



## Joint Statement: Comitology Reform Threatens Innovation

3 December 2020

We, European Associations representing a wide number of economic sectors affected directly or indirectly by comitology rules, re-iterate<sup>1</sup> the request for timely, reliable authorisations of safe products, based on the best available science from the EU's own risk assessment agencies. Such decisions are central for innovation, continued investments, jobs and growth, as well as consumer confidence and safety in the EU. Innovation, in turn, is critical to achieving the goals of the European Green Deal<sup>2</sup> and the EU's industrial strategy<sup>3</sup>.

We regret that the changes to the comitology system proposed by the Commission<sup>4</sup> would not help on any of the above goals, nor are they likely to promote social acceptance of innovation. Instead, the proposed changes would make the processes for product authorisations even more complex and less predictable.

The Plenary of the European Parliament is expected to vote on 16 December 2020 on an amended version of the Commission's proposal<sup>5</sup> which would revert the logic from currently 'approve when safe' to 'approve only when popular'. Concretely, amendments 5, 7, and 16 would enable a minority of Member States to block authorisations of products, even if their safety is confirmed by the risk assessment agencies. This would make authorisations of certain products de facto impossible and would undermine science-based decision-making processes.

**Therefore, we disagree with the proposed comitology reform and urge decision-makers in particular to reject the legal affairs committee's amendments 5, 7 and 16.**

<sup>1</sup> See also [Joint Statement of February 2017](#)

<sup>2</sup> Communication from the EU Commission: The European Green Deal, [COM/2019/640 final](#)

<sup>3</sup> Communication from the EU Commission: A New Industrial Strategy for Europe [COM/2020/102 final](#)

<sup>4</sup> Proposal for a Regulation 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. [COM \(2017\) 85 final](#), 14 February 2017.

<sup>5</sup> Report adopted by the Committee for Legal Affairs, [A9-0187/2020](#), 12 October 2020

## BACKGROUND:

**Comitology** refers to a set of procedures through which EU countries control how the Commission implements EU law. Comitology procedures inter alia apply to pre-market product authorisations, and typically involve the Commission consulting a committee of experts from the Member States (Standing Committee) on draft implementing acts authorising products. If the Member States do not reach a qualified majority in favour or against, the Commission refers to the **Appeal Committee**. In case of no opinion even in the Appeal Committee, the Commission approves the product supported by the EFSA's scientific opinion.

**The Commission's 'comitology reform proposal'** from 2017<sup>6</sup> contains the following three main changes:

- **Change of voting rules:** At the Appeal Committee, abstaining Member States would be seen as "non-participating". This would in some cases threaten the approval of safe but 'politically sensitive' products.
- **Additional votes and delays:** Introduction of up to two additional rounds of voting.
- **Other proposed changes:** Quorum of participating Member States; publication of Member States votes.

**Amendments 5,7 & 16 adopted by the European Parliament's legal affairs committee**<sup>7</sup>:










The present comitology regulation provides for a rather science-based system: It essentially foresees that products should be authorised when proven safe. Vetoing the approval of a safe product requires the qualified majority of Member States (55% of the Member States representing 65% of the EU's population).





The proposal by the EP legal affairs committee (especially amendment 16) essentially foresees that political opinions are more important than the extensive scientific evidence assessing the safety of products. According to the committee, products should only be authorised when they have political support by a qualified majority of Member States (55% of the Member States representing 65% of the EU's population). This, in turn, means that a minority of Member States could block the approval of safe products.

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<sup>6</sup> As referenced in footnote 2

<sup>7</sup> As referenced in footnote 3

<p><b><u>AESGP</u></b>  The Association of the European Self-Care Industry (AESGP) is the voice of the manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe, also referred to as self-care / consumer healthcare products.</p>	
<p><b><u>AMFEP</u></b>  The Association of Manufacturers and Formulators of Enzyme Products.</p>	
<p><b><u>ANIMALHEALTH EUROPE</u></b>  The voice of the animal medicines industry in Europe.</p>	
<p><b><u>COCERAL</u></b>  The European association representing the trade in cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agrosupply. COCERAL is the voice of collectors, distributors, exporters, importers and agribulk storers of the above mentioned commodities.</p>	
<p><b><u>COPA-COGECA</u></b>  The united voice of farmers and their cooperatives in the European Union. COPA – representing over 23 million farmers and their families and COGECA – representing over 22.000 European agri-cooperatives speak with the same voice through a common Secretariat in Brussels.</p>	
<p><b><u>ECPA</u></b>  The European Crop Protection Association represents the crop protection industry in Europe.</p>	
<p><b><u>EFFA</u></b>  The European Flavour Association (EFFA) is the voice of flavours in Europe, leading a Europe-wide strategy to the benefit of the flavour industry, its customers and consumers alike. EFFA’s Members are comprised of 11 Flavour Houses and 12 National Flavour Associations from across Europe, representing 12 European countries.</p>	
<p><b><u>EFPIA</u></b>  The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 36 national associations, 39 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA’s mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy. Our vision is for a healthier future for Europe. A future based on prevention, innovation, access to new treatments and better outcomes for patients.</p>	
<p><b><u>EUROSEEDS</u></b>  Euroseeds is the voice of the European seed sector. It represents the interests of those active in research, breeding, production and marketing of seeds of agricultural, horticultural and ornamental plant species. Today, Euroseeds, with more than 34 national member associations from EU Members States and beyond, represents several thousand seed businesses, as well 67 direct company members, including from seed related industries.</p>	

<p><b><u>EUROPABIO</u></b>  The European Association for Bio-industries represents the biotechnology industry in agriculture (seeds), pharmaceuticals and industrial biotech.</p>	
<p><b><u>FEDIOL</u></b>  FEDIOL, The EU vegetable oil and proteinmeal industry association, represents the interests of the European oilseed crushers, vegetable oil refiners and bottlers.</p>	
<p><b><u>FEFAC</u></b>  The European Feed Manufacturers' Federation is the voice of the European feed industry.</p>	
<p><b><u>FEFANA</u></b>  The EU Association of Specialty Feed Ingredients and their Mixtures represents manufacturers and traders of feed additives, functional feed ingredients, premixes and other mixtures of specialty ingredients.</p>	
<p><b><u>UECBV</u></b>  The European Livestock and Meat Trades Union (UECBV) represents national federations of livestock traders, meat industry, and meat traders. Through its 52 national member federations, UECBV is the voice for some 20,000 trading and industrial companies.</p>	