

# **COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT**



## **STATEMENT ON TETRACHLOROETHYLENE AND THE REPRODUCTIVE HEALTH OF WORKERS IN THE DRY-CLEANING INDUSTRY**

### **Introduction**

1. The Committee has been asked to advise the Health and Safety Executive (HSE) and other Government Departments on the implications of an epidemiological study in the dry-cleaning industry. This concerns the potential risks of reproductive and developmental toxicity from tetrachloroethylene to employees, the general public, and consumers arising specifically from its use in dry-cleaning establishments. We understand that our conclusions will be presented to the Health and Safety Commission's Advisory Committee on Toxic Substances.

### **Background**

2. Tetrachloroethylene (perchloroethylene or ethylene tetrachloride,  $C_2Cl_4$ ) is a colourless, non-flammable chlorinated hydrocarbon solvent with widespread industrial application. It has been used in the dry-cleaning industry for over thirty years and currently it accounts for about 80% of the total solvent use in dry-cleaning.

3. The use of tetrachloroethylene in the workplace is controlled in the UK under the Health and Safety at Work etc. Act 1974 and the Control of Substances Hazardous to Health Regulations, 1994. Under these regulations employers are required to prevent, or if this is not reasonably practicable, adequately control exposure of employees and other persons to substances hazardous to health. The 8-hour Occupational Exposure Standard is currently 50 parts per million (ppm) and the short term exposure limit is 100 ppm.

4. In the European Union (EU) tetrachloroethylene is classified as a category 3 carcinogen (possible risk of irreversible effects), but not as a substance toxic to reproduction.

5. The Committee considered tetrachloroethylene in 1993 following the publication of studies which suggested that exposure to tetrachloroethylene may be linked to spontaneous abortion (miscarriage). At that time we concluded that the available epidemiological evidence, although based on studies that were

methodologically weak, was consistent with the view that tetrachloroethylene may be a reproductive toxicant in humans. However, we recognised that the available animal data did not support this view.[1] After we reached our conclusions, HSE commissioned a further epidemiological study of the possible reproductive toxicity of tetrachloroethylene in the dry-cleaning industry.

6. A draft risk assessment of tetrachloroethylene has been prepared by the UK (jointly by HSE and the Department of the Environment, Transport and the Regions) under the EU Existing Substances Regulation (ESR). The review had access to information which was not available when the Committee considered the issue in 1993. The section on toxicity for reproduction, including human developmental toxicity, was made available to us.

### **The study funded by the Health and Safety Executive**

7. In 1994 the HSE commissioned a retrospective occupational cohort study of reproductive outcome in women currently or previously employed in dry-cleaning shops or laundry units. We have been given the results in the form of a report to HSE [2] and also as a manuscript submitted for publication.[3] So far, only the data on spontaneous abortions have been fully analysed.

8. The key findings of the research were that:

- i) within the dry-cleaning group the risk of spontaneous abortion was statistically significantly higher in the operator group than in the non-operator group; adjusted odds ratio 1.63 with 95% Confidence Interval (CI) 1.01-2.66,  $p=0.04$ , equivalent to 63% excess risk;
- ii) consistent findings were obtained for exposed pregnancies of dry-cleaning operators compared both with unexposed pregnancies prior to the first exposed pregnancy and with unexposed pregnancies after the last exposed pregnancy; adjusted odds ratios 1.67, 95% CI 1.17-2.36 and 1.82, 95% CI 1.09-3.05, respectively. These are based on non-overlapping data sets;
- iii) the risk of spontaneous abortion for pregnancies conceived while women were employed as non-operators in dry-cleaning establishments was no greater than that for pregnancies occurring while women were not employed in either the dry-cleaning or laundry industries; adjusted odds ratio 1.02, 95% CI 0.65-1.60 (compared with unexposed pregnancies prior to first exposed pregnancy).

9. The Committee considered five questions:

- i) Whether it agreed that the study's main conclusion (that dry-cleaning machine operators had a higher risk of spontaneous abortion than non-operators) was supported by the data?
- ii) If so, could any conclusions be drawn about the rôle of

tetrachloroethylene in the observed increased risk?

iii) Whether the effect, whatever the cause, was restricted to operators and if so, by implication, is there no risk to the general public and consumers (on dry-cleaning premises)?

iv) Does the study provide sufficient evidence that exposure to tetrachloroethylene is not associated with low birthweight?

v) Whether the research alters the balance of the argument in the ESR review in terms of its assessment of tetrachloroethylene's toxicity for reproduction?

## Conclusions

10. Our conclusions are:

i) We *consider* that the study showed that dry-cleaning machine operators had an increased risk of spontaneous abortion compared with non-operators. This is consistent with other published work. We *agree* that there is an epidemiological association between the job category and spontaneous abortion.

ii) We *are of the opinion*, however, that there is no evidence for a plausible biological mechanism by which tetrachloroethylene could cause this effect and that other factors could have contributed to the observed risk. We *conclude*, therefore, that the increased risk of spontaneous abortion could not be specifically attributed to exposure to tetrachloroethylene.

iii) The evidence that non-operators were at no increased risk leads us to *conclude* that, by implication, there is no risk to the general public who visit dry-cleaning premises.

iv) We are aware that the researchers are conducting further analyses on the relationship between low birthweight and job category. We cannot comment on this aspect of the study until this work has been completed.

v) The draft ESR review concludes that 'Although there is no convincing evidence that tetrachloroethylene causes developmental toxicity in humans, concern has been raised regarding the risk of spontaneous abortion in, particularly, dry-cleaning workers.'. We *conclude* that this study adds a little weight to the existing epidemiological evidence for the risk of spontaneous abortion in dry-cleaning workers, but that on balance it does not change the conclusion in the draft ESR review concerning the rôle of tetrachloroethylene.

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## References

1. Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (1994). 1993 Annual Report of the Committees on Toxicity, Mutagenicity, Carcinogenicity of Chemicals in Food, Consumer Products and the Environment. London: HMSO.
2. Doyle P, Roman E and Beral V. Study to investigate the reproductive toxicity of perchloroethylene, Report to the Health and Safety Executive (July 1997).
3. Doyle P, Roman E, Beral V and Brooks M (1997). Spontaneous abortion in dry cleaning workers potentially exposed to perchloroethylene. *Occup Environ Med*; in press.