REGULATIONS

COMMISSION REGULATION (EU) No 143/2011
of 17 February 2011

THE EUROPEAN COMMISSION,

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


Whereas:

(1) Regulation (EC) No 1907/2006 provides that substances meeting the criteria for classification as carcinogenic (category 1 or 2), mutagenic (category 1 or 2) and toxic for reproduction (category 1 or 2) in accordance with Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ( 2 ), substances that are persistent, bioaccumulative and toxic, substances that are very persistent and very bioaccumulative, and/or substances for which there is scientific evidence of probable serious effects to human health and environment giving rise to an equivalent level of concern may be subject to authorisation.

(2) Pursuant to Article 58(4) of 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ( 3 ), as from 1 December 2010 Article 57(a), (b) and (c) of Regulation (EC) No 1907/2006 shall refer to the classification criteria laid down respectively in Sections 3.6, 3.5 and 3.7 of Annex I to Regulation (EC) No 1272/2008. Therefore, references in this Regulation to the classification criteria referred to in Article 57 of Regulation (EC) No 1907/2006 should be made in accordance with that provision.

(3) 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) is very persistent and very bioaccumulative in accordance with the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 pursuant to Article 57(e) and set out in Annex XIII to that Regulation. It has been identified and included in the candidate list in accordance with Article 59 of that Regulation.

(4) 4,4’-Diaminodiphenylmethane (MDA) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 pursuant to Article 57(a) of that Regulation. It has been identified and included in the candidate list in accordance with Article 59 of that Regulation.

(5) Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins – SCCPs) are persistent, bioaccumulative and toxic, and very persistent and very bioaccumulative in accordance with the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 pursuant to Article 57(d) and (e) respectively and set out in Annex XIII to that Regulation. They have been identified and included in the candidate list in accordance with Article 59 of that Regulation.

(6) Hexabromocyclododecane (HBCDD) and the diasteroisomers alpha-, beta- and gamma-hexabromocyclododecane are persistent, bioaccumulative and toxic in accordance with the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 pursuant to Article 57(d) and set out in Annex XIII to that Regulation. They have been identified and included in the candidate list in accordance with Article 59 of that Regulation.

(7) Bis(2-ethylhexyl) phthalate (DEHP) meets the criteria for classification as toxic for reproduction (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 pursuant to Article 57(c) of that Regulation. It has been identified and included in the candidate list in accordance with Article 59 of that Regulation.

(8) Benzyl butyl phthalate (BBP) meets the criteria for classification as toxic for reproduction (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 pursuant to Article 57(c) of that Regulation. It has been identified and included in the candidate list in accordance with Article 59 of that Regulation.

(9) Dibutyl phthalate (DBP) meets the criteria for classification as toxic for reproduction (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 pursuant to Article 57(c) of that Regulation. It has been identified and included in the candidate list in accordance with Article 59 of that Regulation.

(10) The abovementioned substances have been prioritised for inclusion in Annex XIV to Regulation (EC) No 1907/2006 by the European Chemicals Agency in its recommendation of 1 June 2009 (1) in accordance with Article 58 of that Regulation.


(12) For each substance listed in Annex XIV to Regulation (EC) No 1907/2006, where the applicant wishes to continue to use the substance or place the substance on the market, it is appropriate to set a date by which applications must be received by the European Chemicals Agency, in accordance with Article 58(1)(c)(iii) of that Regulation.

(13) For each substance listed in Annex XIV to Regulation (EC) No 1907/2006 it is appropriate to set a date from which the use and placing on the market is prohibited, in accordance with Article 58(1)(c)(i) of that Regulation.

(14) The European Chemicals Agency recommendation of 1 June 2009 has identified different latest application dates for the substances listed in the Annex to this Regulation. These dates should be set on the basis of the estimated time that would be required to prepare an application for the authorisation, taking into account the information available on the different substances and specifically the information received during the public consultation carried out in accordance with Article 58(4) of Regulation (EC) No 1907/2006. Factors such as the number of actors in the supply chain, their homogeneity or heterogeneity, the existence of ongoing substitution efforts and information on potential alternatives and the expected complexity of the preparation of the analysis of alternatives should be taken into account.

(15) In accordance with Article 58(1)(c)(iii) of Regulation (EC) No 1907/2006, the latest application date is to be set at least 18 months before the sunset date.

(16) Article 58(1)(e) in conjunction with Article 58(2) of Regulation (EC) No 1907/2006 provides for the possibility of exemptions of uses or categories of uses in cases where there is specific Community legislation imposing minimum requirements relating to the protection of human health or the environment that ensures proper control of the risks.


packaging materials by imposing requirements on the quality, stability, and safety of the immediate packaging materials. It is therefore appropriate to exempt the use of DEHP, BBP, and DBP in the immediate packaging of medicinal products from authorisation under Regulation (EC) No 1907/2006.


(19) On the basis of the information currently available it is not appropriate to set exemptions for product and process orientated research and development.

(20) On the basis of the information currently available it is not appropriate to set review periods for certain uses.

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

HAS ADOPTED THIS REGULATION:

Article 1
Annex XIV 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 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, 17 February 2011.

For the Commission
The President
José Manuel BARROSO

In Annex XIV to Regulation (EC) No 1907/2006 the following table is inserted:

<table>
<thead>
<tr>
<th>Entry Nr</th>
<th>Substance</th>
<th>Intrinsic property(ies) referred to in Article 57</th>
<th>Transitional arrangements</th>
<th>Exempted (categories of) uses</th>
<th>Review periods</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)</td>
<td>vPvB</td>
<td>Latest application date (1) 21 January 2013</td>
<td>Sunset date (2) 21 July 2014</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>EC No: 201-329-4, 81-15-2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>4,4’-Diaminodiphenylmethane (MDA)</td>
<td>Carcinogenic (category 1B)</td>
<td>Latest application date (1) 21 January 2013</td>
<td>Sunset date (2) 21 July 2014</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>EC No: 202-974-4, 101-77-9</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Hexabromocyclododecane (HBCDD)</td>
<td>PBT</td>
<td>Latest application date (1) 21 January 2014</td>
<td>Sunset date (2) 21 July 2015</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>EC No: 221-695-9, 247-148-4, 3194-55-6, 25637-99-4, 134237-50-6, 134237-51-7, 134237-52-8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC No: 204-211-0, 117-81-7</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry Nr</td>
<td>Substance</td>
<td>Intrinsic property(ies) referred to in Article 57</td>
<td>Transitional arrangements</td>
<td>Exempted (categories of) uses</td>
<td>Review periods</td>
</tr>
<tr>
<td>----------</td>
<td>-----------</td>
<td>-----------------------------------------------</td>
<td>--------------------------</td>
<td>-------------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td></td>
<td>CE No: 201-557-4</td>
<td></td>
<td>21 July 2013</td>
<td>21 January 2015</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CAS No: 84-74-2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(1) Date referred to in Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006.
(2) Date referred to in Article 58(1)(c)(i) of Regulation (EC) No 1907/2006.