

Commission Regulation (EU) 2018/782 of 29 May 2018  
establishing the methodological principles for the risk  
assessment and risk management recommendations referred to  
in Regulation (EC) No 470/2009 (Text with EEA relevance)

*Article 1*

**Subject matter**

1 This Regulation sets out the methodological principles for the scientific risk assessment and risk management recommendations referred to in Articles 6 and 7 of Regulation (EC) No 470/2009 that shall be applied by the Agency when preparing opinions on the MRLs of pharmacologically active substances which may be permitted in food of animal origin under that Regulation.

2 The methodological principles for the scientific risk assessment are set out in Annex I.

3 The methodological principles for the risk management recommendations are set out in Annex II.

*Article 2*

**Definitions**

For the purposes of this Regulation, in addition to the definitions set out in Regulation (EC) No 470/2009, the following definitions shall apply:

- ‘major metabolites’ means metabolites comprising  $\geq 100$   $\mu\text{g}/\text{kg}$  or  $\geq 10$  % of the total residue in a sample collected from the target animal species in the metabolism study,
- ‘marker residue’ means a residue whose concentration is in a known relationship to the concentration of total residue in an edible tissue,
- ‘dairy starter cultures’ means prepared cultures of microorganism employed in the manufacture of a variety of dairy products including butter, cheese, yoghurt and cultured milk.

*Article 3*

**Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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**Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) 2018/782. 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](#)

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Done at Brussels, 29 May 2018.

*For the Commission*

*The President*

Jean-Claude JUNCKER

**Changes to legislation:**

There are outstanding changes not yet made to Commission Regulation (EU) 2018/782. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

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**Changes and effects yet to be applied to :**

- Art. 1 words substituted by [S.I. 2019/676 reg. 10\(2\)\(a\)](#)
- Art. 1 words substituted by [S.I. 2019/676 reg. 10\(2\)\(b\)](#)

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

- Signature words omitted by [S.I. 2019/676 reg. 10\(3\)](#)
- Annex 1 para. 2(4) words omitted by [S.I. 2019/676 reg. 10\(4\)\(e\)](#)
- Annex 1 para. 3(2) words omitted by [S.I. 2019/676 reg. 10\(4\)\(h\)](#)
- Annex 1 para. 3(5) words omitted by [S.I. 2019/676 reg. 10\(4\)\(k\)\(ii\)](#)
- Annex 1 para. 1(1) words substituted by [S.I. 2019/676 reg. 10\(4\)\(a\)](#)
- Annex 1 para. 1(2) words substituted by [S.I. 2019/676 reg. 10\(4\)\(b\)](#)
- Annex 1 para. 1(7) words substituted by [S.I. 2019/676 reg. 10\(4\)\(c\)\(i\)](#)
- Annex 1 para. 1(7) words substituted by [S.I. 2019/676 reg. 10\(4\)\(c\)\(ii\)](#)
- Annex 1 para. 1(8) words substituted by [S.I. 2019/676 reg. 10\(4\)\(d\)](#)
- Annex 1 para. 2(4) words substituted by [S.I. 2019/676 reg. 10\(4\)\(f\)](#)
- Annex 1 para. 2(6) words substituted by [S.I. 2019/676 reg. 10\(4\)\(g\)](#)
- Annex 1 para. 3(2) words substituted by [S.I. 2019/676 reg. 10\(4\)\(i\)](#)
- Annex 1 para. 3(5) words substituted by [S.I. 2019/676 reg. 10\(4\)\(j\)\(i\)](#)
- Annex 1 para. 3(5) words substituted by [S.I. 2019/676 reg. 10\(4\)\(j\)\(ii\)](#)
- Annex 1 para. 3(5) words substituted by [S.I. 2019/676 reg. 10\(4\)\(k\)\(i\)](#)
- Annex 1 para. 3(6) words substituted by [S.I. 2019/676 reg. 10\(4\)\(l\)](#)
- Annex 2 para. 2(1) words omitted by [S.I. 2019/676 reg. 10\(5\)\(a\)\(ii\)](#)
- Annex 2 para. 2(1) words substituted by [S.I. 2019/676 reg. 10\(5\)\(a\)\(i\)](#)
- Annex 2 para. 2(7) words substituted by [S.I. 2019/676 reg. 10\(5\)\(b\)](#)