



**Hoffmann-La Roche**

54-106

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Direct Dial 201-235-3286

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The Docket Office  
Docket No. H-049  
U.S. Department of Labor  
Occupational Safety and Health Administration  
Room N2625  
200 Constitution Avenue, N.W.  
Washington, DC 20210

OSHA  
DOCKET OFFICER  
DATE FEB 10 1995  
TIME \_\_\_\_\_

RE: NPRM 59 FR 58884 et. seq. (Nov. 15, 1994) *Respiratory Protection*

Dear Sirs:

Hoffmann-La Roche is a major manufacturer of vitamins, medicinal chemicals, pharmaceutical products and medical diagnostics. Roche has been headquartered in Nutley, New Jersey for over 60 years, and maintains facilities throughout the United States. Roche has a commitment to operate its facilities in a safe and healthful manner. We have reviewed the proposed rule for **Respiratory Protection** and offer our comments below.

**Background**

Roche, like other pharmaceutical companies, believes that engineering controls should be the primary means for minimizing the potential exposures of substances to our employees. Due to the biological activity and potency of the substances used in our industry, respirators are used along with extensive engineering controls to give added protection to our workers. At our Nutley site we have approximately 600 respirator users employed in our production, research and development (R&D), and maintenance departments. All users are involved in a complete respiratory protection program that encompasses the major elements described in the proposed regulation.

**Fit Testing**

We perform quantitative fit testing (QNFT) on respirator users utilizing the TSI Portacount Respirator Fit Tester upon initial assignment of the respirator and every two years thereafter. We

have performed over 1600 QNFTs in the last five years.

### **Frequency of Testing**

OSHA is proposing that fit testing be performed annually after the initial fitting. We believe that refitting should be performed every two years. We reviewed our data of our pharmaceutical, bulk chemical and maintenance groups and found that in a two year cycle only 16 of 233 people, or 6.86%, had a change in assigned respirators. Is this rate any different than would be seen with annual fit testing?

Reading the explanation on page 59 FR 58914, column one, it appears that the proposed **annual** fit testing requirement does not have sufficient data to support it. This data should be gathered before a final decision is made.

OSHA's argument that fit testing "provides an opportunity to check on comfort and problems with the respirator wearer and reinforces respirator training..." cannot be denied. However, this type of check and reinforcement can be achieved in other ways, such as through periodic inspections by the line supervisor or safety and industrial hygiene personnel.

We believe that converting to annual fit testing would pose an unnecessary expense and use of occupational safety and health resources while adding little or no value to our respirator program.

### **Fit Testing Equipment**

OSHA states (ref:59 FR 58914) that the conventional use of a chamber and aerosol generator is currently the only accepted method. While OSHA asserts that other methods will be accepted in the future, the present use of the Portacount would be treated as a *de-minimis* violation.

When we were considering the purchase of a testing system, we found that the Portacount Fit Tester was superior in its cost, set-up, calibration, ease of use, and in just about every aspect when compared to the conventional chamber and aerosol generator method. We have been successfully using the TSI Portacount Respirator Fit Tester for the past seven years and have performed over 2000 tests.

We are quite confident in the adequacy of this equipment and believe that the information for its acceptance is available. We urge OSHA to make a favorable decision on this technological advancement in the final rule so that the use of the Portacount system would not be treated as a violation.

### **Three QNFT Requirement**

OSHA is proposing to require that each wearer undergo three independent QNFTs in order to qualify to wear the respirator. At the present time we are performing one test which consists of nine different exercises. Our experience has been that the person conducting the test can tell within the first few exercises whether the wearer will pass or not. We know of no scientific report or study which supports the need for three independent tests.

It also is confusing to us why OSHA would allow only one qualitative fit test (QLFT) to be acceptable. In the past we used QLFT before switching to QNFT and found QLFT to be less reliable, less exact, and more subjective. It relies on the test subject's olfactory or other senses which tend to vary from person to person and can change through the course of the test. With this in mind, it seems illogical that one QLFT would qualify a wearer while three QNFTs would be necessary.

This extra testing would pose an unnecessary financial burden. Presently, three employees are fit tested per hour. If three tests per person were required, it would take up to one hour each, thereby tripling our present costs. It is our firm belief that one QNFT is sufficient and that performing three independent tests represents no added benefit to our employees.

### **Hazardous Exposure Level**

The proposed standard is requiring that "If there is no PEL, TLV or REL for the hazardous chemical, an exposure level based on available scientific information including material safety data sheets" be determined. We take exception to this paragraph as written and strongly disagree with OSHA for several reasons.

Is OSHA asking that hazardous exposure limits (HELs) be prepared for research compounds? Because there is little or no information on these compounds while they are in the developmental stage, setting HELs for them would be impossible. This rule should provide a specific exemption for research compounds.

In the manufacturing of a chemical, isolated intermediates usually are involved as well as many byproducts. Is OSHA asking that a HEL be set for all hazardous chemicals that could be encountered in the work place, including isolated intermediates and byproducts? For each final product there may be as many as a dozen isolated intermediates. This would mean that a dozen HELs would have to be established to produce a single product.

Concurrently, in order to establish a hazardous exposure level, a validated sampling and analytical method must be prepared to assess

potential exposures. We have worked with a contractor to develop such a method using NIOSH protocols, and found that the cost was over \$90,000 just for a single substance. If the pharmaceutical industry is forced to establish these levels for all isolated intermediates and develop sampling and analytical methods as well, the total cost would make producing a product prohibitively expensive.

The risk assessment process to set these types of levels has not been standardized and would vary from company to company. Thus, it is possible that different values would be set by different companies for the same compound. It also is possible that levels could be set at too high a concentration, thereby creating a false sense of security. In these instances, a person may refrain from using a respirator when he/she may actually need one. Additionally, a company may refrain from improving engineering controls because of the belief that the worker is being protected. Until the risk assessment process is standardized and accepted, this aspect of the proposal should not be promulgated.

The setting of hazardous exposure levels is a very complex and time consuming process that must be based on good scientific information. OSHA is attempting to condense this process into a very simplistic single paragraph. We recommend that this paragraph be withdrawn and that the idea be more fully explored and expanded into a separate ruling.

We hope that you find these comments useful in the formation of the final regulation.

Sincerely,



Kenneth D. Semel, CIH  
Associate Manager, Industrial Hygiene

KDS/ks