November 13, 2015

U.S. Food and Drug Administration
U.S. Environmental Protection Agency
U.S. Department of Agriculture

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

The 23 undersigned investors and investor advocates, collectively representing $23.7 billion in assets under management, appreciate the opportunity to comment on the federal government's initiative to revise the coordinated framework for the regulation of biotechnology. The current Coordinated Framework, which was created in 1986 as a guidance document, has failed to adequately serve investors and the companies in which we invest.

We urge the FDA, EPA, and USDA to develop and institute strong, mandatory federal regulations of the products of biotechnology, founded on the following principles.

1. Clear and enforceable regulations that apply to all organisms developed using genetic engineering (GE) processes, including genomic editing and RNA interference.
2. Regulation of the broader range of risks of the products of biotechnology, including long-term health impacts, pesticide residues on food, and direct and indirect environmental impacts;
3. Improved regulation of non-GE crop contamination, ensuring that the cost of preventing or paying for contamination are borne by the users of the product, not the companies impacted by contamination.
4. Mandatory labeling of GE food products.

Clear and enforceable regulations that apply to all organisms developed using GE processes

While the FDA currently regulates GE foods under the Generally Recognized as Safe (GRAS) provisions of the Food Drug and Cosmetics Act (FFDCA), this voluntary system allows industry to determine the test type and methodology to demonstrate GRAS, without sufficient FDA oversight of methods or outcomes. The limited and unstandardized tests performed do not instill public confidence in the technology or provide adequate safety. As a result, the market has experienced widespread consumer boycotts, state ballot initiatives that have broken spending records, and brand reputational damage, creating substantial uncertainty in the food industry. Agency-mandated long-term safety tests are necessary to instill public confidence and de-escalate the public relations campaigns waged by interest groups.

Also, as currently constituted, companies who undertake thorough and comprehensive testing may be put at a competitive disadvantage to companies that use inadequate testing methods to demonstrate GRAS. This creates the undesired outcome that the safest companies and technologies are likely to become non-competitive in the marketplace, while consumers are insufficiently protected. As investors, we request that a clear and comprehensive regulatory system be developed that will enable a stable and fair marketplace that consumers trust.

We also seek consistent enforcement of such regulations across the industry. The gaps in the current framework have led the USDA to decline to regulate crops developed with newly-developed GE processes, or older processes that evade regulation, such as glyphosate-resistant Kentucky Bluegrass. Adoption of this new GE plant is expected to exacerbate glyphosate-resistance and glyphosate overuse, instigate consumer backlash and litigation, and could produce other unintended impacts on public health and the environment. Biotechnology products elevate risk and uncertainty for companies throughout the marketplace, thus it is necessary that all products be regulated, regardless of the genetic engineering process that was used to develop them.

Regulation of the broader range of risks of the products of biotechnology

The USDA's current risk assessment process does not adequately account for direct or indirect environmental impacts, due to a narrow interpretation of the plant pest provisions of the Plant Protection Act of 2000; the lack of detailed regulations under the Act; and the lack of implementation of the broad authority provided by the Act to regulate engineered plants as noxious weeds. Similarly, the EPA has relied on microbial testing guidance, instead of assessing the indirect environmental risks appropriate for plants. Under this framework, the adoption of new GE crops has led to an epidemic of glyphosate-resistant "superweeds" and non-GE crop contamination. In response to superweeds, farmers are using even more glyphosate, and other toxic herbicides. In addition, the EPA has continually increased the allowable limits of glyphosate on crops to accommodate for new GE varieties through an opaque process that does not provide a history of regulatory decisions and changes.

The current regulatory framework has been unable to prevent herbicide-resistant weeds, increased herbicide use, or increased pesticide residues in agricultural products, creating systemic risk for the food sector. The lack of sufficient impact analysis in this regulatory system has facilitated the increasing dependence of the agricultural system on mono-crop industrial systems that deplete topsoil, decrease crop diversity, and increase frontline and fenceline community exposure to pesticides. This unnecessary systemic risk decreases long-term shareholder value throughout the food industry by increasing future costs and promoting an inequitable distribution of risk. Exposure to risk by individual companies includes legal liability for a variety of impacts, such as loss of organic or non-GMO certification from GE crop contamination, and excessive pesticide residue on food from direct applications of glyphosate to herbicide-resistant crops. Companies also face reputational risk from impacts that occur throughout the supply chain.

Improved regulation of non-GE crop contamination

Currently, the costs of preventing and paying for contamination are borne by companies impacted by contamination, directly and through their supply chains, rather than the companies using biotechnology products. Based on information from 268 farmers from 17 U.S. states, more than 30 percent of farmers seeking to grow organic crops reported that unintended GMO presence has been found or suspected on their farms, according to a report by Food & Water Watch and the Organic Farmers' Agency for Relationship Marketing. As of January 2011, there were more than 300 reported cases of contamination incidents worldwide in which genetically modified seeds or crops were found in fields of products for which they were not intended. Some of these cases resulted in major worldwide trade disruptions and have cost farmers, food processors, and supermarkets billions of dollars. The companies that own the engineered seed should be responsible for paying for the cost of harm from contamination. Those that desire to keep their crops free of GE contamination should not be responsible for either preventing it by

employing methods that add cost or reduce productivity, or pay for the results of contamination, as is currently the case.

Mandatory labeling of GE food products

More than 90% of Americans support GMO labeling, according to several polls by national news and research organizations over the last several years (e.g. New York Times, 7/7/13, "Strong Support for Labeling Modified Foods"). Consumers' strong preference for labeling has led to the widespread adoption of third-party, non-GMO certifications, public controversies about whether or not certain companies are using GE ingredients, lawsuits to companies marketing "natural" products that incorporate GMOs, and an emerging patchwork of consumer-driven state laws regarding labelling. Third-party certifications in particular push the cost of labeling onto companies not using biotechnology products, rather than the developers and users of this emerging technology. Mandatory federal labeling would efficiently and accurately provide consumers with the transparency consumers are demanding, while creating fairness for companies by removing labeling costs from non-GE companies.

We call on the FDA, EPA, and USDA to develop a comprehensive regulatory framework that addresses the environmental and economic impacts of GE organisms. Such a system will not only better protect consumers, but will ensure a consistent and fair playing field for companies which increases certainty and reduces both short- and long-term risk.

Signed,

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