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Subject: Notification 2023/158/L

Draft law on the placing on the market of genetically modified organisms as products or components of products

Delivery of a detailed opinion pursuant to Article 6(2) of Directive (EU) 2015/1535 of 9 September 2015

Delivery of comments pursuant to Article 5(2) of Directive (EU) 2015/1535 of 9 September 2015

Sir,

Within the framework of the notification procedure laid down in Directive (EU) 2015/1535 ⁽¹⁾, the Luxembourgish authorities notified to the Commission on 3 April 2023 the **“Draft law on the placing on the market of genetically modified organisms as products or components of products”** (hereafter “the notified draft”).

According to the notification message, the notified draft lays down rules for the *“placing on the market of genetically modified products such as cotton, animals and decorative flowers as well as genetically modified foodstuffs and feed placed on the market. It shall not apply to the cultivation or rearing of such products in the European Union. It does not concern plant reproductive material”*.

¹) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, OJ L 241, 17.9.2015, p. 1.

According to the national authorities the notified draft is a revision of the law on the control of the use and dissemination of genetically modified organisms, made necessary following the adaptations of the European legislative framework in recent years.

The examination of the notified draft has prompted the Commission to issue the following detailed opinion and comments.

1. Detailed opinion

1.1 Scope of the notified draft with regard to part C of Directive 2001/18/EC

The Commission notes at the outset that the wording of several provisions of the notified draft is very similar to the wording of provisions of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 ⁽²⁾, on the deliberate release into the environment of genetically modified organisms (hereafter, ‘GMOs’), what tends to suggest that this draft is due to constitute a transposition measure of part C of that Directive.

To that regard, the attention of the Luxembourgish authorities is drawn to the fact that neither the notification message, nor the notified draft indicates that this draft is due to constitute a transposition measure of Directive 2001/18/EC. If that were the case, the provisions of the notified draft, once adopted, should be notified to the Commission in accordance with Article 34 of that Directive. In accordance with Article 7(1), point (a), of Directive (EU) 2015/1535, as interpreted by the Court of Justice (see, judgment of 22 January 2002, Canal Satélite Digital, C-390/99, point 48), the Member States are under no duty to notify technical measures whereby Member States comply with binding Community measures which result in the adoption of technical specifications. This however is limited to the extent that the national legislation merely transposes EU legislation without adding additional rules or altering their scope.

The Commission recalls that Article 1 of Directive 2001/18/EC provides that “*In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when: (...) placing on the market genetically modified organisms as or in products within the Community*”. In accordance with Article 4(2) of this Directive, any person, before submitting a notification under part C of the Directive, applicable to the placing on the market of GMOs as or in products, shall carry out an environmental risk assessment. The information, which may be necessary to carry out the environmental risk assessment, is laid down in Annex III of the Directive.

²) 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, OJ L 95, 7.4.2017, p. 1.

It results from Article 12(1) of Directive 2001/18/EC that Articles 13 to 24 of this Directive, that constitute the main provisions of its part C, shall not apply to any GMO as or in products as far as they are authorised by EU legislation which provides for a specific environmental risk assessment carried out in accordance with the principles set out in Annex II and on the basis of information specified in Annex III of the Directive.

In this respect, authorisation procedures for the placing on the market of genetically modified food and feed under Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003, on genetically modified food and feed, include the principles set out in Directive 2001/18/EC.

In accordance with that Regulation, genetically modified food and feed are placed on the market only after a scientific evaluation of any risks which they may present for human and animal health and, as the case may be, for the environment. Such environmental risk is assessed in line with the relevant Annexes of Directive 2001/18/EC, as provided for in its Articles 5(5)(a) and 17(5)(a) for, respectively, genetically modified food and feed. In this context, the conditions of derogation laid down in Article 12 of Directive 2001/18/EC are fulfilled by the procedures laid down in Regulation (EC) No 1829/2003 ⁽³⁾ for genetically modified food and feed. Therefore, the scope of the notified draft needs to exclude the placing on the market of genetically modified food and feed, which is regulated under Regulation (EC) No 1829/2003.

Besides, it results from Article 12(2) of Directive 2001/18/EC that Articles 13 to 24 of this Directive shall not apply to any GMO as or in products as far as they are authorised by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency ⁽⁴⁾, provided that a specific environmental risk assessment is carried out in accordance with the principles set out in Annex II to this Directive and on the basis of the type of information specified in Annex III to this Directive. Article 6 of Regulation (EC) No 726/2004 includes the principles set out in Directive 2001/18/EC, and defines harmonized provisions on the authorisation of medicinal product for human use containing or consisting of genetically modified organisms within the meaning of Article 2 of Directive 2001/18/EC. It results from those considerations that notified draft should not apply to the matters harmonised under Regulation (EC) No 1829/2003 or Regulation (EC) No 726/2004.

³() 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.

⁴ () OJ L 136, 30/04/2004 (p.1)

1.2 Scope of the notified draft with regard to Regulation (EC) No 1829/2003 and Regulation (EC) No 726/2004

The Commission notes that, according to the notification message, the notified draft applies to genetically modified food and feed placed on the market. However, this is not confirmed by the provisions of the notified draft. Indeed, Article 5 of that draft, defining its scope, provides that it shall not apply to GMOs as or in products in so far as they are authorised by European legislation which provides for a specific environmental risk assessment.

In this regard, the attention of the Luxembourgish authorities is drawn to the fact that genetically modified food and feed to be placed on the market are specifically subject to the full harmonisation resulting from the provisions of Regulation (EC) No 1829/2003. The adoption of national provisions regarding matters subject to full harmonisation, such as under Regulation (EC) No 1829/2003, undermines the direct applicability of that Regulation.

In the case where, contrary to what is indicated in the notification message, the notified draft is not due to apply to genetically modified food and feed, the wording of Article 5 of the notified draft still raises legal concerns.

Indeed, Article 5(1) reads : “ *This Law shall not apply to GMOs as or in products in so far as they are authorised by European legislation which provides for a specific environmental risk assessment, carried out in accordance with the principles set out in Annex II and on the basis of the information specified in Annex III, without prejudice to the additional requirements laid down in the legislation, and which lays down requirements for risk management, labelling, monitoring, where appropriate, public information and safeguard clauses at least equivalent to those contained in this Act* ”.

The Commission notes that Article 5(1) of the notified draft is very similar to the wording of Article 12(1) of Directive 2001/18/EC, which refers to GMOs as or in products authorised by EU legislation on the basis of the relevant Annexes of that Directive.

The wording of Article 5(1) of the notified draft appears therefore to make the applicability of specific EU provisions conditional upon an equivalence with the substance of the provisions set out in the notified draft and its annexes. If this is the case, the notified draft, if adopted in its current form, would be contrary to EU law, as it would undermine the direct applicability of the provisions of Regulation (EC) No 1829/2003.

Article 13 of the notified draft does not appear capable of altering the above-mentioned conclusions. This provision reads: “*GMOs placed on the market under this Law or issued pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed shall be labelled under the conditions laid down in Annex IV and, where appropriate, under the conditions*

laid down in Article 4 (6) of Regulation (EC) No 1830/2003". The wording of this provision does not allow to clarify the link between the notified draft and Regulation (EC) No 1829/2003.

An identical conclusion may be reached with regard to Article 5(2) of the notified draft, which reads: *«This Act shall not apply to GMOs as or in products in so far as they are authorised by Regulation (EC) No 726/2004 ⁽⁵⁾, provided that a specific environmental risk assessment is carried out in accordance with the principles set out in Annex II and on the basis of the type of information specified in Annex III (...) »*. Such a wording, if adopted, would undermine the direct applicability of the provisions of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

For the above reasons, the Commission delivers a detailed opinion provided for in Article 6(2) of Directive (EU) 2015/1535 to the effect that Article 5 of the notified draft, on the placing on the market of genetically modified organisms as or in products, would be in breach of Directive 2001/18/EC, Regulation (EC) No 1829/2003 and Regulation (EC) No 726/2004 should it be adopted without giving due consideration to the above observations.

The Commission would remind the Luxembourgish Government that under the terms of Article 6(2) of the above-mentioned Directive (EU) 2015/1535, the delivery of a detailed opinion obliges the Member State, which has drawn up the draft technical regulation concerned, to postpone its adoption for six months from the date of its notification.

This deadline comes to an end on 4 October 2023.

The Commission further draws the attention of the Luxembourgish Government to the fact that, under this provision, the Member State, which is the addressee of a detailed opinion, is obliged to inform the Commission of the action which it intends to take as a result of the opinion.

Should the Luxembourgish Government not comply with the obligations foreseen in Directive (EU) 2015/1535, or should the text of the draft technical regulation under consideration be adopted without account being taken of the abovementioned objections or be otherwise in breach of European Union law, the Commission may commence proceedings pursuant to Article 258 of the Treaty on the Functioning of the European Union.

⁵() Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p. 1.

2. COMMENTS

2.1 Placing on the market of GMOs

Article 2(7) of Directive 2001/18/EC provides that ‘product’ means a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market.

Pursuant to Article 3(1) and 15(1) of Regulation (EC) No 1829/2003, the latter applies to GMOs for food/feed uses, food/feed containing or consisting of GMOs and food/feed produced from GMOs and food ingredients produced from GMOs. Article 2(10) of Regulation (EC) No 1829/2003 defines ‘produced from GMOs’ as meaning ‘derived, in whole or in part, from GMOs, but not containing or consisting of GMOs’.

Article 2(11) of the notified draft defines the term ‘product’ as a ‘preparation consisting of, or produced from, or containing a GMO or a combination thereof, placed on the market’. The indication ‘produced from GMO’ does not appear in the definition of ‘product’ in Directive 2001/18/EC. This indication only appears in the definitions set out in Article 2(10) of Regulation (EC) No 1829/2003, which is directly applicable in all Member States, to designate food and feed that is derived from GMOs but which does not contain GMOs. Therefore, it appears that the definition of ‘product’ under the notified draft exceeds the scope of the notion of ‘product’ in Directive 2001/18. Therefore, the notified draft could be interpreted as applying to products not consisting of nor containing GMOs and which, therefore, are not ‘products’ within the meaning of Directive 2001/18 thus giving rise to legal uncertainty as to its relationship with that Directive.

As regards the procedure for the placing on a market of GMOs laid down in the notified draft, this procedure seems to mirror the procedure laid down in part C of Directive 2001/18/EC. On that point, the Commission notes that the definition of “*placing on the market*” set out in Article 2(5) of the notified draft does not correspond to the definition set out in Article 2(4) of Directive 2001/18/CE, as it does not exclude the operations that do not constitute ‘placing on the market’ under Article 2(4) of Directive 2001/18/CE and which are regulated in Part B of that Directive (which concerns the deliberate release of GMOs for purposes other than placing on the market (such, for example, research). The attention of the Luxembourgish authorities is drawn to the fact that the notified draft should either exclude those operations from the notion of “*placing on the market*”, or provide for a procedure corresponding to Part B of Directive 2001/18/CE.

As concerns the requirements set out in Part C of the Directive 2001/18/CE, Articles 13 to 15 of that Directive provide for the steps to be followed by the notifier, and the competent authority of the Member State where a GMO is to be placed on the market for the first time, the Commission and the competent authorities of the other Member States. That procedure consists, in particular, of a notification and the drawing up of an assessment report by the competent authority of the Member State that received the

notification. This assessment report is to be sent to the Commission, which must, within 30 days of receipt, forward it to the competent authorities of the other Member States.

Articles 6 to 8 of the notified draft contain provisions that seem intended to mirror the procedure set out under Directive 2001/18/EC for the placing on a market of GMOs as or in products. However, the time-limits provided for in the notified draft do not accurately reflect the time-limits set out in Directive 2001/18/EC. This could lead to a situation of non-compliance with that Directive. The notified draft does not mention the procedure followed by the Commission in accordance with Directive 2001/18/EC and, in particular, it does not mention the fact that the Commission must forward the assessment report prepared by the competent authority of the Member State where the GMO is to be first placed on the market to the competent authorities of other Member States within the time-limit set by Directive 2001/18/EC. Therefore, the notion of ‘circulation of the assessment report’ used in Article 8(1) of the notified draft, as a starting point for the time-limit of 60 days for the minister to issue reasoned objections, is unclear. Under Article 15 of Directive 2001/18/EC, the ‘date of circulation of the assessment report’ corresponds to the date when the Commission forwards the assessment report of the assessing Member State to the competent authorities of the other Member States whereas, under Article 8(1) of the notified draft read in conjunction of Article 7(2) of that draft, it could be understood as being the date when the Luxembourgish Minister sent the assessment report to the notifier.

Finally, Article 18 of Directive 2001/18/EC addresses the situation in which a decision of the European Commission is needed. It provides that, in cases where an objection is raised and maintained by a competent authority or the Commission, the Commission must adopt and publish a decision within 120 days in accordance with the procedure laid down in Article 30(2) of the Directive.

Article 10(1) of the notified draft seems to be intended to transpose that Article 18 of Directive 2001/18/EC into national law and provides that ‘*[w]here an objection is raised and maintained in accordance with Articles 8, 9 and 12, a decision shall be adopted and published within 120 days in accordance with the procedure laid down in Article 5 of Regulation (EU) No 182/2011*’. However, its wording raises legal uncertainty, since, as mentioned above, the procedure followed by the Commission in accordance with Directive 2001/18/EC is not referred to in the notified draft. Indeed, while the time-limit of 120 days laid down in Article 18 of Directive 2001/18/EC runs from the expiry of the period of 105 days following the circulation by the Commission of the assessment report prepared by the competent authority which received the notification, Article 10(1) of the notified draft seems to make that time-limit run from an ‘objection raised and maintained [in accordance with Articles 8, 9 and 12]’ of the notified draft and, therefore, from an objection raised by the Luxembourgish minister. Therefore, the starting point of the time-limit for the adoption of the decision of the Commission, as set out in Directive 2001/18/EC, is not properly reflected under Article 10(1) of the notified draft. Besides, it would be more appropriate to refer to the procedure laid down in Directive 2001/18/EC,

rather than to the procedure laid down in Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers ⁽⁶⁾.

The attention of the Luxembourgish authorities is drawn to the necessity of adapting the provisions of the notified draft so as to comply with the provisions of Directive 2001/18/EC, and to avoid any legal uncertainty.

2.2 Official controls

Article 14 of Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law⁽⁷⁾/, rules on animal health and welfare, plant health and plant protection products, sets out methods and techniques for official controls. Article 13 of Regulation (EU) 2017/625 sets out requirements as regards written records of official controls.

The scope of some provisions of the notified draft appears to overlap with the scope of the above-mentioned provisions of Regulation (EU) 2017/625.

Indeed, the scope of Article 18(1) of the notified draft, setting out the powers of the agents of the Luxembourg Veterinary and Food Administration, appears to overlap with Article 14 of Regulation (EU) 2017/625. Article 18(5) of the notified draft, requiring the establishment of a written report of the official control, appears to overlap with Article 13(2) of Regulation (EU) 2017/625.

The attention of the Luxembourgish authorities is drawn to the necessity of adapting the provisions of the notified draft so as to avoid undermining the direct applicability of Regulation (EU) 2017/625.

The Luxembourgish authorities are invited to take these comments into account.

⁶() Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, OJ L 55, 28.2.2011, p. 13.

⁷() Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)Text with EEA relevance, OJ L 95, 7.4.2017, p. 1.

The Commission furthermore recalls that once the definitive text has been adopted, it must be communicated to the Commission in accordance with Article 5(3) of Directive (EU) 2015/1535.

Yours faithfully,

For the Commission

Thierry Breton
Member of the Commission