Directive 2008/112/EC of the European Parliament and of the Council of 16 December 2008 amending Council Directives 76/768/EEC, 88/378/EEC, 1999/13/EC and Directives 2000/53/EC, 2002/96/EC and 2004/42/EC of the European Parliament and of the Council in order to adapt them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (Text with EEA relevance)

Article 1

Amendments to Directive 76/768/EEC

Directive 76/768/EEC is hereby amended as follows:

1. the word ‘preparation’ or ‘preparations’ within the meaning of Article 3(2) of Regulation (EC) No 1907/2006, in its version of 30 December 2006, shall be replaced by ‘mixture’ or ‘mixtures’ respectively throughout the text;

2. in Article 4a(1), point d shall be replaced by the following:

   (d) the performance on their territory of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this Directive, no later than the date on which such tests are required to be replaced by one or more validated methods listed in Commission Regulation (EC) No 440/2008 of 30 May 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)[(1)] or in Annex IX to this Directive.;

3. from 1 December 2010, Article 4b shall be replaced by the following:

   Article 4b

   The use in cosmetic products of substances classified as carcinogenic, germ cell mutagenic or toxic for reproduction, of category 1A, 1B and 2, under part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures[(2)] shall be prohibited. To that end the Commission shall adopt the necessary measures in accordance with the regulatory procedure referred to in Article 10(2). A substance classified in category 2 may be used in cosmetics if the substance has been evaluated by the Scientific Committee on Consumer Safety (SCCS) and found acceptable for use in cosmetic products.;

4. from 1 December 2010, in Article 7a(1), the last sentence of the second subparagraph of point (h) shall be replaced by the following:

   The quantitative information required under (a) to be made publicly accessible shall be limited to substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

   (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

   (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

(c) hazard class 4.1;

(d) hazard class 5.1.;

5. in Annex IX, the first sentence shall be replaced by the following:

‘This Annex lists the alternative methods validated by the European Centre on Validation of Alternative Methods (ECVAM) of the Joint Research Centre available to meet the requirements of this Directive and which are not listed in Regulation (EC) No 440/2008.’.

(**1**) OJ L 142, 31.5.2008, p. 1.';

(**2**) OJ L 353, 31.12.2008, p. 1.';