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Key terms: [biomarkers](#); [bitumen](#); [epidemiology](#); [exposure](#); [feasibility study](#); [road paving](#)

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Cancer risk for European asphalt workers

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Objectives The feasibility of a European epidemiologic study of cancer risk among asphalt workers was examined in Western Europe. The study was motivated by occupational and public health concern about possible health risk from exposure to bitumen fumes.

Methods Information on the accessibility and quality of epidemiologic resources, retrospective worker records, mortality and cancer incidence records, and exposures was requested from research institutes and road paving and asphalt mixing companies in 15 European countries.

Results Research institutes and asphalt companies in 12 countries responded. It was found that at least 44 companies in seven countries can be included in a retrospective mortality study of a minimum of 32 000 employees with 356 000 person-years (over 100 lung cancers). Coal tar will be an important confounder for these data. The power of a cohort study of workers who have never worked with tar-containing materials remains insufficient. Even in an ambispective study extending to the year 2005, the expected lung cancer deaths in a tar-free cohort would be only four.

Conclusions The results suggest that a case-referent study of lung cancer, nested in an international cohort of asphalt workers, represents the design of choice, conditionally on the possibility of assessing relevant individual life-time exposures. A cross-sectional determination of relevant biomarkers of exposure such as adducts in lymphocytes or the presence of metabolites of polycyclic aromatic compounds in urine in a group of workers exposed to bitumen fumes will provide further relevant information.

Key terms bitumen, biomarkers, epidemiology, exposure, feasibility study, road paving.

Extracts of steam-refined and air-refined bitumens¹⁴ are recognized as possible human carcinogens, while undiluted bitumens cannot be classified as to carcinogenicity (1, 3), given the insufficient epidemiologic evidence on

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14 In Europe, "asphalt" refers to what is known as "asphalt mix" (hot-mix asphalt) in North America. This is a mixture of graded mineral aggregates such as sized stone fractions, sands, and fillers (eg, fine limestone), a binder (bitumen), and an adhesion improver such as diamine and, previously, tar. Cutback bitumens and bitumen emulsions are mainly used for spraying and surface treatment. The European term "bitumen" corresponds to the North American "asphalt" or

the carcinogenic potential of bitumens (1, 3, 4). As a consequence, carcinogenicity evaluations of bitumens have relied on animal bioassay data.

Assessment of the carcinogenicity of bitumen fumes may have far-reaching industrial, economic, and public health implications. Bitumens are commonly being applied as the binder in asphalt mixes and in roofing applications. Previously, carcinogenic tar-based binders and adhesives have been used. A total of 712 million tons of hot mix asphalt was produced in Western Europe, the United States, and Australia in 1992 (5). The number of workers exposed to bitumen fumes is considerable (6, 7). For example, the number of current and former highway maintenance workers at all levels of the United States government exceeded 500 000 in 1989 (8).

Hansen (9, 10) reported unusually elevated overall cancer incidence and mortality among Danish mastic asphalt workers. Excess incidence was reported for all cancers and cancers of the oral cavity, esophagus, rectum, and lung. The study was subsequently criticized for selection and confounding biases (11), but the reply of the author (12) seemed to withstand the criticism.

Twenty epidemiologic studies related to cancer hazards among asphalt workers and roofers were identified and reviewed in a recent meta-analysis (4). The bulk of these studies was characterized by poor exposure data. In particular, the data were insufficiently specific to address the possible carcinogenicity of bitumen fumes. The aggregated results suggested an increased risk among roofers for cancers of the lung, stomach, and possibly skin cancer and leukemia. The excess may have been caused by polycyclic aromatic hydrocarbons (PAH) from coal tar products. The aggregated relative risks for road pavers and highway maintenance workers were consistently lower than for roofers for cancers of the lung, stomach, bladder, and skin. Their risk of skin cancer, however, was significantly elevated, according to one study only. In this study, miscellaneous and unspecified asphalt workers had a significant excess of lung cancer.

Because of the uncertainties, it was recognized that there was a need to assess the human carcinogenic hazard from exposure to bitumen fumes, asphalt fumes, and occupational exposures such as those found in road pavement applications. Consideration was given to the conduction of a large multicenter epidemiologic study to-

gether with a biomarker study. The major task of an international study would consequently be to assess the carcinogenic hazard from bitumen fumes, while controlling for confounding from exposures originating from coal tar, additional products with a substantial content of PAH, and other potential confounders, such as asbestos, silica dust, and motor engine exhaust.

An epidemiologic feasibility study was conducted in the United States (13). The conclusion reached was that "alternatives other than an industry-wide historical cohort mortality study be explored to assess the health effects of exposure to asphalt [p 4-4]". The conclusion was based on the low proportion of American companies having maintained employee records for a sufficiently long period and on the small size of most of the companies.

In 1993, the International Agency for Research on Cancer (IARC) and the European asphalt and bitumen/oil industry agreed to conduct an epidemiologic feasibility study on the cancer risk from bitumen-fume exposure among road pavement and asphalt mixing workers employed by European asphalt companies. The feasibility study was coordinated by IARC. The details can be found in an internal IARC report (14) and are summarized in this document.

Methods

The feasibility study involved companies and employees in road pavement and asphalt mixing operations. Roofing and waterproofing were not considered. Fifteen European countries with competent resources in occupational epidemiology and road paving and asphalt mixing companies affiliated with the European Asphalt Pavement Association (EAPA), the European producers and contractors of asphalt mixes, were selected: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, The Netherlands, Norway, Spain, Sweden, Switzerland, and the United Kingdom. A collaborator was identified in each country from among occupational epidemiologists. In most countries, an industry representative was nominated to identify suitable companies and to facilitate communication between them and the national epidemiologists.

"asphalt cement," referring to a binder composed of residuals from the nondestructive vacuum distillation of crude petroleum oil. This is to be distinguished from carcinogenic coal-based tar-derived materials. Wherever coal-tar has been abandoned, bitumen fumes represent the major current occupational exposure experienced by roofers. For details, see references 1 and 2. "Fumes," as used in this study, refer to both gaseous materials and condensed particles in a cloud from heated solid matter.

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Two questionnaires (available upon request from IARC) were constructed. An epidemiology questionnaire was sent to each of the national epidemiologists in the 15 countries. The information requested concerned human and material resources and funding for the national component study, availability of death and incidence records, record linkage, and confidentiality and protection of personal data. A company questionnaire was sent to each of the selected companies in the 15 countries. It concerned the history of road paving and asphalt mixing operations, the availability of data on materials used, employee records (access, period, retention, completeness, content, quality, size), exposure data, and information on tobacco smoking.

The questionnaire data were not systematically validated. Attempts were made to obtain missing data or clarify ambiguous data with the help of the collaborator or industry representative.

National feasibility was assessed by the following criteria: (i) availability of information needed for the establishment of the cohort, (ii) resources for the completion of the national component study, (iii) availability of unbiased employee files (personnel files and records), (iv) possibility of characterizing relevant exposures, and (v) collaborative motivation of the industry.

The assessment of the feasibility of the multicentric study was based on study size, power, the projected quality of exposure data, and induction-latency considerations.

For a cohort mortality scenario, cohort sizes and follow-up periods were estimated on different assumptions. For each feasible company, estimates were calculated of the cohort sizes and person-years that were expected to accrue during the different calendar periods and for the age groups. The data were then aggregated both within and across countries. Cohort sizes, expected numbers of lung cancer cases, and power figures (Poisson, no lagging) were calculated for two mutually exclusive (but combinable) types of cohorts, that is, entry cohorts (ie, cohorts defined as of entry to the asphalt industry) and cross-sectional cohorts (cohorts defined as its members belonging to the asphalt work force at some point in time with no data on previous employments; this deficiency derives from the fact that full-coverage, unbiased employee rolls are available for considerably later periods of time relative to the starting of the road paving or asphalt mixing operations in a number of companies). Another pertinent dimension was the timing of the study in regard to follow-up for cancer mortality. The following three options were considered: retrospective (follow-up until 1995), prospective (1995–2005), and ambispective (retrospective and prospective) follow-up. To correct for occasional incomplete company data, an annual turnover rate of work force was assumed at 10%, and an average age of 20 years was assumed at the onset

of exposure, with 40 years in the cross-sectional cohorts, if not otherwise indicated. The size of the nested case-referent study can be approximated from the lung cancer figures. The expected numbers were calculated using country-, age- and calendar-specific male mortality rates. The prospective (1995–2005) numbers of expected cancers were estimated according to the latest rates available.

Results

Collaborators in eight countries (Austria, Belgium, Greece, Ireland, Italy, Spain, Switzerland, and the United Kingdom) reported unavailability of sufficient data or resources for the establishment of a national cohort. Therefore seven countries (Denmark, Finland, France, Germany, The Netherlands, Norway, and Sweden) were left in which the study would be possible. Mortality follow-up can be done in all seven countries. Nationwide high-coverage cancer registries capable for incidence follow-up are operative in Denmark, Finland, Norway, and Sweden. In The Netherlands, the coverage of the nationwide register is high from the end of the 1980s.

Company size

For 44 of the 52 companies that responded in the seven countries, the information was sufficient for assessing feasibility. Thirteen of them were large companies (over 500 employees at the time of the survey), 13 were medium-sized (50–500 employees), and 18 were small (< 50 employees).

Employment files

The 44 feasible companies had their complete employee files established at the time of becoming operative or some subsequent time. "Completeness," for the purposes of this study, referred to the availability of person identification, date of birth, and job characterization or job title; all this for all employees. The files usually covered both those who were employed at the time of the establishment of the complete record system (employed survivors, ie, cross-sectional component of the cohort) and those who were employed subsequently ("entry" component).

Records of individual periods of employment are accessible in 41 companies, unavailable in two big German companies, and possibly accessible in one of the Norwegian companies. Job titles are missing in the records of 18 companies, and the availability of job titles was uncertain for six companies, leaving 20 companies with individual job titles recorded. Data on tobacco smoking are available in the files of 15 companies or their occupa-

Table 1. Numbers of companies reporting selected products and procedures. (N = total number of feasible companies, Yes = used, No = not used, ? = usage unknown)

	Denmark (N = 5)			Finland (N = 8)			France (N = 2)			Germany (N = 2)			The Netherlands (N = 18)			Norway (N = 7)			Sweden (N = 2)			All (N = 44)		
	Yes	No	?	Yes	No	?	Yes	No	?	Yes	No	?	Yes	No	?	Yes	No	?	Yes	No	?	Yes	No	?
Mixing	5	—	—	7	1	—	2	—	—	2	—	—	14	4	—	7	—	—	2	—	—	39	5	—
Surface dressing	2	1	2	2	1	5	2	—	—	2	—	—	—	—	18	5	2	—	2	—	—	15	4	25
Recycling	4	—	1	1	2	5	2	—	—	2	—	—	14	2	2	4	3	—	2	—	—	29	7	8
Coal tar	4	—	1	1	2	5	1	—	1	2	—	—	6	9	3	2	4	1	2	—	—	18	15	11
Coal-tar pitch	3	1	1	—	3	5	2	—	—	2	—	—	—	—	18	2	4	1	2	—	—	11	8	25
Petroleum pitch	1	1	3	—	3	5	2	—	—	—	2	—	—	—	18	1	5	1	2	—	—	6	11	27
Asbestos	1	2	2	—	3	5	—	2	—	1	1	—	—	—	18	1	3	3	2	—	—	5	11	28
Quartz sand	—	3	2	—	1	7	2	—	—	1	1	—	—	—	18	1	3	3	2	—	—	6	8	30

tional health care providers, but their smoking data do not cover all of the work force.

Materials, products, processes

Qualitative or quantitative data, or both, on asphalt products, application methods, and changes in procedures will be available for at least 18 companies. For 18 and possibly more Dutch companies, the availability of data on asphalt mixes remained unknown. It is likely that, on closer scrutiny, additional information will be found, in comparison with what was reported. Table 1 summarizes the reported application of selected products and procedures.

Coal tar had been applied until 1990–1991 mainly as a constituent in fluxed and cutback bitumens and as an adhesion improvement in the two French and the two German companies, and nine out of the 18 Dutch companies. In Denmark, the use of coal tar and coal-tar pitch remained unknown for two out of six companies at this stage. In Denmark, Finland, Norway, and Sweden, the use of coal tars in road paving ceased in the 1970s, though there was some uncertainty about this cessation in some of the companies. Ten of the 44 companies in the seven countries reported having used asbestos, presumably in hot mixes.

Five companies reported having used asbestos and being likely to be able to supply data on periods and quantities. Eleven reported not having used asbestos, and for 28 companies the information was missing. As examples of asbestos use, the two Swedish companies reported having employed asbestos to a very limited extent only in hot asphalt mix (0.5 %) during 1970–1971.

Industrial hygiene data

Reports of levels of airborne contaminants in road paving or asphalt mixing or both are available in Denmark, Finland, The Netherlands, Norway, and Sweden concerning current work conditions. Data on concentrations

of total dust, bitumen fumes, PAH, and benzo[a]pyrene during the 1970s are available in Denmark, Finland, and Sweden for selected worksites and periods. A German company has data on asbestos exposure in the early 1970s. Exposure levels of bitumen fumes, PAH, silica dust from quartz dust, and aldehydes during recycling and repaving have been measured in Sweden during the mid-1980s. Surveys of exposure of road pavers to substances and mixtures such as bitumen fumes, volatile hydrocarbons, and PAH were carried out in The Netherlands and three Nordic countries during 1990–1993. Concentrations of 1-pyrenol in urine in road pavers have been determined in Finland, Sweden, and The Netherlands (15).

Cohorts

A total of 32 000 employees in 44 companies will be able to supply some 350 000 person-years of follow-up in retrospect, but their follow-up will be only 11 years in average duration (table 2). A 10-year extension of the follow-up until 2005 will be satisfactory in terms of follow-up and power, but coal-tar fumes remain an important confounder. A tar-free cohort would be desirable for studying the carcinogenicity of bitumen fumes, but it will be smaller in size and much younger than a mixed cohort of asphalt workers. The young age of the tar-free cohort explains the low expected numbers of lung cancers and the relatively low power for these cancers even in an ambispective study spanning 19 years of follow-up.

Discussion

A retrospective or ambispective cohort study of lung cancer in a combined cohort of tar-exposed and tar-free workers is feasible, but individual assessment of past exposures to bitumen fumes, coal-tar fumes, asbestos, silica dust, engine exhaust from traffic and pavement

Table 2. Anticipated cohorts for mortality follow-up. (Minimum SMR = minimum standardized mortality ratio for lung cancer detectable at $\alpha = 0.10$ and $\beta = 0.20$)

	Retrospective cohort (until 1995)	Prospective cohort (until 2005)	Ambispective cohort (until 2005)
Total cohort			
Entry cohort			
Number of companies	44	44	44
Number of persons	15 700	15 200	15 700
Mean follow-up (years)	11	10	21
Person-years	165 800	152 500	318 300
Expected cancers	35	45	80
Expected lung cancers	5	10	15
Minimum SMR	2.4	1.9	1.8
Cross-sectional cohort			
Number of companies	41	41	41
Number of persons	16 000	13 700	16 000
Mean follow-up (years)	12	10	22
Person-years	190 200	136 500	326 700
Expected cancers	355	585	940
Expected lung cancers	120	190	310
Minimum SMR	1.2	1.2	1.2
Entry + cross-sectional cohort			
Number of companies	44	44	44
Number of persons	31 700	28 900	31 700
Mean follow-up (years)	11	10	21
Person-years	356 000	289 000	645 000
Expected cancers	390	630	1 020
Expected lung cancers	125	200	325
Minimum SMR	1.2	1.2	1.1
Tar-free cohort			
Entry cohort			
Number of companies	20	20	20
Number of persons	8 800	8 500	8 800
Mean follow-up (years)	10	10	20
Person-years	84 800	84 900	169 700
Expected cancers	8	14	22
Expected lung cancers	0.2	1	1
Minimum SMR	14.3	5.0	5.0
Cross-sectional cohort			
Number of companies	10	10	10
Number of persons	1 000	700	1 000
Mean follow-up (years)	7	10	17
Person-years	7 400	7 100	14 500
Expected cancers	4	10	14
Expected lung cancers	1	2	3
Minimum SMR	5.0	3.5	3.0
Entry + cross-sectional cohort			
Number of companies	20	20	20
Number of persons	9 800	9 200	9 800
Mean follow-up (years)	9	10	19
Person-years	92 200	92 000	184 200
Expected cancers	12	24	36
Expected lung cancers	1	3	4
Minimum SMR	5.0	3.0	2.6

equipment, and tobacco smoking will pose serious cost problems in distinguishing independent effects of various exposures, primarily of bitumen fumes, in a large cohort.

Exposures to fumes from tar-based materials are likely to represent the most severe confounders of the bitumen fume-lung cancer association. Coal-tar products were used in fluxed and cutback bitumens until the 1990s

and as adhesion improvers until the 1980s in some central European countries. The statistical power for a cohort whose members had never used tar-originated products turned out to be insufficient. A doubling of the expected number of lung cancers in a tar-free cohort would be needed for reasonable power for a standardized mortality ratio of lung cancer of the order of 2. Such doubling of the study size seems an unlikely possibility.

Asbestos was used in five companies in this study, and for 28 the usage remained unknown. In the Nordic countries, asbestos has been used for special purposes and in minor quantities during short periods.

For the construction of the individual qualitative exposure histories, data on specific job titles and the proportions of various methods are needed in addition to data on the products applied. Exposure levels to 4- to 6-ring aromatic hydrocarbons are highest among mastic asphalt workers, whereas exposure levels for volatile hydrocarbons are highest during surface dressing (16). This difference illustrates the need for data on job titles and application methods also for the estimation of exposure levels.

In summary, a considerable number of the members of the cohort would have been exposed to coal tar, and further confounders are a likely possibility. All of the confounders cannot be assessed for the cohort members for cost reasons, and the removal of confounding exposures originating from coal tar, which is likely to be the most serious confounder, by excluding subjects with such exposure would result in an insufficiently powerful study. To resolve the questions pertaining to cost-effectiveness, deconfounding, and statistical power, alternatives will be sought for. A case-referent study nested in a cohort would represent an obvious choice, with cases defined as lung cancer deaths (possibly augmented by incident cases where feasible) and referents representing a sample of the study population follow-up from which the cases emerged. The history of exposure to bitumen fumes, tar fumes, asbestos, silica dust, engine exhaust, and tobacco smoking would need to be reconstructed for the cases and the referents from all of the available company data, such as manual files, and possibly through interviews of the cases and referents or their next-of-kin. Complete lifetime job histories would ideally need to be assessed, and period-specific indicators would be constructed for each relevant exposure. Confounding, mainly by bitumen fume-lung cancer association, would be controlled by multivariate modeling of carefully derived exposure data. There are indications to the effect that the coal tar-bitumen correlation will not necessarily be overly tight throughout the entire period of pertinent exposures. Therefore the control of confounding from exposures to coal-tar fumes would improve. The confounding potential from tobacco smoking will depend on the associatedness of smoking and exposure to bitumen fumes. The general time trends suggest a negative correlation, that is, if tobacco smoking has decreased over time among these workers. Within specified time windows, however, there is no reason to expect an association, unless the subpopulation unexposed to asphalt fumes has drastically different smoking habits than the exposed one.

The extent of the added effort required for the case-referent study will be assessed. A retrospective case-

referent study would encompass at least some 150 lung cancer cases and some 300–500 referents. Extending the study to 2005 would increase the number of cases to over 300. The case-referent study necessitates the enumeration and follow-up of the cohort, which in turn implies that the cohort study would have to be done anyway. It would even be profitable to do so, since unexpected cancer sites may emerge that would require further scrutiny in the subsequent case-referent setup.

A biomarker study could be incorporated into the case-referent study, the biomarker data then adding to the possibilities of searching determinants of biological indicators of dose, such as DNA (deoxyribonucleic acid) or protein adducts, and of early biological effect, such as the activation of *ras* or other proto-oncogenes or the deactivation of suppressor genes among workers occupationally exposed to bitumen fumes. The tar-free cohort would be sufficiently large to investigate markers of biologically effective dose or early effect in a cross-section with a marker prevalence of 3–6/1000. A feasibility study with animal models is under way. The design of the study may require some modification to adapt to the possibilities for a valid determination of the relevant biomarkers.

In conclusion, an international multicentric cohort mortality study on asphalt workers is feasible in at least 44 companies in seven European countries. The total size of the study would be sufficient to detect an increased risk of lung cancer of the order of 20% (10% with 10 additional years of follow-up); however, some of the study population may have been exposed to tar as well as bitumen, and control of confounding is likely to introduce problems because of the excessive amount of effort required in the individual recording of determinants and confounders in the total cohort. A multicentric cohort of workers who have been employed in tar-free companies only or solely during tar-free time periods can be considered, but the small size and the young age of the workers will make the power for studying lung cancer mortality insufficient, unless the cohort size can be considerably increased or its average age increased. The cohort size can probably be increased from what is anticipated on the basis of the responses. The chosen study design is a retrospective case-referent study nested in the entire cohort, possibly augmented with a prospective component. Exposures to bitumen, tar, and other important confounders would need to be reconstructed in the retrospective assessment of the work histories of a moderately small group of subjects; the feasibility of such an exercise has not been evaluated, however, but the design would represent a clear cost-efficiency improvement over the cohort design in exposure assessment and control of confounding. Well over 100 lung cancer cases will be expected in retrospect, and an extension to 2005 would increase the number of cases to over 300 but postpone

the completion of the study. Another way of improving the power of the study would be to encourage additional companies, even additional countries, to participate. Southern Europe is still poorly represented in the context of this study.

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