

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906-AA36

National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table—II

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Proposed rule; notice of public hearing.

SUMMARY: This document announces a public hearing to receive information and views on the Notice of Proposed Rulemaking (NPRM) entitled "National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table—II."

DATES: The public hearing will be held on February 29, 1996, from 1:00 p.m. to 5:00 p.m.

ADDRESSES: The public hearing will be held in Conference Room D in the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas E. Balbier, Jr., Director, Division of Vaccine Injury Compensation, at (301) 443-6593.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act (Public Law 99-660, as amended, Title XXI of the Act) provides a system of no-fault compensation for certain individuals who have been injured by specific childhood vaccines: namely, diphtheria, tetanus, pertussis, polio, measles, mumps or rubella vaccines. Section 2114 of the Act contains a Vaccine Injury Table (the Table) which lists these vaccines and the time periods in which certain adverse events, e.g., injuries, disabilities, illnesses, or death, must occur in order for claimants to be entitled to a presumption that the event was vaccine-related. The Table was amended by regulation pursuant to Section 312 of the Act in the Final Rule published in the Federal Register on February 8, 1995 (60 FR 7678). The Secretary has proposed further revisions of the Vaccine Injury Table and accompanying Qualifications and Aids to Interpretation based on the findings of an Institute of Medicine report, which was released in late 1993, and the recommendations made by two advisory bodies, the National Vaccine Advisory Committee and the Advisory Commission on Childhood Vaccines. Among other changes, this proposed rule will add vaccines against Hepatitis B and hemophilus influenzae type b to the Table. The NPRM was published in

the Federal Register, November 8, 1995: Vol. 60, No. 216, Pages 56289-56300. The public comment period closes May 6, 1996.

In view of the importance of the Vaccine Injury Compensation Program and the effect of the NPRM, the Secretary has determined that, in addition to the 180-day period for written comments on the NPRM, an informal public hearing will be held. This hearing is to provide an open forum for the presentation of information and views concerning all aspects of the NPRM by interested persons.

In preparing a final regulation, the Secretary will consider the administrative record of this hearing along with all other written comments received during the comment period specified in the NPRM. Individuals or representatives of interested organizations are invited to participate in the public hearing in accord with the schedule and procedures set forth below.

The hearing will be held on February 29, 1996, beginning at 1:00 p.m., in Conference D in the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. The hearing will be held following the noon adjournment of the February 28-29 meeting of the Advisory Commission on Childhood Vaccines.

The presiding officer representing the Secretary, HHS, will be Mr. Thomas E. Balbier, Jr., Director, Division of Vaccine Injury Compensation, Bureau of Health Professions (BHP), Health Resources and Services Administration.

Persons who wish to participate are requested to file a notice of participation with the Department on or before February 15, 1996. The notice should be mailed to Division of Vaccine Injury Compensation, BHP, Room 8A-35, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. To ensure timely handling any outer envelope should be clearly marked "NPRM Hearing." The notice of participation should contain the interested person's name, address, telephone number, any business or organizational affiliation of the person desiring to make a presentation, a brief summary of the presentation, and the approximate time requested for the presentation. Groups that have similar interests should consolidate their comments as part of one presentation. Time available for the hearing will be allocated among the persons who properly file notices of participation. If time permits, interested parties attending the hearing who did not submit a notice of participation in advance will be allowed to make an oral

presentation at the conclusion of the hearing.

Persons who find that there is insufficient time to submit the required information in writing may give oral notice of participation by calling Mr. Thomas E. Balbier, Jr., Director, Division of Vaccine Injury Compensation, at (301) 443-6593 no later than February 15, 1996. Those persons who give oral notice of participation should also submit written notice containing the information described above to the Department by the close of business February 22, 1996.

After reviewing the notices of participation and accompanying information, the Department will schedule each appearance and notify each participant by mail or telephone of the time allotted to the person(s) and the approximate time the person's oral presentation is scheduled to begin.

Written comments and transcripts of the hearing will be made available for public inspection as soon as they have been prepared, on weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5:00 p.m. at the Division of Vaccine Injury Compensation, Room 8A-35, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Dated: January 30, 1996.

Ciro V. Sumaya,
Administrator.

[FR Doc. 96-2322 Filed 2-2-96; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Parts 525, 541, 555, 571, and 581

[Docket No. 95-95, Notice 1]

Exemptions From Average Fuel Economy Standards; Federal Motor Vehicle Theft Prevention Standard; Federal Motor Vehicle Safety Standards; Bumper Standard

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of public meeting; request for comments.

SUMMARY: This notice announces a public meeting at which NHTSA will seek information from small volume manufacturers and the public on regulatory problems of such manufacturers. Previously, NHTSA announced that it is interested in developing a legislative package tailored to reduce the burden of its requirements

on small businesses and manufacturers. NHTSA is requesting suggestions for actions with respect to NHTSA's Corporate Average Fuel Economy (CAFE) regulations, Theft Prevention Standard, Federal Motor Vehicle Safety Standards, and Bumper Standard, that govern the compliance and exemption of such vehicles. This notice also invites written comments on the same subjects.

DATES: The public meeting will be held on Wednesday, March 13, 1996, at 9:00 a.m. An agenda for the meeting will be made based on the number of persons wishing to make oral presentations and will be available on the day of the meeting. Those wishing to make oral presentations at the meeting should contact Taylor Vinson, at the address or telephone number listed below, by the close of business Monday, February 26, 1996. Written comments may be submitted at any time before or after the meeting, but not later than April 4, 1996.

ADDRESSES: *Public meeting:* The public meeting will be held in Rooms 6244–6248, Nassif Building (DOT headquarters), 400 Seventh Street, SW, Washington, DC.

Written comments: Written comments should be sent to the Docket Section, National Highway Traffic Safety Administration, Room 5109, 400 7th Street, SW., Washington, DC 20590, ATTN: Docket No. 95–95; Notice 1.

FOR FURTHER INFORMATION CONTACT: Taylor Vinson, Office of Chief Counsel, NHTSA, 400 7th Street, SW, Washington, DC 20590 (telephone 202–366–5263).

SUPPLEMENTARY INFORMATION:

Regulatory Reform

Calling for a new approach to the way Government regulates the private sector, President Clinton has asked Executive Branch agencies to improve the regulatory process. Specifically, the President requested that agencies (1) cut obsolete regulations; (2) create grassroots partnerships by meeting with those affected by regulations and other interested parties; and (3) make more frequent use of consensual rulemaking such as regulatory negotiation.

This is the second of NHTSA's announced meetings to create grassroots partnerships with regulated industries that do not deal with NHTSA on a daily basis. By meeting with these groups, NHTSA believes that it can derive a better understanding of their needs and concerns. Other groups that the agency plans to meet with are manufacturers of school buses, heavy trucks, child seats, and lamps and reflectors. The agency

met on December 12, 1995, with manufacturers of multistage vehicles.

As part of its contribution towards regulatory reform to reduce unnecessary regulatory burdens, NHTSA has announced that it plans to develop a legislative package tailored to reduce the burden of its requirements on small manufacturers. Such a package could include longer leadtimes for small manufacturers and greater flexibility in granting small-manufacturer exemptions. NHTSA recognizes that small volume manufacturers are faced with somewhat different problems than manufacturers who produce in larger quantities. Therefore, the agency has decided to hold a public meeting to receive the comments of this group and the public on how the regulatory process might be improved without any diminution of regulatory goals.

Small-Volume Manufacturers

Under the current statutes and regulations administered by NHTSA, there is no specific definition of "small-volume manufacturer". However, eligibility for application for exemption from average fuel economy standards and motor vehicle safety standards is statutorily predicated upon the volume of production. This statutory criterion is reflected in the agency's regulations. Under 49 CFR Part 525 *Exemptions From Average Fuel Economy Standards*, a manufacturer who produces fewer than 10,000 passenger automobiles may apply for an exemption. Similarly, under 49 CFR Part 555 *Temporary Exemption From Motor Vehicle Safety Standards*, a manufacturer whose total motor vehicle production (passenger cars and all other types) does not exceed 10,000 may apply for an exemption on grounds that compliance would cause it substantial economic hardship. Thus, at present, a manufacturer whose annual motor vehicle production does not reach 10,000 units can apply for regulatory relief that is not available to manufacturers whose yearly production is greater. NHTSA, therefore, considers any manufacturer of motor vehicles that which fabricates not more than 10,000 units a year to be a "small-volume manufacturer" within the meaning of its outreach program, regardless of whether it has petitioned for exemption under Part 525 or Part 555.

Importers of vehicles for resale are statutorily treated as "manufacturers" for most purposes and required to comply with obligations of fabricating manufacturers. Aside from factory-owned U.S.-based concerns importing certified vehicles, importers of vehicles for resale generally import vehicles originally intended for sale in a country

other than the United States and thus not manufactured to conform to Federal requirements. Such importers are treated as "registered importers" (RIs) in the agency's authorizing statute and under 49 CFR Part 592. None imports more than 10,000 units a year. The agency is well aware of the problems faced by RIs in qualifying nonconforming vehicles for entry and modifying them after entry. However, these problems are of a different nature than those faced by small manufacturers actually involved in fabrication. For this reason, the agency does not intend to include non-fabricating small-volume manufacturers in the agenda for this meeting.

The following paragraphs briefly describe the existing statutory provisions regarding the establishing of standards and the NHTSA regulations implementing those provisions.

Corporate Average Fuel Economy (CAFE)

The CAFE standards originate in 49 U.S.C. Chapter 329—*Automobile Fuel Economy*. This chapter requires passenger automobiles to meet a CAFE standard of 27.5 miles per gallon for each model year. Under 49 U.S.C. 32902(d)(1), a manufacturer may apply for a CAFE exemption if it produced less than 10,000 passenger automobiles in the model year 2 years before the model year for which application is made. An exemption for the model year may be granted if the agency finds that the applicable CAFE standard is more stringent than the maximum feasible average fuel economy level that the manufacturer can achieve, and then prescribes an alternative standard that is based upon the finding.

The exemption provisions of Chapter 329 have been implemented by 49 C.F.R. Part 525 *Exemptions From Average Fuel Economy Standards*. This regulation sets out the contents of applications and the application procedures. Exempted manufacturers and their individual CAFE standards are listed at 49 C.F.R. 531.5(b).

Theft Prevention Standard

The agency's efforts to reduce the theft of motor vehicles are governed by 49 U.S.C. Chapter 331—*Theft Prevention*. Under Sec. 33102, NHTSA is required to issue a theft prevention standard that applies to parts of vehicles that have been designated high theft lines. Sec. 33103 requires NHTSA to extend the standard to vehicle lines that have not been designated high theft. Sec. 33106 allows manufacturers to apply for exemption for passenger motor vehicles equipped with antitheft

devices. However, the right to apply is independent of the quantity of vehicles produced by the applicant. Sec. 33114 prohibits the importation of either a motor vehicle or replacement part covered by a theft standard unless it conforms to the standard. The prohibition is absolute and does not provide for importing noncomplying vehicles or parts and subsequently bringing them into compliance with the theft prevention standard.

Chapter 331 has been implemented in pertinent part by 49 C.F.R. Part 541 *Federal Motor Vehicle Theft Prevention Standard* and Part 543 *Exemption From Vehicle Theft Prevention Standard*. Part 541 requires the marking of parts in the manner prescribed. Part 543 contains the procedures for applying for theft prevention standard exemptions. Vehicles with antitheft devices that are exempted in their entirety from the standard are listed in Appendix A of Part 541. Some of them are produced by small-volume manufacturers within the meaning of this notice.

Federal Motor Vehicle Safety Standards

49 U.S.C. Chapter 301—*Motor Vehicle Safety* is the authority for the regulations published under 49 C.F.R. Part 571 *Federal Motor Vehicle Safety Standards*. Every motor vehicle must meet all applicable Federal motor vehicle safety standards by virtue of Sec. 30112(a), except as provided elsewhere in Sec. 30112, and in Secs. 30113 and 30114. Sec. 30113(d) provides that a manufacturer whose annual motor vehicle production is 10,000 units or less is eligible to apply for an exemption under Sec. 30113(b)(3)(B)(i), on the basis that compliance would cause substantial economic hardship to a manufacturer that has tried to comply with the standard in good faith.

Some small-volume manufacturers have petitioned for temporary exemption from the safety standards on grounds other than substantial economic hardship, principally electric vehicle manufacturers who argue that an exemption would facilitate the development and field evaluation of a low-emission vehicle, a basis allowed by Sec. 30113(b)(3)(B)(iii). Eligibility to apply is not predicated upon limited production volume. This and the remaining categories of exemptions (innovative safety devices, equivalent overall level of safety) are available to all manufacturers regardless of production (though only 2,500 vehicles per year can be exempted). Nevertheless, the agency intends to include all four categories of statutory exemption in this review, even though

they affect all manufacturers and not just those whose volume is limited.

Sec. 30113 *General exemptions* has been implemented by 49 C.F.R. Part 555 *Temporary Exemption From Motor Vehicle Safety Standards*. Under the authority of this regulation, in effect since 1973, over 100 applications have been considered, and the greater part of them granted.

Sec. 30114 *Special exemptions* provides NHTSA with the authority to exempt a motor vehicle or an item of motor vehicle equipment on terms that the agency decides are necessary "for research, investigations, demonstrations, training, or competitive racing events." Since its original enactment in P.L. 100-562, *The Imported Vehicle Safety Act of 1988*, Sec. 30114 has been implemented solely with respect to the importation of vehicles and equipment, in 49 C.F.R. Sec. 591.5(j)(i). However, that statutory provision appears to have other applications as well, such as permitting manufacturers to operate non-conforming prototype vehicles on the public roads.

Bumper Standards

Reduction of damage from motor vehicle accidents is the purpose of 49 U.S.C. Chapter 325—*Bumper Standards*. Sec. 32502 requires NHTSA to promulgate bumper standards for passenger motor vehicles as defined by the statute. A limited exemption authority is provided to NHTSA by Sec. 32502(c) to exempt from any part of a standard a multipurpose passenger vehicle or a make, model, or class of a passenger motor vehicle manufactured for a special use, if the standard would interfere unreasonably with the special use of the vehicle. However, this exemption authority is silent as to the right of a manufacturer to petition for relief. At the most, a manufacturer could petition only for relief of a class and not for relief on an individual basis, no matter what the volume of the manufacturer's production.

The statutory requirement for a standard has been implemented by 49 C.F.R. Part 581—*Bumper Standard*. The regulation is silent on exemption procedures.

Comments

The agency believes that it would be helpful to have comments on the following topics, with respect to the statutory authority and regulations discussed above—

- Expansion or addition of exemption authority.
- Administrative/compliance burdens.

- Deferred compliance until end of phase-in period for phased-in regulations.

- Cost effectiveness.
- Costs to consumers of the existing regulation and the changes suggested by the commenter.
- Costs to regulated parties of testing or certification.
- Effects on fuel economy, theft prevention, safety, or property damage.
- Effects on small business.
- Enforceability.
- Whether the statute or regulation reflects a "common sense" approach to solving the problem.

Written statements should be arranged by the CFR Part numbers addressed, be as specific as possible and provide the best available supporting information. Suggestions should be accompanied by a rationale for the suggested action and a forecast of the expected consequences of that action. Statements also should specify whether any change recommended in the regulatory process would require a legislative change in NHTSA's authority.

Procedural Matters

The agency intends to conduct the meeting informally so as to allow for maximum participation by all who attend. Interested persons may ask questions or provide comments during any period after a person has completed his or her presentation on a time allowed basis, as determined by the presiding official. If time permits, persons who did not ask prior to the meeting for an opportunity to speak, but would like to make a statement, will be afforded an opportunity to do so.

Those speaking at the public meeting should limit their presentations to 20 minutes. If the presentation will include slides, motion pictures, or other visual aids, please so inform the contact person identified above so that the proper equipment may be made available. Presenters should bring at least one copy of their presentation to the meeting so that NHTSA can readily include the material in the public record.

A schedule of participants making oral presentations will be available in the designated meeting room before the beginning of the meeting. NHTSA will place a copy of any written statement in Docket No. 95-95; Notice 1. The public may inspect the Docket for comments and statements which may be received before or after the meeting. A verbatim transcript of the meeting will be prepared and also placed in the NHTSA docket as soon as possible after the meeting.

Participation in the meeting is not a prerequisite for the submission of written comments. NHTSA invites written comments from all interested parties. It is requested but not required that 10 copies be submitted.

If a commenter wishes to submit certain information under a claim of confidentiality, three copies of the complete submission, including purportedly confidential business information, should be submitted to the Chief Counsel, NHTSA, Room 5219, at

the street address given above, and copies from which the purportedly confidential information has been deleted should be submitted to the Docket Section. A request for confidentiality should be accompanied by a cover letter setting forth the information specified in the agency's confidential business information regulation (49 CFR Part 512.)

All comments received before the close of business on March 21, 1996, will be considered in formulating a

decision on the issues raised. After the closing date, NHTSA will continue to file relevant comments and information in the docket as it becomes available. It is therefore recommended that interested persons continue to examine the docket for new material.

Issued: January 30, 1996.

Barry Felrice,

*Associate Administrator for Safety
Performance Standards.*

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