CropLife Europe's comments on the Grand Duchy of Luxembourg's proposed "*Draft law on the placing on the market of genetically modified organisms as or in products*"[1] notified pursuant to Directive (EU) 2015/1535

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CropLife Europe represents companies developing agricultural solutions in the sectors of chemical pesticides, biopesticides, plant biotechnology, and digital and precision agriculture.

Key messages:

The draft law conflicts with harmonised EU rules on the placing on the market of GMOs, established in Directive 2001/18/EC on the deliberate release of GMOs into the environment ("the GMO Directive"). Those harmonised rules, which already had to be implemented in domestic law long time ago, do not need to be duplicated as this creates legal uncertainty. The notified measure is not just a belated transposition of EU law, but also introduces new provisions which conflict with the GMO Directive. In so doing, it breaches one of the key principles of the EU internal market - the **free movement of goods** and the **principle of sincere cooperation**.

The notified measure **cannot be lawful if it conflicts with the harmonised provisions of EU law**. This unlawful conflict cannot be concealed through the TRIS procedure. CropLife Europe calls on the Commission to exercise its powers pursuant to Art 258 TFEU and to deliver a reasoned opinion on the matter**.**

CropLife Europe respectfully submits the following observations on the "*Draft law on the placing on the market of genetically modified organisms as or in products*" notified by the Grand Duchy of Luxembourg ('the notified measure') pursuant to Directive (EU) 2015/1535 ("the Standstill Directive")[2].

1. ***The notified measure does not justify the need for an additional national authorisation procedure for GM products***

The stated policy rationale for the notified measure is that is necessary, "[*i*]*n view of the important changes in the European legislative framework in recent years, a revision of the Law on the Control of the Use and Dissemination of Genetically Modified Organisms is necessary*"[3]. However, the notified measure is unable to identify any of those alleged important changes. The EU legislative framework concerning genetically modifies organisms ("GMOs") has been largely stable in recent years[4] (subject to usual technical amendments over time).

[1] TRIS Notification Number: 2023/0158/L (Luxembourg) : https://technical-regulation-information-system.ec.europa.eu/en/notification/23147

[2] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

[3] See TRIS Notification summary.

[4] The most recent changes to the GMO Directive and GFFR concern transparency requirements (set out in Regulation (EU) 2019/1381) which are directly applicable and therefore do not require acts of national transposition.

The core measures have been, and remain:

1. **Directive 2001/18/EC** on the deliberate release of GMOs into the environment ("the GMO Directive);
2. **Regulation (EC) 1829/2003** on genetically modified food and feed ("the GFFR");
3. **Regulation (EC) 1830/2003** concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms ("the TLR"); and
4. **Directive 2009/41/EC** on contained use of genetically modified micro-organisms. Regulation (EC) 1946/2003 on transboundary movements of GMOs ("the GMMR").

Therefore, there are no "changes" to which the notified measure actually responds. Moreover, it makes no explicit claim to transpose any new EU laws.

2. ***The notified measure overlaps with the existing harmonised provisions of EU laws and creates legal uncertainty***

The TRIS Notification summary describes the scope of the measure in the following terms:

> " *5. Draft law on the placing on the market of genetically modified organisms as products or components of products.*
> 6. *This draft law concerns the* ***placing on the market*** *of genetically modified organisms as products or components of products […]*
> 8. *The scope of this draft law is 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"* [emphasis added].

However, application of the existing EU legal framework has already resulted in 15 approvals of GM cotton, 6 approvals of GM carnations (both for uses other than cultivation), and 76 GM food and feed approvals[5]. No GM animals or derived products are on the EU market, but the European Food Safety Authority has had in place "*Guidance on the environmental risk assessment of genetically modified animals*" [6] for over 10 years. For these reasons, the notified measure appears to be an (imperfect) duplication of the harmonised rules already established in EU law – rather than a measure regulating an aspect unregulated by EU law. The Standstill Directive applies only in areas where EU law has not already established a harmonised regulatory framework.[7]

The overlap is apparent, for example, in the *prima facie* common scope of the notified measure and the GMO Directive:

Notified Measure	**GMO Directive – 2001/18**
Art. 1 Subject	Art. 1 Objective
"*This Law lays down the rules for the* ***placing on the European market of genetically modified organisms as or in products***" [emphasis added].	*"In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative*

[5] https://food.ec.europa.eu/plants/genetically-modified-organisms/gmo-register_en

[6] https://www.efsa.europa.eu/en/efsajournal/pub/3200

[7] See COMMISSION NOTICE, Guide on Articles 34-36 of the Treaty on the Functioning of the European Union (TFEU), C 100/38, Official Journal of the European Union 23.3.2021, section 1 (see also, section 3.1.1):

"*From a legal perspective, the principle of the free movement of goods has been a key element in creating and developing the internal market. Articles 34 to 36 TFEU define the scope and content of the principle by prohibiting unjustified restrictions on intra-EU trade. However, they are only applicable in non-harmonised areas.*

Harmonisation legislation consists of EU regulations and directives which aim at creating common rules which are applicable in all Member States […] Harmonised legislation has specified the meaning of the internal market in many areas and has thereby framed the principle of the free movement of goods in concrete terms for specific products. Nevertheless, the fundamental function of the Treaty principles as a key anchor and a safety net for the internal market remains unaltered."

	provisions of the Member States and to protect human health and the environment when: *—* *carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community,* *—* ***placing on the market genetically modified organisms as or in products*** *within the Community"* [emphasis added].

This overlap is confirmed by the common definition in both measures of "*placing on the market*"[8], "*organism*"[9], "*GMO*"[10], "*product*"[11] and the identical scope of exemptions[12]. The focus of the notified measure is on "*placing on the market*", for which the equivalent in the GMO Directive is so-called "Part C" (commercial use) applications.[13]

3. The notified measure introduces new provisions which conflict with the GMO Directive and breaches the free movement of goods potentially hampering the EU single market rules.

However, many of the Articles in the notified measure appear to be retrograde measures. For example, Article 14 of the notified measure reverses the presumption in Article 22 of the GMO Directive. Instead of enforcing the ability of approved GMOs to circulate freely, it reframes this as actively empowering authorities to restrict or suspend:

Notified Measure	**GMO Directive**
Art. 14. Free movement	Art. 22 Free circulation
"The Minister, on the advice of the ALVA, ***may restrict or suspend the placing on the market*** *in the Grand Duchy of Luxembourg of GMOs, as or in products,* ***if they do not comply with the requirements of this Law and its implementing regulations****"* [emphasis added].	*"Without prejudice to Article 23, Member States* ***may not prohibit, restrict or impede the placing on the market of GMOs,*** *as or in products,* ***which comply*** *with the requirements of this Directive"* [emphasis added].

Given the history of unlawfully maintained safeguard measures on GMOs and the impact on the single market, this is of great concern.

Similarly, Article 15 of the notified measure transforms Article 23 of the GMO Directive from a discretionary

to mandatory and automatic power, and does not acknowledge the overarching role which the European Commission must play in such cases to police unlawful use of safeguard powers:

[8] Article 2(5) of the Notified Measure and Article 2(4) of the GMO Directive.
[9] Article 2(9) of the Notified Measure and Article 2(1) of the GMO Directive
[10] Article 2(10) and Annex I A of the Notified Measure and Article 2(2) and Annex I A of the GMO Directive
[11] Article 2(11) of the Notified Measure and Article 2(7) of the GMO Directive
[12] Article 3 of the Notified Measure and Article 3 of the GMO Directive
[13] Article 1

Notified Measure	GMO Directive
Art. 15. Safeguard clause	Art. 23 Safeguard clause
"Where the ALVA or the Minister, by reason of new or additional information which has become available after the authorisation has been given and which affects the environmental risk assessment or because of the re-evaluation of existing information on the basis of new or additional scientific knowledge, has specific reasons to consider that a GMO as or in a product which has been properly notified and authorised in writing in accordance with this Law presents a risk to human health or the environment, ***the ALVA shall take the emergency measures referred to in Article 21*** *and the Minister responsible for Agriculture shall take the administrative measures referred to in Article 22"* [emphasis added].	"*1. Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that* ***Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory****.* *The Member State shall ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including information to the public.* ***The Member State shall immediately inform the Commission and the other Member States of actions taken under this Article and give reasons*** *for its decision, supplying its review of the environmental risk assessment, indicating whether and how the conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based.* *2. Within 60 days of the date of receipt of the information transmitted by the Member State,* ***a decision shall be taken on the measure taken by that Member State in accordance with the regulatory procedure referred to in Article 30(2)*** *[…]*" [emphasis added].

These (non-exhaustive) examples may suggest that the Grand Duchy of Luxembourg is making a belated attempt to transpose the GMO Directive into domestic law, but presenting this instead as a new measure and subject to the Standstill Directive. If this is the case, we would ask the **Commission to consider the need to exercise its powers pursuant to Article 258 TFEU**.[14] In any event, a faithful transposition into domestic law would not require a TRIS notification – only those measures which might go *beyond t*he regulatory aspects already harmonised. Such a measure cannot be lawful where it actually conflicts with the harmonised provisions of EU law. This unlawful conflict cannot be concealed through the TRIS procedure.

[14] "*If the Commission considers that a Member State has failed to fulfil an obligation under the Treaties, it shall deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its observations.*
If the State concerned does not comply with the opinion within the period laid down by the Commission, the latter may bring the matter before the Court of Justice of the European Union."