Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers
EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

   • Reasons for and objectives of the proposal

This initiative follows up on a statement by the President of the Commission in his State of the Union address to the European Parliament in September 2016 when he said: *It is not right that when EU countries cannot decide among themselves whether or not to ban the use of glyphosate in herbicides, the Commission is forced by Parliament and Council to take a decision. So we will change those rules – because that is not democracy.*

On several occasions concerning the adoption of acts which are subject to the comitology procedure, the Commission has found itself in the past years in a situation where it is legally obliged to take an authorisation decision in the absence of a qualified majority of the Member States taking position (either in favour or against) in the committee. This 'no opinion' situation is in the Commission's view particularly problematic when it concerns politically sensitive matters of direct impact on citizens and businesses, for instance in the field of health and safety of humans, animals or plants.

The majority of Union legal acts adopted each year are adopted by the Commission pursuant to the powers conferred on it by the European Parliament and the Council as co-legislator, either by means of delegated acts under Article 290 TFEU or as implementing acts under Article 291 TFEU. Unlike for delegated acts under Article 290 TFEU, the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers under Article 291(3) TFEU are laid down in advance in regulations adopted by ordinary legislative procedure. Such rules and principles are set out in Regulation (EU) No 182/2011 (the 'Comitology' Regulation).

The present proposal provides for targeted and limited amendments to Regulation (EU) No 182/2011 and thus relates to implementing acts only.

The Commission reported to the European Parliament and the Council on the implementation of Regulation (EU) No 182/2011 in February 2016. That report concluded that the Regulation allowed the effective use of the Commission's implementing powers under the control of Member States. The present proposal therefore does not aim at changing the comitology framework as such. The report however also outlined a limited number of problematic cases, notably in relation to decision-making on genetically modified organisms (GMOs). In these cases, there has never been a qualified majority amongst Member States in favour or against a draft Commission decision authorising genetically modified organisms (GMOs) and genetically modified (GM) food and feed. Instead, all votes resulted in so-called 'no opinion' outcomes, i.e. that the committee could not reach a position either in favour or against a draft act. This result was then always repeated in the appeal committee, a body that is meant to help decision-making in sensitive and problematic cases. As a consequence,

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1 State of the Union Address 2016: https://ec.europa.eu/priorities/state-union-2016_en
2 In 2016 the Commission adopted 137 delegated acts and 1494 implementing acts.
decisions in this field had to be taken systematically without the support of a qualified majority of Member States in the Committee\textsuperscript{5}.

The Commission has already taken steps to take account of the specific situation in the field of GMOs. Following the Directive for authorisations of cultivation\textsuperscript{6}, which entered into force in 2015, the Commission adopted in April 2015 a proposal following the same logic to amend the legislative framework in relation to food and feed\textsuperscript{7}. The solution proposed is maintaining the centralised authorisation process, while allowing opt-out measures by Member States. This proposal is still in the legislative process.

The discussions around the extension of the approval period of the active substance glyphosate in the appeal committee in summer 2016 have shown that the no opinion problem is not limited to GMOs. Also in this case Member States could neither muster a majority in favour or against the approval decision in the appeal committee and the Commission had to decide without the support of the Member States\textsuperscript{8}. As indicated above, this is all the more problematic because these decisions often concern politically sensitive matters of direct impact on citizens and businesses, in particular in the field of health and safety of humans, animals and plants. While the Commission is empowered to decide in such cases, the Commission considers that, due to the particular sensitivity of the issues at stake, Member States should, in these specific situations, also assume their responsibilities in the decision-making process to a greater extent. This, however, is not sufficiently ensured where Member States cannot reach a qualified majority because some of them decide to abstain at the moment of the vote or are not present at the meetings of the committees or of the appeal committee.

The Commission therefore considers that there is a need to address this issue through a few very targeted changes to the rules on comitology procedures. It has accordingly announced an initiative on the modernisation of the comitology procedures in its 2017 Work Programme\textsuperscript{9}.

This proposal contains four targeted amendments. The subject-matter of this proposal is strictly limited to these four targeted amendments and does not extend to any other element of Regulation (EU) No 182/2011. Indeed, the Commission is of the opinion that the system established by Regulation (EU) No 182/2011 has overall proven to work well in practice and struck an appropriate institutional balance as regards the roles of the Commission and the other actors involved. The Commission therefore considers it essential that this system continue to function unchanged but for the targeted amendments proposed. The sole objective of these amendments is to improve the functioning of the comitology procedures at the level of the appeal committee in order to ensure wider political accountability and ownership of

\textsuperscript{5} See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Reviewing the decision-making process on genetically modified organisms (GMOs) of 22.4.2015, COM(2015)176.


\textsuperscript{7} 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, 22.4.2015, COM(2015) 177.

\textsuperscript{8} Commission Implementing Regulation (EU) 2016/4152/1 of 29 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance glyphosate.

politically sensitive implementing acts, without however modifying the legal and institutional responsibilities for implementing acts as organised by Regulation (EU) No 182/2011.

- **The current legislative framework**

Regulation (EU) No 182/2011 sets out the mechanism for the control of the Commission's exercise of implementing powers by Member States. Under the most frequently used procedure, the so-called 'examination procedure', the Commission representatives submit draft implementing acts to a committee composed of representatives from the Member States, which gives its opinion, generally by vote. These votes follow the qualified majority rule as set out in the Treaties. Three scenarios may happen at this stage in the committee voting:

- If there is a qualified majority of Member States in favour of the Commission's draft act (positive opinion) the Commission *must* adopt the act.
- If there is a qualified majority against (negative opinion) the Commission *cannot* adopt the act.
- If there is no qualified majority for or against (no opinion) the Commission *may* adopt the draft implementing act – which means that it may also decide not to adopt it.

The reason behind allowing the Commission to adopt implementing acts as long as there is no qualified majority of Member States against the measure is to ensure effective implementation of the legislation. Only opposition from a qualified majority of Member States can block the adoption by the Commission of implementing acts. On this point, there is a parallelism with the provisions on delegated acts, since for these a (qualified) majority is also needed, albeit not in a committee but in the European Parliament or in the Council, for preventing an act from entering into force.

There are, however, a number of specific cases listed in the Comitology Regulation in which the Commission is legally prevented from adopting the implementing act in a no opinion situation at the stage of the examination committee. This applies in three different cases:

1. in certain policy areas (taxation, financial services, the protection of the health or safety of humans, animals or plants, or definitive multilateral safeguard measures);
2. if the basic act provides that the draft implementing act may not be adopted in a 'no opinion' situation (so-called 'no opinion clause');
3. if a simple majority of the component members of the committee opposes the draft act.

In such cases, the Commission refers the implementing act to the appeal committee, which is also composed of Member State representatives, but at a higher level. If in the appeal committee there is again a no opinion, the Commission may adopt the draft. This means that in such cases, the Commission is confronted at the end of the examination procedure with a no opinion scenario, it has discretion whether or not to adopt the draft implementing act.

This discretion for the Commission in case of a no opinion was introduced by Regulation (EU) No 182/2011. Before 2011, in case of a no opinion in the committee, respectively if the

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10 The advisory procedure is not relevant here.
Council did not react, the Commission had no alternative but to adopt the draft implementing act. Increased flexibility was introduced to enable the Commission to reconsider the draft implementing act, whether or not it should adopt it or present an amended draft to the committee, taking into account *inter alia* the positions expressed by the Member States within the committee. This is underlined also by recital 14 of Regulation (EU) No 182/2011, which states that "when considering the adoption of draft implementing acts in particularly sensitive sectors, notably taxation, consumer health, food safety and protection of environment, the Commission, in order to find a balanced solution, will, as far as possible, act in such a way as to avoid going against any predominant position which might emerge within the appeal committee".

This flexibility does however not relieve the Commission from its obligation to take a decision in cases like those relating to requests for authorisation of the placing on the market of products or substances. As the producer that has filed an application for authorisation is the right to receive a decision on the request, the Commission is obliged to adopt a decision within a reasonable timeframe. Under the earlier comitology framework, the General Court considered that the Commission had failed to act when it refrained from pursuing the authorisation procedure following a 'no opinion' vote in the committee\textsuperscript{12}.

Out of a total of 1726 opinions delivered by committees in 2015, there were two negative opinions and 36 cases of no opinions, which represent around 2% of the total. 10 of these were referred to the appeal committee which also resulted in a no opinion. In the period 2011-2015 in 36 out of the 40 cases submitted to the appeal committee, the latter has confirmed the 'no opinion' vote. While this concerns an overall low number of cases, these situations occur in very sensitive areas. The appeal committee has therefore not helped in coming to a clear Member State positioning and had little added value so far. The Commission considers that the rules governing the appeal committee therefore need to be changed to allow it to fully play its role.

- **Consistency with existing policy provisions in the policy area**

The proposed amendments to Regulation (EU) No 182/2011 are targeted and limited, addressing exceptional cases at appeal committee level. Since the system set up by the Regulation overall has proven to work well, the Commission considers it essential that this system remain untouched for the remainder.

- **Consistency with other Union policies**

The proposal is consistent with the Commission proposal in relation to genetically modified food and feed\textsuperscript{13}. While that proposal was also partly motivated by the no opinion outcomes in this area, the approach proposed there is to allow Member States to restrict or prohibit the use of genetically modified food and feed on their territory. This addresses the specific situation in this sector and does not relate to the decision-making process itself. The approach followed in the present proposal concerns the procedural rules as such, irrespective of the sector. The two approaches are thus complementary.

The proposal is equally consistent with the two proposed regulations adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and

\textsuperscript{12} Judgment of the General Court of 26 September 2013 in Case T-164/10, Pioneer Hi-Bred International, Inc. v Commission.

\textsuperscript{13} 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, 22.4.2015, COM(2015) 177.
291 of the Treaty on the Functioning of the European Union in accordance with the commitment undertaken in the Interinstitutional Agreement on Better Law-Making. Those proposed regulations do not propose any changes in relation to the decision-making procedures as such, but seek to align existing empowerments to delegated, and in some cases implementing, act empowerments.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**
The proposal is based on Article 291(3) TFEU, the legal basis for Regulation (EU) No 182/2011, which this proposal seeks to amend.

- **Subsidiarity**
The Union has under Article 291(3) TFEU the exclusive competence for laying down the rules and general principles concerning mechanisms for control by Member State of the Commission's exercise of implementing powers.

- **Proportionality**
The proposed amendments are limited to what is strictly necessary to address the issue and are not going beyond what it necessary to achieve the objectives. They are limited to changes at the appeal committee level.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

The proposal provides for limited changes to the procedures for the adoption of implementing acts at appeal committee level. These changes are of a purely institutional and procedural nature, they do not, for instance, change the rules identifying the factors on the basis of which the approval of a substance should be assessed. These changes therefore do not have as such significant economic, environmental or social impacts. Therefore, no impact assessment is needed.

4. LEGAL ELEMENTS OF THE PROPOSAL

The appeal committee was introduced in Regulation (EU) No 182/2011 in order to elevate the debate, in particular in case the examination committee did not deliver an opinion, to a more political level. However, so far it has generally not prevented no opinion situations from arising nor helped clarify the position of Member States, having thus demonstrated limited added value. The changes proposed aim at reducing the risk of no opinion outcomes at the appeal committee level and at facilitating the decision-making and to ensure the political ownership of Member States of certain sensitive decisions. The proposed amendments will, once adopted, need to be reflected in the rules of procedure of the appeal committee, which

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14 COM(2016)799: Proposal for a Regulation of the European Parliament and of the Council adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union and COM(2016)798: Proposal for a Regulation of the European Parliament and of the Council adapting a number of legal acts in the area of Justice providing for the use of the regulatory procedure with scrutiny to Article 290 of the Treaty on the Functioning of the European Union. See point 27 of the Interinstitutional Agreement between the European Parliament, the Council and the Commission of 13 April 2016 on Better Law-Making, OJ L 123, 12.5.2016, p. 1. As regards a number of acts from the field of health and safety which were excluded from the aforementioned, the Commission will make an alignment proposal in due course.
will therefore need to be adapted in accordance with Article 3(7) of Regulation (EU) No 182/2011.

- **Changes to the voting rules for the appeal committee**

Committees, including the appeal committee, deliver their opinion according to Article 5(1) of Regulation (EU) No 182/2011 in the examination procedure by the majority laid down in Articles 16(4) and (5) TEU and, where applicable, Article 238(3) TFEU. Articles 16(4) TEU and Article 238(3) TFEU provide for a double majority. Accordingly a qualified majority is attained if the majority:

1) includes at least 55% of the Member States. This means that a qualified majority has to comprise at least 16 Member States.
2) represents Member States comprising at least 65% of the population of the Union.

In cases where not all the Member States participate in the vote, Article 238(3), sub (a), TFEU defines a qualified majority as at least 55% of the participating Member States, comprising at least 65% of the population of these States. In such cases, a blocking minority must include at least a minimum number of Member States representing more than 35% of the population of the participating Member States, plus one Member State, failing which the qualified majority shall be deemed attained.

Under the current rules abstentions, or Member States that are not present or represented, do not count for attaining a qualified majority in favour or against, but they are not deducted from the overall figures on the basis of which the 55 % of the Member States and the 65 % of the population of the Union are counted. This means in practice that abstentions expressed during votes and absences of Member States that decide not to be present or to be represented lead to a higher likelihood of no opinion outcomes, thus shifting the decision to the Commission. The current rules do not incentivise Member States to vote in favour or against the draft implementing act. The current voting rules therefore have not allowed the appeal committee to play its role.

It is therefore proposed to change the voting rules for the appeal committee in order to reduce the risk of a no opinion scenario and to clarify the positions of the Member States by considering that Member States which are not present, or which abstain, are 'non-participating Member States' for the calculation of the qualified majority. This means that the double majority (55% of Member States representing 65% of population) will be calculated based only on Member States taking part in the vote, thus vote either in favour or against, in accordance with Article 238(3) (a) of the TFEU. The blocking minority will be calculated in accordance with that Treaty provision as well.

In order to ensure that the vote is representative a quorum must be introduced in the Comitology Regulation, providing that a vote shall be considered to be valid only if a simple majority of the Member States are participating members in the vote in the appeal committee. The respective changes will be introduced in Article 6(1) of Regulation (EU) No 182/2011.


16 Currently the rules of procedure foresee a quorum and provide that the presence of the majority of Member States is required, OJ C 183, 24.6.2011, p. 13.
Further referral to the appeal committee at ministerial level

The appeal committee has, as described above, so far generally not prevented no opinion situations from arising nor helped to clarify the position of Member States. Regulation (EU) No 182/2011 makes reference to an appropriate level of representation\(^{17}\) and the Rules of Procedure for the appeal committee, agreed by the Member States, specify that as a general rule the representation in the committee should not be below the level of Permanent Representatives\(^{18}\). Experience shows that Member States were so far in most cases represented by their Permanent Representations.

In order to strengthen the role of the appeal committee in particularly sensitive cases, it is proposed to provide for the possibility of a further referral to the appeal committee where no opinion is delivered. This will allow addressing the problematic issues again at the appropriate political level. To this end it is proposed to provide that the Chair may decide to hold a further appeal committee meeting while indicating that the appropriate level of representation for that meeting is at ministerial level. To allow the organisation of such a further meeting the timeframe for the appeal committee to deliver an opinion should be extended by one month to a total of three months from the initial referral. The respective changes will be included in Article 3(7) of Regulation (EU) No 182/2011.

Make individual Member State representatives' votes at appeal committee level public

The votes of the Member State representatives in the appeal committee are currently covered by the confidentiality rules provided for in the rules of procedures for the appeal committee\(^{19}\), as is the case for the examination and advisory committees\(^{20}\). Article 10 of Regulation (EU) No 182/2011 provides for the information on committee proceedings that can be made public and in relation to the voting refers to the "voting results", i.e. the total voting results only, not the individual Member State votes. The Commission considers that more transparency is needed in relation to the positions that Member State representatives take in the appeal committee. The proposal to make public the votes of the Member States' representatives aims at increasing clarity on the position of Member States. The respective provision to make the individual Member State representatives vote in the appeal committee public will be included in Article 10(1)(e) and (5) of Regulation (EU) No 182/2011.

Foresee the right to refer the matter to the Council for an opinion

Under Article 291 TFEU the Commission is empowered by the legislator to adopt implementing acts under the control of Member States. The European Parliament and the Council have therefore no role in the decision-making procedure itself and their involvement is limited to the right of scrutiny under Article 11 of Regulation (EU) No 182/2011.

According to Article 291(1) TFEU, it is the Member States that are responsible for the implementation of Union acts and that control the Commission in case implementing powers are conferred on it. In cases in which Member States do not come to a clear opinion within this control process there should be a possibility to refer the issue to the Council, as the Union institution in which the Member States governments are represented at ministerial level and

\(^{17}\) Article 3(7) of Regulation (EU) No 182/2011.


\(^{19}\) According to Articles 9(2) and 12(2) of the Standard Rules of Procedure summary records of the meetings shall not mention the position of individual Member States in the Committee's discussions and the Committee's discussions shall be confidential.

\(^{20}\) See Article 10(2) and 13(2) of the Standard Rules of Procedures for Committees, OJ C 206, 12.7.2011, p. 11.
have a global view of all Union policies. It is therefore proposed to enable the Commission to formally refer specific cases after a no opinion outcome in the appeal committee for a non-binding opinion to the Council, with a view to obtaining its political orientation on the implications of the no opinion outcome, including the institutional, legal, political and international implications. The Commission should take account of any position expressed by the Council within 3 months after the referral. In duly justified cases, the Commission may indicate a shorter deadline in the referral.
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amending Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers

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 291(3) thereof,

Having regard to the proposal from the European Commission,

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

Acting in accordance with the ordinary legislative procedure,

Whereas:


(2) The system established by Regulation (EC) No 182/2011 has, overall, proven to work well in practice and struck an appropriate institutional balance as regards the roles of the Commission and the other actors involved. That system should therefore continue to function unchanged except for certain targeted amendments concerning specific aspects of procedure at the level of the appeal committee. These amendments are intended to ensure wider political accountability and ownership of politically sensitive implementing acts without, however, modifying the legal and institutional responsibilities for implementing acts as organised by Regulation (EU) No 182/2011.

(3) In a number of specific cases, Regulation (EU) No 182/2011 provides for referral to the appeal committee. In practice, the appeal committee has been seized in cases where no qualified majority, either in favour or against, was attained within the committee in the context of the examination procedure and thus no opinion was delivered. In the majority of cases this happened in relation to genetically modified organisms and genetically modified food and feed and plant protection products.

(4) Experience has shown that, in the vast majority of cases, the appeal committee repeats the outcome of the examination committee and results in no opinion being delivered. The appeal committee has therefore not helped in providing clarity on Member State positions.

(5) Regulation (EU) No 182/2011 provides that the Commission may in such cases adopt the draft implementing act, thus giving the Commission discretion.

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(6) That discretion is, however, significantly reduced in cases relating to the authorisation of products or substances, such as in the area of genetically modified food and feed, as the Commission is obliged to adopt a decision within a reasonable time and cannot abstain from taking a decision.

(7) While the Commission is empowered to decide in such cases, due to the particular sensitivity of the issues at stake, Member States should also fully assume their responsibility in the decision-making process. This, however, is not the case when Member States are not able to reach a qualified majority, due to, amongst others, a significant number of abstentions or non-appearances at the moment of the vote.

(8) In order to increase the added value of the appeal committee its role should therefore be strengthened by providing for the possibility of holding a further meeting of the appeal committee whenever no opinion is delivered. The appropriate level of representation at the further meeting of the appeal committee should be ministerial level, to ensure a political discussion. To allow the organisation of such a further meeting the timeframe for the appeal committee to deliver an opinion should be extended.

(9) The voting rules for the appeal committee should be changed in order to reduce the risk of no opinion being delivered and to provide an incentive for Member State representatives to take a clear position. To this end only Member States which are present or represented, and which do not abstain, should be considered as participating Member States for the calculation of the qualified majority. In order to ensure that the voting outcome is representative a vote should only be considered valid if a simple majority of the Member States are participating members of the appeal committee. If the quorum is not reached before expiry of the time-limit for the committee to take a decision, it will be considered that the committee delivered no opinion, as is the case today.

(10) The Commission should have the possibility, in specific cases, to ask the Council to indicate its views and orientation on the wider implications of the absence of an opinion, including the institutional, legal, political and international implications. The Commission should take account of any position expressed by the Council within 3 months after the referral. In duly justified cases, the Commission may indicate a shorter deadline in the referral.

(11) Transparency on the votes of Member State representatives at the appeal committee level should be increased and the individual Member State representatives’ votes should be made public.

(12) Regulation (EU) No 182/2011 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

\textit{Article 1}

Regulation (EU) No 182/2011 is amended as follows:

(1) in Article 3(7), the following sixth subparagraph is added:

"Where no opinion is delivered in the appeal committee pursuant to the second subparagraph of Article 6(3), the chair may decide that the appeal committee shall
hold a further meeting, at ministerial level. In such cases the appeal committee shall deliver its opinion within 3 months of the initial date of referral.

(2) Article 6 is amended as follows:

(a) in paragraph 1, the following second subparagraph is added:

"However, only members of the appeal committee who are present or represented at the time of the vote, and do not abstain from voting, shall be considered as participating members of the appeal committee. The majority referred to in Article 5(1) shall be the qualified majority referred to in Article 238(3) TFEU. A vote shall only be considered to be valid if a simple majority of the Member States are participating members."

(b) the following paragraph 3a is inserted:

"3a. Where no opinion is delivered in the appeal committee, the Commission may refer the matter to the Council for an opinion indicating its views and orientation on the wider implications of the absence of opinion, including the institutional, legal, political and international implications. The Commission shall take account of any position expressed by the Council within 3 months after the referral. In duly justified cases, the Commission may indicate a shorter deadline in the referral."

(3) Article 10 is amended as follows:

(a) in paragraph 1, point (e) is replaced by the following:

"(e) the voting results including, in the case of the appeal committee, the votes expressed by the representative of each Member State;"

(b) paragraph 5 is replaced by the following:

"5. The references of all documents referred to in points (a) to (d), (f) and (g) of paragraph 1 as well as the information referred to in points (e) and (h) of that paragraph shall be made public in the register."

Article 2

This Regulation shall not apply to pending procedures on which the appeal committee has already delivered an opinion on the date of entry into force of this Regulation.

Article 3

This Regulation shall enter into force on the 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 Strasbourg,

For the European Parliament
The President

For the Council
The President