

ISF View on Intellectual Property

ADOPTED IN RIO DE JANEIRO, BRAZIL, 28 JUNE 2012

AMENDED BY ISF GENERAL ASSEMBLY ON 8 JULY 2021 AND ON 21 MAY 2025

A POSITION PAPER PREPARED BY THE INTERNATIONAL SEED FEDERATION



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EXECUTIVE SUMMARY

This ISF View on Intellectual Property (adopted in Rio de Janeiro, Brazil, 28 June 2012) supersedes and replaces all previously adopted ISF, including ASSINSEL, positions on Intellectual Property.

Strong and effective Intellectual Property (IP) protection encourages further breeding and research required to meet increasing food, feed, fiber, and fuel needs whilst preserving the planet. Both Plant Breeder's Rights (PBR), also referred to as Plant Variety Protection (PVP) or Plant Variety Rights (PVR), and patents are needed to stimulate the full scope of innovation in agricultural sciences. The most effective IP system balances protection as an incentive for innovation and access to enable others to further improve plant varieties. Therefore, ISF considers that the preferred form of protection for varieties per se is through Plant Breeders Rights. PBR includes the breeder's exception, the objective of which is to allow access to and use for further breeding of commercial varieties that are protected under PBR. The breeder's exception is one of the cornerstones of the PBR system. When patents are used in the field of plant breeding, this balance can be achieved through attention to the definition of patentable subject matter, the scope and quality of patent claims, the duration of patent protection, and exceptions to the patent right for research and breeding.

Protection of plant varieties through Plant Breeder's Rights

ISF recommends that all countries adapt their national PBR laws to take up as many provisions of the UPOV 1991 Act as possible and to ratify the UPOV 1991 Act.

Related to certain provisions of the UPOV 1991 Act, ISF expresses its opinion as follows:

- *Methods used for testing Distinctness, Uniformity and Stability (DUS) characteristics should be conducted with scientific rigor to ensure reproducibility and consistency. ISF favors improvements that enhance the reproducibility, efficiency and harmonization of the DUS testing and examination process, while maintaining the current scope of protection.*
- *Additional phenotypic characteristics, if required, should be defined on a crop-by-crop basis and be reported in UPOV Test Guidelines.*
- *For all purposes including intellectual property protection, a hybrid is a variety. DUS of the hybrid can be assessed either on the hybrid itself or, if indicated in the UPOV Test Guideline of that species, on its parents and the formula that associates them.*
- *ISF is of the opinion that DUS examination reports belong to the PBR-holder who has paid for the examination procedure and that the reference sample of a variety is owned by the PBR-holder. Any samples of parental inbred lines should only be exchanged between examination offices on the basis of a Material Transfer Agreement (MTA) that fully protects the PBR-holder's ownership of the material, following the explicit consent of the PBR-holder.*
- *ISF is convinced that extension of protection of the parent line to the hybrid variety produced with that parent line should mean that all material of the hybrid and all acts performed with that material fall under the protection of the parent line. ISF is also convinced that vegetative reproduction of the protected hybrid variety falls under the protection of the hybrid.*
- *In regard to extension of the right to harvested material, ISF considers that the condition for the PBR-holder to exercise his right at each reasonable opportunity should not require him to act*

against illegal reproduction of material in order to be able to exercise his right on the harvested material resulting therefrom.

- *Farm saved seed (FSS) of protected, proprietary varieties erodes incentives for further innovation and breeding by reducing to the breeders of these varieties the appropriate share of value they created. Therefore, ISF believes that farm-saved seed of protected, proprietary varieties should not be permitted. However, if authorities choose to include the optional exception, as described in Art. 15 (2) of the UPOV 1991 Act, then implementation should include an obligation to pay reasonable remuneration to the breeder.*
- *Proprietary parental lines developed solely for the purpose of producing hybrids and which are not exploited as commercial varieties should not themselves be used by third parties for the purpose of further breeding without the consent of the owner. Access to genetic resources as provided for by the breeders exception would not thereby be curtailed, since all the genetic variability present in the parental lines of a hybrid is present in that hybrid.*
- *ISF strongly supports the concept of essential derivation which allows new technological developments to be taken into account. ISF stresses that determination of essential derivation is not part of the procedure of the granting of the PBR. The Essentially Derived Variety (EDV) principle, whilst appropriately strengthening PBR, does not restrict the breeders' exception which is a key feature of the UPOV Convention. The concept of EDV has drastically decreased plagiarism in plant breeding because all plagiaristic varieties fall under the EDV principle.*
- *For the purpose of EDV assessment, "predominant derivation" may result from: i) The use of plant material of an initial variety for transformation by genetic engineering, selection or back-crossing followed by selection in the breeding process, or ii) The use of molecular marker data, of an initial variety, for the purpose of selection of genotypes very close to the genotype of the initial variety, or in the case of hybrids for the purpose of selection of genotypes very close to the genotype of its parental line(s) or of the initial hybrid itself.*
- *Essentially derived varieties may be obtained, for example, by selection of natural or induced mutants, selection of a somaclonal variant, selection of variant individual plants in the initial variety, by back-crossing or as a result of transformation by genetic engineering. However, mere recourse to these techniques within a breeding process should not of itself be viewed as sufficient evidence of essential derivation. As it can be very challenging for the owner of the initial variety to prove predominant derivation ISF strongly believes that it is necessary to reverse the burden of proof so that it is then placed upon the breeder of the putative EDV, when a high degree of phenotypic and/or genetic conformity between the initial variety and the putative EDV has been established.*
- *ISF strongly endorses the use of DNA-based markers for variety identification purposes and to help determine genetic similarity between varieties to help resolve disputes on essential derivation. DNA markers can also be used, in principle for improvement of the management of reference collections and planning of DUS trials and, for those DNA-based markers that are fully predictive of the expression of DUS characteristics, to simplify the testing of these characteristics. ISF supports the work of the UPOV Working Group on Biochemical and Molecular Techniques, and DNA profiling in particular (BMT) to find new and acceptable applications of DNA-based*

markers in the field of DUS testing. With the present state of technology, the use of DNA-based markers alone for establishing DUS, could significantly decrease the scope of protection and should therefore not be accepted.

Patents for plant related inventions

ISF firmly believes that the IP environment as a whole should maximize the innovation potential both for new plant varieties and for patentable inventions.

With regards to patent use in the field of plant breeding, ISF expresses its opinion as follows: When addressing the question of patentability, solutions need to be found that recognize the specific needs of national or regional seed industries and their respective legislative systems and they must also reflect the need for global movement of seed.

ISF favors rigorous application of the criteria for patentability and urges governments to provide the necessary resources to patent offices and courts to allow for high-quality, fast and cost efficient examination and opposition procedures. As a matter of principle ISF supports that only true inventions are patentable and that discoveries are not. The simple act of discovery alone does not meet standards of patentability. In general, the results of routine work such as conventional crossing and selection should not be patentable. An alternative genetic composition that achieves the same phenotypic characteristic as a prior patented genetic composition should not be deemed to infringe the said prior patent.

The duration of a patent right should be sufficient to allow a fair and reasonable return on investments and innovations should reach the market as expeditiously as possible. Therefore, ISF is concerned about the increasing time and costs required to obtain market approval for regulated traits and technologies which reduce the effective patent duration to an extent that undermines the ability to obtain a fair return on investments. For patents on regulated traits ISF believes that compensation for loss of effective patent duration due to the time taken to obtain regulatory approvals should be available on a case-by-case basis, for example by prolonging patent protection to a reasonably effective period.

For the seed industry both a general research exception and a specific breeders' exception in patent laws should be considered. While PBR laws provide exceptions in a consistent way, research exceptions in patent laws are not harmonized and breeders' exceptions in patent laws are currently available in only a few countries. ISF supports a general research exception which allows for research on (but not with) patented inventions. Such a general research exception can exist in parallel with a specific breeders' exception and should not limit the scope of a specific breeders' exception. Under such a specific breeder's exception, breeding with a commercialized plant variety comprising a patented gene or trait and non-patented genetic background, should not be considered an infringement of the respective patent on the gene or trait under the following conditions: If a new plant variety, resulting from that breeding, is outside the scope of the patent claims, it should be freely exploitable by its developer provided it is not an EDV. However, if the newly developed variety still falls under the scope of patent claims, no commercial acts (as defined in article 14 (1) of the UPOV 1991 Act) should be undertaken with the new variety without prior consent of the patent holder.

Intellectual property in regard to plant genetic resources for food and agriculture

Two international treaties govern terms of Access and Benefit Sharing (ABS) for genetic resources, viz. the Convention on Biological Diversity (CBD) (1993) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) (2004). In October 2010 a Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (the Nagoya Protocol) was adopted as a supplementary agreement to the CBD. ISF firmly believes and strongly supports the absence of retroactivity in the Nagoya protocol. ISF welcomes the recognition given to the ITPGRFA and the vehicle of a standard material transfer agreement as a workable ABS mechanism.

ISF strongly recommends that the list of crops in Annex I of the ITPGRFA should be expanded to include all crop species where breeding occurs and other genetic resources utilized in breeding these crops. Farmers' rights sensu ITPGRFA should not be confused with the optional exception as described in Art. 15(2) of the UPOV 1991 Act, often referred to as the farmers' exception or farmers' privilege.

ISF urges negotiators of the international treaties on biodiversity to respect international agreements on intellectual property and to be mutually supportive of those agreements. Unrestricted access for further breeding and exploitation of the resulting varieties as provided for under the breeder's exception under UPOV should be regarded as fair and reasonable benefit sharing. ISF urges countries to develop the infrastructure to support efficient means to provide legal certainty with regard to ABS through administratively simple processes and not to cause confusion with IP laws. Laws regarding ABS should recognize that IP is an essential component of encouraging innovation, research and commercialization, all of which are prerequisites to make benefit sharing possible.



INTRODUCTION

“Seed is life!” Members of the International Seed Federation (ISF) are committed to breeding and producing the highest quality seed to improve farmers’ productivity. Agriculture is the foundation of civilization and plant breeding is a cornerstone of agriculture. Global population growth coupled with additional demands for food, animal protein, fiber and fuel strengthen the need for increased agricultural productivity. Farmers also require varieties that are better adapted to increasing biotic and abiotic stresses associated with changing climates. Accelerating genetic improvement through the development of new germplasm and technologies is critical to achieving sustainable increases in productivity. Never has the need to develop new and improved crop varieties, while also protecting the environment, been more urgent or more challenging.

Importance of Effective Intellectual Property Protection

Strong Intellectual Property (IP) protection enables developers of new plant varieties and improved seeds to be rewarded for their efforts and investments. An effective IP environment promotes research and development, which ultimately enhances crop production and conservation of genetic resources. Research and development investments are generally long-term and require significant financial resources. Private sector plant breeders and seed producers must be able to get a return on their investment. Seed sales can then continue to fuel cycles of investment based research and development. The ability to sustain investments and to continue research is beneficial for farmers, growers and society as newly developed varieties are better adapted to meet their changing needs.

Brief history on forms of IP in plant breeding

Before specific legal instruments providing IP protection were available in plant breeding, trade secrets and contractual arrangements were used for a limited number of crops to keep new plant varieties and breeding methods proprietary to their developers.

In 1938, plant breeders from many countries gathered in Amsterdam to form the International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL), which is now incorporated in ISF. The main purpose of ASSINSEL was to establish a system that could reward plant breeders for their hard work and consequently encourage them to continue the development of new and improved plant varieties.

During the 1950s and 1960s there was much interest by governments and plant breeders in determining how IP protection could be further developed to encourage private investment into the breeding of plant varieties. As a result, UPOV was established and provided a specifically tailored (sui generis) form of protection known as Plant Breeders Rights (PBR) also known as Plant Variety Protection (PVP) or Plant Variety Rights (PVR). Four texts of the UPOV Convention have been enacted (1961, 1972, 1978 and 1991) and many countries adhere to one or the other text. PBR provides, inter alia, protection against reproducing without authorization a protected variety.

While the structure of DNA was proposed in 1953 it is only during recent decades that methods to characterize genomes in great detail and with increased cost effectiveness have been developed. Through the use of detailed genetic and phenotypic characterization coupled with other types of biotechnological research breeders are better able to associate genes with agronomic function, to alter gene expression, and to more efficiently incorporate useful genes from other varieties, species

or genera. New technologies and knowledge resulting from this research enables plant breeders to more broadly and effectively manage genetic diversity. These advances have also resulted in the development of new breeding methods and can accelerate the rate of genetic gain.

Research can result in patentable subject matter provided that the requirements of national patent laws and patentability criteria as interpreted by national patent offices are met. As the state of science progresses, the subject matter that meets these criteria changes and the scope of claims narrows as those fields of invention become more established. Both PBR and patents are required to provide an IP environment allowing the plant breeding industry to have an adequate research base to meet increasing demands made upon agriculture and horticulture. Nonetheless, achieving such an IP environment, which ultimately must be directed toward the development of new varieties, requires careful balancing especially in areas where protection by PBR and patents overlap. The specificity of how such an optimum balance may be achieved cannot be prescribed in detail for any one country using a single global model. ISF therefore addresses the components that members and policy makers can consider in order to achieve an optimum solution for their country or regional circumstances.

ISF View on IP

In the ISF View on IP, ISF describes important aspects of Plant Breeders Rights (PBR), Patent Protection as well as legislation on Plant Genetic Resources and indicates how these systems can be best optimized for the seed industry to perform its societal and business functions. This version supersedes and replaces all previously adopted ISF, including ASSINSEL, positions on Intellectual Property.

In Chapter 1 ISF addresses PBR in detail. In particular, ISF elaborates aspects of testing new varieties for Distinctness, Uniformity and Stability (DUS). The scope of PBR is addressed, particularly in regard to provisions for the protection of harvested material and Essentially Derived Varieties (EDV). With respect to exceptions to the breeder's right ISF gives its opinion on the meaning of the so-called farmers' privilege.

In Chapter 2 ISF provides its view on the scope and term of patent protection with regard to plant material. ISF indicates the elements that should be examined to find an optimum balance between protection on the one hand and access for further breeding on the other. ISF proposes a balanced solution, one that respects patents for true inventions whilst proposing general and specific exceptions with the goal to preserve access to the genetic diversity represented by the variety for further breeding. ISF further indicates that due to regional considerations it is likely that specific regional approaches will be required to achieve a balance and complementarity of PBR and patents that will optimally encourage research directed to progress plant breeding in its further support of agriculture.

In Chapter 3 ISF analyses additional forms of IP used by plant breeders and seed producers. These include Trademarks, Copyright, Trade Secrets and Contractual Arrangements. As research, product development and sales or licensing become more sophisticated these forms of IP become more important to prevent counterfeiting and to protect "know-how" or other more tangible IP.

In Chapter 4 ISF explains its position regarding IP in respect of international agreements such as the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). ISF urges negotiators of international treaties on biodiversity to

respect international agreements on IP and to be mutually supportive of agreements that encourage the evaluation and use of a broader base of germplasm through mechanisms that facilitate access and benefit sharing.

1. PROTECTION OF PLANT VARIETIES THROUGH PLANT BREEDER'S RIGHTS

Plant Breeder's Rights (PBR), also called Plant Variety Rights (PVR) or Plant Variety Protection (PVP), provide a specifically tailored (*sui generis*) form of protection for varieties developed by plant breeding. The UPOV Convention has provided the main framework to develop PBR since the signature of its first Act in 1961.

1.1 Conditions for the granting of Plant Breeder's Rights

According to the UPOV Convention a variety can be protected if it is:

- *New*;
- *Distinct (D)*;
- *Uniform (U)*;
- *Stable (S)*;
- *Designated by a suitable denomination.*

The grant of the PBR shall not be subject to any further or different conditions.

1.1.1 Novelty

According to article 6 of the UPOV 1991 Act a plant variety shall be deemed to be new if, at the date of filing of the application for a PBR, propagating or harvested material of that variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of that variety within specific time limits in or outside the territory of filing.

When filing an application for PBR the applicant needs to declare the date of first sales. ISF recommends official authorities such as PBR offices to take the date of the invoice as date of first sales.

Furthermore, ISF interprets "exploitation" as "commercial exploitation" to clarify that the disposal of propagating material to others for the purpose of testing does not harm its novelty status.

These conditions should apply for all kinds of varieties, be they sexually or asexually reproduced, pure lines, populations, or hybrids of different kinds. Hybrid parental lines as well should be subject to these same conditions.

Some PBR offices and national laws consider that parental lines are not novel in cases where the hybrids, composed of these parental lines, have already been produced and/or sold. ISF is convinced from its interpretation of the UPOV Convention that the commercialization of a hybrid does not affect the novelty of the respective parental inbred lines. First, F1 hybrid seed exhibits heterosis and consequently is, by definition, different to and more than the sum of the material harvested separately from both female and male parents. Second, seed harvested from an F1 hybrid has undergone one generation of inbreeding and represents a segregating mix of germplasm from both parents of the F1. It is therefore obviously not justified for some PBR offices and national laws to

state that parental lines are not novel in cases where the hybrids, composed of these parental lines, have already been produced and/or sold.

Nonetheless, breeders who wish to protect their parental material in countries which do not (yet) follow this interpretation need to assess the effect of local interpretation on the novelty of parent lines when starting to commercialize their hybrid(s).

In case the possibility for protection in a certain country is opened up for a certain species, a transitional period should be established during which the application of varieties that have been protected outside the territory is allowed. To avoid misuse, the remaining protection period could be set so it provides the same period of protection as in the country where the variety had received its first protection.

1.1.2 Testing for Distinctness, Uniformity and Stability

1.1.2.1 Characteristics for DUS testing

1.1.2.1.1 Basic conditions that a characteristic should fulfill to be used for the purpose of DUS testing

ISF fully supports the principles provided for by UPOV as regards characteristics for DUS testing.

For ISF these principles guarantee the quality and the pertinence of PBR because they define the basic conditions that a characteristic should fulfill to be used for the purposes of DUS testing. A characteristic should meet the following basic criteria:

- a. Result from a given genotype or combination of genotypes (this requirement is specified in article 1(vi) of the UPOV 1991 Act but is a basic requirement in all cases);
- b. Be sufficiently consistent and repeatable in a particular environment;
- c. Exhibit sufficient differentiation between varieties to be able to establish distinctness;
- d. Be capable of precise definition and recognition (this requirement is specified in article 6 of the 1961/72 and 1978 UPOV Acts, but is a basic requirement in all cases);
- e. Allow uniformity requirements to be fulfilled;
- f. Allow stability requirements to be fulfilled, meaning that it produces consistent and repeatable results after repeated propagation or, where appropriate, at the end of each cycle of propagation.

ISF especially draws the attention of the competent national and international PBR authorities to the scientific rigor, which should govern definition and application of methodologies used for testing DUS characteristics. Such attention is essential to ensure reproducibility of results and the consistency of observations made by different competent authorities on the same characteristic.

ISF reaffirms its full support to the applicable guidelines for conducting DUS testing as published by UPOV after consultation with all the stakeholders involved and encourages all present and future UPOV members and others to use those guidelines, in order to harmonize the test results for PBR.

1.1.2.1.2 Classification of characteristics

UPOV Test Guidelines (TG) currently contain standard phenotypic characteristics. They are composed of asterisked characteristics, non-asterisked characteristics, and grouping characteristics.

Nonetheless, the introduction of new (additional) characteristics for DUS testing (as defined in UPOV document TG/1/3 – General Introduction to the examination of DUS -) is possible. These characteristics can be used to help establish distinctness in combination with standard phenotypic characteristics as defined in the TG's and when accepted by the testing authority.

Additional characteristics are consistent with the UPOV 1991 definition of a variety ("Variety means a plant grouping (...) defined by the expression of the characteristics resulting from a given genotype (...)."). Additional phenotypic characteristics should be defined on a crop-by-crop basis. They can be added to the list of characteristics in the TG's or in specific cases to the list of characteristics in the variety description with the agreement of the breeder. Additional characteristics must (i) satisfy the general criteria of characteristics set out above, (ii) have been used by at least one UPOV contracting party in DUS testing and (iii) have been submitted to UPOV.

Additional phenotypic characteristics can include for example quality traits such as sugar content, glucosinolate content, oil content, and protein characteristics (described in detail in the UPOV TG's for barley, wheat and maize). However, on account of their potential effect on the scope of protection in general, but especially in the case of populations and synthetic varieties of cross-pollinating species these protein characteristics should not be used alone and should be applied carefully only if, despite some evidence of distinctness using UPOV standard characteristics, this evidence has failed to establish sufficient distinctness, and only when test procedures for the use of additional characteristics in the determination of DUS have been established by UPOV.

ISF considers that the introduction of additional characteristics should not create new obligations for breeders of already protected varieties. Those breeders should simply be informed by the authority that their varieties have been used in a comparison with new varieties in DUS testing using additional characteristics. Only the official reference sample of the already protected variety should be used for comparison with the "new" variety. Existing variety descriptions cannot be amended unless agreed to by the breeder.

1.1.2.1.3 The use of pest and disease resistance characteristics

Today, one of the essential components of genetic progress provided by plant varieties lies in their ability to offer effective resistance to a considerable range of diseases and pests.

As far as the pest and disease resistance characteristics are concerned, ISF supports initiatives making it possible to use them as characteristics of Distinctness in DUS testing, insofar as:

- *They generally satisfy the basic conditions mentioned above in paragraph 1.1.2.1.1. And, in particular:*
 - *The resistances should be clearly defined, notably by specifying the genus, the species, and if need be the pathotype associated with the resistance. Where there are several pathogenic races, the specific race should also be defined;*

- *The evaluation of distinctness using these characteristics should be documented as a standardized method and that is available through a known publication or once incorporated into the UPOV guidelines for testing the species concerned*
- *A different resistance level is only admissible as a characteristic enabling a test of distinctness if the levels of expression can be clearly established and if test results are consistent and technically reliable.*

1.1.2.1.4 The use of characteristics for the evaluation of DUS with regard to converted varieties

- *In order to assess distinctness between the converted and the original variety from which it was developed, ISF considers it necessary to comply with the UPOV principles stating that a variety is “defined by the expression of the characteristics resulting from a given genotype or combination of genotypes”. In addition, in accordance with the UPOV 1978 and the 1991 Acts, ISF considers that in the distinctness assessment procedure only the inherent nature of the variety counts, without needing to indicate the method of development.*
- *Consequently only converted varieties having a clear phenotypic difference can be considered as distinct from the pre-existing variety. If the differentiating characteristic is not included in the list of the UPOV characteristics, that characteristic should be added to the list by the PBR office as an additional phenotypic characteristic, with the agreement of the breeder(s). The characteristic must fulfill(s) the basic conditions requested by UPOV.*

The following examples illustrate the ISF position:

- a. A variety and its herbicide tolerant form to a given herbicide should be considered as distinct (assessment of distinctness should include the spray of the herbicide). In contrast, two phenotypically “identical” varieties tolerant to the same herbicide but through different mechanisms of tolerance would not be considered as distinct by UPOV in respect of DUS criteria.
- b. A male sterile line should be considered as distinct from its male fertile counterpart. In contrast, male sterile forms of a variety obtained via for instance different cytoplasm should not be considered as distinct.

If the PBR application for a converted variety is filed by the owner of the pre-existing variety or by an authorized licensee of the owner of this pre-existing variety, and if the converted variety differs from the pre-existing variety only by the introduced characteristic, then, a fast-track procedure for assessing distinctness should be possible. This procedure is already used for some species in certain countries. If, during the procedure, other differences are discovered in addition to the introduced characteristics, then, the variety should undergo the normal DUS testing procedure.

1.1.2.1.5 The use of DNA markers

ISF strongly endorses the use of DNA-based markers for variety identification purposes - e.g. in the case of enforcement of intellectual property rights - and to help determine genetic similarity between varieties for use in disputes on essential derivation. In addition, ISF favors improvements that enhance the reproducibility, efficiency and harmonization of the current DUS testing and examination process, while maintaining the current scope of protection.

ISF considers that DNA-based markers can be useful in the DUS testing and examination process under the following conditions:

- *When DNA-based markers are fully predictive of the expression of phenotypic DUS characteristics to simplify the testing of these characteristics (Model 'Characteristic-specific molecular markers' in UPOV document UPOV/INF/18/1).*
- *When used for the calibration of DNA-based markers with respect to the expression of phenotypic characteristics in the management of reference collections and in the proper planning of DUS trials (Models 'Combining phenotypic and molecular distances in the management of variety collections' and 'Calibrated molecular distances in the management of variety collections' in UPOV document UPOV/INF/18/1). The use of phenotypic descriptors together with DNA based data can be acceptable for these purposes provided that no phenotypically similar varieties, which are essential for comparison, are omitted.*

However, ISF is cautious in expanding the use of DNA-based markers in the field of DUS testing and examination beyond these uses because:

- *Except for some specific cases, DNA-based markers are not predictive of the expression of phenotypic characteristics used in DUS testing and examination due to the relatively complex genetic control of many phenotypic characteristics.*
- *The use of molecular markers on their own, without a direct link to a phenotypic characteristic or without use of a distance threshold, could create a significant risk of decreasing minimum distance between varieties to the extreme (e.g. only one base pair), thus jeopardizing the PBR.*
- *If used for Distinctness, then these DNA-based markers also need to be used for Uniformity and Stability and might also be used for checking the hybrid parental formula. These requirements of their use could, at least at the present time, have considerable practical, technical and financial consequences.*
- *DNA-based markers or the methods used to detect them may not be publicly available.*
- *Consensus between UPOV members upon the use of DNA-based markers in the DUS examination process is necessary in order to obtain international acceptance of DUS examination reports. Therefore it is necessary to agree on a harmonized approach before implementing the use of DNA-based markers in different national DUS examination processes and to consider the need for a transitional period.*

Each of these problems needs to be addressed before ISF could consider expanding their use.

ISF supports the work of the UPOV Working Group on Biochemical and Molecular Techniques, and DNA profiling in particular (BMT) to find acceptable applications of DNA-based markers in the field of DUS testing. In particular, the BMT should address the following issues:

- *The development of DNA-based markers that are fully predictive of the expressions of the phenotypic DUS characteristics, especially those that are laborious, time consuming or expensive to test;*
- *The development of methods to use DNA-based markers in combination with phenotypic DUS characteristics for the more efficient management of reference collections and DUS trials;*

- *The impact of using the same set of DNA-based markers that are used for Distinctness, also for determining Uniformity and Stability. This issue is of critical importance for ISF;*
- *The effect of rapidly changing DNA-based marker techniques on the use of DNA-based markers in the DUS examination;*
- *The financial impact of using DNA-based markers in the DUS examination whether as an additional tool or as a substitute for other means of examination.*

ISF concludes that DNA-based markers can be used for identification of varieties, for determining genetic similarity between initial and putative essentially derived varieties, in principle for improvement of the management of reference collections and planning of DUS trials and, for those DNA-based markers that are fully predictive of the expressions of DUS characteristics, to simplify the testing of these characteristics.

ISF considers that with the present state of the art, the use of DNA-based markers alone for establishing DUS, could significantly undermine the strength of protection and should therefore not be accepted.

1.1.2.2 DUS of hybrids

The text of the UPOV Convention was established at the end of the 1950s and adopted in 1961, when hybrids were still the exception. This is the reason why it is mainly framed for autogamous plants, even if some provisions refer specifically to hybrids. This has frequently led to difficulties for breeders when dealing with PBR offices to obtain protection for their hybrids.

ISF considers that, for all purposes including intellectual property protection, a hybrid is a variety. DUS of the hybrid can be assessed either on the hybrid itself or, if indicated in the UPOV Test Guideline of that species, on its parents and the formula that associate them. Some protection offices consider that a hybrid is not a variety as it would not be self-reproducible without change. This is a misinterpretation of the UPOV Convention. Indeed, by the repeated use of its parents, a hybrid can be reproduced unchanged (UPOV 1978, Art. 5(3) and UPOV 1991, Art. 1(vi) (3rd indent)). Consequently, the UPOV criterion of Stability can be fulfilled by a hybrid.

For those species where the UPOV Test Guideline does not indicate the use of the parental varieties for the DUS testing of the hybrid, ISF is of the opinion that it should not be required to send in material of the parental varieties in order to obtain protection for the hybrid.

1.1.2.3 Improving the management, quality and efficiency of DUS testing

- *In-depth collaboration, both among PBR offices and between PBR offices and breeders should be encouraged. PBR Offices should take over already existing DUS examination reports from other PBR Offices. ISF urges UPOV member states to introduce quality assurance programs to assure proper use of the respective TG's and the use of a comprehensive reference collection in DUS testing.*
- *Use of DNA markers is one of the tools to potentially improve the handling of reference collections and the planning of DUS trials.*
- *ISF urges UPOV and other relevant bodies to develop possible additional tools for the handling of reference collections and to investigate the feasibility of setting up a database of varieties of*

common knowledge, including varieties protected or applied for protection under the UPOV system and / or listed or applied for listing on a National level to improve the management of reference collections. This database should contain characteristics and information indicated in the UPOV TG's useful in the process of grouping varieties for the purpose of DUS testing. Such a database should be accessible to plant breeders. In addition PBR authorities are encouraged to publish variety descriptions.

- *ISF is in favor of further involvement of experts from the seed industry in the DUS testing process to improve efficiency and to reduce costs. However, such involvement should be under official supervision.*

1.1.2.4 Ownership of DUS testing report and reference samples

ISF is of the opinion that the DUS examination reports belong to the PBR-holder who has paid for the examination procedure. On request of the breeder a legalized copy of the original DUS examination report should be sent free of charge but for a reasonable handling fee to other PBR offices.

ISF considers that the reference sample of a variety is owned by the breeder. In particular any samples of parental inbred lines should only be exchanged between examination offices on the basis of a Material Transfer Agreement (MTA) that fully protects the breeder's ownership of the material, following the explicit consent of the breeder. PBR offices should provide the breeder with an annual report of the exchanges that have occurred.

1.1.3 Variety denomination

ISF advocates for a global database system for denominations. ISF encourages authorities to make use of such a database to verify the proposals for variety denominations in their respective countries in order to prevent conflicting decisions.

1.1.4 Protection of parental lines of hybrids without the need to provide parental lines to PBR offices

Parental lines are very often not put on the market as such. Therefore some PBR offices require that a condition for granting PBR to this category of varieties is that such parent lines be made available to third parties upon request during or after termination of the PBR. ISF strongly opposes that interpretation on the following grounds:

- *Legally speaking to impose an additional condition for the granting of PBR would be contrary to the UPOV Convention which states that no further or different conditions than in article 5 of the UPOV 1991 Act must be required.*

In the case of hybrids, the genetic variability of the parent lines is available through the respective hybrids which are on the market (see paragraph 3.5).

1.2 Scope of protection of Plant Breeder's Rights

The most recent Act adopted during the 1991 UPOV Conference has not yet been ratified by all member countries. Consequently, some countries still use the UPOV 1978 Act. While both Acts have been used for developing different sui generis systems in various countries, they differ significantly.

ISF strongly supports and prefers the UPOV 1991 Act. Therefore ISF recommends that all countries adapt their national laws to take up as many provisions of the UPOV 1991 Act as possible and ultimately to ratify the UPOV 1991 Act.

1.2.1 UPOV 1978

The scope of protection afforded by the UPOV 1978 Act as mentioned in article 5 is restricted to the following acts using the propagating material of the protected variety:

- *Production for purposes of commercial marketing;*
- *Offering for sale;*
- *Marketing.*

Moreover, the right of the breeder extends to plants or parts thereof normally marketed for purposes other than propagation when they are used commercially as propagating material in the production of ornamental plants or cut flowers.

Furthermore, the repeated use of a variety to produce another (hybrid) variety requires the permission of the holder of the breeder's right.

1.2.2 UPOV 1991

Under the UPOV 1991 Act, as ruled in article 14, the scope of protection in relation to propagating material is extended to:

- *Production or reproduction (multiplication) for all purposes;*
- *Conditioning for the purposes of propagation;*
- *Offering for sale;*
- *Selling or other marketing;*
- *Exporting;*
- *Importing;*
- *Stocking for any of the purposes mentioned above.*

According to paragraph 4 of article 14, more acts can be added by national law.

The scope of protection is subject to exceptions (see paragraph 1.3) to the PBR: the private use exception (UPOV 1991 Art. 15(1)(i)); the experimental purpose exception (UPOV 1991 Art. 15(1)(ii)); the breeders exception (UPOV 1991 Art. 15(1)(iii)), and the optional farmer's exception (UPOV 1991 Art. 15(2)) and to the exhaustion of the PBR (UPOV 1991 Art. 16) (see paragraph 1.2.3).

The acts as listed above apply also to:

- I. The harvested material - including entire plants and parts of plants - that has been obtained through the unauthorized use of propagating material of the protected variety, unless the breeder has had reasonable opportunity to exercise his right on that material. This provision is mandatory for all upov member states.

- II. The products made directly from harvested material that have been obtained through the unauthorized use of harvested material of the protected variety, unless the breeder has had reasonable opportunity to exercise his right on that harvested material. This provision is optional for the upov member states.

The exclusive rights of the PBR-holder on the acts as stated above also apply to material of:

- a. Varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety; (see paragraph 1.4);
- b. Varieties which are not clearly distinguishable from the protected variety;
- c. Varieties (hybrids) whose production requires the repeated use of the protected variety (parent lines).

ISF is convinced that the extension of protection of the parent line to the hybrid variety produced with that parent line should mean that all material and all acts performed with the material of the hybrid fall under the protection of the parent line.

ISF is also convinced that vegetative reproduction of the protected hybrid variety falls under the protection of the hybrid.

1.2.3 The right on harvested material and products derived from the harvested material in relation to the exhaustion of the Plant Breeder's Rights

The extension of the scope of protection, as expressed in Art. 14 UPOV 1991, to the harvested material or to the end product that has been derived from the harvested material has specific limitations. The PBR is only extended to these categories of material if the following occur:

- I. The “unauthorized use” of the propagating or harvested material respectively, and
- II. The absence of “reasonable opportunity” for the pbr holder to exercise his right on the propagating or harvested material.

These two conditions must be considered in connection with the provision of exhaustion, as laid down in article 16 of the UPOV 1991 Act.

Article 16 determines that the right on the material that has been sold in a particular territory where the variety is protected is exhausted, but revives once the material is reproduced in said territory or exported to a country where no PBR exists for that species, except if that exported material is destined for final consumption in that country.

The condition of “unauthorized use” of the propagation material can be fulfilled even if the propagation takes place in a country where the variety is not protected although protection is possible. As the PBR-holder in such circumstances has no reasonable opportunity to exercise their rights they are entitled to act against the harvested material or the product made directly from such unauthorized propagating material if imported in a country where the variety is protected.

In respect to the definition of “unauthorized use”, some persons may argue that in a country where the variety is not protected by PBR the (re)production of propagating material cannot be considered unauthorized. ISF is of the opinion that there is unauthorized use if the breeder has not given his explicit authorization. This can be the case of a breach of contract or once material that has been

sold on the market as the end product is being used as propagating material in a country where the variety is not protected.

In respect to the definition of ‘reasonable opportunity’, there is the requirement that the breeder should first exercise his breeder’s right on the propagating material - if he has a reasonable opportunity to do so - before he can exercise his rights on the harvested material. The issue arises here whether this clause creates an obligation for the breeder to protect his variety in all countries where there is a PBR system in place. In such a case one could argue that there was a possibility for the breeder to obtain PBR on that variety with the opportunity to act against the propagation in that country. However, the term “his right” in article 14(2) of the UPOV 1991 Act, relates to the PBR in the territory in which the breeder can act against the harvested material. Thus, “reasonable opportunity to exercise his right” in relation to the propagating material means a reasonable opportunity in the territory concerned to exercise his right in relation to the propagating material. Furthermore, in particular, “reasonable opportunity to exercise his right” does not mean a reasonable opportunity to obtain a right, for example in another territory.

This interpretation above of the UPOV CAJ Advisory Group has been confirmed by the decision of the German Supreme Court of 14 February 2006, No. X ZR 93/04.

Additionally, the “exercise of his right” means that at the moment of bringing propagating material on the market, the PBR-holder must take care to collect money or make a contractual arrangement with the buyer. According to the minutes of the Diplomatic Conference of the 1991 Convention and its preceding papers this requirement was implemented because the breeder should exercise his right only once and receive a royalty only once and should do so at the earliest possible stage. This was decided upon to avoid uncertain situations for the trade; e.g. where the holder permits free trade of propagating material and exercises his right only on the resulting harvested material.

However, the exercise of the right differs clearly from enforcing the right. ISF considers that the condition for the PBR-holder to exercise his right at each reasonable opportunity should not require him to act against illegal reproduction of material in order to be able to exercise his right on the harvested material resulting from such illegal, unauthorized production.

1.2.4 Provisional protection

Article 13 of the UPOV 1991 Act provides for provisional protection of the breeder during the period between the filing or the publication of the application for breeder’s right and the grant of that right. Article 13 also states that a Contracting Party may provide that the provisional protection shall only take effect with regard to persons who have been notified of the filing of the application by the breeder.

The implementation of this latter provision varies from country to country and is sometimes unnecessarily complicated and cumbersome to execute. ISF urges countries to agree on a harmonized implementation of the provision and recommends that either the publication of the filing in the official publication of the national PBR-office or the use of a label with the notification “PBR pending” should be deemed sufficient to inform the professional user of the existence of a filed PBR-application.

1.2.5 Proposals for further improvement

- *The act of “offering for sale” listed as one of the acts that require the authorization of the PBR-holder (article 14 (1)(a) of the UPOV 1991 Act) should not only refer to the plant material but should also include the placing of advertisements in the territory of the PBR or offers for sale anywhere which can be accessed in said territory.*
- *The act of the transfer of material of a protected variety from one country to another country through the territory of the PBR should be added to the acts as listed in article 14 (1)(a) of the UPOV 1991 Act. The protection of the end product made directly from the harvested material of the protected variety should be implemented by all UPOV member states.*

1.3 Exceptions to the Plant Breeder’s Rights

1.3.1 Breeder’s exception

During the conference that led to the first UPOV Convention of 1961, the founding members agreed unanimously on “the principle of independence” as a basis for the PBR system. This means that a new, distinct variety is independent from the varieties that were used to create this variety during the breeding process. At that time this was a strong deviation from the patent rights system that is founded on “the principle of dependence”, meaning that if a patent is a further developed teaching of another patent, the later patent is dependent upon the first patent. For the founders of the UPOV Convention the principle of independence was considered to be important for the stimulation of innovation in breeding. This follows from the fact that breeding is, by definition, the creation of improved varieties by recombining the characteristics of existing varieties. Consequently, the breeder’s exception was introduced into the UPOV Convention to allow the use of PBR protected varieties for further breeding. The breeder’s exception is one of the cornerstones of the PBR-system.

As an exception to the general principle of independence the concept of “essentially derived varieties” was introduced in the UPOV 1991 Act (see paragraph 1.4). The breeder’s exception as specified in article 15 (1)(iii) of the UPOV 1991 Act provides for an exception to the PBR for “acts done for the purpose of breeding other varieties” and for the commercialization of the new varieties obtained, except if these new varieties are EDV’s.

1.3.2 Farmer’s exception

From the start of agriculture, some 8-10,000 years ago, farmers have saved seed from their own crops for re-sowing; there was no other form of seed supply. In fact that practice was the norm and indeed, in some places, is still practised in circumstances where the only seed available to plant a new crop is seed harvested from a prior season on-farm harvest. Seed that is saved by farmers from the growing of cultivars they have selected themselves does not impact the rights of third parties.

During the 20th Century, scientific plant breeding based on accumulated new genetic knowledge and new technologies has increasingly been undertaken by full-time professional plant breeders. These changes have together expanded both the level of performance that new varieties can achieve and the efficiency by which those achievements can be accomplished. Plant breeders have created and are still creating new varieties that are used by an increasing number of farmers worldwide. Cultivation of these new varieties, which integrate more and more useful genetic variability, together

with the use of improved cultural practices have resulted in dramatic increases in agricultural production.

The consequence of that necessary evolution is that plant breeding has become an essential activity to support agriculture.

In order to evolve step by step, the first UPOV Convention limited the scope of PBR to the production, for commercial marketing, of the reproductive or vegetative propagating material of the new variety, and for offering for sale or marketing such material. The reproduction of propagating material by using these seeds on their own farm, but not allowing commercialization of the produced seeds fell outside the scope of the PBR. That was an implicit recognition of the so-called “farmer’s exception” that refers to the restriction of the scope of protection to commercialized material of the protected variety in the UPOV Acts 1961, 1972 and 1978.

Thirty years later, in 1991 the UPOV Convention was reviewed and the reference to “commercial marketing” was cancelled, thus extending the PBR to inter alia all acts of (re)production with the propagating material. However, two exceptions to PBR in this respect were then introduced:

- *A compulsory exception for acts done privately and for non-commercial purposes, thus allowing seeds to be produced and used by subsistence farmers.*
- *An optional exception as described in Art. 15 (2) of the Act, often referred to as the farmer’s exception (also known as the ‘farmer’s privilege’ or as ‘farm saved seed’) which can permit farmers within reasonable limits and subject to the safe-guarding of the legitimate interests of the breeder, to use for propagating purposes, on their own holding, the product of the harvest which they have obtained by planting, on their own holding, of the protected variety.*

ISF members consider that strong and effective intellectual property protection is necessary to ensure an acceptable return on a research investment and to encourage further breeding and research that will be essential to meet the challenges humankind has to face in the coming years, i.e. feeding an increasing population whilst preserving the planet.

Farm saved seed of protected, proprietary varieties erodes incentives for further innovation and breeding by reducing to the breeders of these varieties the appropriate share of value they created. Therefore, ISF believes that farm-saved seed of protected, proprietary varieties should not be permitted. However, if authorities choose to include the optional exception, as described in Art. 15(2) of the UPOV 1991 Act, then implementation should include an obligation to pay reasonable remuneration to the breeder.

The recommendation adopted by the Diplomatic Conference of 1991, indicating that the optional exception “should not be read so as to be intended to open the possibility of extending the practice commonly called “farmer’s exception” to sectors of agricultural or horticultural production in which such a privilege is not a common practice on the territory of the contracted party concerned” must also be taken into account.

1.4 Essential Derivation

1.4.1 Legal background

An essentially derived variety (EDV) is a variety defined in Article 14 (5)(b) of the UPOV 1991 Act, which states that a variety shall be deemed to be essentially derived from another variety, the initial variety, when:

- a) It is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety and;
- b) It is clearly distinguishable from the initial variety and;
- c) Except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

According to Article 14(5)(c) of the 1991 UPOV Convention, essentially derived varieties may be obtained, for example, by selection of natural or induced mutants, by selection of a somaclonal variant, by selection of variant individual plants in the initial variety, by repeated back-crossing¹ or as a result of transformation by genetic engineering. This list is not an exhaustive list. Therefore, ISF considers that other existing or future technologies may also result in obtaining an EDV.

1.4.2 ISF general considerations on essential derivation

ISF strongly supports the concept of essential derivation, which allows new technological developments to be taken into account. ISF considers that this principle, whilst appropriately strengthening PBR, does not unreasonably restrict the breeders' exception, a key feature of the UPOV Convention.

The purpose of incorporating the EDV principle into the UPOV 1991 Act was to provide effective protection to a breeder who developed an original genotype – i.e. an initial variety. The EDV concept was meant to affirm the scope of protection of the initial variety to include certain types of derived varieties obtained via methods such as the ones referred to above.

The principle of essential derivation involves questions of scope of protection and enforcement of both the rights of the breeder of the initial variety as well as the breeder of the EDV. It is, therefore, left to the initiative of the breeder to enforce these rights. ISF stresses that the determination of essential derivation is not part of the procedure of the granting of the PBR. However, official description data of the varieties based on UPOV guidelines should be available after granting of rights to enable breeders to compare their varieties.

ISF actively promotes international agreed-upon professional rules and usages for assessing essential derivation and for solving disputes for all crops. ISF has so far developed guidelines for EDV disputes pertaining to perennial ryegrass, maize, oilseed rape, cotton and lettuce. ISF notes that even if there are not yet international agreed-upon professional rules and usages for assessing essential derivation and for

¹ Repeated backcrossing means 2 backcrosses or more. Trait introgression could be obtained by repeated back-crossing.

solving such disputes for all crops, the concept has already provided greater clarity for breeders in their research and product development programs and has contributed to reduce infringements.

In 2024, ISF revised its Trade and Arbitration rules and specific rules have been included for settling EDV disputes between companies that adhere to the ISF arbitration rules. (<https://worldseed.org/our-work/trade-rules/>)

1.4.3 ISF interpretation of essential derivation

1.4.3.1 The technical aspect: the derivation

For a variety to be considered as essentially derived it must fulfil three requirements in relation to the initial variety:

- a. Predominant derivation from the initial variety (article 14 (5)(b)(i));
- b. Clear distinctness in the sense of the UPOV Convention (article 14 (5)(b)(ii));
- c. Conformity to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety, except for the differences that result from the act of derivation (article 14 (5)(b)(iii)).

If one of the above requirements is not fulfilled, there is no essential derivation.

Therefore, ISF makes the following analysis:

A. PREDOMINANT DERIVATION

An EDV may have been predominantly derived from the initial variety or from a variety that has itself been predominantly derived from the initial variety. If we take the chain A-B-C, where A is the initial variety, variety B is predominantly derived from A and variety C is predominantly derived from B, then C will also be predominantly derived from A. If C meets the remaining requirements for essential derivation it will be regarded as an EDV from A. Following this line of reasoning it is in theory possible to have an unlimited "cascade" of predominant derivation. Whether any predominantly derived variety in such a case can still be considered as essentially derived from the initial variety will depend on the level of conformity that still exists between the derived variety and the initial variety.

ISF is of the view that the primary function of the criterion of predominant derivation, enshrined in Article 14(5)(b)(i) of the 1991 UPOV Act, is to establish a requirement relating to the genetic source of the variety. It is understood that predominant derivation requires the physical use of material of the initial variety (or "genetic source") and often takes the form of acts as listed in 1.4.1. Predominant derivation implies that more of the initial variety is retained in the derived variety than would normally be retained of a parent variety by crossing and selection. This can be evidenced by a high genetic conformity.

ISF is of the opinion that from the point of view of predominant derivation, it is worthwhile to differentiate between so-called mono-parental derived varieties (varieties derived from one single parent) and multi-parental derived varieties, where two or more genomes are mixed. Mono-parental derived varieties are, per definition, predominantly derived from their initial variety, whereas in the case of multi-parental derived varieties, predominant derivation may result from selectively retaining one of the genomes (the genome of the initial variety) such as through repeated backcrossing.

The wording 'predominant derivation' implies there can be no more than one initial variety. The present ISF position on predominant derivation does not modify the scope of the protection under UPOV 1991

and allows the EDV provision to evolve with plant breeding techniques, while keeping the freedom to operate under the breeder's exception.

B. DISTINCTNESS

Before assessment of essential derivation of a variety takes place, it should be established that this variety is clearly distinguishable from the initial variety (according to Article 7 of the UPOV 1991 Convention).

ISF considers that the assessment of distinctness and essential derivation need to be maintained separately.

The question of distinctness is a question of granting the right whereas the question of essential derivation is a question of the scope of protection. The assessment of distinctness is based on clear difference between varieties; whereas the assessment of essential derivation is based on conformity between varieties.

Furthermore, the responsibility to decide whether the criterion of distinctness has been met and then to grant property title (if the variety is also new, uniform and stable) rests with the official services, whereas the demonstration of essential derivation is the business of the PBR-holder of the presumed initial variety.

C. CONFORMITY TO THE INITIAL VARIETY

The degree of conformity of a putative EDV to the initial variety should be assessed on the basis of the expression of the essential characteristics which result from the genotype of the initial variety, except from the differences which result from the act(s) of derivation.

In case of mono-parental derivation, all differences result necessarily from one or several acts of derivation. Because all the differences resulting from the act of derivation are not taken into consideration for the assessment of conformity, mono-parental derivation inevitably leads to an EDV.

In case of multi-parental derivation, differences may result either from the random recombination of the different genotypes used, or from one or several acts of derivation only. Repeated backcrossing is an example of multi-parental derivation that leads to an EDV.

According to ISF, for both mono-parental and multi-parental derived varieties, the assessment of an EDV is not linked to the number of differences between an EDV and its initial variety (which is not limited to one or very few differences) but rather depends on how those differences have been obtained.

The differences may include differences in essential characteristics. The definition of essential characteristics should not be restricted to a limited sub-set of DUS or additional characteristics. In this context of defining essential characteristics, the adjective "essential" can be used interchangeably and synonymously with the terms "relevant" and "important" (see UPOV TG/1/3 Chapter 2 and 7). The essential characteristics of a variety will differ from one species to another and may evolve over time. Essential characteristics may be of different nature, such as phenotypic, agronomic, end-user focused or other, but they must be useful for the users of the propagating material or of the harvested material and/or directly obtained products.

D. REVERSAL OF THE BURDEN OF PROOF

It can be very challenging for the owner of the initial variety to prove predominant derivation. Consequently, ISF strongly believes that it is necessary for breeders to have the right to reverse the burden of proof, so that it is then placed upon the breeder of the putative EDV, when a high degree of phenotypic and/or genetic conformity between the initial variety and the putative EDV has been established. If the owner of the initial variety has been able to show convincingly that the conformity requirement is fulfilled, the owner of the putative EDV will then have to prove that there is no predominant derivation; i.e. that he has not predominantly used the initial variety or a variety essentially derived from that initial variety.

To facilitate this process, ISF continues to develop guidelines for a variety of specific crops in which a genetic threshold is established in order to support EDV dispute procedures. If the putative EDV is found to fulfill the conformity and distinctness requirement, then the requirement (a) "predominant derivation from the initial variety" (see 1.4.3.1) has also to be fulfilled in order for the putative EDV to be truly considered as essentially derived.

1.4.3.2 The legal aspect: the dependence

The principle of dependence only exists in favor of a non-essentially derived protected variety. This means that:

- a. The initial variety must be protected (article 14 (5)(a)(i));
- b. The initial variety is not itself an EDV (article 14 (5)(a)(i));
- c. Dependence can only exist from one protected initial variety (article 14 (5)(b)).

If one of these requirements is not fulfilled, there is no dependence. Each EDV shall only be dependent on one variety, the protected initial variety, and an EDV can never be an initial variety itself.

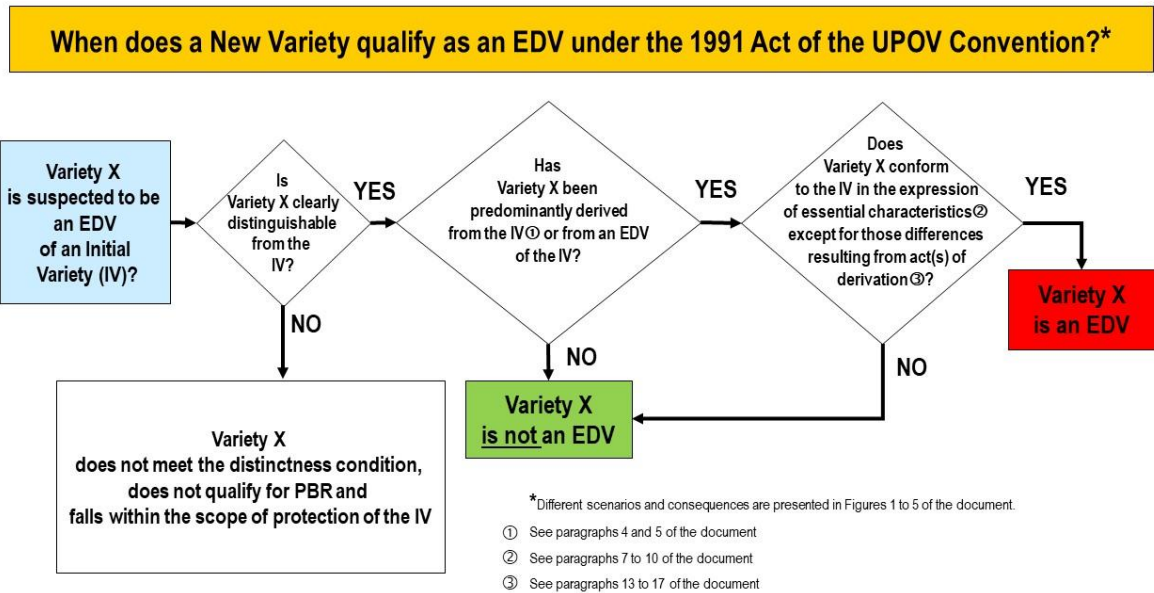
Essential derivation is a question of technical fact, whereas dependency resulting therefrom is a potential legal consequence. Therefore, if a variety has been proven to be an EDV, it remains an EDV forever. When the protection period of the initial variety has been exhausted, all varieties derived therefrom remain essentially derived from that initial variety. However, they will not be legally dependent upon that -no longer- protected initial variety. The EDVs in the chain will also not be dependent from each other. The principle of dependency has been introduced solely to protect the interest of the initial breeder.

1.4.4 Entry into force of the EDV clause

ISF is of the opinion that varieties that were of common knowledge before the date of entry into force of the EDV clause in PBR legislation should remain independent.

1.4.5 Interpretation and wording of the essential derivation

Although different wordings for the EDV concept have been implemented in some national laws, ISF is of the opinion that each such wording should be interpreted in a manner that is consistent with the principles embodied in the UPOV 1991 Act.



1.5 Enforcement

Intellectual property rights are enshrined in law. They provide an economic and legal mechanism to stimulate innovation and are central to sustaining a successful plant breeding industry. The products of innovation are new improved varieties which constitute an important component of Intellectual Property (IP). Infringements of IP cause losses to the global seed industry and can undermine incentives for further innovation.

It is the responsibility of IP holders to make sure that their rights are enforced within the legal framework under which they operate in different parts of the world. However, beyond individual IP management and in addition to the actions from official bodies, another aid to enforcement of IP rights is to establish independent and private organizations that take care of the interest of the breeder's IP as already established in several countries. ISF believes that it is an issue of continuing importance to educate stakeholders about the value of intellectual property. The seed itself and the genetic information it contains are not the same, and therefore the distinction between tangible and intangible goods must be part of the core message to stakeholders.

In light of the technically complex nature of plant breeding, ISF is of the opinion that countries should develop the relevant legal and technical expertise in the judicial system to resolve disputes in this field of applied scientific endeavour. ISF strongly recommends that courts should use the expertise of official DUS testing institutes for resolving technical matters.

Arbitration is a preferred solution for resolving disputes between seed companies. This can be facilitated through the dispute settlement rules as provided by ISF.

2 PATENTS FOR PLANT RELATED INVENTIONS

The scope and complexity of agricultural sciences especially in the area of plant breeding and genetics have significantly expanded in the last decades. Sophisticated methods of plant breeding and variety development based on advanced technologies such as DNA markers and genome sequencing have been developed, which enhance the possibilities for more precise and efficient breeding. These advancements have in many crops significantly shortened the product development cycle, and have created both new opportunities and challenges for the seed industry especially in the area of protection of intellectual property.

ISF considers that both plant breeder's rights (PBR) and patents are efficient protection systems, which are needed to stimulate the full scope of innovation in agricultural sciences. Both systems have inherent differences based on the nature of the innovation they protect. Nonetheless, ISF considers that the preferred form of protection for varieties per se is through plant breeders rights.

While the two systems – PBR and patent – cannot be fully harmonized, it is key to ensure their smooth interaction. A key requirement for any IP system is to achieve the right balance between protection as an incentive for innovation and access to enable others to further improve and innovate. With regard to the interaction between PBR and patents this means, that both systems need to be carefully implemented to provide incentives for innovation while continuing to encourage and ensure access to genetic variability and improvements. It also means that the benefit of the breeder's exception under PBR needs to be preserved even when patents are involved.

The balance between protection and access is influenced by the scope and quality of patent claims, the duration of patent protection, and exceptions to the patent right for research and breeding. ISF is cognizant of the fact that understanding of IP systems in the seed area – both PBR and patents – and their respective use in licensing and enforcement requires continuing education and discourse among breeders and other stakeholders in PBR and patent offices, governments, NGOs and grower associations.

2.1 Patentability

ISF believes that inventions relating to traits made by humans (generally described as traits introduced or modified in the genome by human actions such as human-made mutant traits or GM traits) and modern technologies should be eligible for patent protection.

ISF is cognizant of the fact that the patentability of traits based on naturally occurring genetics assembled in the target plant by crossing and selection ("native traits") and traditional breeding processes is currently debated.

ISF firmly believes that, when addressing the question of patentability, solutions need to be found which maximize the innovation potential both for new varieties and patentable inventions. Solutions must recognize the specific needs of national or regional seed industries and their respective legislative systems and they must also reflect the need for global movement of seed.

2.2 Prerequisites for patentability

To maximize innovation through the grant of high-quality patents, ISF favors rigorous application of the criteria for patentability and urges governments to give the necessary means in terms of human

resources and skills to patent offices and courts to allow for high-quality, fast, cost efficient and transparent examination and opposition procedures.

As for any area of technology, plant related inventions (including sequences or partial sequences of genes, or molecular markers) should only be granted a patent, if the same rigorous patentability criteria, namely novelty, industrial application and non-obviousness, are fulfilled. In general, the results of routine work such as conventional crossing and selection should not be patentable.

As a matter of principle ISF supports that only true inventions are patentable and that discoveries are not. This principle should also apply to the scientific field of plant breeding. The simple act of discovery alone does not meet standards of patentability. For example, numerous plant traits already exist within plant germplasm that have not yet been discovered. The discovery of a new trait in such plant germplasm should not by itself make that trait patentable.

2.3 Scope and duration of protection

The patent system has in many countries not yet been adequately adapted to protect living, self-reproductive material. Making copies of patented subject matter, an activity usually restricted by the patent right, is an intended and expected use for propagating materials such as seed. Such an expectation may result in exhaustion of the patent rights after the sale of seed with regard to the next propagation of the seed. ISF considers that patent protection extends also to a product obtained through propagation or multiplication provided it possesses the same patented characteristics or – when it comes to genetic information – to all material in which the genetic information is contained and performs its function.

ISF considers that an alternative genetic composition which achieves the same phenotypic characteristic as a prior patented genetic composition should not be deemed to infringe the said prior patent. To help achieve this goal patent offices should limit the scope of patent claims to the specific compositions described or deposited by the applicant.

ISF is of the opinion that the duration of the patent right should be sufficient to allow a reasonable return on investment for the inventor. ISF firmly believes that innovations should reach the market as expeditiously as possible. Therefore, ISF is concerned about the increasing regulatory efforts and times as well as costs required to obtain market approval for regulated traits and technologies which reduce the effective patent duration to an extent that undermines the ability to obtain a fair return on the investment. For patents on regulated traits ISF believes that compensation for loss of effective patent duration when excessive time is taken to obtain regulatory approvals should be available on a case-by-case basis, for example by prolonging patent protection to a reasonable effective period.

2.4 Exceptions from the scope of protection

In ISF's view certain exceptions from patent rights are necessary in the field of plant breeding to maximize the potential for innovation. Any such exception needs to strike the right balance between the freedom to innovate (breed) and the incentive to innovate and should follow the guideline provided in article 30 TRIPs i.e. they should "(i) not unreasonably conflict with a normal exploitation of the patent and (ii) do not unreasonably prejudice the legitimate interests of the patent owner, and (iii) taking account of the legitimate interests of third parties."

ISF is of the opinion that for the seed industry both a general research exception and a specific breeders' exception in patent laws should be considered. While PBR laws provide exceptions in a consistent way, research exceptions in patent laws are not harmonized and breeders' exceptions in patent laws are currently available in only a few countries.

2.4.1 General research exception in patent law

ISF supports a research exception which allows for research on (but not with) patented inventions². Research needs to be dedicated to the creation of new knowledge on, or an improvement of, the invention. While it should be permitted to further improve inventions, mere use as a research tool should not be permitted. In that, the area of plant related innovations should not be treated any differently than are other areas of technology. A research exception can exist in parallel to a breeders' exception and should not limit the scope of a breeders' exception.

2.4.2 Specific breeder's exception in patent law

Breeding and developing new varieties may not qualify as "research" under the research exception of patent laws and therefore ISF recommends in addition a specific breeder's exception.

A plant variety which is subject to patent protection may comprise two protectable aspects:

- *A gene or trait, which can be patented in several legislations, and*
- *The genetic background, which in most countries can be protected by plant breeders' rights. The genetic background can also be patented in very few countries.*

Breeding with a commercialized plant variety comprising a patented gene or trait and non-patented genetic background should not be considered an infringement of the respective patent on the gene or trait in the following context: ISF is of the opinion that if a new plant variety, resulting from that breeding, is outside the scope of the patent claims, it should be freely exploitable by its developer provided it is not an EDV of a variety protected by PBR.

However, if the newly developed variety still falls under the scope of the patent claims, no commercial acts (as defined in article 14 (1) of the UPOV 1991 Act) should be undertaken with the new variety without prior consent of the patent holder. To compensate the patentee for loss of effective patent duration for the patented trait, mechanisms can be in place to ensure a commercially reasonable term of effective patent protection (see also 2.3 for compensation of patent term when excessive time is taken in the evaluation of regulatory compliance).

² If a new improvement resulting from that research is outside the scope of the patent claims it should be freely exploitable. However, if the improvement still falls within the scope of the patent claims no commercial acts are permissible without consent of the patent owner.

³ This also applies to the use of plant material covered by product by process claims.

2.4.3 *Specific farm saved seed exception in patent law*

ISF does not endorse any exception for farm-saved-seed (FSS) whether under PVP or patent law. However, if a legislator chooses to provide a FSS exception for patents, the same principles as elaborated in 1.3.2 should apply.

2.4.4 *Infringement and low level presence of patented gene*

There is legal uncertainty regarding the IP consequences of unintended, low level presence of seeds with patented traits or genes. ISF is of the opinion that incidental presence of these seeds does not constitute IP infringement.

2.5 Patent information

In view of the increasing impact of patents on commercialized varieties and the difficulty that breeders have in determining which patents cover which varieties ISF is of the opinion that information regarding patent rights applicable to commercialized varieties should be readily available to the public.

2.6 Licensing

ISF is not in favor of compulsory licensing. However, ISF acknowledges the principle of compulsory licensing in the case of public interest as provided for in patent laws.

ISF encourages contractual voluntary licensing under fair, reasonable and non-discriminatory (FRAND) terms.



3 OTHER FORMS OF PROTECTION

The effect of the statements in 3.1 to 3.4 may vary from country to country according to the national legislations, including jurisprudences.

3.1 Trademarks

A trademark is a word, phrase, symbol, device or a combination of these elements used to identify products made by a specific company and to distinguish them from products of other companies. Trademarks are frequently used in the plant breeding and seed trade business and are an important means to help prevent sale of counterfeit products. Variety denominations are by definition the generic name of the variety and can therefore not be used as trademark for that variety.

3.2 Copyright

A copyright gives authors, composers and artists the exclusive rights to reproduce and distribute their literature or works of art. Authors can be individuals or companies. ISF recommends that copyright protection should be considered for catalogs, product brochures, labels or packaging.

3.3 Trade secrets

To be eligible as a trade secret general standards (Art. 39 of TRIPS) must be met: (i) The information must be secret (i.e. not generally known among, or readily accessible to, circles that normally deal with the kind of information in question); (ii) It must have commercial value; (iii) It must have been subject to reasonable steps by the rightful holder of the information to keep it secret (e.g. through confidentiality agreements).

ISF believes that trade secrets constitute an important component of IP for the seed industry. Any confidential business information which provides an enterprise a competitive edge may be considered a trade secret. Trade secrets encompass manufacturing or industrial secrets and commercial secrets. With regard to the field of plant breeding and biotechnology, the following are examples of intellectual property that can be maintained as trade secrets: parental inbred lines of hybrids, breeding records, specific methods that are used in the laboratory, workshop, greenhouse or field; gene-agronomic trait associations, molecular markers used in marker assisted selection.

3.4 Contracts

A contract is an agreement entered into by two or more parties with the intention of creating reciprocal legal obligations.

A contract can also be linked to notices on seed bags, tags connected to seed bags, or on sales documents indicating that grower or purchaser agrees contractually to certain terms. Due to the long production and distribution chain in a number of crops, the specific end-user is generally unknown to the breeder. Consequently, these forms of contracts (bag tag or shrink-wrap licenses, which are widely used in the software industry) provide the opportunity for breeders and trait providers to inform end users and competitors about its rights and their obligations (e.g. protection of intellectual property, and stewardship obligations).

Clauses that could be stipulated may include, for example:

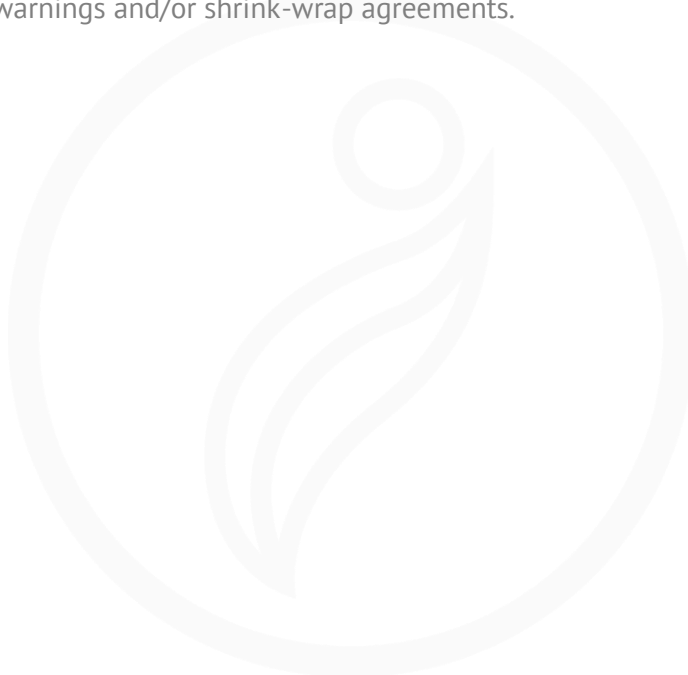
- *The non-exhaustive and exclusive right of the breeder for reproduction;*

- *The export and import restrictions on seed;*
- *The extension of protection to harvested material;*
- *An obligation of the farmer to pay a royalty on farm saved seed used for replanting;*
- *The prohibition for the farmer to sell farm saved seed for the purpose of replanting;*
- *That any parental lines that might inadvertently be in a bag of hybrid seed remain the property of the breeder;*
- *Stewardship obligations regarding transgenic crops and harvested seed;*
- *The right of the breeder to be provided with the information required for the purposes of auditing and verifying the proper use of protected varieties.*

3.5 ISF code of conduct related to proprietary parental lines of hybrids

ISF members consider that proprietary parental lines developed solely for the purpose of producing hybrids and which are not exploited as commercial varieties themselves, should not themselves be used by third parties for the purpose of breeding, except when agreed upon by the owner. With regard to the breeder's exception, all of the genetic variability that is present in the parental lines of a hybrid is present in that hybrid.

Seed of proprietary parental lines may incidentally be included in bags of commercial hybrid seed. Proprietary parental lines may also incidentally happen to be present in fields in which hybrids are grown. In both cases, this presence results from technicalities in producing and processing hybrid seed and does not reflect the owner's intent to make its parental lines available to the public. ISF considers that it should not be permissible to take advantage of this presence by using those proprietary parental lines for further breeding. In addition, to protect themselves against the unauthorized use of proprietary parental lines, for the purposes of breeding, breeders may use any relevant legal mechanisms including bag tag warnings and/or shrink-wrap agreements.



4 INTELLECTUAL PROPERTY IN REGARD TO PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

In the past 10,000 years, since the origin of agriculture, farmers have selected planting material from the diversity available to them. They utilized genetic resources for centuries through free exchange across regions and phenotypic selection. By incorporating and re-mixing genetic diversity into new varieties, modern plant breeding has resulted in more variation than could otherwise have been available to farmers and consumers worldwide.

All nations are strongly dependent on each other in terms of genetic resources for food and agriculture. Each nation grows or imports food crops whose origin lies outside their national boundaries, and are thus inherently dependent on multiple and foreign sources of germplasm. The historic wide-spread distribution and use of plant genetic resources for food and agriculture is evident in the ancestry of individual crop varieties. Farmers and breeders have traditionally relied on open access to these genetic resources¹.

4.1 International treaties

There are two international treaties that govern the terms of access and benefit sharing (ABS) for genetic resources, viz. the Convention on Biological Diversity (CBD) (1993) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) (2004). In October 2010 a Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (the Nagoya Protocol) was adopted as a supplementary agreement to the CBD².

4.1.1 *The Convention on Biological Diversity (CBD)*

Sovereign rights over genetic resources and the authority of national governments to determine access to those resources are central concepts in the CBD. Sovereign rights to determine access are in a completely different realm to the requirements for obtaining intellectual property protection. The approach mandated by the CBD requires “prior informed consent” on the basis of “mutually agreed terms” with “countries of origin”. The Nagoya Protocol does not impose new binding rules directly on users of genetic resources. It requires Parties to put national access and benefit sharing regimes in place, and mandates several specific measures to be implemented if the Party chooses to require prior informed consent as a condition for granting access to genetic resources.

The CBD and the Nagoya Protocol recognize other international access and benefit sharing instruments and therefore genetic resources covered by agreements in the framework of these other instruments – such as the ITPGRFA – are not subject to Protocol obligations.

4.1.2 *The Convention on Biological Diversity (CBD)*

The Nagoya Protocol provides a framework for access and benefit sharing under the CBD. The Nagoya Protocol makes no mention of retroactivity. ISF therefore advocates that through national implementation policy legislators adhere to the Protocol without adding retroactivity clauses thereby providing both users and providers with greater legal certainty.

ISF welcomes the recognition given to the ITPGRFA and the vehicle of a standard material transfer agreement as a workable ABS mechanism. ISF recognizes that the contracting parties to the ITPGRFA finalized the Standard Material Transfer Agreement (sMTA) in 2006. Furthermore ISF supports the

work underway in the Expert Group on Terms of the sMTA to propose recommendations for improving the implementation of the sMTA. ISF is of the view that ABS arrangements should be made in a constructive manner and should be facilitated by the use of standard material transfer agreements that are consistent with prior informed consent and mutually agreed terms, such as the mechanism of the sMTA.

ISF emphasizes that it regards access – for further breeding and exploitation of the resulting varieties – as provided for under the breeder’s exception of PBR protected varieties, as fair and reasonable benefit sharing. This is also the case for varieties bred from material obtained under the Nagoya protocol. Any benefit sharing for genetic resources that is claimed on top of this ‘free access’ goes against this principle.

ISF stresses the importance of there being no direct linkage of access and benefit sharing procedures with the specific criteria required to obtain PBR or patent protection. Nonetheless, as part of a standard material transfer agreement, reference to intellectual property should be possible.

With regard to compliance, ISF urges parties to establish national rules and obligations on access and benefit sharing and to provide clarity regarding facilitated access procedures and compliance obligations. Compliance obligations are a separate matter from the criteria required to obtain Intellectual Property (IP).

4.1.3 The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization

The ITPGRFA, which in harmony with the CBD, provides for the conservation and sustainable use of Plant Genetic Resources for Food and Agriculture (PGRFA), delineates a regime for access and benefit sharing for those resources. For many important food crops the Treaty establishes a Multilateral System (MLS) that facilitates access to those materials that have been placed within it and is designed to operate on the principle that countries are interdependent on PGRFA, thereby implicitly affirming the scientific and historical soundness of the “common heritage” approach.

In creating the Multilateral System for PGRFA the Treaty provides facilitated access to genetic resources (of an agreed list of crops in Annex 1 of the Treaty) and specifies conditions for benefit sharing. Articles 12.3(a) through (h) of the Treaty acknowledge the applicability of intellectual property rights. ISF interprets the article 12.3(d)3 as follows:

- *It is not possible to claim any intellectual property or other rights that limit the facilitated access to the PGRFA, or their genetic parts or components, in their form received from the Multilateral System.*
- *It is possible to claim intellectual property or other rights that limit access to the genetic parts or components isolated or inherited from the material received, provided that the criteria for the granting of the respective intellectual property right and ITPGRFA requirements are fulfilled. IP rights, where granted, should not limit access to the initial genetic material.*
- *Varieties protected by PBR are available without restriction for further breeding and demonstrate a contribution to Access and Benefit Sharing.*

ISF urges the expansion of the list of crops in Annex I of the ITPGRFA to include all crops where breeding occurs and other genetic resources utilized in breeding these crops.

The term farmers' rights appears both in the preamble and in a separate provision of the ITPGRFA. It draws its origin from debates in the late 1970s and was seen by some to be a means of rewarding farmers and their communities for their past contributions and to encourage them to continue conserving and improving plant genetic resources while also allowing them to benefit from the improved use of PGRFA through modern plant breeding.

Farmers' rights should not be confused with the optional exception as described in Art. 15(2) of the UPOV 1991 Act, often referred to as the farmer's exception explained in Chapter 1.3.2 of this paper.

Plant breeder's rights are an exclusive right granted to the breeder by the State/Organisation for production and commercialization of a new plant variety as specified in chapter 1.2. Such a new plant variety must unequivocally meet the following requirements: it must be *new, distinct, uniform and stable*. On the other hand, farmers' rights are an acknowledgement of the contribution of farmers and their forebears in selecting and maintaining landraces.

The farmer's exception sensu UPOV is an optional exception to the PBR aimed at enabling farmers to use seed harvested from a protected variety on their own land.

The ITPGRFA recognizes the importance of supporting the efforts of farmers and local and indigenous communities in the conservation and sustainable use of plant genetic resources for food and agriculture. The Treaty lists actions that could promote such efforts and gives governments the responsibility for implementing them, subject to national law.

4.2 Intellectual property and the international treaties

ISF urges the negotiators of the international treaties on biodiversity to respect the international agreements on intellectual property and to be mutually supportive of those agreements.

ISF is also of the opinion that implementation of biodiversity agreements should not negatively impact IP rules and legislation. Moreover, it is important to separate the conditions that are required to be met for patentability from those that are designed to ensure compliance with contractual agreements made under the ITPGRFA, CBD or Nagoya Protocol.

ISF urges countries to develop the infrastructure to support an efficient means to provide legal certainty through administratively simple processes providing for prior informed consent and access and benefit sharing via bilateral mechanisms as envisaged by the CBD and not to cause confusion with any IP laws and legislation. Such laws should not negatively impact the ability to obtain IP protection since it is an essential component of encouraging research and potential commercialization which in turn are prerequisites to allow benefit sharing.

- 1 ISF position paper 'Plant Genetic Resources for Food and Agriculture', Christchurch, May 2007
- 2 ISF position paper on Nagoya protocol, Rio de Janeiro, June 2012
- 3 ISF position paper 'Interpretation of Article 12.3(d) of the International Treaty on Plant Genetic Resources for Food and Agriculture', 2005.

ANNEX 1: LIST OF ABBREVIATIONS

ABS	Access and Benefit Sharing
BMT	UPOV Working Group on Biochemical and Molecular Techniques, and DNA profiling in particular
CAJ	Legal and Administrative Committee (of UPOV)
CBD	Convention on Biological Diversity (www.cbd.int)
DNA	Deoxyribonucleic Acid
DUS	Distinctness, Uniformity and Stability
EDV	Essentially Derived Variety
FRAND	Fair, Reasonable and Non-Discriminatory
FSS	Farm Saved Seed
GM	Genetic Modification
IP	Intellectual Property
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture (http://www.planttreaty.org/)
MAT	Mutually Agreed Terms
MLS	Multilateral System
PBR	Plant Breeders Rights
PGRFA	Plant Genetic Resources for Food and Agriculture
PIC	Prior Informed Consent
PVP	Plant Variety Protection
PVR	Plant Variety Rights
SMTA	Standard Material Transfer Agreement
TG	Test Guideline
TRIPS	Trade Related Intellectual Property rights (http://www.wto.org/english/tratop_e/trips_e/trips_e.htm)
UPOV	International Union for the Protection of new varieties of plants (www.upov.int)