

REACH  
RoHS 3  
MDR

## REACH

Registration, Evaluation, Authorisation and Restriction of Chemicals

Specifically Annex XIV ("Authorisation")

EUROPEAN CHEMICALS AGENCY  
DEHP entry added to the candidate list for SVHC due to its **reprotoxic properties** [57(e)].

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

EUROPEAN CHEMICALS AGENCY  
DEHP entry added to the candidate list for SVHC due to its **endocrine disrupting properties to the environment** [57(f)].

**Sunset date for the use of DEHP.**  
Exemptions granted for medical devices.

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

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

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

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

MEMBER STATE COMMITTEE  
Opinion on draft recommendation adopted.

EUROPEAN CHEMICALS AGENCY  
Recommendation published.

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

EUROPEAN COMMISSION  
Latest application date for authorisation.

**Sunset date after which use of DEHP is banned.**

PVC Med  
TR ALLIANCE

## Timeline of European regulations on DEHP

### MDR

Medical Device Regulation

EUROPEAN COMMISSION  
Proposal for regulation.

### 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.

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.**

**RoHS 3 enters into force.**

RoHS 3 goes into effect for medical devices containing DEHP.

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

2008 28 October

2011 February

2012 26 September

2014 12 December

2015 21 February

31 March

4 June

2016 31 December

2017 7 March

5 April

5 May

25 May

6 July

2018 5 June – 6 August

12 December

12 December –

2019 12 March

26 June

10 July

22 July

2021 26 May

22 July

21 December

2023 27 November

2025 27 May