Dennis L. Knepp
P.O. Box 1014
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Jeff Haferman
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16 April 2008

Attention: Dr. Robert Leavitt
               Branch Chief, Executive Secretary, EATF

Subject: CheckMate LBAM-F particle size distribution

Reference: Your letters to the EATF dated March 13 and April 9, 2008

Dear Dr. Leavitt:

Your letters of March 13 and April 9, 2008 to the members of the environmental advisory task force (EATF) for the light brown apple moth eradication program contain scientific errors. The errors are your claims that CheckMate consists of large particles that are delivered in insignificant amounts. In fact both of these claims are false. This letter and the accompanying analysis show that the micro-capsules in CheckMate constitute a health hazard which should have been investigated prior to spraying.

In the attachment we analyze the Suterra measurements of micro-capsule size that are attached to your first letter. Although the data from the particle size analyzer could be more complete with little effort, it is possible to estimate the average particle size, the median particle size, and also the concentration of PM_{10} from the data you provide. The term PM_{10} refers to micro-capsules with diameters less than or equal to 10 micrometers in diameter. PM_{10} in sufficient concentration is a known health hazard, no matter the composition of the particulates. The issue of micro-capsule size is critical. The CDFA's erroneous science in this regard was used to justify the omission of an inhalation toxicity study prior to the spraying of Monterey.

In the Consensus Statement the Department of Pesticide Regulation states: "The micro-capsule particles are very large by inhalation standards (25 micrometers in diameter or larger) and unable to reach the deep lung. As a result, an inhalation toxicity study, which is designed to examine systemic effects resulting from inhalation into the lung, would not be useful and was not conducted. If inhaled, because of the large size, these micro-capsules are not likely to reach the pulmonary (air exchange) region of the lung."

This statement leads one to rightly conclude that inhalation toxicity studies are necessary

if the concentration of PM_{10} is large. You had this data, yet you failed to recommend the inhalation toxicity study.

This letter provides several results from a very straightforward analysis. First the average particle diameter is at most 17 micrometers, much smaller than the CDFA has been promoting. Second the median micro-capsule size is at most 10 micrometers, far smaller than your claim.

Finally the concentration of PM_{10} is so large as to be a health threat. In our calculation of PM_{10} caused by aerial spraying, we assume that all the CheckMate spray ends up suspended in the 2 meters of air at ground level. Our result of 128 $\mu gm/m^3$ (micro-gram per cubic meter) for the concentration of PM_{10} is very disturbing.

According to EPA Report EPA-452/R-05-005a, page 3-14, there is an increased rate of mortality from increased concentrations of PM_{10}. In a major multi-city study described in this report, researchers found that the rate of mortality increased 2.8% for every increase of 50 $\mu gm/m^3$ in PM_{10} concentration. It follows that from CheckMate, one would expect an increase in mortality of 7%.

In another study from the Harvard School of Public Health and published in Environmental Health Perspectives (2000), researchers measured an increase in hospital admissions for heart and lung disease due to increased PM_{10} concentration. The increase in pneumonia was 1.95% for every increase of 10 $\mu gm/m^3$ in PM_{10} concentration.

We are particularly concerned about these huge concentrations of PM_{10} added by aerial spraying because our results assume that there is no run-off of the pesticide over time. Since the pesticide is intended to last for 30 to 90 days, one would expect that wind and run-off would concentrate the micro-capsules in various places and that other places would be relatively free of the pesticide. In this case the local PM_{10} concentrations would be even greater than 128 $\mu gm/m^3$.

We note that in your letter you state that the micro-capsules are encased in water droplets that average over 1,000 micrometers in diameter. This is not relevant to the issue of PM_{10}. In fact, since the spray is very similar to fog, the particles may dry out or, instead, may collect additional water immediately after release. Everyone has seen light rain dry up before reaching the ground. The water coating will cause the micro-capsules to initially stick to rooftops, buildings, and trees. After the water evaporates (the evaporation time depends on the weather), they will dislodge from rooftops and trees and will continue to be stirred up and blown about by human activity and the wind. The micro-capsules will certainly be carried into homes and buildings.

The large discrepancy between the scientific calculations herein based on actual data and the CDFA statements on micro-capsule size warrants serious consideration. We believe that the large concentrations of PM_{10} during and after the aerial spraying of Monterey and Santa Cruz are responsible for the illnesses and health complaints of over 600 of our citizens.

We feel that several steps are necessary before the CDFA resumes aerial spraying.

1. Perform and provide to the public the results of an independent inhalation study.

2. Determine the amount of time that micro-capsules of CheckMate remain in human lung tissue.

3. Provide statistical analysis of the size distribution of CheckMate micro-capsules.

4. Determine the height distribution of the micro-capsules.

5. Determine the amount of PM_{10} that might be carried into a home or business from foot traffic.

We recommend that all these measurements be performed and analyzed by independent scientists. Finally, we would like an independent investigator to determine the origin of the original CDFA claims on particle size.

Sincerely,

Dennis L. Knepp, Ph.D.

Jeff Hafferman, Ph.D.

Dr. Knepp has a Ph.D. in Electrical Engineering from the University of Pennsylvania. He has worked in the area of re-entry physics and has solved problems involving the effects of the ionosphere on radar and communications systems. He has published over 50 peer-reviewed papers and symposia articles in the area of electromagnetic propagation of radio waves in the ionosphere. Dr. Knepp is a Fellow of the Institute of Electrical and Electronics Engineers (IEEE) and an associate editor of the journal Radio Science.

Dr. Haferman has a Ph.D. in Mechanical Engineering from the University of Iowa. He did post-doctoral work at the NASA-Goddard Laboratory for Atmospheres, and has published peer-reviewed papers in the areas of Atmospheric Science, Heat Transfer, and Electromagnetic Scattering. Dr. Haferman is also a member of the Monterey City Council.

Analysis of the micro-capsule size distribution from the aerial application of the CheckMate pesticide

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1. Density of PM_{10} from a nominal CheckMate LBAM-F aerial application

According to the US Environmental Protection Agency, particles of any material that are 10 micrometers (10 μm) and less in diameter are a risk to human health. Particles with diameters less than or equal to 10 μm are referred to as PM_{10}. An EPA fact sheet dated July 17, 1997 states "research had shown that the particles of greatest health concern were those equal to or less than 10 micrometers that can penetrate into sensitive regions of the respiratory tract." This section presents a calculation of the mass density of PM_{10} that would be expected after a "nominal" aerial spraying of CheckMate.

We use the CDFA nominal application rate of 2.97 fluid ounces of CheckMate per acre. Eighteen percent of this is called a pheromone by the CDFA; the other 82 percent consists of so-called inerts. According to the Coulter measurements (attached and dated 12 March 2008) 1.2 percent of the total volume of CheckMate has diameter less than 10 micrometers, that is, 1.2 percent of the 2.97 fluid ounces consists of PM_{10}.

For the nominal CDFA application rate of 2.97 fluid ounces per acre, the volume of PM_{10} applied in an area is:

$$
\begin{aligned}
\text{VolPM}_{10} &= 0.012 \times \frac{2.97 \text{ fl oz}}{\text{acre}} \times \frac{2.956 \times 10^{-5} m^3}{\text{fl oz}} \\
&= 1.054 \times 10^{-6} \frac{\text{cubic meters}}{\text{acre}} \\
&= 2.603 \times 10^{-10} \frac{\text{cubic meters}}{\text{square meter}}
\end{aligned}
$$

Now the specific gravity of CheckMate LBAM-F is equal to 0.98. In other words, the density is 0.98 grams per cubic centimeter. This is the actual value from the Material Safety Data Sheet (MSDS) on the Suterra web site for CheckMate OLR-F. Then it is straightforward to calculate the total mass of PM_{10} particles as:

$$
\begin{aligned}
\text{MassPM}_{10} &= 2.603 \times 10^{-10} \frac{\text{cubic meters}}{\text{square meter}} \times \frac{0.98 \ gm}{cm^3} \times \left(\frac{100 \ cm}{m}\right)^3 \\
&= 2.55 \times 10^{-4} \frac{gm}{m^2}
\end{aligned}
$$

The factor 0.98 gm/cm^3 is the mass density of CheckMate OLR-F, not CheckMate LBAM-F, however the inert material is identical, to our knowledge. The quantity MassPM_{10} is the mass

density applied per square meter. In the analysis below we calculate the number of micro-capsules of PM_{10} applied over an area.

All measurements of the effect of PM_{10} are based on the density of PM_{10} in the air we breath. To calculate this value we need to know the height distribution of the micro-capsules. Since this is not available, assume that the micro-capsules are uniformly distributed in the 2 meters immediately above the ground.

This calculation could be improved if the CDFA would provide measurements of the height distribution of the micro-capsules. Both short and long term measurements are needed since the micro-capsules are designed to last for 30 to ninety days. In addition, run-off and wind will cause the micro-capsules to accumulate in certain places. Information on micro-capsule accumulation over time is also needed for a more accurate calculation.

Given the assumption of a uniform distribution of micro-capsules in the lower 2 meters of the atmosphere, the mass per unit volume is:

$$
\begin{aligned}
\text{MassPM}_{10} &= \frac{2.55}{2} \times 10^{-4} \, \frac{gm}{\text{cubic meter}} \times \frac{1 \times 10^6 \mu gm}{gm} \\
&= 128 \, \mu gm/m^3
\end{aligned}
$$

The result of 128 $\mu gm/m^3$ for the concentration of PM_{10} is very alarming. According to EPA Report EPA-452/R-05-005a, page 3-14, there is an increased rate of mortality from increased concentrations of PM_{10}. In a major multi-city study described in this report, researchers found that the rate of mortality increased 2.8% for every increase of 50 $\mu gm/m^3$ in PM_{10} concentration. It follows that from CheckMate spraying, one would expect an increase in mortality of 7%.

In another study from the Harvard School of Public Health and published in Environmental Health Perspectives (2000), researchers measured an increase in hospital admissions for heart and lung disease due to increased PM_{10} concentration. The increase in pneumonia was 1.95% for every increase of 10 $\mu gm/m^3$ in PM_{10} concentration.

These measurements of large increases in health problems caused by increased PM_{10} are very likely the explanation for the health problems reported by 600 citizens of Monterey and Santa Cruz after the 2007 CheckMate sprayings.

2. Average micro-capsule diameter

Prior to the spraying of Monterey and Santa Cruz, the California Department of Food and Agriculture was concerned about the quantity of very small particles from their spraying program and addressed it in the Consensus Statement. In this document they state: "The micro-capsule particles are very large by inhalation standards (25 micrometers in diameter or larger) and unable to reach the deep lung. As a result, an inhalation toxicity study, which is designed to examine systemic effects resulting from inhalation into the lung, would not be useful and was not conducted. If inhaled, because of the large size, these micro-capsules are not likely to reach the pulmonary (air exchange) region of the lung."

The above calculation of the amount of PM_{10} is so large as to cause measurable health problems, contrary to the statements of the CDFA. Given the enormity of this error, we also decided to investigate the CDFA's claims regarding average particle size.

Before starting this calculation, first consider a bucket full of tennis balls and marbles. Assume that the volume of the marbles is small and most of the space in the bucket is taken

up by the tennis balls. However, it is possible to have many marbles in even a small volume in the bucket so that the average diameter of the balls in the bucket is small. It turns out that the same is true for CheckMate LBAM-F.

To calculate the average micro-capsule diameter we need the probability density function of the particle size. This can be obtained from the tabular data for the cumulative distribution of the amount (by volume) of CheckMate as a function of micro-capsule diameter. This table appears on the bottom of the attachment dated 12 March 2008 and referred to as the Coulter LS particle size analyzer data.

Reading directly from the table, 1.2% of a unit volume of CheckMate has diameter less than 10.01 μm; 23.8% of a unit volume has diameter greater than 10.01 μm and less than 67.97 μm; 25% of a unit volume has diameter greater than 67.97 μm and less than 97.21 μm; 25% of a unit volume has diameter greater than 97.21 μm and less than 125.8 μm; 15% of a unit volume has diameter greater than 125.8 μm and less than 152.2 μm; 10% of a unit volume has diameter greater than 152.2 μm and less than 200 μm. The values of the percentages in the above paragraph are obtained by subtracting the percentages given in the Coulter data. This is a routine method to obtain a discrete probability density function from a cumulative distribution function.

Now simplify the probability density to a discrete function wherein the volume is assumed to be composed only of micro-capsules with the six particle diameters cited above. The discrete probability density function is given in Figure 1. This discrete probability density

Diameter (micrometer)	Probability
10.01	0.012
67.07	0.238
97.21	0.25
125.8	0.25
152.2	0.15
200	0.10

Figure 1: Simplified probability density function of CheckMate micro-capsule diameter by volume.

collects the probability over a range of particle diameters and replaces the range of diameters by a single value. It is obvious that this discrete probability density function overestimates the number of large micro-capsules. For example, from the figure in the Coulter data, a lot less than 10 percent of the volume has diameter of 200 μm. Thus this calculation of average micro-capsule diameter will also be an overestimate. However, it should be simple for the operator of the Coulter particle counter to obtain more complete data to get a more accurate value (which will be smaller than the value calculated here).

Now let the six values of the diameter in Figure 1 be denoted by the symbol d_i for $i = 1, \ldots, 6$ with probabilities p_i for $i = 1, \ldots, 6$. To compute the average micro-capsule diameter we first need to know the number of micro-capsules with diameter d_i in a unit volume. The

number of micro-capsules in a unit volume with diameter d_i is

$$n_i = \frac{p_i}{v_i} \qquad i = 1, \ldots, 6$$

where v_i is the volume occupied by a single particle of diameter d_i. This is simply the percentage of the volume occupied by particles with diameter d_i divided by the volume of a single particle of diameter d_i. The volume of a sphere of diameter d_i is

$$v_i = \frac{4}{3}\pi \left(\frac{d_i}{2}\right)^3 \qquad i = 1, \ldots, 6$$

So the average diameter is given by the equation

$$d_{Avg} = \frac{\sum_{i=1}^{6} d_i \times n_i}{\sum_{i=1}^{6} n_i}$$

where the sum $\sum_{i=1}^{6} n_i$ is the total number of particles (of all sizes) in the unit volume. All the values used in this equation are given above. The result for the average micro-capsule diameter is $d_{Avg} = 16.9 \ \mu m$.

Given the data from the Coulter particle counter (interpreted correctly), the calculation of average particle diameter is straightforward, as demonstrated. Please keep in mind that this value is actually an overestimate. If the CDFA provides more detailed information from more complete measurements of CheckMate LBAM-F, the true value of the average micro-capsule diameter will turn out to be smaller than $16.9 \ \mu m$.

3. Median micro-capsule diameter

The median is the diameter of that micro-capsule in the middle of the size distribution. In other words half of the micro-capsules are smaller than the median and half are larger. To find the median from the discrete distribution in Figure 1, we first calculate the number of micro-capsules of each size and then find the size of the micro-capsule in the middle of this distribution.

The number of micro-capsules of each size in a unit volume is:

$$n_i = \frac{p_i}{v_i} \qquad i = 1, \ldots, 6$$

Once we examine each of the six values of n_i, the median is readily seen to be 10.01 micrometers. Quite simply, the quantity of small micro-capsules is so great relative to the quantity of the larger micro-capsules that the median size is equal to the size of the small particles.

Remember that this calculation of the median size is based on the discrete distribution in Figure 1. In fact, if more information from the measurements were made available, the actual median would be found to be even smaller.

4. Number of Micro-capsules in CheckMate LBAM-F

In this section we compute the number of particles of diameter less than 10 micrometers in a volume of 2.97 fluid ounces of CheckMate LBAM-F. The CDFA states that 2.97 fluid ounces is applied per acre in a "nominal" CheckMate application. The smaller particles are known to be more important to health because they penetrate more deeply into the lungs. For this reason we examine the measurements for diameters less than 10 μm more closely. The Coulter data plot indicates that particles with diameter less than 10 μm can be fairly well modeled by a distribution where about one-third of the particles have diameter of 4 μm and two-thirds of the particles have diameter of 8 μm.

Particles of diameter of 8 μm:

Total volume of $8\mu m$ micro-capsules per acre:

$$V_{8\mu m} = \frac{2}{3} \times 0.012 \times \frac{2.97 \text{ fl oz}}{\text{acre}} \times \frac{2.956 \times 10^{-5} m^3}{\text{fl oz}} = 7.02 \times 10^{-7} m^3/\text{acre}$$

The total number of particles is simply the total volume divided by the volume of a single particle. It follows that the total number of 8 μm micro-capsules applied per acre, square foot, and square meter is:

$$\begin{aligned} N_{8\mu m} &= \frac{7.02 \times 10^{-7} m^3/\text{acre}}{\frac{4}{3}\pi(4 \times 10^{-6}m)^3} \\ &= 2.6 \times 10^9/\text{acre} \\ &= 5.97 \times 10^4/\text{ft}^2 = 59,700/\text{ft}^2 \\ &= 6.43 \times 10^5/m^2 \end{aligned}$$

Particles of diameter of $4\mu m$:

Total volume of 4 μm micro-capsules per acre:

$$V_{4\mu m} = \frac{1}{3} \times 0.012 \times \frac{2.97 \text{ fl oz}}{\text{acre}} \times \frac{2.956 \times 10^{-5} m^3}{\text{fl oz}} = 3.51 \times 10^{-7} m^3/\text{acre}$$

The total number of particles is simply the total volume divided by the volume of a single particle. It follows that the total number of 4 μm micro-capsules applied per acre, square foot, and square meter is:

$$\begin{aligned} N_{4\mu m} &= \frac{3.51 \times 10^{-7} m^3/\text{acre}}{\frac{4}{3}\pi(2 \times 10^{-6}m)^3} \\ &= 1.05 \times 10^{10}/\text{acre} \\ &= 2.41 \times 10^5/\text{ft}^2 = 241,000/\text{ft}^2 \\ &= 2.59 \times 10^6/m^2 \end{aligned}$$

Total number of particles per square foot:

$$N_{\text{Total}} = N_{8\mu m} + N_{4\mu m} = 301,000/\text{ft}^2$$

The final result is that the CDFA measurements of CheckMate micro-capsule size predict that there will 301,000 micro-capsules deposited over a square foot.

5. Number of "equivalent" female moths

This section is a calculation of the amount of chemical pheromone deposited per square foot in units of "female moths." According to the CDFA, the amount of pheromone contained in the body of a female moth is one nanogram (1,000,000,000 nanograms is 1 gram). The "pheromone" in CheckMate is manufactured, not obtained from female moths.

The "pheromone" component constitutes 18% of CheckMate by volume. For the nominal CDFA application rate of 2.97 fluid ounces per acre, the volume of chemical pheromone applied in an area is:

$$
\begin{aligned}
\text{VolPher} &= 0.18 \times \frac{2.97 \text{ fl oz}}{\text{acre}} \times \frac{2.956 \times 10^{-5} m^3}{\text{fl oz}} \\
&= 1.58 \times 10^{-5} \frac{\text{cubic meters}}{\text{acre}}
\end{aligned}
$$

Then it is straightforward to calculate the total mass of the "pheromone" as:

$$
\begin{aligned}
\text{MassPher} &= 1.58 \times 10^{-5} \frac{\text{cubic meters}}{\text{acre}} \times \frac{0.98 \ gm}{cm^3} \times \left(\frac{100 \ cm}{m}\right)^3 \\
&= 15.49 \frac{gm}{\text{acre}} \\
&= 3.55 \times 10^{-4} \frac{gm}{ft^2}
\end{aligned}
$$

The factor 0.98 gm/cm^3 is the mass density of CheckMate OLR-F, not CheckMate LBAM-F, however the inert material is identical, to our knowledge.

The number of equivalent female moths per square foot is then the quantity MassPher divided by the number of grams of pheromone per moth, which is $1 \times 10^{-9} gr/\text{moth}$. The result is 355,000 "female moth equivalents" per square foot.

6. Conclusions

Figure 2 summarizes the results of these analyses. All the results are a direct consequence of the Suterra data published on the CDFA web site and included in the attachments. In fact, we believe that a first year college student could derive these results with little difficulty. We feel that the CDFA's failure to derive these same results should be investigated given the importance of these issues to respiratory health.

Mass density of PM$_{10}$ particles:	128 micrograms/cubic meter
Average diameter of the micro-capsules:	Less than 16.9 micrometers
Median diameter of the micro-capsules:	Less than 10 micrometers
Number of PM$_{10}$ particles per square foot:	301,000

Figure 2: Primary results of this calculation.

7. Conversion factors

$$
\begin{aligned}
1 \text{ fluid ounce} &= 2.956 \times 10^{-5} m^3 \\
\text{Vol of sphere of radius r:} &= \frac{4}{3}\pi r^3 \\
1{,}000{,}000 \text{ micrometers} &= 1 \text{ meter} \\
3.281 \text{ feet} &= \text{meter} \\
1 \text{ acre} &= 43{,}560 \text{ ft}^2 \\
1 \text{ acre} &= 4047 \text{ m}^2
\end{aligned}
$$

8. References

Letter from Dr. Robert Leavitt, Branch Chief, to the LBAM Environmental Advisory Task Force, dated April 9, 2008. This letter is a revision of the March 12 letter.

Letter from Dr. Robert Leavitt, Branch Chief, to the LBAM Environmental Advisory Task Force, dated March 13, 2008.
Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS, US Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, North Carolina, EPA-452/R-05-005a, December 2005.

A. Zanobetti, J. Schwartz, and D. W. Dockery, "Airborne Particles Are a Risk Factor for Hospital Admissions for Heart and Lung Disease," *Environmental Health Perspectives*, Vol. 108, N0. 11, November 2000. The authors are with the Environmental Epidemiology Program, Department of Environmental Health, Harvard School of Public Health, Boston, Mass.

"Health and Environmental Effects of Particulate Matter." The US EPA Fact Sheet on particulate matter is on the web at the address:
http://www.epa.gov/ttn/oarpg/naaqsfin/pmhealth.html The information cited above appears towards the end of the EPA document under the section on background.

Consensus Statement of Human Health Aspects of the Aerial Application of Microencapsulated Pheromones to Combat the Light Brown Apple Moth, October 31, 20007.

Attachment: CDFA Letter:

Letter from Dr. Robert Leavitt, Branch Chief, to the LBAM
Environmental Advisory Task Force, dated March 13, 2008.

March 13, 2008

Dear EATF members,

At our last meeting, Laurie Gibson asked the question about the LBAM-F particle size distribution. There is a reference in Dr. Inge Werner's report about micro-capsules with a diameter as small as 10 micrometers and an average of 30 micrometers.

I have discussed this by phone with Dr. Bryn Phillips at the Granite Canyon Marine Pollution Studies Laboratory. He said that he only did a quick and dirty particle size check with an ocular (eye) microscope. He said "I would not characterize this as a thorough particle size distribution". Dr. Phillips recommended that a thorough study be done with better equipment, in particular a Coulter counter with imaging software.

It turns out that the manufacturer, Suterra, has the Coulter counter and does thorough particle size distribution studies for quality control. In addition, Suterra pulls samples from across the bottle to give a representative sample. Suterra provided a copy of an analysis of LBAM-F to Dr. Bob Dowell who discussed the results at the meeting. The actual graph and analysis is enclosed.

You can see from the analysis that the median micro-capsule (50 percent larger and 50 percent smaller) is 97 micro-meters. You can also see that 1.2 percent of the micro-capsules are smaller than 10 micrometers in diameter.

In addition, the formulated product is mixed with water for application. When applied, the microcapsules are encased in water droplets that average 1,000 micrometers in diameter. The microcapsules then need to adhere to the surface on which they land.

If you have any other questions or concerns about this matter, please call or e-mail me.

Sincerely,

Robert Leavitt, Ph.D.
Branch Chief, Executive Secretary, EATF

CDFA Plant Health & Pest Prevention Services • 1220 N Street, Room 341 • Sacramento, California 95814   **State of California**
Telephone: 916.654.0768 • Fax: 916.653.2403 • www.cdfa.ca.gov   Arnold Schwarzenegger, Governor

Posted 3/14/08

COULTER™

File name: x71036.$01   Group ID: X71036
Sample ID: 121059
Operator: DMB   Run number: 1
Comments: Representative Sample of LBAM-F
Optical model: Fraunhofer
LS 230   Small Volume Module
Start time: 8:25 6 Sep 2007   Run length: 59 Seconds
Obscuration: 43%
PIDS Obscur: 66%
Software: 2.05   Firmware: 2.02 2.02

Differential Volume
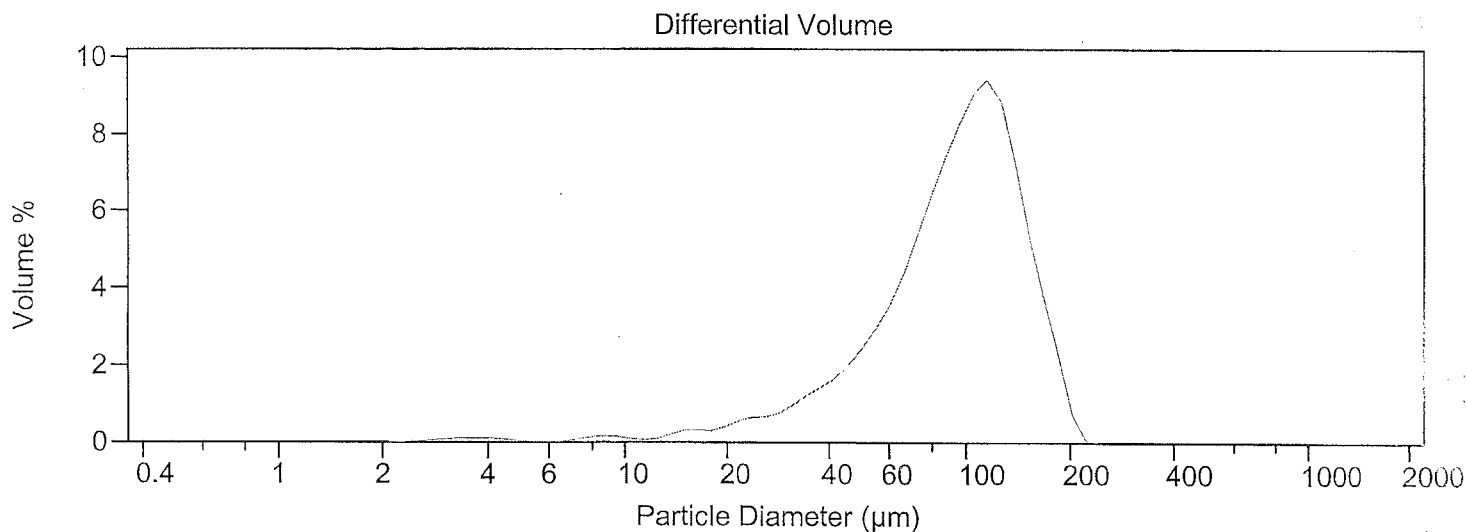
Volume Statistics (Arithmetic)   x71036.$01

Calculations from 0.375 μm to 2000 μm

Volume   100.0%
Median: 97.21 μm

% <	1.2	25	50	75	90
Size μm	10.01	67.97	97.21	125.8	152.2

Attachment: CDFA Letter:

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April 9, 2008

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You can see from the analysis that the median micro-capsule (50 percent larger and 50 percent smaller) is 97 micro-meters. You can also see that 1.2 percent of the micro-capsules by volume are smaller than 10 micrometers in diameter.

In addition, the formulated product is mixed with water for application. When applied the microcapsules are encased in water droplets that average 1,000 micrometers in diameter. The microcapsules then tend adhere to the surface on which they land.

If you have any other questions or concerns about this matter, please call or e-mail me.

Sincerely,

Robert Leavitt, Ph.D.
Branch Chief, Executive Secretary, EATF

CDFA Plant Health & Pest Prevention Services ● 1220 N Street, Room 341 ● Sacramento, California 95814
Telephone: 916.654.0768 ● Fax: 916.653.2403 ● www.cdfa.ca.gov

State of California
Arnold Schwarzenegger, Governor

Attachment: A few pages from:

Review of the National Ambient Air Quality Standards for
Particulate Matter: Policy Assessment of Scientific and Technical
Information, OAQPS, US Environmental Protection Agency,
Office of Air Quality Planning and Standards, Research Triangle
Park, North Carolina, EPA-452/R-05-005a, December 2005.

⊕EPA United States
Environmental Protection
Agency

Review of the National Ambient Air Quality Standards for Particulate Matter:

Policy Assessment of Scientific and Technical Information

OAQPS Staff Paper

Review of the National Ambient Air Quality Standards for Particulate Matter:

Policy Assessment of Scientific and Technical Information

OAQPS Staff Paper

3.3.1 Premature Mortality

This section includes an overview of the CD's findings on (1) mortality associations with short-term PM exposure, with emphasis on results from newly available multi-city analyses; and (2) mortality associations with long-term PM exposure.

3.3.1.1 Mortality and Short-term PM Exposure

Historical reports of dramatic pollution episodes have provided clear evidence of mortality associated with high levels of PM and other pollutants, as summarized in the 1996 CD (EPA, 1996a, pp. 12-28 to 12-31). More recently, associations between increased daily mortality and various indicators of PM have been reported at much lower concentrations in a large number of areas with differing climates, PM composition, and levels of gaseous co-pollutants. Since the last review, a large number of new time-series studies of the relationship between short-term exposure to various indicators of PM and mortality have been published, including several multi-city studies that are responsive to the recommendations from the last review (CD, p. 8-24). Included in the PM CD are results from numerous studies that have been conducted in single cities or locations in the U.S. or Canada, as well as locations in Europe, Mexico City, South America, Asia and Australia (Table 8A in the CD). As was observed based on the more limited studies available in the last review, the associations reported in the recent studies on short-term exposure to PM_{10} and mortality are largely positive, and frequently statistically significant. Staff have focused on the results of studies conducted in the U.S. and Canada in this assessment; effect estimates from U.S. and Canadian multi-city and single-city studies are presented in Figure 3-1 for associations between PM_{10}, $PM_{2.5}$ and $PM_{10-2.5}$ and mortality.[5]

In this review, the CD has emphasized the results of the multi-city studies as being of particular relevance. The multi-city studies combine data from a number of cities that may vary in climate, air pollutant sources or concentrations, and other potential risk factors. The advantages of multi-city analyses include: (1) evaluation of associations in larger data sets can provide more precise effect estimates than pooling results from separate studies; (2) consistency in data handling and model specification can eliminate variation due to study design; (3) effect modification or confounding by co-pollutants can be evaluated by combining data from areas with differing air pollutant combinations; (4) regional or geographical variation in effects can be evaluated; and (5) "publication bias" or exclusion of reporting of negative or nonsignificant findings can be avoided (CD, p. 8-30).

The National Morbidity, Mortality and Air Pollution Study (NMMAPS) is the largest available multi-city analysis, and included analyses of PM_{10} effects on mortality in 90 U.S. cities (Samet et al., 2000a,b; Dominici et al., 2003a). Additional, more detailed, analyses were conducted in a subset of the 20 largest U.S. cities (Samet et al., 2000b). The NMMAPS study

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[5] The effect estimates in Figure 3-1 (for mortality effects) and in Figure 3-2 (for morbidity effects; discussed below in section 3.3.2) have been plotted in order of decreasing study power, using as an indicator the natural log of the product of the number of study days and number of health events per day.
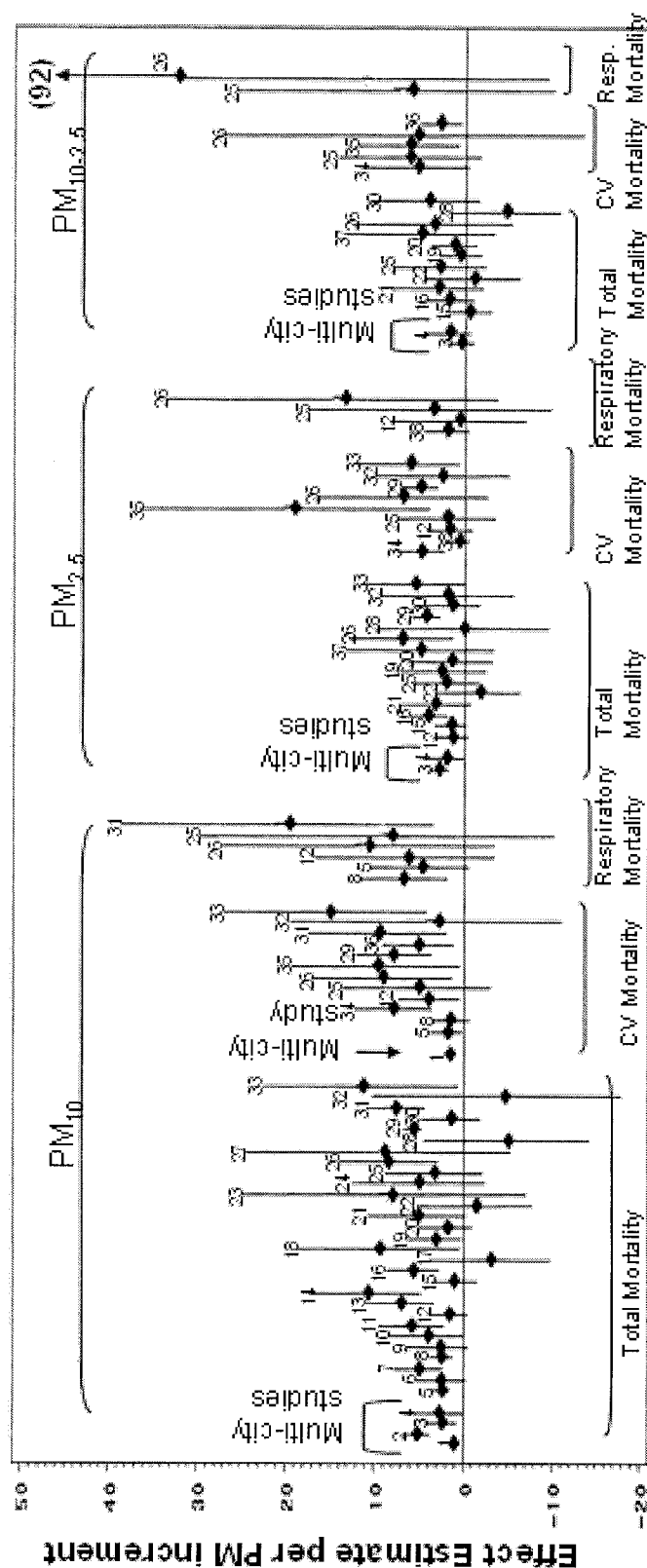
Figure 3-1. Excess risk estimates for total nonaccidental, cardiovascular, and respiratory mortality in multi-pollutant (in bold font below) and single-pollutant models for U.S. and Canadian studies. PM increments: 50 μg/m³ for PM₁₀ and 25 μg/m³ for PM₂.₅ and PM₁₀₋₂.₅. Results presented from time-series studies that did not use GAM or were reanalyzed using GLM.

1. **Dominici et al. (2003a), 90 U.S. cities**
2. **Schwartz (2003b), 10 U.S. cities**
3. **Klemm and Mason (2003), 6 U.S. cities**
4. **Burnett and Goldberg (2003), 8 Canadian cities**
5. Moolgavkar (2003), Cook County
6. Kinney et al. (1995), Los Angeles
7. Schwartz (2003b), Chicago
8. Ito and Thurston (1996), Cook County
9. Schwartz (2003b), Pittsburgh
10. Styer et al. (1995), Cook County
11. Schwartz (2003b), Detroit
12. Moolgavkar (2003), Los Angeles
13. Schwartz (2003b), Seattle

14. Schwartz (2003b), Minneapolis
15. Klemm and Mason (2003), St. Louis
16. Klemm and Mason (2003), Boston
17. Schwartz (2003b), Birmingham
18. Schwartz (2003b), New Haven
19. Chock et al. (2000), Pittsburgh (<75 y.o.)
20. Chock et al. (2000), Pittsburgh (75+ y.o.)
21. Klemm and Mason (2003), Kingston-Harriman
22. Klemm and Mason (2003), Portage
23. Schwartz (2003b), Canton
24. Schwartz (2003b), Spokane
25. Ito (2003), Detroit
26. Fairley (2003), Santa Clara County

27. Schwartz (2003b), Colorado Springs
28. Klemm and Mason (2003), Topeka
29. Tsai et al. (2000), Newark
30. Klemm and Mason (2003), Steubenville
31. Pope et al. (1992), Utah Valley
32. Tsai et al. (2000), Elizabeth
33. Tsai et al (2000), Camden
34. Lipfert et al. (2000), Philadelphia
35. Mar et al. (2003), Phoenix
36. Ostro et al. (2003), Coachella Valley
37. Klemm and Mason (2000), Atlanta
38. Ostro et al. (1995), Southern California

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was designed to use a multi-city approach such as that recommended following an earlier report of time-series study reanalyses that recommended investigating the role of co-pollutants in PM-health outcome relationships by conducting multi-city studies, using consistent analytical approaches across cities (HEI, 1997, p. 38; Samet et al., 2000c, p. 1). The NMMAPS used a uniform methodology to evaluate the relationship between mortality and PM_{10} for the different cities, and the results were synthesized to provide a combined estimate of effects across the cities. The authors reported associations between total and cardiorespiratory mortality and PM_{10} that were robust to different modeling approaches and to adjustment for gaseous co-pollutants. For total mortality, the overall risk estimate for all cities is a statistically significant increase of 1.4% (using more stringent GAM) or 1.1% (using GLM) per 50 $\mu g/m^3$ PM_{10} (Dominici et al., 2003a; CD, p. 8-33). Key components of the NMMAPS analyses include assessment of the potential heterogeneity in effects and effects of co-pollutants, as discussed below in sections 3.4.3 and 3.6.4, respectively.

Another major multi-city study used data from 10 U.S. cities that were selected from NMMAPS cities where daily PM_{10} monitoring data were available (in many areas, monitoring is done on a 1-in-3 or 1-in-6 day basis) (Schwartz, 2003b). The authors reported a statistically significant association between PM_{10} and total mortality, with an effect estimate of an increase of 3.4% per 50 $\mu g/m^3$ PM_{10} (in reanalyzed GAM results) or 2.8% per 50 $\mu g/m^3$ PM_{10} (using GLM) (Schwartz, 2003b; CD, p. 8-38). The CD observes that the effect estimates from this study are larger than those reported in NMMAPS, and suggests that the availability of more frequent monitoring data may partly account for the differences (CD, p. 8-39).

In the previous review, results for one key multi-city study were available, in which associations were assessed between daily mortality and PM_{10}, $PM_{2.5}$, and $PM_{10-2.5}$ measurements from six U.S. cities (the "Six Cities" study) (Schwartz, et al., 1996). The authors reported significant associations for total mortality with $PM_{2.5}$ and PM_{10}, but not with $PM_{10-2.5}$. Reanalyses of Six Cities data have reported results consistent with the findings of the original study, with statistically significant increases in total mortality ranging from 2% to over 3% reported for results from more stringent GAM or GLM analyses using either $PM_{2.5}$ (per 25 $\mu g/m^3$ increment) or PM_{10} (per 50 $\mu g/m^3$ increment), whereas $PM_{10-2.5}$ was only significantly associated with mortality in one of the six cities (Steubenville) (Schwartz, 2003a; Klemm and Mason, 2003; CD, p. 8-40 to 8-41).

Using data for the eight largest Canadian cities, mortality was associated with $PM_{2.5}$, PM_{10}, and $PM_{10-2.5}$ and the effect estimates were of similar magnitude for each PM indicator (Burnett et al., 2000; Burnett and Goldberg, 2003). Using either more stringent GAM or GLM, the authors reported increases ranging from 2% to 3% in total mortality for each PM indicator. The association between mortality and $PM_{2.5}$ generally remained statistically significant in a number of analyses when gaseous co-pollutants and 0- and 1-day lags were included in the models, although in a few instances the effect estimates were reduced and lost statistical

significance. Associations with PM_{10}, and $PM_{10-2.5}$ did not reach statistical significance, though the effect estimates were similar in magnitude to those for $PM_{2.5}$. While the associations reported with $PM_{10-2.5}$ were somewhat increased in magnitude in reanalyses, they did not reach statistical significance. The CD concludes that it is difficult to compare the relative significance of associations with $PM_{2.5}$ and $PM_{10-2.5}$, but for this study, "overall, they do not appear to be markedly different" (Burnett and Goldberg, 2003; CD, p. 8-42).

The CD also highlights results of analyses from a major European multi-city study, the Air Pollution and Health: A European Approach (APHEA) study, that evaluated associations between mortality and various PM measures (CD, section 8.2.2.3.3). In the analyses that included data from 29 European cities, overall effect estimates of 2 to 3% increased risk of mortality per 50 $\mu g/m^3$ PM_{10} were reported; reanalysis resulted in reduced effect estimate size, though the authors conclude that their findings are robust to the application of alternative modeling strategies (Katsouyanni et al., 2003; CD, p. 8-47). Taken together, the CD concludes that multi-city studies in the U.S., Canada, and Europe reported statistically significant associations with effect estimates ranging from ~1.0 to 3.5% increased risk of total mortality per 50 $\mu g/m^3$ PM_{10} (CD, p. 8-50).

In considering the results from single-city analyses, Figure 3-1 shows that almost all effect estimates for $PM_{2.5}$ are positive and a number are statistically significant, particularly when focusing on the results of studies with greater precision. As summarized in the CD, effect estimates for total mortality from the multi-city studies range from ~1 to 3.5% per 25 $\mu g/m^3$ $PM_{2.5}$. For the relatively more precise single-city studies, effect estimates range from approximately 2 to 6% per 25 $\mu g/m^3$ $PM_{2.5}$ (CD, p. 9-28). Figure 3-1 also shows effect estimates for $PM_{10-2.5}$ that are generally positive and similar in magnitude to those for $PM_{2.5}$ and PM_{10}, but for total mortality, none reach statistical significance. Staff notes that on a unit mass basis, the effect estimates for both $PM_{2.5}$ and $PM_{10-2.5}$ are generally larger than those for PM_{10}, which is consistent with $PM_{2.5}$ and $PM_{10-2.5}$ having independent effects (CD, p. 9-25).

In general, effect estimates are somewhat larger for respiratory and cardiovascular mortality than for total mortality. In the NMMAPS analyses using data from the 20 largest U.S. cities, the effect estimates for deaths from cardiorespiratory causes were somewhat larger than those for deaths from all causes (1.6% versus 1.1% increased risk per 50 $\mu g/m^3$ PM_{10}, using GLM) (Dominici, et al., 2003a; CD, p. 8-78). In Figure 3-1, for all three PM indicators, it can be seen that not only is the effect estimate size generally larger for cardiovascular mortality, but the effect estimates are also more likely to reach statistical significance. This is particularly true for $PM_{10-2.5}$, where two of the five effect estimates for cardiovascular mortality shown are positive and statistically significant (Mar et al., 2003; Ostro et al., 2003). For respiratory mortality, effect estimates are often larger than those for either total or cardiovascular mortality, but they are often less precise, which would be expected since respiratory deaths comprise a small proportion of total deaths. The CD concludes that effect estimates fall in the range of 3 to 7%

per 25 $\mu g/m^3$ $PM_{2.5}$ for cardiovascular or cardiorespiratory mortality, and 2 to 7% per 25 $\mu g/m^3$ $PM_{2.5}$ for respiratory mortality in U.S. and Canadian cities. The magnitude of the effect estimates for $PM_{10-2.5}$ are similar to those for $PM_{2.5}$, generally falling in the range of 3 to 8% for cardiovascular mortality and 3 to 16% for respiratory mortality per 25 $\mu g/m^3$ $PM_{10-2.5}$ (CD, p. 8-306).

While some of the studies conducted in Europe, Mexico or South America use gravimetric PM measurements (e.g., PM_{10}, $PM_{2.5}$, $PM_{10-2.5}$), many of the non-North American studies use PM indicators such as TSP, black smoke (BS) or coefficient of haze (COH), and the Australian studies used nephelometric measures of PM. While effect estimates for different PM indicators may not be quantitatively comparable, the CD observes that "many of the newly reported analyses continue to show statistically significant associations between short-term (24-hr) PM exposures indexed by a variety of ambient PM measurements and increases in daily mortality in numerous U.S. and Canadian cities, as well as elsewhere around the world" (CD, p. 8-24). These effect estimates are generally within (but toward the lower end of) the range of PM_{10} estimates previously reported in the 1996 PM AQCD.

As discussed in section 8.2.2.5 of the CD, associations have been reported between mortality and short-term exposure to a number of PM components, especially fine particle components. Three recent studies have used $PM_{2.5}$ speciation data to evaluate the effects of air pollutant combinations or mixtures using factor analysis or source apportionment methods to link effects with different $PM_{2.5}$ source types. These studies reported that fine particles from combustion sources, including motor vehicle emissions, coal combustion, oil burning and vegetative burning, were associated with increased mortality. No significant increase in mortality was reported with a source factor representing crustal material in fine particles (CD, p. 8-85). These studies indicate that exposure fine particles from combustion sources, but not crustal material, is associated with mortality.

The findings of these studies, while providing some insight into what sources of fine particles might be associated with mortality, are not directly relevant to evaluating effects of thoracic coarse particles from different sources. Combustion sources are a major contributor to $PM_{2.5}$ emissions, but not $PM_{10-2.5}$, while crustal material is an important component of $PM_{10-2.5}$ but only a small portion of $PM_{2.5}$. Staff observes that no epidemiologic evidence is available to evaluate effects of different components or sources of thoracic coarse particles. One study that does have some relevance to considering the effects of $PM_{10-2.5}$ from different sources assessed the contribution of dust storms to PM_{10}-related mortality. The authors focused on days when dust storms or high wind events occurred, during which thoracic coarse particles are the dominant fraction of PM_{10}, in Spokane. No evidence was reported of increased mortality on days with high PM_{10} levels related to dust storms (average PM_{10} level was 221 $\mu g/m^3$ higher on

Attachment: First page of:

A. Zanobetti, J. Schwartz, and D. W. Dockery, "Airborne Particles
Are a Risk Factor for Hospital Admissions for Heart and Lung
Disease," *Environmental Health Perspectives*, Vol. 108, No. 11,
November 2000. The authors are with the Environmental
Epidemiology Program, Department of Environmental Health,
Harvard School of Public Health, Boston, Mass.

Airborne Particles Are a Risk Factor for Hospital Admissions for Heart and Lung Disease

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We examined the association between particulate matter ≤ 10 μm; (PM_{10}) and hospital admission for heart and lung disease in ten U.S. cities. Our three goals were to determine whether there was an association, to estimate how the association was distributed across various lags between exposure and response, and to examine socioeconomic factors and copollutants as effect modifiers and confounders. We fit a Poisson regression model in each city to allow for city-specific differences and then combined the city-specific results. We examined potential confounding by a meta-regression of the city-specific results. Using a model that considered simultaneously the effects of PM_{10} up to lags of 5 days, we found a 2.5% [95% confidence interval (CI), 1.8–3.3] increase in chronic obstructive pulmonary disease, a 1.95% (CI, 1.5–2.4) increase in pneumonia, and a 1.27% increase (CI, 1–1.5) in CVD for a 10 μg/m^3 increase in PM_{10}. We found similar effect estimates using the mean of PM_{10} on the same and previous day, but lower estimates using only PM_{10} for a single day. When using only days with $PM_{10} < 50$ mg/m^3, the effect size increased by ≥ 20% for all three outcomes. These effects are not modified by poverty rates or minority status. The results were stable when controlling for confounding by sulfur dioxide, ozone, and carbon monoxide. These results are consistent with previous epidemiology and recent mechanistic studies in animals and humans. *Key words:* air pollution, distributed lag, hierarchical model, hospital admissions, meta-analysis, meta-regression. *Environ Health Perspect* 108:1071–1077 (2000).
[Online 23 October 2000]
http://ehpnet1.niehs.nih.gov/docs/2000/108p1071-1077zanobetti/abstract.html

In the last decade many studies have assessed the association between daily deaths or hospital admissions and air pollution, both in Europe and in the United States (*1–12*). Almost all of these studies reported associations between airborne particles (and sometimes other pollutants) and deaths or hospital admissions within a few days of exposure, but they have differed in the exact lag between exposure and outcome used. They have also differed in whether they examined only associations with a 24-hr averaged exposure or considered effects spread out over several days.

When studies have considered the possibility of lags or multiday effects, they usually have used ad hoc approaches based on the best fit in individual cities, which can be subject to substantial variability due to stochastic error. A systematic approach, which used a multicity analysis to overcome stochastic variability, would help clarify this situation. This has recently been applied successfully to the association between particulate matter ≤ 10 μm (PM_{10}) and mortality (*13*). Past studies have traditionally relied on simple moving averages of pollution to assess the potential for the effect of air pollution on health to persist for more than 1 day after exposure. However, it is quite possible that the effect of air pollution decreases gradually over several days, perhaps after first rising to a peak. In that case, a weighted moving average, with weights that decline to zero after several days, would be more appropriate than a simple moving average or single day's exposure (*13*).

It is possible to include air pollution values on multiple days to directly estimate the effect of different lags, but this approach is limited in single-city analyses because multicollinearity makes the estimated effects of different lags very noisy. Although these estimates have large variance, they are unbiased, and hence a multiple-city analysis, which can average out the noise, makes this approach feasible (*13*). We have applied such a multicity approach to estimate the association between PM_{10} and hospital admissions for heart and lung disease, including the distribution of effects over time.

A multicity approach estimating the association between air pollution and hospital admissions has several other advantages. The National Academy of Sciences has stated that identifying individuals most sensitive to the adverse effects of particulate air pollution is a research priority (*14*). Multicity analyses allow us to investigate whether demographic or economic factors are modifiers of the pollution effect. In addition, multicity approaches provide opportunities to separate the effect of different air pollutants, analyses which are of limited utility in single-city analyses (*15*). The present analysis examined distributed lag effects on hospital admissions, confounding by copollutants, and effect modification by socioeconomic factors in 10 locations from across the United States with daily measurements of PM_{10} but widely varying relationships between PM_{10} and other pollutants.

Data and Methods

Data

To examine the effect of PM_{10} at multiple lags, we needed cities with daily PM_{10} monitoring, rather than the more usual 1 day in 6 monitoring schemes. We selected 10 cities from across the United States that met this criterion: Canton, Ohio; Birmingham, Alabama; Chicago, Illinois; Colorado Springs, Colorado; Detroit, Michigan; Minneapolis/ St. Paul, Minnesota; New Haven, Connecticut; Pittsburgh, Pennsylvania; Seattle, Washington; and Spokane, Washington. We chose the metropolitan county containing each city, except for Minneapolis and St. Paul, which were combined and analyzed as one city. We analyzed daily counts of hospital admissions for cardiovascular disease [CVD; *International Classification of Disease, 9th revision* (ICD-9) 390–429], chronic obstructive pulmonary disease (COPD; ICD-9 490–496, except 493), and pneumonia (ICD-9 480–487), in persons ≥ 65 years of age. The data were extracted from the Health Care Financing Administration (Medicare; Baltimore, MD) billing records, which we obtained for the years 1986–1994. The Medicare system provides hospital coverage for all U.S. citizens aged 65 and over.

Daily meteorologic measurements such as mean temperature, relative humidity, and barometric pressure, were obtained from the nearest National Weather Service surface station for each county (EarthInfo CD NCDC Surface Airways, EarthInfo Inc., Boulder, CO).

Air pollution data for PM_{10} were obtained from the U.S. Environmental Protection Agency's Aerometric Information Retrieval System (AIRS) (*16*). Many of the cities have more than one monitoring location. To ensure that our exposure measure best represented general population exposure and not local conditions, monitors within the

Attachment: A few pages from:

Consensus Statement of Human Health Aspects of the Aerial Application of Microencapsulated Pheromones to Combat the Light Brown Apple Moth, October 31, 20007.

Consensus Statement on Human Health Aspects of the Aerial Application of Microencapsulated Pheromones to Combat the Light Brown Apple Moth

October 31, 2007

This document represents a scientific consensus of the Department of Pesticide Regulation (DPR) and the Office of Environmental Health Hazard Assessment (OEHHA) on the available health and safety data of the pheromone products associated with the Light Brown Apple Moth (LBAM) eradication program. This is one of the first instances of the aerial application of this material over a highly populated area. Scientists from DPR and OEHHA reviewed the available information and prepared this document with input from the Department of Public Health. This document is not intended to be a detailed human health risk assessment, an epidemiological study of exposed individuals, or an evaluation of occupational exposure. The purpose of this document is to provide information on the toxicity of microencapsulated pheromones, the potential for exposure, and to provide recommendations.

General Information

Pheromones are naturally occurring volatile chemicals and have been loosely described as "pheromone perfumes." Certain insect species produce them, in very small amounts, to influence the behavior of other individuals of the same species. Many lepidopteran species (butterflies and moths) use pheromones to attract mates. These pheromones consist of mixtures of similar chemicals, and the relative amounts of several pheromone chemicals determine which specific moths are attracted.

Synthetically produced pheromones can be used to control insect pests. All the lepidopteran pheromones approved for pest control use are chemicals produced by female moths to attract mates. By releasing a specific pheromone mixture into the air, it is possible to disorient males looking for females. The pheromone alters behavior, not the insects' health or reproductive competence; but it results in many females' failure to mate and lay eggs. Pheromone pesticide products may be applied using slow-release dispensers (often attached to trees) or applied by ground or aerial spray equipment.

Toxicity Information on the Pheromone Active Ingredients in the Products Used to Combat LBAM

The U. S. Environmental Protection Agency (U.S. EPA) defines lepidopteran pheromones chemically as unbranched aliphatic chains (9 to 18 carbon atoms) ending in an alcohol, aldehyde, or acetate functional group and containing up to 3 double bonds in the chain. U.S. EPA has also made two relevant determinations about these chemicals: 1) that they are sufficiently similar toxicologically to be considered as a group, that is, toxicology data on one pheromone is applicable to the other pheromones; and 2) that their toxicity is so minor that they are exempt from the requirement of a tolerance (Federal Register 60, No. 168, pp 45060 to 45062, August 30, 1995). These pheromones are often referred to as Straight Chained Lepidopteran Pheromones (SCLPs).

9) Polyvinyl alcohol- polymer commonly used in shampoos and cosmetics, feminine hygiene and incontinence products, children's play putty, glue, lubrication drops for hard contact lens wearers and other products.
10) Tricaprylyl methyl ammonium chloride- commonly used in the manufacture of various pesticides and pharmaceuticals; contributes to product purity.
11) Sodium Phosphate- naturally occurring substance. Sodium phosphate is also an additive in egg products and is a prescribed laxative prior to procedures such as colonoscopy.

The percentages of these ingredients are still confidential business information. This document does not review the toxicity of these compounds individually, but addresses the formulated product.

While this information is important, DPR noted that inert ingredients other than water are present in very small amounts and exist primarily as the polyurea shell enclosing the pheromones. These particles consist mostly of pheromones. After application of the particles, the pheromones are slowly emitted over a 30- to 90-day period, and the polyurea shell will biodegrade into urea, a low toxicity compound normally found as a result of the breakdown of proteins in the human body.

Another important point is that DPR scientists have reviewed the most relevant data: toxicity studies on the formulated product as a whole. DPR scientists reviewed an acute dermal toxicity study using Checkmate PBW-F, which uses the same microencapsulation as Checkmate OLR-F and LBAM-F. The primary difference is in the selection of pheromones contained within the microencapsulated particles. In the study of Checkmate PBW-F, 2,000 mg/kg was applied to the skin of rabbits and resulted in no mortality, but some diarrhea. The results led to a Category III rating for dermal toxicity. Similarly, an eye irritation study in rabbits, in which 100 mg doses were instilled in the eyes, led to a Category III rating for eye irritation, which means the product was moderately irritating.

Materials that cause eye and skin irritation could reasonably be expected to cause some respiratory irritation if a sufficient amount were inhaled. The animal study results are consistent with the Suterra Checkmate OLR-F and LBAM-F labels that state that the products cause moderate eye and skin irritation. This label designation is for the undiluted product rather than for the significantly diluted water suspension that is actually applied.

The microcapsule particles are very large by inhalation standards (25 micrometers in diameter or larger) and unable to reach the deep lung. As a result, an inhalation toxicity study, which is designed to examine systemic effects resulting from inhalation into the lung, would not be useful and was not conducted. If inhaled, because of the large size, these microcapsules are not likely to reach the pulmonary (air exchange) region of the lung. However, such large particles are likely to be deposited in the nasal passages, pharynx, larynx, and tracheo-bronchial region and are either absorbed or moved to the larynx and swallowed. If a sufficient amount of large particles (regardless of

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composition) is inhaled, it is plausible that it could cause irritation of the throat, coughing, sneezing, and excess mucus production in the upper respiratory system.

Taken together, the toxicity data on the pheromones and on microencapsulated products suggest the possibility that exposure to a sufficient amount of airborne Checkmate microcapsule particles could result in some level of eye, skin, or respiratory irritation. However, as the product is diluted and applied over a large area, the degree of exposure as well as the potential for irritation should decrease significantly.

Application and Deposition

The maximum application rates allowed by the label are 20 grams of A.I. per acre per application, corresponding to 83 grams per acre of the Checkmate product. These application rates are very low, both in absolute terms and when compared with the ground or aerial application rates of almost any other pesticide. To put this amount in perspective, a tablespoon of sugar weighs almost 20 grams. The product consists primarily of the polyurea-microencapsulated pheromone suspended in water.

The material applied is a diluted mixture that contains 2.1% A.I. (pheromone). Tank samples collected during the first week of application showed concentrations of the A.I. varied from 0.69% to 3.0%, indicating settling might have occurred in the mixture. Some visual observations also indicated a problem with the product staying well mixed in the application equipment. Changes are being made to the mixing and loading equipment to address this problem in future applications. At the highest proposed application rate, the theoretical concentration of the product hitting the ground should be 0.460 milligrams A.I./square foot. During the first week of application, deposition measurements showed deposition rates below this calculated theoretical maximum. (These data will be available later.) This indicates there were not "pockets" of higher than intended deposition resulting from the tank concentration variations.

Illness Complaints

Before the current LBAM eradication effort, DPR had received few complaints involving pheromones, and has no persuasive cases on file attributed to pheromone exposure in the absence of additional pesticides. DPR evaluated two cases, one in 1982 and one in 1989, as "unlikely" to be related to exposure to pheromone alone or to pheromone with an adjuvant. Another 1982 case provided insufficient information to evaluate. These cases did not involve Checkmate products.

California law requires physicians to report known or suspected pesticide-related illnesses to their local health department within 24 hours after seeing a patient. The health department forwards these reports to the State. Only one pesticide illness report (PIR) was received from the Monterey County Health Department during or soon after the Checkmate spraying September 9-12, 2007. A 57-year old man was diagnosed with pharyngeal irritation after visiting a doctor on September 16. The exposure date was listed as September 16, which was after the Checkmate spraying had been completed.