Department of Pesticide Regulation

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SUBJECT: RESPIRATOR ASSIGNED PROTECTION FACTORS AND INFORMATION ON COMPLIANCE WITH LEGAL REQUIREMENTS FOR RESPIRATORS

I reviewed the Final Rule on Assigned Protection Factors promulgated by the Occupational Safety and Health Administration (OSHA, 2006). The rule amends several sections in the Code of Federal Regulations Title 29, Parts 1910, 1915, and 1926, and substantiates respirator assigned protection factors (APFs) used by OSHA to classify effectiveness of respiratory protection. This memo reviews evidence cited by OSHA (2006) and discusses the extent to which it can support respiratory protection factors in exposure assessments, and reviews available information on compliance with requirements to use respiratory protection.

Regulations for respirator use generated by the California Division of Occupational Safety and Health (Cal/OSHA) are in the California Code of Regulations (CCR), Title 8, Section 5144 (8 CCR 5144). Table 1 below is identical to that in 8 CCR 5144 and on page 50188 in OSHA (2006). Figure 1 shows three kinds of air-purifying respirators. These are grouped together as Type 1 in Table 1, and were referred to as “Class 1” respirators in OSHA (2006). Much of the discussion in OSHA (2006) was devoted to justifying an APF of 10 (i.e., a 10-fold, or 90%, concentration reduction) for these respirators. OSHA (2006) combined data from filtering facepiece and elastomeric respirators, as available studies suggested no significant difference in protection factors between them. Cal/OSHA adopted the final rule from OSHA (2006) effective March 6, 2007, following a public hearing held on January 18 (Cal/OSHA, 2007). Regulations from the California Department of Pesticide Regulation (DPR) cite 8 CCR 5144 for respirator selection and use requirements (3 CCR 6739). These facts provide regulatory support for reliance by DPR on APFs justified in OSHA (2006), due to the incorporation of those APFs into 8 CCR 5144.

Conclusions: OSHA (2006) provides strong support for an APF of 10 for use of half-mask air-purifying respirators with non-volatile or semi-volatile pesticides, and limited support for an APF of 10 in exposure scenarios involving fumigants or other volatile pesticides. Studies about compliance with legally required respirator use provide limited data suggesting some non-compliance occurs, but non-compliance in California does not appear to be widespread based on a study conducted by DPR.

Table 1. Assigned Protection Factors Table from OSHA (2006)

TABLE 1.—ASSIGNED PROTECTION FACTORS [5]

Type of respirator [1,2]	Quarter mask	Half mask	Full face-piece	Helmet/ hood	Loose-fitting facepiece
1. Air-Purifying Respirator	5	[3] 10	50	.....	.....
2. Powered Air-Purifying Respirator (PAPR)	.....	50	1,000	[4] 25/1,000	25
3. Supplied-Air Respirator (SAR) or Airline Respirator					
• Demand mode	.....	10	50	.....	.....
• Continuous flow mode	.....	50	1,000	[4] 25/1,000	25
• Pressure-demand or other positive-pressure mode	.....	50	1,000	.....	.....
4. Self-Contained Breathing Apparatus (SCBA)					
• Demand mode	.....	10	50	50	.....
• Pressure-demand or other positive-pressure mode (e.g., open/ closed circuit)	.....	.....	10,000	10,000	.....

Notes:

[1] Employers may select respirators assigned for use in higher workplace concentrations of a hazardous substance for use at lower concentrations of that substance, or when required respirator use is independent of concentration.

[2] The assigned protection factors in Table 1 are only effective when the employer implements a continuing, effective respirator program as required by this section (29 CFR 1910.134), including training, fit testing, maintenance, and use requirements.

[3] This APF category includes filtering facepieces, and half masks with elastomeric facepieces.

[4] The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a WPF or SWPF study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

[5] These APFs do not apply to respirators used solely for escape. For escape respirators used in association with specific substances covered by 29 CFR 1910 subpart Z, employers must refer to the appropriate substance-specific standards in that subpart. Escape respirators for other IDLH atmospheres are specified by 29 CFR 1910.134 (d)(2)(ii).

Figure 1. Examples of Air-Purifying Respirators: A) Preformed Filtering Facepieces, B) Flat-Fold Filtering Facepieces, and C) Elastomeric Type (NIOSH, 2009)

A)

B)

C)

Assigned Protection Factors

OSHA (2006) is divided into seven sections as listed below:

- I: contains definitions used in the final rule (pages 50122 – 50124)
- II: contains a brief history of respirator regulations and APFs (pages 50124 – 50127)
- III: Methodology for Developing APFs for Respirators (pages 50127 – 50145)
- IV: contains a brief statement about the importance of respiratory protection (page 50145)
- V: contains analyses of the economic impacts of the regulations (pages 50145 – 50157)
- VI: Summary and Explanation of the Final Standard (pages 50147 – 50184)
- VII: addresses legal requirements of agency rulemakings (pages 50184 – 50187)

The summary in this memo relies primarily on discussion in sections III and VI.

Methodology for Developing APFs for Respirators

The first part of this section addresses some general comments that OSHA received on the draft regulation they released in 2003. Commenters claimed that studies OSHA relied on were subject to selection bias and observer effect, and that workplaces where workers were monitored were not representative (page 50129). OSHA refuted the claim of selection bias, or "cherry-picking," by saying that this "is a matter of concern for all scientific studies," and that peer reviewers typically evaluate its effects before a study is accepted for publication in a peer-reviewed journal." Most of the studies used by OSHA (2006) were published, and OSHA was confident that data were not cherry-picked. With regard to observer effect, OSHA (2006) responded that, "The mere presence of an observer does not, in and of itself, presume that there will be an observer effect." In the submitted studies, OSHA believed that the observers were monitoring equipment rather than worker practices, and thus had little impact on the latter. OSHA also did not believe the studies were too limited to represent a variety of workplaces and activities, as the studies occurred in various settings.

In responding to the first two of these claims, OSHA (2006) noted it had "repeatedly asked the commenters who raised this concern to identify studies" where either selection bias or the observer effect occurred, but "in no case did the commenters provide any example to support their allegations."

Other concerns that OSHA (2006) addressed included (pages 50130 – 50131) position of the sampling probe during studies (should be as close to the face as possible, between nose and mouth), and whether or not sensitive analytical methods allowed very low concentrations to be measured inside the respirator and exaggerated protection factors (OSHA concluded that sensitive analytical measurements are appropriate to capture actual workplace exposures).

Data from four types of studies were submitted to OSHA in support of respiratory protection factors. Study types were defined as follows (quoted from pages 50123 – 50124):

- *Effective Protection Factor (EPF) study:* A study, conducted in the workplace, that measures the protection provided by a properly selected, fit-tested, and functioning respirator when used intermittently for only some fraction of the total workplace exposure time (i.e., sampling is conducted during periods when respirators are worn and not worn). EPFs are not directly comparable to WPF values because the determinations include both the time spent in contaminated atmospheres with and without respiratory protection; therefore, EPFs usually underestimate the protection afforded by a respirator that is used continuously in the workplace.

- *Program Protection Factor (PPF) study:* A study that estimates the protection provided by a respirator within a specific respirator program. Like the EPF, it is focused not only on the respirator's performance, but also the effectiveness of the complete respirator program. PPFs are affected by all factors of the program, including respirator selection and maintenance, user training and motivation, work activities, and program administration.

- *Workplace Protection Factor (WPF) study:* A study, conducted under actual conditions of use in the workplace, that measures the protection provided by a properly selected, fit-tested, and functioning respirator, when the respirator is worn correctly and used as part of a comprehensive respirator program that is in compliance with OSHA's Respiratory Protection Standard at 29 CFR 1910.134. Measurements of C_o and C_i [concentrations outside and inside the mask, respectively] are obtained only while the respirator is being worn during performance of normal work tasks (i.e., samples are not collected when the respirator is not being worn). As the degree of protection afforded by the respirator increases, the WPF increases.

- *Simulated Workplace Protection Factor (SWPF) study:* A study, conducted in a controlled laboratory setting and in which C_o and C_i sampling is performed while the respirator user performs a series of set exercises. The laboratory setting is used to control many of the variables found in workplace studies, while the exercises simulate the work activities of respirator users. This type of study is designed to determine the optimum performance of respirators by reducing the impact of sources of variability through maintenance of tightly controlled study conditions.

OSHA considered only WPF and SWPF studies in determining APFs, arguing that any study that monitors exposure when a respirator is not worn, as is done in EPF and PPF studies, would underestimate the protection from the respirator itself (page 50128). Both WPF and SWPF studies were combined and reported as "WPF." Table III-1 on pages 50133 – 50134 summarizes studies used to support the APF of 10 for half-mask filtering facepiece and elastomeric respirators. OSHA evaluated each study before use, verifying that, "test subjects were trained properly, fit tested, medically evaluated, and in compliance with the requirements of the OSHA Respiratory Protection Standard...researchers had to demonstrate compliance with the required respirator program before OSHA included the study in its database."

Among the 31 studies OSHA found acceptable for determining the APF of 10, OSHA counted 1,339 samples. OSHA included only studies that measured particulates; a few studies that measured vapor concentrations were omitted. Table 2 summarizes available information about these 31 studies. Most of the half-face (and full-face) studies were briefly described in OSHA (2003); geometric mean and 5th percentile WPFs were also reported for each data set. As OSHA (2006) relied on 5th percentile values to justify the APF, the lowest 5th percentile calculated for

each study are reported in the last column of Table 2. When multiple values were reported (e.g., for different respirators or analyte), the lowest value is given in Table 2.

Five of the 5th percentile WPFs shown in Table 2 are less than 10, the APF that OSHA (2006) determined was supported by these data. Table III-2 in OSHA (2006) summarized the number of samples for each respirator class with WPFs less than 10. OSHA refers to samples with WPFs less than 10 as "failures," and calls the percentage of samples failing as the "failure rate." The target failure rate is 5% (i.e., fewer than 5% of samples fail to have WPFs above 10). For filtering facepiece respirators overall (classes 1 – 4), 12 samples out of 760 (1.6%) failed, and for elastomeric (class 5) respirators, 26 samples of 579 (4.5%) failed. Combining all half-mask respirators yielded 38 of 1,339 samples (2.8%) below 10. OSHA (2006) concluded that the failure rate less than 5% supported their decision to set the APF at 10.

To test the impact that the excluded data (including studies with vapors) would have on the failure rate, Table III-3 in OSHA (2006) reports that 403 samples were not used; of these, 31 had WPFs less than 10, for a failure rate of 7.7%. Combining these samples with the ones used to support the APF yielded a total of 1,742 samples; of these, 69, or 4.0%, had WPFs less than 10. Thus, adding in excluded samples would not result in a failure rate above 5%, and would not change OSHA's conclusion about the APF for half-mask respirators.

After comparing numbers of samples having WPFs less than 10, OSHA (2006) then summarized the 5th percentile across all samples for each respirator class in Table III-4. For filtering facepiece respirators overall (classes 1 – 4), the 5th percentile was 18.1, with a 90th percent confidence interval of 15 – 22. For elastomeric (class 5) respirators, the 5th percentile was 12.0, with a 90th percent confidence interval of 7 – 14. For all half-mask respirators, the 5th percentile was 14.7, with a 90th percent confidence interval of 13 – 18. OSHA (2006) argued that these results also supported an APF of 10 for half-mask air purifying respirators.

The National Institute for Occupational Safety and Health (NIOSH) standards for certifying respirators have changed over the years, and OSHA (2006) examined one study by Colton and Bidwell, which included respirators certified under both old and new standards, to address concerns that some of the studies used respirators certified under the older standard. They found that the one respirator certified under the old standard performed as well as the two respirators certified under the new standard.

Table 2. Respirator Workplace Protection Factor Data Used by OSHA (2006) to Support an Assigned Protection Factor for Half-Mask Air-Purifying Respirators [a]

Class [b]	Study	Analyte	OSHA (2006) Figure 1	Number of Samples Counted by OSHA [c]	Number of Workers [d]	5th WPF [e]
1	Dixon & Nelson 1985 talk [f]	Asbestos	1	26	NA	**5**
1	Myers & Zhuang 1993 talk [f]	Fe	2	21	17	NA
1	Wallis *et al.* (1993)	Mn	3	69	NA	**7**
1	Colton, Johnston, Mullins, Rhoe & Meyers 1990 talk [f]	Al	4	23	5	13
1	Johnston & Mullins 1987 talk [f]	Al	5	13	3	32
1	Johnston & Mullins 1987 talk [f]	Si	6	15	3	24
1	Johnston & Mullins 1987 talk [f]	Ti	7	18	3	24
1	Colton & Bidwell 1999 talk [g]	Pb	8	143	21	NA
1	Bidwell & Janssen (2004)	Ca, Si	9, 10	73 + 73 = 146	19	24
3	Myers & Zhuang 1993 talk [f]	Pb, Zn	11, 12	19 + 20 = 39	22	**7**
3	Colton & Mullins 1992 poster [f]	Fe, Mn, Ti, Zn	13, 14, 15, 16	31+32+28+32 = 123	20	33
4	Colton, Mullins & Rhoe 1990 talk [f]	Pb, Zn	17, 18	62 + 62 = 124	17	36
5	Dixon & Nelson 1985 talk [f]	Asbestos	19	46	NA	11
5	Gaboury & Burd 1993 study [f]	BaP [h]	20	18	22	**9**
5	Lenhart & Campbell (1984)	Pb	21	25	25	19
5	Myers *et al.* (1996)	Pb, Zn	22, 23	46 + 46 = 92	22	**7**
5	Myers *et al.* (1996)	Fe	24	30	16	24
5	Myers & Zhuang (1998)	Ti, Cr	25, 26	35 + 33 = 68	22	282
5	Colton, Mullins & Bidwell 1994 talk [f]	Cd, Pb	27, 28	68 + 57 = 125	36	15
5	Dixon & Nelson (1984) [f]	Pb	29	42	11	160
5	Colton & Bidwell 1995 talk [g]	Pb	30	130	19	71
5	Myers & Zhuang 1993 talk [f]	Ca	31	3	1	NA

[a] Studies mentioned in Table III-1 of OSHA (2006). NA = not available.
[b] Respirator classes defined in OSHA (2003): 1 = filtering facepiece air purifying respirator, with no other features. 2 – 4 = filtering facepiece air purifying respirator, with combinations of features including adjustable head straps, exhalation valve, double shell construction, and foam ring liners. 5 = elastomeric air purifying respirator.
[c] Number of samples reported in Table III-1 of OSHA (2006).
[d] Number of workers monitored in study.
[e] Workplace protection factor, the concentration outside the respirator divided by the concentration inside. When multiple values were reported, the lowest value is given here. Values less than 10 are bolded.
[f] Study summarized by Nelson (1995) or OSHA (2003). Study report unavailable.
[g] Study briefly summarized as newly submitted data in OSHA (2006), pages 50142 - 50144.
[h] BaP = Benzo(a)pyrene

OSHA (2006) evaluated the database with one final approach (pages 50138 – 50140). OSHA divided each concentration measured outside a respirator by the permissible exposure limit (PEL) for the chemical; the result was the "hazard ratio. OSHA then plotted the hazard ratios against the 1,339 WPFs in its database. Cases in which the hazard ratio exceeded the WPF were defined as "overexposures," because the concentration inside the respirator would exceed the PEL (the same result would occur if concentrations inside the respirator were compared directly with the PEL; the approach to overexposure taken by OSHA, however, would also work in cases where concentrations inside the respirator are not available, which is the typical situation). Five of 1,339 samples fell into the overexposure category. In addition to the graphical comparisons, OSHA cited two studies, one using a Monte Carlo simulation, and one a binomial analysis pitting successes against failures. After reviewing these studies, OSHA stated that its own calculations showed that, "the <5% of workers who fail to achieve an APF of 10 are still being protected."

Section III ends with OSHA's conclusions regarding the updated database supporting an APF of 10 (pages 50141 – 50145). First, OSHA argues, the updated database "includes the best available data." Second, the data meet OSHA's traditional criterion of a 5% failure rate, supporting an APF of 10. Third, inclusion of excluded data did not change this conclusion. Fourth, OSHA found that respirators certified under the older NIOSH standard performed as well as respirators certified under the newer standard, thus adequately addressing the concern raised by commenters that respirators certified under the obsolete standard were used to support the APF. Finally, "OSHA concluded that workers participating in effective respirator programs had an extremely low risk of overexposure." A series of definitive statements follow (page 50142):

> In conclusion, the extensive quantitative analyses of the databases clearly indicate that both filtering facepieces and elastomeric respirators are capable of achieving an APF of 10. The results demonstrate that no statistical justification exists for assigning an APF of less than 10 to either of these two types of respirators. Finally, the results show that an APF of 10 is an underestimate of the true protection provided by both types of respirators. Therefore, the final APF of 10 determined by this rulemaking provides employees who use respirators with an extra margin of safety against airborne contaminants.

<u>Summary and Explanation of the Final Standard</u>

OSHA (2006) revised its definition of APF to clarify that a proper respiratory program is needed to achieve full protection: "Assigned protection factor (APF) means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by this section."

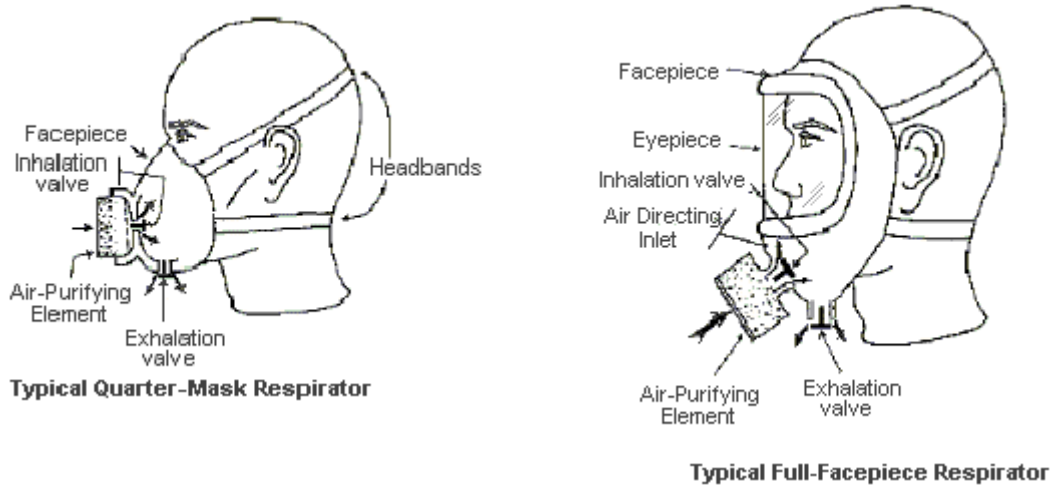
On page 50157, OSHA notes that its criterion in determining whether data support an APF of 10 ("the 5th percentile of the geometric distribution of individual protection factors in a WPF

study") means that, "about five percent of the employees who use the respirator under these workplace conditions may not achieve the level of protection assigned to the respirator (or class of respirators), even after they receive proper fit testing and use the respirator correctly under a comprehensive respiratory protection program."

OSHA (2006) added Footnote 5 to Table 1, to emphasize that APFs do not apply to emergency-escape situations. OSHA believes that under emergency conditions it is not feasible to accurately determine exposure levels, which are essential to determine APFs.

Most of OSHA (2006) was devoted to assigning an APF to half-mask respirators. However, OSHA assigned other protection factors, as well. First, OSHA justified an APF of 5 for quarter mask air purifying respirators (pages 50158 – 50160). A single study, conducted in 1976, supports this APF. Several commenters suggested considering quarter-mask respirators as structurally similar to half-mask respirators, and to use the APF of 10 supported for half-mask. However, others commented that quarter masks fit differently, with a lower seal on the chin instead of below the chin like both half- and full-face respirators. As a result of this difference, OSHA said there was "ample qualitative evidence" that quarter masks tend to slip when wearers talk or move around. Figure 2 shows a sketch of a quarter-mask respirator. To be health-protective, OSHA selected an APF of 5.

Figure 2. Quarter Mask and Full Facepiece Air-Purifying Respirators (OSHA, 2008)



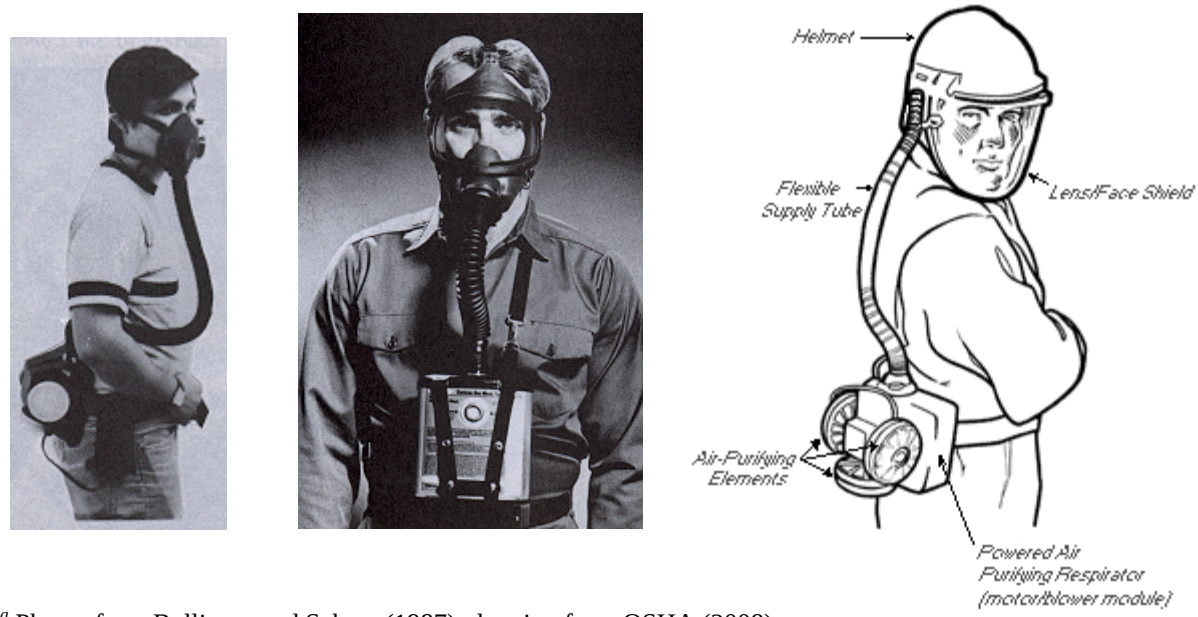
Following the discussion of quarter-mask respirators, OSHA returned to half-mask respirators and the justification for the APF of 10 (pages 50160 – 50165). Some commenters recommended an APF of 5 for filtering facepieces. One reason for this recommendation was that in WPF studies most of the failures (WPF < 10) in the data set reviewed by OSHA (2003) were filtering facepieces rather than elastomeric respirators (see Figure 1 for examples of both respirator types). However, OSHA performed a chi-square test comparing proportions of failures for each

respirator type and found no significant difference; furthermore, when OSHA's database was updated with newly submitted data the failure rate for elastomeric respirators was actually greater (OSHA, 2006). Also, some commenters asserted that adequate seals and fit testing are not possible with filtering facepiece respirators. Commenters did not submit data to support the assertion, however, and studies reviewed by OSHA contradicted it. Furthermore, OSHA noted (page 50164), "When a respirator user cannot perform a user seal check with a particular respirator model, then that respirator cannot be used by that employee, and the employer must find another respirator model on which a user seal check can be performed. This requirement applies to all tight-fitting facepieces, including filtering facepieces and elastomeric half masks. How easy or difficult it is for an employee to perform a user seal check on a particular type of respirator is not an issue that precludes other employees from using that respirator. Therefore, the comments on user seal checks do not provide convincing evidence that would support decreasing the APF for filtering facepieces to 5."

OSHA (2006) went on to discuss its rationale for the APF for full-face air-purifying respirators (pages 50165 – 50166), as shown above in Figure 2. An APF of 50 was first assigned in 1976 based on quantitative respirator fit testing, in which five of six models reduced concentrations by at least 100-fold and the sixth reduced concentrations 70-fold. OSHA (2003) also examined a WPF study conducted in a lead smelter, in which the 5th percentile WPF was 95, although the study authors concluded that 50-fold protection was all that could be reliably achieved. Finally, OSHA (2003) had access to a SWPF in which seven of 60 measurements were below 100. No new data were submitted beyond these studies, and OSHA (2006) concluded that an APF of 50 was supported by available data.

After APFs had been justified for air-purifying respirators, OSHA (2006) discussed half-mask and full-facepiece powered air-purifying respirators (PAPRs), as well as PAPRs with hoods. OSHA (2009) defines a PAPR as follows: "An air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering." Examples are shown in Figure 3.

Figure 3. Powered Air-Purifying Respirators (PAPRs) [a]



[a] Photos from Bollinger and Schutz (1987); drawing from OSHA (2008).

For half-mask PAPRs, OSHA (2006) relied on a WPF study by Lenhart and Campbell (1984) to justify an APF of 50. A second APF study was not used by OSHA because of excessive leakage due to poor face seals. Two SWPF studies resulted in high protection factors, but OSHA noted that SWPF studies typically yield higher protection estimates than workplace studies.

Like half-mask PAPRs, full facepiece PAPRs are considered by OSHA to be tightly fitting respirators, meaning they need to be fit-tested. OSHA based its APF of 1,000 for full facepiece PAPRs on a single WPF study by Colton and Mullins (page 50167). No one commented on this APF or submitted new data. OSHA also noted that older respirator standards by NIOSH and the American National Standards Institute (ANSI), which it referred to as, "consensus standards," also assigned an APF of 1,000.

OSHA has two APRs for PAPRs with hoods or helmets, 25 and 1,000 (pages 50167 – 50169; see Figure 3 for an example of a PAPR with a helmet). OSHA explained the distinction, for these PAPRs and for supplied-air respirators (SARs), in Footnote 4 in Table 1: "The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a WPF or SWPF study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets/hoods are to be treated as loosefitting facepiece respirators, and receive an APF of 25." OSHA (2003) based its APF of 1,000 on a single study, involving 60 measurements with three respirators. In its final rule, OSHA (2006) requires manufacturers to provide data showing that individual models of

respirators achieve at least that level of protection. OSHA received comments objecting to making hooded/helmeted respirators the only respirators requiring manufacturers to determine the APF for every model. However, NIOSH supported OSHA's requirement, and OSHA retained it. The APF of 25 for loosefitting respirators was based on five WPF studies described in OSHA (2003), as well as ANSI and NIOSH standards.

OSHA considered half-mask and full-facepiece SARs operating in the demand mode (defined as "admit[ting] breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation") to be analogous to air-purifying respirators, as both are operating under negative pressure. Thus, OSHA used the air-purifying respirator WPF studies to assign APFs of 10 and 50, respectively, when the SARs are operated in demand mode (page 50169). When the respirators are operated in continuous-flow or positive pressure modes, OSHA (2006) assigned APFs of 50 for half-mask and 1,000 for full-facepiece. OSHA received no new information or comments about these decisions following the proposed rule in 2003, and retained the APFs in the final rule.

OSHA (2003) described several studies available on SARs with hoods or helmets. After reviewing these data, OSHA proposed an APF of 1,000 for models shown by manufacturers to achieve that level of protection and operating in continuous flow mode; otherwise, the APF is 25. SARs with hoods or helmets are analogous to PAPRs with hoods or helmets (discussed above). SARs with loosefitting facepieces were also considered analogous to the corresponding PAPRs, and OSHA assigned an APF of 25. In the absence of new data or compelling comments to the contrary, OSHA (2006) affirmed these APFs.

Self-contained breathing apparatus (SCBA) can be operated in either demand mode or in positive-pressure modes, including pressure-demand; OSHA (2006) discussed APFs for all of these cases on pages 50169 – 50171. SCBA operated in demand mode was assigned the same APFs as corresponding air-purifying respirators: 10 for half-mask and 50 for full-facepiece. SCBA with a helmet or hood were found by OSHA to have tight-fitting facepieces, and when operating in demand mode OSHA assigned to them an APF of 50. SCBA operating in positive-pressure modes were assigned an APF of 10,000.

OSHA (2006) defined maximum use concentrations (MUCs) as follows (page 50172): "Maximum use concentration (MUC) means the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator, and is determined by the assigned protection factor of the respirator or class of respirators and the exposure limit of the hazardous substance. The MUC can be determined mathematically by multiplying the assigned protection factor specified for a respirator by the required OSHA permissible exposure limit, short-term exposure limit, or ceiling limit. When no OSHA exposure limit is available for a hazardous substance, an employer must determine an MUC on the basis of relevant available information and informed professional judgment."

OSHA (2006) required MUCs to be calculated for mixtures, calculated by dividing each component by its exposure limit, and summing the ratios (page 50176). For single-chemical exposures, if the MUC exceeds the immediately dangerous to life and health level (IDLH) or the performance limits of the cartridge or canister, then the MUC is automatically set at the lower limit.

Support for Using APFs for Vapors and Gases, and Nicas and Neuhaus (2004) Approach

The purpose of MUCs is to allow employers to select appropriate respirators, "especially for use against organic vapors and gases" (page 50171). OSHA (2006) never addressed the discrepancy of using APFs based on particulate studies to select respirators against vapors and gases, although OSHA did verify that half-mask air-purifying respirator APFs would not change if 403 measurement from studies were combined with the 1,339 studies used to generate the half-mask APF (discussed above on page 6 of this memo). However, the excluded studies were not identified by OSHA, nor did OSHA say how many of the excluded measurements were of vapor concentrations.

Here it might be helpful to briefly digress outside of the review of OSHA (2006), to get perspective on available studies using vapors. Nicas and Neuhaus (2004) included three studies with vapors when proposing an alternate approach to APFs. The first of the three studies used mercury; Nicas and Neuhaus (2004) reported that 26 measurements were taken with seven workers. The other two studies used styrene; Nicas and Neuhaus (2004) reported a total of 109 measurements were taken with 32 workers. However, Nicas and Neuhaus (2004) did not report WPFs; instead, they suggested an alternate approach to calculating APFs in which 95% of a worker's WPFs were above the fifth percentile. I wrap up this digression by noting that OSHA (2006) rejected that approach for the following reasons, stated on page 50132:

> By controlling for within-subject variability, APFs based on the Nicas-Neuhaus model will always be smaller than APFs derived using the established method. To account for within-subject variability, the Nicas-Neuhaus model requires repeated measurements on each test subject which is not required by the established method. Consequently, most available WPF studies did not include multiple measures on individual test subjects, resulting in an extremely limited database for applying the Nicas-Neuhaus model. Nicas and Neuhaus were able to analyze only seven half mask respirator studies, comprising a total of 310 data pairs. In comparison, the database established and analyzed by OSHA for determining the final APFs contains 1,339 data pairs from 16 half mask respirator studies. Also, OSHA had rejected for its analyses several of the WPF studies used by Nicas and Neuhaus in developing their model because these studies did not meet the Agency's selection criteria. The Nicas-Neuhaus model is a significant departure from established and accepted practices used by the respirator research community. The Agency has concluded that there are insufficient data to fully evaluate the proposed model, and to incorporate it in setting APFs.

Converting OSHA APFs to DPR Protection Factors

An APF of 10 is equivalent to a 90% protection factor in DPR's exposure assessments: A 10-fold decrease means the concentration inside the respirator would be 10% of the outside concentration (1/10 = 0.1), and 1 – 0.1 = 0.90. Table 3 summarizes DPR protection factors corresponding to OSHA APFs given in Table 1.

Table 3. Respirator Protection Factors by OSHA and DPR [a]

APF [b]	Proportion Penetrating the Respirator [c]	Calculation of DPR Protection Factor [d]	Reported DPR Protection Factor
5	1/5 = 0.2	1 – 0.2 = 0.8	80%
10	1/10 = 0.1	1 – 0.1 = 0.9	90%
25	1/25 = 0.04	1 – 0.04 = 0.96	96%
50	1/50 = 0.02	1 – 0.02 = 0.98	98%
100	1/100 = 0.01	1 – 0.01 = 0.99	99%
1,000	1/1,000 = 0.001	1 – 0.001 = 0.999	99.9%
10,000	1/10,000 = 0.0001	1 – 0.0001 = 0.9999	99.99%

[a] Assigned Protection Factors (APFs) by the Occupational Safety and Health Administration (OSHA, 2006) and the equivalent protection factors used by the California Department of Pesticide Regulation (DPR) in exposure assessment. Note that APFs from OSHA (2006) are based on studies using particulates (including aerosols), although OSHA also did a limited comparison involving an unstated number of measurements using vapors.

[b] APFs from Table 1. APFs are anticipated minimum ratios of chemical concentrations outside to inside a respirator.

[c] The inverse of the APF (i.e., 1/APF) gives the proportion of material penetrating the respirator.

[d] DPR protection factors are calculated by subtracting the proportion of material penetrating the respirator from 1 (i.e., subtract from the whole amount outside the respirator).

Conclusions About Data Supporting Protection Factors

APFs are based on studies using particulates, including aerosols. OSHA excluded studies using vapors. However, OSHA also found that including data from previously-excluded studies, including those with vapors, did not affect the APF of 10 for half-mask air-purifying respirators. This suggests that OSHA (2006) provides limited support for an APF of 10 in exposure scenarios involving fumigants or other volatile pesticides. I conclude that, for non-volatile or semi-volatile pesticides, the APFs approved by Cal/OSHA and justified by OSHA (2006) are strongly supported by the data.

Although the point at which volatility (or vapor pressure) might result in differences in respirator penetration has not been specifically investigated, DPR defines volatile pesticides as those having vapor pressure above approximately 1×10^{-4} mmHg. The North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides has suggested that for exposure

assessment purposes, 1 x 10^{-4} kPa (equivalent to 7.5 x 10^{-4} mmHg) is the limit above which pesticides are considered to be volatile in outdoor uses in the temperature range 20 – 30°C (Norman, 2005). Manufacturer data should be consulted to determine the appropriate respirators for use with fumigants and gas or vapor forms of pesticides.

Respirator Use and Documentation of Compliance (Literature Review Completed August 2010)

OSHA (2006) intentionally excluded all discussion of the extent to which respirators are used in actual workplaces. OSHA and other regulators have been criticized for relying on study-based APFs, because some commenters believe that respirators are not used as legally required on a consistent basis in agriculture. In August 2010, I reviewed available literature on compliance with respiratory protection requirements. The results of this review are summarized below.

Numerous studies have investigated respirator use in U.S. agricultural settings, but with a few exceptions (DPR, 2001; Schenker *et al*., 2002; Mitchell and Schenker, 2008; Salvatore *et al.*, 2008) most were not conducted in California. For convenience, the studies reviewed in this memo were divided into three parts: studies conducted in California alone; national surveys; and studies conducted in states other than California. In evaluating respirator use practices reported outside California, the role of pesticide enforcement, and how it can differ between states, is a factor leading to uncertainty. In California, "DPR directs and oversees the County Agricultural Commissioners (CACs) who carry out and enforce federal and state pesticide and environmental laws and regulations at the local level" (DPR, 2010). Enforcement inspections involving pesticide use include verification that employees are properly using respirators (DPR, 2008). However, California is not the only state with a pesticide enforcement program. For example, the North Carolina Department of Agriculture and Consumer Services conducts inspections and other activities to assure compliance with state and federal pesticide laws (Buhler *et al*., 2007).

<u>California-Specific Studies</u>

From June 1997 through March 2001, DPR conducted a survey of pesticide handlers and field workers in California, to assess the effectiveness of enforcement of pesticide regulations (DPR, 2001). Two-week surveys were conducted during this interval in each of 20 counties, by two-person teams who observed multiple applications and various cultivation tasks. Observations occurred on weekends, evenings and early mornings, as well as during weekdays. Both individual growers and staff of licensed pest control businesses were observed. In 148 cases where product labels required use of respirators, the survey found that 80% of handlers wore the required respirator. Most non-compliance was by growers. Of 87 observations of growers, 76% wore required respirators. Of 61 observations of pest control businesses, 87% wore required respirators. Failure to wear required respirators occurred most often when handlers were applying pesticides with tractors having enclosed cabs (product labels may require respiratory protection for handlers in enclosed cabs, unless the cabs have been certified to provide protection

equivalent to a respirator). DPR (2001) noted that the results of the study were based on limited numbers of observations, and could not be used to "identify these results as statewide trends."

Schenker *et al*. (2002) surveyed use of protective equipment, including respirators, by California farmers in 1993. The study population consisted of 4,500 farm operators, out of a total of 58,000 primary operators for farms that normally produce at least $1,000/year from agricultural products. Responses were received from 1,947 operators (90% male, average age 54, and 88% white), who were asked about practices used to protect themselves from hazards due to dust, sun, noise, pesticides, and tractors. Schenker *et al*. (2002) asked whether pesticides were used, and if so, did operators wear gloves, protective clothing, cartridge or other respirator, face shield or goggles, or rubber boots. Of the surveyed operators, 885 (45%) had mixed, loaded, or applied pesticides (for a median of 9 days) within the previous year. Of these 885 pesticide-handling farmers, 338 (38%) used a respirator; however, participants were not asked whether product labels required respirators. A follow-up survey conducted in 2001 did not ask about pesticide or respirator use, but did ask about use of dust masks and closed-cab tractors (Mitchell and Schenker, 2008). In 1993, 54% and 14%, respectively, responded that they used dust masks and closed-cab tractors. In 2001, the use of dust masks was indicated by just 37% of respondents, while the number driving closed-cab tractors increased slightly, to 17% (Mitchell and Schenker, 2008).

Salvatore *et al.* (2008) conducted a behavioral and biomonitoring study using 73 fieldworkers (not pesticide handlers) on a strawberry farm in Monterey County, to assess how well provisions of the Worker Protection Standard (WPS) and other pesticide-safety programs protect workers from pesticide exposure. Workers gave spot urine samples after reentering the malathion-treated field on the day the restricted entry interval expired. One week before sampling, the workers were surveyed about whether they "usually" practiced several behaviors that would tend to limit their pesticide exposure, including whether they wore "WPS-recommended" clothing: long-sleeved shirt, pants, closed-toe shoes, and a hat. Sixty-seven of the workers (92%) said they usually wear all four clothing items, although only 18 (25%) said they wear clean clothes daily. All of the workers who reported wearing clean clothing also reported wearing all four of the WPS-recommended clothing items. Although Salvatore *et al.* (2008) did not examine questions involving respirator use, their study concerned the effectiveness of legally required training. Responses suggest high compliance when it comes to wearing recommended clothing, but much less so when it comes to the (equally important) care of the clothing. Interestingly, workers were asked about whether they usually wear gloves while picking strawberries; 31 (42%) answered positively, and most indicated they use disposable gloves.

<u>National Data</u>

A national survey of respirator use in several industrial sectors, including agriculture, was conducted by NIOSH and the Bureau of Labor Statistics in 2001 – 2002, summarized by Doney *et al*. (2005) and Greskevitch *et al*. (2007). The full report is available online (BLS/NIOSH,

2003), but does not provide information beyond the summaries regarding respirator use. The 2001 survey was conducted of 40,002 business establishments in all 50 states and Washington, DC; the selection process "excluded agricultural establishments employing 10 or fewer workers." In 2001, agricultural establishments with ≤ 10 employees accounted for approximately 1.3 million employees (Doney *et al*., 2005) and about 75% of all crop-production agricultural establishments (Greskevitch *et al*., 2007).

Nationally and across all sectors, respirator use tended to increase with numbers of employees (Doney *et al*., 2005). Yet 91% of all facilities requiring respirator use responded negatively to one or more of fifteen questions about legally mandated respirator programs, including whether they had written cartridge change-out schedules, whether they assessed medical fitness of respirator-wearing employees, or did fit testing of employees (Doney *et al*., 2005). Agricultural establishments did somewhat better than establishments overall, yet 70% of them had negative responses to respirator program questions (Greskevitch *et al*., 2007). Only one respirator program question concerned use of respirators, and responses from agricultural establishments indicated that 24% used disposable dust masks to protect against gases or vapors (Greskevitch *et al*., 2007). If true (the authors allowed for the possibility that at some facilities persons completing the surveys might not have been the most knowledgeable about respirator use), it would be a serious concern if employees are working around toxic gases or vapors. Of all agricultural establishments responding to the survey, 34% required respirator use for their employees (Greskevitch *et al*., 2007).

Unfortunately, the survey did not provide a breakdown of responses by state. Interpreting the results is complicated by provisions of federal OSHA respirator regulations, which exempt agricultural establishments from their requirements, for reasons explained in the preamble to the final standard (OSHA, 1998): "OSHA did not propose to expand coverage of 29 CFR 1910.134 to agricultural workplaces covered by 29 CFR part 1928, and this final Respiratory Protection standard, like the proposal, does not apply to agricultural operations. The prior standard likewise did not apply to agricultural operations. (See 29 CFR 1928.21.) OSHA received no public comment requesting a change in coverage. Accordingly, the issue of respirator use during agricultural operations was not a part of this rulemaking. OSHA notes, however, that respirator use during pesticide operations and handling is covered by EPA's Worker Protection Standard, 40 U.S.C. part 170, adopted under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136–136y)." While the federal WPS has many requirements regarding respirators, a written respirator program is not required (Code of Federal Regulations, Title 40, Section 170.204). However, in California, pesticide safety regulations require a written respirator program "[i]n any workplace where respirators are required by label, restricted material permit condition, regulation, or employer" (3 CCR 6739). Thus, agricultural employers outside California are not required under federal law to implement the respirator programs surveyed by Doney *et al.* (2005) and Greskevitch *et al.* (2007), yet in California agricultural employers are required to do so if their employees wear respirators for protection against pesticide exposure.

Studies Conducted in States Other than California

More than a dozen studies have investigated use of personal protective equipment (PPE) in states outside of California. Most of these consist of simple surveys asking whether safety measures such as PPE use are routinely taken by farmers and farmworkers, which do not provide useful information about product label-mandated use of respirators. Only four studies that address at least in part the question of compliance with legally required respirator use are included here. Three of the studies were conducted in Midwestern states, and the fourth was in North Carolina.

Perry *et al.* (2002) asked farmers in Wisconsin about the PPE they wear while applying specific pesticides. Perry *et al.* (2002) consulted product labels to determine required PPE, and recorded whether or not the farmers were compliant. Of the fifteen pesticides covered by the survey, respirators were required only for two, terbufos and carbofuran. Three farmers had applied terbufos, and one had applied carbofuran. All four farmers stated that they did not wear the label-required respirator.

Stone *et al*. (1994) surveyed 185 Iowa greenhouse pesticide applicators in 1992, in part about their use of PPE. Respondents included both self-employed applicators (21%) and employees (79%); about half reported having college degrees. Reported application days ranged from 0 to 222 days per year, with a median of 30 days per year, and 26% reported applying fumigants. Applicators were asked whether overall their PPE met requirements on pesticide product labels. Of the 159 applicators who answered that question, 51 (32%) said their PPE consistently met the minimum required on product labels, while 72 (45%) said that their PPE exceeded label requirements. The remaining 36 (23% of respondents answering this question) reported that their PPE "mostly, but not always" met minimum label requirements. They were also asked about specific PPE, including dust masks, chemical cartridge respirators, gas mask with canister, and SCBA. Between 153 and 156 responded to the specific respiratory protection questions. They were given five choices in statements about each type of PPE: "nearly always wear," "wear depending on weather," "wear depending on pesticide," "rarely or never wear," or "unnecessary for my pesticide." The statement, "wear depending on weather," was chosen by two or fewer respondents for each respirator. Combining "nearly always wear" and "wear depending on pesticide" would yield the best estimate of compliance for these data (although "depends on pesticide" might refer to factors other than use required on label, such as a product with an unpleasant odor or one that the applicator perceives as highly toxic). Conversely, combining "rarely or never wear" and "unnecessary for my pesticide" yields an estimate of the number of greenhouse applicators who were not wearing each type of respirator, for whatever reason.

Overall percentages for each type of respirator were as follows:

- Dust mask: 40% wear (14% always), 59% do not (38% never)
- Chemical cartridge respirator: 72% wear (47% always), 27% do not (16% never)

- Gas mask with canister: 22% wear (10% always), 77% do not (45% never)
- SCBA: 18% wear (12% always), 82% do not (47% never)

Thus the percent of applicators who explicitly related the use of respirator protection to a pesticide (either "wear depending on pesticide" or "unnecessary for my pesticide") were 47% for dust mask (i.e., [40 – 14] + [59 – 38]), 36% for chemical cartridge, 44% for gas mask with canister, and 41% for SCBA.

In 1997, Tondl and Schulze (2000) surveyed 139 pesticide-applying Nebraska farmers about PPE use. The survey questioned the farmers about both dust masks and chemical cartridge respirators. About the former, Tondl and Schulze (2000) concluded, "Applicators indicated that dust masks were worn only two percent of the time, even when the label required their use. Only 20% of the applicators wore the required dust mask half the time." When product labels required cartridge respirators, compliance was even worse; only 3% of the applicators wore cartridge respirators when required. This reported compliance rate is extremely low.

In North Carolina, 4,324 enforcement inspections conducted 1995 - 2004 resulted in a total of 143 violations, of which 28 (20%) were cited as "Failure to provide or train workers and handlers on the proper use and care of personal protective equipment" (Buhler *et al.*, 2007). No specific mention was made of respirator use by Buhler *et al.* (2007), and it's unclear how many of the PPE-related violations concerned respiratory protection.

Conclusions about Compliance with Respirator Use Requirements

Studies about respirator use—and PPE use in general—reported in the literature provide limited data but suggest that non-compliance with legally required use does occur. The extent to which it may occur in California cannot be determined from available data, as only one study specifically addressed the issue of concern to us, which is whether or not handlers wear appropriate respirators—and whether respirators are effectively used—when required by pesticide product labels.

DPR (2001) provided a snapshot of compliance with respiratory use requirements in California through early 2001, and suggested that the majority of handlers required to wear respirators did so. However, the study assessed compliance at a limited number of use sites, and for a narrow span of time. It is possible that records of enforcement inspections conducted by DPR and County Agricultural Commissioners might provide more recent California-specific evidence of compliance or non-compliance, and might allow more robust conclusions. I suggest checking with Enforcement Branch records to see if pertinent information is contained within the records and how feasible it would be to use the records to answer this question.

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