

Recommendations to FDA regarding MoCRA

Viewing through the eyes of an economist

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The challenge outlined by IWGACP is an identification issue

IWGACP's recommendations on ambiguity and its economic terms

- IWGACP recognizes the difficulty in distinguishing asbestiform and non-asbestiform amphibole particles in certain circumstances
- IWGACP recommends using the term EMP as an umbrella term for pertinent particles, regardless of how they are formed
- Economists refer to this challenge as an identification issue, which is well-studied and well-documented
 - When data cannot identify the parameter of interest, more descriptive statistics benefit interested parties
 - Generally, to address identification problems, more information is better!

Identifying different EMP types would increase efficiency, save costs, and improve public health

- Resources are not unlimited, known as “scarcity” in economics
- Limited resources need to be allocated efficiently, which is called “optimization” in economic terms
- Optimal resource allocation requires “cost-benefit analysis”
 - Costs increase with the likelihood the sample identified asbestos
 - Among samples that all report large numbers of EMPs, the one that carries a larger risk to public health should be addressed first
 - Reporting the counts of fully identified asbestos EMPs, in addition to an overall EMP count, helps the agency prioritize resources

Recommendation

- Report the total count of EMPs
- Separately report the count of each type of particles
 - Identified asbestos
 - asbestiform amphibole minerals
 - chrysotile
 - Other EMPs, whose impact is uncertain and likely less severe
 - non-asbestiform amphibole minerals
 - particles that contain talc and an amphibole
 - talc particles exhibiting non-platy morphology
 - amphibole minerals with inconclusive habit of growth
- Provides greater information that allows superior allocation of scarce resources and prevents inconsistency with other government agencies

Potential domino effects of redefining “asbestos”

“Asbestos” is a term used by multiple agencies and redefining it as EMPs will create inconsistency

- OSHA monitors the level of asbestos fibers for workers’ safety and sets Permissible Exposure Limits (PEL) for asbestos
- Cosmetic product manufacturing employees likely have a higher level of exposure to cosmetic talc than the end user of this product
- Having one measure for factory floor employees (OSHA) and a separate measure for product uses (FDA) lacks scientific justification; the potentially harmful substance is the same for both, so the measure should be the same

Over ten thousand worksites will be impacted if OSHA also redefines asbestos as EMPs

- Industrial talc is widely used. In the past decade, OSHA has inspected over ten thousand unique sites that manufacture*:
 - Plastic (~6,130)
 - Automotive parts (~3,040)
 - Paper (~2,440)
 - Rubber (~970)
 - Roofing (~560)
 - Paint (~490)
 - Ceramics (~150)
- The impact could go beyond manufacturing industries for the products listed above (e.g., service industries)
- Many other industries are using non-talc minerals that are also subject to the identification challenge of amphibole EMPs

*The Establishment ID is not well populated in the OSHA inspection data. Bates White estimated the unique sites using site names and zip codes.