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**Centre for the Study of Science and Innovation Policy**

**Submission of Information on Synthetic Biology**

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Dr. Stuart Smyth, CSIP research collaborator and Assistant Professor & Research Chair in Agri-Food Innovations at University of Saskatchewan, has produced the following report. Dr. Smyth undertakes research on the economic, environmental and social benefits of innovative agricultural technologies. The following submission of information on synthetic biology in response to the request of the Executive Secretary for “information and supporting documentation” addresses the six topics identified in decision XIII/17 of the Conference of the Parties to the Convention on Biological Diversity (“CBD”) of 16 December 2016. This submission presents the quantified benefits that have resulted from the commercialization of genetically modified crops under a science-based risk assessment regulatory structure, highlighting the potential costs and concerns of an onerous and rigid socio-economic risk assessment regulatory structure for synthetic biology.

**Introduction**

The first research regarding genetic modification pertained to single cell life forms such as bacteria, viruses and micro-organisms. This biotechnology[[1]](#footnote-1) was a technological evolution of modern genetics which began in the early 1950s with the discovery by Watson and Crick (1953) of the double helix in deoxyribonucleic acid (DNA). While this breakthrough received considerable press coverage, the vast potential of the double helix was, to a large degree, grossly under-estimated and, for the next two decades, research continued with minimal public awareness. The next major innovation in the field of genetics occurred in California laboratories in the early 1970s (Cohen et al., 1973; Chang and Cohen, 1974; and Morrow et al., 1974). It was there that the extraction and insertion of genes within the genetic code of an organism was accomplished for the first time and that the technology known as recombinant DNA (rDNA) began to take form.

Research involving genetically modified (GM) micro-organisms continued throughout the 1970s. With the initial rDNA research publications involving *E. coli* in 1973, the research community gained a greater understanding and heightened concern about the future applications of this technology. The researchers involved with GM microbial research were very proactive in developing research guidelines and took it upon themselves to call for a moratorium and a conference for that purpose.

The Gordon Conference on Nucleic Acids held in 1973 was the first public event to call attention to potential risks of GM technology. The attending scientists “… were concerned that unfettered pursuit of this research might engender unforeseen and damaging consequences for human health and the Earth’s ecosystems.” (Berg and Singer, 1995). As a result, in July 1974, a call for a public moratorium on any further rDNA research was issued to enable research scientists to learn more about the technology of micro-organism gene splicing, including the safety of those working in the laboratories (Berg et al., 1974).

The Asilomar Conference, a multi-stakeholder event that brought together leading scientific researchers and governmental regulators, was subsequently held in 1975 to engage in a full and open discussion about the risks of genetic modification. The initial experiments involving rDNA research had raised many questions and concerns about liability and safety of the process. The conference focus was to discuss the risks of the research, the conditions needed to ensure that the risks were adequately addressed and such safety precautions as would be necessary to remove the moratorium and allow for future research to proceed safely. The striking aspect of this conference was that the world’s leading experts on rDNA research developed the safety guidelines for subsequent research themselves, rather than having the guidelines developed and imposed on the scientific research community by government. The process was transparent and open to scientific and public scrutiny; it was in fact designed to reassure those concerned that appropriate steps were being taken to prevent any actual or hypothetical risks from being realized. Officials of the United States National Institutes of Health (NIH) oversaw the development of containment standards for proposed research projects regarding viruses and bacteria that could potentially be harmful to humans if widespread exposure occurred (Singer, 1976). The guidelines developed at the conference were later adopted by the NIH as a requirement to obtain NIH funding. By openly addressing the known and unknown risks associated with the technology, the scientific community involved in rDNA research encouraged a public discourse that resulted in a consensus, despite the limited knowledge existing about the new technology. These NIH guidelines contributed to the eventual risk assessment framework standardization in the early 1980s that provides accommodation for uncertainty.

Subsequent research on this category of life forms has resulted in many modifications that have benefited society and human health. Millions of citizens the world over have benefited from insulin. Further, the baking and cheese industries would be considerably less competitive without the advantage of modified yeasts and enzymes.

The next category of biotechnology research involved genetic modification of animals. With GM animals, the gap between the initial publication and the generation of a commercialized product was over twice that of GM microbes (Table 1). In 1980, the initial publication of research involving transgenic animals was in regards to the genetic transformation of mouse embryos (Gordon et al., 1980). This publication did not trigger the same response within the research community that research on transgenic micro-organisms had in the early 1970s. Familiarity with transgenic research and the evolution of this technology created an environment in which the publishing of transgenic animal research did not trigger calls for moratoriums. New guidelines were not immediately developed to regulate the technology. Rather, the development of transgenic animals was governed by the already very effective NIH regulations on the use of laboratory animals.

By the time the 1988 Symposium on Transgenic Technology in Medicine and Agriculture was held in Bethesda, Maryland, there were over 400 strains of transgenic mice (First and Haseltine, 1988). The focus of the symposium was not on technological risks and the development of research guidelines. Its aim was simply to bring leading experts together to share knowledge about the technology, subsequently resulting in a certain amount of collaborative research. By the time it was held, research had already been underway for a decade and many of the risks arising from the technology had been identified and dealt with. As a consequence, the scientific world perceived no need to focus on additional risk management strategies at the 1988 symposium, as they did at the 1975 Asilomar Conference. The symposium allowed a wider dissemination of knowledge about the potential applications of this biotechnology to animals.

While research with genetically modified animals has been restricted in large part to medical research, there are currently several commercially valued GM animals in existence. One of the best known is the Harvard Mouse (or Onco-mouse) that was genetically modified and is now licensed for cancer research. It was the object of the first patent on a transgenic animal, awarded to Harvard University in 1988. A second commercial technology is the genetic modification of goats in the mid 1990s. This research identified the spider gene that codes for the strength of the silk and inserted the gene into goats. This gene is then expressed in the goats’ milk which is processed to produce a quantity of silk at much higher rates and with greater economies of scale than could be possible from simply using spiders. While these goats are a commercial product, the goats themselves are not commercially available to other firms or consumers. The developer, Nexia Biotechnologies, ensures that the goats and all their possible by-products do not come in contact with the human food supply chain.

Through the 1990s, research on transgenic animals was largely confined to laboratory work and it was not until 2004 that the first transgenic animal became commercially available to the general public. Yorktown Technologies began to sell transgenic zebrafish, known as Glofish® because they carry a translucent jellyfish gene that makes them glow in the dark. Extensions of this research continue with the commercial approval of GM salmon in Canada in 2016. Genetic modification techniques have been applied to dairy cattle in the United States to develop polled dairy cattle.

**Table 1: Major transformation category comparisons**

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| --- | --- | --- | --- | --- |
| **Transform-ation event** | **Date of initial publication** | **Date of corresponding dialogue event** | **Date of first patent awarded** | **Date of first product commercialization** |
| Micro-  organisms | Proceedings of the National Academy of Sciences, 1973  (November) | Asilomar Conference, 1975 | Chakrabarty,  1980 | Novo Nordisk (Denmark), Insulin, 1982 |
| Animals | Proceedings of the National Academy of Sciences, USA, 1980 (December) | Symposium on Transgenic Technology in Medicine and Agriculture, 1988 | Harvard University, April 1988 | Yorktown Technologies, (US),  Zebrafish, 2004 |
| Plants | Nature in May and July 1983, PNAS, August 1983 and Science, November 1983 | Miami Winter Symposia held in Miami, Florida January 1983 | Hibberd, 1985 | Calgene, (US), FlavrSavr™ Tomato, 1994 |

The final category of biotechnology is the genetic modification of plants. In 1983, the first genetic modification of a plant was reported, with tobacco as the host plant, while the first patent on a GM plant, corn, was granted in 1985 (Table 1). Research continued rapidly and by the end of the decade, field trials were underway with multiple GM crop varieties. By the early to mid 1990s, following several years of crop trials, a number of these new GM plants were given variety approval by federal regulators in Canada and the US and commercialized. Field trials were also conducted in the European Union (EU), leading to planting approval for GM corn in 1997, prior to the EU moratorium on GM crop commercialization.

The Miami Winter Symposia on the molecular genetics of plants was held in Miami in 1983,[[2]](#footnote-2) prior to the initial publication on the transgenic plant technology research. The objective of the Symposia was essentially to explore the potential of applying gene technology to plant agriculture by sharing existing knowledge, rather than discussing risk management strategies. To this end, three of the four world-leading researchers presented their research involving transgenic tobacco (Framond et al*.,* 1983; Schell et al., 1983; and Fraley et al., 1983). At this point, GM plants were confined to greenhouses and laboratories. There would be detailed discussions on the implications of field research and commercialization at future meetings.

The first commercial planting of a GM crop occurred in China in 1992 (James and Krattiger, 1996). It involved the planting of 100 acres of transgenic tobacco for the purpose of seed multiplication. The first commercial production of a GM crop for food purposes occurred in 1994 in the United States by Calgene, with 10,000 acres of their transgenic, delayed-ripening tomato, FlavrSavr™. By 1996, other crops were introduced, including cotton, canola, potatoes and maize. Research in this area now covers a wide range of GM varieties, from cereals and oilseeds to fruits and vegetables. James (2017) estimates that by 2016, the annual global production of transgenic crops had reached 185 million hectares in 26 countries, grown by an estimated 18 million farmers.

*Summary*

Biotechnology research, and the regulation of it, has been evolving since the early 1970s. In this nearly 50 year period, there has not been a single human health or environmental adverse risk event, proving the efficacy of the regulatory oversight that has been applied. Since biotechnology research began, scientists and regulators have taken a responsible approach, with the scientific community initiating public discourse with early technology developments, and working with regulators to devise appropriate risk assessment and risk management strategies that are revised and adapted as knowledge is gained. Biotechnology research has now occurred at hundreds of universities, research institutions and private firms, the products of which have been regulated by thousands of regulators globally.

More recently, some categories of biotechnology research described above have been relabelled ‘synthetic biology’. In essence, synthetic biology is the current state of the art of biotechnology, as evolved from the original micro-organism research of the early 1970s. However, unlike the 1970s, risk assessment methodologies for biotechnology are well established and there is a tremendous body of knowledge and expertise that is relevant to appropriately regulating new and future innovations and advancements in the field. Deliberating new rules and regulations via an international forum specifically for ‘synthetic biology’ is unnecessarily precautionary and overlooks almost 50 years of carefully and responsibly developed procedures and best practices by those with the appropriate expertise. In an automotive comparison, new rules for synthetic biology would be the equivalent of placing new regulatory hurdles on engineering automotive advancements that resulted in electric automobiles. The electric automobile is simply the engineering evolution of decades of automobile production research and advancement. Regulating biotechnology in a different risk paradigm does not have any foundations in evidence or experience and cannot be justified.

**Global Benefits of GM Crops**

Any time a transformative technology, such as synthetic biology, is assessed for benefits, impacts and risks, perspective is an important component of the assessment process. When the initial regulatory frameworks for GM crops were being discussed and developed, many governments undertook steps to ensure that thorough science-based risk assessments were conducted and then let the market determine whether the product would be commercially successful (Ludlow et al., 2014). By allowing the market to determine the success of the product, rather than regulators, the benefits of GM crops have been significant. To provide some perspective for the regulatory oversight regarding synthetic biology, it is valuable to provide a synthesis of the benefits provided by GM crops over their 20 years of commercial production (Smyth et al., 2014).

While some GM crop varieties have limited production acreage, such as papaya, eggplant, alfalfa and sugar beets, the benefits of GM crops focused on here are on the observed effects of the four dominant GM crops: canola, corn, cotton and soybeans. The benefits from GM crops can be differentiated into three main categories, economic, environmental and health.

*Economic benefits of GM crops*

With the adoption of GM crops rapidly expanding over the first two decades of availability, the benefits from the technology must be significant otherwise farmers would begin to return to previous crop options. One team of authors has annually examined the economic impacts from GM crops and their most recent data is on the 2015 cropping year, where they estimate that the global economic benefits from GM crops exceeded US$15 billion (Brookes and Barfoot, 2017). Cumulatively, over the period from 1996 to 2015, the authors estimate that the economic benefits of GM crops have reached US$168 billion. The production increases from GM crops have a substantial contribution to improving global food security as Brookes and Barfoot estimate that over the 20 year period of GM crop production, an additional 180 million tonnes of soybeans and 357 million tonnes of corn have been produced that would not have resulted without the technology.

Studies on the economic benefits from GM crops first began to appear about the turn of the millennium, with many of these based on the results from experimental field trial data that were then extrapolated to the crop production area, using an estimated adoption curve. These were rudimentary studies that provided an initial sense of what degree of benefits might be observed, particularly in developing countries. By the time the technology had been adopted for a decade, studies reflecting grower experiences began to appear, based on farmer surveys.

Several articles undertook a detailed assessment of the numerous studies that began to regularly appear following the first decade of GM crop adoption. The first of these was conducted by Carpenter (2010), which examined 168 studies on GM crop yields, finding that 124 of the studies reported yield increases, 32 reported no change and only 13 reporting lower yields. Finger et al. (2011) examined 203 peer reviewed studies, concluding that yield increases are evident with GM crop adoption, but noted that these increases were due to reduced insect and weed population pressures and not to actual genomic yield increases. Yield increases from GM crops are an indirect benefit as the genetic modification of the crop is to provide herbicide tolerance or insect resistance, rather than targeted yield increases. Areal et al. (2013) examined 97 studies comparing yield increases between GM and non-GM, finding GM crops outperformed conventional crop in both developed and developing countries. The most recent study was conducted by Klümper and Qaim (2014), who undertook a meta-analysis of 147 studies on the impacts of GM crops, finding that chemical pesticide use decreased by 37%, crop yields increased by 22% and farmer profits increased by 68%.

While these over-arching studies provide an international sense as to distribution of benefits observed from GM crops, it is useful to draw on some specific examples to further illustrate the level of benefits that have been observed. Subramanian and Qaim (2010) examined Bt cotton adoption in India, finding that it raised vulnerable household incomes (those defined as living on less than $2/day) by 134%. Hutchinson et al. (2010) led a study on the economic benefits of GM corn adoption in the USA, finding that GM corn created $6.8 billion in extra value, with 60% going to non-adopters due to lower insect pressures. Based on a farm survey of nearly 600 canola producers, Gusta et al. (2011) found that GM canola resulted in annual benefits of $350 - $400 million in Western Canada. Yorobe and Smale (2012) found GM corn adoption in the Philippines increased household income from $400/year to $600/year, a 50% increase. Vitale et al. (2014) found Bt cotton adoption in Burkina Faso resulted in a profit of $150/ha versus $70/ha for conventional cotton. Alston et al. (2014) estimate the cumulative global benefits from GM soybeans to be $46 billion over the 15 year period from 1996 to 2010.

*Environmental benefits of GM crops*

The first studies that examined the environmental benefits of GM crops were undertaken following the adoption of Bt cotton in China. Pray et al. (2001) surveyed Chinese farmers in 1999, finding that the adoption of Bt cotton allowed farmers to spray insecticides less frequently, in some instances dropping from 30 per season to 3, but more commonly from 12 to 3-4. Huang et al. (2010) update the Chinese Bt cotton story observing that across the entire sample region insecticide applications dropped from 14kg/ha to 4kg/ha. The spillover of environmental benefits from the lengthy adoption of Bt cotton began to be observed as the authors reported finding that in some non-Bt cotton fields the amount of insecticide used dropped from in excess of 40kg/ha to less than 10kg/ha. Similar environmental benefits from the adoption of Bt cotton in India were quantified by Subramanian and Qaim (2010) where they found Bt cotton reduced pesticide use by 41%.

A detailed study of the environmental changes following a decade of GM canola production in Western Canada identified substantial benefits. Prior to the commercialization of GM canola, the chemicals available to be applied to canola for weed control were limited, with the majority requiring soil application. The commercialization of herbicide tolerant varieties of GM canola allowed producers to begin to use foliar chemical applications. The result of this was that the environmental impact of the chemicals applied to canola dropped by 53% when compared to the chemicals that were previously used on canola (Smyth et al., 2011a). When comparing chemical applications between GM canola production and the alternate scenario where GM canola had not been commercialized, the authors found the total volume of chemicals applied to canola dropped by 1.3 million kg per year. The rapid adoption of GM canola provided improved weed control options, which reduced the use of tillage as a form of weed control, resulting in one million tonnes of carbon being either sequestered by the soil or no longer released from implement passes (Smyth et al., 2011b). Brookes and Barfoot (2017a) show CO2 emission reductions equal to removing 11.9 million cars for one year.

Recent research shows the environmental costs of not adopting GM crops. The federal regulator in Australia approved commercial releases of GM canola in 2003. However, in 2004 canola producing States introduced moratoria preventing commercial production of GM canola. It was not until 2008 when the central canola producing states of New South Wales and Victoria lifted the moratoria, followed by Western Australia in 2010. An examination of the environmental costs of the Australian moratoria was undertaken that estimated what the adoption level for GM canola could have been after one decade of production, from 2004-2014, had the moratoria not been implemented (Biden, 2016). The delayed adoption of GM canola production in Australia cumulatively resulted in the application of an additional 6.5 million kg of chemicals. The application of these additional chemicals were done through an additional 7 million field passes, requiring 8.7 million liters of diesel. The environmental impact of the additional chemicals applied was 14% higher than would have been the case if GM canola had been adopted. Finally an estimated 24 million additional kilograms of greenhouse gases were released.

*Health benefits of GM crops*

Some of the most significant benefits from GM crops, yet least widely recognized, are the health and lifestyle benefits. Identified benefits in this area range from a reduction in pesticide poisonings to less time spent hand weeding fields.

One continuous criticism advanced by critics of biotechnology and GM crops is that GM cotton is responsible for thousands of small landholder farmers committing suicide every year. Research on this subject was conducted by Gruère and Sengupta (2011), who in fact documented a one-third reduction in the suicide rate following the release of Bt cotton among Indian farmers, based on extrapolating the pre-Bt cotton commercialization suicide rate. Furthermore, Kouser and Qaim (2014) identify the health benefits from pesticide poisoning reductions following Bt cotton adoption in India. Their research estimated that the number of pesticide poisonings were reduced by between 2.4 million and 9 million cases a year. They estimated that the financial savings for the Indian Ministry of Health ranged between US$14-51 million.

Research from South Africa following the adoption of GM corn documents the first lifestyle benefits of the technology. Gouse (2013) surveyed small landholders finding that GM corn adoption had resulted in 10-12 fewer days of female hand weeding per season. This research identified that the women farmers spent this time predominantly in one of two areas, hauling more water for their vegetable gardens or spending time with their children.

A final aspect of GM crop benefits are the health benefits from reduced pesticide poisoning. Vitale et al. (2014) surveyed Bt cotton farmers in Burkina Faso over the first three years of adoption. Their farm survey results identified that an estimated 30,000 fewer cases of pesticide poisoning per year were occurring among Bt cotton farmers.

*Summary*

When GM crop research for both herbicide tolerance and insect resistance was being undertaken in laboratories and field trials in the late 1980s and early 1990s, no one could accurately predict how remarkable the benefits summarized above would be. The reduction in chemical use, the shift towards the removal of tillage and fewer farmer pesticide poisonings are quantified benefits resulting from the global adoption of GM crops; had these been envisioned in a benefits assessment in the 1970s they would have been grossly underestimated.

Until a technology is commercialized, adopted and evaluated, it is not possible to accurately estimate the full scale and scope of the potential of an innovation. As is established above, over-restrictive GM crop regulations imposed in the early development of this innovative technology would have resulted in a dramatic economic, environmental and health benefit reductions. Brookes and Barfoot (2017a) estimate the global cumulative farm income benefits from GM crop production between 1996 and 2015 to be US$167.7 billion. Notably, this is predominantly attributable to two technologies only that allow for improved weed and insect control options, which indirectly lower biotic stresses and improve yields. For 2015 alone, the farm income benefit has been estimated to have been US$15.5 billion. Developing country farmers received US$5.15 for each extra dollar invested in GM crop seeds. Genetically modified crops have been adopted by an estimated 16.5 million small landholder farmers in developing countries, providing a valuable tool that contributes to reducing household poverty and increasing food security. Based on this evidence, new innovations that allow widespread commercialization of a broader range of traits have great potential to deliver many more economic, environmental and health benefits, including addressing global challenges such as climate change.

**Potential Benefits of GM Plants for Climate Change Mitigation**

Climate scientists are increasingly concerned over rising levels of carbon dioxide (CO2) in the atmosphere and how this in turn impacts global temperatures. While considerable debate has existed over whether these impacts are due to nature or man, the vast majority (97%) of climate change scientists now have come to a consensus that mankind’s activities are predominantly responsible.[[3]](#footnote-3) To ensure that mankind is able to implement policies and legislation that addresses climate change mitigation, all options need to be available to scientists and policy-makers, particularly advances in plant breeding and development technologies, such as ‘synthetic biology’.

Although agriculture is a greenhouse gas (GHG) emitter, it can also offer a unique opportunity for GHG emission reductions through soils ability to sequester carbon. Researchers in France have theorized that agriculture could be used to stop the rise in carbon dioxide in the atmosphere.[[4]](#footnote-4) They believe the top 16 inches of soil could be the solution. If carbon stocks in the top 16 inches of soil could be increased by 4 parts per 1,000 annually, soil could become a carbon sink that mitigates climate change. However, this is based on current deforestation practices ending.

While most life forms on the planet gain little benefit from increased carbon levels, plants are the exception. If soil sequesters carbon at an increased rate of 4 parts per 1,000, this will increase yields by an estimated 1.3% annually. Current biotechnology research is aiming to modify plants to increase their CO2fixation ability, which also helps them to grow larger. A group of German researchers have developed an *in vitro* CO2 fixation pathway that is 20% more efficient than was previously the case (Schwander et al., 2016). Additional research utilizing both C3 plants (e.g. potato, rice, soybean and wheat) and C4 plants (e.g. corn, oil palm and sugarcane) has already successfully developed a new corn variety to increase its absorption of carbon dioxide by 40%, which is currently undergoing risk assessment by regulatory scientists in the United States.[[5]](#footnote-5)

Innovations of this type hold great potential to improve environmental sustainability. There is a benefit to producing more food per acre with the same level of inputs. If this technology is transferrable to forage crops, higher yields per acre could be achieved for livestock feed and biofuels. Fruits and vegetables varieties have an even greater potential from this technology, given present yield levels. Using CO2 to produce more food per acre is one solution to feeding an increasing global population.

Brookes and Barfoot have estimated that the adoption and production of GM crops in the Americas has resulted in 227 billion tonnes of CO2 not being released into the environment in the 20 year period from 1996-2015, with 23.9 million tonnes in 2015 (Brookes and Barfoot, 2017b). The French scientists behind the 4 parts per 1000 indicate that an estimated 4.3 billion tonnes of carbon are added to the atmosphere each year. The Americas adoption of GM crops have proven to provide a positive contribution to the mitigation of climate change and the application of ‘synthetic biology’ techniques can further contribute to CO2 mitigation strategies through increasing CO2 fixation in plants.

Not only could this plant innovation offer the benefit of increased food production but also the reduction of CO2 in the atmosphere, which is a global environmental target. Perhaps in the right plant species, this carbon absorption innovation could be a game changer in adequately helping to feed a growing global population of 9 billion or more by the year 2050 and help to achieve carbon emission reduction targets at the same time. Such an innovation offers a real solution to improving food security and reducing carbon emissions. We have already begun to see the impacts of increased carbon emissions, this plant innovation could offset CO2 emissions and contribute to climate change mitigation.

**Conclusions**

Twenty years after the initial commercialization of GM crops, there are significant economic, environmental and human health benefits. The degree of benefits could not have been accurately predicted as regulatory frameworks for GM crops were being developed. With the decision to implement science-based regulatory frameworks for GM crops established, this provided the necessary regulatory environment to allow these various GM crop benefits to materialize. More stringent and rigid regulatory requirements would have scaled back the level of GM crop benefits that have occurred.

In the early to mid 1990s when the initial regulations for GM crops were being developed, scientists and regulators in both Europe and North America decided to adopt a science-based risk assessment strategy that was based on existing regulatory frameworks. This strategy proved to be more successful in North America than Europe. In Europe, the risk assessment process has become politicized and thus polarized (Smyth and Phillips, 2014), where innovative agricultural technologies are consistently denied approval. Europe has paid a heavy price for its opposition to biotechnology, losing one-quarter of global agriculture research and development investments over the past 20 years (Smyth, 2017). While Europe is a food secure region, it can afford the luxury of not adopting beneficial agricultural innovations like GM crops, however it can ill afford this luxury when it comes to options available to mitigate climate change.

As governments grapple with implementing legislation to curb GHG emissions, all policy and science options will be essential in successfully meeting this challenge. As the evidence above has indicated, science-based regulations for GM crops have allowed for billions in farm income benefits as well as the reduction of millions of cases of farmer pesticide poisoning.

Nearly 50 years of science and regulator knowledge exists about regulating biotechnology. Rejection of this knowledge and experience in the face of regulating synthetic biology would establish a dangerous precedent for future innovations, where the costs of this action could be even more significant than those of delaying synthetic biology development. Science-based regulatory systems allow innovations to proceed to commercialization after proper and thorough risk assessment (Ludlow et al., 2014). To date there is no quantified reason to deviate from this successful development, regulation and commercialization pathway. To establish such a precedent at this point, 45 years after the initial experiments, sends the wrong message to scientists presently engaged in innovative research. This message has the potential of preventing future human health and environmental benefits from being developed, carrying a huge cost for all societies.

**References**

Alston, J. M., N. Kalaitzandonakes and J. Kruse. 2014. The size and distribution from the adoption of biotech soybean varieties. Chapter 45 in S. J. Smyth, P. W. B. Phillips and D. Castle (eds.) Handbook on Agriculture, Biotechnology and Development, 728-751. Cheltenham, UK: Edward Elgar Publishing Ltd.

Areal, F. J., L. Riesgo and E. Rodriguez-Cerezo. 2013. Economic and agronomic impact of commercialized GM crops: A meta analysis. Journal of Agricultural Science 151: 1: 7-33.

Berg, P., D. Baltimore, H. W. Boyer, S. N. Cohen, R. W. Davis, D. S. Hogness, D. Nathans, R. Roblin, J. D. Watson, S. Weissman and N. D. Zinder. 1974. Potential biohazards of recombinant DNA molecules. Proceedings of the National Academy of Sciences of the United States of America 71: 7: 2593-2594.

Berg, P. and M. Singer. 1995. The recombinant DNA controversy: Twenty years later. Proceedings of the National Academy of Sciences 92: 9011-9013.

Biden, S. 2016. Comparing the Adoption of Genetically Modified Canola in Canada and Australia: The Environmental and Economic Opportunity Costs of Delay. University of Saskatchewan Masters’ of Science Thesis.

Brookes, G. and P. Barfoot. 2017a. GM crops: global socio-economic and environmental impacts 1996-2015. Available online at: http://www.pgeconomics.co.uk/page/43/.

Brookes, G. and P. Barfoot. 2017b. Environmental impacts of genetically modified (GM) crop use 1996–2015: Impacts on pesticide use and carbon emissions. GM Crops and Food 8: 2: 117-147.

Carpenter, J. 2010. Peer-reviewed surveys indicate positive impact of commercialized GM crops.

Nature Biotechnology 28: 4: 319-321.

Chang, A. C. Y. and S. N. Cohen. 1974. Genome construction between bacterial species in vitro: Replication and expression of staphylococcus plasmid genes in escherichia coli. Proceedings of the National Academy of Sciences of the United States of America 71: 4: 1030-1034.

Cohen, S. N., A. C. Y. Chang, H. W. Boyer and R. B. Helling. 1973. Construction of biologically functional bacterial plasmids in vitro. Proceedings of the National Academy of Sciences of the United States of America 70: 11: 3240-3244.

Finger, R., N. El Benni, T. Kaphengst, C. Evans, S. Herbert, B. Lehmann, S. Morse and N. Stupak. 2011. A meta analysis on farm-level costs and benefits of GM crops. Sustainability 3: 743-762.

First, N. L. and F. P. Haseltine. 1988. Transgenic animals. Proceedings of the Symposium on Transgenic Technology in Medicine and Agriculture. Boston: Butterworth-Heinemann.

Fraley, R. T., S. G. Rogers and R. B. Horsch. 1983. Use of a chimeric gene to confer antibiotic resistance to plant cells. In Advances in Gene Technology: Molecular Genetics of Plants and Animals, K. Downey, R. W. Voellmy, F. Ahmad and J. Schultz (eds.). New York: Academic Press, pp. 211-221.

Framond, A. J., M. W. Bevan, K. A. Barton, R. Flavell and M. D. Chilton. 1983. Mini-ti plasmid and a chimeric gene construct: New approaches to plant gene vector construction. In Advances in Gene Technology: Molecualr Genetics of Plants and Animals, K. Downey, R. W. Voellmy, F. Ahmad and J. Schultz (eds.). New York: Academic Press, pp. 159-170.

Gordon, J. W., G. A. Scangos, D. J. Plotkin, J. A. Barbosa and F. H. Ruddle. 1980. Genetic transformation of mouse embryos by microinjection of purified DNA. Proceedings of the National Academy of Sciences of the United States of America 77: 12: 7380-7384.

Gouse, M. 2013. An evaluation of the gender differentiated impact of genetically modified crop adoption: A pilot study in South Africa - GM maize and gender: Evidence from smallholder farmers in KwaZulu-Natal, South Africa. Project report to the Program for Biosafety Systems, International Food Policy Research Institute.

Gruère, G. and D. Sengupta. 2011. Bt cotton and farmer suicides in India: An evidence-based assessment. Journal of Development Studies 47: 2: 316-337.

Gusta, M., S. J. Smyth, K. Belcher, P. W. B. Phillips and D. Castle. 2011. Economic benefits of genetically-modified herbicide-tolerant canola for producers. AgBioForum 14: 1: 1-13.

Huang, J., J. Mi, H. Lin, Z. Wang, R. Chen, R. Hu, S. Rozelle and C. Pray. 2010. A decade of Bt cotton in Chinese fields: Assessing the direct effects and indirect externalities of Bt cotton adoption in China. Science China: Life Sciences 53: 8: 981-991.

Hutchison, W. D., E. C. Burkness, P. D. Mitchell, et al. 2010. Area wide suppression of European corn borer with Bt maize reaps savings to non-Bt maize growers. Science 330: 6001: 222-225.

James, C. 2017. Global status of commercialized biotech/GM crops: 2016. ISAAA Brief 52. Available online at: http://www.isaaa.org/resources/publications/briefs/52/download/isaaa-brief-52-2016.pdf.

James, C. and A. F. Krattiger. 1996. Global review of the field testing and commercialization of transgenic plants, 1986-1995: The first decade of crop biotechnology. ISAAA Briefs 1. Ithaca, N.Y: ISAAA.

Klümper, W. and M. Qaim. 2014. A meta-analysis of the impacts of genetically modified crops. PLOS One 9: 11: 1-7.

Kouser, S. and M. Qaim. 2011. Impact of Bt cotton on pesticide poisoning in smallholder agriculture: A panel data analysis. Ecological Economics 70: 2105-2113.

Ludlow, K. S. J. Smyth and J. Falck-Zepeda. 2014. Socio-Economic Considerations in Biotechnology Regulations. New York: Springer Publishers.

Morrow, J. F., S. N. Cohen, A. C. Y. Chang, H. W. Boyer, H. M. Goodman and R. B. Helling. 1974. Replication and transcription of eukaryotic DNA in escherichia coli. Proceedings of the National Academy of Sciences of the United States of America 71: 5: 1743-1747.

Pray, C., D. Ma, J. Huang and F. Qiao. 2001. Impact of Bt cotton in China. World Development 30: 6: 931-948.

Schell, J., M. Van Montagu, M. Holsters, P. Zambryski, H. Joos, D. Inze, L. Herrera-Estrella, A. Depicker, M. De Block, A. Caplan, P. Dhaese, E. Van Haute, J. P. Hernalsteens, H. De Greve, J. Leemans, R. Deblaere, L. Willmitzer, J. Schroder and L. Otten. 1983. Ti plasmids as experimental gene vectors for plants. In Advances in Gene Technology: Molecualr Genetics of Plants and Animals, K. Downey, R. W. Voellmy, F. Ahmad and J. Schultz (eds.). New York: Academic Press, pp. 191-220.

Schwander, T., L. Schada von Borzyskowski, S. Burgener, N. Socorro Cortina and T. J. Erb. 2016. A synthetic pathway for the fixation of carbon dioxide in vitro. Science 354: 6314: 900-904.

Singer, M. F. 1976. Summary of the proposed guidelines. American Society for Microbiology News 42: 5: 277-287.

Smyth, S. J. 2017. Genetically modified crops, regulatory delays and international trade. Food and Energy Security 6: 2: 78-86.

Smyth, S. J. and P. W. B. Phillips. 2014. Risk, regulation and biotechnology: The case of GM crops. GM Crops and Food: Biotechnology in Agriculture and the Food Chain 5: 3: 170-177.

Smyth, S. J., P. W. B. Phillips and D. Castle. 2014. (Eds.) Handbook on Agriculture, Biotechnology and Development. Cheltenham, UK: Edward Elgar Publishing Ltd.

Smyth, S. J., M. Gusta, K. Belcher, P. W. B. Phillips and D. Castle. 2011a. Changes in herbicide use following the adoption of HR canola in Western Canada. Weed Technology 25: 3: 492-500.

Smyth, S. J., M. Gusta, K. Belcher, P. W. B. Phillips and D. Castle. 2011b. Environmental impacts from herbicide tolerant canola production in Western Canada. Agricultural Systems 104: 5: 403-410.

Subramanian, A. and M. Qaim. 2010. The impact of Bt cotton on poor households in rural India. Journal of Development Studies 46: 2: 295-311.

Watson, J. D. and F. H. C. Crick. 1953. A structure for deoxyribose nucleic acid. Nature 171: 4356: 737-738.

Vitale, J., G. Vognan and M. Ouattarra. 2014. Cotton. Chapter 38 in S. J. Smyth, P. W. B. Phillips and D. Castle (eds.) Handbook on Agriculture, Biotechnology and Development, 604-620. Cheltenham, UK: Edward Elgar Publishing Ltd.

Yorobe, J. M., and M. Smale. 2012. Impacts of Bt maize on smallholder income in the Philippines. AgBioForum 15: 2: 152-162.

1. Biotechnology is defined by the CBD as “any technological application that uses biological systems, living organism, or derivatives thereof, to make or modify products or processes for specific use”, CBD, p. 4; and modern biotechnology is defined by the CPB as “the application of: a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b. Fusion of cell beyond the taxonomic family”, CPB p. 4. [↑](#footnote-ref-1)
2. The full title of the Miami Winter Symposia was ‘Advances in Gene Technology: Molecular Genetics of Plants and Animals’. While most of the presentations dealt with plant technology, three presentations on animal biology embryonic developments were also held. [↑](#footnote-ref-2)
3. http://theconsensusproject.com/. [↑](#footnote-ref-3)
4. http://4p1000.org/understand. [↑](#footnote-ref-4)
5. Personal communication with Oliver Peoples, Chief Scientific Officer, Metabolix. [↑](#footnote-ref-5)