To the Minister of Social Affairs and employment

Gezondheidsraad
Health Council of the Netherlands

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Subject: advisory report *Rubber dusts and rubber fumes*

Dear Minister,

The Health Council of the Netherlands received a request from your ministry to derive a health-based recommended occupational exposure limit. Evaluation of occupational exposures is performed by the Dutch Expert Committee on Occupational Safety (DECOS). This Committee has concluded that it is not possible to derive a health-based recommended occupational exposure limit (HBR-OEL) for rubber dusts or rubber fumes based on the scientific data available. In this advisory letter I explain how this conclusion was reached and which data the Committee would need to derive a HBR-OEL for exposure to rubber fumes and dusts in the future.

Occupational exposure to rubber dusts and rubber fumes

The term rubber is used to describe a wide variety of polymers with elastic properties. Natural rubber (polyisoprene), also called latex, is obtained from the latex tree. Synthetic rubber can be synthesized using about 20 different polymers.[1] Between 15 to 20 different substances can be used in a single rubber compound (either natural or synthetic) in addition to the polymers, including elastomers, fillers, and vulcanising agents.[1] Rubber therefore is a complex composed material and usually contains a large number of chemicals to obtain its desired properties.

Rubber dusts and rubber fumes are complex mixtures of particles, gasses and fumes and vapours that are released during the production of rubber (see text box on the next page). The manufacturing consists of multiple steps that include weighing and mixing, shaping operations, vulcanisation (curing), and post-vulcanisation processes.[4] Exposures involve a mixture of starting materials and impurities (for instance during mixing and weighing) and fumes or dusts from a variety of volatile ingredients, reaction and breakdown products, dependent on the type of rubber and process. The applied raw materials include fillers, vulcanising agents, vulcanisation accelerators and vulcanisation activators.[3]

Downstream in the production process, workers may be exposed to fumes and substances from volatile components, reaction and decomposition products. These includes gases (e.g., carbon disulphide), vapours (e.g., volatile liquids such as toluene), aerosols (e.g., hydrocarbon oil and plasticizers) and hazardous substances of high concern (e.g., N-nitrosamines, aromatic amines and polyaromatic hydrocarbons).

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Definitions of rubber, rubber dusts and rubber fumes
The *Scientific Committee on Occupational Exposure Limits* (SCOEL) of the European Committee has applied definitions by the UK's *Health and Safety Executive* (HSE) for its recommendation in 2016.[2,3] Rubber dusts are defined as "dusts arising in the stages of rubber manufacture where ingredients are handled, weighed, added to or mixed with uncured material or synthetic elastomers", which "does not include dusts arising from the abrasion of cured rubber". The SCOEL noted that rubber process dust is to be determined gravimetrically as the mass of inhalable particles in the workplace air.
Rubber fumes are defined as "fumes evolved in the mixing, milling and blending of natural rubber or synthetic elastomers, or of natural rubber and synthetic polymers combined with chemicals, and in the processes which convert the resultant blends into finished products or parts thereof, and including any inspection procedures where fume continues to be evolved".[2]

Health risks

In 2012, the International Agency for Research on Cancer (IARC) has concluded that occupational exposures in the rubber manufacturing industry can cause leukaemia, lymphoma, and cancers of the urinary bladder, lung, and stomach (IARC group 1).[4] Research also shows that people who work in the rubber-producing industry are more likely to develop prostate cancer, oesophageal cancer and larynx cancer. Genotoxicity was identified as a mechanism of carcinogenic action, however, other mechanisms were also considered likely due to the complexity and changing nature of the exposure mixtures.
There is no formal classification for occupational exposures in the rubber manufacturing industry. Based on a proposal for classification of the Subcommittee Classification of Carcinogenic Substances, occupational exposures in the rubber manufacturing industry can be added to the list of carcinogenic substances of the Ministry of Social Affairs and Employment. Non-carcinogenic effects involved a decreased lung function and an increase of self-reported respiratory symptoms. In addition, allergenic reactions of the skin and respiratory tract were attributed to natural rubber.[3]

Complications for deriving health-based occupational exposure limits

For hazardous substances to which people may be occupationally exposed during their work, the Committee examines whether a HBR-OEL can be derived from scientific research. In other words: an exposure level at which no adverse health effects are expected. Based on a HBR-OEL, the Minister can set a legal limit value for occupational exposure. It is not possible to derive such a limit for rubber dust and rubber fumes because of several complicating factors, as was also addressed by the SCOEL. First, it is not possible to identify an exposure-response for cancer risk in the rubber manufacturing industry, due to a lack of an overall suitable proxy for exposure. Another complicating factor is that exposure in the European rubber manufacturing industry has changed significantly in recent decades. The relevance for studies involving historical exposures is therefore considered questionable.
Overall, in line with the SCOEL it is concluded that because of the highly variable nature of rubber dusts and fumes, general limit values for rubber dusts or fumes may not effectively represent the carcinogenic and genotoxic risk of compounds present in rubber industry.
The Committee notes that only in the UK general limit values are applied, namely worker exposure limits (WELs) of 6 and 0.6 mg/m^3 for dusts and fumes, respectively.[5] These limits probably date from the late 1980s and the DECOS could not ascertain whether they were health-based.

Limit values for raw materials and auxiliary materials
It is therefore currently not possible to derive a HBR-OEL for mixtures released during the rubber production process, which means that no limit value for occupational exposure can be established. For raw materials and auxiliary materials required for the production of rubber, recommended values can be derived, or limit values already exist. Exposure to those separate components can therefore be tested and controlled.

Conclusions of the Committee
The IARC considers exposure in the rubber manufacturing industry to be carcinogenic. As the composition of rubber dusts and rubber fumes is highly variable, a HBR-OEL cannot be derived and exposure cannot be tested.
The Committee notes that research is needed with a focus on the development of relevant exposure proxies. In addition, data on the current exposures in the rubber manufacturing industry are necessary and epidemiological research that provides information on the exposure response-relation of specific substances or proxies.
Finally, the Committee recommends occupational exposure to rubber dust and rubber fumes to be evaluated for carcinogenic properties by the Subcommittee of Classification of Carcinogenic Substances of the Health Council.

I endorse the conclusions of the Committee and I trust that this letter has provided you with sufficient information.

Yours sincerely,

Prof. dr. J.M. Geleijnse,
Vice President

Literature

1 Nederlands Normalisatie-instituut (NEN). *Rubber - Comprehensive review of the composition and nature of process fumes in the rubber industry*. Switzerland, 2017.

2 Health & Safety Executive (HSE). *EH40: Workplace exposure limits* Merseyside, United Kingdom, 2005.

3 Scientific Committee on Occupational Exposure Limits (SCOEL). *Rubber fumes and dusts - Opinion from the Scientific Committee on Occupational Exposure Limits*. Brussels, 2016.

4 International Agency for Research on Cancer (IARC). *Monographs on the evaluation of the carcinogenic risk of chemicals to humans. A Review of Human Carcinogens: Chemical Agents and Related Occupations. Occupational exposure in the rubber-manufacturing industry.*, 2012.

5 Health & Safety Executive (HSE). *EH64 Summary Criteria for Occupational Exposure Limits*. Merseyside, United Kingdom, 1999.

Committee

Members of the Dutch Expert Committee on Occupational Safety for the advisory report *Rubber dusts and rubber fumes*:

- Prof. F.G.M. Russel, Professor of Pharmacology and Toxicology, Radboud University, Nijmegen, *chair*
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Observers:

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