



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market Enforcement

Notification of Regulatory Barriers

Notification Number : 2020/0281/F (France)

Order laying down the list of varieties mentioned in Article 2 of Decree [xx]

Date received : 06/05/2020

End of Standstill : 07/08/2020 (09/11/2020)

Message

Message 002

Communication from the Commission - TRIS/(2020) 01604

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2020/0281/F

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késéket - Ma' jiftaħx il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 202001604.EN)

1. MSG 002 IND 2020 0281 F EN 06-05-2020 F NOTIF

2. F

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4. 2020/0281/F - C00A

5. Order laying down the list of varieties mentioned in Article 2 of Decree [xx]

6. Plant varieties

7. -



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8. The purpose of the draft Order is to lay down the list of varieties resulting from in vitro random mutagenesis, consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents, which will be prohibited from being placed on the market and cultivated in France due to them not having been evaluated and authorised under the regulations on GMOs.

The draft Order contains:

- the list of varieties whose registration in the catalogue has been revoked due to being obtained via in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagens (Annex I to the draft Order).
- the list of varieties which satisfy the conditions for revocation of registration in the catalogue due to being obtained via in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagens (Annex II to the draft Order).

9. At the end of 2014, nine associations sent a letter to the Prime Minister requesting, firstly, the repeal of Article D531-2 of the French Environment Code as it exempts herbicide-tolerant varieties (HTV) from the regulations on genetically modified organisms (GMOs) and, secondly, a moratorium on these HTVs.

The silence maintained by the administration on this request gave rise to an implicit decision of rejection, against which the associations lodged an appeal before the French Council of State (CE). By a decision of 3 October 2016, the latter asked the Court of Justice of the European Union (CJEU) four questions referred for a preliminary ruling and stayed proceedings on the conclusions of the application until the Court had ruled on these questions. By a judgment delivered on 25 July 2018 (case C 528/16), the CJEU thus:

- clarified the scope of Directive 2001/18/EC: the Court states that any product of a mutagenesis technique is a GMO, and that the only products exempt from the evaluation procedure are those of mutagenesis techniques conventionally used in a number of applications and which have a long safety record.
- specified the concept of 'techniques which have conventionally been used in a number of applications and have a long safety record': the judgment states in particular, in point 51, that the Directive cannot be interpreted as excluding from its scope 'organisms obtained by means of new techniques/methods of mutagenesis, which have appeared or have been mostly developed since Directive 2001/18 was adopted'.

The Council of State delivered its decision on 7 February 2020 following the Court's preliminary ruling. It concludes that the techniques of in vitro random mutagenesis subjecting plant cells to chemical or physical mutagenic agents, as well as the techniques of what is termed directed mutagenesis or of genome editing, are not conventionally used techniques which have a long safety record, having appeared or having mainly been developed since the adoption of Directive 2001/18/EC. It follows that the organisms obtained via these techniques must be subject to the regulations on GMOs. Consequently, the Council of State enjoined the Prime Minister to amend the regulations specifying the techniques of mutagenesis exempt from the regulations on GMOs in order to distinguish them from those which, according to its analysis, fall within the scope of this regulation.

It also enjoins the competent authorities to take all the necessary measures resulting therefrom:

- to identify, within the common catalogue of varieties of agricultural plant species, those varieties that would have been registered without having carried out the evaluation to which they should have been submitted having regard to the technique used to obtain them;
- to assess whether it is necessary to initiate the procedure for the withdrawal of the varieties concerned, the suspension or even the destruction of the crops in place.

A Decree on the genetic modification techniques mentioned in Article L531-2 of the French Environmental Code will specify the mutagenesis techniques exempt from the scope of the regulations on GMOs. The draft Decree provides for the exemption of random mutagenesis, with the exception of in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents.

This provision means that plant organisms resulting from in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents fall within the scope of the regulations relating to GMOs. Consequently, once the Decree has been published and is subject to the transitional provisions provided, in particular for growing crops, it will be prohibited in France to cultivate or sell the varieties resulting from in vitro random mutagenesis, consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents, due to them not having been evaluated and authorised under the regulations on GMOs.



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As provided for in Article 2 of the draft Decree, the varieties in question will be included in a list laid down by order, which is the subject of this notification.

The French authorities have identified the varieties listed in the draft Order as originating from in vitro random mutagenesis consisting in subjecting plant cells cultivated in vitro to chemical or physical mutagenic agents. These are the herbicide-tolerant varieties of rapeseed, marketed under the name Clearfield rapeseed, whose method of production described in the bibliography corresponds to this technique.

10. Reference(s) to basic text(s): Article L531-2 of the French Environmental Code

Article D531-2 of the French Environmental Code

Decree No [...] of [date] amending the list of techniques for obtaining genetically modified organisms traditionally used without any noted drawbacks with regard to public health or the environment, notified concomitantly

11. No

12. -

13. No

14. No

15. -

16. TBT aspect

Yes

SPS aspect

No - the draft is neither a sanitary nor phytosanitary measure.

European Commission

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