NIOSH Public Comment Meeting
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Representing the ACC TiO2 Panel

How Many Workers are Exposed to Throughout the Respiratory Route to TiO2 in the Workplace?

Nov 22 DRAFT NIOSH CURRENT INTELLIGENCE BULLETIN: Evaluation of Health Hazard and Recommendations for Occupational Exposure to Titanium Dioxide

"The National Occupational Exposure Survey (NOES), conducted from 1981—1983, estimated that **2.7 million workers** (2.2 million male, 0.5 million female) are potentially exposed to TiO2 (CAS Number 13463-67-7) in 42 standard industrial classifications (SICs) and 246 occupational groups [NIOSH 1983]."

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'The survey observed the use of a "specific agent" or tradename product known to contain the specific agent"

Included:

108,654 exposed to textile mill products

165,824 exposed to electric and electronic equipment

192,970 exposed to machinery except electrical

80,854 exposed to electric, gas and sanitary services

The manufacturing steps which generate dust occur at the beginning and toward the end of the processes. The remaining operations take place in closed systems or in the liquid phase.

Industry estimates place the number of pigment plant workers routinely (once per day) exposed to TiO2 dust at about 2,700 individuals, worldwide.

No reliable estimates of the number of individuals involved in compounding of downstream products is available. However, exposure levels in this step are expected to be at or below those encountered in TiO2 production operations.

The first step in all downstream uses (paints, coatings, plastics, rubber, ink, foodstuffs, etc) is incorporation into an organic or inorganic matrix.

From this point forward to the end-user, and beyond, titanium dioxide is enclosed within this matrix and there is virtually no exposure to TiO2 dusts –to workers, consumers or the environment.

The universe of exposed individuals is limited to workers in the “white” end of TiO2 plants plus those workers involved in the initial compounding of downstream products.

Conclusion

The 1981-83 National Occupational Exposure Survey Grossly Overestimates the Number of Workers in the U.S. with Respiratory Exposure to TiO2!

Is there Ultrafine TiO_2 in the Workplace?

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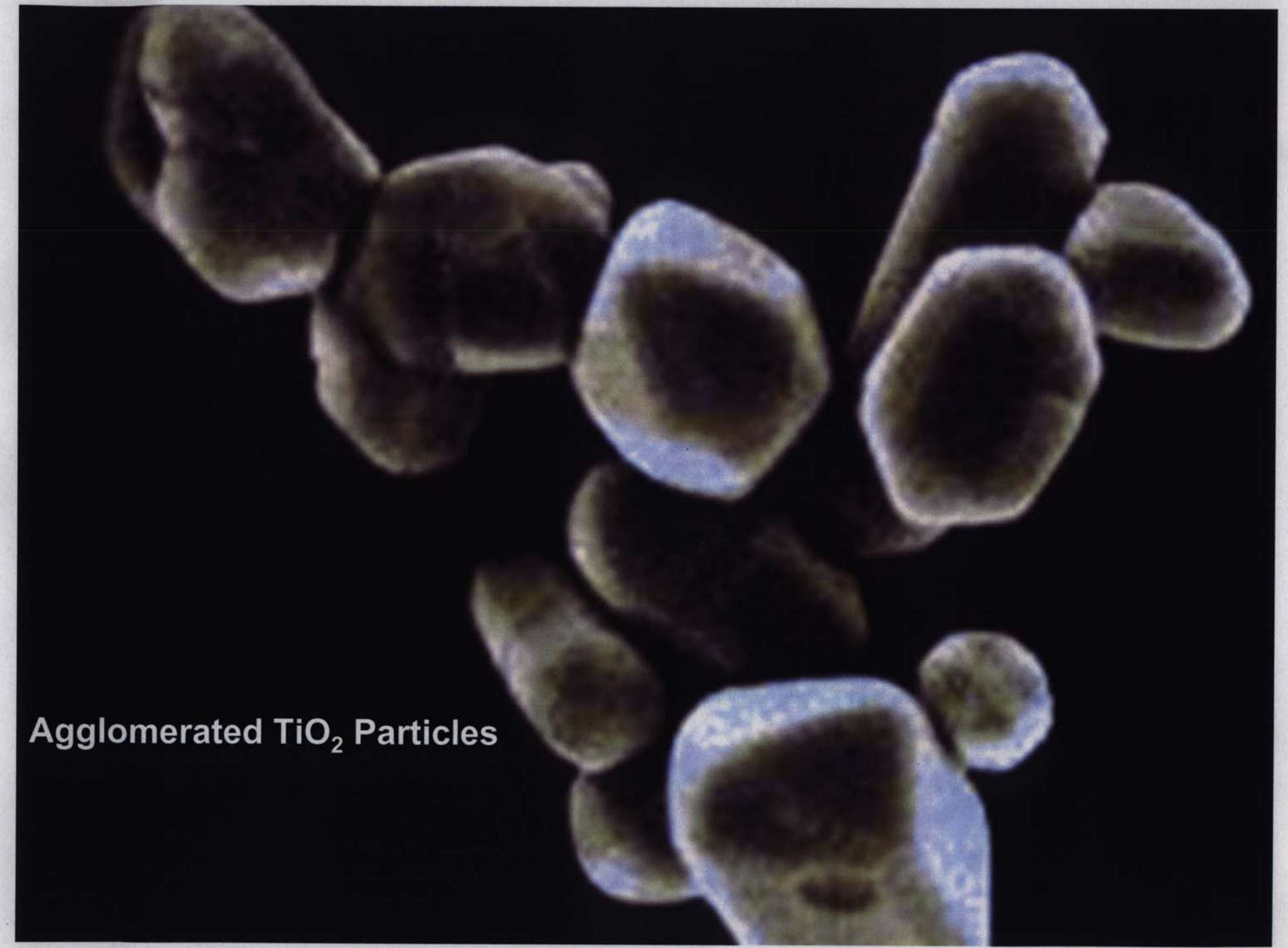
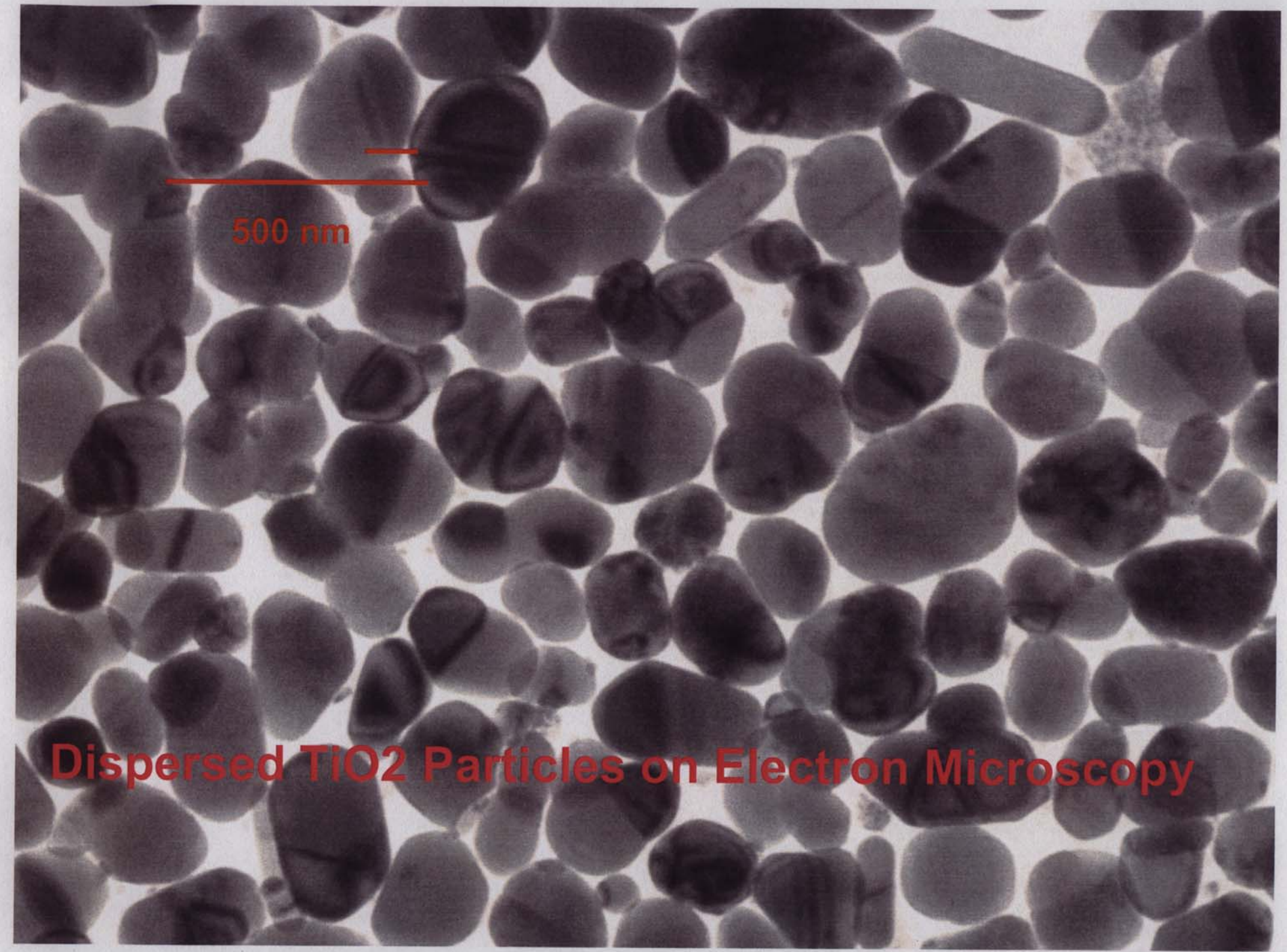
"Data are particularly needed on the airborne particle size distributions and exposures to ultrafines in specific operations or tasks."

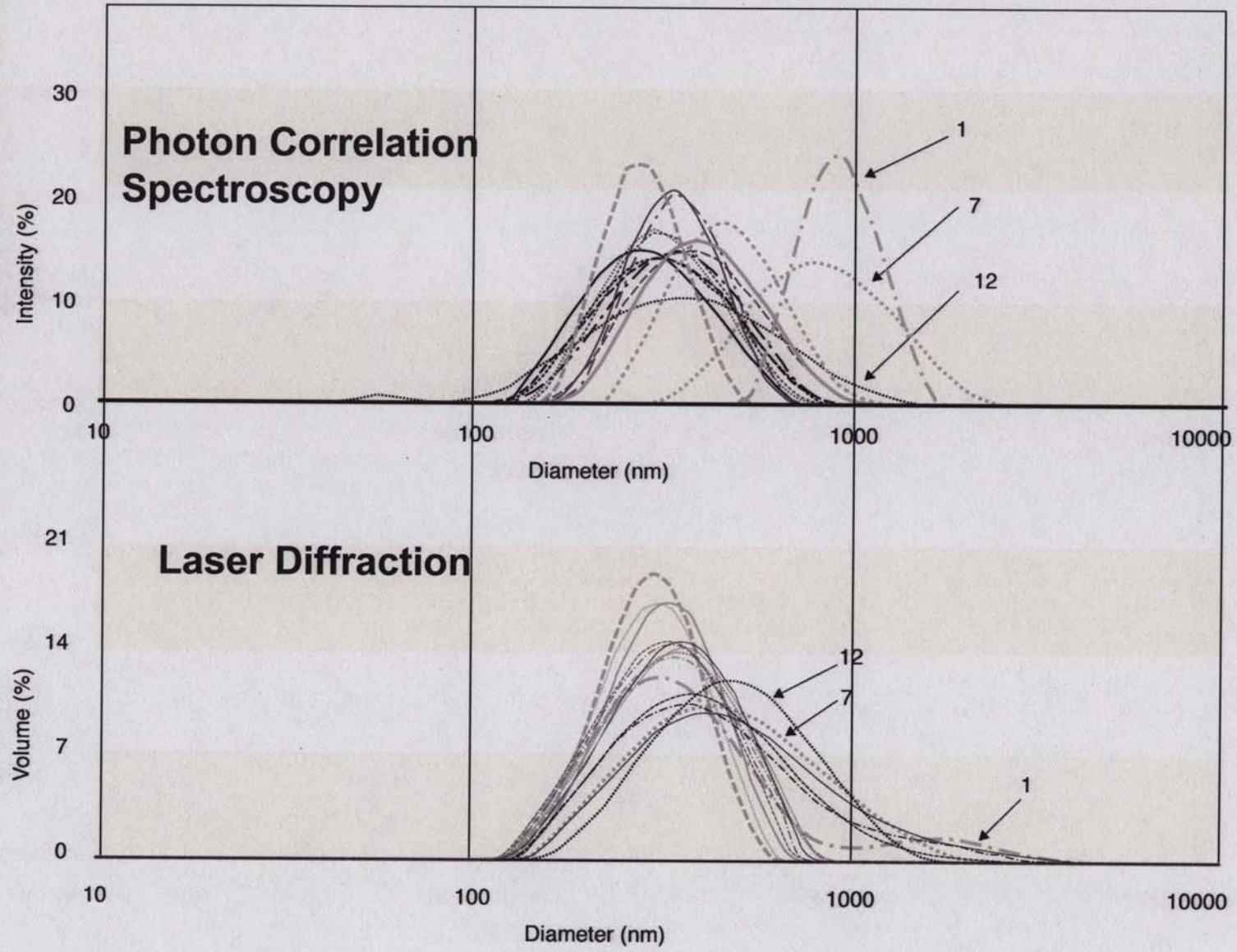
'No data have been published on occupational exposures to ultrafine TiO2."

Limitations of the Fryzek study include *"no information about ultrafine exposures"*


Agglomerated TiO_2 Particles



Dispersed TiO2 Particles on Electron Microscopy



Comparison of Primary Particle Size Distributions as Analyzed PCS and by Laser Diffraction

Other Considerations

- Practical lower limit of particle size reduction with pigmentary size TiO2 by fluid energy grinding is ~0.1 micron -- *physics*
- Energy requirements increase in proportion to the total surface area of the particles – *economics*
- Particles < 0.1 micron do not reflect visible light – *not effective as pigment*
- Ultrafine TiO2 represents < 0.1% of the world wide TiO2 Market

Conclusion

Significant ultrafine TiO_2 exposure is not likely to be present during the manufacturing of pigment grade (fine) TiO_2 using conventional technology!

Are Coal Dust and Other PSLT Particulate Exposures Relevant?

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NIOSH cites at least 12 separate references based on human or animal exposure to **coal dust** in the draft CIB in order to provide "*additional support for the determination that the rat is a reasonable animal model with which to predict human tumor response for other particles, such as TiO2.*"

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"In addition, lung clearance of particles is slower in humans than in rats, by approximately an order of magnitude…, and some humans ***(e.g., coal miners)*** *may be exposed to concentrations resulting in doses that would be considered overloaded in rats. Thus, the doses that cause overloading in the rat may be relevant to estimating disease risk in workers with high dust exposures."* (1008 - 1012)

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"In humans, chronic inflammation has been associated with non-neoplastic lung diseases in workers with dusty jobs. Rom [1991] found a statistically significant increase in the percentage of PMNs in BALF of workers with respiratory impairment who had been exposed to asbestos, ***coal****, or silica (4.5% PMN in cases versus 1.5% PMNs in controls). Elevated levels of PMNs have been observed in the BALF of miners with simple* ***coal workers' pneumoconiosis*** *(31% of total BAL cells versus 3% in controls)]…"* (1103-1108)

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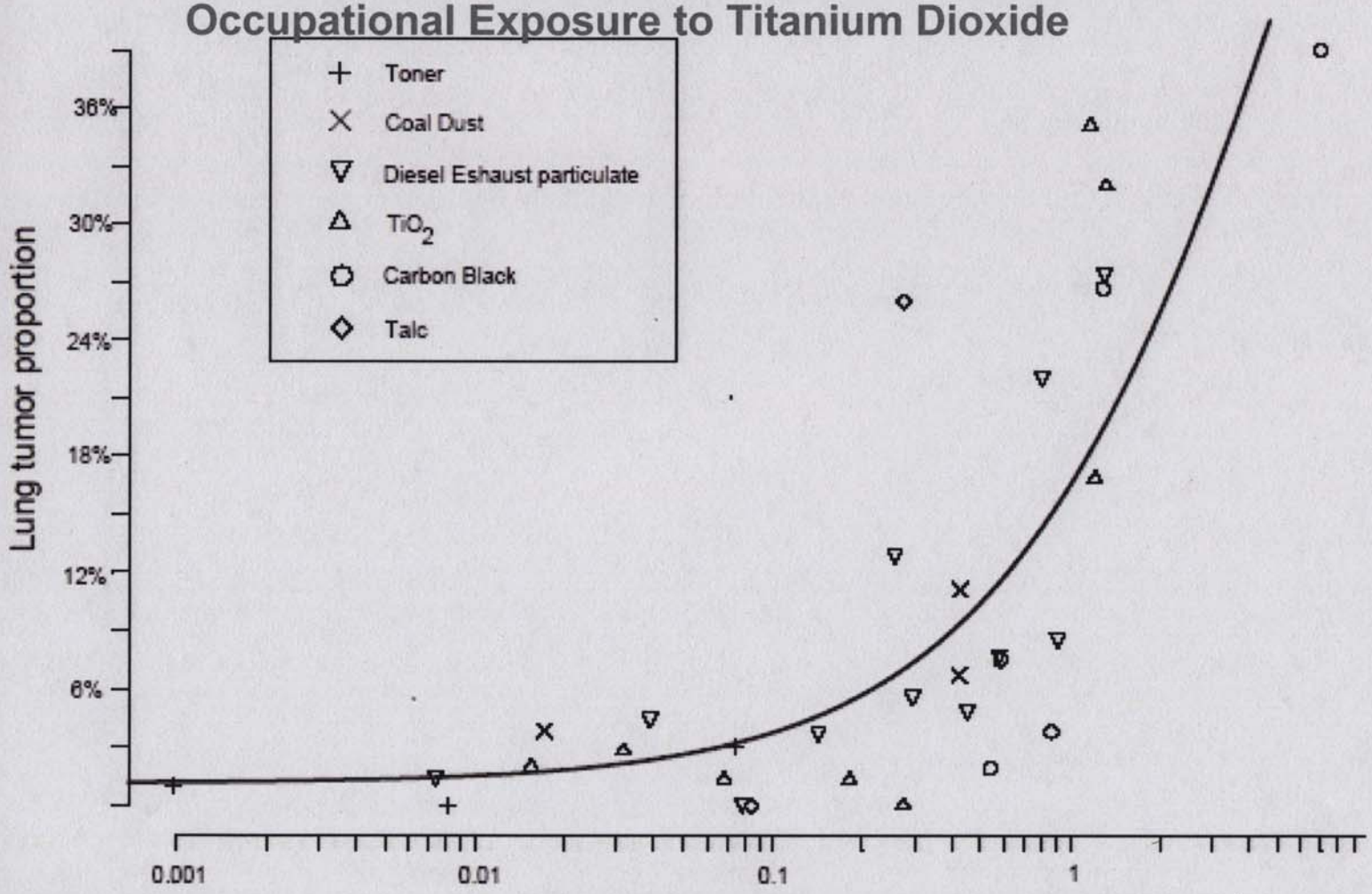

Figure 3-4

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Evaluation of Health Hazard and Recommendations for Occupational Exposure to Titanium Dioxide

"The mechanism of action of TiO2 is relevant to a consideration of the associated risks because, as discussed earlier, the weight of evidence suggests that the tumor response observed in rats exposed to fine and ultrafine TiO2 results from a secondary genotoxic mechanism involving chronic inflammation and cell proliferation, rather than via genotoxicity of TiO2 itself. This effect appears related to the physical form of the inhaled particle (i.e., particle surface area) rather than the chemical compound itself. In this way, TiO2 behaves in a similar manner to other PSLT particles, such as barium sulfate, carbon black, toner, and ***coal****..."* (1523- 1539)

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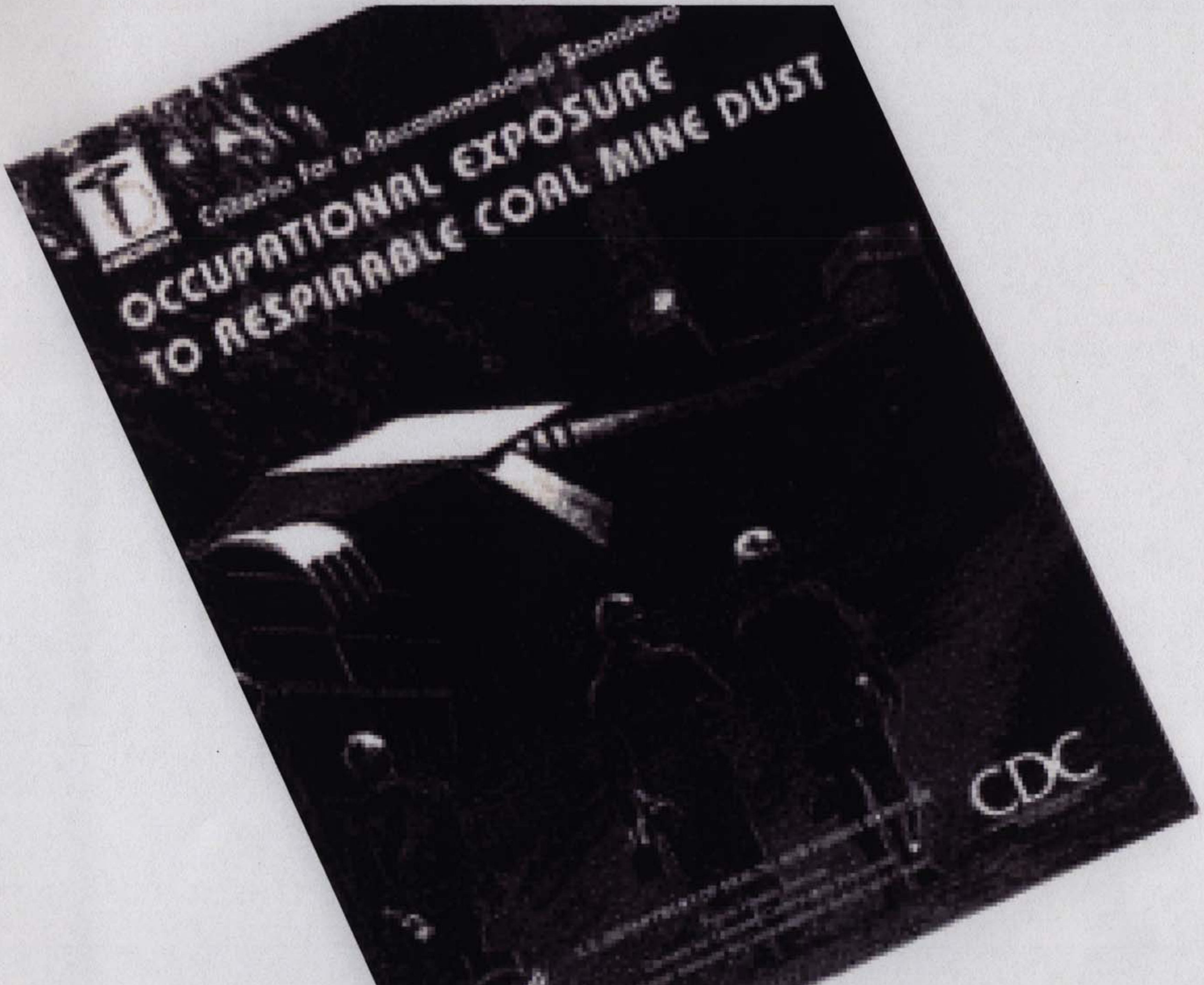
"NIOSH has considered the evidence suggesting that rats may be an inappropriate model for human lung cancer after exposure to particulates and has concluded that the rat is a reasonable model for predicting human lung cancer risks. Although there is not extensive evidence that the overloading of lung clearance, as observed in rats…, occurs in humans, lung burdens consistent with overloading doses in rats have been observed in some humans with dusty jobs ***(e.g., coal miners)****.." (1922-1933)*


Criteria for a Recommended Standard
OCCUPATIONAL EXPOSURE
TO RESPIRABLE COAL MINE DUST
CDC

Criteria for a Recommended Standard: Occupational Exposure to Respirable Coal Mine Dust

"Most studies have reported that mortality from lung cancer is lower than expected among coal miners when compared with general population rates … although some studies have reported elevated lung cancer mortality among coal miners… Mortality from lung cancer was not associated with cumulative exposure to respirable coal mine dust in the two studies that evaluated this relationship… SMR's for lung cancer … have generally been lower than expected among coal miners."

IARC MONOGRAPH VOL 68

"There is … a large body of published literature concerning cancer risks potentially associated with employment as a coal miner, including a small number of exposure-response associations with coal mine dust...

The evidence from occupational cohort studies for an association between coal mine dust and lung cancer has not been consistent; some studies revealed excess risks, whereas others indicated cohort-wide lung cancer deficits.

There is no consistent evidence supporting an exposure-response relation for lung cancer with any of the customary dose surrogates, including duration of exposure, cumulative exposure or radiographic evidence of pneumoconiosis… "

Recommendation

In addition to epidemiological studies of coal mine dust and lung cancer among miners, epidemiological studies among workers exposed to other PSLT particles are also relevant to TiO_2 risk assessment and should be included.

The inclusion of relevant epidemiological studies of workers exposed to all PSLT particles would significantly increase the statistical power of this line of evidence.

This would increase the confidence that the REL for fine TiO_2 is safe for all workers and may even provide confidence in a higher REL.

Thank You