

IRIS AMMONIA ASSESSMENT

Input from The Fertilizer Institute

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Focus on Point of Departure

- Proposed IRIS POD is 12 ppm based on Holness et al, supported by three additional epidemiology studies in the workplace
- TFI proposes a revised POD of 25 ppm based on:
 - Existing extensively reviewed health-based exposure limits of 25 ppm
 - 25 ppm is a NOAEL in the Holness study
 - 25 ppm is a threshold for irritation

25 ppm Used Globally as Foundation for Setting Exposure Limits

- NIOSH REL designed to protect workers for 40 hour workweek over working lifetime – level at which no employee will suffer impaired health or functional capacities or diminished life expectancy
- ACGIH TLV – 25 ppm intended to minimize potential for irritation
- OSHA PEL – 35 ppm – not necessary to establish TWA to protect for chronic effects
- International agencies support 25 ppm

25 ppm NOAEL in Holness Study

- Selection of 12.5 ppm not statistically supported and does not reflect highest occupational exposure in Holness study
- 12.5 ppm actually reflects lower bound estimate of exposure in high exposure category
- Study says workers with ammonia exposures < 50 ppm and most exposures < 25 ppm – no differences in symptoms or lung function
- EPA's own IRIS defines NOAEL as highest level at which there are not biologically significant increases in frequency or severity of adverse effects between exposed and control

25 ppm is Threshold Concentration for Irritation

- Irritation is threshold effect that occurs at the lowest concentration
- Irritation from low concentrations of ammonia is a short term effect that has not been shown to lead to chronic effects
- WHO estimated that 25 ppm would raise systemic ammonia level by 10% over fasting level – well within range of systemic ammonia level

AEGL Committee

- Eminent international panel of physicians and toxicologists appointed by Board of Environmental Studies and Toxicology of US National Research Council
- Mandate is furthering knowledge and advising federal government
- Based on more than 70 peer-reviewed studies, established:
 - Exposure to ammonia at concentrations greater than NOAEL results in irritation
 - Irritation is a threshold effect
 - The threshold level is 30 ppm and is not variable depending on length of exposure, implying applicability to chronic exposures
 - Asthmatics and sensitive subpopulations are not affected below NOAEL

Conclusions

- TFI is advocating a POD of 25 ppm
- Scientifically based and health-protective
- Supported by principal study
- Consistent with the IRIS process

TFI can submit a supplement to most recent comments within the week.

TFI sincerely appreciates the opportunity to provide input into the process of developing an RfC.