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March 16, 1998

VIA FEDERAL EXPRESS

Dr. C. W. Jameson
National Toxicology Program
Report on Carcinogens, MD EC-14
3908 Patriot Drive
P. O. Box 12233
Research Triangle Park, NC 27709

Re: **Comments of Footwear Industries of America, Inc. on the Ninth Biennial Report on Carcinogens**

Dear Dr. Jameson:

The attached comments are submitted on behalf of Footwear Industries of America, Inc. ("FIA") in response to the National Toxicology Program's ("NTP's") notice in the Federal Register, 63 Fed. Reg. 5565 (Feb. 3, 1998), requesting comments on whether it is appropriate to list boot and shoe manufacture and repair (or any other "exposure circumstances") in the Ninth Biennial Report on Carcinogens ("BRC" or "the Report").

FIA is submitting two documents, one addressing the legality of listing boot and shoe manufacture and repair (or any other "exposure circumstances") in the BRC, and the other addressing the scientific inadequacy of the data relied upon by NTP as a basis for listing boot and shoe manufacture and repair in the BRC.

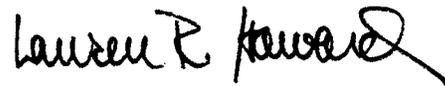
As set forth in the attached comments submitted by the undersigned and Ralph E. Mosely, FIA opposes listing or any other reference to boot and shoe manufacture and repair or any other "exposure circumstances" in the Ninth BRC. From a legal standpoint, we oppose this listing because NTP is expressly exceeding its statutory authority to list chemical substances by listing boot and shoe manufacture and repair or any other "exposure circumstances." From a scientific standpoint, FIA believes that the identification of footwear manufacture and repair as a carcinogenic "exposure circumstance" is unwarranted because:

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- There is no evidence associating cancer with modern U.S. footwear manufacturing plants.
- The two IARC reports cited are 15 and 16 years old and do not represent factory conditions in today's industrialized nations.
- NTP has accepted IARC's reports without independent review to determine whether their findings were applicable to industrial conditions here in the United States. A careful review of the individual studies comprising IARC's two reports clearly reveals that they do not apply.

We thank you for the opportunity to submit these comments prior to the publication of the Report in its final form.

Very truly yours,



Lauren R. Howard
LeAnn M. Johnson
Counsel for Footwear Industries
of America, Inc.

Enclosures

COMMENTS OF FOOTWEAR INDUSTRIES OF AMERICA, INC. ON THE

LEGALITY OF LISTING BOOT AND SHOE MANUFACTURE AND REPAIR IN

THE NINTH BIENNIAL REPORT ON CARCINOGENS

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March 16, 1998

INTRODUCTION

Footwear Industries of America, Inc. ("FIA") opposes the National Toxicology Program's ("NTP's") proposal to list boot and shoe manufacture and repair as an "exposure circumstance" in the Ninth Biennial Report on Carcinogens ("BRC" or "Report") in direct contravention of its legal authority to list chemical substances. 42 U.S.C. § 241(b)(4)(A). For the legal and scientific reasons set forth below, we urge you to determine that it is inappropriate to refer anywhere in the Ninth BRC to boot and shoe manufacture and repair. FIA is the national trade association representing manufacturers and distributors of nonrubber footwear and their suppliers.

A. NTP Lacks Statutory Authority To List Exposure Circumstances In The BRC.

Under the 1993 amendments to the Public Health Service Act, the Secretary of the Department of Health and Human Services ("the Secretary") is required to publish a biennial report which contains a list of all substances that are known, or reasonably suspected, to be carcinogens. 42 U.S.C. § 241(b)(4)(A). There is no legal basis to support NTP's proposal to list "exposure circumstances" in the Report. In fact, NTP has expressly stated that manufacturing processes "do not qualify for formal review for BRC listing because no specific agent, substance or mixture has been identified with the exposures involved." 61 Fed. Reg. 55,165 (1996) (emphasis added). Listing "exposure circumstances" in the Report is therefore in direct contravention of NTP's statutory authority to list only substances, a fact conceded by NTP.

At most, the statute permits inclusion of information concerning the nature of an exposure to one of the specific substances listed in the Report. See 42 U.S.C. §241(b)(4)(B). However, even assuming that industries could properly be listed in this context, the monographs prepared

by the International Agency for Research on Cancer ("IARC"), upon which the Report relies, make no attempt to link footwear manufacturing to any listed substance, with the sole exception of benzene -- a substance that has not been used in the manufacture of shoes in the United States for more than 25 years. IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Vol. 25, Table 2, 262 (1981) ("Monograph Vol. 25"). In fact, the IARC research only suggests a possible link to cancer from leather dust, a "substance" that is not listed as a carcinogen in the Report. Id. at 274.

It is clear that "boot and shoe manufacture and repair" is not a "substance" within the meaning of the statute. It is equally clear that the listing of boot and shoe manufacture and repair does not in any way provide information concerning the nature of exposures to any of the specific substances identified in the Report. Therefore, the Secretary has no authority to include references to the boot and shoe manufacturing and repair industries in any section of the Ninth BRC.

B. There Is No Scientific Basis for Listing the Footwear Industry.

The statute authorizing the Secretary to issue the BRC requires that a credible scientific basis exist before a substance can be listed. 42 U.S.C. §241(b)(4)(A). The legislative history of the statute explains that the phrase "'suspected carcinogens' [was replaced] with 'substances. . . reasonably anticipated to be carcinogens,' in order to make it absolutely clear in the statute that there must be reasonable ground for designating a substance as a putative carcinogen." Joint House-Senate Summary and Explanation (Oct. 14, 1978) as reprinted in 1978 U.S.C.C.A.N. 9063, 9080.

However, there is no credible scientific evidence in the outdated and inconclusive IARC studies on which NTP relies to justify the listing of the footwear industry in the upcoming BRC. Comments of Ralph E. Mosely on Behalf of Footwear Industries of America, Inc. on the Ninth Biennial Report on Carcinogens ("Comments of Ralph Mosely"). In particular, the studies of shoemaking in other (often third-world) countries do not fairly describe the conditions in the technologically advanced operations of American shoe manufacture today.

Modern U.S. boot and shoe manufacturing facilities are marked by: (1) pervasive government occupational health regulations;^{1/} (2) a high degree of automation resulting in the removal of workers from many areas of exposure that existed in the older processes; and (3) a reduction or elimination of the use of certain materials and chemicals that are most suspected of being carcinogens. IARC did not account for these changes in rendering its determination that boot and shoe manufacture and repair is a process associated with increased incidence of cancer. Comments of Ralph Mosely.

When FIA alerted NTP to these problems with the IARC research in 1986, the Fourth Annual Report on Carcinogens deleted the reference to boot and shoe manufacturing repair in the section of the Report identifying technological processes known to be carcinogenic. NTP retained only a brief reference to boot and shoe manufacturing in the Introduction to the BRC, but included several disclaimers, including the following:

- (1) Manufacturing processes "vary significantly" in different countries;
- (2) Manufacturing processes have changed significantly over the last few years; and
- (3) There is a great likelihood of variation in exposures to the cause of cancers.

^{1/} See attached exhibit A, listing applicable regulations.

National Toxicology Program, Fourth Annual Report on Carcinogens at 10.

Because of the lack of valid and credible data justifying the identification of the entire U.S. boot and shoe manufacturing industry as carcinogenic, there is insufficient scientific basis for listing boot and shoe manufacture and repair in the Ninth BRC.

CONCLUSION

Footwear Industries of America, Inc. urges the National Toxicology Program not to list boot and shoe manufacture and repair in the Ninth Biennial Report on Carcinogens. The unwarranted identification of boot and shoe manufacture as an exposure circumstance linked to increased incidence of cancer creates the potential for increased regulation, given that many federal and state health initiatives are launched from NTP findings. In addition, American shoe companies could be faced with unjustified increases in insurance and legal costs.

Such problems would clearly be hard for this beleaguered industry to bear. Imports increased from 175 million pairs in 1968 to more than 1 billion pairs in 1996, capturing more than 90 percent of the U.S. market in that year. With this loss of all but a small share of domestic consumption, U.S. production declined from 642 million pairs in 1968 to less than 150,000 pairs in 1996. As a result, there has been a net loss of more than 230 factories and more than 40,000 jobs in the past decade alone. At the end of 1996, only 45,000 workers still produced nonrubber footwear in this country.

Considering the potentially serious consequences of NTP's decision to list boot and shoe manufacture and repair in this Report, statutory authority and substantial scientific evidence should be required before this entire industry is labeled carcinogenic.

**IARC STUDIES REFERENCED REGARDING
BOOT AND SHOE MANUFACTURING AND REPAIR
AND THEIR
ALLEGED RELATIONSHIP WITH CANCER**

Type of Cancer	Author(s) and Year	Summary of Findings
Mesothelioma	Decouffe, P. (1980) Vianna, N. J. and Polan, A. K. (1978)	<ul style="list-style-type: none"> Asbestos (only known cause of mesothelioma) is not now, and probably never has been, used in U. S. footwear manufacturing industry. Work history of subjects was not detailed - if at any time they "made shoes", they were counted.
Nasal and Lung Cancer	Acheson, E. D. (1976) Acheson, E. D., Cowdell, R. H. and Jolles, B. (1970) Acheson, E. D., Cowdell, R. H. and Rang, E. (1972) Cecchi, F., et al (1980) Decouffe, P. (1979) Delmarre, J. F. M. and Themans, H. H. (1971) Debois, J. M. (1969) Lobe, Von L. P. and Ehrhardt, H. P. (1978) Menck, H. R. and Henderson B. E. (1976)	<ul style="list-style-type: none"> Several studies concerned "wood dust" exposure from wood heels or wood shoes (Dutch and German). U. S. manufacturers do not shape wood to make shoes. Most studies involved limited population samples. Most studies did not consider smoking or snuff use. Many studies emphasized "exceedingly dusty" conditions or "inadequate ventilation" in "small shops".
Hematopoietic and Lymphoreticular Cancer	Vigilani, E. C. (1978) Vigilani, E. C. and Formi, A. (1976) Vigilani, E. C. (1976) Mazzella di Bosco, M. (1964) Aksoy, M. et al (1976), (1978)	<ul style="list-style-type: none"> All these studies involve worker exposure to benzene, a chemical long "banned" in America. Workers in U. S. shoe factories are not exposed to benzene.

**IARC STUDIES REFERENCED REGARDING
BOOT AND SHOE MANUFACTURING AND REPAIR
AND THEIR
ALLEGED RELATIONSHIP WITH CANCER**

<p>Bladder Cancer</p>	<p>Versluis, J. J. (1949) Wyrnder, E. L., et al (1963) Veys, C. A. (1974)</p>	<ul style="list-style-type: none"> • The latest study is over 20 years old and studied deaths only from 1965-1970. • Work history was usually obtained from "occupation" listed on death certificate - work history was poorly documented • Smoking, a primary concern in bladder cancer studies, was not included in most studies.
<p>Other Cancers</p>	<p>Versluis, J. J. (1949) Decouffé, P., et al (1977) Decouffé, P., (1979)</p>	<ul style="list-style-type: none"> • One study is almost 50 years old. • The findings reported were incidental to the main studies. • IARC's own conclusion was that the findings could not be evaluated.

**COMMENTS OF
RALPH E. MOSELY
ON BEHALF OF
FOOTWEAR INDUSTRIES OF AMERICA, INC.**

**REGARDING WHETHER
"BOOT AND SHOE MANUFACTURE AND REPAIR"
SHOULD BE LISTED IN THE
NINTH BIENNIAL REPORT ON CARCINOGENS**

**NATIONAL TOXICOLOGY PROGRAM,
U.S. PUBLIC HEALTH SERVICE
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

NOVEMBER 18-19, 1996

**FOOTWEAR INDUSTRIES OF AMERICA, INC.
1420 K Street, NW, Suite 600
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**TECHNICAL COMMENTS OF RALPH E. MOSELY
ON BEHALF OF FOOTWEAR INDUSTRIES OF AMERICA
Regarding whether "Boot and Shoe Manufacture and Repair"
should be mentioned in the Eighth Biennial Report on Carcinogens**

Good morning. I'm Ralph Mosely, and I am appearing here today on behalf of Footwear Industries of America, Inc. ("FIA"). FIA is the trade association representing U.S. manufacturers of nonrubber footwear, importers/distributors, and a substantial number of suppliers to the leather trades.

I am a Certified Safety Professional and have been involved with professional safety and industrial hygiene activities in both industry and in education since 1966. I have been personally involved with the footwear manufacturing industry for over twenty years, serving for over ten years as the Corporate Director of Employee and Environmental Safety for Genesco, Inc., one of the nation's largest footwear manufacturers, and for another decade as the President of Mosely and Associates, Inc., an industrial and environmental safety consulting firm in Nashville, Tennessee. I also have taught courses in industrial hygiene, hazardous materials, safety management and other safety related areas for seven years as an Associate Professor in the School of Engineering at Tennessee State University and at the University of Tennessee. I have written or edited four books on industrial safety and have served for many years with several professional safety organizations, including the Executive Committee and Board of Directors of the National Safety Council. I am listed in "Who's Who in Science and Engineering", "Who's Who in the South and Southwest" and in "Emerging Leaders in America" and other similar listings for the safety activities in which I have been involved.

I would like to begin by thanking Dr. Hart, Dr. Jameson and others at NTP for extending an invitation to FIA to submit comments and testimony on whether manufacturing processes should be referenced in the Eighth Biennial Report. I had the privilege of addressing the National Toxicology Program Committee on this very issue on April 27, 1987, in Washington. NTP agreed with our conclusions at that time, and removed our industry from the body of the Fourth Annual Report. Unfortunately, this issue has risen again. It is extremely interesting to me that we are making the same points now, in 1996, as we did in 1987. The fundamental issue has not changed in the last 9½ years, and the facts supporting the points I will make today are even more dramatic and supportive.

I. INTRODUCTION

The footwear industry is extremely concerned with the NTP's introductory "mention" of the footwear industry ("Boot and Shoe Manufacture and Repair") in its Annual Reports. We continue to believe, as we have throughout this process, that (1) there is not a shred of evidence associating cancer with footwear manufacture under modern conditions in the United States; in fact, (2) the only comprehensive and recent epidemiological study of the modern domestic footwear industry found virtually no statistically significant incidences of cancer, as had been found in outdated, European factories and those of lesser developed nations; (3) the International Agency for Research on Cancer ("IARC") references which are cited by the NTP in its Fourth Annual Report, as well as the Fifth, Sixth, and Seventh Annual Reports, as well as the draft of the Eighth Biennial Report, were accepted by NTP at face value without independent review to determine whether those findings were applicable to industrial conditions in the United States;

and (4) only substances and not industries or industrial processes were mandated by Congress for inclusion in the Annual Reports.

The NTP is well aware that many federal and state health, safety and environmental initiatives are launched from NTP findings. These regulatory initiatives vary from such actions as the Occupational Safety and Health Act's ("OSHA") Hazard Communications Standard to numerous state safety regulations. Liability insurance costs and toxic tort lawsuits are also driven, in part, by NTP findings. It is critical, therefore, in carrying out its mission -- and certainly everyone recognizes that the NTP has an essential mission -- that the NTP examine very closely the evidence it cites in connection with any substance or industrial process being associated with cancer. Even tentative findings by the NTP in any of its official publications can lead to costs and other ramifications so great that scores of factories could close.

I would like to briefly recount, in the information presented below, the concern of the footwear industry with NTP's listing of "Boot and Shoe Manufacture and Repair", whether in introductory comments, an appendix, or in the main body of the report, as a manufacturing process or industry that is linked to high incidence rates of cancer.

II. HISTORY OF THE FOOTWEAR MANUFACTURING INDUSTRY AND NTP'S ANNUAL REPORTS

In December 1985, the Public Health Service announced in the Federal Register that the NTP's Fourth Annual Report would add "Boot and Shoe Manufacture and Repair (Certain Occupations)" to the list of occupations in which employees are exposed to carcinogens. The footwear industry convened a task force to analyze the NTP's proposed Report and its underlying IARC references.

FIA submitted detailed written comments to the NTP on April 3, 1986, protesting the proposed listing because there was no established causal link between the modern footwear industry in the United States and cancer and, further, the NTP was to review substances, not industries. Although the industry was referenced in the final version of the Fourth Annual Report's Introduction, the section on "Boot and Shoe Manufacture and Repair" was eventually deleted from the final Report because neither the specific causes of the cancers reviewed nor the specific related steps in the processes were identified and because it was recognized that manufacturing processes vary significantly from country to country and from one decade to another. NTP's Fifth, Sixth and Seventh Annual Reports continued that same format, but each year gradually they began to remove the "disclaimers" that had been present in the Fourth Annual Report. NTP's draft Eighth Biennial Report, however, continues to include Boot and Shoe Manufacture and Repair in the Introduction, may also list all the manufacturing processes in an appendix to the report and will reportedly remove more of the "disclaimers" that had been placed in front of the previous listings. Those "disclaimers" from prior years included: (1) that IARC (and by incorporating these statements in their report, NTP) has recognized that manufacturing processes vary significantly from one country to another; (2) that the likelihood is great of variation in exposures to whatever caused the cancers; and (3) that these manufacturing processes have also changed significantly in several countries over the last few years, particularly with regard to the mix of chemicals, etc.

Next, since NTP's Fourth Annual Report would have relied exclusively on IARC's findings with respect to the footwear industry, FIA attempted to present our analysis directly to IARC at its March 10-17, 1987, conference in Lyon, France, at which time IARC endeavored to update all of its 35 Monographs. IARC denied permission for our representative to speak or even

to submit our written report. It is therefore incumbent upon our own government to take particular care before accepting IARC conclusions and to evaluate fairly the evidence or criticism presented by other sources.

III. SUMMARY OF REASONS WHY THE FOOTWEAR MANUFACTURING INDUSTRY SHOULD NOT BE CITED IN NTP's BIENNIAL REPORT

The IARC Monographs relied upon by the NTP are inadequate as a basis of listing the footwear industry in its reports because all of their supporting references contain one or both of the following attributes. First, information about the occupational and personal health histories of the subjects is insufficient to identify the probable causes of the cancers. The references contained little or no information on the smoking or snuff habits of the studies' subjects, even though such information was considered important. There was also little or no information about other environmental exposures to carcinogens, long term employment histories, diet or other health habits.

Second, and equally as important from a researcher's point of view but much more important if you are a worker in an American footwear manufacturing plant, the working conditions studied differ in significant and relevant ways from those found in modern United States boot and shoe manufacturing facilities. Many of the studies referenced foreign manufacturing processes which involved chemicals and conditions not found in today's domestic manufacturing industry. For example, the excessively dusty environments described in certain operations in foreign facilities do not exist in United States plants. Also, several studies involved highly toxic chemicals long ago banned here in our country.

IARC studies, by the very nature of their international focus, are not an appropriate basis for linking United States industries and industrial processes to cancer. While the effects on an

individual of exposure to a substance or chemical should not vary in different countries, a similar analogy cannot be made reliably with respect to industries. Because the processes and chemical exposures in an industry can vary immensely from one country to the next, international industrial studies yield no reliable conclusions about the relative risk of cancer in the United States.

The following sections will discuss in some detail why studies of shoe manufacturing processes in England, Holland, Turkey, Italy and elsewhere, as well as why studies based on outdated domestic processes, cannot support the conclusion that there is an association between cancer and today's boot and shoe industry in the United States.¹

IV. THE IARC STUDIES UNDERLYING THE REPORT DO NOT DEMONSTRATE AN ASSOCIATION WITH CANCER UNDER CONDITIONS IN THE UNITED STATES

In this section, we will review each conclusion contained in the boot and shoe listing and analyze the references supporting those conclusions. Two references were used by NTP in determining whether to include Boot and Shoe Manufacture and Repair as carcinogenic industry. The latest was "IARC Monographs Supplement 4" (the section on Boot and Shoe Manufacture and Repair (Group 1), found on pages 138-139), and published in 1982, ("The Supplement"). The other reference was "IARC Monograph Volume 25, Wood Leather and Some Associated Industries", which was published in 1981, ("The Monograph"). The very fact that these documents are now fourteen and fifteen years old is cause for extreme scientific concern.

¹It cannot be overemphasized that the various references cited in the IARC Monographs focused on specific conditions that do not exist in the United States boot and shoe industry. Also, many of the reports stated that no conclusions could be drawn from their findings. A representative compilation of limiting statements, of the sort referred to here, is contained in the chart at the end of these comments.

- A. **Mesothelioma:** IARC's latest reference associating a specific cancer with the footwear industry states: "three cases of mesothelioma were reported among 3,806 deaths in shoe workers, there was an earlier report of a female shoemaker (whose husband was also a shoemaker) who died of mesothelioma". See the Supplement at pg. 138. The statement is based on work by Decouflé and by Vianna and Polan, respectively. ²

Mesothelioma is a rare type of cancer which may be caused only by an exposure to asbestos fibers. The 1980 report by Decouflé was limited to a review of 3,806 death notices published during the period 1966-77, where "shoemaker" was listed as the last known occupation. During this eleven-year period, the average yearly number of shoe workers employed in the industry was 194,000. From this population, the death notices revealed three deaths from mesothelioma.

Decouflé's paper acknowledges that he was unable to confirm the diagnosis of mesothelioma. He also was unable to investigate the nature of other types of employment the three shoe workers might have had. The individuals are identified in the study as "A," "B," and "C." Individual A was a female, 72 years old at the time of death, whose first year of employment in the shoe industry was 1923. No other information, including the duration of her employment in the shoe industry or the types of jobs that she may have had, is known about her. Worker B was a male who died at the age of 60. The date of his initial employment is unknown. Worker C, a female who died at age 72, began her employment in 1926 and continued as a shoe worker in the industry for 41 years, until 1967. The duration of A and B's employment in the industry, as well as A, B or C's

² See Decouflé, P. (1980) "Mesothelioma Among Shoe Workers" and Vianna, N. J. and Polan, A. K. (1978) "Non-Occupational Exposure to Asbestos and Malignant Mesothelioma in Females." See also IARC Supplement 4 at 138-139.

possible non-shoe related employments, are unknown. Whether these workers were employed in an asbestos-related industry during their careers is not stated on their death notices. However, since they worked in very old plants, dating from before the 1920's, it is possible that they were exposed to asbestos from factory insulation materials. Similarly, environmental exposures to asbestos outside the workplace are unknown.

Decouflé states that he knows of no specific source of asbestos exposure in the shoe industry. He speculates that asbestos filler may be used in rubber soles and heels. Our research shows that asbestos has not been used for these products within at least the last 30 years and that asbestos was probably never used at all. Certainly, today's shoe industry uses no asbestos. Thus, there is no basis on which to expect any association of mesothelioma with modern footwear factory conditions in the United States.

The study by Vianna and Polan specifically focused on non-occupational exposures to asbestos. Their report concluded that "the possibility of a genetic predisposition to malignant mesothelioma" may have been the link to cancer in the studies' subjects. The study acknowledges that the hazards of exposure to asbestos in the general environment is unclear. It recites numerous reports of mesothelioma detected in individuals exposed to asbestos dust from dusty clothing and from asbestos air pollution in the neighborhood. The Supplement cites to only one individual found to have mesothelioma who was also a shoemaker: a female who died at age 85 in 1974. Although neither the Supplement nor the study explains where asbestos exposure may have been found in a shoe factory, the Supplement asserts without explanation that "shoemaker" is an occupation where there is exposure to asbestos.

There is no evidence that asbestos was ever used in the manufacturing of shoes in the United States. Certainly, asbestos is not used in any way in the manufacture of shoes in the United States today. We believe that no fair or reasonable conclusion can be drawn from the Decouflé or Vianna and Polan studies that mesothelioma is associated with shoe manufacturing in the United States. Indeed, the studies themselves draw no such conclusion.

B. Nasal and Lung Cancer: The Report states that "Employment in the boot and shoe industry is causally associated with the development of nasal adenocarcinomas" See the Monograph at page 274. The Monograph reference cited in support of this proposition relies primarily on reports published by E. D. Acheson, a researcher who was primarily interested in nasal cancers discovered in woodworkers, which he believed resulted from exposure to wood dust.

His investigation of woodworkers led to an examination of shoemakers in Northamptonshire, England, in the 1950's through the 1970's. At that time, wood fiberboard was used extensively in the Northamptonshire shoe industry. Wood products are rarely used in the United States shoe industry today, and the limited amount of products that are used come to the shoe factory pre-processed, shaped, beveled and ready for use. As a result, shoe factories in the United States have no wood dust in their environment.

Similarly, papers that speculate on the existence of a link to cancer from leather dust were undertaken in foreign plants where "extremely dusty" conditions prevailed. Due to stringent OSHA regulations in the United States, domestic workers are protected against

exposure to dusty or fume-filled environments through the use of venting and exhaust equipment. Moreover, the use of leather soles has steadily and substantially declined in the domestic industry since the end of World War II. See, the Monograph at page 255. Cutting and grinding of leather soles in English shoe factories was reported to have produced the most dusty conditions in the manufacturing process but are likely not even present in England today. Thus, Acheson concludes:³

It is important to point out that the environmental conditions which gave rise to the cases of intranasal cancer reported in this paper existed in the industry many years ago.

The following is a summary of important points presented in the referenced articles used to support IARC's conclusion of a link between nasal cancer and the boot and shoe industry. Note that the studies used limited sampling with no history on the subjects' use of tobacco or snuff even though such use was considered important. The articles also focus on exceedingly dusty (frequently wood dust) and dirty conditions that are nonexistent in today's U.S. shoe factories:

³Acheson, E. D., "Nasal Cancer in the Furniture and Boot and Shoe Manufacturing Industries," *Preventive Medicine* 5 (1976), at 295. Acheson describes at 308 of his study that among the dustiest jobs in the shoe factories were: (1) sorting leather in the rough stuff room; (2) the revolution process of operating insole surface scouring machines; and (3) heel and sole trimming and scouring.

The "rough stuff" room was the location where sole leather was sorted from the tannery before using. Today, in the U.S., many soles are already pre-cut when they reach the factory, and the "rough stuff" room does not exist. The operations referenced all relate to cutting or grinding functions with leather soles, not uppers. Upper leather is tanned through a different process than is sole leather, however, all cutting or grinding operation in U. S. shoe factories are subject to OSHA's strict rules on ventilation and dust capture. Also, because the use of leather soles has declined, any problem associated with dust from related operations is also diminished.

1. Acheson, E. D., "Nasal Cancer in the Furniture and Boot and Shoe Manufacturing Industries," Preventive Medicine 5, 295-315 (1976)
 - (a) The article reports cases diagnosed between 1950-1974 in Northamptonshire, England. Pg. 309.
 - (b) Fourteen of the twenty patients examined worked in the dustiest operations. "The analysis of the location of the cases within the industry very much strengthens the evidence in favor of a causal relationship between the inhalation of dust associated with the manufacture of boots and shoes and nasal cancer." Pg. 311.
 - (c) "The material therefore suggests that the excess of nasal cancer extends to these men who often work in small shops under dusty conditions without adequate ventilation." Pg. 312.
 - (d) Snuff "may be a contributory factor and deserves further study." Pg. 313.
 - (e) Acheson concludes that nasal cancer was a risk for men who "are concerned with the dusty operations used in the manufacture and repair of leather footwear."
 - (f) He states that many changes have now been made in ventilation and hygiene. Pg. 314.
2. Acheson, E. D., Cowdell, R. H., and Jolles, B., "Nasal Cancer in the Northhamptonshire Boot and Shoe Industry," Br. Med. J., i, 385-393 (1970)
 - (a) The study covers only 1953 to 1967. Pg. 385.
 - (b) The study suggests a causal relationship with dust and a possible link with wood products through "vegetable infusions from wood, bark, fruit, leaves, galls, etc., used in tanning leather for soles and heels." Pg. 390.
 - (c) It references the Debois (1969) study of 29 cases of nasal cancer, two of which were shoemakers, as the "only reference which we have found to nasal cancer in workers in the footwear trades." Pg. 391.
3. Acheson, E. D., Cowdell, R. H., and Rang, E., "Adenocarcinoma of the Nasal Cavity and Sinuses in England and Wales," Br. J. Indus. Med., 29, 21-30 (1972)

Summary -- Same data as Acheson study (1970) except for one case from Wales that was added.

4. Cecchi, F., et al., "Adenocarcinoma of the Nose and Paranasal Sinuses in Shoemakers and Woodworkers in the Province of Florence, Italy (1963-77)," Br. J. Indus. Med., 37, 222-225 (1980)

Study of cancers of the nose and paranasal sinuses of both shoemakers and woodworkers from Florence, Italy, identified between 1963 and 1977.

- (a) "Much of the shoe manufacturing is done in small establishments and home work shops." Pg. 222.
- (b) Only seven shoemakers were in study (only three woodworkers). Of the seven, five were "heavily exposed to leather dust." Summary emphasizes heavy "intensity of exposure (probably not less than 10 hours a day six days a week) and the poor ventilation of the work rooms." Pgs. 223-224.

5. Debois, J. M., "Tumors Found in the Nasal Cavities of Woodworkers," Tijdschr. v. Geneeskd., 2, 92-93 (1969-Lemish)

Thirty workers were examined between 1958-1968. Only two were listed as "shoemakers." No mention was made of exposure duration. Since this was a study of "woodworkers," and the study is Flemish, we may assume that wooden shoes are being made.

6. Decouflé, P., "Cancer Risks Associated with Employment in the Leather and Leather Products Industry," Arch. Environ. Health, 34, 33-37 (1979)

The study concerned leather workers, shoe workers and shoe repairers, and incorrectly theorized exposure to hexavalent chrome in the tanning process (trivalent chrome is the standard tanning valence) along with exposure to azo dyes, various amines and syntans that could be the cause of cancers found among workers in the leather industry. (Note that the study lacked any exposure data on the chemicals to which it cited).

7. Delemarre, J.F.M. and Themans, H.H., "Adenocarcinoma of the Nasal Cavities," Ned. T. Geneeskd., 115, 688-690 (1971)-(Dutch)

The translation of this Dutch report appears to indicate that of the 16 patients studied from 1965-1968, only one was a shoemaker, but his job was to shape/finish/smooth Dutch wooden shoes.

8. Lobe, Von L.P. and Ehrhardt, H. P., "Adenocarcinoma of the Nose and Paranasal Sinuses - An Occupational Disease in Workers in the Wood Industry," Dtsch. Gesundheitswes, 33, 1037-1040 (1978)-(German)

The study concerned woodworkers. Table 5 contains the only mention of shoe making, but even that reads "shoemaker, wood grinder", so we may assume again

that wooden heels or soles or entire shoes were being made and the exposure was to wood dust, not leather dust.

9. Menck, H. R., and Henderson, B. E., "Occupational Differences in Rates of Lung Cancer," J. Occup. Med., 18, 797-801 (1976)

The study concerned lung cancer in Los Angeles County for those who died from 1968-1970 (2161 deaths) and 1,777 lung cancer deaths from 1972-1973. Although some limited references are made to leather products and shoe repairing, there is no reference to boot or shoe manufacturing.

C. Hematopoietic and Lymphoreticular Cancer: The Supplement states that "the occurrence of leukemia and aplastic anemia among shoe workers exposed to benzene is well documented." See the Supplement at page 139 and the Monograph at page 274. Of the papers cited in the IARC Monographs relating to hematopoietic and lymphoreticular cancer, Volume 25, previously referenced, and volume 29, Benzene, pages 93 - 148, published in 1982, both deal with exposure to benzene.

Briefly stated, these articles are statistical studies of benzene as a causative factor in certain blood diseases such as leukemia and aplastic anemia. All were written in the mid-to-late 1970's (except Di Bosco - 1964) and the effects on workers of the ban on benzene was by then just being noted.

Although this fact was acknowledged in the Monograph, it was given little weight or emphasis.⁴ This is surprising considering the radical turnabout that appears to have occurred as a result of the benzene ban. In fact, it could be argued that in view of the more current findings, this older data now warranted nothing more than a footnote reference.

⁴See Monograph Volume 25, p. 271.

As mentioned in our earlier comments, benzene has not been used in the United States boot and shoe manufacturing industry for probably at least 25 years. Consequently, there can be no concern of benzene-related cancer arising from the domestic boot and shoe manufacturing industry today.⁵

D. Bladder Cancer: The Supplement asserts "There is evidence of an increased risk of bladder cancer associated with employment in the leather industry. Although boot- and shoemakers were included in these studies, it is not possible to determine whether the risk related to them in particular or to other occupational subgroups." See the Supplement at page 138. Studies relied on by IARC concerning bladder cancer conclude that it may be associated with heavy smoking and with exposure to liquid or paste dyes used by shoe repairers in small shops.⁶ There is absolutely no link asserted to shoe manufacturing. Because the manufacturing and repairing industries are distinct segments of the broader

⁵The five papers discussed in the Monograph are as follows: (1) Vigiliani and Forni (1976) "Benzene and Leukemia." The article studies the exposure of benzene to acute and chronic leukemia. The only reference to the footwear industry states that "the most convincing cases of benzene leukemia are those occurring in factories where there were outbreaks of chronic benzene poisoning." The study concluded that in another industry in which the use of benzene as a solvent had been suspended in 1964, no new cases of aplastic anemia or leukemia had been detected. (2) Vigiliani (1976) "Leukemia Associated with Benzene Exposure." In this article, Vigiliani again notes that possible benzene-related leukemia was evident in shoe workers prior to the banning of benzene as a solvent for inks and glues in Italy in 1963. (3) Mazzella Di Bosco (1964) "Considerations on Some Cases Benzol Induced Leukemia Occurring in Shoe Factory Workers." This paper was translated from Italian by faculty members of the State University of New York at Binghamton. The paper studies only leukemia cases which arose from the possible association with benzene in the workplace prior to the 1963 ban on benzene in Italy. (4) Aksoy, et al (1976) "Types of Leukemia in Chronic Benzene Poisoning -- A Study of Thirty-Four Patients"; and (5) Aksoy and Erdem (1978) "Follow-up Study on the Mortality and the Development of Leukemia in 44 Pancytopenic Patients with Chronic Exposure to Benzene." These reports review workers in Turkey who were subjected to extremely high concentrations of benzene over periods of up to 15 years under conditions that do not, and probably never have, existed in the United States.

⁶The studies linking bladder cancer to the overall leather industry is Veys, C.A. (1974) and Widner, et al (1963), neither of which assert a link between bladder cancer and the shoe manufacturing industry.

leather products industry grouping, the Report should make clear that there is no evidence of risk of bladder cancer in the U.S. shoe manufacturing industry.

- E. Other Cancers Not Previously Specified:** The Supplement comments on several hypotheses - generating surveys that have suggested associations between boot and shoe manufacture or repair and cancers of the lung, oral cavity and pharynx and stomach, but states that "in view of the design of the pertinent studies", these findings could not be evaluated. See the Supplement at page 139.

The Monograph also referenced a study by Versluys in 1949 and two studies by Decouflé, et al (1977 and 1979), but those studies were hampered by insufficient work histories. For example, persons were included that had, at any time, worked as "shoehands", "shoemakers", or "shoe repairers". These results were incidental to the studies' main purposes. Again, the Monograph itself states that "these findings cannot be evaluated". See the Monograph at page 274.

- F. Miscellaneous Comments About the IARC Reports:** The two IARC reports, the Supplement and the Monograph make no assertion of a cancer link to the industry other than for the specific types of cancers discussed above, which were supported by references to production processes and environmental conditions that are substantially different from those that exist in the modern U. S. boot and shoe manufacturing industry.

The Supplement contains no information at all concerning worker exposure to agents or processes linked with cancer. The Monograph, in its section entitled "Qualitative and Quantitative Data on Exposures", has a table of one survey of dust

concentration levels and particle sizes done in a UK plant in 1976 and a listing of chemicals that "are or have been found" in boot and shoe manufacturing plants. Many involve chemicals that have not been used in U.S. plants in decades, if at all, and the only data regarding worker exposure to chemicals came from a UK study that did not list reference information regarding a date or specific location. Interestingly, it reported that the only levels of "solvent vapors" in excess of permissible levels were those associated with exhaust ventilation systems rated "poor" or "none". This study obviously was accomplished some time prior to the date the Monograph was published (1981). Modern footwear manufacturing plants, and particularly those in the United States, have stringent exhaust ventilation requirements under OSHA regulations so that exposure to dusts or solvent vapors is minimal or non-existent.

In the absence of substantial and reliable evidence that U.S. shoe workers are today exposed to substances that are specifically listed by NTP as carcinogenic, the Boot and Shoe Manufacturing Industry should not be listed, even in the Introduction or in an Appendix, as a carcinogenic industry or process.

V. CONCLUSION

The FIA appreciates this opportunity to provide its comments as NTP continues preparation of the Eighth Biennial Report. The FIA believes strongly that its members will be irreparably harmed if this Report lists the Boot and Shoe Manufacturing Industry, either in introductory comments, the body of the Report itself or in an Appendix. Some have suggested that if NTP wishes to comment upon IARC's reference to the Boot and Shoe Manufacturing Industry, notwithstanding the fact that FIA (as well as many others) believe that only substances

and not industries or industrial processes were mandated by Congress for inclusion in the Annual Reports, that such a comment should not be made in the body of the Report, but as anecdotal comments, complete with the necessary "disclaimers", such as, (1) the age of the IARC Monograph (1981) and Supplement (1982), (2) that most processes studied have changed significantly since the time they were studied, and, (3) that there may be significant differences in safety and environmental regulations governing footwear factories throughout the world that may bring about conditions unlike those reviewed by IARC. We do not share that concept. We believe that a fair and careful review of the evidence underlying the Eighth Biennial Report demonstrates conclusively that there is no evidence of an abnormal association of cancer with the modern boot and shoe industry in the United States, and therefore no mention at all should be made of IARC's fifteen year old report.

⁷ Monographs were based on studies even older than 1981 and 1992.

REVIEW OF INDUSTRIAL AND ENVIRONMENTAL SAFETY REGULATIONS FOR THE FOOTWEAR INDUSTRY

ASBESTOS

Law:

Williams-Steiger Occupational Safety and Health Act (OSHA), Clean Air Act (CAA), Federal Toxic Substance Control Act (TSCA)

Regulations:

29 CFR 1910, General Industry Standards

29 CFR 1926, Asbestos Standard for Construction Industry

40 CFR 61, National Emission Standards for Hazardous Air Pollutants (NESHAPS)

52 CFR 5618, Asbestos Abatement Projects, Worker Protection Rule

DREDGING, FILLING OR CONSTRUCTION IN STREAMS OR FLOODPLAINS

Law:

Rivers and Harbors Act of 1899, Clean Water Act of 1977 and the Marine Protection, Research and Sanctuaries Act of 1972, as amended.

Regulations:

33 CFR 320-330

40 CFR 404

EMISSIONS TO THE ATMOSPHERE

Law:

The Clean Air Act (CAA) and Amendments of 1970, 1973, 1977, 1978, 1990 and others

Regulations:

40 CFR 50, National Primary and Secondary Ambient Air Quality Standards (NAAQS)

40 CFR 60, Standards of Performance for new Stationary Sources

40 CFR 61, National Emissions Standards for Hazardous Air Pollutants (NESHAPS)

HAZARD COMMUNICATION/RIGHT-TO-KNOW

Law:

Williams-Steiger Occupational Safety and Health Act of 1970 (OSHA)

Regulations:

29 CFR 1910.1200, Hazard Communication and Right-to-Know

HAZARDOUS MATERIALS TRANSPORTING

Law:

Hazardous Materials Transportation Act

Regulations:

49 CFR Parts 171 through 177

HAZARDOUS WASTE GENERATION, STORAGE, TREATMENT AND DISPOSAL

Law:

Resource Conservation and Recovery Act of 1976 (RCRA), Solid Waste Disposal Act Amendment of 1980, Hazardous and Solid Waste Amendments of 1984 (HSWA)

Regulations:

40 CFR Parts 260 through 268

OCCUPATIONAL SAFETY AND HEALTH REGULATIONS

Law:

Williams-Steiger Occupational Safety and Health Act of 1970 (OSHA)

Regulations:

29 CFR 1900-1999

POLLUTION SOURCE REDUCTION

Law:

Pollution Prevention Act of 1990, Superfund Amendments and Reauthorization Act of 1986 (SARA)

Regulations:

None promulgated to date under Pollution Prevention Act; 40 CFR Part 322 (c), and 326 apply under SARA

PUBLIC DRINKING WATER SUPPLY

Law:

Safe Drinking Water Act of 1974 and Amendments

Regulations:

40 CFR Parts 141, 142, and 143, National Primary and Secondary Drinking Water Regulations

PURCHASE OR SALE OF PROPERTY - ENVIRONMENTAL AUDITS

Law:

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)

Regulations:

40 CFR Parts 300 through 306

RELEASE/STORAGE OF OIL AND OTHER PETROLEUM PRODUCTS

Law:

Federal Water Pollution Control Act Amendments of 1972, Clean Water Act of 1977 and Amendments of 1987, and the Oil Pollution Act of 1990

Regulations:

40 CFR part 110, Discharge of Oil; Part 112 - Oil Pollution Prevention, Part 113 - Liability Limits for Small Onshore Storage Facilities, and part 114 - Civil Penalties for Violation of Oil Pollution Prevention Regulations

SARA III REQUIREMENTS

Law:

Superfund Amendments and Reauthorization Act of 1986 (SARA), also known as the Emergency Planning and Community Right-to-Know Act of 1986

Regulations:

40 CFR Part 355, Emergency Planning and Notification, 40 CFR Part 372, Toxic Chemical Release Reporting; Community Right-to-Know

SPILLS AND ACCIDENTAL RELEASES TO THE ENVIRONMENT

Law:

Comprehensive Environmental Response Compensation and Liability Act of 1980 (CERCLA)

Regulations:

40 CFR Part 302, Designation, Reportable Quantities, and Notification

STORM WATER DISCHARGES

Law:

Clean Water Act Amendments of 1987

Regulations:

40 CFR 122, 123 and 124, National Pollutant Discharge Elimination System Permit Application Regulation for Storm Water Discharges

UNDERGROUND STORAGE TANKS

Law:

Resource Conservation and Recovery Act of 1976 (RCRA); Hazardous and Solid Waste Amendments of 1984 (HSWA); Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)

Regulations:

40 CFR, part 264 and Part 280, Underground Storage Tanks

POLYCHLORINATED BIPHENYLS (PCB's)

Law:

Federal Toxic Substances Control Act (TSCA)

Regulations:

40 CFR, Part 761, Polychlorinated Biphenyls (PCB's) Manufacturing Processing, Distribution in Commerce, and Use Prohibitions

WASTE DISPOSAL SITES

Law:

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund)

Regulations:

40 CFR Parts 300 - 310

**WASTEWATER DISCHARGE TO
MUNICIPAL SANITARY SEWER SYSTEM**

Law:

Federal Water Pollution Control Act Amendments of 1972, Clean Water Act of 1977 and Amendments of 1987

Regulations:

40 CFR 403, Pretreatment Regulations; 40 CFR 404-470, Effluent Guidelines and Standards for Selected Industrial Classifications

**WASTEWATER DISCHARGES TO
SURFACE WATERS**

Law:

Federal Water Pollution Control Act Amendments of 1972, Clean Water Act of 1977 and Amendments of 1987

Regulations:

40 CFR 122 and 125, National Pollutant Discharge Elimination System Permit Regulations; 40 CFR 401-470, Effluent Guidelines and Standards for (Selected Industrial Classifications); 40 CFR Part 133, Secondary Treatment Regulation

WETLANDS

Law:

Clean Water Act of 1977 and Amendments of 1987

Regulations:

40 CFR par 230, 401 and 404, Guidelines for Specifications of Disposal Sites for Dredged or Fill Material