Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (Text with EEA relevance)

DIRECTIVE (EU) 2015/412 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Having regard to the opinion of the Committee of the Regions[(2)],

Acting in accordance with the ordinary legislative procedure[(3)],

Whereas:

(1) Directive 2001/18/EC of the European Parliament and of the Council[(4)] and Regulation (EC) No 1829/2003 of the European Parliament and of the Council[(5)] establish a comprehensive legal framework for the authorisation of genetically modified organisms (GMOs), which is fully applicable to GMOs to be used for cultivation purposes throughout the Union as seeds or other plant-propagating material ('GMOs for cultivation').

(2) Under that legal framework, GMOs for cultivation are to undergo an individual risk assessment before being authorised to be placed on the Union market in accordance with Annex II to Directive 2001/18/EC taking into account the direct, indirect, immediate and delayed effects, as well as the cumulative long-term effects, on human health and the environment. That risk assessment provides scientific advice to inform the decision-making process and is followed by a risk management decision. The aim of that authorisation procedure is to ensure a high level of protection of human life and health, animal health and welfare, the environment and consumer interests, whilst ensuring the effective functioning of the internal market. A uniform high level of protection of health, the environment and consumers should be achieved and maintained throughout

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the territory of the Union. The precautionary principle should always be taken into account in the framework of Directive 2001/18/EC and its subsequent implementation.

(3) Pursuant to the conclusions adopted by the Council on 4 December 2008 on Genetically Modified Organisms ('2008 Council conclusions'), it is necessary to look for improvement of the implementation of the legal framework for the authorisation of GMOs. In this context, the rules on risk assessment should be, where needed, regularly updated to take account of continuous developments in scientific knowledge and analysis procedures, in particular regarding the long-term environmental effects of genetically modified crops as well as their potential effects on non-target organisms, the characteristics of receiving environments and the geographical areas in which genetically modified crops may be cultivated, and the criteria and requirements for assessing GMOs producing pesticides and herbicide tolerant GMOs. Therefore, the Annexes to Directive 2001/18/EC should be amended accordingly.

(4) In addition to the authorisation for placing on the market, genetically modified varieties also need to comply with the requirements of Union law on the marketing of seed and plant propagating material, as set out in particular in Council Directives 66/401/EEC[(6)], 66/402/EEC[(7)], 68/193/EEC[(8)], 98/56/EC[(9)], 1999/105/EC[(10)], 2002/53/EC[(11)], 2002/54/EC[(12)], 2002/55/EC[(13)], 2002/56/EC[(14)], 2002/57/EC[(15)] and 2008/90/EC[(16)]. Among those Directives, Directives 2002/53/EC and 2002/55/EC contain provisions which allow the Member States to prohibit, under certain well defined conditions, the use of a variety in all or in part of their territory or to lay down appropriate conditions for the cultivation of a variety.

(5) Once a GMO is authorised for cultivation purposes in accordance with the Union legal framework on GMOs and complies, as regards the variety that is to be placed on the market, with the requirements of Union law on the marketing of seed and plant propagating material, Member States are not authorised to prohibit, restrict, or impede its free circulation within their territory, except under the conditions defined by Union law.

(6) Experience has shown that cultivation of GMOs is an issue which is more thoroughly addressed at Member State level. Issues related to the placing on the market and the import of GMOs should remain regulated at Union level to preserve the internal market. Cultivation may however require more flexibility in certain instances as it is an issue with strong national, regional and local dimensions, given its link to land use, to local agricultural structures and to the protection or maintenance of habitats, ecosystems and landscapes. In accordance with Article 2(2) of the Treaty on the Functioning of the European Union (TFEU), Member States are entitled to have the possibility to adopt legally binding acts restricting or prohibiting the cultivation of GMOs in their territory after such GMOs have been authorised to be placed on the Union market. However, the common authorisation procedure, in particular the evaluation process conducted primarily by the European Food Safety Authority (the 'Authority'), should not be adversely affected by such flexibility.

(7) In the past, in order to restrict or prohibit the cultivation of GMOs, some Member States had recourse to the safeguard clauses and emergency measures pursuant to Article 23 of

Directive 2001/18/EC and Article 34 of Regulation (EC) No 1829/2003 as a result of, depending on the cases, new or additional information made available since the date of the consent and affecting the environmental risk assessment, or of the reassessment of existing information. Other Member States have made use of the notification procedure set out in Article 114(5) and (6) TFEU which requires putting forward new scientific evidence relating to the protection of the environment or the working environment. In addition, the decision-making process has proved to be particularly difficult as regards the cultivation of GMOs in the light of the expression of national concerns which do not only relate to issues associated with the safety of GMOs for health or the environment.

(8) In that context, it appears appropriate to grant Member States, in accordance with the principle of subsidiarity, more flexibility to decide whether or not they wish to cultivate GMOs on their territory without affecting the risk assessment provided in the system of Union authorisations of GMOs, either in the course of the authorisation procedure or thereafter, and independently of the measures that Member States cultivating GMOs are entitled or required to take by application of Directive 2001/18/EC to avoid the unintended presence of GMOs in other products. The grant of that possibility to Member States is likely to improve the process for authorisations of GMOs and, at the same time, is also likely to ensure freedom of choice of consumers, farmers and operators whilst providing greater clarity to affected stakeholders concerning the cultivation of GMOs in the Union. This Directive should therefore facilitate the smooth functioning of the internal market.

(9) In order to ensure that the cultivation of GMOs does not result in their unintended presence in other products and whilst respecting the principle of subsidiarity, particular attention should be paid to the prevention of possible cross-border contamination from a Member State where cultivation is allowed into a neighbouring Member State where it is prohibited, unless the Member States concerned agree that particular geographical conditions render it unnecessary.

(10) The Commission Recommendation of 13 July 2010[(17)] provides guidance to Member States for the development of coexistence measures, including in border areas. The recommendation encourages Member States to cooperate with each other to implement appropriate measures at the borders between Member States so as to avoid unintended consequences of cross-border contamination.

(11) During the authorisation procedure of a given GMO, the possibility should be provided for a Member State to demand that the geographical scope of the notification/application submitted in accordance with Part C of Directive 2001/18/EC or in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 be adjusted to the effect that all or part of the territory of that Member State be excluded from cultivation. The Commission should facilitate the procedure by presenting the demand of the Member State to the notifier/applicant without delay and the notifier/applicant should respond to that demand within an established timelimit.

(12) The geographical scope of the notification/application should be adjusted accordingly unless the notifier/applicant confirms the geographical scope of its notification/application within an established timelimit from the communication by the Commission

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of that demand. Such confirmation, however, is without prejudice to the Commission's powers in accordance with Article 19 of Directive 2001/18/EC or Articles 7 and 19 of Regulation (EC) No 1829/2003, as the case may be, to make such an adjustment, where appropriate, in the light of the environmental risk assessment carried out by the Authority.

(13) Whilst it is expected that most restrictions or prohibitions adopted pursuant to this Directive will be implemented at the stage of consent/authorisation or renewal thereof, there should, in addition, also be the possibility for Member States to adopt reasoned measures restricting or prohibiting the cultivation in all or part of their territory of a GMO, or of a group of GMOs defined by crop or trait, once authorised, on the basis of grounds distinct from and complementary to those assessed according to the harmonized set of Union rules, that is Directive 2001/18/EC and Regulation (EC) No 1829/2003, which are in conformity with Union law. Those grounds may be related to environmental or agricultural policy objectives, or other compelling grounds such as town and country planning, land use, socioeconomic impacts, coexistence and public policy. Those grounds may be invoked individually or in combination, depending on the particular circumstances of the Member State, region or area in which those measures will apply.

(14) The level of protection of human or animal health and of the environment chosen in the Union allows for a uniform scientific assessment throughout the Union and this Directive should not alter that situation. Therefore, to avoid any interference with the competences which are granted to the risk assessors and risk managers under Directive 2001/18/EC and Regulation (EC) No 1829/2003, a Member State should only use grounds with respect to environmental policy objectives relating to impacts which are distinct from and complementary to the assessment of risks to health and the environment which are assessed in the context of the authorisation procedures provided in Directive 2001/18/EC and in Regulation (EC) No 1829/2003, such as the maintenance and development of agricultural practices which offer a better potential to reconcile production with ecosystem sustainability, or maintenance of local biodiversity, including certain habitats and ecosystems, or certain types of natural and landscape features, as well as specific ecosystem functions and services.

(15) Member States should also be able to base the decisions which they adopt pursuant to Directive 2001/18/EC on grounds concerning socioeconomic impacts which might arise from the cultivation of a GMO on the territory of the Member State concerned. While coexistence measures have been addressed by the Commission Recommendation of 13 July 2010, there should also be the possibility for Member States to adopt measures restricting or prohibiting cultivation of authorised GMOs in all or part of their territory under this Directive. Those grounds may be related to the high cost, impracticability or impossibility of implementing coexistence measures due to specific geographical conditions, such as small islands or mountain zones, or the need to avoid GMO presence in other products such as specific or particular products. Furthermore, the Commission has, as requested in the 2008 Council conclusions, reported to the European Parliament and the Council on socioeconomic implications of GMO cultivation. The outcome of that report may provide valuable information for

Member States considering taking decisions on the basis of this Directive. Grounds relating to agricultural policy objectives may include the need to protect the diversity of agricultural production and the need to ensure seed and plant propagating material purity. Member States should also be allowed to base their measures on other grounds that may include land use, town and country planning, or other legitimate factors including those relating to cultural traditions.

(16) The restrictions or prohibitions adopted pursuant to this Directive should refer to the cultivation, and not to the free circulation and import, of genetically modified seeds and plant propagating material as, or in, products and of the products of their harvest, and should, furthermore, be in conformity with the Treaties, in particular as regards the principle of non-discrimination between national and non-national products, the principle of proportionality and Article 34, Article 36 and Article 216(2) TFEU.

(17) Member States' measures adopted pursuant to this Directive should be subject to a procedure of scrutiny and information at Union level. In the light of the level of Union scrutiny and information, it is not necessary to provide, in addition, for the application of Directive 98/34/EC of the European Parliament and of the Council[(18)]. Member States may restrict or prohibit the cultivation of GMOs in all or part of their territory as from the date of entry into force of the Union authorisation and for the whole duration of the consent/authorisation, provided that an established standstill period, during which the Commission was given the opportunity to comment on the proposed measures, has elapsed. The Member State concerned should therefore communicate a draft of those measures to the Commission at least 75 days prior to their adoption, in order to give the Commission an opportunity to comment thereon, and should refrain from adopting and implementing those measures during that period. On the expiry of the established standstill period, the Member State should be able to adopt the measures as originally proposed or amended to take into account the Commission's comments.

(18) During the established standstill period, the authorisation applicant/holder who would be affected by measures restricting or prohibiting the cultivation of a GMO in a Member State should refrain from all activities related to the cultivation of that GMO in that Member State.

(19) Decisions to restrict or prohibit the cultivation of GMOs by Member States in all or part of their territory should not prevent biotechnology research from being carried out provided that, in carrying out such research, all necessary safety measures relating to human and animal health and environmental protection are observed and that the activity does not undermine the respect of the grounds on which the restriction or prohibition has been introduced. Moreover, the Authority and the Member States should aim to establish an extensive network of scientific organisations representing all disciplines including those relating to ecological issues, and should cooperate to identify at an early stage any potential divergence between scientific opinions with a view to resolving or clarifying contentious scientific issues. The Commission and the Member States should ensure that the necessary resources for independent research on the potential risks arising from the deliberate release or the placing on the market