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National Science and Technology Council

Emerging Technologies Interagency Policy Coordination Committee

Office of Science and Technology Policy

1650 Pennsylvania Avenue NW.

Washington, DC 20504

Via <http://www.regulations.gov>

This letter provides comments from the Information Technology and Innovation Foundation<sup>1</sup> to Docket No. FDA-2015-N-3403 “for 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; Request for Information.”

OSTP and the regulatory agencies are to be commended for taking up this complicated challenge, which is long overdue.

If this process is at its conclusion to be judged a success it must without fail deliver one specific outcome: It must restore balance between the degree of regulatory scrutiny a product receives and the degree of hazard it represents. What we have now is a system in which there is no relationship between the degree of regulatory scrutiny and the level of risk a product might pose. If innovation is to be enabled, much less encouraged, that must be repaired.

The charge in this docket is to provide comments in response to five questions. These are quoted below, with comments following. But it must first be noted that aspects of the July 2, 2015 EOP memorandum are fundamentally at odds with the 1986 Coordinated Framework (CF) as updated in 1992, as well as the vast amount of experience accrued over the past 30 years in the United States and around the world. The memorandum tasks Agencies with “clarifying...

(i) which biotechnology product areas are within the authority and responsibility of each agency;

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<sup>1</sup> Founded in 2006, ITIF is a 501(c)(3) nonprofit, nonpartisan research and educational institute – a think tank – focusing on a host of critical issues at the intersection of technological innovation and public policy. Its mission is to formulate and promote policy solutions that accelerate innovation and boost productivity to spur growth, opportunity, and progress.

(ii) the roles that each agency plays for different 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;

(iii) a standard mechanism for communication and, as appropriate, coordination among agencies, while they perform their respective regulatory functions, and for identifying agency designees responsible for this coordination function; and

(iv) the mechanism and timeline for regularly reviewing, and updating as appropriate, the CF to minimize delays, support innovation, protect health and the environment and promote the public trust in the regulatory systems for biotechnology products.

The problem with this tasking is that the major defects associated with the implementation of the CF have only a little to do with the coordination issues enumerated above. The major defect is that the regulatory agencies implanting the Coordinated Framework have drifted from the “product not process” based foundation of the CF, and traveled some distance down the road towards a *de facto* process based regulatory approach. This has led to a situation in which GM crops and foods, which have the most robust and impressive safety records, face the highest degree of regulatory scrutiny. This makes innovation in the food and agriculture sector harder, not easier, at a time when the needs for innovation have never been greater. This must be corrected.

Item (i) above makes this situation worse in that it effectively abandons the scientifically defensible, risk-based triggers of the 1986 Coordinated Framework and the 1992 update. It supplants them with an implicitly process-specific trigger for regulatory oversight for “biotechnology products” which had been considered and, with carefully chosen language, explicitly rejected for the Coordinated Framework. No credible, much less convincing case has yet been made, in the United States or elsewhere, to justify a process-specific approach to regulation.

Focused research, regulatory reviews and a huge amount of experience have consistently upheld the remarkable safety record of these “biotechnology products.”<sup>2</sup> Multiple reviews by governments that adopted

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<sup>2</sup> See European Commission, “A Decade of EU-Funded GMO Research (2001-2010),” Brussels, ISBN 978-92-79-16344-9, at [http://ec.europa.eu/research/biosociety/pdf/a\\_decade\\_of\\_eu-funded\\_gmo\\_research.pdf](http://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf); also Alessandro

process-based regulations have documented extensively the lack of justification, the performance failures, and the indefensibility of process-based approaches to regulation and concluded that such process based regulations are “not fit for purpose.”<sup>3</sup>

The July 2, 2015 EOP memorandum notes that “biotechnology products” refers to “products developed through genetic engineering or the targeted or in vitro manipulation of genetic information of organisms, including plants, animals, and microbes.” But ever since the U.S. National Academy of Sciences first examined this issue in 1987, it has been recognized that the hazards that present risks (exposure to a hazard) are not driven by the production method, but rather by the characteristics (phenotype) of the organism or product.<sup>4</sup>

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Nicolia, Alberto Manzo, Fabio Veronesi, and Daniele Rosellini, “An overview of the last 10 years of genetically engineered crop safety research,” *Crit Rev Biotechnol*, Early Online: 1–12, (2013) Informa Healthcare USA, Inc. DOI: 10.3109/07388551.2013.823595 at <http://www.geneticliteracyproject.org/wp-content/uploads/2013/10/Nicolia-20131.pdf>; and A. L. Van Eenennaam and A. E. Young, 2014. Prevalence and impacts of genetically engineered feedstuffs on livestock populations. *Journal of Animal Science* Vol. 92 No. 10, p. 4255-4278 at <https://www.animalsciencepublications.org/publications/jas/articles/92/10/4255?highlight=&search-result=1#fn1>.

<sup>3</sup> See Parliament of the United Kingdom, House of Commons Select Committee, “EU regulation on GM Organisms not 'fit for purpose',” (26 February 2015) at <http://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/news/report-gm-precautionary-principle/> and <http://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/news/report-gm-precautionary-principle/>; Also, UK Advisory Committee on Releases to the Environment, “Report 1: Towards an evidence-based regulatory system for GMOs” (27 August, 2013) [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/239839/an-evidence-based-regulatory-system-for-gmos.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/239839/an-evidence-based-regulatory-system-for-gmos.pdf); “Report 2: Why a modern understanding of genomes demonstrates the need for a new regulatory system for GMOs” [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/239852/genomes-and-gm-regulation.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/239852/genomes-and-gm-regulation.pdf); “Report 3: Towards a more effective approach to environmental risk assessment of GM crops under current EU legislation” [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/239893/more-effective-approach-gmo-regulation.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/239893/more-effective-approach-gmo-regulation.pdf).

<sup>4</sup> See US National Academy of Sciences, “Introduction of Recombinant DNA-engineered organisms into the environment: Key issues” (1987) National Academy Press, Washington DC, 24pp at [https://books.google.com/books?id=IUErAAAAYAAJ&pg=PA5&lpg=PA5&dq=Introduction+of+Recombinant+DNA-engineered+organisms+into+the+environment:+Key+issues.&source=bl&ots=FvDOVZwNVZ&sig=IJ\\_zcaXjYnsq656AXpiFK-mTXE&hl=en&sa=X&ved=0CCoQ6AEwAmoVChMI6Mi8zKzgvAIVSjM-Ch3EpQ29#v=onepage&q=Introduction%20of%20Recombinant%20DNA-engineered%20organisms%20into%20the%20environment%3A%20Key%20issues.&f=false](https://books.google.com/books?id=IUErAAAAYAAJ&pg=PA5&lpg=PA5&dq=Introduction+of+Recombinant+DNA-engineered+organisms+into+the+environment:+Key+issues.&source=bl&ots=FvDOVZwNVZ&sig=IJ_zcaXjYnsq656AXpiFK-mTXE&hl=en&sa=X&ved=0CCoQ6AEwAmoVChMI6Mi8zKzgvAIVSjM-Ch3EpQ29#v=onepage&q=Introduction%20of%20Recombinant%20DNA-engineered%20organisms%20into%20the%20environment%3A%20Key%20issues.&f=false)

The successes of agricultural innovation in the United States since adoption of the Coordinated Framework are apparent: the amount of innovation and the accrued experience with crops and foods improved through biotechnology in the United States exceeds that of the rest of the world combined.<sup>5</sup> The resulting benefits have been substantial and there are no confirmed or corroborated reports in the scientific literature of any novel risks to humans or the environment, nor any that derive from the specific processes of genetic modification used, per se.<sup>6</sup>

But the length of time it now takes a product to move from initial field tests to commercial release has lengthened substantially over the past 3 decades, and regulatory compliance times have increased from 44 to 65 months between 2002 and 2011, with costs making up as much as 26 percent of total R&D costs; on average, \$35 million per product.<sup>7</sup> This has taken place at the same time that a vast body of experience with crops improved through biotechnology has been amassed, and robustly confirmed their safety.

The cause has been a combination of bureaucratic failure (no significant updating to the Coordinated Framework since 1992, despite several attempts) although political interference has also clearly played a role.<sup>8</sup> The biggest bureaucratic failure has been the lack of any meaningful update to the Coordinated Framework to

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<sup>5</sup> See USDA, APHIS, BRS database at <http://isaaa.org/resources/publications/briefs/49/default.asp>.

<sup>6</sup> See W. Klümper, and M. Qaim, "A Meta-Analysis of the Impacts of Genetically Modified Crops," (2014) PLoS ONE 9(11): e111629. doi:10.1371/journal.pone.0111629 at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0111629>.

<sup>7</sup> See Phillips McDougall, "The cost and time involved in the discovery, development and authorisation of a new plant biotechnology derived trait - A Consultancy Study for Crop Life International," (September 2011) at <http://croplife.org/wp-content/uploads/2014/04/Getting-a-Biotech-Crop-to-Market-Phillips-McDougall-Study.pdf>.

<sup>8</sup> See, for example, Jon Entine, "White House Ends Its Interference in a Scientific Review - Leaks suggest politics blocked genetically modified salmon. Now the fish is on its way to approval," (21 December 2012), Slate, at [http://www.slate.com/articles/health\\_and\\_science/science/2012/12/genetically\\_modified\\_salmon\\_aquadvantage\\_fda\\_assessment\\_is\\_delayed\\_possibly.html](http://www.slate.com/articles/health_and_science/science/2012/12/genetically_modified_salmon_aquadvantage_fda_assessment_is_delayed_possibly.html).

recalibrate the nature and extent of regulatory oversight so as to restore a closer relationship between the degree of regulatory scrutiny and the potential for hazard that contributes to risks that might need management. There is low hanging fruit to be plucked here<sup>9</sup> that, when harvested, would drastically reduce the exposure of regulatory agencies to the harassment by procedural lawsuits from professional opponents of agricultural innovation.

The call for comments requested input on several specific items, provided below.

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

The distribution of authorities and responsibilities under the Coordinated Framework remains fairly clear. Minor clarifications and adjustments may be indicated, but the question as asked is itself problematic. It is difficult to align the question above with the Coordinated Framework's foundational requirement that regulation focus not on production processes, but on product characteristics representing potential hazards that might require risk management.

As the National Academy of Sciences has repeatedly reaffirmed over the past three decades, there is nothing about the techniques of *in vitro* recombinant DNA techniques (nor any of the newer gene editing methods) that makes them more likely to lead to hazardous products than unregulated articles. The focus on process is misplaced, and should be replaced by a focus on product qualities. The regulatory systems in Australia and Canada have implemented elements of this focus in their regulations, and some consideration of their experiences might be worthwhile.

The necessary outcome of this exercise, however, is very clear: regulatory energies must be refocused on risk, and away from process; proportionality must be restored between the degree of risk a product presents and the level of regulatory scrutiny it receives. Regulatory efforts by agencies have strayed far from this standard, increasing costs, discouraging innovation, and delivering no benefits to the public good. This needs to be corrected.

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<sup>9</sup> L. Val Giddings and Bruce M. Chassy, "Igniting Agricultural Innovation: Biotechnology Policy Prescriptions for a New Administration," Science Progress, Center for American Progress, (1 July 2009) at <http://scienceprogress.org/2009/07/igniting-agricultural-innovation/>.

**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 interagency review process has worked fairly well. It could be strengthened by setting and enforcing consultation response timelines to prevent unnecessary delay in reaching regulatory decisions, as we have too often seen. Some products have languished at the interagency review stage for many months, or even years. There is no scientific reason for this; it does nothing to protect human or environmental health nor to encourage innovation.

**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?**

Explaining the Federal regulatory process to consumers, and defending it against false claims and attacks by special interests, is an area that provides regulatory agencies with substantial opportunity for improvement.

Science-based regulatory oversight under the 1986 Coordinate Framework has confirmed and corroborated the safety of crops and foods improved through biotechnology brought to market to date. But regulatory agencies and Administration officials have not done enough to counter aggressive and misleading campaigns driven by so-called “public interest” organizations demonizing agricultural innovation.<sup>10</sup> The U.S. regulatory system has strong and signal virtues, and Agency and Administration officials can and should do more to explain and defend it against those who seek to mislead the public.

When the U.S. regulatory system is maligned and misrepresented in conspicuous venues, such as the Dr. Oz show, regulatory authorities should challenge the misrepresentations and work with such the media to correct the record. When anti-innovation advocates make claims that are contradicted by the facts and the bureaucratic record, officials should challenge such claims and correct the record. This need not be a huge undertaking, despite the prevalence of mythmaking on the Internet. The opposition propaganda machine is

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<sup>10</sup> Bruce Chassy, David Tribe, Graham Brookes, Drew Kershen, and Joanna Schroeder, “Organic Marketing Report,” (2014) Academics Review at [http://academicsreview.org/wp-content/uploads/2014/04/AR\\_Organic-Marketing-Report\\_Print.pdf](http://academicsreview.org/wp-content/uploads/2014/04/AR_Organic-Marketing-Report_Print.pdf).

driven by a very small handful of professional advocates, and they can be challenged effectively by exposing their audiences to the facts. This is and should be an urgent priority.

**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?**

There are several excellent case studies dating from a 2001 review by EOP/OSTP/CEQ that remain relevant, covering salmon, Bt maize, Ht soybean, farm animals as drug factories, bioremediation with poplars and bacteria, and bacterial biosensing<sup>11</sup>

**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?**

There are a number of specific issues that, if addressed, would improve the focus and efficiency of U.S. regulations under the Coordinated Framework. As mentioned above, balance needs to be restored between the level of hazard posed by a product and the degree of regulatory scrutiny it receives. It would help if categories of exemption from regulation were expanded for products with which we have become familiar, particularly those captured for regulation only because they are derived through biotechnology. That herbicide tolerant crops produced with recombinant DNA techniques continue to be captured for regulatory scrutiny is bad enough; it is scientifically indefensible that this continues when herbicide tolerant crops produced through other methods entirely escape any pre market regulatory scrutiny. Experience has shown

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<sup>11</sup> See CEQ and OSTP Assessment: Case Studies of Environmental Regulations for Biotechnology at [https://www.whitehouse.gov/files/documents/ostp/Issues/ceq\\_ostp\\_study1.pdf](https://www.whitehouse.gov/files/documents/ostp/Issues/ceq_ostp_study1.pdf); and Case Study No. I - Growth-Enhanced Salmon at [https://www.whitehouse.gov/files/documents/ostp/Issues/ceq\\_ostp\\_study2.pdf](https://www.whitehouse.gov/files/documents/ostp/Issues/ceq_ostp_study2.pdf); Case Study No. II - Bt-Maize at [https://www.whitehouse.gov/files/documents/ostp/Issues/ceq\\_ostp\\_study3.pdf](https://www.whitehouse.gov/files/documents/ostp/Issues/ceq_ostp_study3.pdf); Case Study No. III - Herbicide-Tolerant Soybean at [https://www.whitehouse.gov/files/documents/ostp/Issues/ceq\\_ostp\\_study4.pdf](https://www.whitehouse.gov/files/documents/ostp/Issues/ceq_ostp_study4.pdf); Case Study No. IV – Farm Animal (Goat) that Produces Human Drugs at [https://www.whitehouse.gov/files/documents/ostp/Issues/ceq\\_ostp\\_study5.pdf](https://www.whitehouse.gov/files/documents/ostp/Issues/ceq_ostp_study5.pdf); Case Study No. V - Bioremediation Using Poplar Trees at [https://www.whitehouse.gov/files/documents/ostp/Issues/ceq\\_ostp\\_study6.pdf](https://www.whitehouse.gov/files/documents/ostp/Issues/ceq_ostp_study6.pdf); and Case Study No. VI - Bioremediation and Biosensing Using Bacteria at [https://www.whitehouse.gov/files/documents/ostp/Issues/ceq\\_ostp\\_study7.pdf](https://www.whitehouse.gov/files/documents/ostp/Issues/ceq_ostp_study7.pdf).

that hazards associated with herbicide tolerant crops come from inappropriate use of or exposure to the herbicides, not the crops. These can be managed by regulations focused on the herbicides, which are already heavily regulated.

Many of the delays in introduction of new products derived through biotechnology are due to litigation, usually over procedural issues associated with NEPA. These delays have resulted from the litigation itself, and from the chilling effect such litigation has on timely decisions by regulators. Agencies spend enormous amounts of time and energy preparing to defend against such litigation, with no commensurate benefits to human or environmental health. Exposure of regulatory agencies to this kind of harassment could be significantly reduced by adopting exclusions to NEPA for specific product categories. This could most easily be done, perhaps, by extension of existing regulatory decisions, but other approaches are possible. This is something OSTP should direct regulatory agencies to make happen as soon as possible.

Another issue that should be addressed has to do with imports. Imports of food, feed, and fiber derived through biotechnology or any other production method should be scrutinized by the appropriate regulatory authorities only to the extent that is required to protect human and environmental health. This should be coordinated among the regulatory agencies historically involved with the Coordinated Framework, but also those involved in border control.

A coordinated policy on imports will require a uniform and consistent approach to dealing with the low level (adventitious) presence of material that may not have received import approval. There is a time-tested approach from international commodity trade for dealing with the low level presence of nonstandard materials without unduly disrupting trade. This provides an excellent template that is long overdue for extension to products derived through biotechnology or any other techniques.

And finally, it must be noted that some are concerned as to how best to deal with the products of new plant breeding technologies that may not be captured under some definitions of “biotechnology.” As long as these materials are viewed through a “process-based” lens they will present challenges, and regulations will inevitably fail to keep pace with the rapid tempo of scientific advance. But this problem does not exist in regulatory systems that focus on the qualities and characteristics which may be the source of hazards and risks associated with a product. As noted above, taking a process-based approach to these products would be ill-considered, particularly when countries that adopted such approaches in decades past are now recognizing



their weaknesses, and trying to figure out how to correct them (footnotes 2 and 3). This alone provides a compelling argument against process based regulation.

Sincerely,

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