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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Doc. No. AMS–NOP–21–0008]

RIN 0581–AE02

Inert Ingredients in Pesticides for Organic Production

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: This advance notice of proposed rulemaking (ANPR) seeks input from stakeholders about how to update the United States Department of Agriculture (USDA) organic regulations on inert ingredients in pesticides used in organic production. The USDA Agricultural Marketing Service (AMS) seeks comments on alternatives to its existing regulations that would align with the Organic Foods Production Act of 1990 (OFPA) and the U.S. Environmental Protection Agency's (EPA) regulatory framework for inert ingredients. Information from public comments would inform AMS's approach to this topic, including any proposed revisions of the USDA organic regulations.

DATES: Comments must be received by November 1, 2022.

ADDRESSES: To submit comments on the ANPR, use any of the following procedures:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. You can access this ANPR and instructions for submitting public comments by searching for document number, AMS–NOP–21–0008.
- *Mail:* Jared Clark, Standards Division, National Organic Program, USDA–AMS–NOP, 1400 Independence Ave. SW, Room 2642–S., Ag Stop 0268, Washington, DC 20250–0268.

All submissions received must include the docket number AMS–NOP–21–0008, and/or Regulatory Information Number (RIN) 0581–AE02 for this ANPR. AMS seeks information and feedback on specific topics listed in this ANPR. Commenters are also invited to provide information and perspectives on inert ingredients for topics not requested by AMS in this notification. Specific and relevant information and data to support your comments is encouraged, including, scientific, environmental, manufacturing, industry, or impact information. Comments received will be posted to *https://www.regulations.gov.*

To access the document, related documents, and comments received, go to *https://www.regulations.gov/* (search for Docket ID AMS–NOP–21–0008).

FOR FURTHER INFORMATION CONTACT: Jared Clark, Standards Division, National Organic Program. Telephone: (202) 720–3252. Email: *jared.clark@usda.gov.*

SUPPLEMENTARY INFORMATION:

I. Summary

This ANPR seeks input from stakeholders about how to rectify the USDA organic regulations' references to outdated EPA policy on inert ingredients used in pesticide products. The outdated references are inconsistent with current EPA requirements. This causes problems in the organic industry and for AMS's administration of the USDA organic regulations (see Background section).

Inert ingredients (''inerts''—also identified as ''other ingredients'' on pesticide labels) are substances other than the ''active'' (*i.e.,* pesticidal) ingredients included in formulated pesticide products. Inert ingredients added to pesticides may function, for example, as adjuvants, solvents, diluents, stabilizers, or preservatives. Pesticide labels do not typically disclose the identity (common or chemical name) of the inert ingredients in the product.

For organic crop and livestock production, current USDA organic regulations allow EPA List 3 and List 4 inert ingredients to be used in pesticide products when the product includes active ingredients permitted by the organic regulations. Together, EPA List 3 and List 4 include more than 2,700 inert ingredients.[1] AMS does not know how many of these inert ingredients are included in products used in organic production, but it is likely a relatively small subset of these 2,700 ingredients. These lists were last updated by the EPA in 2004 and will not be updated again (see Background section).

In this ANPR, AMS's National Organic Program (NOP) seeks comments that will assist the Agency in assessing the feasibility of alternatives that could replace the references to these outdated EPA lists. Information from public comments would inform AMS's approach to this topic, including any proposed revisions of the USDA organic regulations. AMS seeks comments to identify alternatives as well as to receive information about obstacles and the costs and benefits of options. Stakeholders that may be affected by future actions on this topic include pesticide manufacturers, certified organic operations, consumers, certifying agents, and other interested parties.

II. Background

Inert ingredients are key components of formulated pesticide products. These ingredients can, for example, increase the effectiveness of pesticidal products, increase a product's shelf-life, or prevent degradation.[2] Inert ingredients, being a key component of pesticide products, are specifically identified in the Organic Foods Production Act of 1990 (OFPA). Under OFPA at 7 U.S.C. 6517(c)(1)(B)(ii), the National List may provide for the use of substances in an organic farming or handling operation if the substance is used in production and contains synthetic inert ingredients that are not classified as inerts of toxicological concern by the EPA, in addition to the general considerations for National List substances at 7 U.S.C. 6517(c)(1)(A) and 6518(m).

In a December 16, 1997, proposed rule to establish the National Organic Program (62 FR 65850), AMS proposed that all inert ingredients not classified by the EPA as ''of toxicological

[1] ''Categorized List of Inert Ingredients (Old Lists),'' U.S. Environmental Protection Agency, *https://www.epa.gov/pesticide-registration/categorized-lists-inert-ingredients-old-lists.*

[2] ''Inert Ingredient Frequently Asked Questions,'' U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, December 2015, *https://www.epa.gov/sites/default/files/2015-12/documents/faqs.pdf.*

concern'' be allowed when formulated with allowed active ingredients. During this time, the EPA classified inert ingredients using categorical lists to group these substances by toxicological concern and risk. While the proposed regulatory text did not reference the EPA Lists, AMS stated in the preamble of the proposed rule that only EPA List 1 was to be used to identify inert ingredients of toxicological concern.

In February 1999, in response to this proposed rule, the National Organic Standards Board (NOSB or Board), a Federal advisory committee established by the OFPA, recommended that inert ingredients appearing on:

- EPA List 1 and List 2 be prohibited;
- EPA List 3 be prohibited unless specifically approved by the NOSB; and
- EPA List 4 should generally be allowed, unless explicitly recommended for prohibition.[3]

AMS agreed with the NOSB's recommendation. In the December 21, 2000, final rule (65 FR 80547), EPA List 4 was added to the National List. This allowed any synthetic substance on EPA List 4 to be in pesticide products used in organic crop and livestock production (when used in conjunction with pesticides containing allowed active ingredients). Subsequently, AMS amended the National List to include an allowance for EPA List 3 inert ingredients for use in crop production only in passive pheromone dispensers, effective November 3, 2003 (68 FR 61987). EPA List 1 and List 2 contain only synthetic substances. They remain prohibited and are not listed as allowed on the National List.

When NOP added these lists, referencing an entire set of substances in a single entry on the National List, as recommended by the NOSB, limited disruption to the organic industry because it allowed most inert ingredients that were approved by organic certifying agents prior to implementation of the USDA organic regulations. The regulatory framework that relied on EPA List 3 and List 4 also reduced the administrative burden on the NOSB and on AMS, as the effort to evaluate each allowed synthetic inert substance on the National List would have likely exceeded available resources. As a result, pesticides containing inert ingredients of toxicological concern (*i.e.,* EPA List 1 and List 2) were not allowed in organic production, but organic producers continued to have access to pesticides containing inert ingredients on EPA List 3 and List 4.

The EPA moved away from their own categorical list system while AMS developed regulations to establish the NOP and the USDA organic requirements (7 CFR part 205). The passage of the Food Quality Protection Act of 1996 (FQPA, 7 U.S.C. 136 *et seq.*) mandated that the EPA develop tolerances (or tolerance exemptions) for inert ingredients used in food-contact products. These tolerances, which are the maximum amount of a pesticide allowed to remain in or on a food, are codified in EPA regulations at 40 CFR part 180. As a result, new and existing inert ingredients are approved for use through EPA's rulemaking process, and the EPA Lists referenced in the USDA organic regulations are no longer updated.[4]

In response to these lists no longer being updated, the NOSB passed an April 2010 recommendation to replace references to EPA List 3 and List 4.[5] This recommendation proposed a system in which the NOSB would evaluate inert ingredients on EPA List 3 and List 4 for a synthetic or nonsynthetic determination (the terms ''synthetic'' and ''nonsynthetic (natural)'' are defined in the organic regulations at 7 CFR 205.2). Following classification, the list of the nonsynthetic inert ingredients would be presented as the ''first choice,'' or preferred, inert ingredients for manufacturers when formulating pesticide products for organic production. Under this recommendation, synthetic inert ingredients could only be added to the National List through the petition process to the NOSB. This work was to be conducted through a working group comprised of NOSB members, representatives from the EPA's Design for the Environment/Safer Choice program, and AMS. This working group eventually led to the development of a subsequent October 2015 NOSB recommendation.

In October 2015, the NOSB recommended an annotation change to address the National List references to EPA List 3 and List 4.[6] This recommendation, like the 2010 recommendation, suggested a change to the annotations at 7 CFR 205.601(m) and 205.603(e) to remove references to EPA List 3 and List 4. This recommendation suggested replacing these references as follows:

- Allow inert ingredients that are permitted in ''minimum risk pesticide'' products that are exempt from registration as described in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). (Note: as of February 2016 (80 FR 80653), this list of inert ingredients is codified at 40 CFR 152.25(f)(2));
- Allow substances listed on EPA's Safer Choice program's Safer Chemical Ingredients List; and
- Allow inert ingredients exempt from the requirement of a tolerance at 40 CFR 180.1122 (only for use in passive pheromone dispensers).

The working group continued through 2017 with a goal of rulemaking prior to the NOSB's 2020 List 4 sunset review (a process in which National List substances are reviewed every five years to assess continued OFPA compliance).

Given the emphasis the NOSB gave the Safer Choice program to help resolve the issue with the outdated lists, AMS consulted with the Safer Choice program in September 2021. This consultation explored ways EPA's program could assist with a solution to the references to EPA List 3 and List 4 in the National List. The meeting highlighted many reasons why the Safer Choice program is not well suited to help address this issue. First, there is a discrepancy between the structure of the programs: the NOP is a regulatory program, while the Safer Choice program is a voluntary program that exists outside of a regulatory framework. The issues associated with this discrepancy are further explained in the Regulatory Challenges section.

Second, the expertise, review criteria, and structure of the Safer Choice program is focused on review of cleaners and disinfectants, not crop and livestock pest control products. As a result, it does not directly translate to review of crop and livestock pest control materials. Further, the Safer Choice program generally does not meet the needs of AMS or NOSB in addressing the outdated references to the EPA lists in the organic regulations, as replacement inert ingredients in the

[3] National Organic Standards Board Joint Committee Meetings, Washington, DC, May 1–2, 1992; Minneapolis, Minnesota, May 4–6, 1992, *https://www.ams.usda.gov/sites/default/files/media/NOSB%20Meeting%20Minutes%26Transcripts%201992-2009.pdf.*

[4] ''Categorized Lists of Inert Ingredients (Old Lists),'' U.S. Environmental Protection Agency, *https://www.epa.gov/pesticide-registration/categorized-lists-inert-ingredients-old-lists.*

[5] ''Inerts in Pesticides Allowed for use in Organic Production,'' Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP), April 29, 2010, *https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20on%20Inerts%20in%20Pesticides.pdf.*

[6] ''Formal Recommendation from National Organic Standards Board (NOSB) to the National Organic Program (NOP),'' October 29, 2015, *https://www.ams.usda.gov/sites/default/files/media/CS%20LS%20EPA%20List%204InertsAnnotation_final%20rec.pdf.*

National List must meet specific requirements of the OFPA, including human and environmental health impacts, natural substitute products, toxicological concerns, and compatibility with organic farming. While Safer Choice may consider similar criteria in their review of products, they do not consider them in the scope of crop and livestock production, nor are they considerations which would be easily integrated into their system.

At the conclusion of the NOSB's October 2020 sunset review for EPA List 4 substances, AMS had not yet initiated rulemaking to address these references, for reasons discussed in the Regulatory Challenges section and elsewhere in this ANPR. Acknowledging the lack of rulemaking on this topic, the NOSB discussed voting to remove EPA List 4 from the National List to encourage rulemaking action.[7] Ultimately, the Board voted to not recommend removal of EPA List 4 inert ingredients from the National List,[8] noting a desire to minimize market disruption. In August 2021, AMS renewed the listing of EPA List 4 on the National List until March 15, 2027 (86 FR 41699).

During its October 2020 meeting, the Board also passed a resolution encouraging coordination between the Board and the NOP to replace the outdated reference to EPA List 4 on the National List.[9] This resolution requested that AMS work with NOSB to develop an alternative review process for inerts, work with NOSB to develop an implementation timeline, and coordinate with NOSB on progress to develop an alternative to EPA List 4. This ANPR solicits feedback on alternatives, and comments received would inform AMS's approach on this topic, which may include further consultation with the NOSB and proposed revisions to the USDA organic regulations.

[7] ''Public Comment Webinar,'' United States Department of Agriculture, National Organic Standards Board, October 20, 2020, *https://www.ams.usda.gov/sites/default/files/media/TranscriptsNOSBOctober2020.pdf*.

[8] ''Formal Recommendation from National Organic Standards Board (NOSB) to the National Organic Program (NOP),'' 2022 Sunset Reviews—Crops, October 30, 2020, *https://www.ams.usda.gov/sites/default/files/media/CS2022SunsetRecs_webpost.pdf*.

[9] ''NOSB Resolution from National Organic Standards Board (NOSB) to the National Organic Program (NOP),'' Resolution on EPA List 4 Inerts, October 30, 2020, *https://www.ams.usda.gov/sites/default/files/media/NOSBResolutionList4InertsRec_webpost.pdf*.

III. Potential Replacements for EPA List 3 and/or List 4

In this ANPR, AMS describes five options (in sections A–E) for updating references to inert ingredients in the USDA regulations on organic production. These options were received as recommendations from the NOSB or identified as possibilities by AMS. AMS also outlines some of the advantages and disadvantages of each option. We did not include an option that references the Safer Choice program for reasons explained in the Background section. A robust alternative to the existing regulations may require implementing more than one option. Commenters are invited to comment on the costs and benefits, obstacles or other aspects of these options.

A. Allow Inert Ingredients Permitted by EPA in Minimum Risk Pesticides

This option would replace the reference to EPA List 4, in part, with an allowance for inert ingredients allowed by EPA regulations in ''minimum risk pesticides.'' Minimum risk pesticides are pesticides that are exempt from regulation under FIFRA because they pose little to no risk to human health or the environment.[10] These inerts are listed in Table 2 at 40 CFR 152.25(f).

This option would:

- Satisfy the OFPA requirement that inert ingredients not be classified by the EPA as ''inerts of toxicological concern,'' as the EPA review process for all food-use inert ingredients includes a robust evaluation of toxicity and exposure risks;
- Be similar to current regulations, and relies on the EPA's assessment of inert ingredients; and
- Not allow substances currently used in formulated pesticide products (in compliance with current USDA organic regulations at § 205.601(m) and § 205.603(e)) that are not on EPA Table 2 at 40 CFR 152.25(f). This could eliminate products currently available to organic producers and/or require manufacturers to reformulate.

B. Allow Specific Inert Ingredients Permitted by EPA

This option focuses on List 4 only, to explore a partial solution with respect to that list. This option would replace reference to EPA List 4 with an allowance for an inert ingredient that is exempt from the requirement of a tolerance. These inert ingredients are listed at 40 CFR part 180 subpart D (§§ 180.900–180.1381). Active ingredients in these sections that are exempt from the requirements of a tolerance that do not have an allowed use as an inert would not be permitted.

This option would:

- Satisfy the OFPA requirement that inert ingredients not be classified by the EPA as ''inerts of toxicological concern,'' as the EPA review process for all food-use inert ingredients includes a robust evaluation of toxicity and exposure risks;
- Be similar to current regulations, as this option relies on the EPA's assessment of inert ingredients. Inerts permitted by the EPA are codified (appear in the Code of Federal Regulations [CFR]) and could be easily cross-referenced within the USDA organic regulations. When EPA adds or removes inert ingredients, the USDA organic regulations would not require corresponding revisions. Additional engagement with EPA in their rulemaking process by AMS and stakeholders may be warranted to stay informed of changes to EPA regulations; and
- Potentially permit the use of more inert substances compared to the number of inert substances on EPA List 4 (approximately 870 substances) and EPA List 3 (approximately 1,850 substances).

C. Replace EPA List 3 With EPA-Allowed Inert Ingredients of Semiochemical Dispensers

This option would focus on List 3 only, to explore a partial solution with respect to that list. This option would replace the current reference to EPA List 3 (for inert ingredients used in passive pheromone dispensers) at 7 CFR 205.601(m)(2) with reference to the current EPA framework for inert ingredients in ''semiochemical dispensers.'' Semiochemicals are chemicals that are emitted by plants or animals and modify the behavior of the receiving species (*e.g.,* disruption of mating for the purposes of pest control). Special conditions for the exemption of these inert ingredients appear in EPA regulations at 40 CFR 180.1122 (''Inert ingredients of semiochemical dispensers; exemptions from the requirement of a tolerance''). These special conditions include, among other things: (1) Exposure that must be limited to inadvertent physical contact only; and (2) design of the dispenser must preclude any contamination by its components of the raw agricultural commodity or processed foods/feeds derived from the commodity by virtue of its proximity to the raw agricultural

[10] ''Minimum Risk Pesticide: Definition and Product Confirmation,'' U.S. Environmental Protection Agency, February 1, 2021, *https://www.epa.gov/minimum-risk-pesticides/minimum-risk-pesticide-definition-and-product-confirmation*.

commodity or as a result of its physical size (see 40 CFR 180.1122(a)(1)). Exposure must be limited to inadvertent physical contact only. The design of the dispenser must be such as to preclude any contamination by its components of the raw agricultural commodity or processed foods/feeds derived from the commodity by virtue of its proximity to the raw agricultural commodity or as a result of its physical size.

This option would:

- Continue to allow passive pheromone dispensers; and
- Simplify the review of formulated products for certifying agents and third parties who review inputs for compliance with USDA organic regulations.

D. List Inert Ingredients Individually on the National List

As a replacement to List 3 and/or List 4, inert ingredients could be migrated to the USDA organic regulations at 7 CFR part 205 as individual itemized or grouped listings. This would result in a codified list of inert ingredients, contained within the National List. In developing a list of inert ingredients, EPA List 3 and List 4, as well as work done by the EPA (either by AMS in cooperation with EPA or extracted from the list of inerts permitted in minimum risk pesticides at 40 CFR 152.25(f)(2)), could be used to identify inert ingredients for proposal for inclusion on the National List. Alternatively, inert ingredients for consideration could be identified by pesticide manufacturers or other parties through petitions to the NOSB. In either case, the individual substances would be reviewed by the NOSB, and, if recommended, inert ingredients could be added to the National List by AMS through the rulemaking process.

This option would require substantial work by both the NOSB and AMS. Specifically, this option would:

- Require coordination or validation of these inert ingredients by the EPA to verify they are not of toxicological concern to meet the OFPA requirement that synthetic inert ingredients not be classified by the Administrator of the EPA as ''inerts of toxicological concern'';
- Require a sunset review of approximately 190 substances currently in use in organic-compliant pest control products every five years as required by OFPA at 7 U.S.C. 6517(e). This change would nearly double the number of substances currently present on the National List (approximately 230 substances) and would significantly increase the NOSB's and NOP's workload; and
- Likely require a lengthy implementation period to minimize disruption and provide adequate time for submission of petitions, NOSB review, and AMS rulemaking.

E. Take No Action (Status Quo)

This option would maintain the status quo and continue to rely on historical EPA List 3 and List 4. Any person may submit a petition to add an inert ingredient to the National List according to 7 CFR 205.607 and the procedures in NOP 3011.[11] Currently, NOSB consideration of these petitions are at the discretion of the Board.[12]

This option would:

- Continue to conflict with current EPA regulations. EPA has revoked the use of certain List 4 inert ingredients in pesticide formulations. AMS would need an effective mechanism to identify and communicate these discrepancies between EPA tolerance assessments and List 4 inert ingredients;
- Potentially lead to stagnation in development of alternative products for organic production, including products with potentially lower toxicity, and loss of confidence among stakeholders/industry in NOP's ability to address pressing regulatory needs; and
- Potentially result in the removal of EPA List 3 and List 4 from the National List at the conclusion of NOSB's next sunset review. AMS would prefer not to remove List 3 and List 4 from the National List in the absence of a viable alternative.

IV. Regulatory Challenges

In this section, AMS describes the regulatory challenges related to updating the USDA organic regulations on synthetic inert ingredients used in organic crop and livestock production. AMS invites specific comments related to these topics in the Request for Public Comments section below.

Referencing Third-Party Lists

All options discussed in this ANPR would rely on lists or regulations maintained by EPA. Some options would rely on codified listings that have completed notice-and-comment rulemaking. NOSB's recommendation that AMS reference the EPA Safer Chemical Ingredients List brings the regulatory challenges associated with third-party lists to the forefront of this discussion. Referring to a third-party (non-codified) list would pose several regulatory challenges:

- Updates to third-party lists would require oversight and management by the third party, rather than AMS. For example, opportunities for public input about revisions to the list (or revisions to the standards/criteria used to assess substances) may be more limited or less transparent than provided by AMS during its notice-and-comment rulemaking.
- Any reference to a list that is not within the CFR—and that is required to understand or comply with the regulations—would require approval by the Director of the Federal Register, as dictated by the Federal regulations related to ''incorporation by reference'' (see 1 CFR part 51). The Director's decision is outside of AMS's control.
- AMS would be required to refer to only one publication (*i.e.,* an edition with a specific publication date) of a list within the USDA organic regulations (see 1 CFR 51.1). Providing notice of the change in the **Federal Register** and updating the CFR would be some of the steps necessary to update the reference to a new edition of the list (1 CFR 51.11).

Individual Listings for Inert Ingredients on the National List

As discussed in the Background section of this ANPR, AMS originally referenced EPA Lists in the USDA organic regulations to prevent disruption to the industry and to reduce the administrative burden on the NOSB and AMS. AMS is aware that some stakeholders may prefer to include permitted inert ingredients to be individually listed in the USDA organic regulations. AMS also recognizes that stakeholders may believe that the intent of OFPA was to individually list inert ingredients on the National List.

Individual listings of inert ingredients on the National List would greatly increase the Board's and AMS's workloads due to the required process and timeline. Generally, petitioned substances undergo an NOSB review process that can take one to two years. This review process is supported by third-party technical reports, stakeholder engagement, and NOP staff. If the review process results in a recommendation for rulemaking, the rulemaking process can take an additional one and a half to three years. In total, this means a petition to add or remove a substance can take up to two and a half to five years before the process is completed. Substances

[11] ''Procedure: National List Petition Guidelines,'' United States Department of Agriculture, National Organic Program, *https://www.ams.usda.gov/sites/default/files/media/NOP%203011%20Petition%20Procedures.pdf.*

[12] ''Petitions for Inert Ingredients under the National Organic Program,'' Notice 11–6, United States Department of Agriculture, National Organic Program, February 3, 2011, *https://www.ams.usda.gov/sites/default/files/media/NOP-Notice-11-6.pdf.*

recommended for removal through the sunset process would need to undergo rulemaking, which takes approximately two years before the recommended removal is reflected in the regulations. This increased workload may be beyond the administrative capacity of the NOSB, contracted partners, and NOP staff.

V. Request for Public Comments

Over the years, AMS's references to third-party lists of substances (*i.e.,* the EPA Lists) served to reduce the impact on the NOSB and on AMS to review each inert substance separately. As AMS considers options for future rulemaking to replace these obsolete lists, the Agency seeks comments on how to balance: (1) The disadvantages of relying on external agencies/organizations or external lists; (2) available resources (including time) of the NOSB and AMS; and (3) statutory requirements under OFPA. AMS also invites comments from the public on the topic areas listed in this section of the ANPR. We would also consider comments on other topic areas related to inert ingredients in organic production.

General

- Should AMS replace the references in the USDA organic regulations to the outdated EPA List 3 and List 4? What problems are caused by the current references to EPA List 3 and List 4?
- How do various options align (or not align) with the statute (OFPA) and with AMS's authority, as provided under the statute, to regulate inert ingredients?
- What other options might be available that AMS and NOSB have not considered?

Third-Party (Non-Codified) Lists

- Should AMS rely on third-party list(s) as a means of evaluating inert ingredients permitted in organic production? If so, which third-party list(s) would be appropriate, and why?
- To what degree should the National List include individual substances allowed as synthetic inert ingredients versus referencing third-party lists established outside of AMS?
- How feasible or acceptable is it for AMS to reference third-party lists (lists that exist outside of Federal regulations that are not published in the CFR) to update current references on the National List to EPA List 3 and List 4?
- How does the approval and update process (via incorporation by reference) affect the feasibility of referencing a third-party list(s) for inert ingredients on the National List? For example, if a third-party list of inerts is not published in editions, it is ineligible for incorporation by reference. Conversely, if a third-party list were published in editions, AMS would need to take rulemaking action to update the reference to a newer edition.

Administrative Capacity

- AMS recognizes that it takes time and effort for the NOSB to perform a sunset review for each item on the National List, and there are likely hundreds of substances used as inert ingredients under current USDA organic regulations. How could AMS and the NOSB complete the necessary sunset reviews if substances were listed individually on the National List?
- How should the time constraints influence the approach that AMS should take regarding inert ingredients?
- The referenced Safer Choice program framework includes accreditation of third-party organizations, evaluation of substances against published standards by those accredited organizations, agency review of the evaluation, and publication of a list of approved substances. If AMS adopted a similar framework to that of the Safer Choice program, what would this look like, and would it address the regulatory challenges and capacity constraints outlined in this ANPR? What additional AMS staff resources would be required to accomplish this?
- If inert ingredients are individually listed, which set of substances from EPA List 3 and List 4 should be initially migrated to the National List, and how would those substances be identified?
- AMS notes that the NOSB has received more than 15 petitions to add specific inert ingredients to the National List, yet none have been recommended for addition to the National List.[13] If the established petition process is used to amend the National List to add or remove inert ingredients [14] would this approach satisfy the needs of the organic industry?

EPA Process and References

- How should the phrase in OFPA ''not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern'' be interpreted in light of the EPA's current regulations and regulatory scheme for inert ingredients (see 7 U.S.C. 6517(c))?
- If none of the inert ingredients permitted under EPA regulations are considered to be of toxicological concern to the EPA, should AMS permit all EPA allowed inert ingredients in pesticides for organic production? What are the risks and benefits associated with this option?
- If any inert ingredients that are allowed by EPA should not be permitted under USDA organic regulations, what are those substances and why should they not be permitted as inert ingredients used in organic production?
- Can inert ingredients currently allowed by EPA regulations (*i.e.,* in the Code of Federal Regulations) be sorted or classified according to toxicological concern? If some substances are of more concern, should AMS prohibit specific substances, or groups of substances, while allowing all other substances allowed as inert ingredients by the EPA? What criteria, specifically, would be appropriate for AMS to consider when assessing ''toxicological concern''?
- If inerts at 40 CFR 152.25(f)(2) were used with active ingredients in pesticide products that are not exempt from regulation (*i.e.,* not ''minimum risk pesticides'') the inert ingredient would require a tolerance (or exemption from the requirements of a tolerance) at 40 CFR part 180 for use in food or feed crops. AMS understands that there is not uniformity among 40 CFR 152.25(f)(2), 40 CFR part 180, and EPA List 4 (*e.g.,* a substance may be listed on EPA List 4 and 40 CFR 152.25(f)(2) but not be present at 40 CFR part 180). What combination of these EPA regulatory citations, if any, would be acceptable and provide the least disruption to industry?
- Would the scope of allowed inert ingredients be clear if AMS adopted a reference to 40 CFR part 180 subpart D (or a subsection therein)? Is there a subsection of Subpart D that would be preferable to a reference to the entire Subpart D? Are there inert ingredients listed on EPA List 4 that are being used in organic-compliant herbicides for farmstead maintenance (roadways, ditches, right of ways, etc.) and ornamental crops, which do not appear in 40 CFR part 180 subpart D? Are there alternatives within Subpart D that could substitute for inerts in currently formulated products?

VI. Conclusion and Next Steps

Given the background, key regulatory challenges, and options for consideration outlined in this ANPR, AMS is seeking comment on potential and preferred paths forward. Specifically, we seek comment on feasible alternatives to the allowance of

[13] ''Petitioned Substances,'' United States Department of Agriculture, National Organic Program, *https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned.*

[14] ''Procedure NOP 3011,'' March 11, 2016, *National Organic Program Handbook,* United States Department of Agriculture, National Organic Program, *https://www.ams.usda.gov/sites/default/files/media/Program%20Handbk_TOC.pdf.*

EPA List 3 and List 4, unforeseen legal and regulatory challenges not mentioned in this ANPR, estimated impacts to industry of each option, and preferred method (or combination of methods) for addressing these listings. When possible, comments should be accompanied by citations of supporting sources.

Comments received in response to this ANPR would inform AMS's approach on this topic regarding the allowance of inert ingredients in organic production. Substantive, well-reasoned, constructive comments would assist in identifying if there are unforeseen challenges or a viable alternative to move forward into rulemaking. Comments generally in support or opposition to alternatives identified in the ANPR would assist AMS in identifying the acceptability of the presented options in the absence of other alternatives.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2022–18928 Filed 9–1–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

10 CFR Part 851

[EHSS–RM–20–WSHP]

RIN 1992–AA61

Worker Safety and Health Program

AGENCY: Office of Environment, Health, Safety and Security, U.S. Department of Energy.

ACTION: Notice of proposed rulemaking and request for public comment.

SUMMARY: The U.S. Department of Energy (DOE or the Department) is proposing to amend its current worker safety and health program regulation. The proposed amendment would make corrections to the worker safety and health program regulation requirements related to beryllium and beryllium compounds for purposes of accuracy and consistency with DOE's Chronic Beryllium Disease Prevention Program regulation, and to clarify that DOE did not intend to adopt the 2016 American Conference of Governmental Industrial Hygienists threshold limit value for beryllium and beryllium compounds.

DATES: Written comments on this proposed rulemaking must be received by the Department on or before October 3, 2022. Please refer to section IV (Public Participation—Submission of Comments) for additional information on the comment period.

ADDRESSES: You may submit comments identified by docket number EHSS–RM–20–WSHP and/or Regulation Identification Number (RIN) 1992–AA61, in one of two ways (please choose only one of the ways listed):

1. *Federal e-Rulemaking Portal: www.regulations.gov.* Follow the instructions in the portal for submitting comments.

2. *Email: Rulemaking.851@hq.doe.gov.* Include docket number EHSS–RM–20–WSHP and/or RIN 1992–AA61 in the subject line of the email. Please include the full body of your comments in the text of the message or as an attachment. For detailed instructions on submitting comments and additional information on the rulemaking process, see section IV of this document.

Docket: The docket, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available. A link to the docket web page can be found at: *www.energy.gov/ehss/worker-safety-and-health-program-10-cfr-851doe-o-4401b.* This web page contains a link to the docket for this notice on the *www.regulations.gov* site. The *www.regulations.gov* web page contains instructions on how to access all documents, including public comments, in the docket. See section IV of this document for further information on how to submit comments through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. James Dillard, U.S. Department of Energy, Office of Environment, Health, Safety and Security, Mailstop EHSS–11, 1000 Independence Ave. SW, Washington, DC 20585, Telephone: 301–903–1165, or by Email at: *james.dillard@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE incorporates by reference into part 851 the following publication:

American Conference of Governmental Industrial Hygienists (ACGIH®), *Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices* (2016), excluding beryllium and beryllium compounds.

A copy of this publication can be obtained from: ACGIH®, 1330 Kemper Meadow Drive, Cincinnati, OH 45240; telephone number 513–742–2020; or go to: *http://www.acgih.org.*

For a further discussion of this publication, see section III.M of this document.

Table of Contents

I. Authority and Background

A. Authority

DOE has broad authority to regulate worker safety and health with respect to its nuclear and nonnuclear functions pursuant to the Atomic Energy Act of 1954 (AEA), 42 U.S.C. 2011 *et seq.;* the Energy Reorganization Act of 1974 (ERA), 42 U.S.C. 5801 *et seq.;* and the Department of Energy Organization Act (DOEOA), 42 U.S.C. 7101 *et seq.* Specifically, the AEA authorized and directed the Atomic Energy Commission (AEC) to protect health and promote safety during the performance of activities under the AEA. (*See* Sec. 31a.(5) of the AEA, 42 U.S.C. 2051(a)(5); Sec. 161b. of the AEA, 42 U.S.C. 2201(b); Sec. 161i.(3) of the AEA, 42 U.S.C. 2201(i)(3); and Sec. 161p. of the AEA, 42 U.S.C. 2201(p)). In addition, Congress amended the AEA in 2002 by adding section 234C, 42 U.S.C. 2282c, which, among other things, directed DOE to ''promulgate regulations for industrial and construction health and safety at Department of Energy facilities that are operated by contractors covered by agreements of indemnification under section 2210(d) of'' title 42 of the United States Code. In 1974, the ERA abolished the AEC and replaced it with the Nuclear Regulatory Commission (NRC), which became responsible for the licensing of commercial nuclear activities, and the Energy Research and Development Administration (ERDA),