Biotechnology Industry Organization

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
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Submitted Electronically via Federal eRulemaking Portal (http://www.regulations.gov)

Re: Food and Drug Administration Docket No. FDA-2015-N-3403; Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology.

Dear Sir or Madam:

The Biotechnology Industry Organization (BIO) is pleased to submit these comments in response to the Notice of a Request for Information, published by the National Science and Technology Council, Science and Technology Policy Office[1]. BIO is the world's largest biotechnology trade association, representing more than 950 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. Our members are involved in the research and development of healthcare, agricultural, food, industrial and environmental biotechnology products, and BIO represents the majority of the biotechnology product developers in North America. Accordingly, BIO is especially interested in the Administration's efforts to

- clarify the roles and responsibilities described in the *Coordinated Framework for the Regulation of Biotechnology Products*[2]; and
- develop a long-term strategy for the regulation of biotechnology products.

BIO supports the objectives of this initiative, as articulated in the 2 July 2015 memorandum from the Executive Office of the President (EOP)[3], i.e., to

- ensure public confidence in the regulatory system, and
- prevent unnecessary barriers to innovation, while continuing to protect health and the environment.

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[1] 80 FR 60414 October 6, 2015.
[2] 51 FR 23302, June 26, 1986. http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf
[3] Executive Office of the President. *Modernizing the Regulatory System for Biotechnology Products.* July 2, 2015. https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf

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BIO agrees that the time is right for a review of the Coordinated Framework. The agencies now have 30 years of experience reviewing information and data submitted for field trials and commercial approvals, conducting risk assessments, reviewing independent safety studies published in peer-reviewed journals, and evaluating the performance of products that were commercialized. Their diligence has made it possible for BIO members to develop products that have improved the productivity of plant and animal agriculture while decreasing their environmental impacts, enhanced food safety and quality, increased the use of renewable resources and decreased manufacturing costs and energy use. The availability of biotechnology-derived products has not only afforded consumers opportunities to weigh their benefits, it has also allowed regulators and developers to confirm their safety to human health, animal health and the environment. Finally advances in science and technology have provided insights into molecular biology and genetics that have led to a much greater understanding of the genomes of all organisms. That understanding is an essential lens through which the products of genetic engineering should be viewed.

BIO members greatly appreciate this Administration's efforts to "encourage regulatory approaches that protect health and the environment while reducing regulatory burdens and avoiding unjustifiably inhibiting innovation, stigmatizing new technologies or creating trade barriers," and our members are encouraged to hear that the Administration will apply these same principles to this review of the regulatory framework and systems that regulate the products of biotechnology[4].

Regulatory Principles and the Coordinated Framework

In a series of Executive Orders (EO) and memos, most notably EO 13563, EO 13610 and the memo on regulating emerging technologies[5], the White House has clearly described the importance of appropriate regulation to economic growth and innovation. These EOs and memos reaffirmed the principles that must guide development and implementation of a proportionate regulatory system that balances protection of human health and the environment with job creation, innovation and economic competitiveness. These principles, which were articulated in the 1993 Executive Order 12866[6], are not unique to

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[4] *Ibid.*

[5] EO 13563 (January 18, 2011) *Improving Regulation and Regulatory Review* http://www.whitehouse.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review; EO 13610 (May 10, 2012) *Identifying and Reducing Regulatory Burdens* http://www.whitehouse.gov/the-press-office/2012/05/10/executive-order-identifying-and-reducing-regulatory-burdens; Memorandum (March 11, 2011) *Principles for Regulation and Oversight of Emerging Technologies* http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight-of-Emerging-Technologies-new.pdf

[6] EO 12866 (Sept 1993) *Regulatory Planning and Review*. http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf;

the U.S. government's view of appropriate regulation. They are described in a series of OECD documents on regulatory reform[7] and include the following:

- Regulate only if there is a significant problem that must be addressed, and government action is the best method for addressing the problem.
- Determine if regulation is the best form of government action for addressing the problem and, if so, choose the most appropriate level(s) of regulation.
- If regulations are imposed, then the degree of regulation should be commensurate with the degree of risk.
- The benefits of addressing a problem though government regulation should outweigh the costs of such regulation.
- Regulate similar products in similar ways.
- Minimize adverse impact on a fair, competitive and innovative market economy.
- Base regulatory decisions, including the decision to regulate, on the best scientific and technical information.
- Ensure predictability and timeliness in regulatory decision-making.
- Provide ample opportunity for stakeholder involvement and public participation.
- Avoid development of regulations that are inconsistent, incompatible or duplicative of other Federal agencies.
- Tailor regulations to impose the least burden on society, consistent with obtaining the regulatory objectives.
- Select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety) and other advantages.
- Ensure transparent regulatory development and implementation, making regulations and regulatory impact analyses easily accessible to all.
- Review regulations on a regular basis to ensure they still serve regulatory objectives in the least burdensome way.

The Coordinated Framework is grounded in these principles. Key attributes of the Coordinated Framework derive from the recognition that our long history of using living organisms and the products they provide is inextricably linked to genetically improving them through mutation and/or cross-breeding, followed by selection of improved genotypes[8]. Recognizing that most new genetically engineered organisms will resemble those that are modified through traditional methods, the Coordinated Framework relies on the existing statutes that govern those organisms and their products to regulate biotechnology. Thus, it avoids the creation of a duplicative regulatory system while regulating similar products in similar ways.

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[7] OECD (1995) *Recommendation for Improving the Quality of Government Regulation.* Paris. OECD (1997) *The OECD Report on Regulatory Reform: Synthesis,* Paris.

[8] See text in Coordinated Framework (1986) at pages 23302-23303.

This initial premise underlying the structure of the Coordinated Framework - that products developed using new genetic engineering tools would be regulated based on their intended use (e.g., a food, a pesticide), using existing health and safety laws - remains valid today. There is no need for separate legislation focused on the specific process or tools that are used to produce the product.

In addition, the Coordinated Framework recognizes that the risks posed by genetically engineered organisms are similar, in kind and degree, to those with similar traits that were developed using traditional techniques. Therefore, in keeping with the first principle above, the Coordinated Framework acknowledges that many genetically engineered organisms will require no regulatory oversight prior to use. Instead, the agencies are directed to "regulate genetically engineered products no differently than those achieved through traditional techniques."

The 1992 "Federal Oversight" document[9] not only reaffirms the regulatory principles listed above, it also provides very clear statements on how biotechnology products should be regulated. For example, it calls for the following:

- "a risk-based, scientifically sound approach" that is "focused on the characteristic of the product and not on the process by which it was produced"
- "..to ensure limited resources are applied where they will accomplish the greatest ... protection, -oversight will be exercised only where the risk …is unreasonable, i.e., when the value of risk reduction by greater oversight is greater than the cost imposed"
- "the extent and type of oversight will be thus commensurate with the gravity and type of risk being addressed, the costs of alternative oversight options, and the effect of additional oversight on existing safety incentives"
- "these principles confirm the limited extent of current oversight of low-risk activities such as the traditional breeding of farm animals and plants"

The guiding principles articulated in the Coordinated Framework and Federal Oversight policy documents are as valid today as they were decades ago when they were set forth as the approach the U.S. government would apply to regulating biotechnology products. However, implementation of these policies has not always adhered to the guiding principles.

Implementation of the Coordinated Framework and Federal Oversight Policies

Over the years, the three agencies with primary responsibilities for regulating biotechnology products have all drifted away from the guiding principles described above; however the degree to which they deviate from the principles varies with the agency.

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[9] 57 FR 6753, February 27, 1992. Exercise of Federal Oversight within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment

Even though the Coordinated Framework acknowledged that many genetically engineered organisms would not pose a risk and, therefore, would not need to be subjected to pre-market regulation, the agencies elected to assert some form of pre-market regulatory oversight over almost all genetically engineered organisms[10]. Although a range of post-market oversight tools was available to the agencies, by focusing on pre-market stages of product development, they opted for a path that opened the door to ever-increasing regulatory requirements: regulatory review of each product before it could enter the marketplace. For genetically engineered plants, this translated into an event-by-event review. However, in this regard, the U.S. approach is consistent with the rest of the world, as no country has a purely "product-based" approach to biotechnology product regulation. In its review of the Coordinated Framework, we encourage OSTP to study the analysis published by the Advisory Committee on Releases to the Environment in the UK. In three reports they establish a convincing case that the process-based regulation is "not fit for purpose" for organisms genetically modified by any technique[11].

In deciding that almost all genetically engineered organisms would be subject to an extensive pre-market regulatory review, the agencies did not strictly adhere to the principle of "a risk-based, scientifically sound approach" with respect to the products captured by the regulatory system. However, having a regulatory trigger that is not science- or risk-based does not automatically lead to an overly burdensome regulatory system. Irrespective of the breadth of the regulatory trigger, agencies can use science and potential risk as gauges to vary the type of oversight, provide exemptions, or increase or decrease data requirements. The true cost of having a regulatory system that is not risk-based or science-based is exacted in HOW the products are regulated after the trigger has been tripped.

The implementation of the Coordinated Framework has led to significant opportunity costs. For a regulatory system to facilitate the development of safe and beneficial products, it must be rooted in the principle of proportionality: the degree of regulation should be commensurate with the degree of risk. With respect to biotechnology products, the 1992 Federal Oversight policy clearly articulated the fundamental importance of proportionality to an efficient regulatory system: "to ensure resources are applied where they will accomplish the greatest protection, oversight will be exercised

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[10] With respect to genetically engineered plants, this applies less to FDA than the other two agencies. FDA has attempted to keep its oversight of food crops product-based by instituting a pre-market voluntary consultation process, and developers have consistently availed themselves of the opportunity to ensure all issues are resolved prior to commercialization. To date, FDA has not *required* developers of genetically engineered (GE) food crops to seek pre-market regulatory approvals, but has opted to rely on its post market authorities, if needed. Therefore, FDA's oversight of GE plants comes closest to abiding by the first principle: determine if there is a need to regulate. FDA regulation of GE animals, however, has followed a different course.

[11] U.K. Advisory Committee on Releases to the Environment (2103). Report 1: *Towards an evidence-based regulatory system for GMOs*; Report 2: *Why a modern understanding of genomes demonstrates the need for a new regulatory system for GMOs*; Report 3: *Towards a more effective approach to environmental risk assessment under current GMO legislation.*

only when risk is unreasonable, i.e., when the value of risk reduction by greater oversight is greater than the cost imposed."

Unfortunately, these principles have not guided biotechnology product regulation, even though, over time, our knowledge about the genetically engineered products has increased as experience has accrued. This is seen most clearly in USDA's and EPA's regulation of genetically engineered crops today. Many scientific bodies[12] in the 1980's predicted the risks of these crops would be the same as conventional crops that were developed using other genetic improvement tools. In addition, a decade of laboratory experience with genetic engineering had shown the technology itself did not pose risks. Nonetheless, in developing their approach to regulation in the late 1980's and early 90's, USDA and EPA claimed that uncertainty about risks necessitated a cautious approach. They had planned to model the development of ag biotech regulation on NIH's approach to regulating laboratory research on genetically engineered organisms. As experience and scientific understanding grew and low risk was substantiated, the precautionary NIH Guidelines were gradually relaxed until all lab work with genetically engineered organisms could proceed without specific guidelines[13].

The USDA and EPA should have followed NIH's lead. As data on the safety of these products has accumulated and uncertainty about potential risks has decreased, little has been done to reorient the agencies' initial precautionary approaches. Both agencies made a number of attempts to align regulatory oversight with risks, but stopped short: EPA never finalized proposals to exempt both cisgenics and PIPs that did not directly affect the pest; APHIS developed an extension process for petitions but stopped short of exempting crop/trait combinations for which dozens of risk assessments have shown no harm. In an era of diminishing budgets, perpetuating a regulatory system that continues to capture products proven to be safe is especially difficult to justify.

Regulation systems must keep pace with evolving science and technology. Molecular evidence has shown that genetic engineering is less disruptive to plant genomes than conventional breeding; impacts related to the site of insertion are infrequent and manageable; and concerns about interactions between the inserted gene and genetic

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[12] For example: OECD (1985) *Recombinant DNA Safety Considerations*; NAS (1987*). Introduction of DNA-Engineered Organisms into the Environment: Key Issues*; NRC (1989) *Field Testing Genetically Modified Organisms: Framework for Decision-making*.

[13] Miller and Conko (2004). *The Frankenfood Myth.* Praeger Publishing Co. Westport CT.

background are insignificant.[14] In addition, genetically engineered crops have a 25-year history of safe use, and many independent studies[15] have documented their safety. In spite of this molecular evidence and real world experience that supports the safety of these crops and validates the approach articulated in the two policy documents that define the U.S regulatory approach, the regulatory data requirements have continually increased over time.

Large seed companies that are BIO members have been able to meet the ever-increasing data requirements, albeit at significant cost, and, at times, delay of new biotech crop varieties reaching the grower. The existing regulatory framework has worked reasonably well for the products they have developed, which have resulted in significant economic benefits for growers of certain crops and environmental and food safety benefits for all of us[16]. However, it has restricted their product development choices to those crops through which they can recoup the high regulatory costs.

On the other hand, BIO members that are small companies or academic institutions have struggled. The stifling effect of the regulatory system on small ag biotech companies and public sector scientists was verified in the PCAST report to President Obama on agricultural innovation in the U.S.[17] This, in turn, has led to a paucity in the types of crops that have been improved with genetic engineering[18]. As a result, the U.S. regulatory system has effectively nullified the most unique asset of genetic engineering: its flexibility. A valuable gene found in any organism can be inserted into any crop. Therefore, even though most R&D expenditures are directed to high value crops, useful traits/genes discovered and tested for those crops could benefit small acreage crops, as well.

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[14] For example, Weber, N. et.al. (2012) Crop genome plasticity and its relevance to food and feed safety of genetically engineered breeding stacks. Plant Physiology. 160:1842-1853. Federoff, N.editor. (2013) *Plant Transposons and Genome Dynamics in Evolution*. John Wiley and Sons. Schnell, J.M., et.al. (2015) A comparative analysis of insertional effects in genetically engineered plants; consdierations for pre-market assessments. Transgenic Res. 24:1-17. Bradford et al (*Nature Biotechnology*, 2005, Vol. 23, pp 439-444): "The genetic engineering process itself presents little potential for unexpected consequences that would not be identified or eliminated in the variety development process before commercialization."

[15] For example: Mendelsohn, M., J. Kough, Z. Vaituzis and K. Matthews. 2003. *Nature Biotechnology* 21:1003-109; Snell, C., et.al. 2011. *Food and Chemical Toxicology*. Doi:10.1016/j.fct.2011.11.048

[16] Environmental benefits include reducing chemical usage while providing effective, targeted pest control that spares beneficial insects. Brookes and Barfoot. 2015. Global income and production impacts of using GM crop technology 1996-2013. www.pgeconomics .co.uk; Carpenter, J. 2011. Impacts of GM crops on biodiversity. GM Crops 2:1, 1-17; January/February/March 2011; Hutchison, et.al. 2010. Areawide suppression of European corn borer with Bt maize reaps savings to non-Bt growers. Science.330: 222; Munkold, et.al. (1997) Reduced fusarium ear rot in genetically engineered corn. Phytopathology 87:1071 – 1077; Klumper, W. and M. Qaim (2014) . A meta-analysis of the impacts of genetically modified crops. Plos One 9, e111629; Van Eenennaam, A.L. (2014) Prevalence and impacts of genetically engineered feedstuffs on livestock populations. J. Animal Sci. 92:4255-78

[17] President's Council of Advisors on Science and Technology. December 2012. *Report to the President on Agricultural Preparedness and the Agricultural Research Enterprise* https://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast_agriculture_20121207.pdf

[18] Miller, JK and KJ Bradford (2010) The regulatory bottleneck for biotech specialty crops. Nature Biotechnology 10: 1012-1014; Graff, et.al., (2009). The contraction of agbiotech product quality innovation. Nature Biotech. 27: 702-704; Redenbaugh and McHughen (2004) Regulatory challenges reduce opportunities for horticultural biotechnology. Calif. Agriculture 58: 106 – 115.

Regulation of Technological Innovation

Without technological innovation it is difficult to imagine how we will succeed in addressing the global challenges of increasing agricultural productivity sustainably, providing more and cleaner energy, and creating renewable consumer products for more people in the face of diminishing and degraded resources and a changing climate. Technologies that are an outgrowth of our deep understanding of biology at the molecular level have the potential to help meet the needs of a growing and increasingly affluent human population. In addition, the application of biotechnology to agriculture, food processing, energy production and industrial manufacturing has demonstrated in a wide range of concrete instances that technological innovation and environmental protection are mutually reinforcing activities and goals.

Nor can the U.S. improve the economic status of its citizens and deter the erosion of our global competitiveness without innovation. New technologies lead to innovations that drive sustainable economic growth by creating new products and processes; stimulating the creation of new companies and even new industries; improving existing products and processes; and lowering manufacturing costs. In the future, as in the past, countries that are supportive of technological innovation will thrive in the global economy.

However, as this Administration clearly realizes, our ability to rise to the epic environmental and economic challenges before us is hindered by regulations that constrain our ability to innovate and adapt to change. Rigid and outdated regulations retard the developmental pace and diffusion of innovation and inhibit long-term economic growth. Failure to regulate new technologies wisely can disadvantage entire economic sectors and stifle U.S. competitiveness.

BIO believes that U.S. regulation of biotechnology-driven innovation is at a critical juncture that is captured perfectly by this quote from EO 12866:

> " The American people deserve a regulatory system that works for them, not against them; a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today. "
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> *President William J. Clinton, September 30 1993*

The Five Questions

With respect to the specific questions posed by the Request for Information, BIO members have provided the following input.

1. *What additional clarification could be provided regarding which biotechnology product areas are within the statutory authority and responsibility of each agency?*

   Agencies should publish clear guidance on what is and is not subject to their respective pre-market oversight, including clear identification of the specific risks the agencies are responsible for evaluating under their jurisdictions. To address areas of ambiguity and/or overlap in statutory authorities, agencies should:

   - implement transparent, efficient mechanisms for reaching timely conclusions about the specific products within their statutory authorities, and
   - communicate their conclusions to developers as early as possible in the product development process.

   For example, with respect to genetically engineered plants, USDA has a process that developers can use to determine the regulatory status of individual plants. However, in some cases, the process has taken years before USDA has published the request for a determination and their conclusion. Nonetheless, developing similar mechanisms that provide timely, predictable, and transparent conclusions regarding agency oversight of all genetically engineered organisms is strongly encouraged.

   Further, in order to avoid duplication, an individual agency's interpretation of its statutory authority should be fully consistent with other agency determinations of scope. Finally, to provide clarity to developers and the public, an agency's interpretation of its oversight should align with the existing published policies and guidance documents that describe that agency's regulatory scope.

   For products that are not within the scope of agency authority, agencies should be more transparent about these products being outside their authorities because they *do not pose the risk* the agencies are responsible for overseeing. Agencies should also be more communicative about how these products are acceptable for domestic use.

2. *What additional clarification could be provided regarding the roles that each agency plays for different biotechnology product areas, particularly for those product areas that fall within the responsibility of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment?*

The existing division of responsibilities among the three agencies is logical and consistent with each agency's mission, authority and expertise. While experience has helped agencies refine their respective areas of expertise for genetically engineered plants, areas of duplicative and overlapping reviews between agencies remain. This should be resolved and reduced. For example, USDA, FDA and EPA all review much of the same safety data in reaching their conclusions. Additionally, both USDA and EPA oversee field trials of some plant products, imposing duplicative and sometimes inconsistent oversight. The agencies should be clear and transparent about

- the specific risks being addressed by each agency, and
- the tools and expectations for how those risks are addressed.

In some instances, one agency will delay publishing its review of a genetically engineered plant until another agency publishes its review first. For example, EPA has adopted the practice of delaying its regulatory determination for new herbicide uses until after USDA completes its review of the herbicide tolerant crop. This creates unnecessary dependencies and delays in the regulatory process, and confusion for the public. Agency reviews and the publication of the results of such reviews should not be delayed merely because other agencies are at work on reviews pertaining to the same organism - except in individual cases in which there is a scientifically justified basis, supported by pertinent statutory and regulatory authority, for such a delay.

3. *How can Federal agencies improve their communication to consumers, industry, and other stakeholders regarding the authorities, practices, and bases for decision-making used to ensure the safety of the products of biotechnology?*

Agencies should be strongly encouraged to publish clear guidance on the scope of regulations, data requirements, regulatory processes, and bases of decision-making, not only for regulatory reviews of proven products that are about to enter the marketplace, but also for oversight of field trials and other regulatory activities. Publication of clear guidance will greatly increase the transparency and predictability of the regulatory system, clarify the bases for decision-making, resist politicization, and reduce the likelihood that agency scope and practice will inadvertently change or drift over time.

Regulatory agencies should increase their engagement with stakeholders, making stakeholder outreach a regular and ongoing activity-- not only to help stakeholders understand the regulatory systems, but to solicit feedback on the functioning of the regulatory system and its impacts on stakeholders. Agencies should more actively respond to stakeholder feedback with clear explanations in public forums.

Most importantly, agencies should be more proactive in describing how their regulatory processes assure protection of human and animal health and the environment and in defending the validity of their safety assessments and decisions. Agencies should develop a public-facing communication strategy so that each agency's regulatory determinations are more accessible and understandable by the general public. OSTP could also develop and implement a single public-facing communication strategy that not only joins and but also integrates each agency's process and determinations. Agencies should vigorously defend the rigor of their determinations, the risks evaluated, and the scientific bases for their conclusions. Additionally, a coordinated effort from both political and non-political governmental authorities, visibly and vocally supporting the quality of the regulatory process and confidence in the safety of individual products and processes that have been reviewed, will be very helpful. This will further the U.S. position as a strong leader and champion of its regulatory system, and help to improve the global dialogue. Improved levels of public confidence from these efforts might in turn reduce the pressure regulators are experiencing from some stakeholders to increase regulatory scrutiny when it is not scientifically justified.

4. *Are there relevant data and information, including case studies, that can inform the update to the CF or the development of the long-term strategy regarding how to improve the transparency, coordination, predictability, and efficiency of the regulatory system for the products of biotechnology?*

Agencies should be encouraged to implement process improvement projects to identify ways to improve the timeliness, efficiency and predictability of their regulatory processes. USDA conducted such a project in 2011, which resulted in significant improvements in the timeliness of its petition process. The project was based entirely on data and information held by USDA about the internal functioning of its business process. All three agencies could greatly benefit from similar efforts to improve other regulatory processes as well. Agencies should set reasonable timelines for completion of their review processes, and implement process controls to ensure they are able to meet those timelines consistently.

Much of the inefficiency in the current regulatory system results from reviewing the same or similar products-- and the same or similar field trials-- over and over. Agencies should use their long experiences with products of the technology to identify ways to reduce redundant data requirements or review of products for which the agencies are extremely familiar. Agencies can feel confident in acting on this evidence and make the appropriate adjustments when their decisions are paired with a robust stakeholder outreach and communications effort. This strategic use of experience and familiarity to improve the efficient use of limited agency resources should play a central role in the long-term plan for keeping the regulatory system up to date and in any considerations to exempt future products from review when relevant risk assessments have been completed for the same or similar products.

5. *Are there specific issues that should be addressed in the update of the CF or in the long-term strategy in order to increase the transparency, coordination, predictability, and efficiency of the regulatory system for the products of biotechnology?*

   The primary goal of the long-term strategy should be to build mechanisms to allow the regulatory system to be more adaptable in its ability to utilize and incorporate the large body of experience the agencies accumulate over time. The agencies have largely relied on the same set of regulatory practices in regulating products for the past 30 years with little significant change. Regulatory agencies should focus on reducing or removing regulatory burden on familiar traits and products where evidence and experience support such a shift, and to be more adaptable and science-based in their approach to new traits and technologies.

In summary, BIO greatly appreciates this Administration's efforts to encourage regulatory approaches that protect health and the environment while reducing regulatory burdens that impede innovation unnecessarily. Biotechnology's potential for driving innovation is virtually limitless. However, it will only be realized if our regulatory policy is informed by science, guiding principles and past experiences.

Finding the appropriate balance between protection and technological innovation can be difficult, even under the best of circumstances. If the public perceives a technology's risks to be significantly greater than they are, then developing and implementing a regulatory system that allows development of safe and beneficial products becomes even more challenging. In the absence of strong and far-sighted political leadership throughout the United States government, including leadership at the highest levels, it is hard to imagine how the three objectives of protection, innovation and public confidence could achieve an appropriate balance. BIO and its members stand ready to help the government achieve these objectives.

With Sincerest Regards,

Jim Greenwood

James C. Greenwood
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