Dear Madam, Dear Sir,

This is an amicus curiae brief on behalf of Croplife International ("Croplife") and the European Crop Protection Association ("ECPA"). This amicus curiae brief is submitted in accordance with Art. 10(1) of the Rules of Procedure of the Enlarged Board of Appeal following the announcement of the referral under Art. 112(1) b EPC and the publication of the referred questions and the underlying reasoning on April 4, 2019 and the invitation to file written statements as communicated by the EBA in the Official Journal EPO.

Croplife is a global federation representing the plant science industry as well as a network of regional and national associations in ninety-one countries. Croplife's member companies are committed to sustainable agriculture through innovative research and development in the areas of crop protection, seeds and plant technologies. Croplife members invest significant resources to identify and develop innovations for agricultural products such as seeds and traits. These innovations can improve yields or qualities of plants and seeds, thus benefitting the environment, farmers, and the public. Croplife members have to rely on the availability of patent protection for plants and plant-related innovations.

ECPA represents the crop protection industry as well as a network of 32 national associations in Europe. ECPA's 22 multinational company members develop innovative and science-based crop protection solutions. ECPA advocates for an innovation friendly environment in which our industry continues to provide important tools to farmers to ensure a safe, affordable, healthy and sustainable food supply for Europe's citizens. The protection of the intellectual property rights arising from the strong R&D commitments of ECPA members are an important guarantee we depend upon.

Biotechnology and breeding are key drivers for the desired transformation of the European agriculture into a more bio-based, sustainable Bio-economy. To enable this, an effective and clear legal framework is necessary. To promote innovation in this field and to meet new challenges in food production and climate change, adequate IP protection should be maintained according to the
fundamental principles laid down in the Biotech Directive\(^1\) and the European Patent Convention. In the area of biotechnology, Croplife and ECPA members need clarity that technical processes and the results thereof remain patentable. Thus, any gap between EU law (Article 4.2 of the Biotech Directive) and the provisions of the European Patent Convention (Article 53 EPO) as interpreted by the respective competent jurisdictions should be avoided to safeguard a harmonized IP environment which enables innovation.

For these reasons, both associations were deeply concerned about the introduction and retroactive effect of Rule 28 (2) of the Implementing Regulations to the EPC as such; as well as by the subsequent request of the European Patent Office’s ("EPO")\(^2\) to introduce a mandatory disclaimer in any claims related to plants obtained by a technical process,

Croplife, ECPA and their members consequently welcome the decision of the Board of Appeal of the EPO on case T1063/18 declaring said Rule 28(2) as being not applicable in accordance with Art 164(2) EPC because it is in conflict with Article 53(b) of the European Patent Convention as interpreted in G2/12 and G2/13.

In the pending referral case G3/19, the President of the EPO has submitted two questions to the Enlarged Board of Appeal stemming from the Board of Appeal decision T 1063/18, specifically

"1. Having regard to Article 164 (2) EPC, can the meaning and scope of Article 53 EPC be clarified in the Implementing Regulations to the EPC without this clarification being a priori limited by the interpretation of said Article given in an earlier decision of the Boards of Appeal or the Enlarged Board of Appeal?"

and

"2. If the answer to question 1 is yes, is the exclusion from patentability of plants and animals exclusively obtained by means of an essentially biological process pursuant to Rule 28(2) EPC in conformity with Article 53 (b) EPC which neither explicitly excludes nor explicitly allows said subject-matter?"

As a preliminary statement, Croplife and ECPA fully concur with the findings and conclusions of T1063/18.

First of all, Croplife and ECPA affirm that the referral should be considered inadmissible.

Article 112 (1) (b) EPC stipulates that the President of the EPO may only refer a point of law to the Enlarged Board of Appeal in order to ensure uniform application of the law, or if a point of law of fundamental importance arises where two Boards of Appeal have given different decisions on that question.

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\(^2\) Rule 28(2) as introduced by the Administrative Council and taking effect on July 1st, 2017:
However, in the present case, there are no divergent decisions of two Boards of Appeal on the question whether Rule 28(2), in its relation to Article 53(b) EPC, complies with Article 164(2) EPC. This question was discussed only in T 1063/18, taking into account decisions G 2/12 and G 2/13. None of the other decisions mentioned in the Referral deals with the same point of law. Actually, none of the other decisions concerns the issue that a new Rule is in direct contradiction with an Article of the EPC, as interpreted by the Enlarged Board of Appeal, i.e. a situation at least similar to the one in the present case. Therefore, the requirements of Article 112 (1) (b) EPC for a Referral are not met and it should be rejected.

Nevertheless, in order to leave no doubt on the patentability of products exclusively obtained by essentially biological processes and avoid any future legal uncertainty, Croplife and ECPA would favor that the Enlarged Board of Appeal answers the questions raised by the President of the EPO in the following manner:

**Question 1 of the Referral should be answered negatively.**

As a matter of fact, the legislator of the EPC had determined a clear hierarchy between Articles and Rules, which is codified in Article 164 (2) EPC stipulating that in case of conflict between the provisions of the EPC and the Implementing Regulations of the EPC, the provisions of the Convention shall prevail.

It is without doubt, that sometimes the articles of the EPC need to be interpreted and clarified. This interpretative role is however accorded to the Enlarged Board of Appeal.

Such interpretative role has been exercised by the Enlarged Board of Appeal in G 2/12 and G2/13 when the Enlarged Board of Appeal interpreted Article 53 (b) EPC following the principles of the Vienna Convention.

The Administrative Council, on the other hand, is empowered to amend the Implementing Regulations (Rules) without restrictions, thus providing an additional means for clarification of the articles of the EPC. In case of conflict, this empowerment is, however, limited by Article 164 (2) EPC.

In decision G6/95, the principle that a rule taken for the implementation/clarification of the European Patent Convention, cannot be regarded as valid if it contradicts an article of the EPC as interpreted by the Enlarged Board of Appeal, was unambiguously reaffirmed by the latter.

Therefore, any Rule taken for the implementation or clarification of Article 53(b) EPC is necessarily limited by the interpretations of that Article already made by the Enlarged Board of Appeal.
Question 2 of the Referral should likewise be answered in the negative.

The Enlarged Board of Appeal has already established in decisions G 2/12 and G 2/13, that Article 53 (h) FPC does not exclude products exclusively obtained from essentially biological processes from patentability if they meet the regular patent requirements.

As a result, the new rule 28(2) as introduced by the Administrative Council in 2017 as well as any other rule or practice which could have the effect of excluding products exclusively obtained from essentially biological processes will conflict with these decisions and will not be in conformity with Article 53 (b) as already interpreted by the Enlarged Board of Appeal.

As a final comment, Croplife and ECPA want to point out that the introduction of Rule 28 (2) EPC resulted from a legally non-binding Commission Notice (2016/0 411/03) which in turn was a response to a dissatisfaction expressed by certain stakeholders in the breeding community with patents on products obtained by essentially biological processes, but also with the possible vague scope of patents initially granted in that field. Incidentally, Croplife and ECPA note that the Commission Notice was based on the different definition of essentially biological processes for the production of plants and animals contained in the Directive 98/44 which links the technical character of an invention to its reproducibility and should prevail compared to the broader definition of essentially biological processes resulting from the interpretation of Article 53 (b) by the decision G2/07. This means that the European Commission, in its notice, is considering a narrower set of products for exclusion compared to those concerned by decision G2/07.

However, the way to address such situation should not be to indiscriminately and arbitrarily exclude subject matter from patentability, nor to impose disclaimers, but rather to ensure that the EPO would improve its application of the requirements of the EPC to determine whether the patentability of claims directed to plants carrying a novel characteristic, irrespective of the way these plants have been produced. The developing case law of the EPO (T0967/10, T1988/12) shows that this direction has already been taken. Croplife and ECPA strongly believe that high quality patents would meaningfully address the above-mentioned dissatisfaction.

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3 The EU Commission in its Notice on Article 4 (1) (b) of the Biotech Directive, however, admits that:

"The Notice is intended to assist in the application of the Directive, and does not prejudice any future position of the Commission on the matter. Only the Court of Justice of the European Union is competent to interpret Union law."
In summary, Croplife & ECPA respectfully submit that:

The referral should be considered inadmissible as the requirements of Article 112 (1) b) EPC for a Referral are not met. In case the referred questions will be decided admissible, Questions 1 and 2 of the referral G3/19 are to be answered negatively. The current interpretation of Article 53(b) EPC by the Enlarged Board of Appeal in G 2/12 and G 2/13 is maintained and that Rule 28(2) EPC or any other rule or practice having the same effect is considered not applicable.

Yours Sincerely,

[Signatures]

Executive Director

[Logos]