# Letters to the Editor

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## Safety of Qualitative Fit-Testing

*To the Editor:* Respiratory protection of healthcare workers (HCWs) has become a serious issue after the recent SARS outbreak. Respirator fit-testing has been recommended as part of HCW respiratory protection programs.[1–4] Yassi et al[5] review the gaps in our knowledge on this issue and other issues in a recent Journal article. They outline some of the potential benefits of fit-testing but do not consider the potential for adverse effects.

In British Columbia (BC) and other Canadian provinces, thousands of HCWs are being fit-tested annually as part of newly established respiratory protection programs. One preferred testing method is qualitative testing using denatonium benzoate (Bitrex) as the detection agent. At the Workers' Compensation Board (WCB) of BC, we have received information on seven individuals having adverse reactions as a result of denatonium benzoate fit-testing. Five of these resulted in compensation claims being filed with the WCB. Six of the seven adverse reactions involved HCWs, including ambulance workers. Six of the seven adverse reactions occurred during or within minutes of testing, whereas the seventh case involved a delayed skin reaction occurring hours after testing. The adverse manifestations included: dermal reactions (four of seven), upper respiratory tract symptoms (three of seven); and asthmatic reactions (two of seven). Both individuals with asthmatic reactions had preexisting asthma. One individual required intensive care unit (ICU) admission for severe asthma. This person had a history of severe asthmatic reactions, including previous ICU admissions.

Denatonium benzoate is the most bitter substance known and is commonly used to denature consumer products to prevent inadvertent or purposeful consumption of hazardous substances. Qualitative fit-testing with denatonium benzoate has been validated and is commonly selected because it is relatively inexpensive, portable, easily learned, simple, and rapid to perform.[6,7] Animal toxicity studies suggest a low toxicity profile[8] for denatonium benzoate, but the data is limited as it relates to chronic toxicity and hypersensitivity potential for humans.[9] Repeated inadvertent exposure of the population occurs through a variety of consumer products such as suntan lotions, beauty products, and household cleaning products. Adverse reactions to these exposures would be difficult to recognize given that denatonium benzoate would not be listed on most products because of its low percentage content.[9] A search of the medical literature only provided one case report of an individual with severe allergic reactions, including urticaria and asthma, resulting from exposure to a variety of products containing denatonium benzoate.[10]

Any test, no matter how relatively safe, can result in a substantial number of adverse reactions if applied to a large number of people. In some cases, these reactions may be severe or life-threatening as was the case for one asthmatic HCW fit-tested with denatonium benzoate. What are the potential consequences of fit-testing a large number of HCWs repeatedly on an annual basis using this product? Would this reexposure result in sensitization of some individuals? Given the ubiquitous nature of denatonium benzoate in our society, what would be the consequences to these individuals? Are there individuals who have a high risk of adverse reactions such as severe asthmatics or those with certain skin conditions?

Recording adverse reactions would be one way to start addressing the "gap" in our knowledge regarding adverse effects of respirator fit testing of HCWs.

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## Reply

*To the Editor:* Dr. Youakim raises an interesting question regarding respirator programs in British Columbia (BC) and the use of Bitrex for fit-testing. Current standards and guidelines in BC[1–4] do not prescribe medical evaluation before initial respirator training and use. Workers potentially at risk because of latent conditions can only be identified after exposure has occurred and they present with symptoms. Consequently, risk factors associated with prior exposure to cleaning products or other commercially available products, for now, must be gleaned from careful case studies of workers who are already symptomatic. We therefore encourage Dr. Youakim to make the case details regarding adverse health effects and denatonium benzoate exposure generally available.

According to the representatives of the manufacturer of Bitrex (Marfarlan Smith Ltd.) (Smith C, Technical Manager, Macfarlan Smith Ltd., Bitrex, personal communication, 2005) and of 3M (one manufacturer of fit-testing kits) (Narver J, Business Development Manager, Occupational Health and Safety Sales and Services, 3M Corp., personal communication, 2005), to their knowledge. there have been no additional reports of adverse health effects other than those raised during the SARS epidemic. Nor are there any recent reports of contact urticaria associated with denatonium benzoate exposure other than the citation given by Dr. Youakim.[5] However, given the ubiquitous use of denatonium benzoate, sensitization resulting from previous exposure is possible, albeit through different routes of exposure. Also, sensitivity may be the result of the aerosol nature of the exposure rather than chemical activity, and individuals responding adversely to denatonium benzoate may also respond to saccharine-based fit-testing agents (Narver J, Business Development Manager, Occupational Health and Safety Sales and Services, 3M Corp., personal communication, 2005).

Fit-testing is only one part of a "complete" respiratory protection program which, in addition, includes hazard evaluation, health screening, training, respirator maintenance, and recordkeeping. However, without required medical evaluation, as is the case in the United States[6] and the United Kingdom,[7] it is unlikely that individuals at risk might be identified before fit-testing. As noted in our review,[8] ensuring that individuals have properly fitting respiratory protection remains important; Dr. Youakim has issued an alert that denatonium benzoate may pose a health risk for certain individuals. Those responsible for fit-testing should be made well aware of this fact.

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## Environmental Tobacco Smoke (ETS) Exposure in Florence Hospitality Venues Before and After the Smoking Ban in Italy

*To the Editor:* We read with interest the paper by Repace[1] presenting an air quality study conducted for the first time before and after a statewide smoking ban in eight Delaware hospitality venues with real-time measures of respirable suspended particles (RSP) and particulate polycyclic aromatic hydrocarbons (PPAH). Postban levels of RSP ranged from 2.5% to 25% of preban values and averaged 9.4%, whereas postban PPAH concen-

tration ranged from 0.5% to 11% of preban levels and averaged 4.7%. Thus, approximately 90% of RSP and 95% of PPAH can be attributed to tobacco smoke.

A law banning smoking in enclosed public places entered into force in Italy on January 10, 2005.[2] Italy has become the third European country to introduce a smoking ban, following Ireland and Norway. We measured nicotine vapor phase in pubs and discos before and after the smoking ban in Italy. Nicotine was measured using passive samplers, which comprise a plastic cassette (with a windscreen in one side) containing a filter treated with sodium bisulfate (diameter of 37 mm). The samplers were used as personal monitor in four pubs and three discos in Florence. The samplers had to be clipped for approximately 4 hours to a shirt collar or lapel, with the windscreen facing out, away from the clothes. For each venue, two samples before and two after the smoking ban were collected (Table 1). Discos and pubs were selected at random from a sampling universe list. The filters were analyzed at the Laboratory of Barcelona by the gas chromatography (GC/MS) method. The lower limit of detection is 0.01 μg/mL. The nicotine concentration (μg/m$^3$) was obtained by dividing the observed nicotine concentration by the flow rate (24 mL/min) and allowing for the time the filter had been exposed. The method has been previously validated by Hammond et al[3] and used in several studies.[4]

Before the smoking ban, nicotine concentrations ranged from 33.0 to 276.5 μg/m$^3$ with a median value of 138.9 μg/m$^3$. After the smoking ban, concentrations ranged from 1.7 to 8.7 μg/m$^3$ with a median value of 4.5 μg/m$^3$. Postban levels of nicotine ranged from 0.9% to 5.9% of preban values and averaged 3.2% (Table 1).

The median value before the smoking ban (138.9 μg/m$^3$) translates (using the formula of Repace and Lowery[5]) into a lifetime excess lung cancer mortality rate for hospitality industry workers of 180 per 10,000, and the median value after the smoking ban (4.5 μg/m$^3$) into an estimate of six per 10,000 with a decrease in lifetime excess of 97%.

This is the first study on environmental tobacco smoke (ETS) exposure in hospitality premises before and after the smoking ban in Italy. Results of this study confirm those of Repace's air quality study,[1] even if in Delaware hospitality venues, different ETS markers were measured. Thus, a nationwide smoking ban can determine a reduction of approximately 90% to 95% of ETS exposure in hospitality venues, the most ETS-polluted public areas.

More studies are required to monitor the compliance of a nationwide smoking ban for a longer time.

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**TABLE 1**
Concentrations of Nicotine in 4 Pubs and 3 Discos in Florence Before and After the Smoking Ban in Italy (January 10, 2005)

| | Before the Smoking Ban | | After the Smoking Ban | | |
|---|---|---|---|---|---|
| Place | Sampling Date | Nicotine Concentration (μg/m$^3$) | Sampling Date | Nicotine Concentration (μg/m$^3$) | Percent of pre Ban Value |
| Pub 1 | 27 Dec 2004 | 173.61 | 28 Jan 2005 | 4.86 | 2.4 |
| | 27 Dec 2004 | 199.65 | 28 Jan 2005 | 4.17 | |
| Pub 2 | 02 Dec 2004 | 35.59 | 01 Mar 2005 | 1.74 | 5.1 |
| | 02 Dec 2004 | 32.99 | 01 Mar 2005 | 1.74 | |
| Pub 3 | 17 Dec 2004 | 88.14 | 26 Jan 2005 | 4.17 | 5.7 |
| | 17 Dec 2004 | 95.90 | 26 Jan 2005 | 6.25 | |
| Pub 4 | 30 Dec 2004 | 230.90 | 04 Mar 2005 | 1.74 | 0.9 |
| | 30 Dec 2004 | 143.23 | 04 Mar 2005 | 1.74 | |
| Disco 1 | 18 Dec 2004 | 134.62 | 26 Feb 2005 | –§ | 5.3 |
| | 18 Dec 2004 | 175.40 | 26 Feb 2005 | 8.17 | |
| Disco 2 | 24 Dec 2004 | 127.16 | 05 Feb 2005 | –§ | 5.9 |
| | 24 Dec 2004 | 107.04 | 05 Feb 2005 | 6.94 | |
| Disco 3 | 07 Jan 2005 | 276.52 | 12 Feb 2005 | 8.68 | 3.0 |
| | 07 Jan 2005 | 267.05 | 12 Feb 2005 | 7.81 | |
| **All venues** | | | | | |
| Mean | | 149.13 | | 4.83 | 3.2 |
| (SD) | | (76.51) | | (2.70) | |
| Median | | 138.93 | | 4.52 | |

§ The windscreens of the samplers were broken during sampling.

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## Reply

Gorini et al[1] report a 90% to 95% reduction in environmental tobacco smoke (ETS) nicotine concentrations in four pubs and three discos in Florence, following Italy's countrywide smoking ban, in agreement with the pollution reduction reported in a hospitality industry investigation in eight venues using two other atmospheric markers for ETS, respirable suspended particles (RSP), and polycyclic aromatic hydrocarbons (PAH), after Wilmington, Delaware's smoking ban in the United States in 2002.[2] These data are also in agreement with data taken in 20 hospitality venues in Western New York State by Travers et al,[3] which found an 84% reduction in RSP after New York's statewide smoking ban in 2003. Gorini et al[1] also estimate a 40-year working lifetime risk of lung cancer mortality for pub and disco workers from ETS exposure at 18 per 1000, associated with a median nicotine concentration of 138.9 $\mu g/m^3$, using the risk model of Repace and Lowrey.[4] Adjusted to a 45-year regulatory working lifetime, this level of excess ETS-induced risk is an estimated 20 times the "significant risk of material impairment of health" level used by the U.S. Occupational Safety and Health Administration in regulating serious workplace hazards. An ETS-RSP risk model derived by Repace and Lowrey[4] may also be applied to the Wilmington and Western New York data, which had mean estimated ETS-RSP levels of 220 $\mu g/m^3$ and 299 $\mu g/m^3$, respectively, using an ETS-RSP exposure–response relationship of 75 $\mu g/m^3$ daily average for a 40-year working lifetime average ETS-RSP exposure equating to one death per 1000. This method yields mean estimated 45-year working lifetime lung cancer mortality risks of approximately four per 1000 hospitality industry workers averaged over the 28 U.S. venues. Estimated risk of ETS-induced heart disease mortality is 10 times higher than for lung cancer.[5] Air pollution from ETS is far worse than that generated by heavy traffic.[4,6] Attempts to control ETS by ventilation or air cleaning require impossible tornado-like levels of airflow.[7] The study by Gorini et al[1] in Italy generalizes the U.S. results, suggesting that hospitality workers in Europe as well as the United States are at very high risk from workplace passive smoking and benefit greatly from total workplace smoking bans.

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