Timeline of European regulations on DEHP

REACH | RoHS 3 | MDR

REACH
Registration, Evaluation, Authorisation and Restriction of Chemicals

Specifically Annex XIV (“Authorisation”)

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

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

2012 26 September

2014 12 December
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
Sunset date for the use of DEHP.
Exemptions granted for medical devices.

31 March

4 June

2016 31 December

2017 7 March

5 April

5 May

25 May

6 July
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
EUROPEAN CHEMICALS AGENCY
Eight-week public consultation on draft recommendation.

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

12 December –

2019 12 March
EUROPEAN CHEMICALS AGENCY
90-day public consultation on draft recommendation.

26 June
MEMBER STATE COMMITTEE
Opinion on draft recommendation adopted.

10 July
EUROPEAN CHEMICALS AGENCY
Recommendation published.

22 July

2021 26 May

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

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

2023 27 November
EUROPEAN COMMISSION
Latest application date for authorisation.

2025 27 May
Sunset date after which use of DEHP is banned.

2027 31 December

2028 31 December

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

EUROPEAN COMMISSION
RoHS 3 adopted.

OFFICIAL JOURNAL OF THE EUROPEAN UNION
RoHS 3 published in the official journal.

MEMBER STATES
Regulations and provisions to comply with RoHS 3 adopted by member states.

RoHS 3 enters into force.

MDR
Medical Device Regulation

EUROPEAN COMMISSION
Proposal for regulation.

COUNCIL OF THE EU
MDR adopted.

EUROPEAN PARLIAMENT
MDR adopted.

OFFICIAL JOURNAL OF THE EUROPEAN UNION
MDR published in the official journal.

MDR enters into force.

Provisions applied.
Including the justification for the presence of CMR and ED substances, such as DEHP.

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.

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.