Notices

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding: whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 13, 2024 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Economic Research Service

Title: Corn and Soybean Grower Survey.

OMB Control Number: 0536–NEW.

Summary of Collection: 0536–NEW. The proposed data collection will use a survey of corn and soybean farmers in the Midwestern U.S. to study farmers' preferences for participating in programs that support cover cropping and gather new information about current cover cropping practices. The survey will use questions on contract enrollment to examine how contract flexibility, ease of applying, payments, and other aspects of cover crop contracts affect farmers' willingness to enroll their corn and soybean fields in cover crop programs. Results will be compared between farmers with no history of cover cropping in Federal programs and those who have cover cropped in Federal Programs.

Need and Use of the Information: USDA agencies are interested in supporting the long-run adoption of climate smart conservation practices such as cover crops. There are multiple Federal, state, and private programs that support planting cover crops. This study will provide information about current use of cover crops as well as what influences participation on programs for cover crops. Data will be used for research purposes and only reported in the aggregate. The information provided by this study will benefit farmers, non-governmental organizations, and industry stakeholders as well as policymakers and program managers at the local, State, Tribal, and National levels.

Description of Respondents: Individuals.

Number of Respondents: 2,500.

Frequency of Responses: One time.

Total Burden Hours: 2,411 hours.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2024–26252 Filed 11–12–24; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2023–0022]

Movement of Organisms Modified or Produced Through Genetic Engineering; Notice of Additional Modifications Exempt Plants Can Contain

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are adding modifications a plant may contain and qualify for exemption from regulations governing movement of organisms modified or produced using genetic engineering because the modifications are achievable through conventional breeding. An earlier notice proposed five types of modifications. Based on a review of public comments, we have been able to streamline and simplify our description of these modifications and are now finalizing two additional modifications a plant can contain and qualify for exemption. This action updates and clarifies the types of modifications that can be made to plants that qualify for exemption to reflect advances in science and technology, and what is achievable through conventional breeding methods to facilitate the application of biotechnology for the development of new crops.

DATES: The APHIS website will be updated with these additional modifications on November 13, 2024.

FOR FURTHER INFORMATION CONTACT: Dr. Neil Hoffman, Science Advisor, Biotechnology Regulatory Services, APHIS, 4700 River Road, Unit 78, Riverdale, MD 20737–1238; *Neil.E.Hoffman@usda.gov;* (301) 851–3877.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340 govern the movement (importation, interstate movement, or release into the environment) of certain organisms modified or produced through genetic engineering. The U.S. Department of

Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) first issued these regulations in 1987 under the authority of the Federal Plant Pest Act of 1957 and the Plant Quarantine Act of 1912, two acts that were subsumed into the Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) in 2000, along with other provisions. Since 1987, APHIS has amended the regulations seven times, in 1988, 1990, 1993, 1994, 1997, 2005, and 2020.

On May 18, 2020, we published in the **Federal Register** (85 FR 29790–29838, Docket No. APHIS–2018–0034) a final rule [1] that marked the first comprehensive revision of the regulations since they were established in 1987. The final rule provided a clear, predictable, and efficient regulatory pathway for innovators, facilitating the development of organisms modified or produced using genetic engineering (modified organisms) that are unlikely to pose plant pest risks.

The May 2020 final rule described the scope or applicability of regulations and stated that the regulations do not apply to plants with modifications that are achievable through conventional breeding (85 FR 29790–29796). To ensure the regulations do not apply to plants that are equivalent to those that could be developed through conventional breeding, the May 2020 final rule established a regulatory exemption to initially identify and continuously update modifications that are achievable through conventional breeding and, thus, exempt from regulation (85 FR 29791–29796; § 340.1(b)).

Initially, APHIS identified three commonly known modifications achievable through conventional breeding methods, including small insertions/deletions at a single locus of a plant's genome (85 FR 29792; § 340.1(b)(1) through (3)). Specifically, § 340.1(b) exempted plants that contain a single modification of one of the following types, specified in § 340.1(b)(1) through (3):

- The genetic modification is a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template; or
- The genetic modification is a targeted single base pair substitution; or
- The genetic modification introduces a gene known to occur in the plant's gene pool or makes changes in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool.

Knowing that it is impracticable to identify and list the universe of modifications that are achievable through conventional breeding at any given time because of advances in knowledge, technology and conventional breeding methods, the May 2020 final rule also established a process for listing additional modifications that plants can contain while still being exempted from the regulations (85 FR 29793–29795; § 340.1(b)(4)). Thus, § 340.1(b)(4) provides that the Administrator may propose to exempt plants with additional modifications, based on what could be achieved through conventional breeding. Such proposals may either be APHIS-initiated or may be initiated via a request that is accompanied by adequate supporting information and submitted by another party. In either case, APHIS will publish a notice in the **Federal Register** of the proposal, along with the supporting documentation, and will request public comments. After reviewing the comments, APHIS will publish a subsequent notice in the **Federal Register** announcing its final determination. A list specifying modifications a plant can contain and be exempt pursuant to § 340.1(b)(4) is available on the APHIS website at *https://www.aphis.usda/gov/biotech-exemptions.*

On November 15, 2023, we published a notice in the **Federal Register** (88 FR 78285–78291, Docket No. APHIS–2023–0022) proposing the five modifications that plants could contain and be eligible for exemption:

First, we proposed that a diploid or autopolyploid plant with any combination of complete loss of function modifications in one to all alleles of a single genetic locus, or an allopolyploid plant with any combination of complete loss of function modifications in one or both alleles of a single genetic locus on up to four pairs of homoeologous chromosomes, without the insertion of exogenous DNA, would qualify for exemption (proposed 340.1(b)(4)(vi) (Additional Modification 1 (AM1)). APHIS explained that this category was intended to apply to scenarios involving targeted DNA breaks—through insertions, deletions, and other types of modifications (such as a nick)—created using different techniques that might not be expressly outlined in the initial modifications APHIS described in the May 2020 final rule (namely, paragraphs (b)(1) and (2) of § 340.1), but functionally would achieve the same end result—loss of function. In addition, it proposed to extend loss of function mutations without the insertion of exogenous DNA to polyploid plants.

Second, we proposed that any diploid or autopolyploid plant in which the genetic modification is a single contiguous deletion of any size, resulting from cellular repair of one or two targeted DNA breaks on a single chromosome or at the same location(s) on two or more homologous chromosomes, without insertion of DNA, or with insertion of DNA in the absence of a repair template, would qualify for exemption (proposed 340.1(b)(4)(vi)(AM2)). As proposed, allopolyploid plants with additional modifications to homoeologous loci of homoeologous chromosomes would not have qualified for exemption.

Third, we proposed to allow the modifications described at § 340.1(b)(2) and (3) to be made to all alleles of a genetic locus on the homologous chromosomes of autopolyploids (proposed 340.1(b)(4)(vi)(AM3)). As proposed, allopolyploid plants with additional modifications to homoeologous loci of homoeologous chromosomes would not have qualified for exemption.

Fourth, we proposed that plants with up to four modifications, made simultaneously or sequentially, of types that already qualify such plants for exemption when made individually, and provided each modification is at a different genetic locus, would be exempt from regulation because such modifications are achievable through conventional breeding methods (proposed 340.1(b)(4)(vi)(AM4)). It proposed that allopolyploid plants could contain up to four of the proposed complete loss of function modifications described or four modifications described under § 340.1(b)(2) and (3) or a combination thereof, provided each modification is introduced into just one allele; however, allopolyploid plants would not be exempt if they contain a modification that is allowable only in diploid and autopolyploid plants.

Fifth, we proposed that plants that have previously completed voluntary reviews confirming the plants' exempt status as described in § 340.1(e), which provides the process by which developers can request such a confirmation of exempt status, and that have been produced, grown, and observed consistent with conventional breeding methods appropriate for the plant species, could be successively modified in accordance with any of the modifications listed under paragraph 340.1(b) of the regulations (proposed 340.1(b)(4)(vi)(AM5)).

[1] To view the final rule and supporting documents, go to *https://www.regulations.gov/docket/APHIS-2018-0034.*

We initially took comments on the notice through December 15, 2023. In a notice published in the **Federal Register** on December 27, 2023 (88 FR 89362, Docket No. APHIS–2023–0022), we reopened the comment period, and extended it until January 19, 2024.

We received 6,477 comments by the end of the reopened comment period. The comments were diverse and from interest groups, industry representatives, industry trade organizations, private individuals, scientists, plant breeders, and crop specialists.

Based on a review of public comments, we have made several revisions to the five proposed modifications, simplifying and consolidating them into two modification categories, AM1 and AM2. To achieve this, APHIS consolidated the first and second proposed modifications to create the AM1 described in this final notice. The intent of the first and second proposed modifications was to provide developers with greater flexibility in how they could generate targeted breaks in a plant's DNA like those that occur through conventional breeding methods. AM1, as finalized, carries through this intent by building on the existing modification described at § 340.1(b)(1), which currently allows a single targeted break in DNA and self-repair (*i.e.,* a non-templated insertion, deletion, or a combination of insertion and deletion (indel) to rejoin the DNA). AM1 now allows more than one cut to make the targeted break and the use of external templates in some circumstances. The finalized AM1 also carries through the original intent of the proposal by allowing developers to use a deletion of any size resulting from a targeted break, thereby recovering the functionality APHIS originally included in the 2019 proposed rule (84 FR 26514–26541, Docket No. APHIS–2018–0034) but did not expressly articulate in the May 2020 final rule, and which APHIS proposed as additional modifications in the November 2023 notice (88 FR 78286, 88 FR 78288, Docket No. APHIS–2023–0022). Collectively, as described in this final notice, AM1 allows plants with modifications involving an insertion or deletion (indel), or contiguous deletion of any size, made at a targeted location, with or without insertion of DNA if generated without using a repair template, or without insertion of DNA if generated using a repair template, to qualify for exemption.

Similarly, APHIS consolidated the third and fourth proposed modifications to create the AM2 described in this final notice. The intent of the third and fourth proposed modifications was to make modifications that are already listed in the regulations (§ 340.1(b)(2) and (3)) available for use in polyploid plants and to increase the number of modifications that can be made simultaneously or sequentially to plants. AM2 carries through this intent by exempting plants with up to 12 modifications, made simultaneously or sequentially, if each modification occurs in a different gene and is of a type listed under § 340.1(b). By increasing the number of modifications that can be made to a plant, AM2 also effectively allows all modifications listed in § 340.1(b) to be made in all polyploids.

Finally, the fifth proposed modification would have required developers to complete a confirmation process to verify a plant's exempt status before making sequential modifications and outlined conditions to ensure that simultaneous or sequential modifications were made in plants that had been produced, grown, and observed, consistent with conventional breeding practices. APHIS has not finalized a modification associated with this proposal. Instead, to stay true to the voluntary nature of APHIS' confirmation request process and ensure that plants are developed consistent with conventional breeding practices, APHIS will only accept voluntary requests to confirm a plant's exempt status for plants that have been produced. This means APHIS will no longer accept confirmation requests involving plants with hypothetical modifications because, if produced, the plants may not be viable, may not have the intended phenotype, or have a different genotype than originally requested.

We wish to highlight additional distinctions between AM1 and AM2 described in this final notice, and the modifications we initially proposed. First, we are no longer restricting AM1 to loss of function modifications if the gain of function (GOF) modification results from natural DNA repair in the absence of a repair template. We received comments and supporting literature during the comment period that such GOF modifications can be accomplished through conventional breeding techniques. Second, we are no longer making distinctions between allopolyploids and autopolyploids when describing the modifications. We received comments during the comment period indicating the distinction between allopolyploids and autopolyploids was not necessary, with documentation demonstrating that similar modifications can be made in the two ploidy types by conventional breeding. Eliminating this distinction was a key factor that enabled us to consolidate the modifications from five to two and simplify our description of the modifications overall. Third, we are increasing the number of simultaneous or sequential modifications from 4 (as proposed) to 12 (as described in this final notice). In the proposal we published in November 2023, we noted that we welcomed comments from the public on the number of individual modifications that are achievable simultaneously or sequentially in plants based on conventional breeding methods, and comments on the reasons for or against allowing for simultaneous or sequential modifications in all plants. We received comments during the comment period requesting an increase in the number of simultaneous or sequential modifications covered by the exemption and documentation that more than four modifications are possible by conventional breeding. In our discussion below, we further describe these comments and the literature references we received that show 12 simultaneous or sequential modifications are achievable through conventional breeding. Fourth, we are no longer considering hypothetical plants for confirmation requests based on comments we received on AM5 suggesting the exclusion of hypothetical plants from the scope of exemption would simplify the exemption. We are also clarifying that any plant not subject to part 340 (because it is not modified, meets the criteria for a regulatory exemption, or has completed the regulatory status review process) may be modified in accordance with the exemption.

Below, we first discuss the specific comments that resulted in the changes to the modifications we proposed in the November 2023 notice. We then discuss the other comments received on the notice.

Comment: Many commenters felt that we should not make a distinction between Loss of Function (LOF) and GOF mutations in AM1. They noted that the distinction greatly increases the complexity of the modification descriptions.

Response: Proposed AM1 described LOF modifications in all alleles of a single genetic locus in diploids and autopolyploids and on up to four pairs of homoeologous chromosomes in allopolyploids. Our proposal limited the modification to LOF mutations because GOF modifications are statistically less common than LOF mutations, and we thought the same GOF mutation would not be expected to occur across multiple alleles in allopolyploids by conventional breeding. Based on

comments we received demonstrating proof of concept that GOF mutations can occur across all subgenomes in allopolyploids (*e.g.,* (Ostlie, *et al.,* 2015)), we are revising AM1 to allow GOF modifications that result from the generation of insertions and deletions (indels) that occur through DNA break and repair.

Because we are dispensing with distinctions between LOF and GOF and allopolyploids and autopolyploids, we no longer consider it useful to have a separate modification that allows for a deletion of any size (proposed AM2). Instead, we have introduced this functionality into the final AM1. Indels are typically modifications that are under 50 base pairs (bp) whereas deletions of any size are a type of structural variant (Mahmoud, *et al.,* 2019).

As noted previously, we are revising AM1 to: ''An indel or contiguous deletion of any size, made at a targeted location, with or without insertion of DNA if generated without using a repair template, or without insertion of DNA if generated using a repair template.''

We wish to emphasize that AM1 is not prescriptive in how indel modifications or contiguous deletions are made. It is based on the outcome rather than any specific techniques used. We also wish to resolve confusion around our use of the phrase ''without the insertion of exogenous DNA.'' Our intent is to ensure exempt plants are free of foreign DNA in the final product, but not to prohibit foreign DNA used to make the final product. For example, CRISPR-Cas9, a foreign DNA, could be used to make a modification and plants with the modification and lacking CRISPR-Cas9 would still qualify for the exemption. To be clear, to qualify for AM1, the final plant must not retain foreign DNA. Lastly, although we initially defined GOF and LOF based on gene activity, commenters noted they were confused, because LOF of a gene can result in a GOF in phenotype and vice versa. Also, by our proposed definition, promoter deletions that led to either increases or decreases in the expression of a downstream gene could be GOF or LOF, respectively. AM1, as described in this final notice, no longer makes a distinction between LOF and GOF, thereby resolving this confusion and incongruence and mooting these comments.

Comment: The language of the proposed modifications is complex and can be simplified by not making a distinction between autopolyploids and allopolyploids and loss of function and gain of function modifications.

Response: After reading information provided in the comments describing the types of modifications that can be made in allopolyploids, APHIS agrees that our descriptions of modifications that plants can contain and qualify for exemption can be simplified to eliminate the distinction between autopolyploid and allopolyploids and allow gain of function indels. More detail is provided in responses below.

Comment: Many commenters felt the modifications should not make a distinction between autopolyploids and allopolyploids and noted that regulatory authorities in no other countries make this distinction.

Response: Although APHIS initially made a distinction between allopolyploids (such as wheat) and autopolyploids (such as potato) in the proposed modifications, based on our review of the comments and cited literature, we agree that such distinction is not necessary.

For example, we originally proposed that AM4 would have allowed multiple modifications involving single base pair substitutions and insertions described in § 340.1(b)(2) and (3), for autopolyploids as homozygous modifications and for allopolyploids only as heterozygous modifications. In the comments, we learned of two reasons to change our view on this distinction. First, in some allopolyploids, such as wheat, that are largely self-pollinating, homozygous modifications routinely accumulate, and heterozygous alleles are less common (Rutkoski, *et al.,* 2022). Second, doubled haploids are commonly used in breeding to generate homozygous alleles in a single generation in over 250 species (Maluszynski, *et al.,* 2003). Commenters provided 4 examples of 4-to-8 homozygous mutations pyramided in wheat and rapeseed (Tyagi, *et al.,* 2014; Zhang, *et al.,* 2019; Zheng, *et al.,* 2020; Luo, *et al.,* 2021; Wang, *et al.,* 2023b). Given this new information, we have removed the distinction between allopolyploids and autopolyploids in AM2 as described in this final notice.

Similarly, as originally proposed, AM1, would have limited the number of knockouts of a single genetic locus in allopolyploids to four pairs of homoeologous chromosomes, consistent with the limit of four modifications in proposed AM4, but counting modifications differently in autopolyploids and allopolyploids. As described in more detail below in our discussion of final AM2, which allows multiple modifications, we will now count modifications in the same way in autopolyploids and allopolyploids.

Along these lines, as originally proposed, AM3 would have allowed single nucleotide substitutions (also known as base pair substitutions) to all alleles of a single genetic locus in autopolyploids, but not allopolyploids. In response to this proposal, commenters provided references to published scientific data to demonstrate the use of conventional breeding to produce an identical homozygous single nucleotide substitution across all three subgenomes of wheat (Ostlie, *et al.,* 2015). This modification, a cytosine to thymine (C/T) transition that converted valine at amino acid 2004 to an alanine, created resistance to ACCase type inhibitors (Ostlie, *et al.,* 2015) and the researchers enhanced their chances of finding the desired modification by using selection with ACCase inhibitors. To evaluate whether the single nucleotide substitution across all three subgenomes could be found without selection, we examined the EMS generated mutant collection (Krasileva, *et al.,* 2017) that is publicly available through the EnsemblPlants database (*https://plants.ensembl.org/index.html*). The technology created by (Krasileva, *et al.,* 2017) makes it possible to identify mutations across multiple genomes. Plants with the desired mutations can then be crossed to generate plants with the identified mutations across three genomes. Using this source, we identified 11 cases where wheat lines had C/T mutations that resulted in identical mutations in ACCase in all 3 subgenomes (D53N; G55D; V212M; A321T; G543D; G655E; S708N; G1377D; A1848T; G1984E; E2203K) and 2 cases where wheat lines had G/A mutations that resulted in the identical ACCase mutation in all three subgenomes (P647S and L1003F). This finding demonstrated to us that the Krasileva mutagenesis library could be used to identify plants with the identical single nucleotide substitution across all three subgenomes even in the absence of selection. This is a proof of concept that single nucleotide substitutions across subgenomes can be isolated using ordered mutant libraries prepared from allopolyploids.

Mutagenized lines tend to create specific types of DNA modifications. For example, ethyl methanesulfonate (EMS) mutagenesis preferentially converts the base guanine (G) to adenine (A) and the base cytosine (C) to thymine (T) (Leitao, 2012). A similar mutagen, methyl methanesulfonate (MMS) preferentially converts A to T, T to A, A to G, and T to C (Leitao, 2012). Radiation mutagenesis by gamma radiation or fast neutron bombardment

preferentially results in deletions (Wyant, *et al.,* 2022). Historically, breeders have created collections of lines based on naturally occurring variation to be used for their breeding pool. Naturally occurring mutations have been shown to occur at comparable frequencies for all 12 combinations of nucleotide substitutions (Weng, *et al.,* 2018). A recent trend is to characterize the collection by whole genome sequencing (genotyping by sequencing) to facilitate identification of specific mutations. Sequenced collections of diversity panels are available in Arabidopsis (The 1001 Genomes Consortium, 2016), maize (Bukowski, *et al.,* 2018), rice (Zhao, *et al.,* 2021), soybean (Torkamaneh, *et al.,* 2021), cotton (He, *et al.,* 2021), canola (Hurgobin, *et al.,* 2018), tobacco (Thimmegowda, *et al.,* 2018), strawberry (Qiao, *et al.,* 2021), alfalfa (Shen, *et al.,* 2020), sorghum (Jensen, *et al.,* 2020), and wheat (Brinton, *et al.,* 2020), to name a few. In some cases, second releases are available with more sequenced lines covering greater variation than the original. We can expect these community resources to include more species and details over time. Genotyping by sequencing is generally applicable to any species.

Given the new information about the availability, for breeding purposes, of naturally occurring and mutagenized collections genotyped through sequencing, APHIS concludes that it is possible to identify and introduce single nucleotide substitutions and deletions across the subgenomes of allopolyploids by conventional breeding.

As originally proposed, AM3 would have also allowed a modification that introduces a gene known to occur in the plant's gene pool or makes changes in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool for autopolyploids, but not for allopolyploids. In the comments, we were made aware of an example where homozygous copies of a cellulose synthase-like F6 gene were introduced into all three subgenomes of wheat (Danilova, *et al.,* 2019). This new information demonstrates that sequences from the gene pool can be introduced into all subgenomes of allopolyploids by conventional breeding.

Based on the comments and information we collectively received related to the proposed modification described as AM3, and as discussed in the above paragraphs, we are removing the proposed limitation to autopolyploids. The modifications described in § 340.1(b)(2) and (3) apply to a single modification. As a result, they were effectively limited to a single pair of homologous chromosomes in polyploids species. As discussed more fully below, based on the comments and literature in this final notice, we will allow up to 12 such modifications in plants (now AM2). This means modifications can now be made across subgenomes of polyploids and the plants can qualify for exemption from regulation, further removing distinctions involving ploidy plants.

As originally proposed, AM2 would have allowed a modification consisting of a single contiguous deletion of any size in diploids and autopolyploids. Given the proof of concept for using an ordered mutant collection to identify single nucleotide substitutions across subgenomes of allopolyploids, we considered whether a similar approach could be used to identify similar deletions across subgenomes such that allopolyploids would also qualify for proposed AM2. (Krasileva, *et al.,* 2017) identified just 1268 deletions in their mutant collection, which is not surprising based on observations that EMS primarily creates point mutations (Gilchrist and Haughn, 2010). Fast neutron or gamma radiation mutagenesis, however, predominantly creates deletions (Gilchrist and Haughn, 2010; Kumawat, *et al.,* 2019) and mutant population resources using these techniques have been reported (Anai, 2012; Du, *et al.,* 2021). It is likely that ordered mutant collections prepared by fast neutron bombardment or gamma radiation mutagenesis can be used to isolate similar, but not identical, deletions across subgenomes. Given this, and for simplicity, the functionality described in the modification proposed AM2, is now included in the modification described as AM1 in this final notice.

Comment: Many commenters felt that proposed AM4 was overly limiting because breeders routinely combine many more favorable genes, alleles, or quantitative trait loci (QTL) than four during a breeding project. One commenter suggested there should be no upper limit following the lead of other countries such as Canada. Another noted that a complex trait such as flowering time may require the combination of 50 to 100 QTLs.

Response: In the May 2020 final rule, when USDA first adopted the exemption for plants with modifications achievable through conventional breeding, APHIS explained:

''There are many biological and practical factors that affect a plant breeder's ability to develop a new crop variety by introducing genetic variation and intentionally selecting for desired traits. These include the number of targeted loci and type of desired genetic changes, the genetic distance between the desired changes, generation time, breeding system (sexual or asexual), ploidy type and level and genomic complexity, resource availability (time, money, labor, and genomic resources), extent of domestication, and other factors. These factors, and thus the extent of intentionally selected genetic variation that can be introduced, vary widely among plant species. Moreover, new plant breeding techniques can make possible more complex combinations of genetic modifications than can practically be achieved through conventional breeding methods.

Initially, the exemptions will apply only to plants containing a single targeted modification in one of the categories listed. APHIS anticipates scientific information and/or experience may, over time, allow APHIS to list additional modifications that plants can contain and still be exempted from the regulations so that the regulatory system stays up to date and keeps pace with advances in scientific knowledge, evidence, and experience. This may include multiple simultaneous genomic changes.'' (U.S. Department of Agriculture Animal and Plant Health Inspection Service, 2020c).

Since APHIS initially adopted its exemption 4 years ago, there has been steady introgression of desired genes, alleles, and QTLs in several crops through modern conventional breeding methods. Genomic assisted breeding, genetic mapping and studies, high through-put genotyping, speed breeding, multi-parent advance generation inter-crosses, and pyramid breeding strategies, to name a few, have advanced quickly and are now affordable for many crop types. New methods, like OutcrossSeq (Chen, *et al.,* 2021), are consistently emerging to improve and accelerate breeding methods for difficult to breed crops, like those for which no inbred lines are available for genetic study and breeding because they are self-incompatible, clonally propagated, or have a long generation time, making the identification or integration of agronomically important genes difficult, particularly in crops with a complex autopolyploid genome or with predominant asexual reproduction.

We also considered the progress made in breeding potato, a clonally propagated crop. Clonally propagated crops are thought to be difficult to breed because, as a result of not requiring seed production, they accumulate genetic alterations that are detrimental to breeding and hence require

heterozygosity for vigorous growth (Brown, *et al.,* 2017; Kardile, *et al.,* 2022). Recently much progress has been made in breeding inbred diploid potato lines by overcoming self-incompatibility (Kardile, *et al.,* 2022) and purging deleterious alleles causing inbreeding depression in homozygous lines (Zhang, *et al.,* 2021). These developments have led to the first potato elite inbred lines established through selfing that were crossed to successfully exploit heterosis in the F1 generation (Zhang, *et al.,* 2021).

Similarly, in banana, another clonally propagated crop, low fertility and seed viability, abnormal meiosis, and inbreeding depression have been breeding challenges, but some progress has been made in overcoming fertility problems and seed viability by screening for fertile plants and using embryo rescue to improve seed germination ((Brown, *et al.,* 2017; Batte, *et al.,* 2019)). The insight gained in overcoming inbreeding depression in potato will likely be used in other clonal crops such as banana. We are witnessing conventional breeding advancements that were once used nearly exclusively to improve easy to breed crops, now being actively used in breeding programs for difficult to breed crops.

Some crops that play key roles in nutrition security, sustainable agriculture, biodiversity, and cultural traditions, have been overlooked in agricultural crop development because they represent a small percentage of total tonnage and acreage of production or belong to resource poor nations. These crops may be difficult to breed because genetic tools have yet to be developed. However, this situation could change as advanced breeding tools become more affordable, due to the steep decline in sequencing costs, and therefore more widely deployed in all crops.

Commenters provided APHIS with examples demonstrating that many more than four favorable alleles or QTL can be pyramided. In some cases, modifications are made to more than one gene to create the desired trait. In one example, (Ye, *et al.,* 2008) noted that, in theory, with marker assisted selection coupled with gene pyramiding and double haploid practices, ''a plant having as many as twenty target markers can be obtained at an almost perfect certainty in about three rounds of selection.'' APHIS found several examples in rice where 10 to 11 favorable alleles or QTLs were successfully pyramided (Das, *et al.,* 2018; Dixit, *et al.,* 2020; Sandhu, *et al.,* 2021; Yadav, *et al.,* 2021). In one of the cases, the group initially pyramided 15 alleles and QTLs, with at least some in a heterozygous (non-fixed) condition but lost some in later generations that they might have retained had they chosen to use double haploid technology to fix the alleles and QTLs of interest. We found cases for pyramiding eight alleles or QTLs in tomato (Hanson, *et al.,* 2016), eight and perhaps more in wheat (Tyagi, *et al.,* 2014; Rahman, *et al.,* 2020), seven in canola (Wang, *et al.,* 2023b), six in potato (Rogozina, *et al.,* 2021), five in apple (Baumgartner, *et al.,* 2015), five in tobacco (Lewis, *et al.,* 2020), five in soybean (Diers, *et al.,* 2023), five in grape (Hádlík, *et al.,* 2024), four in coffee (de Almeida, *et al.,* 2021; Saavedra, *et al.,* 2023), and three in poplar (Lv, *et al.,* 2021). In many cases, these pyramids were fixed in the homozygous state, while in other species that are typically vegetatively propagated, some were present in the heterozygous state. For the potato and grape examples, the papers describe cases where breeder collections were screened with markers for resistance genes and individuals in the collection, representing historical crosses, were found to have pyramids of resistance genes. The other examples represent cases where the pyramids were specifically bred *de novo* to combine target genes in the population.

Given the breeding advances that have been made in many crops, the number of modifications that can be made in any crop is not static. Periodic updates to the modifications plants can contain and qualify for exemption, like this one, will remain necessary moving forward. In general, the greater the number of favorable alleles or QTLs to be pyramided in a crop, the greater the number of plants that need to be screened to obtain the desired plant. Various techniques, such as second filial (F2) enrichment, are used to reduce the numbers of plants required, but the numbers of plants required nonetheless rise exponentially with the number of alleles or QTLs to be pyramided (Bonnett, *et al.,* 2005; Wang, *et al.,* 2023a). The extent of pyramiding that is possible also depends on whether the alleles or QTLs are all present in elite lines, such that little or no backcrossing may be required to remove deleterious alleles, or whether the alleles and QTLs are being introgressed from multiple different non-elite lines and wild relatives, requiring extensive backcrossing. Taking these factors and the noted differences between species into consideration, in the final notice we are establishing the number of allowable modifications based on a number that is readily achievable in crops with advanced breeding systems and extending this number to all crops as we see evidence of breeding advances being widely deployed. As we described earlier, for rice at least 10 modifications have already been achieved multiple times (Das, *et al.,* 2018; Dixit, *et al.,* 2020; Rahman, *et al.,* 2020; Sandhu, *et al.,* 2021; Yadav, *et al.,* 2021). Given the rapid advances in plant breeding this number of modifications will quickly, if not already, become out of date. Therefore, in this final notice, AM2 will allow up to 12 modifications made simultaneously or sequentially. Setting the limit at 12 modifications also enables an even number of modifications in diploids, triploids, tetraploids, hexaploids, and octaploids. In terms of counting modifications, both a modification to a single allele and a pair of functionally equivalent modifications to a pair of alleles on homologous chromosomes will count as one modification. Thus, where all alleles of a given locus are modified, the maximum number of modified loci is 12 in diploids, 6 in tetraploids, 4 in hexaploids, and 3 in octoploids. Triploids and pentaploid modifications will be counted as tetraploids and hexaploids, respectively. In polyploids, if only one allele is modified in the case of a dominant mutation, the loci modified can exceed 6, 4, and 3 in tetraploids, hexaploids, and octoploids, respectively. In terms of counting, there are at least three cases where multiple DNA breaks or edits can be made and ''counted'' as a single modification:

1. When two guide RNAs are used to cut out a single contiguous portion of a gene or to otherwise make a single deletion of any size.

2. When multiple indels are created near the target site or at any other unintended sites with near homology to the target site with one indel being functional while the other indels have no additional effect.

3. A gene in the gene pool is inserted into the genome or an existing gene is edited several times to correspond to a gene in the gene pool.

As noted previously, in this final notice, the proposed AM4 is renumbered as AM2 and is revised as follows: ''Plants with up to 12 modifications, made simultaneously or sequentially, are exempt from regulation if each modification individually qualifies the plant for exemption and occurs in a different gene.''

With respect to this final version of AM2, we wish to clarify that the phrase ''individually qualifies the plant for exemption'' refers to the modifications described at § 340.1(b) that qualify

plants for exemption and does not include the exemptions described in § 340.1(c). We also wish to note that when AM2 is used in combination with AM1, we are restricting the use of repair templates to create modifications across subgenomes. As noted above, we expect that ordered mutant libraries could be used to identify similar but not identical deletions across subgenomes in allopolyploid species. We have not yet identified any literature demonstrating that identical indel or deletion modifications can be achieved across subgenomes using conventional breeding methods. For this reason, we are restricting the application of AM2 in combination with AM1, when a repair template is used, to allow modification to one pair of homologous chromosomes. If new literature emerges demonstrating an identical indel or deletion modification can be achieved across subgenomes using conventional breeding methods, we will reconsider this restriction.

Comment: Several commenters asked APHIS to clarify whether AM5 applies to plants that have been cleared through the regulatory status review or petition process. Another concern raised was that AM5 would change a voluntary consultation process into a mandatory process with the requirement that the exemption only applied to plants that are ''produced, grown, and observed consistent with conventional breeding methods.'' Another commenter suggested removing the requirement for a plant to be produced, grown, and observed consistent with conventional breeding methods because it is not clear what APHIS meant. Some commenters noted that APHIS could restrict hypothetical, successively modified plants from AM5 by stating in associated guidance that plants that are merely hypothetical in nature would not be eligible for subsequent hypothetical modifications because they have not yet been produced, grown, and observed consistent with conventional breeding methods for the appropriate plant species.

Response: APHIS acknowledges that plants that are not subject to part 340, because they have undergone the petition process, the regulatory status review process, or meet the criteria for regulatory exemption, may be modified in accordance with the exemption. Therefore, it is no longer necessary to use proposed AM5 to describe this allowance. APHIS wishes to clarify that an exempt plant can only contain a single modification to a particular gene. For example, this means that once a modification has been made to a particular gene and that plant is not subject to part 340, plants with successive modifications to the same gene will not qualify for exemption because such modifications are not achievable through conventional breeding.

APHIS agrees with the commenters who suggested that APHIS should no longer consider hypothetical modifications for confirmation requests. APHIS is concerned that allowing large numbers of hypothetical modifications will overburden APHIS with confirmation requests for plants that have little or no value because the plants may not be viable, may not have the intended phenotype, or have a different genotype than originally requested.

Response to General Comments on the Proposed Modifications

Comment: Pay special attention to the massive lawsuits resulting from the human health impacts of glyphosate, which would not have happened if glyphosate-resistant genetically modified organisms (GMOs) had not been released into the environment.

Response: While it is true that glyphosate has been the subject of litigation, APHIS does not agree with the commenter that glyphosate use on glyphosate resistant (GR) crops has been the primary subject of the litigation. Glyphosate is widely used in the residential lawn and garden market business segment. When glyphosate is used in the lawn and garden markets, glyphosate is not sprayed on GR crops. According to Werner Baumann, CEO of Bayer AG, more than 90 percent of the Roundup litigation claims Bayer has faced in recent years have come from the U.S. residential lawn and garden market business segment that do not involve the application of glyphosate onto GR crops (Brooks, 2021).

Comment: Absent case-specific government oversight, testing, and approval of individual GMO products, how would ''voluntary'' testing by manufacturers protect Americans from potentially negative health effects of consuming products engineered under such broad exemptions?

Response: The modifications (AM1 and AM2) described in this final notice pertain to products that otherwise could be produced by conventional breeding. Although conventional breeding is not risk free, the risks associated with it are manageable by accepted standards (National Research Council, 1989). The health effects of products that qualify for exemption are not expected to be different than the risks posed by conventionally bred crops and likewise manageable by accepted standards.

Comment: What level of documentation and data transparency would be required of GMO producers who might exploit the proposed exemptions?

Response: The developers of crops that qualify for exemption have no requirements to submit documentation to APHIS. If they wish confirmation from APHIS that their particular crop meets the criteria for exemption, the developer can request a confirmation request. Information needed for a confirmation request is detailed in a guide found on APHIS' Biotechnology Regulatory Services website (*https://www.aphis.usda.gov/sites/default/files/requesting-confirmation-of-exemption.pdf*). Again, however, we wish to reiterate that this final notice describes modifications pertaining to products that could otherwise have been developed through conventional breeding. This limitation on the scope of the modifications that plants can contain and qualify for exemption precludes the sort of abuse envisioned by the commenters.

Comment: Would third-party testing be required before releasing food products produced using the proposed modifications and exempt from regulation?

Response: Oversight of all food products including those produced using plants that qualify for exemption is conducted by the U.S. Food and Drug Administration (FDA). FDA recently released guidance for industry on foods derived from plants produced using genome editing (U.S. Food and Drug Administration, 2024). FDA explained in the New Plant Variety (NPV) policy that the regulatory status of a food, irrespective of the method by which it is developed, is dependent upon objective characteristics of the food and the intended use of the food (or its components) (57 FR 22984 at 22984).[2] Please see the FDA's guidance for more information (U.S. Food and Drug Administration, 2024).

Comment: One commenter suggested that USDA conduct public trials to establish the modifications are safe before finalizing the exemptions.

Response: We disagree. The modifications described in this final notice only pertain to plants with modifications that could otherwise be achieved through conventional breeding. Conventionally bred crops have a history of safe use. Public field trials of crops with modifications eligible for exemption would not be expected to reveal otherwise because

[2] May 29, 1992 (57 FR 22984–23005; Docket No. 92N–0139).

the use of genetic engineering, in and of itself, does not present an increased plant pest risk (National Research Council, 1987; National Research Council, 1989; National Academies of Sciences Engineering and Medicine, 2016).

Comment: The proposed modifications sidestep National Environmental Protection Act (NEPA) review, transparency, and public participation.

Response: We disagree with this comment. The exemption at § 340.1(b) excludes from the scope of regulation at part 340, modified plants that could have been created through conventional breeding to ensure that plants with similar characteristics are treated similarly from a regulatory perspective. APHIS assessed this exemption in the Programmatic Environmental Impact Statement (PEIS) prepared to support the 2020 revisions to part 340, which included a thorough, detailed, and transparent review, and invited public comment on, the description of why modified plants described at § 340.1(b) fall outside of APHIS's authority under the regulations. APHIS explained that modified plants that qualify for exemption under § 340.1(b), are no different, as a class, and in terms of plant pest risk, from comparable plants that are made through conventional breeding, which, likewise, do not come before APHIS. In May 2020, when APHIS adopted the revised part 340, APHIS expressly stated in the final rule that it would continue to update the modifications that plants can contain and qualify for exemption to further clarify the types of modified plants that do not fall within the scope of regulation. As described in the PEIS, where, as here, modified plants are not within APHIS's scope of regulation or jurisdictional authority, a NEPA analysis is not required. It is also worth noting that the modifications described in this final notice would have also fallen outside the scope of the legacy regulations previously codified at part 340, because plants with such modifications would not have met the definition of a ''regulated article.'' §§ 340.0, 340.1 (2019). Many developers provide transparency by voluntarily submitting confirmation requests to APHIS. When APHIS confirms a modified plant meets the criteria for exemption from regulation, APHIS posts on its website the incoming submission and our response, redacted to protect Confidential Business Information, as appropriate.

Comment: The modifications may increase the amount of genome edited crops in the food supply and lead to an increase in commingling of genome edited crops with crops that are not produced with genetic engineering or genome editing including organic crops. Crops created using genome editing may not be disclosed as bioengineered. For these two reasons, consumers wishing to purchase food made without this technology may have more limited consumer choice.

Response: Again, it is worth noting that the modifications described in this final notice would have also fallen outside the scope of the legacy regulations previously codified at 7 CFR part 340, because plants with such modifications would not have meet definition of a ''regulated article.'' §§ 340.0, 340.1 (2019). With that said, genome edited crops that meet the criteria for exemption from part 340 are currently not permitted to be used in organic production (National Organic Standards Board, 2019). Inadvertent commingling of crops exempted from part 340 would not result in loss of organic certification to the organic producer, however. Although commingling is possible, if it were to occur, we expect it to occur at a low frequency.

As we noted in the PEIS associated with the 2020 revisions to part 340, on average 1 to 3 percent of non-GE farmers have reported commodity rejection by suppliers due to the presence of GE crop material, and the number of organic farms reporting economic losses from the presence of GE material was 0.7 percent in 2010 (U.S. Department of Agriculture Animal and Plant Health Inspection Service, 2020a). In the PEIS, we also noted that we expected innovation in the agricultural biotechnology to increase under revised part 340, and there could be seen a wider variety of modified crop plants in commercial production. If development and adoption by growers of new varieties of modified crop plants does occur, there may be an increase in the potential for incidents of unintended presence of modified crop material in non-modified crops or crop products. This would primarily be due to the possibility that there would be more modified crop varieties in production and therefore more non-modified crop types that could potentially have commingling issues with the corresponding GE crops. An increase in development and adoption of new varieties of modified crops would entail maintaining segregation of modified crop products from a wider variety of non-modified and identity-preserved cropping systems along supply chains.

Though the likelihood of commingling could increase, there are incentives to keep it low. Identity preserved systems are in place to guard against commingled products entering the marketplace and non-modified producers have economic incentives to keep it low. Furthermore, most modified plants exempt from § 340.1(b) are not immediately commercialized as they may still be subject to regulation by FDA and U.S. Environmental Protection Agency (EPA), as appropriate. From our experience with the Am I Regulated Program (AIR) under the legacy regulations, there were roughly 80 cases of plants that completed the AIR process, but only three of the modified plants were or are being grown in the United States for commercial purposes (High Oleic Acid soybean, waxy corn, and a reduced pungency mustard green). Additionally, it has been our experience that many developers whose products meet the criteria for exemption nonetheless ask for confirmation letters because the letters help them market their products domestically and overseas. These letters are posted on the APHIS website and are available to the public. Organic and other growers of non-modified crops have this resource to become aware of new genome edited crops. Conversations between neighbors and other voluntary interactions are another way for an organic grower to learn whether their neighbors are growing GE crops, and if so, to take steps to minimize commingling.

Comment: Some commenters expressed concern about off target and unintended effects.

Response: APHIS considers some off-target and unintended effects. For example, APHIS considers the unintended retention of exogenous DNA inserted as part of the modification process to be an unintended modification (*e.g.,* DNA encoding genome modification machinery such as the Cas9 protein). APHIS also considers modifications to DNA sequences that are highly similar to the target sequence as unintended modifications (*e.g.,* sequences found in multigene families that have the same or highly similar sequences as the intended target, pseudogenes, or other conserved sequences), as those sequences would likely be modified at frequencies exceeding low-similarity promiscuous binding. Except for § 340.1(b)(3) and AM2 involving § 340.1(b)(3) type modifications (*i.e.,* modifications that allow for the insertion of a gene from a plant's gene pool), the modified plant must be free of any DNA that was deliberately inserted as part of the modification process, including vector sequences, and requests to confirm a plant's exempt status should include

scientific methodology describing the design or verification steps taken to anticipate, reduce, and monitor for off-target modifications to highly similar sequences. For § 340.1(b)(3) and AM2 involving § 340.1(b)(3) type modifications, only DNA from within the gene pool may be retained in the plant.

APHIS does not consider modifications occurring at sites without similarity to the target region, as these are associated with spontaneous or other types of background mutation that occur naturally in plants and do not raise plant pest risk concerns in conventional breeding programs. APHIS does not believe it is necessary to regulate such modifications of genome editing in plants because (1) the mutation rate from genome editing at sites without similarity to the target region is low relative to the background mutation rate that occurs in conventional breeding, and (2) whatever changes do occur are likely to be segregated away from the target mutation during the breeding process. Comprehensive CRISPR/Cas off-target analysis on a genome-wide scale has been performed in rice, maize, tomato, and Arabidopsis (Feng, *et al.,* 2014; Peterson, *et al.,* 2016; Nekrasov, *et al.,* 2017; Feng, *et al.,* 2018; Tang, *et al.,* 2018; Lee, *et al.,* 2019). In these cases where the frequency of mutation at sites without similarity to the target region was measured in CRISPR/Cas expressing lines and their progeny, the authors concluded that the rate of mutation was below the level of background mutation induced during seed multiplication or tissue culture (Hahn and Nekrasov, 2019). Although there can be variation in mutation rates due to the nature of the technique used and the biological system to which it is applied, the mutation rates in such conventional breeding techniques as chemical and irradiation-based mutagenesis dwarf the rate associated with genome editing methods.

Due to the nature of plant breeding—in which populations are created and evaluated, and individual plants are selected for the intended modifications—untargeted modifications (or untargeted mutations) are likely to be lost unless they are genetically linked to the targeted modification that is introduced. For these reasons, APHIS does not consider untargeted modifications (untargeted mutations) when determining eligibility for an exemption. This is also consistent with APHIS' approach regarding conventional breeding techniques.

APHIS believes that similar products should have similar regulatory requirements. Crops made by conventional breeding are not reviewed for spontaneous and/or background mutations.

Comment: There should be no exemptions. There needs to be comprehensive safety testing and long-term environmental monitoring for all GE crops.

Response: This comment is outside the scope of this notice, and, for reasons discussed in the final rule (U.S. Department of Agriculture Animal and Plant Health Inspection Service, 2020c), we disagree with the commenter.

Comment: USDA does not and cannot demonstrate that GE plants thus exempted would not pose increased plant pest or noxious weed risks. Plants that are exempt are more disease susceptible, *e.g. Nicotiana attenuata,* low lignin plants.

Response: Consistent with the provisions in § 340.1(b)(4), the modifications that APHIS has described are not based on plant pest risk per se but, instead, are based on whether the modified plant could have been achieved through conventional breeding. Plants produced through conventional breeding are not risk free; rather, their risks are at an acceptable level that has historically not merited regulation. Plants with additional modifications listed in this final notice are not expected to have any greater risk than those having a history of safe use.

Comment: USDA has placed limitations on the modifications and these limitations are not based on plant pest risk.

Response: As described in the regulations, the modifications described in this final notice are based on modifications that could be achieved through conventional breeding. For each modification, APHIS has identified literature and publicly available information indicating proof of concept that the additional modifications are achievable through conventional breeding.

Comment: Modifications should be inclusive of the current state of scientific knowledge and not just the literature record because the literature does not capture the full range of modifications that are achievable through conventional breeding.

Response: Consistent with the provision at § 340.1(b)(4), APHIS has developed the modifications based on available literature and public information (including the comments we received in response to the proposal) describing modifications achievable through conventional breeding.

Comment: The modifications should broaden the origin boundaries for insertions to include any sequences in the kingdom Plantae versus sexual compatibility.

Response: We acknowledge that examples of horizontal gene transfer have occurred in plants on an evolutionary time scale. Our review of the literature indicates these types of insertions do not routinely occur during the conventional plant breeding process. At this time, we will not broaden the modifications to allow insertions from any species within the kingdom Plantae.

Comment: USDA should broadly exempt all gene edited products.

Response: The exemption at § 340.1(b) is for DNA modifications that could be achieved through conventional plant breeding. Based on the available literature and public information, some types of gene editing can accomplish modifications beyond what can currently be achieved through conventional breeding. Although products with these types of edits are not currently exempt from regulation, most non-exempt plants have a pathway for commercialization through the regulatory status review process to evaluate the plant pest risk of those products.

Comment: A commenter advised APHIS to conduct regular and frequent review of regulations to stay relevant in light of new scientific developments.

Response: APHIS agrees and in fact does so. APHIS also reminds stakeholders that under § 340.1(b)(4), they can help APHIS ensure the regulations are current by informing APHIS of new scientific developments that demonstrate that additional modifications are possible through conventional breeding.

Response To Specific Comments on the Proposed Modifications

Comment: APHIS should also consider the de-regulation of cis genetically engineered crops, made by targeted insertion or CRISPR transposition systems (emerging tools to be utilized in crops).

Response: Plants with targeted insertions qualify for the exemption listed at § 340.1(b)(3) if the inserted sequence is found within the plant's gene pool. CRISPR transposition systems can be used to make cisgenic modifications to plants that qualify for exemption provided the CRISPR tools (or any foreign DNA) are segregated away from the final product.

Comment: APHIS should provide guidance for when a plant contains a modification meets more than one of the criteria for exemption.

Response: The commenter has presented an example where two cuts

are made to a single locus, a deletion that would qualify under AM1 and a targeted insertion that would qualify under § 340.1(b)(3). In cases where a plant has been edited in a manner that meets the description of more than one of the modifications listed under § 340.1(b), developers can claim either type of modification as the basis for their confirmation request.

With the new AM2, there will be cases where a plant may have modifications of multiple types listed under paragraph 340.1(b). For example, a developer might make an indel modification to one gene and a single nucleotide substitution to a second gene. In that case the developer should claim AM2 for the multiple modifications and specify the type of each modification made in the plant. APHIS will provide additional examples on its website for greater clarity. It will be fact specific based on the specific nature of the plant. We invite developers to consult with us to determine the appropriate path.

Comment: Commenters raised the point that the notice did not address triploid crops such as watermelon, banana, and plantain and aneuploids such as peppermint and complex auto/allopolyploids such as sweet potato. A commenter also pointed out that for many species the distinction between auto and allopolyploids is not always straightforward. For example, homologous recombination, one of the distinguishing characteristics of autopolyploid is thought to occur to varying degrees in allopolyploids.

Response: As we are no longer making a distinction between autopolyploids and allopolyploids in the modifications described in this final notice, these points are now moot.

Comment: A comment was made that the term ''loci'' is not precise when applied to allopolyploids because it implies a positional relationship remains intact in evolution and positional relationships between homoeologs could have changed during speciation prior to polyploidization.

Response: We agree with the commenter. It can be difficult to tell whether a gene in one subgenome directly corresponds to a similar gene on another subgenome. Confusion can result because gene families may have arisen due to gene duplication prior to the hybridization event that resulted in the speciation, and after speciation genetic rearrangements may have altered positional information (Adams and Wendel, 2005; Soltis, *et al.,* 2014). Furthermore, after speciation gene inactivation may have reduced the number of gene family members on one subgenome relative to another further confounding the evolutionary relationships between genes (Adams and Wendel, 2005; Soltis, *et al.,* 2014). We wish to clarify that our meaning for genetic locus in allopolyploids pertains to a single pair of alleles in each subgenome at a fixed location and need not reflect positional relationships across other subgenomes.

Comment: Commenters requested clarification as to when an external template may be used.

Response: An external repair template may be used to generate a modification and the plant will qualify for an exemption when creating:

1. An indel without insertion of DNA or a single contiguous deletion of any size provided the final product does not retain foreign DNA (AM1). When combined with AM2, application of AM1/AM2 is restricted in creating exact modifications across subgenomes. For indels or deletions that require exact modifications for the desired outcome, the exemption allows modification to one pair of homologous chromosomes. If an external template is used to make an indel or deletion that need not be specific, such as for gene inactivation, the restriction of AM1/AM2 to one pair of homologous chromosomes does not apply;
2. A single base pair (nucleotide) substitution (§ 340.1(b)(2)); and
3. Insertion based on sequences within the gene pool (§ 340.1(b)(3)).

When an external repair template is used to make a targeted insertion representing a sequence outside the gene pool, the plant would not qualify for exemption.

Comment: The proposed modifications are at odds with international regulations especially on the number of edits allowed and with respect to ploidy. The USDA should consider evaluations undertaken by expert agencies in other geographies such as Argentina, Brazil, Canada, and the European Union.

Response: In response to these comments, APHIS has reviewed the frameworks for other international and domestic regulatory agencies that oversee products of biotechnology. Globally, regulatory frameworks for biotechnology leverage different authorities and definitions, and subsequently have different approaches to regulation. One approach uses the definition of a ''living modified organism'' from the Cartagena Protocol on Biosafety (Secretariat of the Convention on Biological Diversity, 2000) to determine what biotechnology products fall under a regulatory scope. This approach is now used by many countries, including Argentina. Beginning in 2015, and continuing with updates through 2021, Argentina has maintained a regulatory framework [3] for new breeding technologies, including genome editing (Lema, 2020). In Argentina, all modified plants require evaluation to determine whether or not they are considered a GMO under Argentina law. Under the ''Argentina Model,'' products developed using genome editing are not considered genetically modified organisms unless they contain a ''new combination of genetic material,'' which it defines as ''change produced in the genome of the organism by the incorporation, in a stable and joint manner, of ONE (1) or more genes or nucleic acid sequences that are part of a defined genetic construction.'' Regardless of the outcome of this analysis, Argentina may impose monitoring requirements on any plant product based on its characteristics and/or novelty. Countries that have adopted approaches that are similar to the Argentina Model, include Chile, Brazil, Paraguay, Uruguay, Colombia, Guatemala, Honduras, Japan, the Philippines, and Israel.

Other countries have also recently considered how to regulate the products of genome editing within their existing regulatory frameworks. For example, in 2023, the Canadian Food Inspection Agency updated their guidance to clarify that genome edited crops do not present novel risks and, like certain other crops grown in Canada, do not require review unless the crop has an herbicide resistance trait or has both a novel trait and a potential to have significant environmental impacts (Government of Canada, 2023b; Government of Canada, 2023a). The United Kingdom also finalized a ''Genetic Technology Act'' [4] in 2023 to establish new regulatory and marketing standards for plants and animals that are ''precision bred'' and remove such products from regulation as genetically modified organisms. Under this law, a modified plant is ''precision bred'' if ''(a) any feature of its genome results from the application of modern biotechnology, (b) every feature of its genome that results from the application of modern biotechnology is stable, (c) *every feature of its genome that results from the application of modern biotechnology could have resulted from traditional processes,* whether or not in conjunction with selection techniques, alone, and (d) its genome does not

[3] *https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-21-2021-346839/texto.*

[4] Genetic Technology (Precision Breeding) Act 2023 (*legislation.gov.uk*).

contain any feature that results from the application of any artificial modification technique other than modern biotechnology produced through precision breeding techniques, so long as they could have resulted from traditional processes.'' (emphasis added).

In February 2024, the European Parliament voted in favor of proposed legislation [5] that would consider plants produced through ''New Genomic Techniques'' (NGT) (like genome editing) as conventional equivalents if such plants could also occur naturally or be produced by conventional breeding. Under the proposal, an NGT plant ''is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications'' of various types (European Commission, 2023b). These include targeted modifications are similar to those APHIS has identified in § 340.1(b)(1) through (3) and in AM1 and AM2 (small insertions, deletions of any length, nucleotide substitutions, and insertions or substitutions of DNA present in the gene pool of the plant). The proposal, which has not yet reached consensus agreement among EU members, includes a mandatory verification that a plant meets the NGT criteria. Most recently, on July 11, 2024, the European Food Safety Authority (EFSA) published an opinion (European Food Safety Authority Panel on Genetically Modified Organisms, *et al.,* 2024) on the definitions and scientific justification of the NGT proposal in response to an analysis by the French Agency for Food, Environmental and Occupational Health & Safety. EFSA concluded that ''it is scientifically justified to consider [certain NGT plants identified in the proposal] as equivalent to conventionally bred plants.'' As a next step, the Council of the European Union will begin negotiations with member states about the specifics of the legislation—that is to say, this law is not yet final.

Changes in regulatory approaches involving products of genome editing are also being made in southeast Asia. Most recently, in July of 2024, Thailand revised its regulations to allow for the certification and subsequent release into the environment of ''organisms developed from gene editing technology,'' defined as ''organisms that have been genetically improved in a manner similar to mutation or hybridization, where the final product contains genetic material from donor organisms that can naturally crossbreed with the recipient organisms.'' In August 2024, the Singapore Food Agency (SFA) published its framework for genome edited crops (Singapore Food Agency, 2024). SFA will regulate crops that contain foreign DNA, which includes crops with DNA that could not have been inserted naturally or been introduced into the crop using conventional breeding techniques. In cases where the developer determines their crop contains foreign DNA, SFA requires the crop to undergo a pre-market safety assessment. For crops with modifications made through genome editing that do not involve the retention of foreign DNA, developers are encouraged (but not required) to notify SFA in cases where they determine their crop does not contain foreign DNA.

Within the United States, in May 2023, the EPA issued a final rule exempting a class of plant-incorporated protectants (PIPs) created using genetic engineering from registration requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and from the food or feed residue tolerance requirements under the Federal Food, Drug, and Cosmetic Act (FFDCA) (U.S. Environmental Protection Agency, 2023). The final rule exempts PIPs from FIFRA registration and FFDCA tolerance requirements in cases where they both pose no greater risk than PIPs that EPA has already concluded meet safety requirements, and when they could have otherwise been created through conventional breeding, as follows: PIPs in which genetic engineering has been used to insert or modify a gene to match a gene found in a sexually compatible plant; and, loss-of-function PIPs in which the genetically engineered modification reduces or eliminates the activity of a gene, which then helps make the plant resistant to pests. EPA's PIP exemption does not limit the number of modifications developers can make using genetic engineering provided the resulting PIPs meet the criteria for exemption. More recently, on February 22, 2024, FDA issued updated guidance related to the handling of NPV to affirm that ''the regulatory status of foods derived from plant varieties produced using genome editing will, like that of food from other plant varieties, be based on the objective characteristics of the food and the intended use of the food (or its components)'' (U.S. Food and Drug Administration, 2024).

Although there are some differences in specific details, in general, we see countries around the world adopting a similar approach as we have for the movement of plants developed using new genome editing techniques: If a modified plant could have been developed using conventional breeding, the level of regulatory oversight will more closely align with a conventionally developed product. In 2020, when APHIS first adopted the exemption for plants with modifications achievable through conventional breeding, APHIS explained:

''There are many biological and practical factors that affect a plant breeder's ability to develop a new crop variety by introducing genetic variation and intentionally selecting for desired traits. These include the number of targeted loci and type of desired genetic changes, the genetic distance between the desired changes, generation time, breeding system (sexual or asexual), ploidy type and level and genomic complexity, resource availability (time, money, labor, and genomic resources), extent of domestication, and other factors. These factors, and thus the extent of intentionally selected genetic variation that can be introduced, vary widely among plant species. Moreover, new plant breeding techniques can make possible more complex combinations of genetic modifications than can practically be achieved through conventional breeding methods.

Initially, the exemptions will apply only to plants containing a single targeted modification in one of the categories listed. APHIS anticipates scientific information and/or experience may, over time, allow APHIS to list additional modifications that plants can contain and still be exempted from the regulations so that the regulatory system stays up to date and keeps pace with advances in scientific knowledge, evidence, and experience. This may include multiple simultaneous genomic changes.'' (U.S. Department of Agriculture Animal and Plant Health Inspection Service, 2020c).

As discussed above, APHIS has received numerous comments and supporting literature and has conducted our own extensive literature review indicating that 12 modifications are within the scope of conventional breeding for diploids and polyploids. Based on this new information, we have eliminated most restrictions on the modification of allopolyploids, eliminated the restrictions with regard to GOF modifications, and increased to 12 the number of modifications that can be made simultaneously or sequentially in plants that qualify for exemption. As such, the modifications described in this final notice bring APHIS' treatment of plants with modifications that are

[5] *https://food.ec.europa.eu/document/download/c03805a6-4dcc-42ce-959c-e4d609010fa3_en?filename=gmo_biotech_ngt_proposal_2023-411_en.pdf.*

achievable through conventional breeding into greater alignment with other countries that have adopted regulatory approaches that consider most genome edited plants as conventional equivalents, including those that allow multiple modifications and modifications in ploidy plants.

Comment: A commenter noted that several modifications might be made to the same genetic locus if successive rounds of mutagenesis were used. Thus, it seems unnecessary to limit targeted base pair substitutions to one base pair in § 340.1(b)(2).

Response: APHIS is not aware, and the commenter did not provide an example of this type of modification made by conventional breeding. Until we have more concrete proof of concept, APHIS will limit targeted modifications to a single modification per gene. This limitation applies to successive modifications made to a plant that qualifies for exemption under § 340.1(b).

Comment: A commenter noted that a certain number of nucleotides can always be present in a plant's genome simply by chance. In the European Union's proposal for the regulation of NGT, insertions or substitutions of up to twenty nucleotides are considered to be exempted from the GMO regulations, irrespective if they result in GOF or LOF. A similar sentiment was expressed in the comment that sequences of smaller sizes from outside the breeder's gene pool should be exempted.

Response: As noted above, the European Union proposal is not yet final and remains under negotiation within the European Union. As part of considering this proposal, the European Commission has made available a document entitled, ''Potential criteria to determine whether a plant obtained by targeted mutagenesis or cisgenesis could also occur naturally or be produced by conventional breeding techniques,'' which includes a disclaimer indicating this ''draft has not been adopted or endorsed by the European Commission (European Commission, 2023a). Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.'' Although we are not revising the modifications to incorporate this suggestion at this time, we will continue to follow developments in the European Union as they are finalized. With that said, we wish to note that within this final notice, in AM1, we allow insertions that occur in the absence of a repair template. This repair could result in a sequence not within the gene pool and there is no restriction on the size of the repair (insertion).

Comment: One commenter asked for clarification as to whether, in proposed AM4 and AM5, heterozygosity refers to genomic rather than allelic.

Response: In the proposed modifications, the heterozygosity referred to allelic. However, the modifications described in this final notice no longer make distinctions between allopolyploids and autopolyploids, so this point in now moot.

Comment: One commenter noted that the observation mandate in AM5 unfairly penalizes crops with excessively long breeding cycles such as trees or berries, and research groups with limited access to field trials such as small universities.

Response: Moving forward, we will only consider confirmation requests for actual plants with up to 12 modifications. Our standard for the exemption is based on a conventional breeding standard and crops with long breeding cycles are also at a similar disadvantage compared to short cycle crops under conventional breeding. The regulatory status review process provides another pathway to commercialization that may be more advantageous for long cycle crops that require more than 12 simultaneous modifications.

Comment: There is ongoing litigation on the revisions to 7 CFR part 340. New modifications should not be finalized prior to judicial ruling on the ongoing litigation.

Response: We disagree with this comment.

In May 2020, when APHIS issued the final rule outlining the updates to 7 CFR part 340, APHIS anticipated scientific information and/or experience would, over time, allow APHIS to list additional modifications that plants can contain and be exempted from the regulations so that the regulatory system stays up to date and keeps pace with advances in scientific knowledge, evidence, and experience. To ensure the regulations do not apply to plants that are equivalent to those that could be developed through conventional breeding, the May 2020 final rule established a regulatory process for continuously identifying and updating modifications that are achievable through conventional breeding and, thus, exempt from regulation (85 FR 29791–29796; § 340.1(b)). To this end, § 340.1(b)(4) provides that the Administrator may propose to exempt plants with additional modifications, based on what could be achieved through conventional breeding through a notice published in the **Federal Register**.

As of August 2, 2024, APHIS has issued 96 responses confirming the exempt status of modified plants, reviewed 70 other modified plants through the regulatory status review process, and continued to gather information and literature about what can be achieved through conventional breeding methods. For example, as discussed more fully above, since APHIS initially adopted its exemption 4 years ago, advances in conventional breeding methods have enabled the steady introgression of desired genes, alleles, and QTLs in several crops (Krishna, *et al.,* 2023; Abdul Aziz and Masmoudi, 2024). Genomic assisted breeding, genetic mapping and studies, high through-put genotyping, speed breeding, multi-parent advance generation inter-crosses, and pyramid breeding strategies have advanced quickly and are now affordable for many crop types (Krishna, *et al.,* 2023; Abdul Aziz and Masmoudi, 2024), and new methods are consistently emerging to improve and accelerate breeding methods for difficult to breed crops, particularly in crops with a complex autopolyploid genome or with predominant asexual reproduction (Chen, *et al.,* 2021). It is important that APHIS update its list of modifications plants can contain and qualify for exemption from regulations to ensure its regulations reflect these advances in science and technology and remain rooted in the best science.

Indeed, since July 2021, APHIS has followed the established regulatory processes to identify modifications that plants can contain without being subject to part 340 (86 FR 37988 (July 19, 2021); 88 FR 78285). In late July 2021, plaintiffs filed a lawsuit in the United States District Court for the Northern District of California to challenge APHIS' May 2020 final rule.[6] During the pendency of this litigation, countries around the globe have updated their biotechnology policies and regulations related to new plant breeding techniques (or plants with modifications achievable through conventional breeding). As described in greater detail above, many of these countries, including the United Kingdom, the Philippines, Singapore, and Thailand, treat genome edited plants (including polyploid plants) that are free of exogenous DNA as conventional plants irrespective of the number of modifications made to the plants. In contrast, because APHIS was an early

[6] *National Family Farm Coalition, et al.* v *Vilsack, et al.* No. 3:21–cv–05695.

leader in establishing a regulatory exemption for plants with modifications that are achievable through conventional breeding, APHIS initially limited developers to a *single* modification of the type described in § 340.1(b)(1) through (3)—a narrower standard for conventional equivalence compared to both international regulatory frameworks and scientific literature describing what can be accomplished today through conventional breeding methods. To ensure the United States maintains its position as a global leader in agricultural biotechnology regulation and that its regulatory system and list of modifications exempt plants can contain is current and accurately reflects what can be achieved through conventional breeding methods, it is essential that APHIS issue this final notice updating the types of modifications plants can contain and qualify for exemption from regulation.

Issuing this notice is also important to avoid differential treatment for products produced through genetic engineering that are otherwise equivalent to conventionally bred and/or developed products. As discussed above, plants with modifications that are achievable through conventional breeding that qualify for exemption, are no different, as a class, and in terms of plant pest risk, from comparable plants that are made through conventional breeding, which, likewise, do not come before APHIS. Updating the list of modifications that plants can contain and qualify for exemption will ensure that APHIS' regulations do not impose unnecessary costs on modified plants that are equivalent to those developed through conventional breeding, including expenses associated with obtaining a permit, complying with permitting conditions, and preparing submissions for regulatory status review (*i.e.,* the case-by-case method for determining whether a modified plant is subject to part 340, described in § 340.5).

To put these costs in perspective, developers with modified plants that do not meet the criteria for regulatory exemption have the option for obtaining a permit that authorizes the use of the modified plant under conditions or submitting a regulatory status review request that seeks a determination that the plant is not subject to part 340, because it is unlikely to present an increased plant pest risk compared to the non-modified version of the plant. To date, roughly 45 percent of APHIS' regulatory status review submissions have involved plants with modifications that would likely meet the criteria for exemption described in this final notice. On average, APHIS has taken roughly 234 days to complete its evaluation of these modified plants and determine they are not subject to regulation under part 340. Until now, developers have incurred costs associated with regulatory uncertainty, obtaining a permit and complying with associated conditions if they wish to engage in regulated activities (which, could range in cost from $13,000–$671,000, depending on a variety of factors) (U.S. Department of Agriculture Animal and Plant Health Inspection Service, 2020b), and preparing regulatory status review submissions for modified plants that were intended to be exempt from regulation, while APHIS has expended staff resources evaluating modified plants that were not intended to fall within the scope of part 340, which has increased workloads, and, in turn, drawn criticism for increased regulatory processing times and calls for improvement (Bass and Kovak, 2024; Kovak and Bass, 2024; US Congress Committee on Appropriations, 2024). Beyond this, if APHIS were to continue imposing unnecessary regulatory costs on plants with modifications achievable through conventional breeding, the United States could face the risk of U.S. investors going to countries with regulatory frameworks that already treat such modifications as conventional equivalents, including global agricultural competitors (Clayton Yeutter Institute Round Table Discussion, 2023), at a time when the United States seeks to advance the U.S. bioeconomy and biotechnology.

Along these lines, in September 2022, the President issued Executive Order 14081, entitled ''Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure Bioeconomy,'' which directs regulatory agencies to improve the efficiency of biotechnology regulations (Executive Office of the President, 2022). Issuing this notice directly supports Section 8 of this Executive Order, will aid the United States in maintaining its position as a global leader in agricultural biotechnology, and will help keep U.S. developers working in the United States on products that help U.S. producers tackle climate, resource, and food security challenges.

Lastly, it is important to note that the modified plants that are described in this final notice and that are eligible for exemption under § 340.1(b) have never been subject to regulation under part 340—these modified plants were not intended to be within the scope of the revised regulations (part 340 (2020)) and were not within the scope of the legacy regulations (part 340 (2019)), and their conventionally bred counterparts have not been subject to regulation. In fact, if the May 2020 final rule that established the exemption for plants with modifications achievable through conventional breeding were to be set aside, it would mean that all the plants containing the modifications described in this notice—and more—would still be outside the scope of regulation.

The following table summarizes the modifications and their applicability to polyploids:

TABLE 1—SUMMARY OF MODIFICATIONS AND APPLICABILITY TO POLYPLOIDS

Notes	Designation	Modification
1 pair of homologous chromosomes	§ 340.1(b)(1)	The genetic modification is a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template.
1 pair of homologous chromosomes	§ 340.1(b)(2)	The genetic modification is a targeted single base pair substitution.
1 pair of homologous chromosomes	§ 340.1(b)(3)	The genetic modification introduces a gene known to occur in the plant's gene pool or makes changes in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool.
1 pair of homologous chromosomes across subgenomes without repair template and one pair of homologous chromosomes with repair template.	340.1(b)(4)(vi)(AM1)	An indel or contiguous deletion of any size, made at a targeted location, with or without insertion of DNA if generated without using a repair template, or without insertion of DNA if generated using a repair template.

TABLE 1—SUMMARY OF MODIFICATIONS AND APPLICABILITY TO POLYPLOIDS—Continued

Notes	Designation	Modification
Allows up to 12 simultaneous (multiplex) or sequential modifications.	340.1(b)(4)(vi)(AM2) ..	Plants with up to 12 modifications, made simultaneously or sequentially, are exempt from regulation if each modification individually qualifies the plant for exemption and occurs in a different gene. Modifications to either a single allele or pair of alleles on homologous chromosomes will count as one modification. See website for information on counting modifications.

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Accordingly, pursuant to the process established under § 340.1(b)(4), we are adopting the two additional modifications articulated in this notice for the reasons set forth in our initial notice and in this final notice.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 6th day of November 2024.

Michael Watson,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2024–26232 Filed 11–12–24; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Environmental Impact Statement; Coon Creek Watershed

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Notice of availability; record of decision.

SUMMARY: This notice of availability presents the Record of Decision (ROD) on a Watershed Project Plan—Programmatic Environmental Impact Statement (Plan-PEIS) for the Coon Creek Watershed prepared in partnership with La Crosse, Monroe, and Vernon Counties, Wisconsin (Sponsors). This notice announces the plan to proceed with the implementation of Alternative 2—Proposed Action—Decommission Dams, identified in the Plan-PEIS. Alternative 2 proposes to decommission all 14 dams by excavating a notch to pass the 100-year flood without impounding water. This action will avoid environmental impacts to the extent possible and mitigate impacts that are unavoidable.

ADDRESSES: You may request a copy of the ROD from: Steve Becker, NRCS State Conservation Engineer, 8030 Excelsior Drive, Suite 200, Madison, WI 53717.

FOR FURTHER INFORMATION CONTACT: Steve Becker; telephone: (608) 400–6176; or email: *steve.becker@usda.gov.* Individuals who require alternative means for communication should contact the U.S. Department of Agriculture (USDA) Target Center at (202) 720–2600 (voice and text telephone (TTY)) or dial 711 for Telecommunications Relay service (both voice and text telephone users can initiate this call from any telephone).

SUPPLEMENTARY INFORMATION:

Decision

Natural Resources Conservation Service (NRCS) has prepared a ROD following completion of the Plan-PEIS. The Plan-PEIS provides a retrospective analysis of the existing flood control project and then evaluates alternatives for the final disposition of 14 flood control dams. The purpose of the Plan-PEIS is to ensure agencies consider the environmental impacts of their action in decision making. NRCS involvement is through Public Law 83–566, Watershed Protection and Flood Prevention Act, as amended. The ROD is available for viewing at the following link: *https://www.wfkandccwatersheds.com/2023.*

NRCS has decided to assist the Sponsors with implementing Alternative 2 which proposes to decommission all 14 dams in the watershed.

Background

The Coon Creek Watershed has an area of 90,601 acres (141.6 square miles) to the confluence with the Mississippi River. The focused planning area for the Plan-PEIS is 68,762 acres (107.4 square miles). The Plan-PEIS is follows an original Watershed Work Plan developed in 1958 to reduce flood damages in the Coon Creek valley under the Watershed Protection and Flood Prevention Act of 1954, as amended.

The major problems in the watershed in 1958 were floodwater damages to: crops and pasture, fences, farmsteads, machinery, buildings, livestock, county and township roads and bridges, and urban areas of Coon Valley and Chaseburg. Project measures implemented under the original Watershed Work Plan included 14 flood control dams installed between 1961 and 1964 with a total capacity of 1,160 acre-feet to regulate flood flows from 21 square miles, or 27 percent of the watershed above the village of Coon Valley. Project measures also included a multitude of land treatment practices to reduce erosion and sedimentation behind the dams. The dams have now completed their Federal interest or original economic evaluation period of 50 years.

On the night of August 27, 2018, seven watershed dams over-topped and three dams failed including the Luckasson Dam (CC 21); Blihovde Dam (CC23); Korn Dam (CC 29). Rainfall amounts up to 11 inches were reported on the night of August 27 and early morning of August 28. Additional rainfall amounts up to 7 inches were reported in the afternoon of August 28 after the dam failures.

The dams failed (breached) along the interface between the earthfill and highly jointed sandstone abutments. Each breach extended full depth to the valley floor. No one was injured or killed. Large debris fields were observed downstream of the dams for about 2 miles. Barns and outbuildings were destroyed. An unoccupied house was moved off its foundation. Agricultural lands and road crossings were damaged. Engineering investigations concluded that flow through the jointed sandstone during high pool stage caused internal erosion and piping of the earthfill dam and contributed to the failures. The Sponsors and NRCS are concerned that a similar vulnerability exists in the remaining 11 dams.

Environmental Review

The ROD summarizes the findings of the Plan-PEIS and provides the basis for a decision to decommission 14 flood control dams in the Coon Creek watershed. The watershed project plan and the environmental document were combined in the single Plan-PEIS document. NRCS is the lead Federal agency responsible for the content and quality of the Plan-EIS for the purposes