BRIEFING NOTE:

European Commission proposal to amend comitology procedure

Background:

The European Commission published on 14 February a legislative proposal to reform the Comitology Procedure (Regulation 182/2011) (the process by which committees of member state representatives help the Commission to implement legislation). Reforming the comitology procedure is one of the key aims of the 2017 European Commission work programme and is driven by what the Commission views as inefficiencies in the current process whereby Member States are unwilling to take decisions on a range of sensitive topics such as GMOs and pesticides, novel foods and new pharmaceutical products. This affects a range of industries including: crop protection, feed, seeds, food and drinks, pharmaceuticals and vaccines.

In his State of the Union Speech in November 2016, European Commission President Jean Claude Juncker made reference to the need to change the current Comitology decision making process, stating that *'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'.*

This approach was also mirrored in Commission Vice-President Timmermans' Better Regulation Package which states: "The Commission will consider amendments to the rules governing EU-wide authorisation procedures in certain sensitive sectors in order to ensure that - rather than leaving to the Commission alone the responsibility to act where they cannot give an opinion - Member States have the final say for decisions."

Need for Change

Today's proposal is driven largely by past failures from Member States to reach qualified majority support for authorizations of 'sensitive' products such as GMO authorisations. In these cases, the Commission does not want to be 'forced' to authorize.

The proposal aims to increase transparency and accountability in the process and reduce the number of 'no opinion' positions coming from the committees. Commission President, Juncker, has indicated that he sees these changes as a way of stopping Member States "hiding behind Brussels" with regard to decisions that need to be made on sensitive issues such as GMO approvals.

Such a revision of comitology where the Commission would refuse to grant product authorisations in case of no qualified majority could effectively mean a stop for authorisations of 'sensitive' products.

Proposed Changes:

A number of options have been proposed regarding to amend to the comitology procedures for taking decisions on product authorizations. The main thrust of the changes would apply at the appeals committee stage (where decisions go if there is no majority after a first round of voting.)

The proposal includes four targeted amendments aimed at enhancing transparency about the positions taken by Member States, and ensuring more accountability in the decision-making process.

1. **Changes of voting rules in appeal committee -** Member States not present or abstaining are "non-participant" members for the calculation of qualified majority. This would end the current system whereby abstaining member countries are given weight when calculating a qualified majority. This would save the Commission from having to make a final decision in case of abstentions.
2. **Second referral to the appeal committee at ministerial level -** in the case of a no opinion vote in appeal committee there could be a second appeal committee with Member States at ministerial level with the idea of reaching a consensus.
3. **Increasing voting transparency** at the Appeal Committee level by making public the votes of Member State representatives;
4. **Ensuring political input** by enabling the Commission to refer the matter to the Council of Ministers for an Opinion if the Appeal Committee is unable to take a position.

Industry perspective

From an industry perspective, any one of these options would make product authorizations even more difficult when there is 'no opinion' by the Member States (when a qualified majority in favour of authorization does not materialize).

The options would introduce an even greater political dimension to any product approval procedure and be a step away from science-based decision making. Ultimately this would have negative effect approving new innovative products.

It would be more beneficial for industry if the Commission implemented the current system properly, whereby, in cases where no qualified majority is reached the Commission takes a final decision based on the evidence.

Legislative Procedure and Next Steps

The proposal will follow the ordinary legislative procedure and thus will go to the European Parliament and Member States for approval (and in that process, the proposals will likely be amended).Member states decisions on the proposal will be taken by qualified majority. Conciliation between the Council and the EP before approval of the final proposal can also be foreseen.