

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.544, amend table 1 to paragraph (a)(1) by adding, in alphabetical order, an entry for the commodity “bean, mung, dry seed” to read as follows:

§ 180.544 Methoxyfenozide; tolerances for residues.

- (a) * * *
- (1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * *	*
Bean, mung, dry seed	0.5
* * * * *	*

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DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 391

[Docket No. FMCSA–2022–0111]

Qualifications of Drivers: Medical Examiner’s Handbook Regulatory Guidance

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notification of regulatory guidance.

SUMMARY: FMCSA announces the availability of the Medical Examiner’s Handbook (MEH), which includes updates to the Medical Advisory Criteria published in the Code of Federal Regulations (CFR). The MEH provides information about regulatory requirements and guidance to medical examiners (ME) listed on FMCSA’s National Registry of Certified Medical Examiners (National Registry) who perform physical qualification examinations of interstate commercial motor vehicle (CMV) drivers. The January 2024 edition of the MEH replaces all previous handbook editions.

DATES: This guidance is applicable on January 22, 2024.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590, (202) 366–4001, *FMCSAMedical@dot.gov*. If you have questions on viewing material in the docket, call Dockets Operations at (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Availability of Documents

To view comments or any documents mentioned as being available in the docket, go to <https://www.regulations.gov/docket/FMCSA-2022-0111/document> and choose the document to review. To view comments, click “Browse All Comments.” If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

II. Legal Basis

FMCSA has statutory authority under 49 U.S.C. 31136(a)(3) and 31149(c)(1)(A)(i)—delegated to the Agency by 49 CFR 1.87(f)—to establish regulations to ensure the physical condition of CMV operators is adequate to enable them to operate the vehicles safely. The guidance in the MEH and Medical Advisory Criteria is related to the physical qualification regulations required by those sections.

The notice and comment rulemaking procedures of the Administrative Procedure Act (APA) do not apply to interpretative rules and general statements of policy (commonly called “guidance”) (5 U.S.C. 553(b)(A)). The MEH is a guidance document that does not amend any Agency regulation or establish any requirements for MEs or drivers not found in existing regulations. Accordingly, FMCSA was not required under the APA to solicit public comment on the MEH. Nevertheless, to ensure that the MEH provides clear, useful, and relevant information for stakeholders and as encouraged by DOT policy,¹ FMCSA opted to make a draft of the MEH available for public review and comment (87 FR 50282 (Aug. 16, 2022)).

¹ Section 14(f) of DOT 2100.6A (Rulemaking and Guidance Procedures) states that it is DOT policy to encourage providing an opportunity for public comment on guidance documents, as public input can be very helpful in formulating and improving the guidance that DOT offers.

Although FMCSA voluntarily provided an opportunity for public comment on the MEH, its decision to do so does not make applicable any of the other procedural requirements in the APA or most of the other statutes or Executive orders that would apply if the opportunity for prior notice and public comment were required.

III. Background

FMCSA’s mission is to reduce crashes, injuries, and fatalities involving large trucks and buses. A critical element of FMCSA’s safety program is ensuring CMV drivers are in adequate physical condition to operate the vehicles safely. MEs on the National Registry make the determination regarding a driver’s physical qualification.

The Federal Motor Carrier Safety Regulations (FMCSRs), in 49 CFR 391.41 through 391.49, provide the basic driver physical qualification standards for interstate CMV operators. MEs make physical qualification determinations on a case-by-case basis and may consider guidance to assist with making those determinations.

FMCSA first posted the MEH to its website in 2008 to provide guidance to MEs on the physical qualification standards in the FMCSRs and the conducting of the physical qualification examination. FMCSA has also issued guidance for MEs in the form of Medical Advisory Criteria, now published at 49 CFR part 391, Appendix A. However, FMCSA withdrew the MEH in 2015 because some of the information was obsolete or was prescriptive in nature, and informed MEs and training organizations that the MEH was no longer in use and should not be considered as Agency guidance.

FMCSA’s Medical Review Board (MRB) was established to provide FMCSA with medical advice and recommendations on medical standards and guidelines for the physical qualifications of CMV operators, ME education, and medical research (49 U.S.C. 31149(a)(1)). The MRB, in view of its statutory creation and advisory function, is chartered by DOT as an advisory committee under the Federal Advisory Committee Act (5 U.S.C. Ch. 10). See also *Announcement of Establishment of the Federal Motor Carrier Safety Administration Medical Review Board* (70 FR 57642 (Oct. 3, 2005)). The Secretary appoints MRB’s members to reflect expertise in a variety of medical specialties relevant to the driver fitness requirements of FMCSA (49 U.S.C. 31149(a)(2)).

To assist in the development of the MEH, FMCSA, in collaboration with its

Chief Medical Officer, requested advice from the MRB for the Agency to consider via MRB Task Statement 17–1. Specifically, FMCSA asked the MRB to review and provide recommendations for streamlining the MEH. This included removing non-regulatory directive language and updating and removing obsolete information. At public meetings, the MRB discussed the development of the new MEH and Medical Advisory Criteria and reviewed drafts of the MEH. Details of the meetings, including MRB Task Statement 17–1, are posted on the Agency's public website at <https://www.fmcsa.dot.gov/medical-review-board-mrb-meeting-topics>.

After consideration of the public comments and further internal review, FMCSA is now issuing a revised MEH, which includes updated Medical Advisory Criteria, with the goal of providing information about regulatory requirements and guidance for MEs to consider when making physical qualification determinations in conjunction with established best medical practices. In addition to being included in the MEH, the revised Medical Advisory Criteria are being published in Appendix A to 49 CFR part 391 concurrent with this notification. The final version of the criteria is identical in both publications.

The Agency notes that the updated MEH reflects the fact that medical certification under 49 CFR 391.64 for certain drivers who participated in FMCSA's Vision Waiver Study Program is no longer available. On January 21, 2022, FMCSA published a new alternative vision standard and eliminated physical qualification under § 391.64 (87 FR 3390). As of March 22, 2023, all Medical Examiner's Certificates, Form MCSA–5876, issued under § 391.64 became void. FMCSA is aware that references to medical certification under § 391.64 exist in FMCSA's current regulations and forms. The Agency plans to remove obsolete provisions in an upcoming technical amendment rule.

IV. Comments Received

FMCSA received 67 comments in response to the draft MEH from a wide range of commenters, including individuals; medical providers (such as MEs listed on the National Registry and Concentra); drivers; motor carriers (including owner-operators and Schneider National, Inc.); a patient advocacy group (the Alliance of Sleep Apnea Partners (ASAP)); safety advocacy groups (a joint comment was filed by the Truck Safety Coalition (TSC), Citizens for Reliable and Safe

Highways (CRASH), and Parents Against Tired Truckers (PATT)); the National Transportation Safety Board (NTSB); five members of Congress who filed a joint comment; and additional associations. Specifically, the medical associations were the American Academy of Sleep Medicine (AASM), the American College of Occupational and Environmental Medicine (ACOEM), and the American Physical Therapy Association. The trade associations were the American Trucking Associations (ATA), the National Association of Small Trucking Companies, the National Beer Wholesalers Association, the Owner-Operator Independent Drivers Association (OOIDA), and the Truckload Carriers Association.

The comments covered a variety of topics. Although the APA notice and comment requirements do not apply to guidance documents, FMCSA provides its responses to some of the comments in the interest of transparency.

General Comments

Some commenters wanted FMCSA to provide more specificity regarding certain types of evaluations and stated the draft MEH is less useful than the previous MEH due to its lack of specificity. Most of the physical qualification standards are broadly stated, and establishing specific testing requirements, such as methodology and acceptable laboratory values, would have to occur through rulemaking. Thus, FMCSA believes the level of specificity in the current version of the MEH is appropriate for a regulatory guidance document.

However, FMCSA made numerous changes to improve the overall clarity, quality, and substance of the MEH based on suggestions from commenters. For example, based on comments from ACOEM and an individual, FMCSA edited several sections to emphasize privacy protections for the individuals being examined, particularly that the right to receive a copy of the Medical Examination Report Form, MCSA–5875, is personal to the individual and does not depend on who paid for or requested the physical qualification examination. In response to a comment from OOIDA, FMCSA also clarified when the individual's consent is required for the ME and the employer to request and receive protected health information about the individual being examined.

FMCSA incorporated a suggestion from OOIDA to add that individuals may request a second opinion and physical qualification examination from another ME if they choose but are expected to provide the same medical

information to both MEs. In response to comments from an individual and ACOEM, FMCSA also stated that MEs should visualize the body while examining an individual and conduct an inguinal hernia examination for all males.

ACOEM also asked FMCSA to clarify issues regarding incomplete examinations, and the MEH now states that once an ME begins an examination, the results must be reported to the National Registry even if the examination is not completed. At the request of ACOEM and two MEs, FMCSA clarified issues relating to the use of the determination pending status, including that it does not extend the expiration date of an individual's current Medical Examiner's Certificate, Form MCSA–5876. One commenter, who is both an ME and a commercial driver's license holder, noted that some MEs do not use the most current versions of forms, so FMCSA clarified that using the current form is mandatory.

FMCSA made several other revisions to the MEH in response to comments and suggestions from ACOEM. For example, FMCSA clarified that the alternative vision standard is applicable only if the worse eye cannot be corrected to meet the distant visual acuity standard with corrective lenses. FMCSA added that if the individual meets the vision standard while wearing corrective lenses, it is not necessary to document the distant visual acuity without corrective lenses. FMCSA also added that when it is indicated that a medical exemption is required, the Medical Examiner's Certificate, Form MCSA–5876, is not valid unless the individual applies for and is issued the medical exemption from FMCSA. It was emphasized that MEs may certify an individual for less than the maximum period whenever they determine they need to monitor the individual more frequently. FMCSA moved the discussion of renal dialysis from the section on cardiovascular diseases to the section on diabetes because diabetes leads to a greater incidence of kidney disease than cardiovascular disease does.

In addition, ACOEM requested that FMCSA establish a regular cadence for updating the MEH. FMCSA intends to update the MEH periodically.

Concentra and ACOEM questioned why certain medical expert panel reports and other guidance were included in the draft MEH, while others were not. After reviewing the comments, FMCSA agrees that including some reports but not others has the potential to create confusion.

The more recent evidence reports and medical expert panel reports are readily available on FMCSA's website at <https://www.fmcsa.dot.gov/regulations/medical/reports-how-medical-conditions-impact-driving>. Thus, FMCSA decided to remove references to these additional sources of information from the MEH. FMCSA notes that evidence reports and medical expert panel reports are disseminated by FMCSA in the interest of information exchange and are not official Agency guidance.

FMCSA revised the sections on narcolepsy and idiopathic hypersomnia based on comments by AASM and an individual. FMCSA deleted the references to obstructive sleep apnea (OSA) and added that the conditions should be diagnosed with an overnight lab-based sleep study followed by a Multiple Sleep Latency Test the next morning.

FMCSA made several changes in the section relating to the scheduled drug and alcohol standards in light of comments by *SAPList.com*. For example, FMCSA clarified that DOT-regulated drug and alcohol testing is not part of the physical qualification examination but may be conducted concurrently with the examination for pre-employment or other authorized purposes. FMCSA also clarified that substance abuse professionals are not certified and not part of non-DOT drug testing. FMCSA also provided a more in-depth discussion of the intent of Questions 31 and 32 on the Medical Examination Report Form, MCSA-5875.

Obstructive Sleep Apnea (OSA)

Of the 67 comments received, 36 referenced OSA. Of these, 27 commented only on OSA.

Several commenters, including ATA and OOIDA, indicated that the guidance in the MEH relating to OSA runs afoul of Public Law 113-45 (127 Stat. 557 (Oct. 15, 2013), 49 U.S.C. 31305 note), which provides FMCSA may implement or enforce a requirement providing for the screening, testing, or treatment of CMV operators for sleep disorders only if the requirement is adopted pursuant to a rulemaking proceeding. When drafting the MEH, FMCSA was mindful of Public Law 113-45. However, Public Law 113-45 is not applicable here because the MEH offers only guidance and FMCSA has not adopted requirements regarding OSA screening, testing, or treatment. Because this is not a rulemaking proceeding, FMCSA cannot accommodate the requests by commenters that FMCSA require MEs to use specific, objective criteria for OSA

screening, treatment, and treatment evaluation.

FMCSA has gone to great efforts throughout the MEH to distinguish between regulatory requirements and non-binding guidance. The MEH states that MEs are free to choose whether to utilize guidance and recommendations as a basis for decision-making and that when the terms "recommend," "consider," "may," "should," or "could" are used in the MEH, they are used in a recommendatory or permissive sense and relate to guidance. In particular, the MEH states that the FMCSRs do not include requirements for MEs to screen individuals for OSA or to recommend that an individual be referred for OSA testing and do not include preferred diagnostic testing methods, treatment methods, or requirements by which to assess compliance with treatment. Instead, the MEH presents various considerations for ME when making a physical qualification determination.

Several commenters, including ASAP, ATA, CRASH, PATT, and TSC, indicated FMCSA should initiate a rulemaking to develop specific OSA screening, testing, and treatment requirements for CMV drivers rather than to issue more guidance. The notice issued in 2017 withdrawing an advance notice of proposed rulemaking explains FMCSA's reasons for not proceeding with a rulemaking on OSA (see Evaluation of Safety Sensitive Personnel for Moderate-to-Severe Obstructive Sleep Apnea, 82 FR 37038 (Aug. 8, 2017)).

Several comments were received regarding the link in the MEH to the November 21, 2016, joint MRB and Motor Carrier Safety Advisory Committee recommendations regarding OSA. FMCSA continues to include the link in the final MEH for ease of access. As suggested by NTSB, FMCSA added text to state that the joint recommendations includes information on screening and diagnosing individuals with moderate-to-severe OSA, and not just certifying such individuals.

AASM, ASAP, OOIDA, and an individual questioned why the draft MEH included a window of 3 to 5 years for retesting individuals diagnosed with moderate-to-severe OSA treated with continuous positive airway pressure. FMCSA removed the recommendation of a time frame for retesting. FMCSA added that "untreated moderate-to-severe OSA is associated with cardiovascular and cerebrovascular morbidity, metabolic disease, and mortality" in response to a comment from AASM.

AASM recommended that FMCSA remove "moderate-to-severe" from the statement that untreated moderate-to-severe OSA may contribute to certain adverse conditions because they may be experienced at any level of OSA severity. FMCSA determined that the focus of the guidance is appropriately on moderate-to-severe OSA because it is likely to interfere with the ability to control and drive a CMV safely as required by the applicable standard.

Several commenters stated that MEs should not consider a single factor as being determinative with respect to whether an individual needs to be screened for OSA. FMCSA agrees and reiterates that the MEH provides guidance stating that the use of multiple risk factors is a reasonable approach to identify individuals at risk for moderate-to-severe OSA, rather than relying only on a single factor. The MEH guidance leaves it to the ME to determine whether an individual needs to be screened based on the individual circumstances.

AASM and ASAP recommended adding that moderate-to-severe OSA is to be "adequately treated" or "treated effectively." As indicated in the MEH, determining whether treatment is adequate or effective should be left to the ME to determine based on the individual circumstances.

High Blood Pressure

Several commenters, including ACOEM and Concentra, stated that the hypertension table from the 2013 expert panel recommendations titled "Medical Examiner Physical Qualification Standards and Clinical Guidelines for Cardiovascular Disease and Commercial Motor Vehicle Driver Safety" was vague, confusing, and difficult to understand. FMCSA agrees that the table has the potential to create confusion. FMCSA therefore decided to remove the hypertension table from the MEH and to continue the current guidance in the Medical Advisory Criteria. FMCSA is currently conducting research on this topic and will update the MEH based on the final report if warranted.

Non-Insulin-Treated Diabetes Mellitus

The NTSB and ACOEM stated that the information provided for non-insulin-treated diabetes is inadequate and that there should be some guidance on the complications and co-morbidities of non-insulin-treated diabetes mellitus. FMCSA does not have a medical standard specific to non-insulin-treated diabetes mellitus, and therefore cannot provide the level of specificity sought by these commenters.

However, FMCSA provided some additional information, including considerations for MEs when making a physical qualification determination for an individual with non-insulin-treated diabetes mellitus. In addition, FMCSA is in the process of seeking approval from the Office of Management and Budget for a new Non-Insulin-Treated Diabetes Mellitus Assessment Form. If approved, FMCSA will post the form on its website for MEs to use as a voluntary, optional tool to request additional information, with the individual's consent, when making a physical qualification determination for an individual with non-insulin-treated diabetes mellitus. It will also update the MEH with this information if approved.

Out of Scope Comments

Some commenters requested changes to the MEH that are beyond the scope of this guidance, including some that would require rulemaking and changes to existing law.

V. Publication of the Regulatory Guidance

Each guidance document issued by FMCSA must be published on a publicly accessible DOT internet website on the date of issuance (49 U.S.C. 113 note).² Accordingly, in addition to being available in this docket, the MEH will be available in

² See section 5203(a)(2)(A) and (a)(3) of the Fixing America's Surface Transportation Act, Public Law 114–94, 129 Stat. 1312, 1535 (Dec. 4, 2015).

FMCSA's Guidance Portal (<https://www.fmcsa.dot.gov/guidance>) and on FMCSA's website at <https://www.fmcsa.dot.gov/regulations/medical/medical-regulations-and-guidance-resource-links> and on the National Registry website at <https://nationalregistry.fmcsa.dot.gov/resource-center>.

FMCSA expects to review the guidance no later than 5 years after it is published and will consider at that time whether the guidance should be withdrawn, reissued, or incorporated into FMCSA's regulations.

Robin Hutcherson,
Administrator.

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