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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms

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1. INTRODUCTION

Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms[1] (GMOs) and Regulation (EC) No 1830/2003 of the European Parliament and of the Council, concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs[2] are two of the several building blocks of the EU's legal framework for GMOs.

The objective of Directive 2001/18/EC is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when carrying out the deliberate release into the environment of GMOs for any other purposes than placing on the market within the EU and when placing on the market GMOs as or in products within the EU.

Regulation (EC) No 1830/2003 provides a framework for the traceability of products consisting of or containing GMOs, and food and feed produced from GMOs, with the objectives of facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures.

2. LEGAL BASIS

Directive 2001/18/EC empowers the Commission to adopt delegated acts, as referred to in Article 29a(2), with a view to the following:

- establishing derogatory criteria and information requirements for the notification for the placing on the market of certain types of GMOs, as provided for in Article 16(2),
- establishing minimum thresholds below which products where adventitious or technically unavoidable traces of authorised GMOs cannot be excluded do not have to be labelled as GMOs, as provided for in Article 21(2),

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

[2] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, OJ L 268, 18.10.2003, p. 24.

- establishing lower thresholds than 0,9 %, below which the labelling requirements set out in the Directive do not apply to traces of GMOs in products intended for direct processing, as provided for in Article 21(3),
- establishing specific labelling requirements for GMOs that are not placed on the market within the meaning of that Directive, as provided for in Article 26(2),
- adapting the Annexes to technical progress, as provided for in Article 27.

Regulation (EC) No 1830/2003 empowers the Commission to adopt a delegated act, as referred to in Article 9a(2), to supplement that Regulation by establishing and adapting a system for the development and assignment of unique identifiers to GMOs, as provided for in Article 8.

Pursuant to Article 29a(2) of Directive 2001/18/EC and Article 9a(2) of Regulation (EC) No 1830/2003, the power to adopt delegated acts concerning the matters listed therein is conferred on the Commission for a period of five years from 26 July 2019. The present report in respect of the exercise of the delegations of power during this five-year period is submitted by the Commission to the European Parliament and the Council, as required in both cases. The delegations of power are to be tacitly extended for periods of identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. EXERCISE OF THE DELEGATIONS

3.1. EMPOWERMENTS USED DURING THE REPORTING PERIOD

During the reporting period, the Commission used one empowerment, as described below.

- Article 27 of Directive 2001/18/EC

  Article 27 of Directive 2001/18/EC empowers the Commission to amend certain Annexes to that Directive (Sections C and D of Annex II, Annexes III to VI, and Section C of Annex VII) in order to adapt them to technical progress. On 8 March 2018, the Commission adopted Commission Directive (EU) 2018/350 amending Directive 2001/18/EC as regards the environmental risk assessment of GMOs[3]. This Directive amended Annexes II, III, and IV to Directive 2001/18/EC in order to adapt them to the technical progress, in particular incorporating the essential elements of the revised guidance of the European Food Safety Authority (EFSA) on the environmental risk assessment of GM plants[4].

3.2. EMPOWERMENTS NOT USED DURING THE REPORTING PERIOD

Certain empowerments have not been used during the reporting period for the reasons explained below.

[3] 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.

[4] EFSA Panel on GMO, Guidance on the environmental risk assessment of genetically modified plants. EFSA Journal 2010;8(11):1879.doi:10.2903/j.efsa.2010.1879. www.efsa.europa.eu/efsajournal.htm

- Article 16(2) of Directive 2001/18/EC

  Article 16 of Directive 2001/18/EC allows a Member State competent authority, or the Commission on its own initiative, to make a proposal on criteria and information requirements to be met for the notification for the placing on the market of certain types of GMOs, which would replace the standard requirements set out under Article 13(2) of the Directive. The adoption of the delegated act establishing the specific criteria and information requirements would, in addition to complying with the requirements set out in Article 29a of the Directive, require the consultation of EFSA and a comment period for the public. No Member State competent authority or the Commission have made a proposal under this Article. In particular, in the reporting period, based on the limited number of notifications received under that Directive for the placing on the market of GMOs as or in products, the Commission considered the standard requirements set out under Article 13(2) of the Directive to be appropriate. The Commission has therefore not yet made use of this delegated power.

- Article 21(2) of Directive 2001/18/EC

  Article 21(2) of Directive 2001/18/EC empowers the Commission to supplement that Directive by establishing minimum thresholds below which products where adventitious or technically unavoidable traces of authorised GMOs cannot be excluded do not have to be labelled as GMOs. Threshold levels are to be established according to the product concerned. For products intended for direct processing, for food and for feed, thresholds for the adventitious or technically unavoidable presence of authorised GM material are already established by Article 21(3) of Directive 2001/18/EC and Articles 12(2) and 24(2) of Regulation (EC) No 1829/2003 of the European Parliament and of the Council[5], respectively.

  The Commission has not yet made use of this delegated power. In the reporting period, work focused on ensuring an even application of the 'zero tolerance', applicable in absence of a threshold, regarding seeds.[6]

- Article 21(3) of Directive 2001/18/EC

  For products intended for direct processing, Article 21(3), first subparagraph, of Directive 2001/18/EC establishes a threshold of 0,9 %, below which the GMO labelling requirements do not apply to adventitious or technically unavoidable traces of authorised GMOs. Article 21(3), second subparagraph, of Directive 2001/18/EC empowers the Commission to supplement that Directive by establishing lower thresholds for these products. In the reporting period, the Commission considered the threshold of 0,9 % to be appropriate and effective. The Commission has therefore not yet made use of the delegated power to establish lower thresholds for these products.

[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] Seed testing convergence, endorsed during the meeting of the Regulatory Committee of Directive 2001/18/EC held on 4 June 2020. https://food.ec.europa.eu/system/files/2020-07/reg-com_2001-18-ec_20200604_result_seed-testing-convergence.pdf

- Article 26(2) of Directive 2001/18/EC

  Article 26 of Directive 2001/18/EC concerns the labelling of GMOs to be made available for operations that are not regarded as placing on the market, referred to under Article 2(4), second subparagraph (making available GMOs for contained use activities or deliberate releases complying with the requirements laid down in Part B of Directive 2001/18/EC). Article 26(1) in conjunction with Annex IV sets out labelling requirements for these GMOs. Article 26(2) empowers the Commission to amend Annex IV by establishing specific labelling requirements for these GMOs. In the reporting period, the Commission considered the labelling requirements in the relevant sections of Annex IV to be appropriate for these GMOs. The Commission has therefore not yet made use of this delegated power.

- Article 8 of Regulation (EC) No 1830/2003

  Article 8 of Regulation (EC) No 1830/2003 empowers the Commission to supplement that Regulation by establishing and adapting a system for the development and assignment of unique identifiers to GMOs taking account of developments in international fora. Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for GMOs[7] entered into force on 16 January 2004. This act was adopted based on Article 8 of Regulation (EC) No 1830/2003 in its version applicable until 26 July 2019. In line with the delegated power, it may be revised in the future to adapt the system for the development and assignment of unique identifiers if needed.

4. CONCLUSION

The Commission sees the need for a tacit extension of the delegations of power concerning the matters listed in Article 29a(2) of Directive 2001/18/EC and Article 9a(2) of Regulation (EC) No 1830/2003 for a period of five years as from 26 July 2024, in accordance with those Articles. The rationale for the delegations of power has not changed. They are important to maintain the necessary flexibility in the legal framework, to adjust it to scientific, technological and other developments and to experience gained with the application of the framework, and to allow the Commission to act in the areas where it did not act to this moment, but may need to do so in the future. Thereby, the powers granted are important for achieving the objectives of Directive 2001/18/EC and Regulation (EC) No 1830/2003.

With this report, the Commission complies with the reporting requirements established in Article 29a(2) of Directive 2001/18/EC and Article 9a(2) of Regulation (EC) No 1830/2003.

The Commission invites the European Parliament and the Council to take note of this report.

[7] Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms, OJ L 10, 16.1.2004, p. 5.