European Union - Commission launches public consultation on preliminary guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices

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Today, following a request from the European Commission, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) provided Guidelines on the benefit-risk assessment of the presence, in the medical devices specified in the mandate, of phthalates which have one or more of the following properties: carcinogenic, mutagenic, toxic to reproduction (CMR) or endocrine-disrupting (ED).

On their basis, the Commission is launching a public consultation where interested parties are invited to submit their comments on the scientific evidence online by 29 April 2019.

These Guidelines describe the methodology on how to perform a benefit-risk assessment (BRA) for the justification of the presence of CMR 1A or 1B and/or ED phthalates (CMR/ED phthalates) in medical devices and/or or parts or materials used therein at percentages above 0.1% by weight (w/w). They also consider the evaluation of possible alternatives for these phthalates used in medical devices. They are intended to be used by the relevant stakeholders e.g. manufacturers, notified bodies and regulatory bodies. The approach of these Guidelines may also be used for a

BRA of other CMR/ED substances present in medical devices.â€‹

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