International Agency for Research on Cancer

World Health Organization

October 18, 2011

Occupational exposures to bitumens and their emissions

Lyon, France, October 18, 2011 The WHO/International Agency for Research on Cancer's Monographs programme re-evaluated various occupations that entail exposures to bitumens and bitumen emissions, including road paving, roofing, and application of mastic asphalt.
After an 8-day comprehensive review, the Working Group concluded that:

- occupational exposures to oxidized bitumens and their emissions during roofing are 'probably carcinogenic to humans'[1] (Group 2A);
- occupational exposures to hard bitumens and their emissions during mastic asphalt work are 'possibly carcinogenic to humans' (Group 2B); and
- occupational exposures to straight-run bitumens and their emissions during road paving are 'possibly carcinogenic to humans' (Group 2B).

Background
Bitumens are produced by distillation of crude oil during petroleum refining, and also occur naturally. Bitumens can be divided into broad classes according to their physical properties and specifications required for the different uses. The major use of bitumens is in asphalt for road paving; other uses include roofing, waterproofing, and sealing and painting. Application of bitumens may generate hazardous emissions.

"Bitumen" was reviewed by previous IARC Monographs Working Groups in 1985 and in 1987. At the time, studies on exposed workers were few, and their results were difficult to interpret because of concomitant exposure to coal-tar, a known cancer-causing compound, and other exposures (e.g. diesel engine exhaust, silica, etc.). Different types of extracts, fume condensates and pooled mixtures of bitumens had been tested in experimental animals, and there was sufficient evidence for the carcinogenicity of some of them.

Key additional studies
Today a number of additional epidemiological studies are available, including a meta-analysis of 20 studies published until 1994, a number of additional individual studies, and the IARC multicenter cohort study. In addition, a large number of studies in exposed workers and in in-vivo and in-vitro experimental systems have become available.

Conclusions of the IARC Working Group

A- Occupational exposures to oxidized bitumens and their emissions during roofing
The body of available data from cancer studies in humans points to an association between exposures to oxidized bitumens during roofing and lung cancer and tumours in the upper aerodigestive tract. In support of these findings, extracts and fume condensates of oxidized bitumens, which are used primarily in roofing applications, showed sufficient evidence of carcinogenicity in experimental animals. Taking these data together, the Working Group evaluated occupational exposures to oxidized bitumens and their emissions during roofing as "probably carcinogenic to humans" (Group 2A).

B- Occupational exposures to hard bitumens and their emissions during mastic asphalt work
Based on two positive studies among mastic asphalt workers, the Working Group concluded that there was limited evidence in humans for the carcinogenicity of occupational exposures during mastic asphalt work. This type of bitumens has not been tested in experimental animals. In consequence, occupational exposures to hard bitumens and their emissions during mastic asphalt work were classified as "possibly carcinogenic to humans" (Group 2B).

C- Occupational exposures to straight-run bitumens and their emissions during road paving
On the basis of an earlier meta-analysis, the IARC multi-center study and several more recent independent studies, the Working Group concluded that there was inadequate evidence in humans for the carcinogenicity of occupational exposures during road paving with straight-run bitumens. Also, there was inadequate evidence in experimental animals for the carcinogenicity of extracts and of fume condensates of this type of bitumens. However, studies of workers exposed to bitumen emissions during paving with straight-run bitumens showed mutagenic and genotoxic/cytogenetic effects in these workers. Similar effects were also observed in experimental systems under controlled conditions. This strong mechanistic evidence led to the classification of occupational exposures to straight-run bitumens and their emissions during road paving as "possibly carcinogenic to humans" (Group 2B).

[1] See annex for definition of IARC groupings.

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Annex

ABOUT THE IARC MONOGRAPHS

What are the IARC Monographs?

The IARC Monographs identify environmental factors that can increase the risk of human cancer. These include chemicals, complex mixtures, occupational exposures, physical and biological agents, and lifestyle factors. National health agencies use this information as scientific support for their actions to prevent exposure to potential carcinogens. Interdisciplinary working groups of expert scientists review the published studies and evaluate the weight of the evidence that an agent can increase the risk of cancer. The principles, procedures, and scientific criteria that guide the evaluations are described in the Preamble to the IARC Monographs.
Since 1971, more than 900 agents have been evaluated, of which approximately 400 have been identified as carcinogenic or potentially carcinogenic to humans.

Definitions

Group 1: The agent is carcinogenic to humans.

This category is used when there is sufficient evidence of carcinogenicity in humans. Exceptionally, an agent may be placed in this category when evidence of carcinogenicity in humans is less than sufficient but there is sufficient evidence of carcinogenicity in experimental animals and strong evidence in exposed humans that the agent acts through a relevant mechanism of carcinogenicity.

Group 2.

This category includes agents for which, at one extreme, the degree of evidence of carcinogenicity in humans is almost sufficient, as well as those for which, at the other extreme, there are no human data but for which there is evidence of carcinogenicity in experimental animals. Agents are assigned to either Group 2A (probably carcinogenic to humans) or Group 2B (possibly carcinogenic to humans) on the basis of epidemiological and experimental evidence of carcinogenicity and mechanistic and other relevant data. The terms probably carcinogenic and possibly carcinogenic have no quantitative significance and are used simply as descriptors of different levels of evidence of human carcinogenicity, with probably carcinogenic signifying a higher level of evidence than possibly carcinogenic.

Group 2A: The agent is probably carcinogenic to humans.

This category is used when there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals. In some cases, an agent may be classified in this category when there is inadequate evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals and strong evidence that the carcinogenesis is mediated by a mechanism that also operates in humans. Exceptionally, an agent may be classified in this category solely on the basis of limited evidence of carcinogenicity in humans. An agent may be assigned to this category if it clearly belongs, based on mechanistic considerations, to a class of agents for which one or more members have been classified in Group 1 or Group 2A.

Group 2B: The agent is possibly carcinogenic to humans.

This category is used for agents for which there is limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals. It may also be used when there is inadequate evidence of carcinogenicity in humans but there is sufficient evidence of carcinogenicity in experimental animals. In some instances, an agent for which there is inadequate evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals together with supporting evidence from mechanistic and other relevant data may be placed in this group. An agent may be classified in this category solely on the basis of strong evidence from mechanistic and other relevant data.

Group 3: The agent is not classifiable as to its carcinogenicity to humans.

This category is used most commonly for agents for which the evidence of carcinogenicity is
inadequate in humans and inadequate or limited in experimental animals.
Exceptionally, agents for which the evidence of carcinogenicity is inadequate in humans but sufficient in experimental animals may be placed in this category when there is strong evidence that the mechanism of carcinogenicity in experimental animals does not operate in humans.
Agents that do not fall into any other group are also placed in this category.
An evaluation in Group 3 is not a determination of non carcinogenicity or overall safety. It often means that further research is needed, especially when exposures are widespread or the cancer data are consistent with differing interpretations.

Group 4: The agent is probably not carcinogenic to humans.

This category is used for agents for which there is evidence suggesting lack of carcinogenicity in humans and in experimental animals. In some instances, agents for which there is inadequate evidence of carcinogenicity in humans but evidence suggesting lack of carcinogenicity in experimental animals, consistently and strongly supported by a

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broad range of mechanistic and other relevant data, may be classified in this group.

Definitions of evidence, as used in IARC Monographs for studies of cancer in humans

The evidence relevant to carcinogenicity from studies in humans is classified into one of the following categories:
Sufficient evidence of carcinogenicity: The Working Group considers that a causal relationship has been established between exposure to the agent and human cancer. That is, a positive relationship has been observed between the exposure and cancer in studies in which chance, bias and confounding could be ruled out with reasonable confidence. A statement that there is sufficient evidence is followed by a separate sentence that identifies the target organ(s) or tissue(s) where an increased risk of cancer was observed in humans. Identification of a specific target organ or tissue does not preclude the possibility that the agent may cause cancer at other sites.
Limited evidence of carcinogenicity: A positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence.
Inadequate evidence of carcinogenicity: The available studies are of insufficient quality, consistency or statistical power to permit a conclusion regarding the presence or absence of a causal association between exposure and cancer, or no data on cancer in humans are available.
Evidence suggesting lack of carcinogenicity: There are several adequate studies covering the full range of levels of exposure that humans are known to encounter, which are mutually consistent in not showing a positive association between exposure to the agent and any studied cancer at any observed level of exposure. The results from these studies alone or combined should have narrow confidence intervals with an upper limit close to the null value (e.g. a relative risk of 1.0). Bias and confounding should be ruled out with reasonable confidence, and the studies should have an adequate length of follow up. A conclusion of evidence suggesting lack of carcinogenicity is inevitably limited to the cancer sites, conditions and levels of exposure, and length of observation covered by the available studies. In addition, the possibility of a very small risk at the levels of exposure studied can never be excluded.

Fore more information, please contact

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The International Agency for Research on Cancer (IARC) is part of the World Health Organization. Its mission is to coordinate and conduct research on the causes of human cancer, the mechanisms of carcinogenesis, and to develop scientific strategies for cancer control. The Agency is involved in both epidemiological and laboratory research and disseminates scientific information through publications, meetings, courses, and fellowships. If you wish your name to be removed from our press release e-mailing list, please write to com@iarc.fr.