

8 Douglas Avenue
Wahroonga NSW 2076

10 September 2014

Director – Infrastructure Projects
Department of Planning and Environment
Number: SSI 13_6136
Major Projects Assessment
GPO Box 39
SYDNEY NSW 2001

RE: NorthConnex Application Number: SSI 13_6136

I thank you for the opportunity to make a submission in relation to the Environmental Impact Statement in relation to the above project.

I object to the project described in the EIS being approved in its current form.

I request that the following issues be considered by the Department of Planning. In doing so the Department must act as gatekeeper and protect the community from environmental harm:

1. The ventilation stack at the Northern end of tunnel is proposed to be placed in the centre of a densely populated residential area in Wahroonga. In this area there are around 9,300 school children as well as multiple aged care facilities, hospitals, businesses and homes.
2. To my knowledge never before has a ventilation stack been placed in such a densely populated area.
3. The obvious problem is that the stack will concentrate the pollutants from the vehicles passing through the tunnel and then disperse these pollutants over Wahroonga. This is in contrast to the modelling in the EIS which suggests that the effects of the pollutants can be averaged over the area of the tunnel.
4. Of concern these pollutants include PM_{2.5} and smaller particles sometimes called ultra-fines. The World Health Organisation in their Fact Sheet N°313 (attached) stated:

There is a close, quantitative relationship between exposure to high concentrations of small particulates (PM₁₀ and PM_{2.5}) and increased mortality or morbidity, both daily and over time. Conversely, when concentrations of small and fine particulates are reduced, related mortality will also go down – presuming other factors remain the same. This allows policymakers to project the population health improvements that could be expected if particulate air pollution is reduced.

5. In Press Release 221 dated 17 October 2013 (attached) the World Health Organisation stated that:

Particulate matter, a major component of outdoor air pollution, was evaluated separately and was also classified as carcinogenic to humans (Group 1).

6. There is no accepted safe exposure level to particulate matter, yet they are the very particles that the stack will concentrate and then dispersed over a residential area.
7. Other medical studies highlight increased death from heart disease, increased risks of lung cancer, stroke, poor lung growth in children, increased asthma, and recent research suggesting low birth weight for pregnant women, increased autism, and congenital heart defects.
8. My daughter goes to a school within 500 metres of the proposed ventilation stack. I do not want her to discover in 10 years time that the NSW Government failed to properly assess the safety risks and she, along with her class mates, is facing life threatening consequences by simply going to school.

To address my concerns I request that the following actions be taken:

1. The Department of Planning not approve the project in its current form;
2. Alternative locations (in a non-residential area) for the ventilation stack be considered; and
3. That alternative transport options to ease congestion on Pennant Hills Rd be considered such as an orbital surface route.

Yours faithfully



Stephanie Keats

Media centre

Ambient (outdoor) air quality and health

Fact sheet N°313

Updated March 2014

Key facts

- Air pollution is a major environmental risk to health. By reducing air pollution levels, countries can reduce the burden of disease from stroke, heart disease, lung cancer, and both chronic and acute respiratory diseases, including asthma.
- The lower the levels of air pollution, the better the cardiovascular and respiratory health of the population will be, both long- and short-term.
- The "WHO Air quality guidelines" provide an assessment of health effects of air pollution and thresholds for health-harmful pollution levels.
- Ambient (outdoor air pollution) in both cities and rural areas was estimated to cause 3.7 million premature deaths worldwide in 2012.
- Some 88% of those premature deaths occurred in low- and middle-income countries, and the greatest number in the WHO Western Pacific and South-East Asia regions.
- Policies and investments supporting cleaner transport, energy-efficient housing, power generation, industry and better municipal waste management would reduce key sources of urban outdoor air pollution.
- Reducing outdoor emissions from household coal and biomass energy systems, agricultural waste incineration, forest fires and certain agro-forestry activities (e.g. charcoal production) would reduce key rural and peri-urban air pollution sources in developing regions.
- Reducing outdoor air pollution also reduces emissions of CO₂ and short-lived climate pollutants such as black carbon particles and methane, thus contributing to the near- and long-term mitigation of climate change.
- In addition to outdoor air pollution, indoor smoke is a serious health risk for some 3 billion people who cook and heat their homes with biomass fuels and coal.

Background

Outdoor air pollution is a major environmental health problem affecting everyone in developed and developing countries alike.

WHO estimates that some 80% of outdoor air pollution-related premature deaths were due to ischaemic heart disease and strokes, while 14% of deaths were due to chronic obstructive pulmonary disease or acute lower respiratory infections; and 6% of deaths were due to lung cancer.

Some deaths may be attributed to more than one risk factor at the same time. For example, both smoking and ambient air pollution affect lung cancer. Some lung cancer deaths could have been averted by improving ambient air quality, or by reducing tobacco smoking.

A 2013 assessment by WHO's International Agency for Research on Cancer (IARC) concluded that outdoor air pollution is carcinogenic to humans, with the particulate matter component of air pollution most closely associated with increased cancer incidence, especially cancer of the lung. An association also has been observed between outdoor air pollution and increase in cancer of the urinary tract/bladder.

Ambient (outdoor air pollution) in both cities and rural areas was estimated to cause 3.7 million premature deaths worldwide per year in 2012; this mortality is due to exposure to small particulate matter of 10 microns or less in diameter (PM_{10}), which cause cardiovascular and respiratory disease, and cancers.

People living in low- and middle-income countries disproportionately experience the burden of outdoor air pollution with 88% (of the 3.7 million premature deaths) occurring in low- and middle-income countries, and the greatest burden in the WHO Western Pacific and South-East Asia regions. The latest burden estimates reflect the very significant role air pollution plays in cardiovascular illness and premature deaths – much more so than was previously understood by scientists.

Most sources of outdoor air pollution are well beyond the control of individuals and demand action by cities, as well as national and international policymakers in sector like transport, energy waste management, buildings and agriculture.

There are many examples of successful policies in transport, urban planning, power generation and industry that reduce air pollution:

- **for industry:** clean technologies that reduce industrial smokestack emissions; improved management of urban and agricultural waste, including capture of methane gas emitted from waste sites as an alternative to incineration (for use as biogas);
- **for transport:** shifting to clean modes of power generation; prioritizing rapid urban transit, walking and cycling networks in cities as well as rail interurban freight and passenger travel; shifting to cleaner heavy duty diesel vehicles and low-emissions vehicles and fuels, including fuels with reduced sulfur content;
- **for urban planning:** improving the energy efficiency of buildings and making cities more compact, and thus energy efficient;
- **for power generation:** increased use of low-emissions fuels and renewable combustion-free power sources (like solar, wind or hydropower); co-generation of heat and power; and distributed energy generation (e.g. mini-grids and rooftop solar power generation);
- **for municipal and agricultural waste management:** strategies for waste reduction, waste separation, recycling and reuse or waste reprocessing; as well as improved methods of biological waste management such as anaerobic waste digestion to produce biogas, are feasible, low cost alternatives to the open incineration of solid waste. Where incineration is unavoidable, then combustion technologies with strict emission controls are critical.

In addition to outdoor air pollution, indoor smoke is a serious health risk for some 3 billion people who cook and heat their homes with biomass fuels and coal. Some 4.3 million premature deaths were attributable to household air pollution in 2012. Almost all of that burden was in low-middle-income countries as well.

The 2005 "WHO Air quality guidelines" offer global guidance on thresholds and limits for key pollutants that pose health risks. The

Guidelines indicate that by reducing particulate matter (PM₁₀) pollution from 70 to 20 micrograms per cubic metre (µg/m), we can cut air pollution-related deaths by around 15%.

The Guidelines apply worldwide and are based on expert evaluation of current scientific evidence for:

- particulate matter (PM)
- ozone (O₃)
- nitrogen dioxide (NO₂) and
- sulfur dioxide (SO₂), in all WHO regions.

Particulate matter

Definition and principal sources

PM affects more people than any other pollutant. The major components of PM are sulfate, nitrates, ammonia, sodium chloride, black carbon, mineral dust and water. It consists of a complex mixture of solid and liquid particles of organic and inorganic substances suspended in the air. The most health-damaging particles are those with a diameter of 10 microns or less, (\leq PM₁₀), which can penetrate and lodge deep inside the lungs. Chronic exposure to particles contributes to the risk of developing cardiovascular and respiratory diseases, as well as of lung cancer.

Air quality measurements are typically reported in terms of daily or annual mean concentrations of PM₁₀ particles per cubic meter of air volume (m³). Routine air quality measurements typically describe such PM concentrations in terms of micrograms per cubic meter (µg/m³). When sufficiently sensitive measurement tools are available, concentrations of fine particles (PM_{2.5} or smaller), are also reported.

Health effects

There is a close, quantitative relationship between exposure to high concentrations of small particulates (PM₁₀ and PM_{2.5}) and increased mortality or morbidity, both daily and over time. Conversely, when concentrations of small and fine particulates are reduced, related mortality will also go down – presuming other factors remain the same. This allows policymakers to project the population health improvements that could be expected if particulate air pollution is reduced.

Small particulate pollution have health impacts even at very low concentrations – indeed no threshold has been identified below which no damage to health is observed. Therefore, the WHO 2005 guideline limits aimed to achieve the lowest concentrations of PM possible.

Guideline values

PM_{2.5}

10 µg/m³ annual mean
25 µg/m³ 24-hour mean

PM₁₀

20 µg/m³ annual mean
50 µg/m³ 24-hour mean

In addition to guideline values, the Air Quality Guidelines provide interim targets for concentrations of PM₁₀ and PM_{2.5} aimed at promoting a gradual shift from high to lower concentrations.

If these interim targets were to be achieved, significant reductions in risks for acute and chronic health effects from air pollution can be expected. Progress towards the guideline values, however, should be the ultimate objective.

The effects of PM on health occur at levels of exposure currently being experienced by many people both in urban and rural areas and in developed and developing countries – although exposures in many fast-developing cities today are often far higher than in developed cities of comparable size.

"WHO Air Quality Guidelines" estimate that reducing annual average particulate matter (PM₁₀) concentrations from levels of 70 µg/m³, common in many developing cities, to the WHO guideline level of 20 µg/m³, could reduce air pollution-related deaths by around 15%. However, even in the European Union, where PM concentrations in many cities do comply with Guideline levels, it is estimated that average life expectancy is 8.6 months lower than it would otherwise be, due to PM exposures from human sources.

In developing countries, indoor exposure to pollutants from the household combustion of solid fuels on open fires or traditional stoves increases the risk of acute lower respiratory infections and associated mortality among young children; indoor air pollution from solid fuel use is also a major risk factor for cardiovascular disease, chronic obstructive pulmonary disease and lung cancer among adults.

There are serious risks to health not only from exposure to PM, but also from exposure to ozone (O₃), nitrogen dioxide (NO₂) and sulfur dioxide (SO₂). As with PM, concentrations are often highest largely in the urban areas of low- and middle-income countries. Ozone is a major factor in asthma morbidity and mortality, while nitrogen dioxide and sulfur dioxide also can play a role in asthma, bronchial symptoms, lung inflammation and reduced lung function.

Ozone (O₃)

Guideline values

O₃

100 µg/m³ 8-hour mean

The recommended limit in the 2005 Air Quality Guidelines was reduced from the previous level of 120 µg/m³ in previous editions of the "WHO Air Quality Guidelines" based on recent conclusive associations between daily mortality and lower ozone concentrations.

Definition and principal sources

Ozone at ground level – not to be confused with the ozone layer in the upper atmosphere – is one of the major constituents of photochemical smog. It is formed by the reaction with sunlight (photochemical reaction) of pollutants such as nitrogen oxides (NO_x) from vehicle and industry emissions and volatile organic compounds (VOCs) emitted by vehicles, solvents and industry. As a result, the highest levels of ozone pollution occur during periods of sunny weather.

Health effects

Excessive ozone in the air can have a marked effect on human health. It can cause breathing problems, trigger asthma, reduce lung function and cause lung diseases. In Europe it is currently one of the air pollutants of most concern. Several European studies have reported that the daily mortality rises by 0.3% and that for heart diseases by 0.4%, per 10 $\mu\text{g}/\text{m}^3$ increase in ozone exposure.

Nitrogen dioxide (NO_2)

Guideline values

NO_2

40 $\mu\text{g}/\text{m}^3$ annual mean

200 $\mu\text{g}/\text{m}^3$ 1-hour mean

The current WHO guideline value of 40 $\mu\text{g}/\text{m}^3$ (annual mean) was set to protect the public from the health effects of gaseous.

Definition and principal sources

As an air pollutant, NO_2 has several correlated activities.

- At short-term concentrations exceeding 200 $\mu\text{g}/\text{m}^3$, it is a toxic gas which causes significant inflammation of the airways.
- NO_2 is the main source of nitrate aerosols, which form an important fraction of $\text{PM}_{2.5}$ and, in the presence of ultraviolet light, of ozone.

The major sources of anthropogenic emissions of NO_2 are combustion processes (heating, power generation, and engines in vehicles and ships).

Health effects

Epidemiological studies have shown that symptoms of bronchitis in asthmatic children increase in association with long-term exposure to NO_2 . Reduced lung function growth is also linked to NO_2 at concentrations currently measured (or observed) in cities of Europe and North America.

Sulfur dioxide (SO_2)

Guideline values

SO_2

20 $\mu\text{g}/\text{m}^3$ 24-hour mean

500 $\mu\text{g}/\text{m}^3$ 10-minute mean

A SO_2 concentration of 500 $\mu\text{g}/\text{m}^3$ should not be exceeded over average periods of 10 minutes duration. Studies indicate that a proportion of people with asthma experience changes in pulmonary function and respiratory symptoms after periods of exposure to SO_2 as short as 10 minutes.

The (2005) revision of the 24-hour guideline for SO_2 concentrations from 125 to 20 $\mu\text{g}/\text{m}^3$ was based on the following considerations.

- Health effects are now known to be associated with much lower levels of SO_2 than previously believed.
- A greater degree of protection is needed.
- Although the causality of the effects of low concentrations of SO_2 is still uncertain, reducing SO_2 concentrations is likely to decrease exposure to co-pollutants.

Definition and principal sources

SO₂ is a colourless gas with a sharp odour. It is produced from the burning of fossil fuels (coal and oil) and the smelting of mineral ores that contain sulfur. The main anthropogenic source of SO₂ is the burning of sulfur-containing fossil fuels for domestic heating, power generation and motor vehicles.

Health effects

SO₂ can affect the respiratory system and the functions of the lungs, and causes irritation of the eyes. Inflammation of the respiratory tract causes coughing, mucus secretion, aggravation of asthma and chronic bronchitis and makes people more prone to infections of the respiratory tract. Hospital admissions for cardiac disease and mortality increase on days with higher SO₂ levels. When SO₂ combines with water, it forms sulfuric acid; this is the main component of acid rain which is a cause of deforestation.

WHO response

- WHO develops and produces "Air quality guidelines" recommending exposure limits to key air pollutants.
- WHO creates detailed health-related assessments of different types of air pollutants, including particulates and black carbon particles, ozone, etc.
- WHO produces evidence regarding the linkage of air pollution to specific diseases, such as cardiovascular and respiratory diseases and cancers, as well as burden of disease estimates from existing air pollution exposures, global and regional.
- WHO's "Health in the green economy" series is assessing the health co-benefits of climate mitigation and energy efficient measures that reduce air pollution from housing, transport, and other key economic sectors.
- WHO's work on "Measuring health gains from sustainable development" has proposed air pollution indicators as a marker of progress for development goals related to sustainable development in cities and the energy sector.
- WHO assists Member States in sharing information on successful approaches, on methods of exposure assessment and monitoring of health impacts of pollution.
- The WHO co-sponsored "Pan European Programme on Transport Health and Environment (The PEP)", has built a model of regional, Member State and multi-sectoral cooperation for mitigation of air pollution and other health impacts in the transport sector, as well as tools for assessing the health benefits of such mitigation measures.

For more information contact:

WHO Media centre
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E-mail: mediainquiries@who.int

Related links

WHO Air quality guidelines - 2005
global update

WHO Global Health Observatory
Recent data on air quality.

Air pollution and cancer: IARC's
2013 assessment

Review of evidence on the health
aspects of air pollution
(REVIHAAP)

Health in the green economy –
series

Measuring health gains from
sustainable development

WHO's work on indoor air pollution
and health

WHO Regional Office for Europe's
work on air quality

More general information on air
pollution



17 October 2013

IARC: Outdoor air pollution a leading environmental cause of cancer deaths

Lyon/Geneva, 17 October 2013 – The specialized cancer agency of the World Health Organization, the International Agency for Research on Cancer (IARC), announced today that it has classified outdoor air pollution as *carcinogenic to humans* (Group 1).¹

After thoroughly reviewing the latest available scientific literature, the world's leading experts convened by the IARC Monographs Programme concluded that there is *sufficient evidence* that exposure to outdoor air pollution causes lung cancer (Group 1). They also noted a positive association with an increased risk of bladder cancer.

Particulate matter, a major component of outdoor air pollution, was evaluated separately and was also classified as *carcinogenic to humans* (Group 1).

The IARC evaluation showed an increasing risk of lung cancer with increasing levels of exposure to particulate matter and air pollution. Although the composition of air pollution and levels of exposure can vary dramatically between locations, the conclusions of the Working Group apply to all regions of the world.

A major environmental health problem

Air pollution is already known to increase risks for a wide range of diseases, such as respiratory and heart diseases. Studies indicate that in recent years exposure levels have increased significantly in some parts of the world, particularly in rapidly industrializing countries with large populations. The most recent data indicate that in 2010, 223 000 deaths from lung cancer worldwide resulted from air pollution.²

The most widespread environmental carcinogen

"The air we breathe has become polluted with a mixture of cancer-causing substances," says Dr Kurt Straif, Head of the IARC Monographs Section. "We now know that outdoor air pollution is not only a major risk to health in general, but also a leading environmental cause of cancer deaths."

The IARC Monographs Programme, dubbed the "encyclopaedia of carcinogens", provides an authoritative source of scientific evidence on cancer-causing substances and exposures. In the past, the Programme evaluated many individual chemicals and specific mixtures that occur in outdoor air pollution. These included diesel engine exhaust, solvents, metals, and dusts. But this is the first time that experts have classified outdoor air pollution as a cause of cancer.

"Our task was to evaluate the air everyone breathes rather than focus on specific air pollutants," explains Dr Dana Loomis, Deputy Head of the Monographs Section. "The results from the reviewed studies point in the same direction: the risk of developing lung cancer is significantly increased in people exposed to air pollution."

IARC Monographs evaluations

Volume 109 of the IARC Monographs is based on the independent review of more than 1000 scientific papers from studies on five continents. The reviewed studies analyse the carcinogenicity of various pollutants present in outdoor air pollution, especially particulate matter and transportation-related pollution. The evaluation is driven by findings from large epidemiologic studies that included millions of people living in Europe, North and South America, and Asia.

¹ Please note that the summary evaluation will be published by *The Lancet Oncology* online on Thursday 24 October 2013

² <http://www.iarc.fr/en/publications/books/sp161/index.php>

IARC: Outdoor air pollution a leading environmental cause of cancer deaths

The predominant sources of outdoor air pollution are transportation, stationary power generation, industrial and agricultural emissions, and residential heating and cooking. Some air pollutants have natural sources, as well.

"Classifying outdoor air pollution as carcinogenic to humans is an important step," stresses IARC Director Dr Christopher Wild. "There are effective ways to reduce air pollution and, given the scale of the exposure affecting people worldwide, this report should send a strong signal to the international community to take action without further delay."

For more information, please contact

Véronique Terrasse, Communications Group, or at +33 (0) 645 284 952 ;
or Dr Nicolas Gaudin, IARC Communications

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.

IARC: Outdoor air pollution a leading environmental cause of cancer deaths

Annexes

Evaluation groups - 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*

IARC: Outdoor air pollution a leading environmental cause of cancer deaths

carcinogenicity in humans but *evidence suggesting lack of carcinogenicity* in experimental animals, consistently and strongly supported by a broad range of mechanistic and other relevant data, may be classified in this group.

Evidence for studies in humans - Definition

As shown previously, the evidence relevant to carcinogenicity is evaluated using standard terms. For studies in humans, evidence is defined 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.

In some instances, the above categories may be used to classify the degree of evidence related to carcinogenicity in specific organs or tissues.