

January 19, 2024

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4700 River Road, Unit 98  
Riverdale, MD 20737–1238

*Submitted electronically via Federal eRulemaking Portal*

**RE: Proposed Exemptions: Movement of Organisms Modified or Produced through Genetic Engineering (APHIS-2023-0022-0001)**

Dear Dr. Hoffman,

As groups representing farmers, developers, academic and research institutions, state regulators, retailers, cooperatives, and other stakeholders, we are writing to express our strong, general support for the five proposed exemptions to genetic modifications in plants. USDA’s proposal would exempt additional plant varieties indistinguishable from and pose no greater plant pest risk than varieties developed using conventional breeding, and thus do not warrant continued oversight under 7 C.F.R. Part 340. However, there are scientifically supported improvements that should be made to the proposed exemptions upon finalization, which we discuss further below.

Importantly, these exemptions would allow some in the U.S. agricultural community to access vital new innovations needed to address global food, energy, supply chain security, climate change, and environmental stewardship, among many other challenges facing our society. Unfortunately, however, the proposal still falls short. We urge the USDA-APHIS Biotechnology Regulatory Service (BRS) to swiftly finalize and implement these proposed exemptions with the improvements detailed below, as well as those advocated for in supplemental comments of individual signers of this letter to ensure that all agricultural crops can benefit from these important innovations.

***Benefits of Gene Editing for Food, Agriculture, and the Environment***

We strongly support U.S. agriculture having improved access to innovations in plant breeding via gene editing, as these innovations stand to greatly benefit efforts to productively and sustainably feed, fuel, and clothe a growing global population, as well as offer increased value to consumers. The United Nations projects the planet’s population to approach 10 billion people by 2050. To meet the food and other consumer needs of this growing population, a recent report estimated under the status quo an additional 70-80 million hectares (173-198 million acres) of land would need to be converted to agricultural production by 2030 to avoid greatly exacerbating global food insecurity.<sup>1</sup> For comparison, this is an area slightly larger than the state of Texas. Given the scarcity of additional, highly productive arable land around the world, without improvements in agricultural productivity, converted agricultural lands will likely come from deforestation, as well as transition of wetlands, prairies, and other

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<sup>1</sup> Brennan, Tom, Nicolas Denis, Nelson Ferreira, Amandla Ooko-Ombaka, Pradeep Prabhala, and Stephanie Stefanski. November 7, 2023. *Striking the balance: Catalyzing a sustainable land-use transition*. <https://www.mckinsey.com/industries/agriculture/our-insights/striking-the-balance-catalyzing-a-sustainable-land-use-transition>

environmentally sensitive lands.<sup>2</sup> These outcomes would be catastrophic for climate change and biodiversity.

However, crops developed using new genetic improvement technologies, including gene editing, can help avoid these land conversion worst case scenarios and generally improve environmental outcomes. By making genetic improvements to increase crop yields on lands already in production, it will allow us to meet agricultural production needs without needing to enter significant new areas of land into production.<sup>3,4</sup>

It is important to note these improvements could not only enable direct yield increases but could better protect existing agricultural production from both biotic and abiotic stresses, reducing yield losses. For instance, as climate change places greater pressure on water supplies and reduces precipitation in some regions, gene editing can enhance drought-tolerance in crops.<sup>5</sup> This technology can also improve crop salinity-tolerance as coastal croplands and irrigation sources face greater encroachment from ocean flooding.<sup>6</sup> Gene editing can also be used to develop crop varieties more resistant to pests or to better utilize nutrients, optimizing agricultural uses of pesticides, fertilizer, and other crop inputs.<sup>7,8</sup> In addition, genetic improvements can also enhance the sustainability of crop production through traits that facilitate practices such as no-till and cover cropping. These applications can both increase the productivity of agriculture and improve the sustainability and reduce the environmental impact of agricultural production.

Additional uses of gene editing can develop new varieties that have a direct benefit to consumers. Numerous proof-of-concept and innovations moving toward commercialization can improve the shelf life of agricultural products. This would result in fruits, vegetables, ornamentals, and other goods staying fresh longer, increasing consumer access to nutritious foods and reducing waste.<sup>9</sup> Gene editing can also

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<sup>2</sup> Gibbs, H.K., A.S. Ruesch, F. Achard, M.K. Clayton, P. Holmgren, N. Ramankutty, and J.A. Foley. September 21, 2010. "Tropical forests were the primary sources of new agricultural land in the 1980s and 1990s." *Proceedings of the National Academy of Sciences of the United States of America*. Vol. 107, Iss. 38. <https://www.pnas.org/content/107/38/16732>

<sup>3</sup> Chen, Wenkan, et al. March 25, 2022. "Convergent selection of a WD40 protein that enhances grain yield in maize and rice." *Science*. Vol. 375, Iss. 6587. <https://www.science.org/doi/10.1126/science.abg7985>

<sup>4</sup> Beracochea, Valeria, Margarita Stritzler, Laura Radonic, Emilia Bottero, Cintia Jozefkovicz, Flavia Darqui, Nicolás Ayub, Marisa López Bilbao, and Gabriela Soto. December 8, 2022. "CRISPR/Cas9-mediated knockout of SPL13 radically increases lettuce yield." *Plant Cell Reports*. Vol. 42. P. 645-647. <https://link.springer.com/article/10.1007/s00299-022-02952-0>

<sup>5</sup> Sami, Abdul, Zhao Xue, Saheera Tazein, Ayesha Arshad, Zong He Zhu, Ya Ping Chen, Yue Hong, Xiao Tian Zhu, and Ke Jin Zhou. September 10, 2021. "CRISPR–Cas9-based genetic engineering for crop improvement under drought stress." *Bioengineered*. Vol. 12, Iss. 1. P. 5814-5829. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8808358/>

<sup>6</sup> Wang, Tianya, et al. November 26, 2021. "CRISPR–Cas9-based genetic engineering for crop improvement under drought stress." *Frontiers in Plant Science*. Vol. 12. <https://www.frontiersin.org/articles/10.3389/fpls.2021.779598/full>

<sup>7</sup> Sun, Lin, et al. November 30, 2023. "Construction of Host Plant Insect-Resistance Mutant Library by High-Throughput CRISPR/Cas9 System and Identification of A Broad-Spectrum Insect Resistance Gene." *Advanced Science*. <https://onlinelibrary.wiley.com/doi/10.1002/adv.202306157>

<sup>8</sup> Sathee, Lekshmy, B. Jagadhesan, Pratheek H. Pandesha, Dipankar Barman, Sandeep Adavi B., Shivani Nagar, G.K. Krishna, Shailesh Tripathi, Shailendra K. Jha, and Viswanathan Chinnusamy. June 14, 2022. "Genome Editing Targets for Improving Nutrient Use Efficiency and Nutrient Stress Adaptation." *Frontiers in Genetics*. Volume 13. <https://www.frontiersin.org/articles/10.3389/fgene.2022.900897/full>

<sup>9</sup> Shipman, Emma N., Jingwei Yu, Jiaqi Zhou, Karin Albornoz, and Diane M. Beckles. January 1, 2021. "Can gene editing reduce postharvest waste and loss of fruit, vegetables, and ornamentals?" *Horticulture Research*. 8, No. 1. <https://www.nature.com/articles/s41438-020-00428-4>

be used to directly biofortify or enhance the nutritional qualities of foods which would aid in improved health and nutrition outcomes of consumers here in the U.S. and around the world.<sup>10</sup>

To realize the immense benefits of these innovations, our regulatory system must continue to adapt to reflect their importance for consumers, our environment, and the future of our food and agriculture production systems, the inherently low risk these products pose, and the realities of our agricultural research, production, and marketing systems. The proposed exemptions make significant positive steps to accomplish these vital objectives.

### ***General Support and Feedback on the Proposed Exemptions***

As noted above, we generally support the five proposed exemptions and believe they are scientifically justifiable in that new plant varieties resulting from the proposed exempted edits could have resulted from conventional breeding techniques and will not pose a plant pest risk. If finalized, these exempted edits would offer greater, low risk tools for researchers and developers to improve plant varieties, actualizing the consumer, environmental, and production benefits described above.

### ***Expansion to Allopolyploids***

While we are generally supportive of the proposed exemptions, we are concerned with several aspects which we would urge BRS to address, first of which is limiting the use of some of the proposed exemptions for allopolyploids. At the outset, let us be clear that the proposed modifications for exemption are no more likely to result in a plant pest risk in allopolyploids than they would in diploids or autopolyploids. Further, there are several economically important allopolyploids, including wheat, cotton, peanuts, and canola, which would be severely limited by the exemptions as proposed. We believe there is sufficient literature available to justify expanding the proposed exemptions for allopolyploids as discussed below.

For example, in the first proposed exemption (AM1), BRS proposes establishing an exemption for diploid or autopolyploid plants with any combination of loss of function (LOF) modifications in one to all alleles of a single genetic locus. These mutations are well-established to be common occurrences of conventional breeding in both diploids and polyploids and would not result in varieties posing an increased plant pest risk. However, under the proposal BRS would limit the exemption in allopolyploid plants to any combination of LOF modifications in one or both alleles of a single genetic locus on up to four homoeologous chromosomes.

To support this proposed limitation, BRS cites a study in which researchers used ethyl methanesulfonate (EMS) mutagenesis to induce LOF mutations in granule-bound starch synthase (GBSSI) genes in tetraploid durum wheat. When the null mutants were crossbred, the researchers were able to develop amylose-free waxy allopolyploid durum varieties by establishing the null alleles across four homoeologous chromosomes.<sup>11</sup> While we support BRS' rationale for using this conventional breeding example as justification for the exemption of LOF edits, we would point BRS to research where similar

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<sup>10</sup> Kumar, Dileep, Anurag Yadav, Rumana Ahmad, Upendra Nath Dwivedi, and Kusum Yadav. July 14, 2022. "CRISPR-Based Genome Editing for Nutrient Enrichment in Crops: A Promising Approach Toward Global Food Security." *Frontiers in Genetics*. Vol. 13. <https://www.frontiersin.org/articles/10.3389/fgene.2022.932859/full>

<sup>11</sup> Li, Siyu, et al. January 3, 2020. "Production of waxy tetraploid wheat (*Triticum turgidum* L.) by EMS mutagenesis." *Genetic Resources and Crop Evolution*. 67. P. 433-443. [https://www.researchgate.net/publication/338373969\\_Production\\_of\\_waxy\\_tetraploid\\_wheat\\_Triticum\\_turgidum\\_durum\\_L\\_by\\_EMS\\_mutagenesis](https://www.researchgate.net/publication/338373969_Production_of_waxy_tetraploid_wheat_Triticum_turgidum_durum_L_by_EMS_mutagenesis)

proof-of-concept backcrossing of EMS induced mutations in allohexaploid common wheat has been used to establish homozygous null GBSSI alleles in two genes across six homoeologous chromosomes, producing amylose-free waxy wheat.<sup>12</sup> In this same study, researchers used the same EMS process to induce mutations in two puroindoline genes, which were crossed to produce homozygous hard grain variants in common wheat.

Moreover, traditional breeding methods, such as double haploid breeding in wheat and rapeseed, have been used to achieve complete homozygosity at all loci across all four or six homoeologous chromosomes.<sup>13,14,15,16</sup> This method has been used to establish homozygous alleles in allopolyploids, such as fungus resistance in wheat.<sup>17</sup>

In fact, the types of genetic modifications that can be obtained in allopolyploids via conventional breeding techniques correspond very well with all the proposed exemptions. For example, by coupling either chemical or radiological mutagenesis with targeting induced local lesions in genomes (TILLING) methods to identify mutations, researchers have identified millions of mutations in allopolyploids, including large or small deletions, insertions, and single nucleotide polymorphisms (SNPs).<sup>18,19</sup> Researchers have then utilized double haploid techniques to establish homozygosity of these mutations across two or more pairs of homoeologous chromosomes.<sup>20,21</sup> These common conventional breeding methods demonstrate the proposed exemptions for diploids and autopolyploids can also be accomplished in allopolyploids. To that end, we urge the BRS to expand the proposed exemptions to allow their complete utilization by allopolyploids upon finalization.

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<sup>12</sup> Dong, Chongmei, Jessica Dalton-Morgan, Kate Vincent, and Peter Sharp. March 1, 2009. "A Modified TILLING Method for Wheat Breeding." *The Plant Genome*. Vol. 2, Iss. 1. P. 39-47. <https://access.onlinelibrary.wiley.com/doi/10.3835/plantgenome2008.10.0012>

<sup>13</sup> Santra, Meenakshi, Hong Wang, Scott Seifert, and Scott Haley. September 15, 2017. "Doubled Haploid Laboratory Protocol for Wheat Using Wheat–Maize Wide Hybridization." *Wheat Biotechnology*. Vol. 1679. P. 235-249. [https://link.springer.com/protocol/10.1007/978-1-4939-7337-8\\_14](https://link.springer.com/protocol/10.1007/978-1-4939-7337-8_14)

<sup>14</sup> Colorado State University. April 8, 2022. "Doubled Haploid Wheat Production." *Grin-U Education*. <https://www.youtube.com/watch?v=jrsbZQma1A4>

<sup>15</sup> Zhang, Lianquan, et al. February 2011. "Synthesizing double haploid hexaploid wheat populations based on a spontaneous allopoloidization process." *Journal of Genetics and Genomics*. Vol. 38, Iss. 2. P. 89-94. <https://www.sciencedirect.com/science/article/abs/pii/S1673852711000051>

<sup>16</sup> Möllers, C., and M.C.M. Iqbal. 2009. "Doubled Haploids in Breeding Winter Oilseed Rape." *Advances in Haploid Production in Higher Plants*. P. 161-169. [https://link.springer.com/chapter/10.1007/978-1-4020-8854-4\\_13](https://link.springer.com/chapter/10.1007/978-1-4020-8854-4_13)

<sup>17</sup> Wiśniewska, Halina, et al. January 2019. "Production of wheat-doubled haploids resistant to eyespot supported by marker-assisted selection." *Electronic Journal of Biotechnology*. P. 11-17. <https://www.sciencedirect.com/science/article/pii/S0717345818300423>

<sup>18</sup> Uauy, Cristobal, Francine Paraiso, Pasqualina Colasuonno, Robert J. Tran, Helen Tsai, Steve Berardi, Luca Comai, and Jorge Dubcovsky. August 28, 2009. "A modified TILLING approach to detect induced mutations in tetraploid and hexaploid wheat." *BMC Plant Biology*. 9, No. 115. <https://bmcpantbiol.biomedcentral.com/articles/10.1186/1471-2229-9-115>

<sup>19</sup> Zhang, Junli, et al. September 13, 2023. "Sequencing 4.3 million mutations in wheat promoters to understand and modify gene expression." *Proceedings of the National Academy of Sciences of the United States of America*. Vol. 120, Iss. 38. <https://www.pnas.org/doi/10.1073/pnas.2306494120>

<sup>20</sup> Lu, Yin, et al. November 28, 2016. "Microspore Induced Doubled Haploids Production from Ethyl Methanesulfonate (EMS) Soaked Flower Buds Is an Efficient Strategy for Mutagenesis in Chinese Cabbage." *Frontiers in Plant Science*. Vol 7. 1780. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5147456/>

<sup>21</sup> Savadi, S., P. Prasad, P.L. Kashyap, and S.C. Bhardway. November 1, 2017. "Molecular breeding technologies and strategies for rust resistance in wheat (*Triticum aestivum*) for sustained food security." *Plant Pathology*. Vol. 67, Iss. 4. P. 771-791. <https://bsppjournals.onlinelibrary.wiley.com/doi/10.1111/ppa.12802>

## *Exogenous DNA Clarification*

Regarding the first proposed exemption (AM1), we are concerned language BRS has used related to exogenous DNA could significantly limit the utility of this exemption. In the proposal, BRS states:

*Modifications resulting from insertions of exogenous DNA do not currently qualify for exemption and, likewise, LOF mutations created through insertion of exogenous DNA such as T-DNA (the transferred DNA of the (Ti) plasmid of Agrobacterium used in the transformation of plant cells) or transposons (DNA sequences that can move and integrate to different locations within the genome), would not qualify for exemption as proposed.*

As drafted, this language suggests any modification *resulting* from the insertion of exogenous DNA would not qualify for exemption, even if that inserted DNA is not *retained* within a plant. Despite that some genetic modification systems use exogenous DNA for transformation – DNA which is later removed from the null segregant – as drafted, merely using these exogenous modification systems would result in a plant being ineligible for exemption. Given that there is no reasonable or scientific justification for this requirement, we assume BRS intended to specify that plants *retaining* exogenous DNA would be ineligible for exemption. We request that BRS revise this proposed exemption to reflect this more appropriate interpretation.

## *Multiplexing and Simultaneous Edits*

We also have concerns with proposed exemption number four (AM4), which would limit the number of modifications in a plant to four individual modifications that would qualify for exemption. We appreciate that BRS is attempting to facilitate multiplex editing, but BRS does not provide a scientific rationale for this restriction. Per our discussion above, double haploid breeding in multiple species has successfully demonstrated that fixation of hundreds of alleles and mutations across entire genomes in polyploid species. Limiting the exemption would impede the use of multiplexing, including the modification of more complex biological structures co-regulated by multiple genes, such as plant metabolic pathways or resistance to biotic or abiotic stressors.

As advancements in genetics occur, our knowledge of polygenic and co-expressed traits is also deepening, revealing that many traits are controlled by numerous genes at multiple loci.<sup>22</sup> For example, a recent study modifying  $\gamma$ -aminobutyric acid (GABA) in tomatoes targeted five genes, which exceeds the proposed number of modifications under exemption four.<sup>23</sup> The relatively low threshold in this proposed exemption could delay or preclude the development of certain innovations if researchers must rely on the fifth proposed exemption (AM5) of sequential modification following the voluntary confirmation process to achieve additional modifications.

Moreover, it is not unreasonable to suggest far more modifications could result from conventional breeding practices. When breeding strategies use marker assisted selection coupled with gene pyramiding and double haploid practices, “a plant having as many as 20 target markers can be obtained

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<sup>22</sup> Abdelrahman, Mohamed, Zheng Wei, Jai S. Rohila, and Kaijun Zhao. October 6, 2021. “Multiplex Genome-Editing Technologies for Revolutionizing Plant Biology and Crop Improvement.” *Frontiers in Plant Science*. Vol. 12. <https://www.frontiersin.org/articles/10.3389/fpls.2021.721203/full#B36>

<sup>23</sup> Li, Rui, Ran Li, Xindi Li, Daqi Fu, Benzhong Zhu, Huiqin Tian, Yunbo Luo, and Hongliang Zhu. June 22, 2017. “Multiplexed CRISPR/Cas9-mediated metabolic engineering of  $\gamma$ -aminobutyric acid levels in *Solanum lycopersicum*.” *Plant Biotechnology Journal*. Vol. 16, Iss. 2., P. 415-427. <https://onlinelibrary.wiley.com/doi/10.1111/pbi.12781>

at an almost perfect certainty in about three rounds of selection.... theoretically unlimited number of genes can be pyramided if such intermediate genotypes are produced and the breeding program is continued.”<sup>24</sup> BRS’ own literature review included in this proposal identified instances where up to seven genes were combined using pyramiding.<sup>25</sup>

Retaining the low threshold limit of four simultaneous edits impedes innovations which could require a higher number of modifications, and it places U.S. researchers and farmers at a disadvantage to international competitors. Canada, for example, does not impose a quantitative limit on the number of modifications, so long as the resulting plant does not contain exogenous DNA and meets several other safety requirements (e.g., does not alter/increase known allergens or toxins related to human health).<sup>26</sup> Permitting only four simultaneous edits could increase the regulatory burden on basic research, testing, and deployment of new plant varieties. As a result, developers may choose to conduct research in countries where rules are less restrictive and not as likely to impede research and development. This would both harm our nation’s research capacity and allow agricultural producers outside the U.S. first access to important new innovations.

This limit also erroneously implies there is inherently greater risk posed by processes resulting in more edits than those with fewer edits falling below this subjective threshold, ignoring the risk (or lack thereof) of the resulting plant and the traits expressed by modification. This inappropriately places a regulatory burden based on the process by which a plant was created—not the resulting product—in disagreement with the long-standing, foundational principles of the Coordinated Framework for the Regulation of Biotechnology.<sup>27</sup>

We strongly urge BRS to raise this simultaneous modification threshold, as there are numerous scientific justifications that could allow for a much higher or no limit. Finally, like with the other proposed exemptions, we encourage BRS to expand this exemption to permit homozygous modifications in allopolyploids, as there is ample evidence to demonstrate that gene pyramiding has been used via conventional breeding techniques to successfully stack homozygous traits in allopolyploids.<sup>28,29,30</sup>

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<sup>24</sup> Ye, Guoyou, and Kevin F. Smith. January 2008. “Marker-assisted gene pyramiding for inbred line development: Basic principles and practical guidelines.” *International Journal of Plant Breeding*. [https://www.researchgate.net/publication/228347487\\_Marker-assisted\\_gene\\_pyramiding\\_for\\_inbred\\_line\\_development\\_Basic\\_principles\\_and\\_practical\\_guidelines](https://www.researchgate.net/publication/228347487_Marker-assisted_gene_pyramiding_for_inbred_line_development_Basic_principles_and_practical_guidelines)

<sup>25</sup> Ramalingam, Jegadeesan, et al. November 19, 2020. “Gene Pyramiding for Achieving Enhanced Resistance to Bacterial Blight, Blast, and Sheath Blight Diseases in Rice.” *Frontiers in Plant Science*. Vol. 11. <https://www.frontiersin.org/articles/10.3389/fpls.2020.591457/full>

<sup>26</sup> Government of Canada. Health Canada. Health Products and Food Branch. Food Directorate. Updated July 2022. *Appendix 1: Health Canada Guidance on the Novelty Interpretation of Products of Plant Breeding*. <https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidelines-safety-assessment-novel-foods-derived-plants-microorganisms/guidelines-safety-assessment-novel-foods-2006.html#a5>

<sup>27</sup> Executive Office of the President. 2017. *Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology*. P. 4. [https://usbiotechnologyregulation.mrp.usda.gov/2017\\_coordinated\\_framework\\_update.pdf](https://usbiotechnologyregulation.mrp.usda.gov/2017_coordinated_framework_update.pdf)

<sup>28</sup> Wang, Zhaoyang, Fucai Wang, Zihan Yu, Xiaorui Shi, Xianming Zhou, Pengfei Wang, Yixian Song, Dengfeng Hong, and Guangsheng Yang. June 2023. “Pyramiding of multiple genes generates rapeseed introgression lines with clubroot and herbicide resistance, high oleic acid content, and early maturity.” *The Crop Journal*. Vol. 11, Iss. 3. P. 895-903. <https://www.sciencedirect.com/science/article/pii/S2214514122002495>

<sup>29</sup> Kaur, Satinder, Jaspreet Kaur, G.S. Mavi, Guriqbal Singh Dhillon, Achla Sharma, Rohtas Singh, Urmila Devi, and Parveen Chhuenga. December 22, 2020. “Pyramiding of High Grain Weight With Stripe Rust and Leaf Rust Resistance in Elite Indian Wheat Cultivar Using a Combination of Marker Assisted and Phenotypic Selection.” *Frontiers in Genetics*. Vol. 11. <https://www.frontiersin.org/articles/10.3389/fgene.2020.593426/full>

<sup>30</sup> Dong. “A Modified TILLING Method for Wheat Breeding.”



### *Previous Regulatory Status Review Exemption*

In the fifth proposed exemption (AM5), BRS proposes that plants that have previously completed the voluntary confirmation process (CR) and that have been produced, grown, and observed consistent with conventional breeding methods for the appropriate plant species, may be successively modified in accordance with the exemptions because allowing for such successive modification is consistent with plant development in conventional breeding programs. While this proposal is reasonable, we feel it is incomplete.

BRS has found dozens of plants reviewed through its Regulatory Status Review (RSR) process do not pose a plant pest risk and could have been achieved through conventional breeding. However, as drafted, this proposed exemption would not extend to plant varieties which have successfully completed the RSR process. We urge BRS to extend this proposed successive modification exemption to plant varieties which have completed RSR.

### ***Additional Considerations***

There are several other items we encourage BRS to consider as it contemplates finalization of these additional proposed exemptions. First, we urge BRS to finalize additional exemptions as soon as is possible, ideally no later than mid-2024. The modification exemptions under existing regulations are very narrow, permitting few researchers and developers to utilize them, directing a significant number of products through BRS' RSR process. As BRS noted at its November 2023 stakeholder meeting, RSR timelines are currently greatly protracted with only 20 percent of applications meeting review timelines specified in regulation over the past year.<sup>31</sup> Approving additional scientifically justifiable exemptions could permit low-risk modifications to avoid unnecessary review, saving both time and resources for BRS and developers.

Allowing additional exemptions would also expedite development and deployment of the much-needed production, environmental sustainability, and consumer-focused innovations as discussed above. We also have competitiveness concerns, both for our research and development and agricultural production communities. Swift finalization of the new exemptions would allow for the U.S. to continue to maintain a competitive edge in the development and deployment of genetic innovations in agriculture and will allow our U.S. farmers to maximize their productivity and sustainability, while offering important new products for global consumers.

Finally, we encourage USDA to continue to engage with co-regulators at FDA and EPA and advocate for their adoption of scientifically justifiable exemptions. A risk-proportionate, streamlined regulatory pathway for genetic modifications at BRS, including appropriate exemptions, is essential and helpful for maximizing the potential of modern genetic improvement technologies. However, under the Coordinated Framework, a fragmented regulatory approach between agencies can still unnecessarily impede innovations and blemish international perceptions of the U.S. support for science-based regulation. We appreciate BRS' historic support for engaging with co-regulators to advance these important pro-innovation approaches and encourage USDA to continue to adopt this posture when engaging with co-regulators on this approach and others in the future.

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<sup>31</sup> United States Department of Agriculture. Animal and Plant Health Inspection Service. Biotechnology Regulatory Services. N.D. *FY2023 Data Snapshot*. Accessed December 10, 2023. <https://www.aphis.usda.gov/brs/pdf/data-snapshot-handout-2023.pdf>

We appreciate BRS for offering this important proposal, for the opportunity to comment, and reaffirm our support for swiftly finalizing these exemptions with the modifications discussed above. Doing so will better enable research communities to offer vital innovations necessary to meet the production, sustainability, quality, and nutrition needs of U.S. agricultural producers and consumers around the world.

Sincerely,

Agribusiness Association of Iowa  
Agribusiness Council of Indiana  
Agricultural Retailers Association  
Alabama Agribusiness Council  
American Farm Bureau Federation  
American Seed Trade Association  
American Society of Plant Biologists  
American Soybean Association  
American Sugarbeet Growers Association  
Arkansas Soybean Association  
Beet Sugar Development Foundation  
Biotechnology Innovation Organization  
California Citrus Mutual  
California Specialty Crops Council  
Cherry Marketing Institute  
Crop Science Society of America  
Donald Danforth Plant Science Center  
Far West Agribusiness Association  
Florida Citrus Mutual  
Florida Fertilizer & Agrichemical Association  
Florida Fruit and Vegetable Association  
Georgia Agribusiness Council  
Independent Professional Seed Association  
International Fresh Produce Association  
Illinois Soybean Association  
Indiana Soybean Alliance  
Iowa Soybean Association  
Kansas Agribusiness Retailers Association  
Kansas Grain and Feed Association  
Kansas Soybean Association  
Kentucky Soybean Association  
Minnesota Canola Council  
Montana Agricultural Business Association  
National Alfalfa & Forage Alliance  
National Association of Wheat Growers  
National Association of State Departments of Agriculture  
National Corn Growers Association  
National Cotton Council  
National Council of Farmer Cooperatives  
National Onion Association



National Potato Council  
National Sorghum Producers  
Nebraska Agri-Business Association  
Nebraska Soybean Association  
North American Blueberry Council  
North Carolina Soybean Producers Association  
North Dakota Soybean Growers Association  
Oklahoma Agricultural Cooperative Council, Inc.  
Ohio Soybean Association  
Pacific Northwest Canola Association  
Rocky Mountain Agribusiness Association  
Southern Crop Production Association  
Tennessee Soybean Association  
Texas Soybean Association  
U.S. Canola Association  
U.S. Peanut Federation  
U.S. Wheat Associates  
USA Rice  
Wisconsin Agri-Business Association  
Western Growers