

**COMMISSION IMPLEMENTING DECISION (EU) 2018/1790****of 16 November 2018****repealing Decision 2002/623/EC establishing guidance notes on the environmental risk assessment of genetically modified organisms***(notified under document C(2018) 7513)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC <sup>(1)</sup>, and in particular the first paragraph of Annex II thereto,

Whereas:

- (1) Commission Decision 2002/623/EC <sup>(2)</sup> established guidance notes on the objectives, elements, general principles and methodology of the environmental risk assessment referred to in Annex II to Directive 2001/18/EC.
- (2) Extensive supplementary explanations regarding the implementation of Annex II to Directive 2001/18/EC have been given in more recent and more detailed guidance documents on the environmental risk assessment of genetically modified organisms ('GMOs') adopted by the European Food Safety Authority ('the Authority') and by the European Medicines Agency ('the Agency'). After the adoption of those more detailed guidance documents, Decision 2002/623/EC has progressively lost its added value.
- (3) Commission Directive (EU) 2018/350 <sup>(3)</sup>, which amended Directive 2001/18/EC, updated Annex II to Directive 2001/18/EC by incorporating and building upon the strengthened guidance of the Authority on the environmental risk assessment of genetically modified plants, adopted in October 2010 <sup>(4)</sup>, while taking into account that Annex II applies to all GMOs and not only to genetically modified plants. Decision 2002/623/EC itself served as a basis for the elaboration of the guidance of the Authority. As a result, the provisions of Annex II to Directive 2001/18/EC are now more detailed and the guidance notes established by Decision 2002/623/EC are no longer needed.
- (4) Decision 2002/623/EC should therefore be repealed.
- (5) Decision 2002/623/EC should also be repealed in the interest of simplification in order to reduce the number of guidance documents that must be taken into account by operators and competent authorities when carrying out an environmental risk assessment under Annex II to Directive 2001/18/EC.
- (6) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 30(1) of Directive 2001/18/EC,

HAS ADOPTED THIS DECISION:

*Article 1*

Decision 2002/623/EC is repealed.

<sup>(1)</sup> OJ L 106, 17.4.2001, p. 1.

<sup>(2)</sup> Commission Decision 2002/623/EC of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 200, 30.7.2002, p. 22).

<sup>(3)</sup> Commission Directive (EU) 2018/350 of 8 March 2018 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms (OJ L 67, 9.3.2018, p. 30).

<sup>(4)</sup> EFSA Panel on Genetically Modified Organisms (GMO); Guidance on the environmental risk assessment of genetically modified plants. *EFSA Journal* 2010; 8(11):1879. [111 pp.]. doi:10.2903/j.efsa.2010.1879.

*Article 2*

This Decision is addressed to the Member States.

Done at Brussels, 16 November 2018.

*For the Commission*  
Vytenis ANDRIUKAITIS  
*Member of the Commission*

---