



# Minimum-Risk Products Exempted under 40 CFR 152.25(f) under the Authority of FIFRA 25(b)

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# Presentation Purpose and Agenda



- Purpose:
  - What is the minimum risk exemption?
  - The 4A List
  - Potential changes to the exemption, RE: inert ingredients



# FIFRA Mandate



- The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) was enacted to manage the risks of pesticides.
- FIFRA obligates EPA to register only those pesticides that do not cause unreasonable adverse effects on human health or the environment
  - EPA licenses the sale and use of pesticides
- Public health pesticides must be effective in order to meet the registration standard
  - EPA routinely requires efficacy data to support registration of public health pesticides such as skin applied insect repellents
- Labels must effectively communicate safe and appropriate use of the product



# FIFRA Exemption



- FIFRA section 25(b) authorizes EPA to exempt pesticides that are “of a character” for which FIFRA regulation is not required
- EPA exempted minimum risk products in 1996 under the authority of section 25(b)
  - Human and environmental exposures to these products were judged to be safe based on the use patterns existing in 1996
  - The full text of the exemption is in 40 CFR 152.25(f)



# Minimum Risk Exemption



- Minimum risk pesticide products qualify for the exemption by meeting the criteria specified in the Code of Federal Regulations at 40 CFR 152.25(f)
- This regulation specifies the active and inert ingredients that may be used in minimum risk products and specifies how these products must be labeled
  - “...in the most current List 4A”
- Products must not make pesticidal claims regarding specific public health pests
- Pesticide products that do not qualify for the exemption must be licensed/registered (under FIFRA section 3)



# Inert Ingredient Lists



- 1987 Inert Ingredient Policy Statement
  - List 1: Inert Ingredients of Toxicological Concern
  - List 2: Potentially Toxic Inert Ingredients/High Priority for Testing
  - List 3: Inerts of Unknown Toxicity
  - List 4: Inerts of Minimal Concern
- 1989 Subdivision of List 4
  - List 4A: Minimal risk inert ingredients
  - List 4B: Other ingredients for which EPA has sufficient information to reasonably conclude that the current use pattern in pesticide products will not adversely affect public health or the environment.



# Potential Changes to 152.25(f) for Inert Ingredients



## Action:

- Replace the current reference to the 4A List in 40 CFR 152.25(f)(2) with a table similar to the one on the internet
  - **Possible layout of table for 40 CFR 152.25(f)(2)**
    - CAS Reg. No. (or none)
    - Common chemical name/Label display name
    - CA Index name
    - Food-use
    - Nonfood-use
  - **Add a cross-reference to 40 CFR 180.950**
- Changes to the codified list would be accomplished via notice and comment -- rulemaking



# Possible Table for 152.25(f)(2)



| CAS Reg. No. | Common Chemical Name/Label Display Name | CA Index Name  | Food-Use? |
|--------------|---|--|-----------|
| 25637-84-7   | Glyceryl dioleate                       | 9-Octadecenoic acid (9Z)-, diester with 1,2,3-propanetriol | no        |
| 298-14-6     | Potassium bicarbonate                   | Carbonic acid, monopotassium salt                          | yes       |
| 121-33-5     | Vanillin                                | Benzaldehyde, 4-hydroxy-3-methoxy-                         | yes       |



# Why a Common Chemical Name?



## Background:

- Greater specificity
- Assist State inspectors
- Examples of Common Chemical Names
  - Citric acid  
(1,2,3-Propanetricarboxylic acid, 2-hydroxy-)
  - Glyceryl dioleate  
(9-Octadecenoic acid (9Z)-, diester with 1,2,3-propanetriol)
- In March 2009, OPP updated the inert ingredient list (on the web) to include a common name

[http://www.epa.gov/opprd001/inerts/section25b\\_inerts.pdf](http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf)



# What the Label Could Look Like



- Pulled from existing label
  - glycine soja oil
  - ricinus communis seed oil
  - rosmarinus officinalis leaf oil
  - cymbopogon schoenanthus oil
  - thuja occidentalis leaf oil
  - mentha piperita oil
  - cymbopogon nardus oil
  - eugenia caryophyllus flower oil
  - geranium maculatum oil
  - tocopherol
- Using a common chemical name
  - soybean oil
  - castor oil
  - rosemary oil
  - lemongrass oil
  
  - cedar oil
  - peppermint oil
  - citronella oil
  - clove oil
  
  - geranium oil
  - Vitamin E



# Benefits



- Benefits:
  - Codified tables would be a clear source of information for all users regarding inert ingredients acceptable for use in exempted products
  - Less confusion for the states
  - Purchasers would have understandable information concerning the ingredients in the products purchased



# Questions?



- For additional information on these potential changes to 152.25(f)(2)

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