



# USDA ANPR: Inerts in Organic Inputs

The BPIA Perspective

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# Brief History of Organic Regulation

## USDA/AMS National Organic Program

### Organic Foods Production Act of 1990 (“OFPA”)

- Established standards for organic crop and livestock production.
  - Inerts Standard: “not classified by [EPA] as inerts of toxicological concern.”

### NOP Regulations

- National Organic Program formed in 2000 to regulate organic farming.
- Regulations established in [7 CFR Part 205](#) in December 2000 ([65 FR 80547](#)).
  - Subpart G: “**THE NATIONAL LIST OF ALLOWED AND PROHIBITED SUBSTANCES**”
    - §205.601 and §205.602 applicable to “**organic crop production.**”
      - Nonsynthetic (“natural”): allowed unless specifically prohibited in §205.602.
      - Synthetic: prohibited unless specifically allowed in §205.601.
    - Similar sections established for **livestock** and **handling**.

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# So... What About Inerts????

Where the problem started

## The Good News!

- NOP Regulations identified a broad list of allowable inerts for use in organic crop production based on EPA's approved lists for use in pesticide products.

## The Bad News!

- Those Regulations referenced EPA “lists” used by EPA for prioritizing review of inert ingredients required by 1987 Inerts Policy.
  - 7 CFR §205.601(m) allows use of “synthetic inert ingredients” approved by EPA
    - “EPA List 4 - Inerts of Minimal Concern” (subparagraph (m)(1))
    - “EPA List 3 - Inerts of unknown toxicity - for use only in passive pheromone dispensers” (subparagraph (m)(2)).
  - Livestock use allows List 4 under 7 CFR §205.603(3)
  - These lists were last updated in **October 2004!!!!**

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# So... What About Inerts????

Why this is still a problem

## EPA Finished Its Review of Inert Ingredients

- Nonfood use inerts meet “not of toxicological concern” standard. Food-use inerts meet FQPA “reasonable certainty of no harm” standard.
  - Includes EPA List 4 and many previously on EPA List 3.
- New inerts (approved after October 2004) also meet these standards, but they are **NOT ALLOWED** for use in organic crop and livestock production inputs because they were not on a list last published in **OCTOBER 2004!**
- If lists were still maintained, all approved inerts would be “List 4” and allowed for use in organic crop and livestock production.

## NOP Still Relies on the Outdated 2004 Lists

- Before October 2004, when ingredients were reassessed to List 4, they would be added to the allowable ingredients list.
- Since October 2004, there have been no additions.

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# What's “ANPR” Got to Do with It???

USDA's “Advanced Notice of Proposed Rulemaking” –  
Problem Identification

## Acknowledgement of the Problem

- USDA, NOSB, and the regulated industry acknowledge there is a problem.
  - Lists are outdated and no longer relevant but are included in the codified regulations.
  - The regulations require a “sunset review” of all ingredients on the **NATIONAL LIST** every 5 years.
  - NOSB has been troubled by renewing these outdated “lists” every 5 years and wants a better solution.
  - So do we!

# What's “ANPR” Got to Do with It???

ANPR in the wild – Moving towards a solution

## Issuance of the ANPR

- USDA issued an ANPR in September 2022 ([87 FR 54173](#)).
  - ANPR's are early-stage proposals that seek comment and input.
  - It is likely the first step in a multi-step process that may include additional ANPRs or Proposed Rules before proceeding to the Final Rule stage.
- Poses questions about current system, proposes some solutions, and solicits comments on how to address this issue.
- Comment period ended on December 31, 2022.
  - BPIA provided comments that address this conundrum and provide an efficient, transparent, and equitable solution.
  - USDA received 386 total comments.

# What's BPIA's Grand Solution?

Keepin' it simple! – Consistency with other programs

## “Negative” Rather Than “Positive” Inerts Listings

- Incorporate all EPA-approved inert ingredients as “allowed” synthetics under 7 CFR §205.601(m) [crops] and §205.603(e) [livestock].
- NOSB still has the ability to make recommendations to NOP to specifically exclude inerts it deems unacceptable for use in organic inputs.
  - Exclusions constitute a “negative list.” The EU uses a “negative list” system for pesticides generally, including for organic use.
  - Proposals to exclude would be subject to notice and comment rulemaking, affording affected parties the opportunity to file comments that support or oppose the recommendation.
  - USDA's NOP program staff are the ultimate arbiters of what is approved/disapproved for use.

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# What's BPIA's Grand Solution?

Keepin' it simple! – Leveraging EPA's inert data reviews

## Reliance on US EPA Inerts Review Process

- All inerts used in pesticide products, including products intended for organic use, must be reviewed and approved by EPA.
  - EPA's already done the “heavy-lifting” during its review to ensure safety of ingredients when used in pesticide products.
  - Allows NOSB to focus its time on reviewing other aspects of the NOP requirements for crops, livestock, and handling.
  - NOSB still is tasked with the “sunset review” to determine that inerts are still consistent with organic regulations.
- OFPA and NOP Regulations already incorporate reference to inerts approved by EPA.



# What Happens Next—USDA

Seeing behind the curtain in Oz

## USDA's Review of Comments

- USDA has to thoroughly review and vet the comments received.
  - Not all comments are substantive. Many are just “no, don’t use them” or similar.
  - Others use “boilerplate” language provided by an NGO. These are often lumped as “one comment” when reviewed.
  - There are only a handful of truly “substantive” comments to review.

## Real Change is Coming, But When?

- Likely to be an additional request for comments on one or more items.
- Could be another ANPR or a Proposed Rule. Not likely to see Final Rule in the short- to intermediate-term.
- When will it publish? No mandated time for the next Notice. Best guess is sometime this calendar year, but perhaps not until 2024.

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# What Happens Next—BPIA

Our work is not done

## BPIA's Review of Comments

- Organics Subcommittee will review the submitted comments.
  - Identify the substantive comments.
  - Compile tallies of the options proposed and compare to our proposal.
  - Build consensus with other stakeholders.
  - Continue to work with USDA/AMS to develop a workable solution.

## BPIA Workshop on Inerts

- Looking to set up a workshop to include USDA, EPA, organic certifiers, and other stakeholders to discuss the inerts issue.

# Prognosis

Fasten your seatbelts! It's gonna be a bumpy ride.

## Change is Hard

- The references to the EPA “lists” is written into codified regulations.
  - Not a “simple” policy change. The only way to change it is to open up the book with “rulemaking.”
- Comments received are from disparate groups (e.g., organic farming and products interests, pesticide industry, inert manufacturers, consumers, environmental activists, academia), each with its own agenda and ideas.
  - NOP must be very deliberate in its evaluation of comments and its more-refined proposal going forward.

# Abbreviations for Reference

## A Guide to Bureaucratic Alphabet Soup

USDA: US Department of Agriculture

AMS: Agricultural Marketing Service (unit of USDA)

NOP: National Organic Program (program unit under USDA/AMS)

NOSB: National Organic Standards Board (advisory board to USDA)

EPA: US Environmental Protection Agency

OFPA: Organic Foods Production Act of 1990

FQPA: Food Quality Protection Act of 1996

CFR: Code of Federal Regulations (where rules and regulations are “codified”)

ANPR: Advanced Notice of Proposed Rulemaking