I would like to thank you for inviting me to take part in this seminar, given my long-standing collaboration with UPOV and my background in plant breeding as director of the Spanish Plant Variety Office, which was in charge of plant protection, as well as in other international bodies.

I have followed the debate on the legal protection of plant varieties and on NBTs.

I personally attended and took active part in the preparation and the sessions that led to the approval of the 1991 UPOV Convention.

I can clearly remember the discussions and different approaches resulting in the 1991 Convention.

The plant breeding methods available at the time were the classic ones, while Molecular Genetics had not made any contribution to the development of new varieties yet.
I should recall that the first GM crop (Bt cotton) was not introduced in the US until 1996. What is known today as "New Breeding Techniques" (NBTs), which are the main subject of my speech, did not exist.

I have been asked to give my opinion about the impact of NBTs on the Convention currently in force and on the general principles of Plant Protection as governed by the Convention.

Let me say a few preliminary words about the methods available before 1991.

These were basically **crossing** and **mutation**, both including **selection** across several generations from sexual reproduction (crossing) and asexual reproduction (mutation). Chemical and physical procedures were used for these purposes and the output was completely random, so it could not be known whether the targeted gene had been actually affected or not. This is why so many years were needed to carry out selection by cloning, grafting, etc. Only a stroke of luck (mainly in ornamental plants) could lead to something able to be registered and protected or patented.

None of the numerous attempts undertaken to directly hit the target gene was successful: "**targeted mutation**" was an ideal.
Precisely this ideal has been achieved with NBTs. We must see whether these new methods fit into the current Convention.

I think that mutation also deserves some specific remarks. This is a word that comprises a wide variety of biological facts: changes in a nucleotide, in a DNA segment (addition or loss), in parts of a chromosome, in an entire chromosome (inversions, translocations, whether reciprocal or not), in complete or incomplete genomes (polyploids, aneuploids), etc. Each of these variants can bring about changes in the phenotype, be they purely cosmetic or truly relevant and of high value.

To talk about "mutation" as if it were a single biological reality, as I have been hearing in respect of EDVs, and to say that they are "all" EDVs, is in my opinion unbecoming of any organisation in charge of protecting plant variety innovation and breeding.

The crossing method has a powerful variant—backcrossing, which allows us to introduce the desired gene into a valuable variety with the legitimate purpose of making it still more valuable: this is the goal of breeders, and their activity, i.e. progress in agriculture, is what the UPOV legally protects.

While it is easy to introduce a gene of great interest via backcrossing or mutation, it is just as easy to introduce a
gene with zero value. The aim was to obtain a variety that was *almost identical* to the initial variety but still *distinct* thanks to the incorporation of a characteristic merely intended for registration purposes by achieving compliance with legal protection requirements. This is a sheer act of genetic piracy.

Prior to 1991, the Convention did not offer a legal basis to stop this kind of piracy. This is the reason why the concept of an *Essentially Derived Variety* was introduced in 1991, specifically in Art. 14. The Convention thus solves this problem.

Thanks to the availability of new techniques, it is now possible to directly handle the DNA to introduce, modify and correct genes.

For instance, inserting a gene from a bacterium into a plant to make it resistant to a given disease; replacing a detrimental gene with another one; or, finally, correcting a defect in a gene just as you would correct a misspelled word in a written text using a computer programme—a procedure known as *gene editing* which, albeit recent, is already delivering outstanding results.

The issue raised with NBTs is whether these techniques fall within the scope of plant variety protection under the 1991 UPOV Convention.
There are two aspects to consider:

(1) *Are NBTs to be accepted as plant breeding methods compliant with plant protection requirements?*

The answer is obvious: **Of course they are,** since NBTs produce **targeted mutations and corrections of genome defects, and these are accepted breeding methods.** The varieties thus obtained must then be evaluated for compliance with the requirements of Distinctness, Uniformity, Homogeneity and Novelty to determine its eligibility for protection.

(2) **What types of varieties can be obtained using NBTs? Are all varieties obtained using NBTs to be considered EDVs?**

NBTs are techniques that modify genes or gene sequences with great precision (finally targeted mutation!).

Such changes imply introducing traits which did not exist in a given species or were impossible to introduce via crossing, or correcting defective genetic information.

This is a topic of major importance, since if ALL plant varieties bred via NBTs are EDVs, the Convention would be rejecting and limiting scientific innovation by putting the
spotlight on the tools used, not on the results obtained. In other words, if we considered ALL varieties bred via NBTs to be EDVs, we would be missing what really matters: whether the changes in the new variety add significant value, which is actually what the industry is interested in with a view to advancement and progress.

Not to mention the damage and harm this would cause to small and medium-sized research companies, which make up most of the research fabric.

Let us take a look at this along with Art. 14(5). This article lays down the requirements that must be met by a new variety in order to be considered an EDV. These are:

(a) The Convention says **being clearly distinguishable from the initial variety**. This is obvious and even unnecessary to mention, since if the variety were identical there would be no room for protection.

*Is an NBT variety clearly distinguishable from the initial variety?*  
Of course it is, since a different variety has been obtained. One or more important characters have been changed.
(b) The Convention says that a variety is essentially derived if: (i) it is predominantly derived from the initial variety (...) while retaining the expressions of the essential characteristics that result from the genotype or combination of genotypes of the initial variety. (ii) It also says that it is distinguishable from the initial variety.

It must therefore, if it retains the essential characteristics, be distinguishable only by unimportant secondary characteristics.

(c) The Convention says conforming to the initial variety.

There is conformity with the initial if the essential characters of the initial are retained.

Would the NBT variety conform to the initial variety?

The concept of conformity should be construed in a manner consistent with the spirit of the UPOV Convention. Therefore, what should be assessed is whether it conforms to the initial variety in its essential characteristics, i.e. those which add value. Based on this, if the NBT variety incorporates a relevant characteristic comprised under what the Convention calls ESSENTIAL CHARACTERISTICS, the answer is: It does not conform to the initial variety.
(d) The Convention says expressing the same essential characteristics as the initial variety. Everyone working with a particular crop (breeders, growers, marketers...) perfectly know which are those and which ones are needed.

For example, resistance to a parasite affecting the crop, a flower colour which does not exist in a particular species and therefore cannot be obtained via crossing or mutagenesis, or a rice variety able to synthesise provitamin A, etc.

These examples are real, they are ESSENTIAL CHARACTERISTICS, and they can only be introduced using NBTs.

Does an NBT variety express the same essential characteristics as the initial variety?
No, because one or more essential characteristics are added or corrected (golden rice, blue flowers in roses, resistance to stalk borer in corn, etc.).

Therefore, THE 1991 UPOV CONVENTION IS INDEED IN A POSITION TO ENCOMPASS THE NEW BREEDING TECHNIQUES WITHIN THE GENERAL PLANT PROTECTION PRINCIPLES.
The objective pursued by UPOV Member States in the 1991 Convention was never to restrict innovation, but to prevent plagiarism.

NBTs allow breeders to obtain new varieties without plagiarism. They are unique methods as regards the introduction of traits which do not exist in a species or would be impossible to produce via crossing and selection, or the correction of defects in hereditary information, which is tantamount to introducing a new essential characteristic.

The Convention does cover NBTs. However, if the 2022 Explanatory Notes are accepted, the 1991 Convention should be reformed, as I notified the UPOV in my letter of March 9, 2022, since they involve a material modification of article 14(5). And it would be illicit to amend the Convention via some explanatory notes. It is one thing to explain it and another to amend it.

The Convention is still open to innovation.