

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EU) No 283/2013. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

ANNEX

INTRODUCTION **Information to be submitted, its generation and its presentation**

5. **Tests on vertebrate animals**

- 5.1. Tests on vertebrate animals shall be undertaken only where no other validated methods are available. Alternative methods to be considered shall include *in vitro* methods and *in silico* methods. Reduction and refinement methods for *in vivo* testing shall also be encouraged to keep the number of animals used in testing to a minimum.

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Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by [S.I. 2019/556 reg. 21\(4\)](#)
- Annex Pt. A s. 8 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xiv\)](#)
- Annex Pt. A s. 1 point 1.4 word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 176(2)(a)(i) by [S.I. 2020/1567 Sch. 2 para. 61](#)
- Annex Pt. A s. 1 point 1.4.1 word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 176(2)(b) by [S.I. 2020/1567 Sch. 2 para. 61](#)
- Annex Pt. B s. 9 words omitted by [S.I. 2019/556 reg. 21\(5\)\(c\)\(vi\)](#)
- Art. 1(1) Art. 1 renumbered as Art. 1(1) by [S.I. 2019/556 reg. 21\(2\)\(a\)](#)
- Art. 1(2) inserted by [S.I. 2019/556 reg. 21\(2\)\(b\)](#)