Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms (Text with EEA relevance)

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(a) **[**[F1]'full validation procedure' means:

(i) the assessment, through a ring trial according to international standards, involving national reference laboratories of the method performance criteria set by the applicant as compliant with the document entitled 'Definition of minimum performance requirements for analytical methods of GMO testing'[(1)] referred to:

— in the case of genetically modified plants for food or feed uses, food or feed containing or consisting of genetically modified plants and food produced from or containing ingredients produced from genetically modified plants or feed produced from genetically modified plants, in point 3.1.C.4. of Annex III to Commission Implementing Regulation (EU) No 503/2013[(2)];

— in all other cases, in point 1(B) of Annex I to Regulation (EC) No 641/2004;

and

(ii) the assessment of the precision and trueness of the method provided by the applicant.**]**

(b) 'small and medium-sized enterprise (SME)' means small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC[(3)];

(c) 'developing countries' means beneficiary countries as referred to in Article 2 of Council Regulation (EC) No 980/2005 of 27 June 2005 applying a scheme of generalised tariff preferences[(4)];

(d) 'application' where used without further specification, means an application for authorisation submitted in accordance with Article 5 or 17 of Regulation (EC) No 1829/2003, including applications submitted under other Community legislation which are transformed or supplemented in accordance with Article 46 of that Regulation. It also refers to applications for renewal of authorisations according to Article 11 or 23 of Regulation (EC) No 1829/2003 and modifications of authorisations according to Articles 9(2), 10, 21(2) or 22 of that Regulation, where the CRL is requested to test and validate a method of detection and identification**[**[F1];**]**

(e) **[**[F2]'GMO containing a single transformation event' means a GMO that has been obtained through a single transformation process;

(f) ‘GMO containing stacked transformation events’ means a GMO containing more than one single transformation event obtained by conventional crossing, co-transformation or re-transformation.**]**

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) No 120/2014 of 7 February 2014 amending Regulation (EC) No 1981/2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and the Council as regards the Community reference laboratory for genetically modified organisms (Text with EEA relevance).

F2 Inserted by Commission Implementing Regulation (EU) No 120/2014 of 7 February 2014 amending Regulation (EC) No 1981/2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and the Council as regards the Community reference laboratory for genetically modified organisms (Text with EEA relevance).

(1) **[**[F1]http://gmo-crl.jrc.ec.europa.eu/doc/Min_Perf_Requirements_Analytical_methods.pdf, CRL and European Network of GMO laboratories, 13 October 2008.**]**

(2) **[**[F1]OJ L 157, 8.6.2013, p. 1.**]**

(3) OJ L 124, 20.5.2003, p. 36.

(4) OJ L 169, 30.6.2005, p. 1.

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) No 120/2014 of 7 February 2014 amending Regulation (EC) No 1981/2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and the Council as regards the Community reference laboratory for genetically modified organisms (Text with EEA relevance).

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EC) No 1981/2006. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Regulation revoked by S.I. 2019/705 reg. 390 (This amendment not applied to legislation.gov.uk. Reg. 390 substituted by regs. 389-477 immediately before IP completion day by virtue of S.I. 2020/1504, regs. 1(2), 17(21)(22))
- Regulation revoked by S.I. 2019/705, reg. 477 (as substituted) by S.I. 2020/1504 reg. 17(22)