March 18, 2020

The Coalition for Responsible Gene Editing in Agriculture
Center for Food Integrity
2900 NE Brooktree Lane
Gladstone, MO 64119

*Submitted electronically*

Dear Sir or Madam:

On behalf of the American Soybean Association (ASA), I write to provide comments on the Coalition for Responsible Gene Editing in Agriculture's (the Coalition) draft Framework for the Responsible Use of Gene Editing in Agriculture (the Framework). ASA represents all U.S. soybean farmers on domestic and international policy issues important to the soybean industry and has 26 affiliated state associations representing 30 soybean-producing states. We appreciate the work and mission of the Coalition in drafting the Framework and welcome the opportunity to provide feedback.

As the Coalition noted in the introduction to the Framework, gene editing presents a significant new opportunity for the food and agriculture community. Whether improving production and more sustainability managing inputs; offering consumers improved quality, nutrition, and variety; developing new uses for agricultural feedstocks; or better enabling producers to feed a rapidly growing global population, there are few challenges facing agriculture and food production that this powerful tool cannot help to address. To that end, we share the Coalition's goal in helping consumers and other stakeholders see the value of this tool and trust in its use.

However, it is vital that we learn from the lessons of the past. In steps to proactively build public trust in this tool, ASA believes the Coalition is working to address an important takeaway from the use of traditional biotechnology over the past 30 years. However, as we will discuss below, we are concerned that as drafted, the Framework may inadvertently repeat or magnify other challenges that continue to confront traditional biotechnology.

**Safety and Quality**

The Coalition has chosen to focus the Framework "on uses of gene editing that produce variation in native alleles that could occur or be achieved through selective breeding between species that are sexually compatible." While the Framework acknowledges that these are not the only uses of gene editing, we understand the calculated decision the Coalition seems to have made in focusing on applications of the technology where there seems to be growing consensus among domestic and international regulators that, 1) these products are very low risk and pose no unique risk when compared to traditionally bred plant varieties, and 2) are thus likely to face reduced

regulatory scrutiny. The Coalition itself states that, "because of gene editing's precision, the likelihood of unintended changes to the DNA with negative impact is much less with gene editing than some other breeding techniques." ASA shares this perspective and believes it is backed by sound science.

With that in mind, we find it concerning that the tone of the Framework is as focused on the safety of gene edited products to the degree that it is. The "Safety and Quality" section of the guidelines is the single longest commitments section of the entire Framework. Even more confusing is that the Framework states repeatedly that the Coalition is operating under the assumption researchers and developers are complying with all applicable state, local, and federal laws and regulations, which should further mitigate any safety concerns.

The average American consumer is increasingly removed from agriculture and food production, and has a difficult time placing weight and value on the overwhelming volume of available information about food. Combatting misinformation and misunderstandings is very difficult. Regardless of whether the Coalition admits at the outset of the Framework that gene editing is incredibly safe, the immense focus on safety as an area of concern could easily encourage a narrative to the contrary – a narrative which history has taught us is incredibly challenging to reverse.

**Research and Development**

While the Framework is very thorough, we are concerned that attribute may also establish unintended burdens that could preclude small developers and academics from participating in the market. ASA believes our research and development community is enriched by academics and small developers. They often have deep, personal relationships with farmers and communities across the country, enabling them to partner in conducting their work. This leads to better, more practical research outcomes and applications. Academics and small developers conduct a great deal of basic research, which is then refined into specific commercial agricultural innovations. It is also important to note that they regularly operate with small staffs and shoestring budgets, often supplemented by students and interns. Competition is increasingly fierce for limited grants and private investment dollars, as USDA Economic Research Service data shows relatively stagnant research funding levels since the 1970s[1].

Market participation of academics and small developers is critical for building public trust in gene editing. A 2011 study commissioned by Crop Life International found that bringing a new biotechnology crop variety to market cost an average of $136 million and took approximately 13 years[2]. These costs – including research and development, regulatory, market facilitation, among others – have no doubt inflated since. The magnitude of these expenses has established a significant market barrier for small developers and academics, not to mention limited applications of the technology for specialty and minor use crops where these significant investments are difficult to recoup. This has led to our current market for agricultural

[1] "Agricultural Research Funding in the Public and Private Sectors", U.S. Department of Agriculture-Economic Research Service. https://www.ers.usda.gov/data-products/agricultural-research-funding-in-the-public-and-private-sectors/

[2] "Cost of Bringing a Biotech Crop to Market", Crop Life International. https://croplife.org/plant-biotechnology/regulatory-2/cost-of-bringing-a-biotech-crop-to-market/

biotechnology, which the general public perceives is dominated by large developers specializing in a handful of large market commodities.

The Framework's definition of commercial research indicates it expects its commitments could fall on research taking place in an academic setting in addition to private or commercial research. These commitments could include significant content development, research, and regular website and literature updates; continual, proactive stakeholder outreach; engagement with Framework verifiers on fulfillment of Framework commitments and process feedback; among other expectations. These processes could be repeated multiple times from the research stage to when products enter commerce. While we appreciate that the Framework's rigor is likely an intentional calculation, we encourage the Coalition to carefully consider the burdens this may present.

Such significant commitments for responsible use verification could lead to several scenarios, none of which ASA believes are favorable for the technology or public trust. One outcome is that academics, small developers, and their commercial partners – feeling pressure to achieve a "responsible use" designation – invest significant time, energy and staff resources into Framework compliance, eating into their already tight project budgets. Factoring these costs into research proposals could decrease their competitiveness when seeking investors or applying for grants, leading to whole a new set of market barriers that will limit applications for this new technology. Another possible outcome is that, calculating the cost and burden of Framework compliance, academics and small developers will opt not to participate at all. This would significantly limit participation in the Framework, undermining the Coalition's goal of widespread market transparency and building public trust.

The Coalition states in the Framework's objectives that it aims to be "credible, workable, and affordable." These are laudable goals, but we worry an attempt to overcompensate towards credibility has undermined the Framework's workability and affordability, which can in turn only diminish its ultimate credibility. Whether developing a tiered process for applicants; identifying ways to streamline various requirements within sections; triaging Framework commitments only to those most essential for building public trust; or some other solution, the Coalition should seriously consider the comprehensive burden the Framework places on researchers and developers so as to maximize support and participation.

**Producer and Farm Group Engagement**

Finally, moving forward, we invite greater discourse between the Coalition and producer groups representing America's farmers and agricultural communities. As mentioned, we share the Coalition's goal of building public trust for this new technology, as many of the challenges we face in production, sustainability, and providing high quality products to consumers and end users hinge on access to and support for tools like gene editing.

We appreciate that assembling a document as foundational as the Framework can be daunting, as there are many perspectives to consider. Our intent is to constructively add value to your efforts, having been the primary users of traditional biotechnology for the past 30 years, with many thoughtful insights about what has been positive with legacy technologies and what should be improved as new tools are deployed.

On behalf of America's soybean farmers, thank you for the opportunity to comment, and we stand ready to work with you towards accomplishing these important goals.

Sincerely yours,

/s/

Caleb Ragland
Chairman
Regulatory Advocacy Team
American Soybean Association