Commission Regulation (EC) No 761/2009 of 23 July 2009 amending, for the purpose of its adaptation to technical progress, Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance)

COMMISSION REGULATION (EC) No 761/2009

of 23 July 2009

amending, for the purpose of its adaptation to technical progress, Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1907/2006 of 18 December 2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[(1)], and in particular Article 13(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 440/2008[(2)] contains the test methods for the purposes of the determination of the physico-chemical properties, toxicity and eco-toxicity of substances to be applied for the purposes of Regulation (EC) No 1907/2006.

(2) It is necessary to update Regulation (EC) No 440/2008 to include changes to certain test methods and to include several new test methods adopted by the OECD. Stakeholders have been consulted on this proposal. Those amendments adapt the methods in question to scientific and technical progress.

(3) The provisions concerning vapour pressure to include the new effusion method should be revised.

(4) It is necessary to add a new method to measure length weighted geometric mean diameter of fibres.

(5) It is appropriate to update Regulation (EC) No 440/2008 to include with priority a new in vitro test method for skin irritation, in order to obtain a reduction of the number of animals to be used for experimental purposes, in accordance with Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and

administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[3]. Although a draft in vitro test method for skin irritation is still under discussion within the OECD, it is appropriate in this exceptional case to include method B 46 in this Regulation. Method B 46 should be updated as soon as possible once an agreement has been reached within the OECD or if further information justifying such a revision becomes available.

(6) The provisions concerning the algal inhibition test need to be revised to include additional species and to meet the requirements for hazard assessment and classification of chemicals.

(7) It is necessary to add a new method to measure aerobic mineralisation in surface water, by virtue of a simulation biodegradation test and a new method to assess toxicity to the genus *Lemna*, by virtue of a growth inhibition test.

(8) Regulation (EC) No 440/2008 should therefore be amended accordingly.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 440/2008 is amended as follows:

1. Part A is amended as follows:

   (a) Chapter A.4 is replaced by Chapter A.4 as set out in Annex I to this Regulation;

   (b) Chapter A.22 as set out in Annex II to this Regulation is added;

2. Part B is amended as follows:

   Chapter B.46 as set out in Annex III to this Regulation is added;

3. Part C is amended as follows:

   (a) Chapter C.3 is replaced by Chapter C.3 as set out in Annex IV to this Regulation;

   (b) Chapters C.25 and C.26 as set out in Annexes V and VI to this Regulation are added.

Article 2

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 July 2009.

For the Commission

Stavros DIMAS

Member of the Commission

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 761/2009. (See end of Document for details)*

ANNEX I

A.4. VAPOUR PRESSURE

1. METHOD

This method is equivalent to OECD TG 104 (2004).

1.1. INTRODUCTION

This revised version of method A.4(1) includes one additional method; Effusion method: isothermal thermogravimetry, designed for substances with very low pressures (down to 10^{-10} Pa). In the light of needs for procedures, especially in relation to obtaining vapour pressure for substances with low vapour pressure, other procedures of this method are re-evaluated with respect to other applicability ranges.

At the thermodynamic equilibrium the vapour pressure of a pure substance is a function of temperature only. The fundamental principles are described elsewhere (2)(3).

No single measurement procedure is applicable to the entire range of vapour pressures from less than 10^{-10} to 10^5 Pa. Eight methods for measuring vapour pressure are included in this method which can be applied in different vapour pressure ranges. The various methods are compared as to application and measuring range in Table 1. The methods can only be applied for compounds that do not decompose under the conditions of the test. In cases where the experimental methods cannot be applied due to technical reasons, the vapour pressure can also be estimated, and a recommended estimation method is set out in the Appendix.

1.2. DEFINITIONS AND UNITS

The vapour pressure of a substance is defined as the saturation pressure above a solid or liquid substance.

The SI unit of pressure, which is the pascal (Pa), should be used. Other units which have been employed historically are given hereafter, together with their conversion factors:

1 Torr	=	1 mm Hg	=	$1{,}333 \times 10^2$ Pa
1 atmosphere	=	$1{,}013 \times 10^5$ Pa		
1 bar	=	10^5 Pa		

The SI unit of temperature is the kelvin (K). The conversion of degrees Celsius to kelvin is according to the formula:

$T = t + 273{,}15$

where, T is the kelvin or thermodynamic temperature and t is the Celsius temperature.

TABLE 1

Measuring method	**Substances**		**Estimated repeatability**	**Estimated reproducibility**	**Recommended range**
	Solid	**Liquid**			

a When using a capacitance manometer

Dynamic method	Low melting	Yes	up to 25 % 1 to 5 %	up to 25 % 1 to 5 %	10^3 Pa to 2 × 10^3 Pa 2 × 10^3 Pa to 10^5 Pa
Static method	Yes	Yes	5 to 10 %	5 to 10 %	10 Pa to 10^5 Pa 10^{-2} Pa to 10^5 Pa[a]
Isoteniscope method	Yes	Yes	5 to 10 %	5 to 10 %	10^2 Pa to 10^5 Pa
Effusion method: vapour pressure balance	Yes	Yes	5 to 20 %	up to 50 %	10^{-3} to 1 Pa
Effusion method: Knudsen cell	Yes	Yes	10 to 30 %	—	10^{-10} to 1 P
Effusion method: isothermal thermogravimetry	Yes	Yes	5 to 30 %	up to 50 %	10^{-10} to 1 Pa
Gas saturation method	Yes	Yes	10 to 30 %	up to 50 %	10^{-10} to 10^3 Pa
Spinning rotor method	Yes	Yes	10 to 20 %	—	10^{-4} to 0,5 Pa

a When using a capacitance manometer

1.3. PRINCIPLE OF THE TEST

In general, the vapour pressure is determined at various temperatures. In a limited temperature range, the logarithm of the vapour pressure of a pure substance is a linear function of the inverse of the thermodynamic temperature according to the simplified Clapeyron-Clausius equation:

$$\log p = \Delta \frac{Hv}{2,3} RT + constant$$

where:

p = the vapour pressure in pascals
ΔHv = the heat of vaporisation in J mol^{-1}
R = the universal gas constant, 8,314 J mol^{-1} K^{-1}
T = the temperature in K

1.4. REFERENCE SUBSTANCES