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Comments to DOL

NIOSH COMMENTS ON OSHA
GUIDELINES ON BIOTECHNOLOGY

50 FR 14468
Docket Number H-042

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NIOSH has reviewed OSHA's announced Guidelines on Biotechnology (50 FR 14468) published April 12, 1985. In the guidelines, OSHA states that "no new regulations that would specifically cover biohazards are warranted." OSHA's conclusion is based on the agency's belief that workers employed in this industry will be afforded adequate protection by application of: Section 5(a) of the Occupational Safety and Health Act; exposure limits given in 29 CFR 1910, Subpart Z; 29 CFR 1910.20, Access to Employee Exposure and Medical Records; 29 CFR 1910.1200, Hazard Communication; Exposure to Toxic Chemicals in Laboratories (draft); 29 CFR 1910.134 Respiratory Protection (being updated); and 29 CFR 1910 Subparts J, D, E, L, H, S, and N.

NIOSH is concerned about this approach for several reasons. First, it does not seem reasonable to suggest that workers will be covered by the provisions of a rule that has not been promulgated (i.e. exposure to toxic chemicals in laboratories). Similarly, it is difficult to ascertain how the proposed changes in 29 CFR 1910.134 will affect the protection afforded these workers.

The second concern is of a more fundamental nature. OSHA proposes to use Section 5(a) of the Occupational Safety and Health Act. Section 5(a) requires that:

. . . each employer (1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards. . . .

While in principle NIOSH endorses such an approach, we believe that this industry presents an uncommon work environment where the potential hazards are not "recognized." This concern is based on the following research needs identified by NIOSH:

- ' The effectiveness and reliability of engineering and work practice controls used in well controlled industrial scale fermentation technology need to be evaluated for the range of process technologies to be used. NIOSH is now conducting a control technology study as a first step toward this goal to determine the extent to which bacterial strains used in the fermentation process are entering the workplace air.
- ' Development or demonstration of containment with improved effectiveness and cost-efficiency may be necessary.
- ' Monitoring is a major component in the protection of workers in all industries. Research is needed to develop sampling and analytical methods and instruments to measure airborne and surface concentrations of genetically modified organisms.

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' Ongoing medical surveillance and epidemiology among biotechnology workers is needed to assure that no health effects are occurring.

' It should be determined whether or not workers in biotechnology will be at risk of sensitization to microbial proteins and products generated in the course of fermentation and product extraction processes.

We recognize that OSHA cannot promulgate a standard in the absence of data demonstrating a risk of material impairment of health or functional capacity. However, because these research needs indicate vast gaps in knowledge, NIOSH recommends that OSHA include, as part of their guidelines, requirements for increased industrial hygiene surveillance and medical monitoring.

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16. Abstract (Limit: 200 words) This testimony reviewed the position of NIOSH concerning OSHA proposed guidelines on biotechnology. In the guidelines OSHA stated that there was no evidence to warrant the issuance of new regulations specifically covering biohazards as workers would be adequately protected under already existing standards. NIOSH voices the feeling that it is not reasonable to expect that workers will be covered by provisions of a rule that has not been promulgated. It is also hard to predict how proposed changes in 29 CFR 1910.134 would affect the protection afforded to these workers. The second item concerns the use of Section 5(a) of the Occupational Safety and Health Act which states that each employer will provide a place of work free from recognized hazards, whereas many hazards present may not be recognized as such. NIOSH was conducting a study to determine the extent to which bacterial strains used in the fermentation process enter the workplace air. NIOSH cautioned that it may be necessary to develop containment with improved effectiveness and cost efficiency, that monitoring methods must be more deeply studied to measure airborne and surface concentrations of genetically modified organisms, that ongoing medical surveillance and epidemiology among biotechnology workers must assure that no health effects are occurring, and that steps should be taken to ensure that biotechnology workers are not at risk of sensitization to microbial proteins and products generated in the course of fermentation and product extraction processes.						
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