Annex to the letter to Member States of the European Patent Organisation, 26 June 2017:

Comments on the proposal put forward by the President of the European Patent Office (EPO) for adoption by the Administrative Council regarding the exclusion from patentability of “plants or animals exclusively obtained by means of an essentially biological process” in the Implementing Regulations of the European Patent Convention (EPC).

General comment:
The adoption of this proposal will not prevent the EPO from granting patents on conventionally bred plants and animals. It is further not consistent with the interpretation of EU law provided by the European Commission in November 2016. According to the proposal presented by the EPO, some of these patents will no longer be granted in future. But at the same time, new loopholes are being created that allow the avoidance of the relevant prohibitions. Consequently, there will be an overall increase in the number of patents granted on conventional breeding.

The proposal fails to provide the long-awaited legal clarity that is necessary for traditional breeders to operate. It will also further expedite the handing over of resources needed for the production of our daily food to big corporates at the expense of smaller breeders, farmers, consumers, biodiversity and food security.

Therefore, we urge you to prevent the Administrative Council from adopting this proposal unless further changes are made.

Proposed changes.
The proposed EPO addition to the Implementing Regulations is insufficient to put an end to the patenting of conventionally bred plants and animals. Additional changes are necessary (see grey box below). In addition, the text accompanying the proposed change, which will inform the way the EPO interprets the new rule, contains a number of very problematic points, in particular paragraphs 40 – 42 and paragraph 51.

Paragraphs 40 – 42 mention several categories of mutations that: a) emerge at random and spontaneously in nature, b) are randomly triggered by traditional methods and c) occur due to more targeted technical methods such as CRISPR-Cas (gene editing) and genetic engineering. According to the proposal, all of these mutations are considered to be patentable, without any clear distinction between random processes and more targeted technical interventions.

Thus, the proposal is not consistent with the interpretation of the European Biotech Directive 98/44/EC presented by the European Commission (EC) in November 2016, which concludes that only methods of genetic engineering which directly intervene in the genome of plants and animals are regarded as patentable. The proposal is also not consistent with the European Parliament resolutions from 2012 and 2015, which called on the EPO “also to exclude from patenting products derived from conventional breeding and all conventional breeding methods, including SMART breeding (precision breeding) and breeding material used for conventional breeding.”
Instead, the text should make clear that the meaning of “essentially biologically processes” is equivalent to conventional breeding processes, including the exploitation of random mutations and all breeding material as well as all steps used in the process, such as selection and/or propagation (including selfing).

With regard to paragraph 51, the current proposal risks eroding the prohibitions of Article 53 (b) by extending the meaning of “microbiological processes”. After the G1/98 decision was taken by the Enlarged Board of Appeal, the EPO no longer granted patents on plants and animals on the legal basis of considering them to be the product of a microbiological process.

Paragraph 51 in the proposal now states that all cells derived from plants or animals which can be cultured in isolated form should be regarded as equivalent to microorganisms and, therefore, be regarded as patentable. The patents on the individual cells would then, of course, also apply to plants and animals consisting of these cells or emerging from them. Examples are oocytes and sperm cells used in cattle breeding. This entirely new interpretation by the EPO creates a very worrying loophole that is highly likely to simply accelerate the patenting of conventionally bred plants and animals. Paragraph 51 must be corrected or deleted.

In the light of these comments, we propose the following text be proposed for adoption by the Administrative Council:

Article 1
Paragraph (b) of Rule 27 of the Implementing Regulations to the EPC shall be amended as follows:
"(b) without prejudice to Rule 28, paragraph 2, plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;"

Article 2
Rule 28 of the Implementing Regulations to the EPC shall be amended as follows:
1. The current text shall become paragraph 1 (a) to (d).
2. The following new paragraph 2 shall be added:

"(2) Under Article 53(b), European patents shall not be granted in respect of plants or animals and related breeding material including genetic information and isolated cells exclusively obtained by means of an essentially biological process such as crossing or selection or other random processes for the modification of genomes."

Article 3
This decision shall enter into force on 1 July 2017. Rules 27 and 28 EPC as amended by Articles 1 and 2 of this decision shall apply to European patent applications filed on or after this date, as well as to European patent applications and European patents pending at that time.