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

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

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 sets out requirements for the environmental risk assessment of 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. Other guidance documents issued by EFSA and by the European Medicines Agency are relevant to the environmental risk assessment of GMOs other than plants.

(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, which is not legally binding.

(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) The Guidance was essentially designed for notifications for the purpose of placing on the market ('Part C notifications') of genetically modified plants, while Annex II to Directive 2001/18/EC applies to both Part C notifications and notifications for other purposes than placing on the market ('Part B notifications'). Therefore, certain

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requirements resulting from the incorporation of the Guidance in Annex II should only apply to Part C notifications, as they would be irrelevant or disproportionate in the context of Part B notifications, which essentially concern experimental releases.

(7) 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 terminology used to describe the six steps of the assessment approach as described in the Guidance.

(8) 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 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.

(9) 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, including its use on a genetically modified plant, falls under the scope of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[(4)] and will be carried out at Member State level to take into account the specific agricultural conditions.

(10) 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 Part C notifications and 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.

(11) 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)].

(12) 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.

(13) 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,

HAS ADOPTED THIS DIRECTIVE:

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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 29 September 2019 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, 8 March 2018.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

Directive 2001/18/EC is amended as follows:

(1) Annex II is amended as follows:

(a) Section C is replaced by the following:

C. **Methodology**

Guidance issued by the European Food Safety Authority is available for the implementation of this section for Part C notifications.

C.1. *General and specific considerations for the e.r.a.*

1. *Intended and unintended changes*

As part of the identification and evaluation of the potential adverse effects referred to in Section A, the e.r.a shall identify the intended and unintended changes resulting from the genetic modification and shall evaluate their potential to cause adverse effects on human health and on the environment.

Intended changes resulting from the genetic modification are changes that are designed to occur and which fulfil the original objectives of the genetic modification.

Unintended changes resulting from the genetic modification are consistent changes which go beyond the intended change(s) resulting from the genetic modification.

Intended and unintended changes can have either direct or indirect, and either immediate or delayed effects on human health and on the environment.

2. *Long-term adverse effects and cumulative long-term adverse effects in the e.r.a. of Part C notifications*

Long-term effects of a GMO are effects resulting either from a delayed response by organisms or their progeny to long-term or chronic exposure to a GMO or from an extensive use of a GMO in time and space.

The identification and evaluation of the potential long-term adverse effects of a GMO on human health and on the environment shall take into account the following:

(a) the long-term interactions of the GMO and the receiving environment;

(b) the characteristics of the GMO which become important on a long-term basis;

(c) data obtained from repeated deliberate releases or placings on the market of the GMO over a long period.

The identification and evaluation of the potential cumulative long-term adverse effects referred to in the introductory part of Annex II shall also take into account the GMOs deliberately released or placed on the market in the past.

3. *Quality of the data*

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In order to carry out an e.r.a. for a notification under Part C of this Directive, the notifier shall collate already available data from scientific literature or from other sources, including monitoring reports, and shall generate the necessary data by performing, where possible, appropriate studies. Where applicable, the notifier shall justify in the e.r.a. why generating data by studies is not possible.

The e.r.a. for notifications under Part B of the Directive shall be based at least on already available data from scientific literature or from other sources and may be supplemented by additional data generated by the notifier.

Where data generated outside Europe is provided in the e.r.a., its relevance to receiving environment(s) in the Union shall be justified.

Data provided in the e.r.a for notifications under part C of this Directive shall comply with the following requirements:

(a) where toxicological studies carried out to assess risk to human or animal health are provided in the e.ra., the notifier shall provide evidence to demonstrate that they were conducted in facilities which comply with:

  (i) the requirements of Directive 2004/10/EC; or

  (ii) the "OECD Principles on Good Laboratory Practice" (GLP), if carried out outside the Union;

(b) where studies other than toxicological studies are provided in the e.r.a., they shall:

  (i) comply with the principles of Good Laboratory Practice (GLP) laid down in Directive 2004/10/EC, where relevant; or

  (ii) be conducted by organisations accredited under the relevant ISO standard; or

  (iii) in the absence of a relevant ISO standard, be conducted in accordance with internationally recognised standards;

(c) information on the results obtained from the studies referred to in points (a) and (b) and on the study protocols used shall be reliable and comprehensive and shall include the raw data in an electronic format suitable for carrying out statistical or other analysis;

(d) the notifier shall specify, where possible, the size of effect that each study performed intends to detect and justify it;

(e) the selection of sites for field studies shall be based on relevant receiving environments in view of the potential exposure and impact that would be observed where the GMO may be released. The selection shall be justified in the e.r.a.;

(f) the non-genetically modified comparator shall be appropriate for the relevant receiving environment(s) and shall have a genetic background comparable to the GMO. The choice of the comparator shall be justified in the e.r.a.