Biotechnology Innovation Organization

May 15, 2017

The Honorable Scott Pruitt
Administrator, Environmental Protection Agency
Air and Radiation Docket and Information Center
1200 Pennsylvania Avenue NW
Washington, DC 20460

Docket ID No. EPA-HQ-OA-2017-0190

Dear Administrator Pruitt:

The Biotechnology Innovation Organization's ("BIO") Industrial and Environmental Section ("IES") is pleased to provide the U.S. Environmental Protection Agency ("EPA") input to inform its Task Force evaluation of existing regulations under Executive Order 13777, "Enforcing the Regulatory Reform Agenda."[1]

I. INTRODUCTION

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, and industrial and environmental biotechnology products. BIO IES represents more than 70 companies leading the development of new technologies for producing conventional and advanced biofuels, renewable chemical intermediates, bioplastics, and other bioproducts, bioprocesses, and biocatalysts. Through the application of industrial biotechnology, BIO IES members are improving conventional biofuel and chemical processes, furthering advanced and cellulosic biofuel production technologies, speeding development of new energy crops, and building complex molecules that often cannot be produced using traditional chemical techniques.

BIO's IES is pleased to share the information below on advanced and cellulosic biofuels, and renewable chemicals with EPA. Please consider the importance of these important fuels and products as the Administration evaluates existing regulations. These brief comments are intended to stress the importance of certain regulations and policies to further the goals of the federal Renewable Fuel Standard (RFS) and the development of biofuels and bioproducts. They are not intended to be a detailed review of all aspects of existing regulations and policies that affect the biofuels and bioproducts industries.

II. ADVANCED AND CELLULOSIC BIOFUELS

Proper, consistent and stable implementation of the federal Renewable Fuel Standard ("RFS") statute through 2012 spurred investment, research and development in, which resulted in the commercialization of advanced and cellulosic biofuels. As a result, according to a 2014 footprint analysis conducted for Fuels America, the RFS now creates $184.5 billion of economic output, 852,056 jobs, and $46.2 billion in wages and $14.5 billion in taxes

[1] Proposed Rule issued by the EPA: Evaluation of Existing Regulations. (n.d.). In accordance with Executive Order 13777, "Enforcing the Regulatory Reform Agenda," 82 Fed. Reg. 17793 (April 13, 2017), https://www.federalregister.gov/documents/2017/04/13/2017-07500/evaluation-of-existing-regulations

1201 Maryland Avenue SW
Suite 900
Washington DC 20024
202.962.9200 P
202.488.6301 F
bio.org

each year in the United States.[2] In addition to being an economic driver, the RFS has been a critical piece of our nation's energy, climate, and security policy. It has spurred innovation beyond biofuels to the development of cleaner and more efficient technologies and manufacturing processes while curbing our dependence on foreign oil. Because of the RFS, renewable fuels displaced an amount of gasoline equivalent to 527 million barrels of crude oil in 2015. That's roughly the volume of oil imported annually from Saudi Arabia and Kuwait combined.[3]

To ensure the continued growth of the advanced and cellulosic biofuels industry; to spur the development of new investment, innovation, and job growth; and to enhance energy and national security, EPA must improve its implementation of RFS by doing the following:

- issue its annual Renewable Volume Obligations (RVO) under the RFS ***on time***;
- interpret its general waiver authority as it did before 2013;[4]
- make process improvements for RFS pathway approvals – not only to clear backlogs of pending approval petitions but to speed new approval decisions;
- work to facilitate inclusion of additional biofuels under the RFS program;
- update lifecycle analyses and evaluations of the environmental impact of biofuels; and
- reject all proposals to change the Point of Obligation under the RFS.

Below, please find descriptions for each of these points.

A. Issuing the RFS RVOs on time

Timely implementation of the RFS RVOs is critical to the growth and stability of the advanced and cellulosic biofuels industry. Previous delays have had a significant impact on the investment and finances of these companies. As BIO pointed out in its comments on the RFS Program: Standards for 2017 and Biomass-Based Diesel Volume for 2018"[5] ("2017 RFS"), EPA does not dispute that its delays in annual rulemaking failed to drive increased use of advanced biofuels in 2014 and 2015. As the Agency stated in the 2014-2016 RFS Rule, "[t]he final 2014 standards are based on actual production levels in 2014, possibly suggesting that the 2014 standards we are finalizing are what would have happened in the marketplace absent a rulemaking."[6] And further, "[t]he final standards for 2015 are being set late in the 2015 calendar year, so it is not clear how much extra renewable fuels (and thus costs) the standards are requiring above what the marketplace would have supplied absent them."[7] Allowing the marketplace, which continues to be dominated by oil companies

[2] John Dunham & Associates, Inc., (April 15, 2014). Fuels America, Fuels America Impact Methodology Study: Renewable Fuel Drives Economic Growth, Retrieved from http://fuelsamerica.guerrillaeconomics.net/2014 Fuels America Methodology.pdf; https://fuelsamerica.org/facts/

[3] Urbanchuk, J. (Feb. 5, 2016). ABF Economics: Contribution of the Ethanol Industry to the Economy of the United States in 2015. Retrieved from http://ethanolrfa.org/wp-content/uploads/2016/02/Ethanol-Economic-Impact-for-2015.pdf

[4] Proposed Rule issued by the EPA: Renewable Fuel Standard Program: Standards for 2014, 2015, and 2016 and Biomass-Based Diesel Volume for 2017, 80 Fed. Reg. 33100, 33104 n.12, 33117 n.46 (June 10, 2015), https://www.gpo.gov/fdsys/pkg/FR-2015-06-10/pdf/2015-13956.pdf ("2014-2016 RFS Proposal").

[5] Proposed Rule issued by the EPA: Renewable Fuel Standard Program: Standards for 2017 and Biomass-Based Diesel Volume for 2018, 81 Fed. Reg. 34778 (May 31, 2016), https://www.gpo.gov/fdsys/pkg/FR-2016-05-31/pdf/2016-12369.pdf

[6] Proposed Rule issued by the EPA: Renewable Fuel Standard Program: Standards for 2017 and Biomass-Based Diesel Volume for 2018, 81 Fed. Reg. 34777 (May 31, 2016), https://www.federalregister.gov/d/FR-2016-05-31/renewable-fuel-standard-program-standards-for-2017-and-biomass-based-diesel-volume-for-2018

[7] *Id.*

and obligated parties, to set required volumes of renewable fuel, without taking into account the statutory requirements and goals, is inconsistent by definition with the RFS statute and its purposes.

BIO appreciates EPA's commitment to issuing future RVOs on time in accordance with the statute. Adhering to this timeline will give biofuel producers and their investors' certainty on the market for advanced and cellulosic biofuels for the year ahead. This certainty will spur much needed ongoing investment in the industry.

B. EPA must reject its unwarranted and unlawful expansion of its general waiver

The biggest challenge the advanced biofuels industry has faced in recent years is the regulatory uncertainty created by EPA's unwarranted and unlawful expanded interpretation of its general waiver authority under the RFS in the Agency's 2014-2016 RFS rule. The advanced biofuel industry's cumulative capacity-building delay corresponds with the timing of this rule, which has led to a shortfall in investment of about $22.4 billion since 2013.[8] EPA's methodology, combined with its delays in RFS-related rulemakings since 2013 have been the primary drivers of this investment shortfall, due to their chilling effect on the industry and its investors.

EPA must interpret its general and cellulosic waiver authorities under the RFS statute as it did prior to 2013. Specifically, it must recognize that the term "supply" refers to wet gallons of biofuels. It plainly does not include infrastructure and other factors impacting the distribution of the gallons. It is not within EPA's authority to create competition for limited market space between advanced and conventional biofuel producers. EPA should create market space for all renewable fuels that can be produced, up to the volumes established in the statute. For further detail on this point, please see Attachment A, which is a copy of BIO's comments to EPA on the 2014-2016 rule.

EPA must also abandon the methodology that limits future market space to past production performance, due to its chilling effect on new production. EPA has acknowledged that RINs can incentivize infrastructure for and consumer marketing of higher renewable fuel blends.[9] The Agency should allow the RIN system to work and should not unduly impose duplicative distribution infrastructure and marketing costs on renewable fuel producers.

C. Improve pathway approval process

BIO and its members have stressed to EPA, both in comments and in meetings, it is essential that the Agency improve and hasten its decisions on RFS pathway approvals. To date, EPA has simply taken too long to make its decisions on pathway approvals, with devastating results to individual companies and the entire biofuels industry. In the near term, EPA's delays are a contributing factor to the Agency setting annual fuel volume requirements that fail to account for significant quantities of potentially qualifying renewable fuels. In the longer term, EPA's delays on pathway approvals are impeding the success of

[8] BIO Estimating Another Year of Chilled Investment in Advanced Biofuels Due to RFS Uncertainty https://www.bio.org/sites/default/files/Estimating_Another_Year_of_Chilled_Investment.pdf

[9] Dallas Burkholder, "A Preliminary Assessment of RIN Market Dynamics, RIN Prices, and Their Effects," EPA Office of Transportation and Air Quality (May 14, 2015); *see also* 2014-2016 RFS Rule at 77458-59.

the RFS program. Perversely, as is shown in Figure 1 below, this is particularly the case for producers of advanced and cellulosic biofuels, which have lower greenhouse gas emissions.

Figure 1: Average Time for EPA to Address New RFS Biofuel Pathways Submitted between April 2010 and June 2016

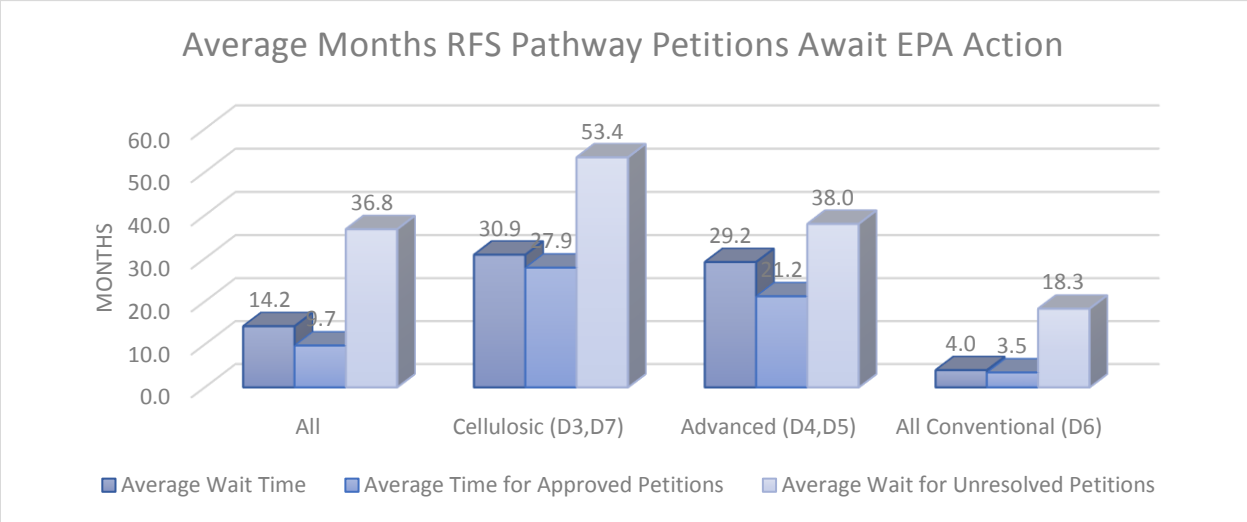

Figure 1 makes clear that average wait times for all petitions can be misleading: in particular, the average numbers mask the delays in approval decisions on RFS pathways for cellulosic and advanced biofuels. Those delays are counterbalanced by EPA's relative success in expeditiously approving a subset of conventional biofuel petitions. BIO and its members urge EPA to make similar process improvement achievements with regard to review and approval of petitions submitted for cellulosic and advanced biofuel producers.

In November 2014, EPA implemented the Efficient Producer process to evaluate the lifecycle greenhouse gas emission scores for conventional biofuel producers who expanded production beyond their grandfathered capacity. As of April 2017, EPA has approved 71 Efficient Producer petitions – representing 33 percent of all U.S. ethanol biorefineries. These petitions have been approved, on average, within **3 months** of their filing.

Because Efficient Producer petitions, which represent more than 50 percent of all pathway petitions filed, have been resolved quickly, EPA has reduced the average wait time for all petitions to slightly more than 14 months. For all conventional pathway petitions, the wait time has been reduced to just **4 months** (measured from the date a petition was first filed). Nonetheless, for those conventional biofuel pathway petitions outside the Efficient Producer process, the wait remain longer – **more than 18 months**. For instance, five ethanol producers which originally filed regular pathway petitions in 2013 and 2014 waited more than a year each eventually withdrew them and filed Efficient Producer petitions, receiving approvals within months.

By comparison, aspiring advanced and cellulosic biofuel producers have an even tougher and longer wait time for decisions to be made on their petitions. There are currently 23 companies awaiting final approval on pathway petitions, 20 of which are potential advanced or cellulosic producers. For nine of these companies, EPA has proposed a rule and solicited public comment (one company is a potential conventional biofuel producer, 8 are potential

advanced producers). The comment periods on four proposed rules to approve six of these companies' petitions closed in 2015, yet EPA has taken no further action. For the remaining three companies' petitions, EPA released a proposed rule in January 2017, but has not published it to the Federal Register to begin a formal comment period, and has taken no further action.

Cellulosic biofuel companies have waited on average **more than 30 months** for EPA to address petitions. For the two potential cellulosic biofuel producers whose petitions are still pending, the wait has reached **four-and-a-half years (53.4 months)**. For 15 producers whose petitions were approved, the wait time was **two-and-a-half years (27.9 months)**. However, among those 15 approved producers, six have abandoned plans to produce biofuels. Three additional companies simply withdrew their petitions.

Advanced biofuel companies have waited on average **more than two years (29.2 months)** for EPA to address petitions. For the 18 potential advanced biofuel producers whose petitions are pending (including the 8 awaiting final approval of or initial action on proposed rules), the wait has topped **three years (38 months)**. These very long wait times have deterred additional advanced biofuel companies for producing RFS qualifying fuels. For instance, **just because of these wait times, three additional potential biofuel producers withdrew their petitions and abandoned plans to produce biofuel**.

In sum, EPA's delays on pathway approvals have had and are continuing to have a substantial negative effect on the progress of the RFS program. Multi-year wait times can be fatal for a commercialization plan. Petitioners' lengthy waits for approval of new pathways discourage (and even kill) investment in commercial production of advanced and cellulosic biofuels. Without a pathway to the fuel market, companies find it difficult to attract the investment necessary to initiate, continue, and complete the construction and startup of new facilities. If EPA does not solve this problem as soon as possible, the path to expanded advanced biofuel and cellulosic volumes will likely be choked.

Relatedly, as EPA has acknowledged, "the development and use of new, high-yielding feedstocks, such as algal oils or alternative oilseed crops," could result in "[l]arge increases in the available supply of biodiesel and renewable diesel in future years."[10] We urge EPA to account appropriately for -- and adequately incentivize -- technological developments relating to the use of such feedstocks in fuel production.

We note that in connection with issuing the 2014-2016 RFS Rule in late 2015, EPA promised that it would "continue to work with renewable fuel producers to improve the completeness and accuracy of registration submissions by providing more thorough guidance, planning future enhancements to the CDX system, and proposing regulatory amendments to improve the registration and review process."[11] We urge EPA to take aggressive action on these and other fronts to expedite pathway reviews and approvals.

BIO strongly urges EPA to take immediate steps to expedite the pathway review and approval process, which will increase the available supply of advanced and cellulosic biofuels to meet the RVOs. EPA should devote new resources to clearing its existing backlog, and

[10] Proposed Rule at 34791.
[11] Renewable Fuel Standards for 2014, 2015 and 2016, and the Biomass-Based Volume for 2017: Response to Comments, at 843 (Dec. 2015), available at https://www.epa.gov/sites/production/files/2015-12/d/420r15024/EPA-420-R-15-024.pdf

should also make improvements to ensure that new pathway petitions are processed expeditiously on predictable timelines.

D. EPA should work to facilitate inclusion of additional biofuels and feedstocks under the RFS program

As BIO pointed out in its comments[12] (Appendix I) to EPA's proposed Renewables Enhancement and Growth Support Rule ("REGS"),[13] there are many steps EPA can take to get more advanced and cellulosic biofuels into production and the market. BIO supports the inclusion of new pathways for the production of qualifying cellulosic fuels using short rotation hybrid poplar and willow trees as feedstocks.

In BIO's REGS comments, we noted that the initial interagency draft[14] of the proposed REGS Rule included language that would explicitly expand the Agency's interpretation of the term "algae" to include microorganisms and bioprocesses that perform similar carbon capturing functions to algae and cyanobacteria, including autotrophic organisms. However, this language was not included in the proposed rule. As was noted during the interagency review process, explicit expansion of EPA's interpretation of "algae" in this manner would be well within EPA's authority, would be well received, and would be seen as a means to make available additional feedstock for renewable fuel production, which will further the energy independence and greenhouse gas reduction objectives of the RFS statute and program.[15] For these reasons, *we urge EPA to proceed with a separate request for comments on explicitly including autotrophic organisms as renewable biomass under algae, using the recommended language proposed for consideration during the interagency process*.

BIO would also *urge EPA to expand its definition of renewable biomass under the RFS to include trees established from natural regeneration silvicultural systems and process wood residue established from silvicultural systems*. Expanding the definition of renewable biomass from naturally regenerated forest land, residues, and byproducts from milled logs and pulpwood type logs would make the U.S. Department of Energy's billion-ton study on biomass feasible.[16]

BIO would also encourage EPA to finalize the parts of the proposed REGS rule it identified will enhance and improve the operation of the RFS program and meet the goals mandated by Congress in the statutory provisions that create the program.

---

[12] BIO Submits Comments on EPA Renewables Enhancement and Growth Support Rule, available at https://www.bio.org/press-release/bio-submits-comments-epa-renewables-enhancement-and-growth-support-rule

[13] Renewables Enhancement and Growth Support Rule, 81 Fed. Reg. 80828 (Nov. 16, 2016), available at https://www.gpo.gov/fdsys/pkg/FR-2016-11-16/pdf/2016-25292.pdf

[14] EO12866 Review of EPA Renewables Enhancement and Growth Support Proposed Rule 2060-AS66- 6 21 2016 EPA-HQ-OAR-2016-0041 (Nov. 16, 2016), available at https://www.regulations.gov/document?D=EPA-HQ-OAR-2016-0041-0013

[15] EO12866 Summary Comments on EPA Renewables Enhancement and Growth Support Proposed Rule 2060-AS66- 6 21 2016 EPA-HQ-OAR-2016-0041 (Nov. 16, 2016), available at https://www.regulations.gov/document?D=EPA-HQ-OAR-2016-0041-0013

[16] 2016 BILLION-TON REPORT: Advancing Domestic Resources for a Thriving Bioeconomy, (July 2016), available at https://energy.gov/sites/prod/files/2016/12/f34/2016_billion_ton_report_12.2.16_0.pdf

E. Update lifecycle analyses and evaluations of the environmental impact of biofuels

In August 2016, EPA's Office of Inspector General found that the Agency had not met its commitment to update biofuel lifecycle analyses or the statutory requirement to report program environmental impacts to Congress.[17] In response, EPA recommitted to completing a triennial report to Congress by the end of 2017, but declined to update its lifecycle analysis model. EPA pointed out that it regularly evaluates new biofuel pathway petitions and updates its model accordingly. The Agency also indicated that it will utilize findings from its update of the Motor Vehicle Emission Simulator (MOVES) model when it prepares its triennial report to Congress.

SAE International has noted the flaws in EPA's fuel effects study, used in updating its MOVES model.[18] And in January 2017, the states of Kansas and Nebraska renewed a request for EPA to correct the fuel effects study or cease using the MOVES2014 update.[19] EPA should move expeditiously to correct the flaws in the MOVES2014 model that resulted from flaws in its fuels effects study.

Since the RFS was adopted by Congress in 2005, biofuels have displaced nearly 2.5 billion barrels of oil in U.S. transportation. The United States has reduced greenhouse gas emissions by 752.33 million metric tons of CO2, compared to a scenario without the RFS in place. That reduction is the equivalent of taking 158.4 million cars off the road over the past 12 years.

In its triennial report to Congress due at the end of this year, EPA should properly account for the environmental and energy security benefits of biofuel use. It should either correct the flaws to its fuel effects study or not use the study in its report to Congress. The agency should also note that its unwarranted waivers of biofuel volumes in the 2014-2016 rule cut short the potential to reduce GHG emissions during those years.

F. Reject all proposals to change the point of obligation under the RFS

BIO would like to reiterate the comments[20] (Appendix II) it made on EPA's Proposed Denial of Petitions for Rulemaking to Change the RFS Point of Obligation.[21] BIO is supportive of EPA's proposal to reject the petitions to change the point of obligation. In BIO's view, granting the petitions in question would add unnecessary regulatory complexity and uncertainty to the Renewable Fuel Standard. These concerns have been raised by a number

---

[17] Gilbride, P. "EPA Has Not Met Certain Statutory Requirements to Identify Environmental Impacts of Renewable Fuel Standard." Report No. 16-P-0275, Aug. 18, 2016.
[18] Anderson, J., Wallington, T., Stein, R., and Studzinski, W., "Issues with T50 and T90 as Match Criteria for Ethanol-Gasoline Blends," SAE Int. J. Fuels Lubr. 7(3):1027-1040, 2014, doi: 10.4271/2014-01-9080.
[19] Gray, C.B., Gustafson, A., Conde, J. "Request for Correction of Information submitted on behalf of the State of Kansas, the State of Nebraska, The Energy Future Coalition, and Urban Air Initiative Concerning the U.S. Environmental Protection Agency's EPAct/V2/E-89 Fuel Effects Study and Motor Vehicle Emissions Simulator Model (MOVES2014) Docket ID Nos. EPA–420-R-13-002, FRL-9917-26-OAR." http://fixourfuel.com/wp-content/uploads/2017/01/Jan-2017-Request-for-Correction-MOVES2014.pdf
[20] BIO Submits Comments on EPA's Proposed Denial of Petitions for Rulemaking to Change the RFS Point of Obligation, https://www.bio.org/press-release/bio-submits-comments-EPA-proposed-denial-petitions-rulemaking-change-rfs-point
[21] *See* Notice of Opportunity to Comment on Proposed Denial of Petitions for Rulemaking to Change the RFS Point of Obligation, 81. Fed. Reg. 83776 (Nov. 22, 2016), available at https://www.gpo.gov/fdsys/pkg/FR-2016-11-22/pdf/2016-27854.pdf .

of policy makers[22,23] who recognize changing the point of obligation would jeopardize U.S. economic and job growth and would fail to further the statutory requirements and goals that Congress directed EPA to enforce and pursue when Congress created the program.

III. RENEWABLE CHEMICALS

Renewable chemicals are a relatively new, and an important, high value and growing subsector of the biobased economy, which in 2012 was valued at an estimated $1.25 trillion in the United States, the equivalent of about seven percent of the GDP.[24] A recent report by the U.S. Department of Agriculture ("USDA") shows that by 2014, the biobased products industry contributed $393 billion and 4.2 million jobs to America's recovering economy.[25] The report indicates that the sector grew significantly over a very short period, from 2013 to 2014, creating or supporting an additional 220,000 jobs and $24 billion in only two years.

The biotechnology industry underpins the biobased economy, and U.S. 2012 revenues from biotechnology were greater than $324 billion, the equivalent of at least two percent of GDP, and grew at an annual rate of about 12 percent. The industrial subsector, which includes the production of renewable chemicals, is the fastest-growing portion of the biotech sector, and also the fastest growing subsector within the chemical industry. The business of chemistry is an $801 billion enterprise and one of America's most significant manufacturing industries, accounting for more than 14 percent of all U.S. exports and 15 percent of the world's chemicals. More than ninety-six percent of all manufactured goods are touched by products of chemistry. Renewable chemicals currently comprise about nine percent of total chemical production value, however they have a compound annual growth rate (CAGR) of eight percent - double that of traditional chemicals, and by 2020 are predicted to comprise 11-13 percent of total chemical sales with a value of $400 billion. This rapid growth and contribution to the U.S. economy has occurred despite a regulatory approach which makes it harder for these products to enter the market compared to their traditional counterparts.

A. Implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act

EPA's proposed rulemaking under the Frank R. Lautenberg Chemical Safety for the 21st Century Act which amends the Toxic Substances Control Act of 1976 (TSCA) threatens to make the process for all new chemical regulation even more onerous than before, and its impact is disproportionately greater on the renewable chemicals sector because of its structure and composition, comprising mainly small to medium sized companies.[26][27] It also impacts the larger BIO member companies, who often rely on partnerships with these smaller companies to drive their own research and development and innovation capabilities.

---

[22] Ernst Leads Letter to EPA Expressing Support for Current RFS Point of Obligation, (Feb. 22, 2017), available at https://www.ernst.senate.gov/Ernst-leads-letter-to-epa-expressing-support-for-current-rfs-point-of-obligation

[23] Grassley, Klobuchar Lead 23 Senators in Urging President to Maintain Point of Obligation Under Renewable Fuel Standard, (March 16, 2017), https://www.grassley.senate.gov/Grassley-klobuchar-lead-23-senators-urging-president-maintain-point-obligation

[24] *Robert Carlson, rob@biodesic.com, Bioeconomy Capital LLC, Seattle WA, Biodesic LLC, Seattle WA. March 10, 2016*

[25] Golden, Jay S., Robert B. Handfield, Jessie Daystar, and T. Eric McConnell. "An Economic Impact Analysis of the U.S. Biobased Products Industry." United States Department of Agriculture. N.p., Oct. 2016. Web. Available here, https://www.biopreferred.gov/BPResources/files/BiobasedProductsEconomicAnalysis2016.pdf

[26] Frank R. Lautenberg Chemical Safety for the 21st Century Act https://www.epa.gov/sites/production/files/2016-06/documents/bills-114hr2576eah.pdf

[27] The Toxic Substances Control Act of 1976 , 15 U.S.C. §2601 et seq. (1976)

EPA should consider Executive Order 13777: Enforcing the Regulatory Reform Agenda when implementing any changes to their regulatory approach under TSCA.[28]

B. TSCA Inventory Reset and the New Chemicals Program

The regulation of renewable chemicals is a de facto duplicative process due to the way in which EPA has chosen to interpret TSCA and implement its regulatory authorities. By law, EPA must regulate both the microbe that produces the chemical as well as the chemical itself. This affects how EPA chooses to name "Class II" chemicals, and whether or not EPA considers a chemical to be "new" and therefore subject to regulatory review.

The reason the process is duplicative is because EPA will not decouple the regulation of the chemical from either the biobased feedstock or the microbe used to produce it, even though this has no impact on the risk posed by the chemical, and even though this approach has been made possible for other Class II chemicals produced using petroleum feedstocks and traditional chemistries through use of the Soap and Detergent Association (SDA) Nomenclature System. EPA's approach also results in renewable chemicals being reviewed not only at the point of manufacture, but at each point in the value chain where they are used as intermediates in the development of new products and chemical derivatives. The time these reviews take and the increased cost of this to the downstream customer and the consumer becomes prohibitive, and favors the adoption of existing chemistries instead of the renewable counterpart or alternative. This duplicative process can occur even when the renewable chemical is **identical** to the existing chemical - which acts as an obvious deterrent to the use of biotechnology in the innovation and manufacture of chemicals. This, in turn, threatens the growth of jobs and the development of innovative new feedstocks, products and technologies. In addition, EPA's approach has resulted in numerous redundancies on the TSCA inventory, of chemicals with different Chemical Abstracts Service (CAS) Registry Numbers but which are in fact identical.

When this duplicative regulatory approach is coupled with the change in direction EPA is taking with their implementation of the new chemicals program, this burden becomes even more disproportionate and creates a barrier to commercialization. EPA has inexplicably increased the regulatory burden on bringing new chemicals to the market. This not only impacts innovation by larger companies, but has amplified the impact of their current duplicative approach on small to medium sized companies. The smaller the company the disproportionately greater the resources they require to address the regulatory burden relative to their sales earnings. It also places these companies at a significant competitive disadvantage compared to larger companies. Any additional staff is minuscule for a large multinational which employs thousands, but it is a significant proportion of the costs to a small company, particularly if their product has not entered the market and they have not developed a revenue stream, or, as is typical of smaller companies, they have a less diversified portfolio of commercialized product lines to rely on for income..

BIO has repeatedly described and commented on this issue to the EPA. EPA should reform the way in which it names chemicals in accordance with TSCA as amended to reduce the unnecessary regulatory burden the current approach creates. When a company can

[28] Presidential Executive Order Enforcing the Regulatory Reform Agenda.(n.d.). In accordance with Executive Order 13777, "Enforcing the Regulatory Reform Agenda," 82 Fed. Reg. 12285 (2017-04107) (February 24, 2017), https://www.federalregister.gov/documents/2017/03/01/2017-04107/enforcing-the-regulatory-reform-agenda

demonstrate that a chemical produced from a new or renewable feedstock is identical to an existing chemical on the TSCA Inventory of Chemicals, regardless of the feedstock from which it is derived, EPA should not define that chemical as "new." EPA needs to decouple the risk review of the chemical from the risk review of the feedstock, and needs to expand the feedstocks that that can avail of the SDA nomenclature system in line with its original intent of creating a feedstock neutral approach to naming alkyl ranges.

IV. CONCLUSION

We respectfully urge EPA to work with us and other stakeholders to make the recommended changes laid out in our comments. EPA can make good on the promise of the RFS with a commitment to stable implementation of the program in line with statutory requirements. This will enable EPA to get the program back on track and can help drive the growth of the advanced and cellulosic biofuels industry in the manner that Congress intended and, indeed, required. Furthermore, EPA can support the renewable chemicals industry by recognizing the important role of biotechnology in modern manufacturing and rethink current policies which create barriers to its use in commerce. Regulations which do not discriminate against advanced and cellulosic biofuels, and renewable chemicals will spur the development of new investment, innovation, and job creation while enhancing energy and national security and increasing America's competitive advantage in this sector. We look forward to working with you toward these goals.

Sincerely,

Brent Erickson, Executive Vice President
Biotechnology Innovation Organization (BIO)