Registering and Regulating Insect Repellents at EPA

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Topics to be Covered:

- EPA's role in mosquito control and repellents
 - Are all repellents registered?
- What does EPA registration mean for repellents?
 - Data requirements, risk assessments, labels
- Efficacy and product performance

EPA's Role in Mosquito Repellents

- EPA regulates repellents under the Federal Insecticide, Fungicide, and Rodenticide Act
 - FIFRA defines a pesticide as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest ..."
- FIFRA requires "no unreasonable adverse effects finding"

EPA's Role in Mosquito Control

- Ensure effective mosquito control tools exist that do not pose unreasonable risk to human health and the environment
 - Repellents are one such tool
- Encourage non-chemical mosquito prevention efforts; and
- Educate the public to encourage proper use of insect repellents and mosquitocides

Are all repellents registered by EPA?

- NO!!
- FIFRA exempts certain pesticides from the requirements of registration
 - These are considered minimum risk pesticides
 - Exemption is not permitted if repellent makes a public health claim such as "repels mosquitoes that transmit West Nile Virus"

EPA Registration:What does it mean for repellents?

- Repellent is not expected to pose unreasonable adverse effects (when used according to label directions)
- Before registering a repellent, EPA:
 - Assesses data
 - Conducts a risk assessment
 - Provides comments and approves final labeling

Registration Process: Data Requirements

- Data requirements vary by use and type of chemical
 - Usually requires both toxicity and exposure data
 - Risk = Hazard X Exposure
- In general, skin-applied insect repellents require significant toxicity data
 - Biochemical repellents may be registered with much less toxicity data

Registration Process: Product Performance Data

- Product performance (i.e., efficacy) data required for repellents
- Submitted to support claims of effectiveness against specific pest

Registration Process: Product Performance Data

- General efficacy study standards:
 - Scientifically reproducible study
 - Conducted under GLP
 - Experiments designed to show product is efficacious under real world conditions
 - Data confirm product is efficacious

Are all Repellents Equally Efficacious?

- NO !!!
- For pesticides registered with the EPA, the registrants must demonstrate a certain level of efficacy
 - Efficacy varies, even for same product to repel different pests or species
- EPA does not have efficacy data for products that are not EPA-registered

EPA Registration: Labels

- EPA will work with the registrants to develop language that
 - Is easily understood and followed
 - Contains any use restrictions needed to ensure product does not cause any unreasonable adverse effects
 - Ideally, contains expected duration for efficacy of repellent

Conclusions

- EPA plays a role in education and outreach to the public on pesticides, including repellents
- EPA registers repellents that:
 - Have demonstrated efficacy
 - Are not expected to pose unreasonable adverse effects to humans or the environment when used according to label directions