see these benefits later than they otherwise would have, and most likely at lower levels. The forgone producer and consumer benefits constitute the most immediate costs of regulatory delays on innovation.

Estimating the foregone benefits from delayed innovation is less than straightforward and requires a proper counterfactual. For that purpose, both the economic value of the realized innovation path and the economic value of the innovation path that would have been realized but for the regulatory delay must be calculated. These are generally unobservable and as such they must be estimated through economic modelling techniques.

Previous studies, described in the introduction, that have estimated the foregone economic benefits of biotech innovations due to regulatory delays have used a variety of analytical methods to approach that task. Most of these studies are backward looking, attempting to discover the difference between an actual past course of events and an unknown counterfactual. One study compared the production and income results of Bt cotton growers with those farmers’

⁶⁸ Crop Life International, Product Launch Stewardship, 2015. E.g. Monsanto, *Monsanto Company Receives Final Key Regulatory Approval For Intacta RR2 PRO™ Soybeans, Setting Up Commercial Launch In Brazil* (2013), available at <http://news.monsanto.com/press-release/products/monsanto-company-receives-final-key-regulatory-approval-intacta-rr2-pro-soybe>; Dow AgroSciences, *Dow AgroSciences Announces Launch of Enlist Duo™ Herbicide in the U.S.* (2014), available at <http://newsroom.dowagro.com/press-release/dow-agrosciences-announces-launch-enlist-duo-herbicide-us>; Syngenta, *Syngenta receives Chinese import approval for Agrisure Viptera® corn trait* (2014), available at <http://www.syngenta.com/global/corporate/en/news-center/news-releases/Pages/141222.aspx>.

⁶⁹ Richard E. Just et al., *The Welfare Economics of Public Policy: A Practical Approach to Project and Policy Evaluation* (Edward Elgar Publishing 2004).

experience prior to adopting Bt cotton and with the current experiences of non-adopting farmers to estimate the implied regulatory costs of delayed introduction Bt cotton in India.⁷⁰ Others⁷¹ have used a cost-benefit analysis framework developed by Wesseler et al.⁷² to estimate foregone benefits in years prior to the approval of biotech sugar beets, bananas, and maize. A final example used a health accounting framework to estimate disability-adjusted life years (DALYs) that could have been saved by introducing Golden Rice in India and thereby avoiding cases of vitamin A deficiency that actually occurred. By assigning an accepted value to each DALY they were able to estimate the total value lost.⁷³

This study differs from previous studies in that it is forward looking. That is, we wish to estimate the difference between two possible future economic paths – one where new varieties of biotech soybeans are approved at a ‘normal pace’ in import markets, versus one where regulatory approvals and commercial introduction are delayed. Thus both possible paths lie in the future and are unobservable; both must be estimated, as in a study concerning the indirect costs of regulatory compliance in the Philippines.⁷⁴ That study used an augmented economic surplus model to estimate both total welfare gains as well as the distribution between producer and consumer surpluses.

In this study we are also interested in the potential economic costs of regulatory delays in soybean biotechnologies currently in the pipeline. Since all the possible adoption paths lie in the future, they must be constructed rather than derived through observation. We must therefore take care in building our analytical scenarios in order to ensure as much realism as possible. Here we are interested in examining the economic implications of a normal versus a slower commercialization and adoption of new HT soybean varieties.

As stated earlier, a primary concern is with possible farmer responses to weed resistance to glyphosate. The current standard programme of exclusive and intensive use of glyphosate has become insufficient in some production areas. As a result, some farmers are currently incurring elevated costs for weed control. Alternative control methods at their disposal include additional crop rotations, a

⁷⁰ Pray et al., *The Cost of Biosafety Regulations: The Indian Experience*, Q. J. Intl. Agric. (2005).

⁷¹ Demont et al., *Biodiversity versus Transgenic Sugar Beet: The One Euro Question*, Eur. Rev. Agric. Econ. (2004), Wesseler et al., *The Maximum Incremental Social Tolerable Irreversible Costs (MISTICs) and Other Benefits and Costs of Introducing Transgenic Maize in the EU-15*, Pedobiologia (2007), Kikulwe et al., *Introducing a Genetically Modified Banana in Uganda: Social Benefits, Costs, and Consumer Perceptions*, IFPRI Discussion Paper 767, (2008).

⁷² Wesseler et al., *The Maximum Incremental Social Tolerable Irreversible Costs (MISTICs) and other Benefits and Costs of Introducing Transgenic Maize in the EU-15*, Pedobiologia (2007).

⁷³ Wesseler & Zilberman, *The Economic Power of the Golden Rice Opposition*, Evt & Dev. Econ. (2014).

⁷⁴ Bayer et al., *Cost of Compliance with Biotechnology Regulation in the Philippines: Implications for Developing Countries*, AgBioForum (2010).

return to selective herbicides, and/or increased tillage, all of which have added operational and capital costs.⁷⁵ Different combinations of these tactics can be effective under different conditions, resulting in a broad range of costs of weed management when the RR system must be augmented. For some regions, the cost of weed control could become prohibitive leading to inevitable reductions in yield and production area.⁷⁶

When the new HT varieties described above are approved for cultivation and export and can be deployed commercially, they could enhance the options available to farmers for managing weeds at lower cost, primarily with multiple herbicides supplemented with other methods as needed. If the new HT varieties are delayed in reaching producers, two negative outcomes could result. First, the slower introduction of these cultivars would entail a continuation of current increased costs of managing resistant weeds where they occur. Second, weed resistance to glyphosate may expand beyond its current levels. This would entail increased weed management costs in the future to deal with a larger problem.

Given these conditions, a variety of factors could shape the economic impacts and the rate of adoption of new HT soybeans. We consider here multiple such factors including the current scope and expected progression of glyphosate resistance across various weeds, the average cost savings of new HT soybean varieties, the speed of incorporating new biotech traits into elite soybean varieties in different countries, and the speed of regulatory approvals and potential delays. These potential future occurrences form the basis for three alternative innovation scenarios we examine in this study and which we detail in the next section. We also detail the model we use to describe the market conditions that prevail when the new HT soybean varieties are commercialized.

6 MODEL STRUCTURE AND SCENARIO DEVELOPMENT

In this study we use a previously developed and validated global partial equilibrium model.⁷⁷ The model represents the global market demand and supply conditions of various oilseeds, competing crops, and livestock production for all

⁷⁵ Thomas C. Mueller et al., *Proactive versus Reactive Management of Glyphosate-Resistant or -Tolerant Weeds*, 19 Weed Tech. (2005); Beckie, *Herbicide-Resistant Weed Management: Focus on Glyphosate*, Pest Mgt. Sci. (2011); C. Blake Edwards et al., *Benchmark Study on Glyphosate-Resistant Crop Systems in the United States. Economics of Herbicide Resistance Management Practices in a 5 Year Field-Scale Study*, 70 see *ibid.* at (2014).

⁷⁶ Gianessi & Reigner, *The Value of Herbicides in US Crop Production*, Weed Tech. (2007); M.D.K. Owen et al., *Comparisons of Genetically Modified and Non-genetically Modified Soybean Cultivars and Weed Management Systems*, 50 Crop Sci. (2010).

⁷⁷ Alston et al., *The Size and Distribution of the Benefits from the Adoption of Biotech Soybean Varieties*, in *Handbook on Agriculture, Biotechnology, and Development* (Stuart J. Smyth et al., eds 2014).

major producing and consuming countries. We specify separate supply and demand functions for all oilseed crops and the meal and oil products produced from them in different countries and regions, including the major producing countries (US, Brazil, and Argentina), the major importers (the EU and China), and other significant players in international agriculture markets such as India, South Korea, Japan, Canada, Mexico, and others. The equations below are used to calculate the market clearing conditions for each specific commodity in each country or region. The country- and region-specific prices generated by supply and demand conditions are all interconnected via price linkage equations that include tariffs, taxes, and other relevant price shifting factors.

$$\text{Beginning Stocks}_t = \text{Ending Stocks}_{t-1} \quad (\text{Oilseeds, Meals, Oils}) \quad (1)$$

$$\text{Production} = \text{Harvested Area} \star \text{Yield} \quad (\text{Oilseeds}) \quad (2)$$

$$\text{Production} = \text{Crush} \star \text{Crushing Yield} \quad (\text{Meals, Oils}) \quad (3)$$

$$\text{Total Supply} = \text{Beginning Stocks} + \text{Production} + \text{Imports} \quad (\text{Oilseeds, Meals, Oils}) \quad (4)$$

$$\text{Total Demand} = \text{Crush} + \text{Food Use} + \text{Other Use} + \text{Exports} + \text{Ending Stocks} \quad (\text{Oilseeds}) \quad (5)$$

$$\text{Total Demand} = \text{Food Use} + \text{Feed Use} + \text{Industrial Use} + \text{Ending Stocks} \quad (\text{Meals, Oils}) \quad (6)$$

$$\text{Domestic Use} = \text{Crush} + \text{Food Use} + \text{Other Use} + \text{Ending Stocks} \quad (\text{Oilseeds}) \quad (7)$$

$$\text{Domestic Use} = \text{Food Use} + \text{Feed Use} + \text{Industrial Use} + \text{Ending Stocks} \quad (\text{Meals, Oils}) \quad (8)$$

The partial equilibrium model provides ten-year forecasts for all relevant commodities and markets, and is calibrated by ensuring that the baseline simulation accurately reproduces historical market conditions (supply, demand, stocks, hectareage, prices, trade and other relevant variables) across commodities and geographies. Our analysis then involves evaluation of alternative future adoption paths of new HT soybean varieties during the period 2015–2025. Market conditions in the model baseline represent the global agricultural sector over the same ten year period and assume no adoption of new HT soybeans. In this way, the economic impacts from the adoption of such innovations can be evaluated by comparing the various scenarios (where normal or delayed adoption occurs) against the baseline (where no adoption occurs).

The impacts of regulatory delays on new HT soybean biotechnologies are modelled as a continuation of the production costs presently incurred by farmers, some of whom must manage weeds without the benefit of RR or new HT soybean varieties. Potential cost savings from using the new HT soybean varieties are then estimated as the difference between reported actual costs currently being incurred by farmers in the US, Brazil, and Argentina in managing glyphosate-resistant weeds and weed control costs when no such resistance is encountered.⁷⁸ Based on such figures we use an average cost savings of USD 44.50/ha in all our calculations when the new HT technologies are used.

The normal adoption path of new HT traits takes into account historical patterns of adoption (trait penetration) of HT varieties in the North and South America as well as the expected pipeline releases described above. Regulatory delays cause a deferral of the normal adoption path but the rate of adoption after the delay will likely remain similar. After calculating the projected market outcomes from the introduction and adoption of HT soybean varieties in terms of prices and quantities supplied and demanded, we can then determine the difference in consumer and producer surplus between each scenario outcome and the baseline. The surplus changes are specified as follows:

$$\Delta PS_{R,S} = P_0 Q_0 (K - Z) (1 + 0.5 Z_{\epsilon S}) \quad (9)$$

$$\Delta PS_{R,O} = -P_0 Q_0 Z (1 + 0.5 Z_{\epsilon O}) \quad (10)$$

$$\Delta CS_{R,O} = (P_0 - P_1) C_0 + 0.5 (C_1 - C_0) (P_0 - P_1) \quad (11)$$

where ΔPS is the difference in producer surplus, ΔCS is the difference in consumer surplus, the subscript R denotes a particular country or region, the subscript S denotes soybeans, and the subscript O denotes all other crops in the model. P_0 is a baseline price and P_1 is a scenario price. In parallel fashion C_0 and Q_0 are baseline quantities demanded and supplied, respectively, and C_1 and Q_1 are scenario quantities demanded and supplied. Our model is used to estimate these market effects under the following scenarios:

Scenario 1 is concerned with the adoption of new HT soybean varieties, which we will model as happening in two different time frames. We will compare timely approvals and normal pace of commercialization and adoption of the new HT soybean varieties (scenario 1A) and regulatory delays and asynchrony in major importing countries that lead to a three-year delay in commercialization and adoption of such varieties (scenario 1B). When farmers are able to adopt the new HT varieties they realize USD 44.50/ha savings in variable costs. Adoption paths

⁷⁸ NASS, Agricultural Resource Management Survey: U.S. Soybean Industry, 2012; REM, Cost Increases Caused by Resistant and Tolerant Weeds, 2014; Vargas et al., 2012).

in both scenario 1A and 1B are such that 80% of hectareage is planted with HT soybean varieties, both new and traditional RR, within ten years from their commercial introduction and remains at that level thereafter.⁷⁹ The adoption paths in the US, Brazil, and Argentina assumed here are therefore more conservative than those historically observed for RR soybeans in these countries. Given these scenarios, we can evaluate the economic implications of regulatory delays by comparing the economic impacts of a normal adoption path (scenario 1A) against those of a slower adoption path (scenario 1B).

The second scenario allows for the possibility that a slower commercialization of new HT soybean varieties due to regulatory delays may lead to the exit of marginal hectareage from soybean production. This is a potential market outcome that could materialize. Current data from the US, Argentina, and Brazil suggests that there is significant variance in the costs of managing glyphosate-resistant weeds from one region and one field to another (e.g., in the case of Argentina cost increases range from USD 18/ha to USD 121/ha). Furthermore, current data indicates that for areas of high weed control costs, profits have been negative and cropping uneconomical. As weed resistance to glyphosate continues to develop in the absence of new HT varieties, it is possible that some marginal lands would be taken out of production and allocated to other uses. Scenario 2, then, examines the impact of a small decrease in production area (0.5 million hectares across the US, Brazil, and Argentina in total) during the slower adoption scenario considered in 1B.

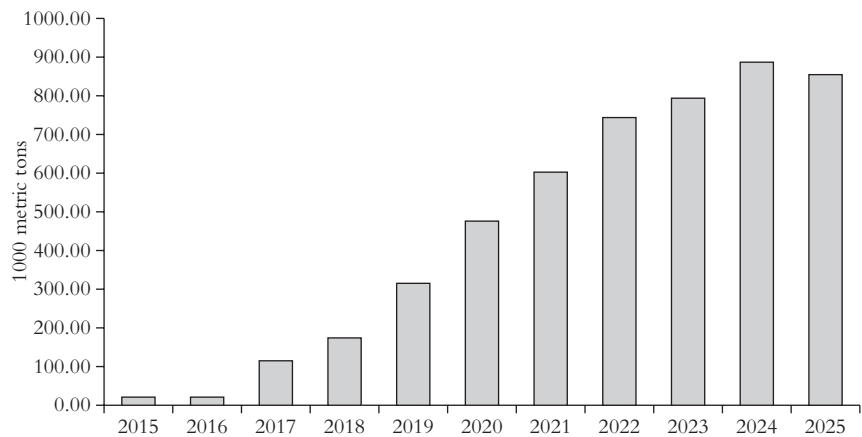
7 EMPIRICAL RESULTS

In scenarios 1A and 1B we examine the economic impacts of new varieties of HT soybeans on projected grain markets. In the first phase, scenario 1A, as commercial introduction and adoption of new HT soybean varieties progress at a normal pace, farmers realize reductions in weed management costs and the associated efficiency gains in their production systems. Cost efficiency gains result in expansion of soybean hectareage and supplies among adopting producers, with the expected results. As Figure 1 shows, production volume in the three major soybean producing countries, Argentina, Brazil, and the USA, increases steadily, with the net increase standing at over 850,000 metric tons more than in the baseline case by

⁷⁹ The adoption level of 80% as well as the cost savings are generally considered conservative and are maintained as such by design. For instance, adoption of herbicide tolerant soybeans in most countries has exceeded 95% of hectareage.

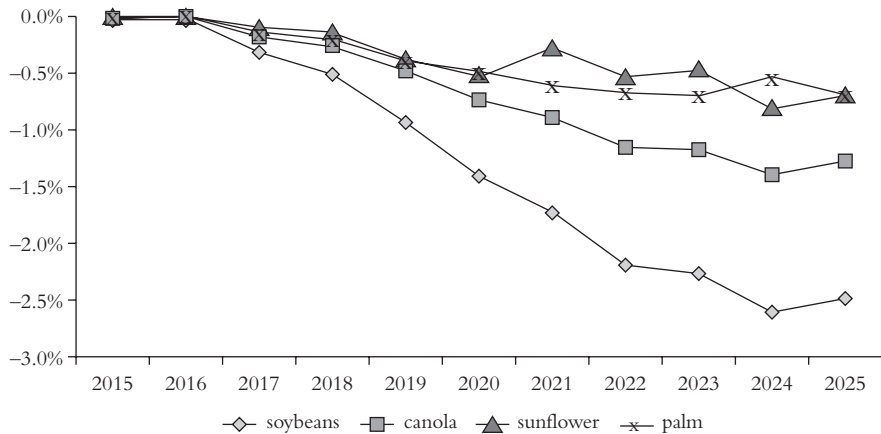
2025. Importing countries share in the greater availability of soybean products, as our model indicates that exports from these three countries increase along with production.

Figure 1 Change in Production: ARG, BRA & USA



The increase in supply of soybean products leads to a decrease in market prices not only for soybeans but for other oilseeds as well, as they are substitute products. Figure 2 illustrates the soybean price declines gradually as cost efficiencies expand across greater hectareage until it is 2.5% lower than the baseline case by 2025. As soybeans become cheaper relative to other oilseeds, overall demand shifts away from other oilseeds in favour of soybeans. With the lower demand, prices of other oilseeds decline as well (Figure 2). The lower prices benefit consumers of all oilseed products, especially consumers of soybean products. Producers lose on a per unit basis from lower prices, but the increase in production efficiency and higher volume more than make up for the decline for those who adopt the new HT varieties. Producers in countries where they are restricted from adopting biotech soybeans are faced with lower selling prices and much more limited options on controlling costs and as a result experience an overall decline in profitability and welfare.

Figure 2 Oilseed Price Changes



The introduction of new HT soybean varieties as described in Scenario 1A generates almost USD 40 billion in economic value across all soybean markets in 2015–2025. Of the total net welfare gains resulting from this innovation path, producers capture approximately 56% (USD 22.06 billion) and consumers 44% (USD 17.59 billion). Producers in large adopting and exporting countries (the US, Brazil, Argentina) and consumers in large importing countries (China, the EU) benefit the most. Table 2 outlines the changes in producer and consumer surpluses (in USD million) from the changes in market prices and quantities brought about in scenario 1A, relative to the baseline case.

If regulatory approvals are delayed, as in scenario 1B, the benefits described above accrue to producers and consumers at a later time and at lower levels. In this scenario, commercialization is delayed by three years, so the adoption process begins later. The market effects of adoption follow a substantially similar, although not identical, path as in scenario 1A after the late start. As a result, cost savings and market effects (e.g., production increases, prices changes) realized are smaller. As illustrated in Figure 3, by 2025 soybean prices under scenario 1B drop by 1.8%, compared to the baseline, rather than the 2.5% we saw in scenario 1A. The smaller price change limits the economic benefits to both producers and consumers. Producer and consumer surpluses shown in Table 3 are about half of those shown earlier for the case of timely approvals and normal adoption paths. Worldwide, the economic impact of the slower adoption of new HT soybean varieties is almost USD 21 billion. Producers' share of these economic gains is about 62% (USD 12.9 billion) while consumers' share is 38% (USD 7.8 billion). The overall economic gains from the new HT soybean varieties are about half of those realized in scenario 1A.

Figure 3 Soybean Price Changes from Baseline, Normal v. Slower Adoption Path

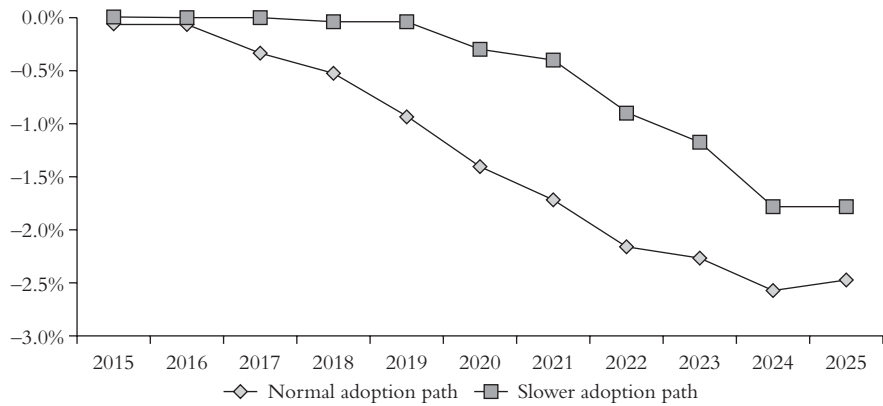


Table 2 Change in Producer and Consumer Surplus from Adoption of HT Technologies: 2015 – 2025 (in USD million)

SCENARIO 1A – Normal Adoption Path											
	Soybeans		Rapeseed		Sunflower		Palm Oil		Total PS	Total CS	
	PS	CS	PS	CS	PS	CS	PS	CS			
United States	9,749	2,885	(35)	59	(27)	23	–	31	9,687	2,998	
Argentina	4,567	2,899	–	–	(71)	57	–	–	4,496	2,957	
Brazil	10,894	2,683	–	–	(4)	4	(10)	13	10,880	2,701	
European Union – 28	(81)	721	(718)	794	(184)	175	–	153	(982)	1,842	
Ukraine	(245)	106	(60)	4	(216)	212	–	–	(521)	322	
China	(629)	5,515	(470)	550	(49)	45	–	186	(1,148)	6,296	
Japan	(9)	161	0	75	–	–	–	15	(9)	251	
India	(698)	690	(234)	234	(15)	15	(1)	259	(948)	1,198	
Indonesia	(30)	165	–	–	–	–	(923)	307	(953)	472	
Thailand	(3)	104	–	–	–	–	(58)	43	(62)	147	
Vietnam	(14)	100	–	–	–	–	–	17	(14)	117	
Egypt	(1)	101	–	–	0	2	–	31	(1)	133	
World	22,066	17,598	(2,206)	2,180	(867)	857	(1,664)	1,499	17,329	22,134	

Table 3 Change in Producer and Consumer Surplus from Adoption Path of HTT Technologies: 2015 – 2025 (in USD million)

	SCENARIO 1B – Slower Adoption Path											
	Soybeans				Rapeseed				Sunflower			
	PS		CS		PS		CS		PS		CS	
	PS	CS	PS	CS	PS	CS	PS	CS	PS	CS	PS	CS
United States	5,356	1,271	(15)	27	(11)	9	–	(2)	5,330	1,306		
Argentina	2,661	1,293	–	–	(30)	24	–	–	2,631	1,317		
Brazil	6,342	1,205	–	–	(2)	2	1	(1)	6,341	1,206		
European Union – 28	(36)	315	(323)	358	(76)	73	–	(7)	(435)	739		
Ukraine	(111)	47	(27)	2	(90)	89	–	–	(229)	138		
China	(277)	2,472	(212)	247	(20)	19	–	(10)	(510)	2,727		
Japan	(4)	70	(0)	33	–	–	–	(1)	(4)	103		
India	(312)	309	(106)	106	(6)	6	–	(13)	(425)	408		
Indonesia	(13)	73	–	–	–	–	49	(16)	36	57		
Thailand	(1)	46	–	–	–	–	3	(2)	1	44		
Vietnam	(6)	44	–	–	–	–	–	(1)	(6)	43		
Egypt	(0)	44	–	–	(0)	1	–	(2)	(1)	43		
World	12,959	7,837	(995)	983	(362)	358	86	(78)	11,688	9,100		

While the welfare gains in scenario 1B are far from trivial, they are significantly less than those in scenario 1A. We can define the cost of regulatory delay as the difference between these two estimates of producer and consumer surplus – roughly USD 19 billion worldwide for the 2015–25 period. Table 4 shows the distribution of such costs. Both producers in large exporting countries (US, Argentina, Brazil) and consumers in large importing ones (China, the EU) incur the largest losses from the slower introduction of new HT soybean varieties.

Table 4 Cost of Slower Innovation – SCENARIO 1A-SCENARIO 1B – 2015 – 2025 (in USD million)

	Soybeans		Rapeseed		Sunflower		Palm Oil		Total PS	Total CS
	PS	CS	PS	CS	PS	CS	PS	CS		
United States	4,393	1,614	(19)	33	(16)	13	–	33	4,358	1,692
Argentina	1,906	1,606	–	–	(41)	34	–	–	1,865	1,639
Brazil	4,552	1,478	–	–	(3)	3	(10)	14	4,539	1,495
European Union – 28	(45)	406	(395)	436	(108)	102	–	160	(547)	1,103
Ukraine	(135)	59	(33)	2	(125)	123	–	–	(293)	184
China	(351)	3,043	(258)	303	(29)	27	–	196	(638)	3,568
Japan	(5)	90	(0)	41	–	–	–	16	(5)	148
India	(385)	381	(128)	128	(9)	9	(1)	272	(524)	790
Indonesia	(17)	91	–	–	–	–	(972)	323	(989)	415
Thailand	(2)	59	–	–	–	–	(61)	45	(63)	104
Vietnam	(8)	56	–	–	–	–	–	18	(8)	74
Egypt	(1)	57	–	–	(0)	1	–	33	(1)	90
World	9,107	9,761	(1,211)	1,197	(505)	499	(1,750)	1,577	5,641	13,034

In addition to the slow-down in the introduction and adoption of new HT varieties, in scenario 2 we consider the possibility that weed management on some marginal land becomes too expensive, leading to a portion of the area currently devoted to soybean production being diverted to other uses. The amount of hectareage ultimately exiting soybean production is shaped by weed resistance build-up over time, and also by commodity prices, relative soybean profitability, and other economic conditions in the model. As a result, the amount of hectareage that exits soybean production varies from one year to another but the net difference from the baseline is always less than 0.5 million hectares across the US, Argentina, and Brazil in any given year. Such land readily comes back into production when adoption of new HT soybean varieties makes soybean production economical. Because of the reduction in hectareage, then, production decreases relative to the baseline, leading to relative soybean price increases of up to 1.5% for a few years. As the adoption of the bundle of new HT events (stacked products containing multiple HT traits in one variety) progresses after the regulatory delay, lower production costs and more effective weed control allow farmers to bring this land back into production and supplies recover leading again to falling prices but later than in scenario 1B.

Table 5 reports the total economic impacts from the adoption of new HT varieties under this modified delayed adoption scenario as well as how they are distributed among producers and consumer across different countries. Figures in Table 5 suggest then that the overall economic gains from the adoption of new HT varieties are not very much different from those realized in scenario 1B—roughly USD 21 billion of total gains in 2015–2025. This is not surprising as the adoption paths of the new varieties and the amount of hectares they occupy under 1B and 2 are very similar. What is quite different, however, is the distribution of such economic gains. Even small and temporary reductions in land use and supplies like those considered here partially reverse price declines that would have occurred from the adoption of the new HT soybean varieties and as a result reverse the gains of consumers. Instead, all such benefits are transferred to adopting producers. Land owners and producers cultivating the marginal lands also lose but such losses are not separately represented in the Table.

Scenario 2 demonstrates illustrates that regulatory delays can slow down the path of commercial introduction and adoption which results in sizeable economic losses for both producers and consumers (scenarios 1A and 1B). But regulatory delays can also contribute to shifts in resource use (land and other inputs) which can, in turn, affect both the size and distribution of economic benefits from innovation. In our scenario 2, even a very small decline in land use in key exporting countries is sufficient to wipe out all consumer gains in the period of analysis.

Table 5 Change in Producer and Consumer Surplus from Adoption Path of HT Technologies: 2015 – 2025 (in USD million)

SCENARIO 2 – Slower Adoption Path & Reduction in Acreage												
	Soybeans		Rapeseed		Sunflower		Palm Oil		Total PS	Total CS		
	PS	CS	PS	CS	PS	CS	PS	CS				
United States	7,876	13	(1)	1	(1)	(1)	0	(29)	7,876	(16)		
Argentina	4,053	80	0	(1)	(2)	(2)	0	0	4,052	78		
Brazil	8,791	104	0	0	0	0	9	(12)	8,800	92		
European Union – 28	0	(9)	(13)	19	8	(7)	0	(143)	(5)	(140)		
Ukraine	(12)	3	(2)	0	6	(6)	0	0	(8)	(3)		
China	(4)	192	(12)	8	3	(2)	0	(162)	(13)	36		
Japan	0	(2)	0	1	0	0	0	(14)	0	(15)		
India	(24)	25	(7)	6	0	0	1	(227)	(30)	(196)		
Indonesia	0	3	0	0	0	0	824	(274)	824	(271)		
Thailand	0	(1)	0	0	0	0	53	(41)	53	(42)		
Vietnam	(1)	0	0	0	0	0	0	(15)	(1)	(15)		
Egypt	0	(1)	0	0	0	0	0	(27)	0	(28)		
World	20,644	409	(50)	49	28	(28)	1,500	(1,347)	22,122	(917)		

8 CONCLUSION

In this study we have analysed the economic impact of a delay in the commercialization and adoption of new soybean technologies caused by regulatory delays. Our results demonstrate how the national regulatory decisions of importing countries can be transmitted through trade networks and affect global markets. Regulatory decisions in different countries are a significant consideration in decisions by biotech firms regarding the commercialization of new crop varieties. While commercialization of new biotech crops may be delayed in order to avoid the costs of trade disruptions due to the presence of unapproved varieties in international commodity shipments, such delays also incur opportunity costs, which we have attempted to quantify here. New biotech innovations (HT soybeans) approaching commercialization have been assumed to enter the market with a three-year lag due to regulatory delays and asynchronies across key importing countries. Such regulatory delays are in line with those experienced over the last decade. We find that when these new soybeans are approved and commercialized in a timely fashion the economic benefits from their adoption are large – USD 40 billion for the ten-year period we analysed – and all market participants benefit, including both producers and consumers. If the new traits are delayed in reaching the market, however, not only are the economic benefits reduced significantly but their distribution is changed as well. Consumers lose a disproportionate share of the welfare gains from innovation as the commercialization of the new soybean varieties is delayed. In scenario 2, probably the more realistic case where land use is also affected by the slower adoption path, consumer welfare gains are almost entirely wiped out.

It is important to note here that our measures of social welfare impacts from regulatory delays on new HT soybean varieties are only partial due to our inability to measure the impacts of certain outcomes. We have not considered here the environmental impacts of cropping systems and practices that may be used when new HT soybean varieties are not available. Biotech HT crops have been designed around herbicides that control weeds with less machinery use and less tillage. In the absence of such crop-herbicide systems, soybean growers could resort to weed control methods with greater environmental impact, especially on soils. We have also restricted our analysis to the soybean market; other crops traded on world markets, notably maize, canola, and others, have also experienced systematic regulatory delays and asynchronous approvals in recent years and may do so in the future. Accounting for the economic implications of such broader delays in technology introduction and adoption could greatly increase the global welfare costs of biotechnology regulatory process and asynchrony. There are also the unseen, long-term effects of the overall slow-down in research and development

due to the expectation of approval delays. These include further delays in innovation and products that are delayed or never developed, as well as firms that are never started and jobs never created. The costs are not easy to quantify but are nonetheless real.

The social welfare changes estimated here also have important implications for food security, especially in lower income countries. Food security is sometimes thought of only in terms of the availability of a sufficient quantity of food, but nutritional content is just as important. In particular, access to protein of sufficient quality and quantity, including animal protein, is a critical component of a comprehensive definition of food security.⁸⁰ A reliable, economical supply stream of livestock feed is crucial to providing consumers worldwide with affordable, quality protein-based foods. Thus significant regulatory delays resulting in asynchronous approvals cannot only impact farmers and seed developers, but also restrict consumer access to adequate nutrition. All these are potentially fruitful topics for future research.

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