Timeline of European regulations on DEHP 1/2

PVC Med ALLIANCE

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
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
EUROPEAN COMMISSION
Proposal for regulation.

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
EUROPEAN COMMISSION
RoHS 3 adopted.

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

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

2017 7 March
COUNCIL OF THE EU
MDR adopted.

5 April
EUROPEAN PARLIAMENT
MDR adopted.

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

25 May
MDR enters into force.

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)].

Timeline of European regulations on DEHP 2/2

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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 – 12 March
2019
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
RoHS 3 enters into force.

2021

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

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
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
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.