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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Since the entry into force of Regulation (EC) No 1829/2003[1], there has never been a qualified majority amongst Member States in favour of or against a draft Commission Decision authorising Genetically Modified Organisms (GMOs) and Genetically Modified (GM) food and feed. The result has always been a "no opinion" for all stages of the procedure (Standing Committee and Appeal Committee under currently applicable rules, or the Council in the past). As a result, the authorisation decisions have been adopted by the Commission, in accordance with applicable legislation, without the support of the Member States' committee opinion. The return of the dossier to the Commission for final decision, very much the exception for the procedure as a whole, has become the norm for decision-making on GM food and feed authorisations. Regulation (EC) No 1829/2003 allows Member States to adopt measures restricting or prohibiting the use of authorised GMOs and GM food and feed only if they are able to demonstrate that the product in question is likely to pose risks to health and to the environment. The reasons why Member States vote against are diverse. They often express national concerns which do not only relate to issues associated with the safety of GMOs for health or the environment.

The European Commission was appointed on the basis of a set of Political Guidelines presented to the European Parliament. In these Guidelines, a commitment was taken to review the legislation applicable to the authorisation of GMOs.

The results are set out in the Communication reviewing the decision-making process on Genetically Modified Organisms (GMOs)[2].

The Commission concludes that the legal framework for decision-making on GM food and feed needs to be adapted.

The Commission therefore proposes to extend the solution agreed in Directive (EU) 2015/412[3] by the European Parliament and by the Council on GMO cultivation to GM food and feed in respect of democratic choice and in the interest ofconsistency.

2. THE CURRENT LEGISLATIVE FRAMEWORK

2.1. Introduction

The European Union has in place a comprehensive legal framework for the authorisation, traceability and labelling of GM food and feed.

Regulation (EC) No 1829/2003 on GM food and feed covers food, food ingredients, and feed containing, consisting of or produced from GMOs. It also

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1 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.

2 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committe of the Regions, Reviewing the decision-making process on genetically modified organisms (GMOs), COM(2015)178.

3 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 Member States to restrict or prohibit the cultivation of genetically modified organisms (GMO) in their territory (OJ L 68, 13.3.2015, p. 1).

covers GMOs for other uses such as cultivation, if they are to be used as source material for the production of food and feed. These different products are designated in this document as "GMOs and GM food and feed".

Regulation (EC) No 1829/2003 has put in place an authorisation procedure whose aim is to ensure that the placing on the market of the products concerned will not pose a risk to human and animal health and the environment. In order to do so, a scientific risk assessment is at the centre of the procedure: every authorisation for placing on the market of a product has to be duly justified and the main ground on which such a justification can rely is scientific assessment[4]. The legislation gives responsibility for this scientific risk assessment to the European Food Safety Authority (EFSA), in cooperation with the scientific bodies of the Member States.

Regulation (EC) No 1829/2003 contains provisions allowing the Commission or Member States to adopt emergency measures against the placing on the market/use of an authorised GMO, where it appears that the product is likely to constitute a serious risk to health or to the environment. These measures require scientific evidence demonstrating that the product is likely to pose a serious risk to health or to the environment.

2.2. The decision-making process for authorising GMOs and GM food and feed

Regulation (EC) No 1829/2003, read in the light of Article 41 of the Charter of Fundamental Rights and the case-law of the Court of justice[5], requires the Commission as risk manager to take a decision on an application for authorisation in a reasonable period of time (to grant an authorisation or refuse an authorisation).

Since the entry into force of Regulation (EC) No 1829/2003, Member States have never expressed a qualified majority in favour or against a Commission draft decision. A "no opinion" (no qualified majority in favour or against the draft decision) has been expressed at all stages of the procedure (Standing committee and Appeal committee under currently applicable rules). As a result, the authorisation decisions have been adopted by the Commission, in accordance with applicable legislation, without the support of the Member States' committee opinion.

The reasons invoked by Member States to justify that they abstained or voted against a draft decision of authorisation of a GMO or a GM food and feed are usually not based on science but on other considerations.

At the same time, even if Regulation (EC) No 1829/2003 allows the Commission to take into consideration, in addition to the risk assessment carried out by EFSA, "other legitimate factors", the Commission has not been in a position to refer to those factors in order to justify a refusal of the

[4] Articles 7 and 19 of Regulation (EC) No 1829/2003 provide that the Commission may, in addition to EFSA's opinion, take into account "*other legitimate factors relevant to the matter under consideration*".

[5] CJEU, C-390/99, Canal Satélite Digital SL, par. 41.

authorisation of products considered safe by EFSA[6] and, in any case, it could only do so for the EU as a whole.

Until recently, the Union legal framework did not allow Member States to oppose to the use of GMOs for cultivation and other uses and GM food and feed on their territory by other means than expressing a negative vote during the decision-making process leading to the authorisation of GMOs and GM food and feed or, once the authorisation is granted, by invoking safeguard clauses/emergency clauses. These clauses have been used by some Member States in the case of GMOs for cultivation and, in a more limited way, in the case of GM food and feed.

Other Member States have made the choice to adopt unilateral bans or "de facto" bans, preventing the use of GMOs for cultivation or GM food and feed on their territory or making it subject to conditions which, being not possible to fulfil, lead to the same result. These unilateral measures have been challenged before national jurisdictions or the Court of justice.

Regarding cultivation of GMOs, Directive (EU) 2015/412 grants 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. It also covers GMOs for cultivation whose authorisation is pending or which are already authorised under Regulation (EC) No 1829/2003. That Directive in no way affects the science-based EU authorisation procedure under Directive 2001/18/EC or under Regulation (EC) No 1829/2003.

However, that Directive does not cover GMOs and GM food and feed authorised under Regulation (EC) No 1829/2003.

3. RESULTS OF THE COMMISSION's REVIEW

In line with the Political Guidelines issued for the Commission on 15 July 2014, the Commission Communication [XXX, please add COM number] sets out the Commission's findings resulting from its review of the decision-making process of GMOs and GM food and feed. The Communication concludes that the current legal framework should be amended, by extending the approach agreed in Directive (EU) 2015/412 to other products covered by the Regulation (EC) No 1829/2003.

Directive (EU) 2015/412 has been adopted very recently. This proposal is largely inspired from that Directive, including its objectives and the mechanisms foreseen to achieve them. The conclusions drawn by the Union legislature during the negotiation process can thus be applied to this proposal.

The proposal draws heavily on Directive (EU) 2015/412, and flows directly from the political mandate to the Commission on the basis of the Political Guidelines it was

[6] The use by the Commission of the "other legitimate factors" mentioned in Regulation (EC) No 1829/2003, to refuse to grant the authorisation could be legally defensible if justified by overriding reasons of public interest of the same nature as those mentioned in Article 36 TFEU and related case-law of the Court of justice (see for instance, CJEU, 20.02.1979, Case 120/78 Rewe-Zentral (Cassis de Dijon) [1979] ECR 649) and by objectives of general interest as referred to in Article 52(1) of the Charter of fundamental rights of the European Union and relevant Court's case-law (see for example CJEU, 12.07.2012, Case C-59/11, Association Kokopelli, ECLI:EU:C:2012:447).

elected on. As in the case of Directive (EU) 2015/412, the practical effect of the proposal will depend on the extent to which Member States make use of its provisions.

4. LEGAL ELEMENTS OF THE PROPOSAL

4.1. Summary of the proposal

The Commission proposal amends Regulation (EC) No 1829/2003, under the ordinary legislative procedure, to introduce new provisions allowing Member States to restrict or prohibit the use of GMOs and GM food and feed covered by the GMO legal framework, in part or all of their territory, in complement to the possibilities already offered to Member States with respect to GMOs for cultivation by Directive (EU) 2015/412.

The additional powers granted to Member States under this proposal will only concern the possibility to adopt measures in accordance with the Treaty to restrict or prohibit the use of GMOs and GM food and feed on their territory after these products have been authorised. It will thus not affect the procedural and substantial conditions of the authorisation of GMOs and GM food and feed under Regulation (EC) No 1829/2003, which will remain valid for the whole territory of the Union.

The measures adopted by Member States need to be compatible with the internal market, and in particular Article 34 TFEU which prohibits measures of equivalent effects to quantitative restrictions to the free movement of goods. That is why the Member States making use of this proposal will need to justify the measures taken based on grounds to be in accordance with Article 36 TFEU and the notion of overriding reasons of public interest as developed by the case-law of the Court of justice. In addition, the measures envisaged will need to be reasoned and to be compatible with the principles of proportionality and non-discrimination between national and non-national products. Finally these measures will need to comply with the international obligations of the Union.

It will be up to each Member State wanting to make use of this "opt-out" to justify the restriction or prohibition on a case-by-case basis, taking into account the GMO in question, the type of measure envisaged, and the specific circumstances at national or regional level that justify such an opt-out.

As for Directive (EU) 2015/412, Member States will not be allowed to use justifications linked to the assessment of risks to health or to the environment which are comprehensively addressed in the authorisation decision and by the procedures already available in Regulation (EC) No 1829/2003, to address new risks (e.g. “emergency measures” under Article 34 or “supervision” under Articles 9 and 21).

The new possibility offered by the proposal does not cover the placing on the market and use of products not labelled as genetically modified, in accordance with labelling thresholds set under the GMO legal framework (e.g. under Articles 12 and 24 of Regulation (EC) No 1829/2003 food and feed containing an adventitious or technically unavoidable presence of GM material up to 0,9% by ingredient are not labelled).

The Member States which will restrict or prohibit the use of GMOs and GM food and feed already on the market will also have to preserve the rights of the operators, by providing them a reasonable period of time to allow the phasing out of the products concerned.

4.2. Legal basis

The proposal is based on Article 114 TFEU which is, among the legal basis of Regulation (EC) No 1829/2003, the legal basis which is relevant for the adoption of the measures provided for in this proposal.

4.3. Subsidiarity and proportionality principles

4.3.1. Conformity of the proposal with the principle of subsidiarity

According to Article 5(3) TEU, under the principle of subsidiarity, in areas not falling within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but rather, by reason of the scale of effects of the proposed action, be better achieved at Union level.

The current Union legal framework fully harmonises the authorisation procedure of GMOs and GM food and feed and allows Member States to adopt measures restricting or prohibiting the use of GMOs and GM food and feed only under the conditions set out in that legal framework. Currently, that framework contains limited possibilities for Member States to express other considerations than those associated with the safety of the product, outside their vote in the committees.

The proposal will change this situation as it enables Member States to adopt on their territory measures to restrict or prohibit the use of GMOs and GM food and feed, based on legitimate considerations other than those linked to the safety of the products, provided that those measures are in line with EU law.

In accordance with Article 5(3) TEU, the proposed amendments do not affect the provisions of Regulation (EC) No 1829/2003 pursuing an objective which is better achieved at Union level. This is the case of the Union procedure of authorisation, based on risks, and of the provisions which allow uniform and coordinated Union actions against potential risks caused by GMOs, such as the provisions on emergency measures or the provisions on supervision, all of them aiming at ensuring a high level of safety throughout the Union. In Directive (EU) 2015/412 the European Parliament and the Council recalled that this objective is better achieved at Union level, and have thus prohibited Member States to adopt measures interfering into these matters[7].

[7] Its recital 2 provides that *"a uniform high level of protection of health, the environment and the consumers should be achieved and maintained throughout the territory of the Union"* whereas according to its recital 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."*

However, for issues which are not linked to the risks to health and to the environment, the proposal is based on the underlying assumption that national, regional or local levels of decision-making are the most appropriate levels to address the particularities linked to the use of GMOs and GM food and feed in the different territories of the Union. In view of the variety of situations which can be covered by the proposal, it was considered not appropriate to try to identify more precisely the justifications which could be used by Member States to support their measures, provided that they are compatible with Union law.

This approach is in line with the principle of subsidiarity.

4.3.2. Conformity of the proposal with the principle of proportionality

According to Article 5(4) TEU, under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.

The proposal is limited to only allow Member States to adopt reasoned measures on their territory on the use of GMOs and GM food and feed authorised under the GMO legal framework.

It does not affect the Union procedure of authorisation based on risks which should remain harmonised at Union level in order to maintain a same level of safety throughout the EU. To avoid interference with the procedures of the GMO legal framework which allows the Union and its Member States to react in a quick and coordinated way in the case where a risk to health or to the environment is identified after the GMO has been authorised, Member States are not authorised to base their measures on grounds linked to the safety of the product.

Other mechanisms are provided to ensure that the proposal does not go beyond what is necessary to attain the objective pursued.

Indeed, to ensure that the measures adopted by Member States will be limited to what is needed to achieve the objective pursued, the proposal does not allow Member States to restrict or prohibit the use of products which do not have to be labelled under the GMO legal framework, even if they may contain a small proportion of GMOs or GM food and feed below the thresholds set out therein. Provisions are also established to protect the rights of economic operators which lawfully placed on the market a GMO or a GM food and feed before the Member State adopt measures pursuant to the proposal.

The proposal also foresees that the measures adopted by Member States have to be reasoned, based on compelling grounds compatible with Articles 34 and 36 TFEU and related case-law of the Court of justice and that they have to respect the principles of proportionality and non-discrimination.

These different elements ensure that the proposal does not exceed what is necessary to attain the objective pursued and that it is compatible with the principle of proportionality.

4.4. Choice of instruments

It is proposed to amend Regulation (EC) No 1829/2003 by a Regulation, by application of the principle of "parallélisme des formes". The Commission's obligation to monitor the application of the Regulation in terms of impact on inter alia health and the functioning of the internal market as set out in Regulation (EC) No 1829/2003 on GM food and feed[8], will continue to apply and will include the amending provisions proposed with this Regulation.

5. BUDGETARY IMPLICATION

No

[8] See Article 48(2) of the Regulation.

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amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory

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[9],

Having regard to the opinion of the Committee of the Regions[10],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Directive 2001/18/EC[11] and Regulation (EC) No 1829/2003[12] (hereafter "the GMO legal framework"), establish a comprehensive legal framework for granting the authorisations for the placing on the market of genetically modified organisms (GMOs) and genetically modified food and feed. The aim of these acts is to ensure the safety of GMOs and genetically modified (GM) food and feed, while at the same time, establishing an internal market for those products.

(2) Both Directive 2001/18/EC and Regulation (EC) No 1829/2003 establish a centralised procedure at Union level whereby the Commission is empowered to adopt implementing decisions granting or refusing application for the authorisation of GMOs and GM food and feed, based on an assessment of the potential risks that they could pose to human or animal health, or the environment. Regulation (EC) No 1829/2003 also provides that other legitimate factors may be taken into account, where appropriate.

(3) Commission implementing decisions concerning authorisations for GMOs and GM food and feed are adopted in accordance with the examination procedure provided for

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9 OJ C , , p. .

10 OJ C , , p. .

11 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).

12 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).

in Regulation (EU) No 182/2011[13]. That procedure provides that Member States are to be involved at two stages, namely in the standing committee and later, if necessary, in the appeal committee.

(4) The use of genetic engineering in plants and in food and feed is a subject which divides opinion in the Member States and this is reflected in the decision-making process leading to the authorisation of GMOs and GM food and feed. Since the date of application of Regulation (EC) No 1829/2003, the results of the voting in the committees or in Council show that there has never been a qualified majority either in favour of or against the authorisation of those products. Therefore, authorisations have been adopted by the Commission at the end of the procedure, in accordance with applicable legislation, without the support of the Member States' committee opinion.

(5) Once a GMO or a GM food and feed is authorised in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003, the Member States may not prohibit, restrict or impede the free circulation of that product within their territory, except in accordance with strict conditions which are laid down by Union law –and require to provide evidence of a severe risk to health or to the environment. Some Member States have had recourse to the safeguard clauses and the emergency measures provided for respectively in Articles 23 of Directive 2001/18/EC and Article 34 of Regulation (EC) No 1829/2003. Other Member States have made use of the notification procedure provided for in Article 114(5) and (6) of TFUE which also is required to be based on new scientific evidence relating to the protection of the environment or the working environment. Other Member States have adopted unilateral prohibitions. Some of these measures have been challenged before national jurisdictions or the Court of justice.

(6) That situation was changed recently as regards GMOs for cultivation due to the adoption, on 13 March 2015, of Directive (EU) 2015/412[14] which amended Directive 2001/18/EC to allow Member States to restrict or prohibit the cultivation of GMOs in their territory. The new provisions are primarily aimed at enabling Member States to decide whether or not they wish to permit the cultivation of GMO crops on their territory, without affecting the risk assessment provided in the system of Union authorisations of GMOs. They were intended to provide more predictability to operators and limit the recourse by the Member States to the safeguard clauses provided for in Article 23 of Directive 2001/18/EC and 34 of Regulation (EC) No 1829/2003. It was also expected that those amendments would have a positive impact on the decision-making process for the authorisation of GMOs for cultivation.

(7) The reasons for the amendments made to Directive 2001/18/EC, by Directive (EU) 2015/412 as regards GMOs for cultivation are also relevant for other GMOs and GM food and feed covered by Regulation (EC) No 1829/2003. Indeed, the results of the vote on the implementing decision for the authorisation of products covered by Regulation (EC) No 1829/2003 which are not intended for cultivation in the relevant committee, or in the Council, is always “no opinion” (no qualified majority either in favour of or against the authorisation) and there are also Member States in which the

[13] 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).

[14] 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 (OJ L 68, 13.3.2015, p. 1).

use of these products is prohibited. Taking those matters into account, it is appropriate to amend Regulation (EC) No 1829/2003 in order to provide the possibility for the Member States to restrict or prohibit the use of GMOs and GM food and feed in all or part of their territory, on the basis of compelling grounds compatible with Union law - not related to risks to human and animal health and to the environment, as those are already assessed at Union level, pursuant to Regulation (EC) No 1829/2003. This possibility should not apply to GMOs for cultivation which are already covered by the amendments made to Directive 2001/18/EC, by Directive (EU) 2015/412.

(8) Member States should therefore be allowed to adopt measures restricting or prohibiting the use in all or part of their territory of a GMO or a GM food and feed, or group of GMOs or of GM food and feed, once authorised, provided that such measures are reasoned, based on compelling grounds in accordance with Union law, and are in line with the principles of proportionality and non-discrimination between national and non-national products, and Article 34, Article 36 and Article 216(2) of TFEU.

(9) The restrictions or prohibitions adopted pursuant to this Regulation should refer to the use and not to the free circulation and imports of genetically modified food and feed.

(10) The level of protection of human and animal health and of the environment achieved through the authorisation procedure provided for by Regulation (EC) No 1829/2003 requires a uniform scientific assessment throughout the Union and this Regulation should not alter that situation. Therefore to avoid any interference with the competences which are granted to the risk assessors and risk managers under Regulation (EC) No 1829/2003, Member States should not be authorised to use grounds which are related to risks to health and to the environment which should be dealt with in accordance with the procedure already established in Regulation (EC) No 1829/2003, and in particular its Articles 10, 22 and 34.

(11) Member States's measures adopted pursuant to this Regulation should be subject to a procedure of scrutiny and information at Union level with a view to the functioning of the internal market. In light of the level of scrutiny and information provided in this Regulation, it is not necessary to provide, in addition, for the application of Directive 98/34/EC of the European Parliament and of the Council[15]. The amendments being made to Regulation (EC) No 1829/2003 by this Regulation provide that Member States may restrict or prohibit the use of GMOs or GM food and feed in all or part of their territory for the whole duration of the authorisation, provided that an established standstill period, during which the Commission and the other Member States are 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 3 months prior to their adoption, in order to give the opportunity to the Commission and the other Member States to comment, 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 or the Member States' comments. Member States should be allowed to notify to the Commission measures pursuant to this Regulation before that the product concerned

[15] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37).

by the measures is authorised so that the restriction or the prohibition starts its effects as from the date of entry into force of the Union authorisation.

(12) In the case where a product was lawfully used before a Member State adopts measures pursuant to this Regulation, sufficient time should be given to operators to allow the phasing out of the product from the market.

(13) Measures adopted pursuant to this Regulation, which restrict or prohibit the use of GMOs or GM food and feed should not affect the use in other Member States of these products as well as of products derived from their consumption. In addition, this Regulation and the national measures adopted pursuant to it should be without prejudice to Union law requirements concerning unintended and adventitious presence of GM material in other products and should not affect the placing on the market and use of products complying with these requirements.

(14) Regulation (EC) No 1829/2003 should be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

In Regulation (EC) No 1829/2003 the following Article is inserted:

"*Article 34a*
Restrictions or prohibitions by Member States

1. Member States may adopt measures restricting or prohibiting the use of products referred to in Article 3(1) and 15(1) authorised pursuant to this Regulation provided that such measures are:

   (a) reasoned and based on compelling grounds in accordance with Union law which shall, in no case, conflict with the risk assessment carried out pursuant this Regulation;

   (b) proportional and non-discriminatory.

2. Where a Member State intends to adopt measures as provided for in paragraph 1, it shall first submit to the Commission a draft of those measures, and the corresponding justification. The Commission shall immediately notify to the other Member States the draft measures and the corresponding justification. The Member State may submit the draft measures and such information before the authorisation procedure provided for in Articles 7 and 19 has been completed.

   During a period of 3 months from the date of submission to the Commission of the draft measures and information in accordance with the first subparagraph:

   (a) the Member State shall refrain from adopting and implementing those measures;

   (b) the Commission and the Member States may make any comments they consider appropriate to the Member State which has submitted the draft measures.

3. Measures adopted in accordance with paragraph 1 of this Article shall provide for a reasonable period of time during which existing stocks of the products referred to in Article 3(1) and 15(1) concerned by such measures, which could legally be used before the date of adoption of the measures, may be used up.

4. Measures adopted in accordance with paragraph 1 of this Article shall not affect the use, in the Member State concerned, of food and feed containing an adventitious or technically unavoidable presence of genetically modified material which, by application of the thresholds set out in Articles 12 and 24, are not required to be labelled in accordance with this Regulation.

5. Paragraph 1 to 4 of this Article shall not apply to GMOs for cultivation."

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*