Timeline of European regulations on DEHP

REACH | RoHS 3 | MDR

REACH
Registration, Evaluation, Authorisation and Restriction of Chemicals
Specifically Annex XIV (“Authorisation”)

RoHS 3 (EU 2015/863)
Amendment to the Restriction of Hazardous Substances Directive adding DEHP

MDR
Medical Device Regulation

2008 28 October
- REACH — EUROPEAN CHEMICALS AGENCY: DEHP entry added to the candidate list for SVHC due to its **reprotoxic properties** [57c].

2011 February
- REACH — EUROPEAN COMMISSION: DEHP **reprotoxic properties** added to REACH. Exemptions granted for medical devices.

2012 26 September
- MDR — EUROPEAN COMMISSION: Proposal for regulation.

2014 12 December
- REACH — EUROPEAN CHEMICALS AGENCY: DEHP entry added to the candidate list for SVHC due to its **endocrine disrupting properties to the environment** [57(f)].

2015 21 February
- REACH — **Sunset date for the use of DEHP.** Exemptions granted for medical devices.

31 March
- RoHS 3 — EUROPEAN COMMISSION: RoHS 3 adopted.

4 June
- RoHS 3 — OFFICIAL JOURNAL OF THE EUROPEAN UNION: RoHS 3 published in the official journal.

2016 31 December
- RoHS 3 — MEMBER STATES: Regulations and provisions to comply with RoHS 3 adopted by member states.

2017 7 March
- MDR — COUNCIL OF THE EU: MDR adopted.

5 April
- MDR — EUROPEAN PARLIAMENT: MDR adopted.

5 May
- MDR — OFFICIAL JOURNAL OF THE EUROPEAN UNION: MDR published in the official journal.

25 May
- MDR — **MDR enters into force.**

6 July
- REACH — EUROPEAN CHEMICALS AGENCY: DEHP entry added to the candidate list for SVHC due to its **endocrine disrupting properties for human health** [57(f)].

2018 5 June – 6 August
- REACH — EUROPEAN CHEMICALS AGENCY: Eight-week public consultation on draft recommendation.

12 December
- REACH — EUROPEAN CHEMICALS AGENCY: Draft recommendation published, considering whether exemptions are still justified.

12 December – 12 March **2019**
- REACH — EUROPEAN CHEMICALS AGENCY: 90-day public consultation on draft recommendation.

26 June
- REACH — MEMBER STATE COMMITTEE: Opinion on draft recommendation adopted.

10 July
- REACH — EUROPEAN CHEMICALS AGENCY: Recommendation published.

22 July
- RoHS 3 — **RoHS 3 enters into force.**

2021 26 May
- MDR — **Provisions applied.** Including the justification for the presence of CMR and ED substances, such as DEHP.

22 July
- RoHS 3 — RoHS 3 goes into effect for medical devices containing DEHP.

21 December
- REACH — EUROPEAN COMMISSION: DEHP **endocrine disrupting properties to human health and the environment** added to REACH.

2027 31 December
- MDR — **Deadline for CE marking of all legacy high-risk medical devices.** Presence of DEHP must be duly justified according to the latest relevant SCHEER guidelines.

2028 31 December
- MDR — **Deadline for CE marking of all legacy low-risk medical devices.** Presence of DEHP must be duly justified according to the latest relevant SCHEER guidelines.

2029 1 January
- REACH — EUROPEAN COMMISSION: Latest application date for authorisation.

2030 1 July
- REACH — **Sunset date after which use of DEHP is banned.**