

OPINION

of the French Agency for Food, Environmental and Occupational Health & Safety

concerning the proposal for exposure limit values for chemical agents in occupational environments

Evaluation of the health effects and methods for the measurement of exposure levels in
the workplace for

Perchloroethylene

ANSES's public health mission involves ensuring environmental, occupational and food safety as well as assessing the potential health risks they may entail.

It provides the competent authorities with the necessary information concerning these risks as well as the requisite expertise and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code)

This ANSES Opinion incorporates the expert appraisals undertaken by AFSSET. ANSES became legally operational on 1 July 2010 following the promulgation of the Ministerial Order dated 8 January 2010 enacting its creation, and adopted the missions, knowledge and values of AFSSET and AFSSA.

1. PRESENTATION OF THE ISSUE

ANSES received a formal request on 12 June 2007 from the Directorate General of Labour to conduct an expert appraisal with the aim of determining occupational exposure limits for about 20 substances including perchloroethylene.

2. BACKGROUND

The European Scientific Committee on Occupational Exposure Limits to Chemical Agents (SCOEL) issued an Opinion on the health effects of perchloroethylene (cf SCOEL/SUM/133, February 2008 for public consultation). This expert appraisal, submitted by the European Commission for public consultation until 15 January 2009, recommended, based on an analysis of the health effects, an eight-hour limit value of 20 ppm (or 138 mg.m⁻³) and a 15-minute short-term limit value (STEL) of 40 ppm (or 275 mg.m⁻³). The SCOEL proposed

including the "skin" notation, and also recommended a biological limit value of 0.4 mg of tetrachloroethylene per ml of blood.

3. ORGANISATION OF THE EXPERT APPRAISAL

This expert appraisal was carried out in accordance with the French standard NF X 50-110 "Quality in Expertise - General Requirements of Competence for Expert Appraisals (May 2003)" to ensure compliance with the following points: competence, independence, transparency and traceability.

This issue falls under the responsibility of the Expert Committee (CES) on *expert appraisal for recommending exposure limits for chemical agents in occupational environments* (OEL CES). This committee mandated two rapporteurs (one for the part relating to the health effects and another for the part relating to the metrology) from among the CES experts to conduct this expert appraisal.

The methodological and scientific aspects of the work were regularly submitted to the CES and the conclusions were presented and approved at the OEL CES meeting held on 19 June 2009.

This expert appraisal was therefore conducted by a group of experts with complementary skills.

The scientific aspects of this Opinion are based on the final report released following this collective expert appraisal ("Collective expert report for recommending exposure limit values for chemical agents in occupational environments" dated June 2009, concerning evaluation of the health effects and the methods for the measurement of perchloroethylene exposure levels in the workplace). This report was approved by the Expert Committee at its meeting held on 19 September 2009.

4. OPINION AND RECOMMENDATIONS

In accordance with the findings of the collective expert report issued by the Expert Committee on *expert appraisal for recommending occupational exposure limit values for chemical agents*, ANSES considers that, in the current state of available data, **a carcinogenic effect associated with exposure to perchloroethylene cannot be excluded**. Since the currently available data on carcinogenicity do not allow a dose-response relationship at low doses to be determined and do not allow a correlation to be made with an excess unit risk, ANSES recommends setting a "pragmatic" OEL based on another health effect (neurotoxic effects of perchloroethylene).

For perchloroethylene, ANSES therefore recommends the setting of:

- an 8-hour **occupational exposure limit value** (8h-OEL) of **20 ppm** or 138 mg.m⁻³;
- a 15-minute **short-term limit value** (15min STEL) of **40 ppm** or 275 mg.m⁻³.

The aim of this 8h OEL of 20 ppm (138 mg.m⁻³) is to prevent possible neurotoxic effects in the workplace. The value was established from the results of three studies (Ferroni *et al.*, 1992; Stewart *et al.*, 1977, and Stewart *et al.*, 1981), which came to similar conclusions and estimated that the first neurotoxic effects (LOAEC) were observed in humans around a value

of 100 ppm. The application of a safety factor of 5 to the LOAEC is considered sufficient to take into account both the minor neurological effects that were observed at concentrations below 100 ppm, but for which the evidence is not considered conclusive, and a possible inter-individual variability.

The short-term limit value of 40 ppm (275 mg.m⁻³) is recommended based on two controlled exposure studies in humans, which are considered the most relevant (Rowe *et al.*, 1952, and Stewart *et al.*, 1961), in order to limit exposure peaks and thus prevent possible neurotoxic effects and irritation.

These values are the same as those recommended by the SCOEL in its 2008 draft recommendation and by the Dutch Expert Committee on Occupational Health Safety (DECOS) in 2004.

ANSES **does not recommend** assigning a "**skin**" notation for perchloroethylene because data on controlled exposure to vapours in humans support the conclusion that dermal exposure is not significant compared to inhalation.

After analysis, validated measurement methods suitable for the assessment of occupational exposures were identified. These methods allow not only measurement of the 8hour limit value of 20 ppm (138 mg.m⁻³), but also measurement of the STEL of 40 ppm (275 mg.m⁻³).

Following this expert appraisal, ANSES considers it useful to stress that the preventive measures for chemical risks stipulate that the ALARA¹ principle is to be applied, including in the presence of a substance suspected of being carcinogenic.

Furthermore, ANSES recommends:

- developing solutions that will eventually allow the substitution of perchloroethylene by less harmful substances and/or processes in order to reduce the risks for workers' health and safety, to the extent that a carcinogenic effect associated with exposure to perchloroethylene cannot be ruled out;
- setting up active monitoring of the literature for new data produced on perchloroethylene, since it is classified as a category 3 carcinogenic substance by the European Union.

Signed in six original copies,

the Director General

Marc Mortureux

¹ As Low As Reasonably Achievable.