EUROPEAN
COMMISSION

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COMMISSION DIRECTIVE (EU) .../…

of XXX

amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms

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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[1], and in particular Article 27 thereof,

Whereas:

(1) Directive 2001/18/EC of the European Parliament and of the Council sets out requirements for the environmental risk assessment genetically modified organisms ('GMOs').

(2) On 4 December 2008, the Council adopted Conclusions on GMOs stressing the need to update and strengthen the environmental risk assessment of GMOs, in particular concerning the assessment of long-term environmental effects

(3) Following a request from the Commission, the European Food Safety Authority (EFSA) adopted in October 2010 a Scientific opinion establishing guidance on the environmental risk assessment of genetically modified plants[2] ('the Guidance'), which is a revision of the previous guidance.

(4) Article 3 of Directive (EU) 2015/412 of the European Parliament and of the Council[3] provides that by 3 April 2017 the Commission has to update the Annexes to Directive 2001/18/EC as regards the environmental risk assessment with a view to incorporating and building upon the Guidance.

(5) In order to adapt to technical progress and taking into account the experience gained in the environmental risk assessment of genetically modified plants, the essential elements of the Guidance should be incorporated in Directive 2001/18/EC. In doing so, the principle that the environmental risk assessment should be carried out on a case-by-case basis should be respected.

(6) Part C of Annex II to Directive 2001/18/EC concerns the methodology of the environmental risk assessment. It should be updated in order to incorporate, in particular, the comprehensive step-by-step assessment approach consisting of six steps described in the Guidance and the terminology used.

(7) Part D of Annex II to Directive 2001/18/EC applies to the conclusions of the environmental risk assessment and contains two distinct sections, concerning GMOs

[1] (OJ L 106, 17.4.2001, p. 1.

[2] EFSA Journal 2010;8(11):1879.

[3] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (OJ L 68, 13.3.2015, p. 1).

other than higher plants (section D.1) and genetically modified higher plants (section D.2) respectively. The Guidance considers seven specific areas of risk to be addressed in the environmental risk assessment of genetically modified plants in order to draw conclusions. The structure and content of section D.2 of Annex II should therefore be updated to reflect those areas of risk.

(8) Where the environmental risk assessment concerns a genetically modified plant made tolerant to a herbicide, its scope should be consistent with Directive 2001/18/EC. The environmental risk assessment of the use of a plant protection product to be authorised under Regulation (EC) No 1107/2009 of the European Parliament and of the Council[4], including its use on a genetically modified plant, falls under the scope of that Regulation and will be carried out at Member State level to take into account the specific agricultural conditions.

(9) Annex III B to Directive 2001/18/EC lists the information required in notifications concerning releases of genetically modified higher plants and applies to both notifications for the purpose of placing on the market ("Part C notifications") and notifications for other purposes than placing on the market ("Part B notifications"). Its structure, content and level of detail should be amended to ensure consistency with the Guidance. As most of the changes induced by the Guidance concern the environmental risk assessment of Part C notifications, and in the interest of clarity and simplification for the notifiers and the competent authorities, it is appropriate to modify the structure of Annex III B by separating the requirements concerning Part C notifications from the requirements concerning Part B notifications.

(10) The majority of the requests for authorisation of the placing on the market of genetically modified plants are submitted in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council[5]. In the interest of simplification, it is therefore appropriate to align, to the extent possible, the order of the pieces of information required for Part C notifications in Annex III B to Directive 2001/18/EC with the order followed in Commission Implementing Regulation (EU) No 503/2013[6].

(11) Annex IV to Directive 2001/18/EC sets out additional information requirements only for Part C notifications. The requirements set out in that Annex concerning detection methods should be updated in the light of technical progress, in particular as regards the submission by notifiers of the reference material.

(12) The measures provided for in this Directive are in accordance with the opinion of the Committee set up under Article 30 of Directive 2001/18/EC,

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4 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L309, 24.11.2009, p. 1).

5 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

6 Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (OJ L157, 8.6.2013, p. 1).

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes II, III, III B and IV to Directive 2001/18/EC are amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [*18 months from the date of entry into force*] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

   When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER