

(EU) 2020/2096 修订 REACH 法规附录 17

1) 修订第 3 条目的内容

REACH 法规附录 17 条目 3 包含了对 R65 标签的若干引用，R65 是标准的“R-短语”之一，表示与使用第 67/548/EEC 号理事会指令中规定的物质相关的危险引起的特殊风险。由于该指令已被废除，因此删除第 3 项中对 R65 的引用。由于欧洲化学品管理局（ECHA）于 2015 年 7 月 8 日根据该法规第 69 条编制了一份卷宗，并得出结论，无需对该条目中规定的限制提出修正案。因此，第 6 和第 7 段已变得多余所以予以删除。

2) 删除第 22、67 及 68 条目

REACH 法规附录 17 对第 22 条目五氯苯酚及其盐和酯，第 67 条目十溴二苯醚，第 68 条目 PFOA 及其盐和相关物质规定了限制。由于欧盟 2019 年发布 2019/1021 (EU)，即欧盟 POPs（持久性有机污染物）法规对这些物质规定了更严格的限制。为了避免重复，将 REACH 法规附录 17 中的第 22、67 和 68 条目从予以删除。

3) 删除第 46 条目中壬基酚的 CAS 号和 EC 号

REACH 法规附录 17 的条目 46 最初不含壬基酚的 CAS 或 EC 编号。欧盟委员会法规 (EC) No 552/2009 增加了 CAS 编号和 EC 编号，目的是澄清其含义，并允许经营者和执法机构正确应用。然而，这一添加产生了意想不到的效果，即并非所有壬基酚的异构体现在都包含在条目 46 中。因此，删除这些数字以体现立法者管控壬基酚所有异构体的本意。

4) 修订第 28、29 及 30 条目中的要求

REACH 法规附录 17 的第 28、29 及 30 条目中规定，禁止向市场投放和使用被分类为第 1A 类或第 1B 类的致癌、致基因突变及生殖毒性（CMR）的物质。这些物质是引用欧盟的 1272/2008 (EC)（简称为 CLP 法规）中的物质，因 CLP 中 CMR 1A 或 1B 更新，本条规定也应随之更新。而医疗器械法规 (EU) 2017/745 已包含了有关 CMR 物质的规定，为了避免双重规定，豁免 2017/745 法规范围内的设备，不受 REACH 法规附件 XVII 第 28-30 条目所规定的限制。

5) 更新第 43 条目中偶氮着色剂的测试方法

REACH 法规附录 17 的附件 10 列出了该附录第 43 项中偶氮着色剂的测试方法。其中一些测试方法已经过时，已经被欧洲标准化委员会用更新的测试方法取代。因此，修订附录 10 以反映这些变化。

原方法	更新后方法
EN ISO 17234-1:2010	EN ISO 17234-1:2015
EN ISO 17234-2:2011	EN ISO 17234-2:2011
EN 14362-1:2012	EN ISO 14362-1:2017
EN 14362-3:2012	EN ISO 14362-3:2017

详细信息请查看 (EU) 2020/2096 原文

(EU) 2020/2096 revise REACH Regulation ANNEX XVII

1) Revise Entry 3 of Annex XVII

Entry 3 of REACH Regulation Annex XVII 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. As that Directive has been repealed, the references to R65 should be deleted from entry 3. 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.

2) Delete entries 22, 67 and 68

Restrictions are set out in REACH XVII for entry 22 pentachlorophenol and its salts and esters, entry 67 bis(pentabromophenyl)ether, and entry 68 PFOA and its salts and related substances. The EU's POPs (Persistent Organic Pollutants) Regulation, published in 2019, imposes stricter limits on these substances. In order to avoid duplication, articles 22, 67 and 68 of Appendix 17 to the REACH regulation are deleted.

3) Delete the CAS or EC numbers for nonylphenol in entry 46

Entry 46 of REACH regulation Annex XVII contained no CAS or EC numbers for nonylphenol at first. Commission Regulation (EC) No 552/2009 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.

4) Revise the requirement of entries 28, 29 and 30

Articles 28, 29 and 30 of ANNEX of the REACH Regulation prohibit the placing on the market and the use of carcinogenic, mutagenetic and reproductive toxicity (CMR) substances classified as Category 1A or Category 1B. These substances are referenced in the European Union's 1272/2008 (EC) (CLP Regulation), and as CMR 1A or 1B in the CLP is updated, this provision shall be updated accordingly. However, the Regulation on Medical Devices (EU) 2017/745 already contains provisions on CMR substances. In order to avoid this double regulation, devices falling within the scope of Regulation 2017/745 are exempt from the restrictions set out in Articles 28-30 of Annex XVII of REACH regulation.

5) Update the test method for azo colorants in entry 43

Appendix 10 to Annex XVII to REACH Regulation lists testing methods for azo colourants 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.

the superseded standard	The updated standard
EN ISO 17234-1:2010	EN ISO 17234-1:2015
EN ISO 17234-2:2011	EN ISO 17234-2:2011
EN 14362-1:2012	EN ISO 14362-1:2017
EN 14362-3:2012	EN ISO 14362-3:2017

See (EU) 2020/2096 original for more details



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