EXHIBIT C

Concise International Chemical Assessment Document 59

ASPHALT (BITUMEN)

The layout and pagination of this pdf file are not identical to the version in press

Corrigenda published by 12 April 2005 have been incorporated in this file

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World Health Organization
Geneva, 2004

The **International Programme on Chemical Safety (IPCS)**, established in 1980, is a joint venture of the United Nations Environment Programme (UNEP), the International Labour Organization (ILO), and the World Health Organization (WHO). The overall objectives of the IPCS are to establish the scientific basis for assessment of the risk to human health and the environment from exposure to chemicals, through international peer review processes, as a prerequisite for the promotion of chemical safety, and to provide technical assistance in strengthening national capacities for the sound management of chemicals.

The **Inter-Organization Programme for the Sound Management of Chemicals (IOMC)** was established in 1995 by UNEP, ILO, the Food and Agriculture Organization of the United Nations, WHO, the United Nations Industrial Development Organization, the United Nations Institute for Training and Research, and the Organisation for Economic Co-operation and Development (Participating Organizations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen cooperation and increase coordination in the field of chemical safety. The purpose of the IOMC is to promote coordination of the policies and activities pursued by the Participating Organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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FOREWORD

Concise International Chemical Assessment Documents (CICADs) are the latest in a family of publications from the International Programme on Chemical Safety (IPCS) — a cooperative programme of the World Health Organization (WHO), the International Labour Organization (ILO), and the United Nations Environment Programme (UNEP). CICADs join the Environmental Health Criteria documents (EHCs) as authoritative documents on the risk assessment of chemicals.

International Chemical Safety Cards on the relevant chemical(s) are attached at the end of the CICAD, to provide the reader with concise information on the protection of human health and on emergency action. They are produced in a separate peer-reviewed procedure at IPCS. They may be complemented by information from IPCS Poison Information Monographs (PIM), similarly produced separately from the CICAD process.

CICADs are concise documents that provide summaries of the relevant scientific information concerning the potential effects of chemicals upon human health and/or the environment. They are usually based on selected national or regional evaluation documents or on existing EHCs. Before acceptance for publication as CICADs by IPCS, these documents undergo extensive peer review by internationally selected experts to ensure their completeness, accuracy in the way in which the original data are represented, and the validity of the conclusions drawn.

The primary objective of CICADs is characterization of hazard and dose–response from exposure to a chemical. CICADs are not a summary of all available data on a particular chemical; rather, they include only that information considered critical for characterization of the risk posed by the chemical. The critical studies are, however, presented in sufficient detail to support the conclusions drawn. For additional information, the reader should consult the identified source documents upon which the CICAD has been based.

Risks to human health and the environment will vary considerably depending upon the type and extent of exposure. Responsible authorities are strongly encouraged to characterize risk on the basis of locally measured or predicted exposure scenarios. To assist the reader, examples of exposure estimation and risk characterization are provided in CICADs, whenever possible. These examples cannot be considered as representing all possible exposure situations, but are provided as guidance only. The reader is referred to EHC 170.[1]

While every effort is made to ensure that CICADs represent the current status of knowledge, new information is being developed constantly. Unless otherwise stated, CICADs are based on a search of the scientific literature to the date shown in the executive summary. In the event that a reader becomes aware of new information that would change the conclusions drawn in a CICAD, the reader is requested to contact IPCS to inform it of the new information.

Procedures

The flow chart on page 2 shows the procedures followed to produce a CICAD. These procedures are designed to take advantage of the expertise that exists around the world — expertise that is required to produce the high-quality evaluations of toxicological, exposure, and other data that are necessary for assessing risks to human health and/or the environment. The IPCS Risk Assessment Steering Group advises the Coordinator, IPCS, on the selection of chemicals for an IPCS risk assessment based on the following criteria:

- there is the probability of exposure; and/or
- there is significant toxicity/ecotoxicity.

Thus, it is typical of a priority chemical that

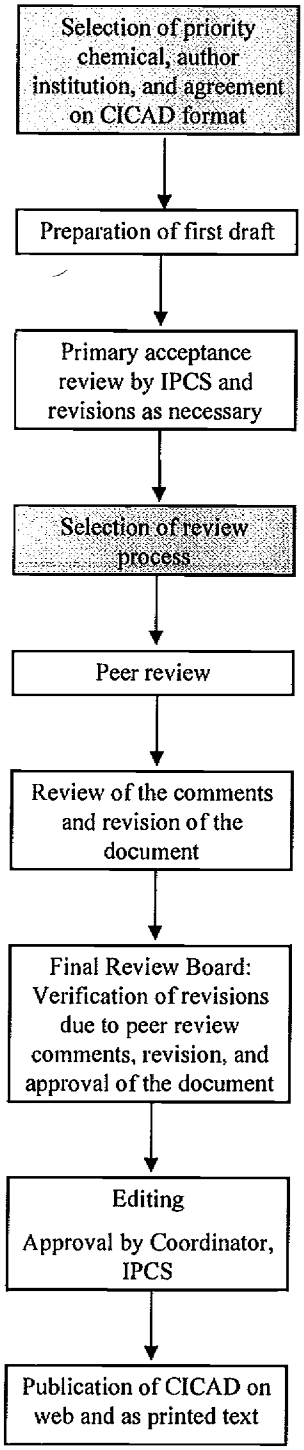
- it is of transboundary concern;
- it is of concern to a range of countries (developed, developing, and those with economies in transition) for possible risk management;
- there is significant international trade;
- it has high production volume;
- it has dispersive use.

The Steering Group will also advise IPCS on the appropriate form of the document (i.e., a standard CICAD or a *de novo* CICAD) and which institution bears the responsibility of the document production, as well as on the type and extent of the international peer review.

The first draft is usually based on an existing national, regional, or international review. When no appropriate source document is available, a CICAD may be produced *de novo*. Authors of the first draft are usually, but not necessarily, from the institution that developed the original review. A standard outline has been developed to encourage consistency in form. The

[1] International Programme on Chemical Safety (1994) *Assessing human health risks of chemicals: derivation of guidance values for health-based exposure limits.* Geneva, World Health Organization (Environmental Health Criteria 170) (also available at http://www.who.int/pcs/).

CICAD PREPARATION FLOW CHART



Advice from Risk Assessment Steering Group

Criteria of priority:

- there is the probability of exposure; and/or
- there is significant toxicity/ecotoxicity.

Thus, it is typical of a priority chemical that

- it is of transboundary concern;
- it is of concern to a range of countries (developed, developing, and those with economies in transition) for possible risk management;
- there is significant international trade;
- the production volume is high;
- the use is dispersive.

Special emphasis is placed on avoiding duplication of effort by WHO and other international organizations.

A usual prerequisite of the production of a CICAD is the availability of a recent high-quality national/regional risk assessment document = source document. The source document and the CICAD may be produced in parallel. If the source document does not contain an environmental section, this may be produced *de novo*, provided it is not controversial. If no source document is available, IPCS may produce a *de novo* risk assessment document if the cost is justified.

Depending on the complexity and extent of controversy of the issues involved, the steering group may advise on different levels of peer review:

- standard IPCS Contact Points
- above + specialized experts
- above + consultative group

first draft undergoes primary review by IPCS to ensure that it meets the specified criteria for CICADs.

The second stage involves international peer review by scientists known for their particular expertise and by scientists selected from an international roster compiled by IPCS through recommendations from IPCS national Contact Points and from IPCS Participating Institutions. Adequate time is allowed for the selected experts to undertake a thorough review. Authors are required to take reviewers' comments into account and revise their draft, if necessary. The resulting second draft is submitted to a Final Review Board together with the reviewers' comments. At any stage in the international review process, a consultative group may be necessary to address specific areas of the science. When a CICAD is prepared *de novo*, a consultative group is normally convened.

The CICAD Final Review Board has several important functions:

- to ensure that each CICAD has been subjected to an appropriate and thorough peer review;
- to verify that the peer reviewers' comments have been addressed appropriately;
- to provide guidance to those responsible for the preparation of CICADs on how to resolve any remaining issues if, in the opinion of the Board, the author has not adequately addressed all comments of the reviewers; and
- to approve CICADs as international assessments.

Board members serve in their personal capacity, not as representatives of any organization, government, or industry. They are selected because of their expertise in human and environmental toxicology or because of their experience in the regulation of chemicals. Boards are chosen according to the range of expertise required for a meeting and the need for balanced geographic representation.

Board members, authors, reviewers, consultants, and advisers who participate in the preparation of a CICAD are required to declare any real or potential conflict of interest in relation to the subjects under discussion at any stage of the process. Representatives of nongovernmental organizations may be invited to observe the proceedings of the Final Review Board. Observers may participate in Board discussions only at the invitation of the Chairperson, and they may not participate in the final decision-making process.

1. EXECUTIVE SUMMARY

This CICAD on asphalt (bitumen) was based upon a review prepared by the US National Institute for Occupational Safety and Health (NIOSH, 2000). Additional data were identified through an updated literature search to February 2003. Information on the peer review of the source document is presented in Appendix 1. Information on the peer review of this CICAD is presented in Appendix 2. This CICAD was approved as an international assessment at a meeting of the Final Review Board, held in Varna, Bulgaria, on 8–11 September 2003. Participants at the Final Review Board meeting are listed in Appendix 3. The International Chemical Safety Card on asphalt (ICSC 0162), produced by the International Programme on Chemical Safety (IPCS, 2002), has also been reproduced in this document.

Asphalt (CAS No. 8052-42-4), more commonly referred to as bitumen in Europe, is a dark brown to black, cement-like semisolid or solid or viscous liquid produced by the non-destructive distillation of crude oil during petroleum refining. Oxidized asphalt (CAS No. 64742-93-4), also called air-blown or air-refined asphalt, is asphalt (CAS No. 8052-42-4) that has been treated by blowing air through it at elevated temperatures to produce physical properties required for the industrial use of the final product. Performance specifications (e.g., paving asphalts and roofing asphalts), not chemical composition, direct asphalt production. The exact chemical composition of asphalt is dependent on the chemical complexity of the original crude petroleum and the manufacturing process. Crude petroleum consists mainly of aliphatic compounds, cyclic alkanes, aromatic hydrocarbons, polycyclic aromatic compounds (PACs), and metals (e.g., iron, nickel, and vanadium). The proportions of these chemicals can vary greatly because of significant differences in crude petroleum from oil field to oil field or even at different locations in the same oil field. While the manufacturing process may change the physical properties of asphalt dramatically, the chemical nature of the asphalt does not change unless thermal cracking occurs. Although no two asphalts are chemically identical and chemical analysis cannot be used to define the exact chemical structure or chemical composition of asphalt, elemental analyses indicate that most asphalts contain 79–88 weight per cent (wt%) carbon, 7–13 wt% hydrogen, traces to 8 wt% sulfur, 2–8 wt% oxygen, and traces to 3 wt% nitrogen.

When asphalts are heated, vapours are released; as these vapours cool, they condense. As such, these vapours are enriched in the more volatile components present in the asphalt and would be expected to be chemically and potentially toxicologically distinct from the parent material. Asphalt fumes are the cloud of small particles created by condensation from the gaseous state after volatilization of asphalt. However, because the components in the vapour do not condense all at once, workers are exposed not only to asphalt fumes but also to vapours. The physical nature of the fumes and vapours has not been well characterized. Nevertheless, a chemical analysis of oxidized roofing asphalt and non-oxidized paving asphalt fumes identified many of the same chemical classes. In addition, differences in the way in which asphalts are handled during paving and roofing operations probably influence the composition of asphalt fumes and vapours. Since the compositions of asphalts and asphalt fumes and vapours vary depending on temperature, manufacturing process, presence of additives and modifiers, and work practices, it should be no surprise to learn that laboratory-generated asphalt fumes that mimic asphalt fumes in the environment are difficult to produce. Researchers have concluded that temperature, rate of stirring, and pulling versus pushing the collection air all affect the chemical composition of the fumes.

The major types of asphalt products are paving asphalts and roofing asphalts. Asphalt is also used in asphalt-based paints as protective coatings to prevent corrosion of metals; in lining irrigation canals, water reservoirs, dams, and sea defence works; in adhesives in electrical laminates; and as a base for synthetic turf. In the USA, approximately 300 000 workers are employed at hot-mix asphalt facilities and paving sites; an estimated 50 000 workers are employed in asphalt roofing operations; and about 1500–2000 workers are employed in approximately 100 roofing manufacturing plants. In Western Europe, there are approximately 4000 asphalt mixing plants employing 5–10 individuals per plant. Approximately 100 000 members of paving crews apply these asphalt mixes to road surfaces across Western Europe.

Although a variety of sample collection and analytical methods are available for evaluating asphalt fume exposures, most of them are non-specific and cannot be used to characterize total asphalt fume exposure. Also, readily accessible body fluids and/or physiological functions have been sampled or monitored for biomarkers of exposure to asphalt fumes. Biomarkers specific to asphalt fume exposures have not yet been identified.

Limited data are available on the concentration of asphalt in environmental media. Characterization of concentrations of asphalt fractions in air samples and plant samples collected at various distances from a highway indicated that these concentrations were <4 × 10^{-3} mg/m^3 and <4 mg/g dry plant material, respectively. An assessment of the effects of runoff from asphalt pavement on streams in California, USA, indicated that concentrations of all polycyclic aromatic hydrocarbon (PAH) analytes in all stream and road runoff samples were below the detection limit of 0.5 μg/litre. Although detectable levels of heavy metals were present in stream and runoff water, the authors concluded that no significant upstream versus downstream differences existed in the concentration of any heavy metal across all streams. Metal concentrations were elevated in runoff water from road surfaces relative to upstream samples. These elevated concentrations could be due to sources other than asphalt (e.g., vehicle emissions, crankcase oil drippings, etc.).

While asphalt fume concentrations associated with health effects have not been well characterized, symptoms of eye, nose, or throat irritation are reported by workers during open-air paving. In the occupational setting, results of recent studies indicate that, in general, most time-weighted average (TWA) air concentrations for total particulates (TP) and benzene-soluble particulates (BSP) ranged from 0.041 to 4.1 mg/m^3 and from 0.05 to 1.26 mg/m^3, respectively. Average personal exposures, calculated as full-shift TWAs, were generally below 1.0 mg/m^3 for TP and 0.3 mg/m^3 for BSP.

Asphalt fumes and vapours may be absorbed following inhalation and dermal exposure. Because asphalt is a complex mixture, its pharmacokinetic behaviour will vary depending upon the properties of the individual constituents. Therefore, it is inappropriate to make generalizations regarding the extent of absorption, distribution, and metabolism of asphalt.

Results of several *in vitro* studies indicate that while field-generated paving asphalt fume condensates were not mutagenic and did not induce DNA adduct formation, paving fume condensates generated in the laboratory were mutagenic and did induce DNA adduct formation. In contrast, one study reported that the particulate fractions of asphalt fumes collected in the personal breathing zone (PBZ) of workers during paving operations were mutagenic in the Ames *Salmonella* assay. Moreover, intratracheal exposure of rats to field-generated asphalt paving fumes caused a statistically significant increase in the level and activity of CYP1A1 (a major PAH-inducible isozyme of cytochrome P450) in the lung and increased micronuclei formation in bone marrow erythrocytes. Only laboratory-generated roofing asphalt fumes have been tested in genotoxicity studies. These fumes have been shown to be mutagenic, to cause increased micronuclei formation, and to inhibit intercellular communication in Chinese hamster lung fibroblasts (V79 cells) and in human epidermal keratinocytes. Equivocal results have been reported for asphalt-based paints. While in one study none of the asphalt-based paints examined demonstrated mutagenic activity, in another study other asphalt-based paints induced DNA adduct formation in adult and fetal human skin samples. Results of carcinogenicity studies indicated that laboratory-generated roofing asphalt fume condensates caused tumours when applied dermally to mice and that some asphalt-based paints contained chemicals capable of initiating tumours in mice. No animal studies have examined the carcinogenic potential of either field- or laboratory-generated paving asphalt fume condensates.

Acute effects of exposure to asphalt among workers in the various sectors of the asphalt industry (hot-mix plants, terminals, roofing application, paving, roofing manufacturing) include symptoms of irritation of the serous membranes of the conjunctivae (eye irritation) and the mucous membranes of the upper respiratory tract (nasal and throat irritation) and coughing. These health effects appear to be mild in severity and transient in nature. Additional symptoms include skin irritation, pruritus, rashes, nausea, stomach pain, decreased appetite, headaches, and fatigue, as reported by workers involved in paving operations, insulation of cables, and the manufacture of fluorescent light fixtures. Results from recent studies indicated that some workers involved in paving operations experienced lower respiratory tract symptoms (e.g., coughing, wheezing, and shortness of breath) and pulmonary function changes; bronchitis has also been reported. The lowest TP exposure that caused respiratory tract problems was 0.02 mg/m^3. However, data from the available studies are insufficient to determine the relationship between asphalt fume exposures and the above reported health effects.

Burns may also occur when hot asphalt is handled. Burned areas usually include the head and neck, arms, hands, and legs.

The largest study to examine the health effects of occupational exposure to asphalt included a cohort of 29 820 workers from eight different countries engaged in road paving, asphalt mixing, roofing, waterproofing, or other specified jobs where exposure to asphalt fumes was possible. Overall mortality for the entire cohort (exposed and non-exposed workers) was below expected (standardized mortality ratio [SMR] = 0.92). For job classifications involving bitumen or asphalt exposure, overall mortality was not elevated (SMR = 0.96); mortality from lung cancer was increased among bitumen workers when compared with ground and building construction workers (SMR = 1.17, 95% confidence interval [CI] = 1.04–1.30). Overall mortality from head and neck cancer was elevated for bitumen workers only (SMR = 1.27, 95% CI = 1.02–1.56). Mortality from other malignant neoplasms was not increased. Further analysis suggested a slight increase in lung cancer mortality among road pavers after adjusting for coal tar pitch and allowing for a 15-year lag (SMR = 1.23, 95% CI = 1.02–1.48).

The investigators (Boffetta et al., 2003b) assessed two different metrics for exposure: average and cumulative exposure. For lung cancer, a positive association was observed for lagged average level of exposure, but not for lagged cumulative exposure. Corresponding indices of unlagged average and cumulative exposure showed a positive dose–response with lung cancer risk based on 63 deaths; relative risks [RRs] were 1.43 (95% CI = 0.87–2.33), 1.77 (0.99–3.19), and 3.53 (1.58–7.89) for 2.2–4.6, 4.7–9.6, and 9.7+ mg/m^3 years of cumulative exposure and 2.77 (95% CI = 1.69–4.53), 2.43 (1.38–4.29), and 3.16 (1.83–5.47) for 1.03–1.23, 1.24–1.36, and 1.37+ mg/m^3 average exposure (*P*-value of test for trend, 0.01 for both variables). The investigators concluded that the exposure–response analyses suggest an association between lung cancer mortality and indices of average level of exposure to bitumen fumes; however, they could not rule out that confounding played some role in this association.

A meta-analysis of 20 epidemiological studies failed to find overall evidence for a lung cancer risk among pavers and highway maintenance workers exposed to asphalt (RR = 0.87, 95% CI = 0.76–1.08). However, the analysis demonstrated an overall statistically significant excess of lung cancer among roofers (RR = 1.78, 95% CI = 1.5–2.1). Because, in the past, roofers have been exposed to coal tar and asbestos, which are known human carcinogens, it is uncertain to what extent these findings may be attributable to asphalt exposures.

The same meta-analysis reported increases in risk of bladder cancer (RR = 1.22, 95% CI = 0.95–1.53), stomach cancer (RR = 1.28, 95% CI = 1.03–1.59), and leukaemia (RR = 1.41, 95% CI = 1.05–1.85) in workers generally classified as asphalt workers, but not roofers. Interpretation of the findings of these 20 studies is limited by a lack of consistency among studies and the potential for confounding by other substances. Furthermore, many of these findings are from studies organized by broad job classifications that are prone to errors in defining asphalt exposures.

The extremely limited nature of the available data to serve as a basis for estimation of exposure of the general population should be borne in mind when attempting to determine exposure of the general population to asphalt, asphalt fumes and vapours, and asphalt-based paints. The concentrations of asphalt fractions — polar aromatics (polars), naphthene aromatics (aromatics), and saturates — measured in air samples collected 2.0–83.6 m from the highway were 0.54–3.96 × 10^{-3} mg/m^3 air, 1.77–9.50 × 10^{-4} mg/m^3 air, and 0.21–1.23 × 10^{-4} mg/m^3 air, respectively. These values are extremely low in comparison with occupational exposures determined in the various sectors of the asphalt industry; personal exposures to TP and BSP ranged from 0.041 to 4.1 mg/m^3 and from 0.05 to 1.26 mg/m^3, respectively. However, the chemical composition of the air samples collected along the highway and at the worksites may differ. In addition to respiratory absorption, dermal absorption may also occur and play a pivotal role in asphalt exposure.

The frequency and concentration of potential asphalt exposures may be lower for the general population than for workers. However, in the general population, there are individuals who may be more sensitive to exposures and therefore exhibit more symptoms or other effects. The extent to which these symptoms occur in the general population has not been studied.

[redacted].

2. IDENTITY AND PHYSICAL/CHEMICAL PROPERTIES

2.1 Definitions and terminology

Asphalt and some asphalt products are described below:

- *Asphalt (CAS No. 8052-42-4) or bitumen*: the residuum produced from the distillation of crude petroleum at "atmospheric and under reduced pressures in the presence or absence of steam" (Puzinauskas & Corbett, 1978). Asphalt is a black or dark brown solid or viscous liquid at room temperature; insoluble in water at 20 °C; partially soluble in aliphatic organic solvents; and soluble in carbon disulfide, chloroform, ether, and acetone (Sax & Lewis, 1987). Outside the USA, asphalt is more commonly referred to as bitumen, and a mixture of bitumen with mineral matter is referred to as asphalt (CONCAWE, 1992). In this document, asphalt is used to refer to the residuum both with and without the addition of mineral matter.