COMMISSION REGULATION (EU) 2020/2096
of 15 December 2020

(TEXT WITH EEA RELEVANCE)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,


Whereas:

(1) Entry 3 of Annex XVII to Regulation (EC) No 1907/2006 contains several references to labelling with R65, which is one of the standard 'R-phrases', indicating special risks arising from the dangers associated with using the substance that were set out in Council Directive 67/548/EEC (2). As that Directive has been repealed, the references to R65 should be deleted from entry 3.

(2) Pursuant to paragraph 6 of entry 3 of Annex XVII to Regulation (EC) No 1907/2006, on 8 July 2015 the European Chemicals Agency prepared a dossier in accordance with Article 69 of that Regulation and concluded that there is no need to propose an amendment of the restriction set out in that entry. Accordingly, paragraphs 6 and 7 of entry 3 have become superfluous and should be deleted.


(4) Entry 46 of Annex XVII to Regulation (EC) No 1907/2006, as first included in Regulation (EC) No 1907/2006, contained no CAS or EC numbers for nonylphenol. Commission Regulation (EC) No 552/2009 (4) added a CAS number and an EC number to that entry, with the intention of clarifying it and allowing operators and enforcement authorities to apply it correctly. That addition however had the unintended effect that not all isomers of nonylphenol are now covered by entry 46. The intention of the legislator at the time of adoption of the restriction should therefore be reflected by deleting those numbers.

(5) Entries 28, 29 and 30 of Annex XVII to Regulation (EC) No 1907/2006 prohibit the placing on the market and use, for supply to the general public, of substances that are classified as carcinogenic, mutagenic or reproductive toxicant (CMR), categories 1A or 1B, and listed in Appendices 1 to 6 to that Annex and of mixtures containing such substances above specified concentrations.


(10) The classifications of substances introduced by Regulation (EU) 2018/1480 apply from 1 May 2020. Stakeholders should be allowed sufficient time to take appropriate measures to comply with the restriction introduced by this Regulation as regards substances classified as CMR category 1A or 1B by Regulation (EU) 2018/1480. Six months period should be sufficient. The date of application does not prevent operators from applying the restrictions related to the CMR substances category 1A or 1B classified under Regulation (EU) 2018/1480 earlier.

(11) Delegated Regulation (EU) 2020/217 will apply from 1 October 2021. The restriction introduced by this Regulation as regards substances classified as CMR category 1A or 1B by Regulation (EU) 2020/217 should therefore apply from 1 October 2021. The date of application does not prevent operators from applying the restrictions related to the CMR substances category 1A or 1B classified under Regulation (EU) 2020/217 earlier.

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Appendix 10 to Annex XVII to Regulation (EC) No 1907/2006 lists testing methods for azocolourants for the purposes of entry 43 of that Annex. Several of the listed testing methods are outdated and have been replaced by the European Committee for Standardization with more up-to-date testing methods. Appendix 10 should therefore be amended to reflect those changes.

Regulation (EC) No 1907/2006 should therefore be amended accordingly.

The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133(1) of Regulation (EC) No 1907/2006.

HAS ADOPTED THIS REGULATION:

**Article 1**

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

**Article 2**

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

Point (6) of the Annex shall apply from 4 July 2020.

Point (8)(b) of the Annex shall apply as follows:

— rows concerning cobalt, benzo[rs]pentaphene and dibenzo[b,de]chrysene; dibenzo[a,h]pyrene shall apply from 1 October 2021,

— rows concerning 1,2-dihydroxybenzene; pyrocatechol, acetaldehyde; ethanol and spirodiclofen (ISO); 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate shall apply from 5 July 2021.

Point 11(b) of the Annex shall apply from 1 October 2021.

Point (12)(b) of the Annex shall apply as follows:

— rows concerning cobalt; ethylene oxide; oxirane, ethanol, 2,2’-iminobis-, N-[(C13-15 branched and linear alkyl) derivs., dioxyhexyl phthalate, halosulfuron-methyl (ISO); methyl 3-chloro-5-[[4,6dimethoxypyrimidin-2yl]carbamoyl] sulfamoyl]-1-methyl1H-pyrazole-4-carboxylate, 2-methylimidazole and dibutylbis(pentane-2,4-dionato-O,O’)tin shall apply from 1 October 2021,

— rows concerning 2-benzyl-2-dimethylamino-4’-morpholinobutyrophenone, propiconazole (ISO); (2RS,4RS;2RS,4SR)-1-{2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl}[methyl]-1H-1,2,4-triazole and 1-vinylimidazole shall apply from 5 July 2021.

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


For the Commission
The President
Ursula VON DER LEYEN
ANNEX

Annex XVII to Regulation (EC) No 1907/2006 is amended as follows:

(1) Column 2 of entry 3 is amended as follows:

(a) paragraph 3 is replaced by the following:

‘3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they:
— can be used as fuel in decorative oil lamps for supply to the general public, and
— present an aspiration hazard and are labelled with H304.’;

(b) paragraph 5 is replaced by the following:

‘5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:

(a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: “Keep lamps filled with this liquid out of the reach of children”; and, by 1 December 2010, “Just a sip of lamp oil – or even sucking the wick of lamps – may lead to life-threatening lung damage”; 

(b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: ‘Just a sip of grill lighter fluid may lead to life threatening lung damage’;

(c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.’;

(c) paragraph 6 is deleted;

(d) paragraph 7 is deleted.

(2) Entry 22 is deleted.

(3) In entries 28-30, the following point (f) is added in paragraph 2 of column 2:

‘(f) devices covered by Regulation (EU) 2017/745’.

(4) In entry 46, the references to CAS number and EC number in paragraph (a) of column 1 are deleted.

(5) Entry 67 is deleted.

(6) Entry 68 is deleted.

(7) The title of Appendix 1 is replaced by the following:

‘Entry 28 – Carcinogens: Category 1A’.

(8) Appendix 2 is amended as follows:

(a) the title is replaced by the following:

‘Entry 28 – Carcinogens: Category 1B’;

(b) the following entries are inserted in the table in order of the index numbers set out therein:

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>EC Number</th>
<th>Index Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>cobalt</td>
<td>027-001-00-9</td>
<td>231-158-0</td>
<td>7440-48-4</td>
</tr>
<tr>
<td>benzo[rst]pentaphene</td>
<td>601-090-00-X</td>
<td>205-877-5</td>
<td>189-55-9</td>
</tr>
<tr>
<td>dibenzo[b,df]chrysene; dibenzo[a,h]pyrene</td>
<td>601-091-00-5</td>
<td>205-878-0</td>
<td>189-64-0</td>
</tr>
<tr>
<td>1,2-dihydroxybenzene; pyrocatechol</td>
<td>604-016-00-4</td>
<td>204-427-5</td>
<td>120-80-9</td>
</tr>
</tbody>
</table>
(9) The title of Appendix 3 is replaced by the following:

Entry 29 – Germ cell mutagens: Category 1 A’.

(10) The title of Appendix 4 is replaced by the following:

Entry 29 – Germ cell mutagens: Category 1 B’.

(11) Appendix 5 is amended as follows:

(a) the title is replaced by the following:

Entry 30 – Reproductive toxicants: Category 1 A’;

(b) the following entry is inserted in the table in order of the index numbers set out therein:

| 'methylmercuric chloride' | 080-012-00-0 | 204-064-2 | 115-09-3’ |

(12) Appendix 6 is amended as follows:

(a) the title is replaced by the following:

Entry 30 – Reproductive toxicants: Category 1 B’;

(b) the following entries are inserted in the table in order of the index numbers set out therein:

| 'cobalt' | 027-001-00-9 | 231-158-0 | 7440-48-4’ |
| 'ethylene oxide; oxirane' | 603-023-00-X | 200-849-9 | 75-21-8’ |
| 'ethanol, 2,2’-iminobis-N-(C13-15 branched and linear alkyl) derivs.' | 603-236-00-8 | 308-208-6 | 97925-95-6’ |
| '2-benzyl-2-dimethylamino-4’-morpholino-butyrophenone' | 606-047-00-9 | 404-360-3 | 119313-12-1’ |
| 'dibutylbis(pentane-2,4-dionato-O,O’')tin' | 650-056-00-0 | 245-152-0 | 22673-19-4’ |
In Appendix 10, the table is replaced by the following table:

<table>
<thead>
<tr>
<th>European standardisation organisation</th>
<th>Reference and title of the harmonised standard</th>
<th>Reference of the superseded standard</th>
</tr>
</thead>
</table>
| CEN                                  | EN ISO 17234-1:2015
Leather – Chemical tests for the determination of certain azo colorants in dyed leathers – Part 1: Determination of certain aromatic amines derived from azo colorants | EN ISO 17234-1:2010 |
| CEN                                  | EN ISO 17234-2:2011
Leather – Chemical tests for the determination of certain azo colorants in dyed leathers – Part 2: Determination of 4-aminoazobenzene | CEN ISO/TS 17234:2003 |
| CEN                                  | EN ISO 14362-1:2017
Textiles – Methods for determination of certain aromatic amines derived from azo colorants – Part 1: Detection of the use of certain azo colorants accessible with and without extracting the fibres | EN 14362-1:2012 |
| CEN                                  | EN ISO 14362-3:2017
Textiles – Methods for determination of certain aromatic amines derived from azo colorants – Part 3: Detection of the use of certain azo colorants, which may release 4-aminoazobenzene | EN 14362-3:2012’ |