National Organic Standards Board
Crops and Livestock Subcommittees
Proposed Annotation Change
EPA List 4 on 205.601(m), and 205.603(e)
August 26, 2015

Introduction

The Crops and Livestock Subcommittees are working towards a solution to reviewing the inerts that were formerly on EPA List 4 by collaborating with the Inerts Working Group and the EPA Safer Choice Program (SCP) (formerly Design for the Environment Program). The NOSB will need to vote on an annotation change before this project can move forward.

Background

Current Listings:
205.601(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
(1) EPA List 4 – Inerts of Minimal Concern.

205.603(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
(1) EPA List 4 – Inerts of Minimal Concern.

In 2010 the EPA told the NOP that EPA List 4 was no longer being maintained and that language referring to it should be removed from the Federal Rule. In 2012 the NOSB passed a recommendation to proceed with reviewing individual inert ingredients and to change the listing on both 205.601(m) and 205.603(e) (Crops and Livestock respectively) to:

> As synthetic other ("inert") ingredients in pesticide formulations as classified by the Environmental Protection Agency (EPA) for use with nonsynthetic substances or synthetic substances listed in this section that are used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
> (i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b);
> (ii) Reserved (for list of approved other ("inert") ingredients).

With this goal in mind, the Inerts Working Group of the NOSB/NOP/EPA has been establishing a relationship with the Safer Choice Program for conducting these reviews. The steps to establishing this process include:

- The NOSB voting to proceed with an annotation change.

- A Federal Register Notice to notify stakeholders of the program and procedures, and rulemaking to amend the National List (subject to public comment).
- The inclusion of a reasonable implementation time (3-5 years) so that manufacturers can apply for SCIL consideration, or petition NOSB, and/or reformulate their products.
- An MOU or other mechanism to finalize the agreement between NOP and SCP.
- Specific instructions and outreach developed for the SCP portion of the review targeted toward manufacturers of pesticide products used in organic production.
- NOSB periodic review of the SCIL list to consider those criteria in OFPA that the SCP does not address (such as compatibility with organic agriculture).

Relevant areas in the Rule

See above

Discussion

The CS and LS propose the following change to 205.601(m)(1) and 205.603(e)(1), EPA List 4 – Inerts of Minimal Concern.

> 205.601(m) and 205.603(e) – As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
>
> (i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b).[1,]
>
> (ii) Substances included on the EPA's Safer Chemical Ingredient List.
>
> (iii) Inert ingredients that are exempt from the requirement of a tolerance under 40 CFR 180.1122 – for use only in passive pheromone dispensers.
>
> (iv) [Reserved] (for any other inerts individually petitioned and reviewed)]

This is very similar to the recommendation by the NOSB in 2012 except that it acknowledges the Safer Chemical Ingredient List and it includes the listing for pheromone dispensers into the main inerts listing (see Appendix II). This clarifies to all stakeholders how the inerts will be reviewed, listed, and allowed (or not) in the future.

The timeline for this process needs to be adequate in order that all inerts currently in use may be reviewed under SCIL, or petitioned and reviewed by NOSB. There also needs to be time for products to be reformulated, if necessary. The goal is to make this transition towards a new review of inerts as seamless for organic producers as possible, with an assurance that formulated

[1] http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf . EPA has published a proposed rule at FR 77:76979 to codify the list of actives and inerts eligible for minimal risk products, when finalized the NOP reference will cite this.

products that are reviewed for inerts and effective are still available to them throughout the change in policy.

The proposal provides a change in the Inerts listing, without specifying a corresponding timeline. NOSB expects that the NOP will create an appropriate grace period for making this change, as they did when the rule first came out in 2000 that limited inerts to only List 4.

The Inerts Working Group has completed a comparison between the SCIL criteria and the NOSB criteria that are used in reviewing materials (see Appendix I). There is a lot of similarity between them but also some gaps that can be addressed by the NOSB in periodic review of the SCIL.

Recommendation

Proposed Motion to change the annotation for EPA List 4 Inerts as follows:

> 205.601(m) and 205.603(e) – As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
>
> (i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b).[2,]
>
> (ii) Substances included on the EPA's Safer Chemical Ingredient List.
>
> (iii) Inert ingredients that are exempt from the requirement of a tolerance under 40 CFR 180.1122 – for use only in passive pheromone dispensers.
>
> (iv) [Reserved] (for any other inerts individually petitioned and reviewed)]

Crops Subcommittee Vote

Motion by: Zea Sonnabend
Seconded by: Harold Austin
Additional Discussion: none
Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Livestock Subcommittee Vote

Motion to accept the List 4 annotation change proposal from the Crops Subcommittee
Motion by: Tracy Favre
Seconded by: Jean Richardson/Ashley Swaffar
Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

[2] http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf . EPA has published a proposed rule at FR 77:76979 to codify the list of actives and inerts eligible for minimal risk products, when finalized the NOP reference will cite this.

Appendix I

Comparison of Review Criteria

Organic Foods Production Act Criteria for Review of Substances Used in Organic Production and EPA Safer Choice Program, Safer Chemical Ingredient List Criteria

Review Criteria for Substances/Chemical Ingredients	
USDA Organic Foods Production Act (7 USC 6501)	**EPA – Safer Choice Program** http://www2.epa.gov/saferchoice
7 USC 6518 **National Organic Standards Board** (m) Evaluation – In evaluating substances considered for inclusion in the proposed National List or proposed amendment to the National List, the Board shall consider -	
(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;	SCP considers potential biotic and abiotic interactions when information is made available; however, such information is not commonly provided with chemical submissions. SCP does review potential negative chemical reactions within products that are reviewed for Safer Chemical label program.
(2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;	**(1)** SCP has established criteria to evaluate toxicity to mammalian and aquatic organism receptors. Importantly, all data are considered even if receptor specific SCP criteria are not established. **(2)** SCP evaluates breakdown products and metabolites of potential concern for all chemicals. **(3)** SCP evaluates bioaccumulation potential and fate (environmental persistence) in the environment. More details available at: http://www2.epa.gov/saferchoice/standard
(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;	SCP considers intended use of products during evaluation and limits the permissible use/application method.

(4) the effect of the substance on human health;	SCP evaluates human health using criteria for **(1)** acute and chronic exposures (criteria for oral, dermal and inhalation routes of exposure) **(2)** dermal and respiratory sensitization **(3)** carcinogenicity and mutagenicity **(4)** Reproductive and Developmental effects See SCIL Master criteria
(5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;	**(1)** SCP considers potential biotic and abiotic interactions when information is made available (although not specific to agroecosystems). **(2)** If provided with toxicity data on soil dwelling organisms SCP would consider these data when evaluating the chemical.
(6) the alternatives to using the substance in terms of practices or other available materials; and	SCP evaluates each chemical ingredient against the appropriate functional use criteria. Chemicals meeting criteria are considered to be safer than comparable chemicals within the functional class.
(7) its compatibility with a system of sustainable agriculture	No comparable SCP criteria, however SCP evaluates impacts on environment, wildlife, and human health, and considers intended use of products during evaluation and limits the permissible use/application method.
Proposed Additional Screening for Inerts, (NOSB recommendation, Oct 2012):	**Authoritative Lists Used in SCIL Review**
1. Toxicity category from EPA :I or II ("danger" or "warning") 2. CA Prop 65 list- as a developmental or reproductive toxicant 3. Carcinogen on EPA's List of Chemicals Evaluate for Carcinogenic Potential *(*known/ likely, probable, or possible human carcinogen) 4. Carcinogen on IARC, U.S. NTP, CA Prop 65 *(*known, likely, probable, possible, reasonably anticipated to be) 5. Nervous system toxicants including cholinesterase inhibitors or chemicals associated with neurotoxicity by other	Authoritative Sources Indicating Carcinogenicity Mutagenicity and Reproductive Toxicity: • International Agency for Research on Cancer (IARC). Agents Classified by the IARC Monographs, Designated Group 1, 2A, or 2B. • US EPA. Integrated Risk Information System (IRIS), Chemicals carcinogenic to humans, likely to be carcinogenic to humans, or suggestive evidence of carcinogenic potential (2005 Guidelines). • California Office of Environmental Health Hazard Assessment (OEHHA). Proposition 65 List of Chemicals Known to the State to Cause Cancer or Reproductive Toxicity. • European Commission Hazard Phrases

mechanism, or listed on Toxic Release Inventory or IRAC or CDPR as similar class 6. Endocrine disruptors – based on EC list 7. Adverse effect on environment, wildlife based on label precautionary statements, including toxic or extremely toxic to bees, birds, fish , aquatic invertebrates, wildlife, other non-target organisms 8. Moderate or high mobility in soil, or soil half-life of 30 days or more, using Groundwater Ubiquity Score (GUS), or calculated using soil aerobic half life and soil binding coefficient. 9. Has data gaps or missing information in EPA documents 10. Contains any contaminants, metabolites that violate these criteria 11. The substance is a known groundwater contaminate, as identified by state of CA or from historic ground water monitoring records.	(Annex VI to the CLP Regulation) or Risk Phrases (Annex VI to the DSD Regulation) indicating possible carcinogenic, mutagenic, or reproductive toxicity: H350, H350i, H351, H340, H341, H360, H361, H362, R45, R49, R40, R46, R68, R33, R60, R61, R62, R63, R64. *Adverse effect on environment, wildlife, including toxicity to non-target ecological receptors is currently not included in our criteria but may be built in to the review.* <u>Authoritative Sources Indicating Persistence Bioaccumulation and Toxicity:</u> • US EPA. Toxic Release Inventory (TRI). Designated PBT. • EU REACH. Substances of Very High Concern due to PBT, vPvB, or vPvT. • Stockholm Convention Persistent Organic Pollutants (POPs). • OSPAR List of Substances of Possible Concern. Hazardous Substances List - Sections A-D. • Chemicals determined to exceed Safer Choice's thresholds for persistence, bioaccumulation, and aquatic toxicity when addressed through the TSCA Work Plan Chemical process. <u>Respiratory Sensitizers:</u> • European Commission Hazard Phrases (Annex VI to the CLP Regulation) or Risk Phrases (Annex VI to the DSD Regulation) indicating possible respiratory sensitization: H334, R42. <u>Dermal Sensitizers:</u> • Dermal Sensitizers from Annex III of the EU Cosmetics Regulation.

	http://ec.europa.eu/enterprise/sectors/chemicals/files/legislation/allergenic_subst_en.pdf Additional substances may be added this year. • European Commission Hazard Phrases (Annex VI to the CLP Regulation) or Risk Phrases (Annex VI to the DSD Regulation) indicating dermal sensitization: H317 or R43 Other Authoritative Lists: • Environment Canada Domestic Substances List, designated PBT • US EPA Toxic Release Inventory (TRI) • US EPA Work Plan Chemicals • US EPA Ozone Depleting Substances (Class I and II) • US EPA Hazardous Air Pollutant (HAP) • ChemSec, Substitute it Now! (SIN) List, designated PBT • Association of Occupational and Environmental Clinics (AOEC), Exposure Codes • IFRA Labeling Manual and IFRA Transparency List • TEDX – The Endocrine Disruptor Exchange, List of Potential Endocrine Disruptors • European Commission Endocrine Priority List • Safer Chemicals, Healthy Families, Mind the Store • California Department of Public Health, Safe Cosmetics Program, Chemicals Known or Suspected to Cause Cancer or Reproductive Toxicity.

Appendix II

EPA regulation

40 CFR §180.1122 Inert ingredients of semiochemical dispensers; exemptions from the requirement of a tolerance.

(a) All inert ingredients of semiochemical dispenser products formulated with, and/or contained in, dispensers made of polymeric matrix materials (including the monomers, plasticizers, dispersing agents, antioxidants, UV protectants, stabilizers, and other inert ingredients) are exempted from the requirement of a tolerance when used as carriers in pesticide formulations for application to growing crops only. These dispensers shall conform to the following specifications:

(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 (RAC) or processed foods/feeds derived from the commodity by virtue of its proximity to the RAC or as a result of its physical size.

(2) The dispensers must be applied discretely. This exemption does not apply to components of semiochemical formulations applied in a broadcast manner either to a crop field plot or to individual plants.

(b) A semiochemical dispenser is a single enclosed or semi-enclosed unit that releases semiochemical(s) into the surrounding atmosphere via volatilization and is applied in a manner to provide discrete application of the semiochemical(s) into the environment.

(c) Semiochemicals are chemicals that are emitted by plants or animals and modify the behavior of receiving organisms. These chemicals must be naturally occurring or substantially identical to naturally occurring semiochemicals.

[58 FR 64494, Dec. 8, 1993]