



December 20, 2011

The Honorable John P. Holdren, Ph.D.
Assistant to the President for Science and Technology, and
Director, Office of Science and Technology Policy
The White House
bioeconomy@ostp.gov

Re: Office of Science and Technology Policy. Request for Information: Building a 21st Century Bioeconomy. [Docket No. 2011-26088] 76 FR 62869. October 11, 2011.

Dear Dr. Holdren:

CropLife America (CLA) is pleased to provide comments to the Office of Science and Technology Policy regarding building the 21st century Bioeconomy. CLA represent the companies that develop, manufacture, formulate and distribute crop protection chemicals and plant science solutions for agriculture and pest management, including products used as and in conjunction with plant incorporated protectants. CLA member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American producers. CLA and its predecessor organizations recently celebrated a 75th anniversary.

CLA lauds the development of a National Bioeconomy Blueprint to move ideas from the lab to market and detail the Administration-wide steps to harness biological research innovations to address national challenges in health, food, energy, and the environment while creating high-wage high-skill jobs. We agree that biological research lays the foundation of a significant portion of our economy, especially agricultural and modern farming production. By better leveraging our national investments in biological research and development, the Administration will grow the jobs of the future and improve the lives of all Americans. We hope that the Blueprint is successful in focusing on reforms to speed up commercialization and open new markets, strategic R&D investments to accelerate innovation, regulatory reforms to reduce unnecessary burdens on innovators, enhanced workforce training to develop the next generation of scientists and engineers, and the development of public-private partnerships.

Global Challenges Require Robust R&D-To-Market Strategies

The crop protection industry is committed to helping farmers produce an affordable and sustainable supply of food to help feed a hungry world and modern agricultural research is vital to this effort.

- Globally, over 900 million people - one-sixth of the world population - suffer from malnutrition. Agricultural output *has to double in the next 20-30 years* in order to feed the world's population, which the United Nations predicts will grow by 1.7 billion more people by 2030. To meet the global challenges of food production and security, high-yield production of biotech crops using crop protection products will continue as the primary agricultural practices.
- The early adoption of crop protection products and the recent rapid adoption of biotech crops have advanced modern agriculture through use of no/reduced tillage production systems and integrated pest management. These approaches provide both economic and environmental benefits including reduced soil erosion and improved soil moisture levels.
- The crop protection industry makes a significant investment in research and development. Intensive scientific research and robust investment in technology during the past 50 years helped farmers double food production with out a change in the footprint of total cultivated farmland. Crop protection is one of the most research-intensive industries in existence, with companies investing about 12% of their turnover in research and development (R&D). The top 10 plant science companies invest an estimated \$3.75 billion in R&D per year to discover, conduct tests to ensure safety and develop new products.
 - Industry estimates that average research and development costs for one new crop protection product to reach commercialization are \$256 million (a 40% increase in the U.S. and Europe over the past decade), and that the process takes an average of ten years (CLA and European Crop Protection Association, 2010. The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000 and 2005-2008. R&D Expenditure in 2007 and expectations for 2010. Final Report, January 2010).
- The rigorous science-based regulation of crop protection and agricultural biotechnology serves as the foundation for the safe use of these technologies. These regulatory processes, and subsequent policies, must continue to be grounded in science if we are to approve new products and advance modern agriculture.

Regulatory Reform is Needed in Crop Protection

CLA has addressed U.S. Environmental Protection Agency regulatory reform separately in comments specific to pesticide registration and submitted to Docket No. EPA-HQOA-2011-0156. In the same docket, CLA was also party to comments from the chemical industry submitted from a coalition led by the American Chemistry Council which addressed several important general regulatory issues. CLA is also a member of the Endocrine Policy Forum, which has submitted more detailed comments to EPA-HQOA-2011-0156 with special relevance to EPA's Endocrine Disruptor Screening Program.

CLA urges reform of several pesticide regulations to stimulate lab-to-market for the benefit of agriculture and the crop protection industry. Each of the following regulatory issues is evidence of duplicative regulation, and wasteful use of government resources. Further, these proposed regulations provide NO additional environmental protection.

1. The permitting plan for aquatic pesticide use, proposed by EPA's Office of Water under the National Pollutant Discharge Elimination System (NPDES) and subject to the Clean Water Act, is duplicative of the registration process for pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).
2. The Endangered Species Act (ESA) consultation process for pesticides conducted by the National Marine Fisheries Service and the U.S. Fish and Wildlife Service is also largely duplicative of the registration process for pesticides under FIFRA.
3. The Federal Food, Drug and Cosmetic Act (FFDCA) §408(i): "Data and information that are or have been submitted to the Administrator under this section ... in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and *to exclusive use and data compensation* to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act." (Emphasis added.) This provision, enacted as part of the Food Quality Protection Act (FQPA) of 1996, was primarily intended to provide intellectual property protection for data specifically required under FQPA to support inert ingredients in pesticide products. Lacking implementing regulations, the procedures for protecting such data are still uncertain and unclear, leaving registrants without adequate means of assuring they are complying with the law. 4. 40 CFR Part 180 contains voluminous information on the specific tolerances and tolerance exemptions for individual pesticide chemicals on the various food and feed commodities. The rules codified here are frequently modified, added to, and updated. Reformatting the information could make it much more useful and usable for stakeholders.
4. EPA's Integrated Risk Information System covers pesticide active ingredients, along with other chemicals. With respect to pesticides, the work it encompasses and the information included are largely duplicative of what the Office of Pesticide Programs accomplishes in the course of regulating pesticides.
5. All Pesticide Registration (PR) notices should be evaluated to determine which remain in effect; which need changes, updating, or replacement; and which should really be

codified as rules in the Code of Federal Regulations. Some specific examples, including proposed PR notices that have not been finalized:

- a. Spray drift
- b. Prohibited words and product names on pesticide labels
- c. Reporting of nanomaterials in pesticide products

6. Standard Operating Procedures for review of pesticide registration applications (across the range of PRA categories, and more) need to be established and improved.

Standardize how the applications are handled, so EPA reviewers know what to do, and can handle applications consistently and more efficiently. Make the SOPs transparent to registrants so they can prepare better and submit more complete and accurate applications. Encourage better, more frequent, more consistent communication between reviewers and applicants. Do not leave the bureaucratic process and decision making to the whims and capriciousness of individual reviewers, without adequate management supervision.

7. Regarding information transfer, there are several improvements to be made:

- Data call-ins are often poorly handled; EPA fails to hold up its side of the obligation (especially timing and decisions), yet yields no leniency to the registrants to make up for the Agency's tardiness and failings, significantly increasing the burden and stress on the registrants.
- Test orders issued under FQPA – need clear rules and procedures for their use, or they should be placed directly under FIFRA data call-in regulations.
- Pesticide registration forms could be improved significantly as a joint project between registrants and regulators.
- Information Collection Requests – greater education of stakeholders about their importance and the opportunity for meaningful input.

8. Regarding procedural clarification, there are several improvements to be made:

- Establish clearer procedures within the Administrative Procedures Act for input to the regulatory process from the variety of internet forums, media, and possibilities. These are being handled too casually and chaotically.
- Clarify the roles and rights of state regulators in EPA regulatory processes, with respect to the Federal Advisory Committee Act, and the corresponding rights and roles of other stakeholders.
- Unnecessary delays in pesticide regulatory decisions made under FIFRA undermine the intellectual property protections that applicants and registrants are afforded under patent statutes and regulations, as well as the exclusive use and data compensation provisions of FIFRA. The delays discourage innovation and penalize innovators.

Regulatory Reform is Needed in Agricultural Biotechnology

CLA urges reform of agricultural biotechnology regulatory processes to stimulate lab-to-market for the benefit of agriculture and industry's technology providers.

1. During the past decade, APHIS has reduced the types of small-scale field trials that may be conducted under 30-day notification procedures, and it more recently proposed to terminate the notification system altogether and require full permits for all field trials. The agency has also required breeders to conduct additional tests to measure things only tangentially related to safety and to include the analyses in petitions for deregulation. Consequently, the length of time it takes for APHIS to approve field trial permits and to grant petitions for non-regulated status has been rising dramatically. These increasing and costly delays are particularly burdensome for small firms with high capital costs and for public sector and non-profit institutions that rely on grants to finance their research. But these delays impact all firms in the industry, and they jeopardize the new product pipeline with significant financial and regulatory uncertainty.

2. Currently, the Plant Protection Act merely requires APHIS to act on petitions for non-regulated status “within a reasonable time,” but does not specify a deadline for making decisions. Regulations promulgated by APHIS stipulate that the agency may take up to 120 days to review applications for field trial permits and up to 180 days to review petitions for non-regulated status. However, APHIS frequently exceeds these periods, often taking three or four times as long. Recently, for example, APHIS took approximately 500 days to review each of two field trial permit applications that were eventually granted in 2008 and 2009.

Similarly, APHIS has frequently taken several years to grant deregulated status to new biotech varieties, with recent highs exceeding four years. The average review time for deregulation petitions submitted prior to 2000 was a mere six months, and only five of the 51 deregulations granted in that time period took longer than 8 months. In contrast, the average review time for petitions submitted from 2000 to 2011 was a stunning 20 months, and the review time for five of the last eight deregulations granted exceeded 30 months. Currently, there are a dozen such petitions outstanding that have been awaiting an APHIS decision for two years or longer. Yet, while a number of petitions have been withdrawn by sponsors for a variety of reasons – typically having to do with concerns about the crop’s potential for commercial success – APHIS has not once denied a deregulation request. This is a testament to the proven overall safety of new biotech crop varieties.

These concerns are not new, nor are American growers the first to raise them. As long ago as November 2004, at a USDA-sponsored workshop on “Public Research and the Regulatory Review of Small-Market (Specialty) Biotechnology-Derived Crops,” several participants expressed their frustration that review times had begun to grow increasingly lengthier beginning around the year 2000. And participants at a January 2007 workshop jointly sponsored by APHIS and the Pew Initiative for Food and Biotechnology agreed that developing a condensed and predictable timeline for APHIS deregulation decisions was essential for “streamlining and fine-tuning the regulatory process.” The published summary of the latter workshop proceedings specifically recommended that APHIS

“[k]eep the timeline and process from submission to decision as short as possible. Some urged that the process be limited to one growing season.”

If the developers of new biotech crop varieties – whether they are large or small firms, public sector institutions, or non-profit organizations – do not have confidence that their applications will be reviewed and acted upon in a timely manner they will become less likely to make the investments in new products that have kept American farmers highly productive and internationally competitive. If instead, developers are able to secure more rapid approvals in other countries such as Brazil and China, and reach the market first in those countries, American farmers will be put at an increasingly large disadvantage compared with their international competitors. Additionally, global food insecurity threatens our rapidly growing world population.

3. In order to improve the permitting and deregulation process and ensure that APHIS follows its statutory obligation to base decisions on sound science, congress should (1) establish a statutory limit on APHIS review periods with judicial review of failure to meet such review periods and (2) direct the executive branch to update the federal regulatory framework to streamline regulatory review processes.

In May 2011, Rep. Stephen Fincher and two co-sponsors introduced a bill – the Expediting Agriculture Through Science Act (H.R. 2031) – that would establish a 180-day time period during which APHIS must make a determination on petitions for non-regulated status. The bill would provide up to two 30-day extensions, but the petition would be automatically approved if APHIS has not acted on it by the end of the combined, 240-day period. In addition, for any such petition that APHIS denied, the bill would require a “written, clear, and comprehensive” explanation for its rejection.

CLA therefore encourages the congress and the administration to consider legislation like this that establishes a maximum review period for both field trial permit requests and petitions for non-regulated status. One or more specified extensions could be added to accommodate APHIS time constraints in addressing requests and petitions that pose special challenges, as the Fincher bill proposes. But it is essential that the total time allotted for agency review be established in legislation, so APHIS cannot inappropriately drag out its review beyond a reasonable time period. Stakeholders understand that APHIS decisions would need to be legally defensible, and this paper does not recommend legislation that would weaken USDA’s legal defensibility of a petition in question.

4. Regarding final petition approval by the Secretary of Agriculture, in order to ensure the allotted review times, CLA recommends creating a meaningful and predictable expectation for applicants. Statutory language should grant automatic approval for any requests or petitions on which the Secretary has not made a determination by the end of the allotted time. The “clock” should begin once the Environmental Assessment is completed by APHIS and the USDA Office of General Counsel determines that deregulation may proceed. In other words, in this phase, this allotted time would be triggered when the petition is awaiting the Secretary of Agriculture’s signature of approval for deregulation. In effect, this serves to preserve the scientific integrity of the regulatory review, and would prevent the politicization of a petition deregulation by

discouraging the Office of the Secretary from “sitting on” a petition due to non-scientific, non-risk based considerations.

5. In addition, CLA urges that in order to prevent APHIS from inappropriately denying field trial permit requests or deregulation petitions in a manner intended to circumvent the allotted time periods, legislation should require the agency to provide applicants with a written, clear, and comprehensive explanation for the agency’s determination. This explanation should have to provide in substantial detail the agency’s scientific rationale for continuing to treat the regulated article as a plant pest.

American agricultural producers, and biotechnology research & development companies alike are deeply concerned by the shaky future of the U.S. as a leader in this innovation. Due to signals from the U.S. government, stakeholders such as these lack the regulatory certainty to continue investing in the U.S. with confidence in its regulatory system.

Agricultural Research Drives Innovation Through a Trained Workforce

CLA urges the Administration to increase the federal funding of food and agricultural research, extension and education and create new opportunities for public-private partnerships. There must be adequate investment in research and training of future agricultural experts to enhance industry lab-to-market approaches. Scientific research forms the cornerstone of modern and safe products that have been registered through a solid, safe, science-based regulatory process. Industry has massive investments in crop protection and agricultural biotechnology research; but public funding is needed as well, to fully leverage research opportunities and provide solutions to growers. Therefore, CLA believes that federal funding for food and agricultural research, extension and education represents a top national priority and a necessary long-term national commitment. In this regard, we agree with the comments submitted to this docket by the National Coalition for Food and Agricultural Research (NCFAR). CLA recognizes that regulatory reform and policies developed today must drive investment and prioritization of research and education, which in turn, stimulates future innovation through new plant and pest biology and crop protection technologies, as well as to train future scientists and employees for agriculture.

In conclusion, modern agriculture must advance based on the use of new technologies in crop protection and agricultural biotechnology. These technologies are hampered by duplicativeness and inefficiencies in regulation--we must strive to access good science through improvements in regulatory processes. Food security through modern agriculture is critical to delivery of human health care, reduction in hunger, and increasing energy supply, all in a sustainable manner with minimal negative impact on the environment. CLA is proud of the long record of success by the science-based crop protection industry which will continue to allow not only American farmers, but consumers world-wide to share in enhanced quality of life and health, through more affordable and sustainable supplies of food, feed, fiber, fuel and industrial products -- benefits and new opportunities offered by modern agriculture.

CLA urges the OSTP to address the limitations in regulation of products in crop protection and agricultural biotechnology. To inhibit advancement from lab-to-market of these technologies, given the current global grand challenges, ignores the current success of modern agriculture and avoids the honest analysis toward solutions for both U.S. and international food security.

Dr. Holdren, CLA offers our assistance to you as the OSTP embarks on development of the Blueprint. Please do not hesitate to contact us as leaders in advocacy of science-based innovation in agriculture. We appreciate the opportunity to comment. If there are questions, please do not hesitate to contact me ([REDACTED]; [REDACTED]).

Sincerely,

A handwritten signature in cursive script that reads "Barbara P. Glenn".

Barbara P. Glenn, Ph.D.
Vice President
Science & Regulatory Affairs