ABSA INTERNATIONAL
1200 Allanson Road • Mundelein, IL 60060-3808 • 866-425-1385 • Fax: 847-566-4580 • E-mail: info@absa.org • Web Site: www.absa.org

November 12, 2015

National Science and Technology Council
Emerging Technologies Interagency Policy Coordination Committee
Office of Science and Technology Policy
1650 Pennsylvania Avenue NW
Washington, DC 20504

Re: Docket No. FDA-2015-N-3403

Dear Members of the National Science and Technology Council,

The American Biological Safety Association (ABSA) International greatly appreciates this opportunity to provide public comments regarding the federal government's request to clarify roles and responsibilities described in the Coordinated Framework for the Regulation of Biotechnology. We believe that there are significant gaps in regulatory oversight of products created through the use of biotechnology and synthetic biology. An assessment of these biological products and the processes used to create them is long overdue. Regulatory gaps include issues surrounding the safety of the staff working with these products, the health and safety of consumers and the general public who may be exposed to these products, and the implications to the natural ecosystems with the release (intentional or unintentional) of these products into the environment. The specific request identified in the October 6, 2015 Federal Register Notice (Docket No. FDA-2015-N-3403) by the Science and Technology Policy Office was to answer one or more of the five questions listed in the Notice. Our responses are provided below after each question:

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

   - The United State Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) is responsible for protecting agriculture from pests and diseases. Accordingly, USDA APHIS regulates

organisms and products that are known or suspected to be plant pests or to pose a plant pest risk, including those that have been altered or produced through genetic engineering. If there is no evidence showing that a plant has characteristics of a plant pest, APHIS no longer has jurisdiction. Also, genetically modified plants created through the use of a gene gun are not regulated. Lastly, genetically modified insects that are not plant pests are also not regulated. As such, USDA APHIS should regulate all genetically modified plants and insects.

- The Food and Drug Administration (FDA) does not regulate food derived from genetically engineered crops (e.g., corn and soybeans). The current version of the Coordinated Framework regulates the product but not the process used to create them. Genetically modified foods are treated as ordinary foods unless they contain substances or demonstrate attributes that are not usual for the product. These criteria are subjective and should be strengthened. Additionally, the FDA should expand its oversight to include the processes used to create the genetically modified foods. Such oversight should include biosafety levels and containment practices for the work and clear and transparent processes for field releases and trials.
- The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) only applies to institutions which receive federal funding. Organizations conducting recombinant and synthetic nucleic acid research which do not receive federal funds are not regulated by the Federal Government. This represents a significant gap with regards to recombinant and synthetic nucleic acid research safety and regulation. All research with recombinant or synthetic nucleic acid molecules should fall under the requirements listed in the NIH Guidelines and other federal requirements.
- The current framework should be simplified to clearly show which agency has responsibility for each biotechnology product. When a new biotechnology product is produced and it is unclear which agency has oversight, a joint panel with members from each agency should convene, with members of the public, to decide which agency will provide oversight.
- A significant benefit to the general public would be to require manufacturers of biotechnology products to develop a publicly available Safety Data Sheet if it will be used for commercial purposes. The process would be similar to the creation of Safety Data Sheets under the Occupational Safety and Health Administration (OSHA). A summary about OSHA's Safety Data Sheets is available online at https://www.osha.gov/Publications/OSHA3514.html. Having a Safety Data Sheet in place for biotechnology products would be in keeping with global harmonization of health hazard information. The Public Health Agency of Canada also has examples of Safety Data Sheets that were created for specific pathogens. These documents are available online at http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php. If manufacturers are not required to produce these Safety Data Sheets, it may be helpful for the responsible regulatory agency to develop recommendations for the safe handling of these organisms.
- A significant public benefit would be for biotechnology products to be assigned risk groups which categorize the hazard associated with the product or a Biological Safety Level (BSL) appropriate for safe work with the product. Currently, the following resources exist to categorize materials according to Risk Group and assign an

appropriate BSL: The NIH Guidelines, Biosafety in Microbiological and Biomedical Laboratories (BMBL), and ABSA International's Risk Group Tables (https://my.absa.org/tiki-index.php?page=Riskgroups). If regulatory agencies provide these classifications, it would increase consistency within the regulated community and avoid confusion which can arise form inconsistent classification by vendors. One such example of inconsistent classifications arises from the American Type Culture Collection (ATCC). ATCC currently notes recommended biosafety levels on the safety information that they provide to end users of their products, which can be infectious agents. This information is available on the ATCC website at http://www.atcc.org/en/Documents/Learning_Center/Material_Safety_Data_Sheets.aspx. However, their website states that his classification is for shipping only and the recipient organization is responsible for assigning a BSL for use at their institution. The Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures also provides the Risk Group classification for all materials provided through the DSMZ website: https://www.dsmz.de/catalogues/catalogue-microorganisms/safety-instructions.html. If the current definitions and requirements for Biological Safety Levels cannot cover emerging technologies, regulatory agencies should advise on appropriate containment and handling procedures by developing an analogous containment structure.

- Organizations creating synthetic biological products should consider employing or consulting with qualified biological safety professionals regarding questions associated with biorisk management considerations (e.g., biosafety, biosecurity, personnel exposure, environmental release, etc.). ABSA International considers access to credentialed biosafety professionals (e.g., Registered Biosafety Professionals and Certified Biological Safety Professionals) to be the gold standard to measure a biological safety professional's qualifications. For example, the National Institutes of Health's (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) require that a Biological Safety Officer (BSO) be appointed if an entity performs certain research covered under the NIH Guidelines. Specifically, the NIH Guidelines state:

  - "The institution shall appoint a Biological Safety Officer if it engages in large-scale research or production activities involving viable organisms containing recombinant or synthetic nucleic acid molecules." (See Section IV-B-3-a of the NIH Guidelines.)
  - "The institution shall appoint a Biological Safety Officer if it engages in recombinant or synthetic nucleic acid molecule research at BL3 or BL4. The Biological Safety Officer shall be a member of the Institutional Biosafety Committee. (See Section IV-B-3-b of the NIH Guidelines.)

  The NIH Guidelines also define the roles and responsibilities of the Biological Safety Officer in Section IV-B-3-c through IV-B-3-c-5. An additional requirement should be the inclusion of a credentialed biological safety professional and an institutional review entity (e.g., Institutional Biosafety Committee) to review production and use of biotechnology products.

- A significant benefit to the general public would be to have a simple, easy to use reference library or database that described the roles of each regulatory agency providing oversight of biotechnology products.
- A significant benefit to the general public would be to have a centralized government website where members of the public could go to determine if a biotechnology product was regulated and by which agency (or agencies).

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?**

   - Although the coordinated framework was designed to evaluate the product and not the process, it is often the process that is the most hazardous component of the creation of the biotechnology product. Regulatory oversight should consider the processes by which these products are created. The process must consider the biosafety level of the research and production activities taking place; and this information should be readily available to public health providers and emergency responders.

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?**

   - A significant benefit to the general public would be to require a Safety Data Sheet be created for each new biotechnology product. The Safety Data Sheet would list the safety and security precautions for the novel product.
   - A significant benefit to the general public would be to have a centralized public website (containing charts / flow charts that help to define the responsibilities of different agencies) where members of the public could go to determine if a biotechnology product was regulated and by which agency (or agencies). This website could also post examples of possible products that would be regulated by each agency, how the product is regulated, and an explanation of why the agency has authority over that particular product.
   - A significant benefit to the general public would be to have a centralized public website where individuals creating or using new biotechnology products could visit to determine if their product was regulated. For example, USDA APHIS has created an excellent website which assists organizations in determining when import permits are required or materials which it regulates and provides excellent guidance on how to prepare documentation for shipments which are not regulated (https://www.aphis.usda.gov/wps/portal/aphis/ourfocus/importexport). A similar website could be developed to assist individuals in navigating different classes of biotechnology products and find the appropriate regulations and agencies which are responsible for those products.
   - A significant benefit to the general public would be for each Agency to develop a training program for users (e.g., researchers, Do-It-Yourself practitioners, Garage

Scientists, members of the general public, etc.) of biotechnology products that discusses the safety and security implications of new biotechnology products.

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 is an excellent paper from the J. Craig Venter Institute titled, "Synthetic Biology and the U.S. Biotechnology Regulatory System: Challenges and Options" that discusses some of the pitfalls of the current coordinated framework. The paper is available at http://www.jcvi.org/cms/fileadmin/site/research/projects/synthetic-biology-and-the-us-regulatory-system/full-report.pdf.
   - The Wilson Center and Alfred F. Sloan Foundation, through the Synthetic Biology Project, provided comments supporting revisions to the Coordinated Framework. The announcement and related documents are available at https://www.wilsoncenter.org/publication/the-dna-the-us-regulatory-system-are-we-getting-it-right-for-synthetic-biology.

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?**

   - A panel of scientists, biosafety professionals, biosecurity professionals, and community members should be established to review the safety and security implications of new biotechnology products in order to provide the necessary knowledge and technical expertise to guide the various regulatory agencies. For example, there is a Chemical Safety Board that can be dispatched to investigate incidents regarding hazardous chemicals. Thus, a Biorisk Management Board should be established to evaluate biotechnology products and investigate issues that arise from the use of those products.
   - All research activities that involve the creation of biotechnology products need to be reviewed by a credentialed biological safety professional and a properly constituted institutional review entity (e.g., Institutional Biosafety Committee). This is not currently a requirement at non-federally funded organizations and should be remedied by requiring this oversight.

Sincerely,

Melissa Morland

Melissa Morland, MS, MBA, RBP, CBSP, SM (NRCM)
President, ABSA International