Regulating Evolution for Sale: An Evolutionary Biology Model for Regulating the Unnatural Selection of Genetically Modified Organisms

Part 2

by

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Originally published in WAKE FOREST LAW REVIEW
42 WAKE FOREST L. REV. 93 (2007)

Specifically, the NRC report concludes (1) that changes at any level of genetic information can have profound environmental consequences, (2) that the consequence of biological novelty depends strongly on the specific environment into which the organism is released, (3) that the significance of the consequences of the introduction of novelty depends on societal values, (4) that the introduction of any type of biological novelty can have unintended and unpredicted effects on recipient communities and ecosystems, and (5) that it is not possible to quantitatively differentiate the genetic environmental risk associated with the release of conventionally bred crop cultivars and the introduction of new GM species.[223]

Perhaps most significantly, the NRC report in essence rejects the *Coordinated Framework* approach of regulating the characteristics of the product rather the process by which the product is created. Specifically, the NRC concluded that genetic engineering can "introduce specific traits or combination of traits that pose unique risks."[224] Moreover, in evaluating APHIS regulatory program for GMOs, the NRC report concludes that with regard to APHIS petitioning process, it is imperative that once a petition is granted there be further monitoring and oversight.[225] Further, the report identifies the treatment of non-target effects and pesticides resistance as superficial and accordingly recommends that APHIS should increase the rigors of its environmental assessments or completely defer to EPA on these issues.[226] The report strongly recommends improvements in post-commercialization testing and monitoring of transgenic plants.[227] Specifically, two different types of ecological monitoring to assess anticipated or long-term incremental environmental impacts are suggested.[228] The first would include a network of trained observers to detect unusual changes in agricultural and unmanaged ecosystems.[229] The second recommendation is for the establishment of a long-term monitoring program that examines planting patterns and uses a subset of species and abiotic parameters as indicators of long-term shifts in an ecosystem.[230]

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223. *See generally id.*

224. *Id.* at 48.

225. *Id.* at 120. Moreover, the report recommends more opportunities for public participation and enhanced peer review in the petitioning process. *Id.* at 168.

226. *Id.* at 178-79.

227. *Id.* at 192-219.

228. *Id.* at 205.

229. *Id.* at 205-07.

230. *Id.* at 205-13. Moreover, the NRC report notes that the ability of

Although the NRC report is focused primarily on APHIS regulation, EPA's proposal to exempt from FIFRA regulation all pesticidal PIPs, which receive genetic material from a sexually compatible plant regardless of whether the PIP was produced by genetic engineering or conventional breeding,[231] is not consistent with the scientific findings of the NRC report. The report rejects the idea that the ecological risks are higher when a gene is moved between organisms that are not closely related as opposed to movement of the gene between closely related or sexually compatible organisms.[232] EPA's focus on sexual compatibility may have some validity from the standpoint of protecting human beings from dietary risks associated with GM foods. For example, moving a gene between closely related or sexually compatible organisms may ensure the types of substances that human beings are exposed to in their diet does not significantly change. If a gene is moved from one variety of corn to another related variety of corn, the chance of the genetic modification resulting in significant new exposures to humans is relatively low. However, in evaluating ecological risks NRC has found that the same analysis does not hold true, and in fact, the movement of genes between closely related organisms can result in the same type and magnitude of ecological risks as moving genes between unrelated organisms.[233] The primary factor in determining the ecological risks associated with the release of the GMO into the environment is the specific environment into which the GMO is released and how such environment is able to handle the new organism.

The second significant recent scientific analysis is the 2005 EPA SAP consideration of the risks of PIPs based on virus coat protein genes.[234] A meeting was held to enable SAP to consider the scientific issues associated with EPA's proposed exemption of certain PIPs that had been genetically modified to be resistant to viral infection.[235] SAP evaluated a number of potential risks associated with these PIPs, including the risk of out-crossing with wild relatives and the risk of the PIP itself becoming weedy.[236] SAP recommended a set of criteria to evaluate species in order to help

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APHIS to monitor is hampered by the lack of baseline and comparative data on environmental impacts of previous agricultural practices. *Id.* at 201.

231. *See supra* notes 121-25 and accompanying text.

232. NRC REPORT, *supra* note 221, at 36-43.

233. *Id.* at 49.

234. SAP REPORT, *supra* note 45.

235. EPA first proposed exempting certain PIPs that had been genetically engineered to be resistant to viral infection in its 1994 proposed rule. *See supra* note 126.

236. SAP REPORT, *supra* note 45, at 11.

determine the likelihood of such events occurring, and it evaluated biological containment and mitigation methods as a potential means for ensuring that the PIP does not out-cross with wild relatives.[237] The SAP report contains the type of science-based criteria that could form the basis of a new comprehensive approach to regulating certain nontraditional risks from GMOs.[238]

In addition to these recent scientific evaluations, a number of legal scholars have evaluated various aspects of U.S. regulation of GMOs and have concluded that there are significant shortcomings. Many of these scholars have concluded that the United States should abandon its policy of relying on existing legal authorities in favor of a new overriding genetic engineering statute that would eliminate many of the regulatory gaps, overlaps, and inconsistencies that currently exist.[239] However, these scholars have not articulated

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237. *Id.*

238. *See generally* SAP REPORT, *supra* note 45.

239. Legal scholars have also evaluated a number of nonregulatory approaches for addressing GMOs. Some commentators have expressed the view that federal regulation of GMOs is not needed at all. The basis for this argument is the belief that the private sector can adequately police itself and ensure that GMOs that are likely to cause human health or environmental problems are not commercially available. However, as can be seen from recent events such as with StarLink corn, the biotech industry has not demonstrated its ability to adequately screen for or control GMOs. In addition, some scholars have evaluated the effectiveness of a variety of common law remedies for addressing potential harms from GMOs. However, none of these theories appear to be adequate. For example, the basis of the theory of strict liability is that the product has a defect that renders it unreasonably dangerous, thereby creating a duty to warn consumers of the danger. However, in order to warn, a manufacturer of a GMO must be able to predict what potential future problems may be. Also, warning a consumer is not a sufficient guard against harm. Although the consumer may be able to heed a warning, once the GMO is released in to the environment where it can reproduce and spread, a warning to a consumer will have no effect. Similarly, under negligence theory it must be established that the manufacturer or supplier breached its duty to a foreseeable plaintiff by failing to act in a reasonable manner. However, damages for negligence are not an adequate remedy because once the GMOs are reproducing and spreading in the environment, there may be no way to control them. Pursuant to a theory of breach of warranty, plaintiffs need to establish that when the defendant sold the product, the defendant made express or implied warranties and the product did not conform to these warranties. The product does not need to be unreasonably dangerous. Breach of warranty is unlikely to be used with regard to GMOs because due to the inherent unpredictability of GMOs, manufacturers will be reluctant to offer or imply warranties. Finally, common law nuisance law may not be adequate. Once a GMO is released, payment of damages may not be adequate because damages will continue to occur as the organism reproduces and moves through the environment. There may be no way to ever "recall" the GMO as you could with a traditional

a clear overriding regulatory standard or decisionmaking approach that could be incorporated into such a statute and could apply to the regulation of all GMOs.[240]

Perhaps two of the most significant scholars addressing legal responses to the risks of GMOs are Professors Thomas O. McGarity and Gregory N. Mandel. Professor McGarity's article focuses on the human risks associated with the consumption of GM foods.[241] He analyzes the use of "substantial equivalency" in the law and shows how it has proven to be ineffective.[242] Professor Mandel's article, on the other hand, looks at the adequacy of existing laws in addressing the environmental risks of GMOs released into the environment in the context of the 2002 NRC report.[243] Mandel, drawing on the regulatory gaps and shortcomings identified in the NRC report, suggests ways to improve the law to better address risks.[244] While

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chemical product. *See* Kunich, *supra* note 5, at 835-40 (describing the difficulties of containing inherently mobile organisms through traditional regulatory approaches).

240. For example, one legal scholar has proposed an alternative new statute, "Transgenic Release Act" ("TRA"), to be administered by EPA and to be the only federal statute regulating the environmental effects of genetically engineered organisms. Under TRA, there would be an EPA-maintained register of transgenic organisms and a center for transgenic research and testing. TRA would not require pre-release testing or certification. Administrative penalties would be available to cover clean-up costs. *Id.* at 859-69.

241. McGarity, *supra* note 67.

242. A full discussion of the potential human health risks associated with genetically modified foods and FDA's regulation of such risks is beyond the scope of this article. For an excellent discussion of these matters, see *id.* In his article Professor McGarity evaluates FDA's approach to GM foods and focuses on the role that the substantial equivalence doctrine has played in such regulation. Professor McGarity concludes that the substantial equivalence doctrine is not adequate to ensure food safety and instead suggests a more precautionary approach be taken in regulating genetically modified foods. Most significantly, he proposes that prerelease notification should be required to provide FDA with an opportunity to review GM foods prior to commercialization. *Id.* at 476-77. He also proposes requiring additional data collection, data evaluation, risk assessment, and monitoring and enforcement. *Id.* at 481, 485.

243. Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167 (2004).

244. Some of the regulatory gaps that Professor Mandel identifies include: (1) EPA does not yet regulate transgenic animals, such as salmon; (2) EPA has not yet begun to evaluate transgenic plants that produce pharmaceuticals or industrial products, or transgenic plants that are drought tolerant, salinity tolerant, or virus resistant; (3) "APHIS does not conduct environmental assessments of transgenic plants submitted through the notification process;" (4) APHIS's environmental risk assessment has been criticized by NRC for

both of these pieces are important contributions to the legal discourse on regulating GMOs, this Article suggests a broader lens through which reform of GMO regulation can benefit. By using evolutionary biology, this Article builds on the work of previous scholars and demonstrates that the regulation of living organisms must go beyond traditional approaches to regulating human behavior by considering the behavior of the organisms themselves.

VI. EVOLUTIONARY BIOLOGY

In 1982, Professor William H. Rodgers, Jr. called upon his colleagues to bring people back into the legal analysis of environmental law.[245] It is now time for a call to bring biology back into the analysis.[246] The conventional wisdom is that "[l]aw deals in human behavior."[247] While this may be true in the vast majority of

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lacking scientific rigor, balance, and transparency, and for relying too heavily on existing scientific literature rather than requiring the development of new experimental data; (5) once APHIS grants a petition for nonregulated status, it no longer has any authority over the GMO or its progeny; (6) FDA does not require pre-market notification; and (7) APHIS requirements about environmental release prevention do not address release or path of pollen. *Id.* at 2230-34. Professor Mandel argues that many of the existing shortcomings can be attributed to the reliance on statutes that predate the advent of GM technology. *Id.* at 2172. To address these concerns, he proposes that statutory and regulatory structures should be revised to overhaul the division of regulatory responsibility. *Id.* at 2246-51.

245. William H. Rodgers, Jr., *Bringing People Back: Toward a Comprehensive Theory of Taking in Natural Resources Law*, 10 ECOLOGY L.Q. 205, 206 (1982).

246. As a general matter, the relationship between law and science has been an uneasy one. Although science intersects with virtually all areas of law, practitioners of the two disciplines do not seem to relate well. Many areas of law, including medical malpractice, patent law, and environmental law, rely heavily on scientific evidence to prove individual cases; however, it seems that scientific knowledge has not been used as effectively to inform policy choices in these areas of the law. *See* Robert J. Condlin, *"What's Really Going On?" A Study of Lawyer and Scientist Inter-Disciplinary Discourse,* 25 RUTGERS COMPUTER & TECH. L.J. 181 (1999). For additional discussion of the relationship between law and science, particularly in the environmental arena, see SHEILA JASANOFF, SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY IN AMERICA (1995); Susan Haack, *Trial and Error: The Supreme Court's Philosophy of Science*, 95 AM. J. PUB. HEALTH, S66 (2005); Wendy E. Wagner, *The "Bad Science" Fiction: Reclaiming the Debate over the Role of Science in Public Health and Environmental Regulation*, 66 LAW & CONTEMP. PROBS. 63 (2003); Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995).

247. Owen D. Jones, *Evolutionary Analysis in Law: An Introduction and Application to Child Abuse,* 75 N.C. L. REV. 1117, 1241 (1997) ("Every legal regime . . . inescapably reflects some behavioral model purporting to draw

legal contexts, in certain areas law may need to look beyond human behavior and extend its reach to address the behavior of other living organisms. Nowhere is this more true than where the law attempts to address disruptions to ecological systems by living organisms, whether genetically modified or non-indigenous. A regulatory regime that stops at considering human behavior may make sense, for example, in addressing risks from the release of a particular chemical substance into the environment as a result of human behavior. In this context, the social value of the human behavior that results in the release can be considered along with the risks posed by the chemical. Once it is determined that the release of a certain amount of the chemical is acceptable, the only concern is how to restrict the human behavior to achieve that goal. Regulatory restrictions that change or limit the human behavior that ultimately presents the risk can be imposed and the risk will be reduced to the desired level.

With living organisms, however, the law must not limit itself to considering human behavior. By their very nature, living organisms can spread and reproduce in the environment. Moreover, living organisms may be able to out-compete other species or cause disruptions to ecological systems. Simply controlling human behavior, short of outright banning the release of such organisms, will not permit an effective response to many of the potential risks posed by such organisms. Accordingly, when designing a system to address the risks posed by living organisms, the law should not limit its inquiry to considering how human beings handle the living organisms. In other words, with regard to certain GMOs, environmental harms cannot solely be prevented by a legal system that strives only to control human behavior. Instead, the law must look further and ask how the organisms themselves are likely to behave once they are released into the environment. Evolutionary biology theory may be useful not only in predicting the behavior of living organisms, but also in designing regulatory systems to address the risks posed by the organisms.[248] With a reasonable understanding of the organisms' likely behavior, the law can be tailored to address potential risks resulting from such behaviors.

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causal arrows between supposed influences and law-relevant behavior.").

248. One of the few attempts to apply evolutionary biology theory to the regulation of nonhuman living organisms was a 2000 student note applying the theory to biotechnology patent law. Through an evolutionary biology analysis, the author proposed that patents be granted only on those "non-naturally occurring [organisms] whose prospects for continued existence are predicated not upon their selection by nature, but upon their selection by people." Ryan M.T. Iwasaka, Note, *From* Chakrabarty *to Chimeras: The Growing Need for Evolutionary Biology in Patent Law,* 109 YALE L.J. 1505, 1510 (2000).

Ironically, evolutionary biology theory has not been used widely in environmental law.[249] It may seem obvious that if the principles of evolutionary biology and ecology belong anywhere in the legal world it should be in the world of environmental law, but until recently environmental law has been somewhat divorced from such considerations. Environmental law has concerned itself with regulating the behaviors of people and business entities and with minimizing releases of hazardous substances and wastes to the air, water, and land. This approach may work with regard to toxic chemical or pollution control, but with the ever increasing development of new technologies involving living organisms, and the increased risks of environmental harms caused by these new living organisms, it is now evident that even settled environmental law has largely bypassed the mission of protecting natural systems from the novel risks associated with GMOs.

A. *Evolutionary Biology Theory*

Although frequently used in popular parlance to suggest some type of predetermined path from simple to complex, the concept of evolution from a biological standpoint is quite simply the process by which change occurs as traits are passed from one generation to the next. Of course, in the early twenty-first century, virtually every schoolchild is aware that such traits are passed from parent to offspring via the transmission of genetic information contained in the DNA.[250]

In nature, periodic random mutations of DNA result in variation occurring among the members of a species. Some variations are more advantageous to survival than others in a particular environment. Individuals that possess the advantageous traits are more likely to survive and pass their genes on to the next generation.[251] For evolution to occur, three factors must be present: (1) variation (caused by mutations in DNA) in the physical and

249. *See* William H. Rodgers, Jr., *Where Environmental Law and Biology Meet: Of Panda's Thumbs, Statutory Sleepers, and Effective Law,* 65 U. COLO. L. REV. 25 (1993).

250. Long before the discovery of DNA by Watson and Crick in the 1950s, for which they were awarded the 1962 Nobel Prize, scientists understood that traits were passed from one generation to the next without understanding the precise biological mechanism for the transmission of such traits.

251. Of course, simply because an organism is more likely to survive than its peers does not necessarily mean that it will be more likely to pass on its genetic material to its offspring. This depends on that organism's ability to mate and reproduce. The ability to mate and reproduce is the subject of a theory related to the theory of "natural selection," which is referred to as "sexual selection." For a description of sexual selection, see *infra* note 255 and accompanying text.

behavioral traits possessed by individuals within a species; (2) heredity—that is, the ability to pass genetic information, including mutated genetic information, necessary for physical or behavioral traits from parent to offspring; and (3) differential reproduction—the tendency of some inherited traits to survive in the gene pool more than others.[252] Differential reproduction is the result of selective pressures that favor some mutations over others, thereby enabling certain organisms to reproduce and limiting the ability of other organisms to reproduce. Because evolution results from the combined effect of these three factors, only the genetic mutations that are favored under the selective pressures of the environment survive in the long term.

The theory of natural selection, first described by Charles Darwin in 1859,[253] states that individuals that have certain traits that confer an advantage to their survival in a particular environment will be more likely to survive (more "fit" from an evolutionary standpoint) and pass the genetic information that leads to such advantageous traits on to their offspring.[254] Individuals who do not possess such advantageous traits will be less likely to survive and reproduce, and, accordingly, their genetic material is less likely to be passed on to future generations. In this way, over many generations, the traits that are more advantageous become more dominant in the populations.

A related, but very different theory, is that of sexual selection. This theory, rather than focusing on an individual's general ability to survive, focuses on an individual's ability to attract mates, successfully mate, and therefore reproduce.[255] If an individual possesses traits that make him or her more likely to be able to

252. For a more thorough description of evolutionary biology, see Jones, *supra* note 247, at 1129-55.

253. CHARLES DARWIN, ON THE ORIGIN OF SPECIES BY MEANS OF NATURAL SELECTION (Special ed., Gryphon Editions 1987) (1859). Although the phrase "the survival of the fittest" is often cited in association with reference to Charles Darwin, in fact, Darwin never uttered those words. The phrase was coined by Herbert Spencer in 1862. Paul Elliott, *Erasmus Darwin, Herbert Spencer, and the Origins of the Evolutionary Worldview in British Provincial Scientific Culture, 1770-1850*, 94 ISIS 1, 24 (2003). Unfortunately, the term is probably responsible for the general misunderstanding of evolutionary biology that permeates modern culture. Suggesting that some organisms are more "fit" for survival implies that there is some absolute notion of a specific combination of traits conferring the most "fitness." In all likelihood there are unlimited combinations of traits that may confer fitness to a particular environment. Moreover, "fitness" is not static. As environmental pressures change, the traits that will confer fitness also change.

254. *See* DARWIN, *supra* note 253, at 470-71.

255. *Id.* at 87-90.

obtain a suitable mate, that individual's genetic material will more likely be passed on than will that of an individual who does not possess such a trait. In the natural world, traits that make an individual more attractive to potential mates may include traits such as large size, robustness, and health—obvious traits that would increase the odds of survival of offspring who inherit such traits from their parents. What is more fascinating to human observers, however, is the spectacular array of "attractiveness" traits that have evolved in nature, the function of which appears to be solely to lure mates. Such traits include vivid coloration, flashy plumage, and elaborate dances and rituals.[256]

In recent years, evolutionary biology theory has undergone its own evolution. The conventional wisdom that evolutionary processes follow a steady, stable pathway has been rejected in favor of a notion of life on earth "in jittery motion . . . ready to dart off in an instant."[257] In other words, evolution is now believed to occur in fits and spurts rather than in a slow, steady progression. Such evolutionary spurts occur in response to environmental pressure and may be more pronounced in response to environmental pressures that are novel or atypical to a geographic locale, such as the quick onset of a severe drought or flood in an area that typically does not experience such extremes.[258] The new understanding of evolutionary biology suggests significant potential implications in the area of the release of GMOs into the environment. If introducing novel environmental pressure can result in spurts of evolution, perhaps introducing novel organisms into the existing environment could have similar dramatic effects.

B. Law and Biology

One area of legal scholarship that has incorporated evolutionary biology theory is the field of "Law and Biology."[259] The field of Law and Biology, largely developed by Margaret Gruter and her colleagues at the Gruter Institute, has been described as an attempt

256. *Id.* Of course, sexual attractiveness in humans is not without its own set of peculiar traits, such as wealth, expensive cars, fashionable clothing, and fashion magazine-worthy body types.

257. WEINER, *supra* note 34, at 112.

258. This new understanding of evolution in nature is related to the "new ecology," which rejects the balance of nature in favor of a more dynamic view of ecological processes. *See generally* DANIEL B. BOTKIN, DISCORDANT HARMONIES: A NEW ECOLOGY FOR THE TWENTY-FIRST CENTURY (1990); Judy L. Meyer, *The Dance of Nature: New Concepts in Ecology*, 69 CHI.-KENT L. REV. 875 (1994).

259. The movement was called "Law and Biology" to emphasize its relation to the "Law and Economics" movement. E. Donald Elliott, *Law and Biology: The New Synthesis?*, 41 ST. LOUIS U. L.J. 595, 596-97 (1997).

to "use the insights of modern biology, particularly the features about the distribution and proliferation of characteristics within populations, and insights into behavioral factors like the evolution of cooperation, in studying law."[260] Law and Biology theory states that any system that exhibits the three features of reproduction, variation, and selection by the environment will evolve in the direction of greater fitness with the environment. The "environment" for law is the larger community: the political culture and values of the community in which the law takes place.[261] Legal precedent is the "reproduction" of law, both in terms of precedent in the case law and the perpetuation of similar statutory schemes through copying and basing one statute on previous statutes.

With regard to GMOs, the law must evolve to address this newly evolved set of risks. In evolutionary terms, the "selective pressure" that will drive this change is the intense public concern, both in the United States and abroad, regarding the risks of GMOs. The only element missing to complete the trio of evolutionary prerequisites to dramatic legal evolution is the variation, or the mutations. In the law, this can only come into being as a new idea. Just as in biological evolution most new changes turn out to be bad or neutral, for the law to evolve there must be a variety of new ideas from which the selective pressures of public concern can hit on the right one. To date, the vast majority of attempts to regulate GMOs have merely been a proliferation of old models. These old models do not work for GMOs. There is a natural evolution of biology and law. Biological organisms evolve in accordance with principles of evolutionary biology—essentially Darwinian natural selection.

This Article proposes that there is a way to use evolutionary biology theory that has been largely ignored by the legal community: using biological models to design legal systems aimed at environmental protection more effectively by incorporating consideration of the evolutionary impacts of biological organisms—or the raw materials that we are working with in an environmental

260. *Id.* at 599.

261. E. Donald Elliot describes three ways in which biological models and insights have been used in the Law and Biology movement. The first is the use of biological models to describe the dynamics of legal systems—i.e., how law works by analogy to other complex systems. The second is to help develop a natural law basis for law through a better understanding of how and why humans are the way they are, particularly in comparison to other animals and particularly in terms of operation or aggressive behavior in groups. The third is to provide insight into how we can design legal systems more effectively. If we have a better understanding of human nature—of the raw materials that we are working with in a legal system—then perhaps we can design laws to work more effectively. *Id.* at 600-12.

legal system—to more effectively design a system that addresses the novel risks posed by human intervention in these biological processes.

In recent years, a number of legal scholars have begun to look to evolutionary biology theory for insights into human social behavior in the hopes that such insights may provide direction for legal reforms.[262] This area of scholarship is based on the scientific recognition that natural selection affects both genetically determined physical and behavioral traits.[263] Accordingly, evolutionary biology may play a predictive role in evaluating what types of human behavior are likely to occur in given circumstances.[264]

Recently, evolutionary biology theory has been studied as a way to understand human behavior, including socially abhorrent behavior, such as rape[265] and child abuse.[266] Although some scholars,

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262. *See supra* note 259 and *infra* notes 264-68 and accompanying text.

263. In 1975, biologist Edward O. Wilson's book, *Sociobiology*, first introduced the idea that selective forces act on genetic behavioral traits, including in humans, in addition to physical traits. *See* WILSON, SOCIOBIOLOGY, *supra* note 10. From 1975 until the late 1980s and early 1990s, scholars and the public alike expressed extreme discomfort with applying this theory to human behavior. In the ensuing years, scholars have refined the theory and in its current iteration, it is more socially acceptable. *See, e.g.*, Owen D. Jones, *Law and Evolutionary Biology: Obstacles and Opportunities,* 10 J. CONTEMP. HEALTH L. & POL'Y 265 (1994). Scholars are now careful to point out that evolutionary biology theory should not be used to argue that simply because a behavior is evolutionarily adaptive, such behavior must be allowed or encouraged. Instead, scholars now make clear that evolutionary biology theory's major limitation is its lack of incorporation of normative values. Thus, while the theory can help us understand why a certain behavior exists, it cannot tell us whether such behavior should be tolerated or encouraged by society or the law. *Id.* at 272-73. Moreover, the theory should not be used to suggest that human beings have no ability to control their behaviors. *Id.* at 274-75.

264. Jones, *supra* note 263, at 277-80. For example, as Jones described, evolutionary biology might predict that stepparents are more likely to kill stepchildren than are biological parents. Such a prediction could influence child welfare policy. *Id.*

265. *See* Owen D. Jones, *Law and the Biology of Rape: Reflections on Transitions*, 11 HASTINGS WOMEN'S L.J. 151 (opining that because the law's ability to prevent rape is a function of its behavioral model of rape, evolutionary biology theory may be an effective model of the behavior, thereby aiding the law in attempting to deter rape); *see also* Brian Kennan, *Evolutionary Biology and Strict Liability for Rape,* 22 LAW & PSYCHOL. REV. 131 (1998) (proposing a new approach to rape prosecution based on evolutionary biology, which would replace the intent element of rape).

266. *See* Jones, *supra* note 247 (setting forth a comprehensive application of evolutionary biology theory to child abuse).

such as Professors E. Donald Elliott and William H. Rodgers, Jr. have studied evolutionary biology in the context of environmental law, their work, unlike what is being proposed in this Article, uses the theory to predict human behavior and uses such predictions to aid in the design of environmental regulation.[267]

In recent years, scholars have increasingly applied evolutionary biology theory to a variety of "non-biological" entities. Richard Dawkin's concept of the selfish gene led to the idea that entities other than genes may also be able to evolve in accordance with natural selection.[268] Dawkins coined the term "memes" to describe entities other than DNA that may be subject to natural selection.[269] The concept of evolutionary biology applying to non-biological memes has led legal scholars to attempt to apply evolutionary

267. *See, e.g.*, E. Donald Elliott, *The Tragi-Comedy of the Commons: Evolutionary Biology, Economic, and Environmental Law*, 20 VA. ENVTL. L.J. 17 (2001) (explaining that in the past two decades legal scholars have increasingly looked at human nature from an evolutionary biology perspective to explain legal phenomena). In this article, Elliott uses evolutionary biology theory to explain the evolution of environmental law. For example, Elliott analogizes the human-environmental relationship to a host-parasite relationship, wherein it is to the advantage of the parasite to preserve its host and maintain a mutually advantageous relationship. *Id.* at 20-25. Some environmental law scholars have used evolutionary biology theory in a variety of other creative ways. For example, Professor Rodgers has used the theory to analyze the human behavior of deception as it occurred in a particular Atomic Energy Act case. William H. Rodgers, Jr., *Deception, Self-Deception, and Mythology: The Law of Salmon in the Pacific Northwest*, 26 PAC. L.J. 821 (1995); *see also* Rodgers, *supra* note 249. In this article, Professor Rodgers cites various evolutionary quirks as a comparison to the human legal framework. The author notes how certain species' current traits, such as a housecat's tail, which at one point served a useful function, are a poor adaptations for an environment full of closing doors; similarly, certain laws continue to "time-lag" in problematic fashion, and remain on the books despite no longer serving society's needs. *Id.* at 52-53. Rodgers argues for a better understanding of the inevitable influences that evolutionary biology plays in the lawmaking norms of society, as laws, like evolutionary biology, influence both history and human behavior. *Id.* at 56-57. He concludes with a plea for a better understanding by those drafting laws to not assume that "their decrees alone can suffice to bring about . . . [a]ltruistic behavior" and that like evolution, lawmaking can result in both adaptation and maladaptation. *Id.* at 74-75.

268. DAWKINS, *supra* note 11. The idea is that any entity that can copy itself is subject to natural selection, provided that the copies possess sufficient fidelity to the original, that random mutation occasionally occurs, creating variability, and that some of the random mutations confer a selective advantage in the environment. Dawkins posits that whenever these conditions, which he calls "Universal Darwinism," exist in the appropriate proportion, the process of natural selection necessarily will occur. *Id.* at 191-92, 322.

269. *Id.*

biology theory to legal concepts such as copyright law. For example, Professor Thomas F. Cotter has argued that principles of evolutionary biology may help to illuminate important issues of copyright law and policy.[270] He describes how copyright affects the way in which ideas and fragments of expression come into existence, compete, and evolve.[271]

VII. AN EVOLUTIONARY BIOLOGY MODEL FOR REGULATING GMOS

A. *General Considerations*

Although the existing legal approaches to regulating GMOs, as well as the refinements suggested by other scholars, adequately address some of the risks associated with GMOs, to fully address these complex issues a more dramatic and transformative approach is warranted. The law must undergo a more dramatic and ongoing evolution to keep pace with the dramatic changes that genetic engineering has made, and has the potential to make, to the evolution of life. This Article proposes that a completely new legal approach drawing on principles of evolutionary biology is needed to address the risk of novel environmental and economic harms caused by human intervention in and manipulation of evolution. The new approach would go well beyond traditional common law theory or conventional regulatory approaches, both of which focus solely on regulating human behavior and largely ignore the behavior of other organisms.

Regulating human behavior cannot adequately address environmental and economic risks created by human manipulation of evolution. For example, traditional environmental standards may limit the quantity of a substance that can be safely released into the environment. However, the quantity of GMOs produced or released into the environment may be irrelevant to GMOs because they are able to reproduce and proliferate in the environment on their own. Traditional environmental law focuses on imposing limitations on where or how a substance can be used. For example, a regulation may prohibit the use of a substance toxic to aquatic organisms within *X* number of feet of a water body, may limit the time of year a substance may be used to avoid wildlife migration events, or may limit the geographic areas in which a substance may be used to avoid exposure to protected species or sensitive ecosystems. Moreover, under FIFRA in particular, use restrictions are accomplished through language contained in the pesticide product

270. Thomas F. Cotter, *Memes and Copyright*, 80 TUL. L. REV. 331 (2005).
271. *Id.* at 351-54.

label.[272] The assumption embedded in the labeling approach is that the only relevant conduct to be controlled is that of the human user of the pesticide. Reliance on labeling instructions is misplaced when addressing risks posed by living organisms capable of reproducing and moving in the environment. When the behavior of the regulated living organisms themselves is taken into account, the shortcomings of such an approach, and the need for a new approach, become apparent.

The new approach should reject regulation on the basis of the product in favor of regulation based on the process used to create the product. Scientific understanding gleaned since the 1986 *Coordinated Framework*, in conjunction with public concern, has demonstrated that ignoring the process by which the organism is created is fraught with problems. Consistent with proposals of other legal scholars, this Article proposes the adoption of a new federal statute to comprehensively address all human health and environmental risks potentially arising out of the introduction of GMOs into the environment and human food supply.[273]

The most logical existing agency to have primary regulatory authority under the new statute is EPA, which is the federal agency with the most expertise in evaluating environmental and human health risks associated with the release into the environment of potentially harmful substances.[274] Due to the considerable scientific uncertainty surrounding GMOs, any statute should adopt a precautionary approach, requiring pre-market agency review with the burden on the entity seeking authorization to provide reasonable assurance that the requisite human health and environmental criteria have been met. To provide such reasonable assurance, submission of specified data should be required to enable the reviewing agency to make an informed decision based on scientific data as to whether the GMO should be permitted to be released into the environment.[275] The type and amount of data required will vary

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272. *See supra* notes 87-89 and accompanying text.

273. *See* Kunich, *supra* note 5, at 870-72; Mandel, *supra* note 243, at 2242-56; McGarity, *supra* note 67, at 489-509.

274. In addition, EPA already has SAP and BSAC, which have significant expertise in and experience evaluating environmental and human health risks associated with GMOs.

275. The term "reasonable assurances" is used in some of the state environmental permitting statutes. Under such a statute, permit applicants that seek certain authorizations have the burden of providing reasonable assurances that the proposed activity will not have adverse effects on the environment. Under Florida law, for example, reasonable assurances are not synonymous with absolute guarantees. Hoffert v. St. Joe Paper Co., 12 F.A.L.R. 4972, 4987 (Dep't. Envtl. Regulation Dec. 6, 1990). The level of evidence the

with the extent of the release and whether adequate physical or biological containment can be ensured. For example, for limited field testing, data demonstrating adequate containment may obviate the need for the type and level of data necessary for full-scale commercial release. The data requirements should reflect the best scientific understanding of the types of risks identified in this Article—i.e., traditional risks, novel risks, and economic risks.[276]

In evaluating data to determine whether to authorize release, the reviewing agency should, cognizant of the uncertainties of releasing living organisms into the environment and the lack of ability to retrieve such organisms once they have reproduced and spread in the environment, employ a binary approach whereby it is recognized that once released, traditional risk minimization mechanisms like labeling instructions may not be meaningful. Once a decision is made to authorize release into the environment, the reviewing agency should not abandon jurisdiction, as APHIS does with its determination of nonregulated status, but instead should retain regulatory jurisdiction over the GMO and require continued monitoring and submission of adverse effects information as EPA does under 40 C.F.R § 174.71. A new statutory provision should authorize the relevant agency to bring enforcement actions seeking administrative, civil, and criminal penalties, and should authorize the destruction of crops and other GMO products if necessary to prevent unacceptable human health or environmental risks.

This Article sets forth a proposed decisionmaking framework that should be used to guide the reviewing agency's decisions on whether to authorize the release of a GMO. Under the decisionmaking framework, EPA would ask specific questions to evaluate each of the types of risks discussed in this Article. Most significantly, with regard to all risk categories other than traditional risks, the decisionmaking framework questions are based at least in part on an evolutionary biology evaluation of the GMO. In other words, the questions focus on the "mutation" and its effect on the organism (e.g., whether the intentional mutation imparts some selective advantage on the organism), the ability of the organism to

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applicant must provide to demonstrate reasonable assurance is case-specific depending on the nature of the issues involved. *See* Fla. Dept. of Transp. v. J. W. C. Co., Inc., 396 So. 2d 778, 789 (Fla. Dist. Ct. App. 1981). Moreover, the reasonable assurance standard does not require an applicant to perform every known test concerning an issue in order to establish entitlement to a permit. Booker Creek Preserv., Inc. v. Mobil Chem. Co., 481 So. 2d 10, 13 (Fla. Dist. Ct. App. 1985). Rather, reasonable assurance means a "substantial likelihood" that the project will be successfully implemented. Metro. Dade County v. Coscan Fla., Inc., 609 So. 2d 644, 648 (Fla. Dist. Ct. App. 1992).

276. *See supra* Part III.

reproduce and pass this trait on to its progeny (e.g., whether the GMO can reproduce, whether it has a reproductive advantage or disadvantage, whether terminator genes or sterility mechanisms are imparted), and the environmental pressures to be asserted on the GMO (e.g., will the GMO be released into an environment where it will have a selective advantage).[277] Consequently, any new federal statute on GMOs should mandate an analysis that must be conducted prior to the release of a pesticidal GMO into the environment.

B. Looking Before You Leap and the Precautionary Principle

Due to the ability of GMOs to spread and reproduce in the environment, rather than attempting to "regulate" the GMOs, some GMOs simply should not be permitted to be released into the environment. In other areas of environmental law, a binary approach, or an "on-off" approach, to regulating environmental risks may not be appropriate. A binary approach results in a high risk of error, either by over-regulating low environmental risks when the switch is off or under-regulating high environmental risks when the switch is on. These risks are referred to as type 1 and type 2 scientific errors, respectively.

A more appropriate approach to regulating many environmental risks, such as releases of chemicals pollutant into the environment, may be through the use of a "rheostat switch," rather than an on/off switch. Under the rheostat switch approach, the level of regulation is adjusted depending on the level of risk presented. For GMOs however, the rheostat approach may not be appropriate. GMOs are living organisms that can spread and reproduce in the environment. Once a GMO is released into the environment, there is no guarantee that regulators will ever be able to gain control over the organism. Accordingly, if an evolutionary biology advantage has been imposed on a GMO enabling it to provide and reproduce readily in the environment, a binary approach may be more appropriate. Under this approach, the off switch would be employed to prevent the release of such organisms into the environment whenever there are potentially high risks. Such an approach would, by its nature,

277. It should be noted that while none of the existing regulatory programs provide for a comprehensive step-by-step analysis of the various types of GMO risk identified in this Article, the agencies do evaluate many of these risk, albeit in a case-by-case, piecemeal fashion. For an example of the risk analysis that EPA conducts in evaluating PIPs, see EPA, PUBL'N NO. 730-F-05-002, *BACILLUS THURINGIENSIS* CRY3BB1 PROTEIN AND THE GENETIC MATERIAL NECESSARY FOR ITS PRODUCTION (VECTOR ZMIR13L) IN EVENT MON863 CORN (006484) FACT SHEET (2005), http://epa.gov/pesticides/biopesticides/ingredients/factsheets/factsheet_006484.htm (last visited Dec. 29, 2006).

result in more type 1 errors by erring on the side of preventing the release of organisms into the environment unless the risks are well understood and determined to be acceptable. Thus, a binary approach employed in this way would be a precautionary approach and would be similar to the approach asserted by proponents of the precautionary principle.

The precautionary principle evolved in the context of international efforts to protect biodiversity.[278] The premise of the principle is that where risks could be catastrophic or irreversible, we should proceed cautiously. The Precautionary Principle, a principle ratified in a number of international environmental agreements, holds that where risks are potentially irreversible or catastrophic, a lack of full scientific understanding should not stand in the way of efforts to reduce such risks.[279] It is not prudent to rush into potentially risky behavior simply because you do not have 100% scientific certainty that the behavior will not result in the feared harm. Some have described this as the "look before you leap" approach to environmental decisionmaking.[280]

Perhaps the most serious concern with pesticidal GMOs stems from the uncertainty of the risks of GMOs. Nowhere does the Precautionary Principle appear to make more sense than with GMOs, as harms arising from GMOs may truly be irreversible due to GMOs' ability to spread and reproduce once released into the environment.[281] Moreover, although the risk of GMO release

278. Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 143 [hereinafter Convention].

279. *See, e.g.*, Treaty on European Union and Final Act, art. 130r(2), Feb. 7 1992, 31 I.L.M. 247, 285 (adopting the precautionary principle as a governing principle of European Union Law); *see also* Convention, *supra* note 278, at 144. The preamble to the Cartegena Protocol on Biosafety provides that it is "[r]eaffirming the precautionary approach contained in . . . the Rio Declaration on Environment and Development . . . ." Final Draft of Biosafety Protocol Approved at Montreal Meeting on Biological Diversity Convention, 23 Int'l. Envtl. Rep. (BNA) 125 (Jan. 29, 2000). Article 10(6) of the Protocol provides that

> [l]ack of scientific certainty due to insufficient relevant scientific information and [knowledge] regarding the extent of potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import . . . shall not prevent that Party from taking a decision, as appropriate . . . in order to avoid or minimize such potential adverse effects.

Id. at 127.

280. *See* NRC REPORT, *supra* note 221, at 64.

281. For further discussion on the need to apply the Precautionary Principle to GMOs, see John S. Applegate, *The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEGAL STUD. 207 (2001).

creating a new superweed or disrupting the balance of natural ecosystems may be small, the consequences could be disastrous and irreversible.[282] The precise nature and magnitude of the risk is difficult to predict because of the almost infinite variety of potential GMOs, the ability of GMOs to reproduce and spread, the complexity inherent in natural ecosystems, and the dearth of long-term data on the effects of GMOs.[283]

C. Addressing Traditional Risks, Novel Risks, Economic Risks, and Uncertain Risks: A Decisionmaking Framework

For traditional risk considerations that GMOs share with conventional chemical substances, such as toxicity or other harm to humans and non-target organisms, the current approaches to determining type and extent of toxicity or other harm to humans and other non-target organism can be employed. Data requirements similar to those for conventional pesticides under FIFRA could be utilized to determine toxicity. However, due to the ability of GMOs to spread in the environment, exposure assessments will have to be tailored to the GMO's biology. If a crop plant is genetically engineered to produce a substance that is not toxic or allergenic when ingested by humans, but is allergenic when inhaled, the reviewing agency will have to consider inhalation routes of exposure. For example, if the GM plant produces the allergenic substance in its pollen, EPA will have to consider likely exposure of humans to such pollen through inhalation. In addition, if the GM plant is able to out-cross with wild relatives which will produce pollen containing the allergen, even greater exposure could occur.

In evaluating whether a GMO passes the first step in the framework related to traditional risk, the threshold question should be whether the applicant has provided reasonable assurances that the GMO is "safe" for humans. The statute should adopt the human safety standard of FFDCA. As to fish and wildlife, a similar safety standard could also apply, but with an "out" for GMOs that provide overriding benefits to public health. For example, a GMO that provides an overriding medical benefit may be allowed even if it is not completely safe for some fish and wildlife.[284]

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282. *See* Kunich, *supra* note 5, at 819.

283. *See* Celeste Marie Steen, *FIFRA's Preemption of Common Law Tort Actions Involving Genetically Engineered Pesticides*, 38 ARIZ. L. REV. 763, 764 (1996).

284. This approach is analogous to, but more protective than, the approach taken in FIFRA, under which the standard for registering a pesticide is based on a cost-benefit analysis, except in the case of public health pesticides, in which the risks of the pesticide are weighed against the health risks, such as the diseases transmitted by the vector to be controlled by the pesticide. *See* 7

To obtain authorization to release the GMO into the environment, the applicant must provide reasonable assurances that the release will not pose adverse novel risks (e.g., an ability to out-cross to wild relatives and potentially cause superweeds). EPA should evaluate the probability that the GMO will be able to out-cross to wild relatives and whether the wild relatives will be given a selective advantage from the genetic modification. This involves a consideration of a number of factors, including whether sexually compatible relatives[285] of the GMO exist in the area in which it is to be released,[286] the ability of the GMO to form viable hybrids with wild or weedy relatives, whether the genetic modification imparts traits that increases the fitness of the wild plant, and whether GMO out-crossed wild plants will be likely to out-compete other plants in the environment, thereby becoming weedy or invasive. For example, if a plant is genetically engineered to be resistant to a certain viral infection that normally kills a large percentage of a sexually compatible weed's seedlings, significantly larger numbers of its seedlings may flourish when the weed gains the ability to resist the viral infection, thereby creating a superweed that can out-compete other plants and whose population is no longer held in check by the virus. If, on the other hand, the weed seedling population is not ecologically limited by the virus, but instead is ecologically limited by some other factor (such as the safe sites for germination), the weed may not have a selective advantage imparted from its viral resistance.[287]

Similarly, to obtain authorization for release, the applicant should be required to provide reasonable assurances that the release of the GMO will not cause adverse risks from the GMO itself becoming more evolutionarily fit—i.e., the risks associated with the GMO itself gaining a selective advantage that is akin to the selective advantage held by invasive non-indigenous species. For this type of risk, however, the presence or absence of wild relatives is irrelevant. The risk assessment instead will focus on whether the

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U.S.C. § 136(bb) (2000) (defining the term "unreasonable adverse effects on the environment").

285. Some examples of crop plants with sexually compatible wild relatives in the United States are barley, plants in the plum family, and watermelons. *See* SAP REPORT, *supra* note 45, at 16.

286. SAP seems to believe that the relevant geographic area is the continental United States. *See id.* at 18. But unless physical barriers exist to prevent the spread to Canada and Mexico, the appropriate consideration may be entire continent. Moreover, as can be seen from the StarLink debacle, once a GMO is commercialized, it may be virtually impossible to prevent it from entering other countries or continents, whether intentionally or inadvertently.

287. *Id.* at 21.

GMO, by virtue of the genetic engineering and/or its introduction into a new environment, has become more "fit." For example, a crop plant that has been bred to rely on the application of chemical insecticides to limit insect pest damage may not be able to survive on its own outside of cultivation with such chemical intervention. If, however, the crop is genetically engineered to make it resistant to the insect pest, it may be able to flourish on its own. Thus, EPA would have to consider the likelihood that the crop itself could become invasive due to the selective advantage imparted on it and the likelihood that the GMO will be fit to compete in nature if it escapes cultivation.

To obtain authorization to release the GMO into the environment, the applicant must provide reasonable assurances that the release will not cause adverse economic risks. The economic risks posed by GMOs include the loss of ability to sell a product as organic due to contamination with GMOs, the economic costs of testing organic crops to determine whether such contamination has taken place, and the risk of a GMO causing a pest species to develop resistance to a particular biological pesticide. The economic risks to organic farmers share many of the same considerations as novel risks—i.e., the ability of the GMO to out-cross. In the case of economic risk, however, the concern is not with out-crossing to wild relatives, but out-crossing to organically grown crops. For example, if pollen from GM corn fertilizes nearby organic corn crops, the organic grower will not be able to sell her product as organic. Moreover, with regard to this type of economic cost, the concern is not with out-crossing to a species that will be more fit in the environment. Any contamination of organic crops, whether resulting in viable progeny or not, may be sufficient to cause economic harms. Accordingly, careful evaluation of the GMO must be done to ensure it does not have the ability to genetically contaminate other crops.

With regard to the development of resistance to economically important biological pesticides due to transgenic plants, the risk considerations are somewhat different. Here, the concern is not with the selective advantage imparted to the transgenic plant, but rather with the evolution of the pest species that feeds on, or is otherwise exposed to, the transgenic plant. To protect against such an outcome, EPA typically requires applications for registration to develop and implement an insect resistance management ("IRM") plan.[288] These plans typically rely on the planting of refuges

288. For examples of EPA's guidance for IRM plans for PIPs, see EPA, *BT* COTTON REFUGE REQUIREMENTS FOR THE 2001 GROWING SEASON (2001), http://www.epa.gov/pesticides/biopesticides/pips/bt_cotton_refuge_2001.htm

surrounding transgenic crops that provide a location and food source for insects that do not expose the insects to the transgenic plant, and therefore, the pesticide, thereby allowing non-resistant insects to survive and reproduce. To date, EPA's practice has been to approve interim IRM plans or allow time for registrants to develop better data and long-term IRM plans.[289] Nevertheless, even with the best IRM plan, if a GMO is able to reproduce and spread in the environment to the extent that it is no longer contained in controlled crop fields that implement IRM, such plans are meaningless. Accordingly, applicants seeking approval for GMOs that produce existing pesticidal substances should be required to conduct an ex ante analysis of the likelihood of the development or acceleration of resistance based on the biology of the relevant pest species and the likely quantity and distribution of the pesticide in the environment.

If the manufacturer cannot provide reasonable assurances that any particular non-traditional risk (novel or economic) will not occur, in order to obtain authorization to release the organism, the manufacturer would have to demonstrate that it could genetically manipulate the GMO not only to have the desired pesticidal trait but also to prevent the nontraditional risk from occurring. In other words, any evolutionary selective advantage that had been imparted as a result of genetic engineering must be eliminated. This could be achieved in a number of ways. For example, to prevent out-crossing with a weedy relative or genetically contaminating other crops, the GMO can be "biologically contained" by genetically engineering it to have pollen of a shape or size that is physically incapable of cross-pollinating other plants. To prevent the GMO from spreading through reproduction, the plant could be engineered to contain a "terminator" gene, which turns off the genetic modification after one generation, or the GMO could be manipulated so that it is sterile and can exist only for one generation. In addition, to address concerns with the development of pest resistance, the manufacturer of the GMO could develop resistance management plans that require refugia to be established to enable "non-resistant" pests to flourish. To address concerns with a lack of control over a GMO once it is out in the environment, the GMO could be genetically engineered to make it susceptible to a specific herbicide, so that some level of control could be established were a problem to occur. Just as there are any number of ways to genetically engineer organisms to make them more evolutionarily "fit" for certain

(last visited Dec. 8, 2006); EPA, *BT* PLANT-INCORPORATED PROTECTANTS (2001), http://www.epa.gov/pesticides/biopesticides/pips/bt_brad2/4-irm.pdf (last visited Dec. 8, 2006) [hereinafter PLANT-INCORPORATED PROTECTANTS].

289. *See* PLANT-INCORPORATED PROTECTANTS, *supra* note 288, at IID53-54.

financial and societal purposes, there is no limit to ways to genetically engineer organisms to make them less evolutionarily "fit" to prevent human health, environmental, and economic harms. Finally, it should be noted that although this Article proposes a decisionmaking framework that ideally would be adopted in a new federal statue designed to address all types of GMOs, until Congress adopts such a comprehensive statute, the proposed framework could be incorporated into the regulatory processes of EPA, FDA, and USDA. However, such a change would most likely require amendments to the agencies' organic statutes to incorporate the regulatory standards proposed in this Article.

VIII. CONCLUSION

Genetic engineering has accelerated and dramatically changed the course of evolution to not only have potential economic and societal benefits, but also to create completely novel and unpredictable risks. Novel approaches that rely on principles of evolutionary biology are needed to address these novel risks. In the past, the United States has relied upon the existing patchwork of statutes and regulations spread among several regulatory agencies to regulate GMOs. Not only has this approach resulted in regulatory inconsistencies and interagency turf battles, but also it is inherently skewed in that it does not take into consideration the different types and degree of risk posed by GMOs. Evolutionary biology theory can provide a framework for a new comprehensive regulatory program to address the entire range of risks posed by GMOs. The approach proposed in this Article addresses the full array of risks and sets forth a clear regulatory standard and decisionmaking framework to guide regulators in determining whether or under what conditions to allow GMOs to be released into the environment. Such an approach is necessary to ensure that the potential risks of GMOs are adequately considered prior to allowing the spread of such organisms in the environment. Now that humans have added the Wright Brothers to the equation of biological evolution through genetic engineering, it is time to put the Wright Brothers into the equation of legal evolution.