



Questions & Answers

Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) Rule Confirmation Process

June 2020

Q: When does the new exemption and confirmation process take effect?

A: The new process takes effect on August 17, 2020.

Q: When APHIS issues its confirmation process guidance, will it be draft or final?

A: APHIS will issue final guidance that aligns with the preamble of the SECURE rule. The final guidance will be posted on the APHIS-BRS SECURE webpage. However, we fully expect the guidance will periodically undergo revisions. APHIS will provide opportunities for the public to submit comments and requests for clarification, and the Agency intends to update it as necessary.

Q: Is APHIS prepared to handle an influx of confirmation requests?

A: We have been building our cadre of biological scientists and preparing for the implementation of SECURE for many months. If APHIS experiences a large influx of requests, we will prioritize those that are for actual plants that have been developed above those that are for hypothetical plants not yet developed. We recommend prospective requestors seek early consultation to efficiently scope out any potential issues.

Q: Will the data/information from the confirmation process be harmonized with the requirements for other federal agencies?

A: APHIS, the U.S. Environmental Protection Agency, and the U.S. Food and Drug Administration, may look at the same plant, but do so for different reasons. Therefore, in some instances, the Agencies may review different information or data to make determinations. We have worked to harmonize with our partner agencies on the terminology we use when working with requestors, and to recognize the work and review of other Agencies and, where possible, eliminate duplicative review.

Q: Will there be barriers for small organizations to navigate the confirmation process?

A: No, APHIS does not anticipate barriers for small organizations. Our goal is to make the rule implementation experience positive for organizations of all sizes. APHIS will conduct technical training webinars and make them available to companies of all sizes to assist them with navigating the regulatory framework. In addition, APHIS is available for consultation with companies of all sizes to respond to regulatory questions or assist in capacity building.

Q: Has APHIS received feedback from foreign stakeholders regarding whether they will consider APHIS confirmation letters acceptable for the purposes of market access?

A: Many countries are already familiar with and have experience with APHIS letters generated under the “Am I Regulated?” (AIR) process. To further this effort, APHIS is initiating additional meetings with many countries to discuss the implementation of SECURE and any implication to trade.

Q: Will APHIS include the rationale for the exemption in the confirmation letters?

A: Yes, APHIS intends to include language in all confirmation letters that explains the scientific underpinning for the exemption being confirmed.

Q: What is the typical timeframe for Agency review and response to requests for exemptions?

A: We expect that APHIS will provide a written response (confirmation letter) within 120 days of receiving a sufficiently detailed exemption confirmation request letter, except in circumstances that could not reasonably have been anticipated.

Q: Does APHIS envision a time lag between responding to a request and posting it online?

A: Once APHIS has provided a confirmation response, we anticipate posting the response on the APHIS-BRS SECURE webpage in 1-2 business days.

Q: What is APHIS’ plan to ensure potential requestors are aware of the voluntary process?

A: APHIS has reached out extensively to stakeholders of all kinds, including researchers, universities and developers of all sizes. We invite suggestions for audiences and settings that may benefit from presentations on the confirmation process. You may submit any such suggestions to ConfirmationRequests@usda.gov.

Q: Will the online interface that APHS uses for confirmation requests be permanent?

A: Initially, APHIS will receive requests for confirmation via submissions to: ConfirmationRequests@usda.gov. We expect that as we gain experience with confirmation requests, APHIS will update and improve the online interface that requesters use to access the confirmation process.

Q: Is APHIS contemplating providing additional exemptions during the phase-in period of the confirmation process?

A: When we start to implement the regulations, we do not expect new exemptions to be available at that time. However, once implementation has begun, we welcome stakeholders to submit requests for expansion of the exemptions as described in § 340.1(b)(4)).

Q: Sometimes the result of DNA repair might be a substitution or the insertion of two base pairs. If such a situation arises, does that fall under the SECURE rule § 340.1(b)(1) or § 340.1(b)(2)?

A: Exemption pursuant to § 340.1(b)(1) in the SECURE rule applies to modifications resulting from endogenous cellular repair in the absence of an exogenous template.

Q: What is the implementation date for the plant-trait-mechanism of action (MOA) combinations that are exempted because they were previously evaluated by APHIS?

A: Any plant-trait-MOAs that APHIS has already reviewed and deregulated will become part of exemption described in § 340.1(c)(1), and will be implemented on August 17, 2020. We are currently developing a list that will be available on the APHIS-BRS SECURE webpage to help identify products that relate to this exemption. We expect to post this list in early August 2020. Over time, APHIS will build-out this list with the new products that have successfully undergone a regulatory status review.

Q: Can a product be exempt from APHIS biotechnology regulations if it is the same as a product that previously navigated the AIR process?

A: No. Previous AIR determinations are limited to that particular requestor and specific plant(s).

Q: If I have a new plant-trait-MOA, what is the new process to work with APHIS regarding its regulatory status?

A: We would recommend that a requestor first look to see if their plant meets one of the four exemptions established in the SECURE rule. If not, we would recommend that they submit a Regulatory Status Review (RSR) request. The RSR process starts for six species (corn, soybean, cotton, potato, tomato, and alfalfa) in April 2021, and for all other plant species in October 2021.

Q: If a certain modification is exempted from the regulation, could a requestor link or connect subsequent requests to make multiple sequential modifications to the same plant and still be exempted?

A: Requestors can submit plants containing multiple modifications for evaluation through the Regulatory Status Review process. We expect it will take about 180 days to perform an initial assessment, and some plants containing the types of changes described in this question could be excluded from regulation under this process. Over time, we anticipate that the process described in § 340.1(b)(4) will enable expansion of the exemptions to allow for multiple modifications in specific plant species based on what could otherwise be achieved through conventional breeding.

Q: Will combinations of modifications qualify for an exemption under SECURE?

A: As a general matter, APHIS does not believe that combinations of modifications made simultaneously or sequentially in the same plant will initially qualify for an exemption under SECURE, with two exceptions. First, if single modifications that are exempt from regulation are

subsequently combined through conventional breeding, the resulting offspring will not be subject to regulation under SECURE. Second, if a plant contains multiple plant-trait-MOA combinations and the same set of plant-trait-MOA combinations was previously deregulated, the plant would not be regulated under SECURE. Plants with other combinations of modifications can be submitted to APHIS for review through the RSR process starting in April 2021 for six species (corn, soybean, cotton, potato, tomato, and alfalfa), and for all other plant species in October 2021.

Q: Is a deletion made using templated repair of a DNA break exempt from the regulations?

A: At this time a deletion made using a templated repair of a DNA break is not exempt from the regulations unless it qualifies for the exemption in § 340.1(b)(3) because it is known to occur in the gene pool of the plant.

Q: Is a deletion made using two DNA breaks, one at each end of the deletion, exempt?

A: At this time a deletion made using two DNA breaks is not exempt from the regulations unless it qualifies for the exemption in § 340.1(b)(3) because it is known to occur in the gene pool of the plant.

Q: If a genome editing tool, such as a base or prime editing, was used to generate a gene sequence with multiple nucleotide variations that is identical to an existing allele in the gene pool of a plant, would the plant qualify for exemption?

A: Yes, a plant containing multiple nucleotide variations in a specific gene sequence would qualify for exemption found at § 340.1(b)(3) (if the resulting gene sequence is identical to an existing allele in the gene pool).

Q: If repair of a DNA break at the same location in two homologous chromosomes in diploid plants results in slightly different mutations, each of which individually qualifies for the exemption in 340.1(b)(1), would the resulting plant be exempt? What if the same occurs on two or more homologous chromosomes in autopolyploid plants, or on two or more homoeologous chromosomes in allopolyploid plants?

A: The exemption in § 340.1(b)(1) applies to plants in which repair of a targeted DNA break results in different molecular alterations on two homologous chromosomes, as long as each alteration results in the complete loss of gene function. In cases where there are functional differences between the two corresponding alleles, the exemption does not apply.

Q: Would an exemption confirmed in one variety (say an insertion/deletion that results in loss of function) be applicable to an edit to the same gene in another variety of the same crop?

A: In general, an exemption confirmed in one variety would be applicable to other varieties of the same crop, provided that the modification is the same in the subsequent varieties or is in the same gene and results in the same functional difference from the unmodified plant.

Q: For genome edited products that qualify for the exemption, is there an expectation the molecular data would be useful or needed?

A: There is no expectation that molecular data will be provided. However, molecular data may be useful or needed depending on what APHIS is specifically being asked to confirm. For example, data would need to be provided for APHIS to confirm that a plant qualifies for an exemption based on a detailed review of the plant. Data would not be required for APHIS to confirm that a plant qualifies for an exemption based on a developer's representation of the modification and the scientific methodology used to justify that the plant qualifies.

Q: If two exempt plants are conventionally bred together, are the offspring also exempt?

A: Yes.

Q: What happens if APHIS is unable to confirm a plant is exempt from the regulations? Will APHIS post those responses?

A: If APHIS reviews a request and concludes that the plant is not eligible for exemption, the request and a response will be returned to the developer without further action. The response will not be publicly posted.