



## HIGH COUNCIL FOR BIOTECHNOLOGIES

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### COMMITTEE ON ECONOMIC, ETHICAL AND SOCIAL ISSUES

PARIS, 12 JUNE 2013

#### **“Plant Biotechnologies and Industrial Property”**

\* THIS RECOMMENDATION WAS ADOPTED BY THE MEMBERS PRESENT AND REPRESENTED AT THE CEES SESSION ON 21 MAY 2013 (SEE LIST IN ANNEX).

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## Introduction

In recent decades, biotechnology developments have brought profound changes in the legal protection of new plant varieties. Although plant varieties<sup>1</sup> could traditionally be protected, in Europe, by a single *sui generis* mechanism, the Proprietary Variety Protection Certificate (PVPC), the types of innovations that can potentially be patent-protected are now far more numerous.

When it was imported in the 1980s on the lines of the American system, the patenting option aimed to provide robust protection for companies investing in plant genetic engineering, particularly those with a background in agrochemicals<sup>2</sup>. Directive 98/44/EC of 6 July 1998 on legal protection of biotechnology innovations thus states, “in the field of genetic engineering, research and development require a considerable amount of high-risk investment [...] (costs of research, of applying for marketing authorisations for GM plants, etc.) [...] and therefore only adequate legal protection can make them profitable. It adds that “regard should be had to the potential of the development of biotechnology for the environment and [...] the utility of this technology for the development of methods of cultivation which are less polluting and more economical in their use of ground [...] and for that of combating hunger in the world”. This decision to extend patent protection to biotechnology inventions in effect provided a strong stimulus for the development of plant genetic engineering.

In parallel, the patentability of plant innovations (GMOs, but also non-GM, as will be seen) brought a great deal more complexity into the rules applying to the protection of innovations in this field. It also produced social and economic effects that are denounced or feared by many different players, including researchers, breeders and farmers. These concerns mainly arise from the increasing *concentration* of the seed production sector around a powerful oligopoly, which itself results from the concentration of increasingly numerous “exclusive rights”. These developments are linked first of all to stronger and increasingly broad-ranging industrial property protection (IP) for new plant varieties: as well as PVPC-protected plant varieties, patent protection now covers plant groups (whether GM or not), genes and traits, including native traits<sup>3</sup>, which is liable to increase the number of technological barriers to the use of plant genetic resources, despite the fact that these are the “raw material” for plant innovation. The second characteristic of the exclusiveness trend is a reinforcement of the means available to protect IP rights: legal texts governing the use by farmers of their “farm-saved seeds” and preventing them from re-sowing their fields with seeds they have harvested from a protected variety, or forcing them to pay a licensing fee<sup>4</sup>; legal proceedings facilitated by legislative changes (such as the 29 October 2007 Counterfeit Deterrence Act) and fears that IP rights-holders will find it easier to sue farmers or breeders for patent infringements if they use patented material, even unknowingly, in their professional activities; strengthened contractual provisions for purchases of certain seeds in order to guard against techniques such as retro-genetic engineering, etc.

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<sup>1</sup> “A plant variety” means a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder’s right are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics and considered as a unit with regard to its suitability for being propagated unchanged.” (UPOV Convention 1991, Art.1)

<sup>2</sup> These companies (Monsanto, Syngenta, Pioneer, etc.) began to work mainly on transgenic plants from the late 1980s. They are often cited in contrast to a different category of companies, known as “conventional” seed companies (Limagrain, RAGT, Desprez, etc.), which work mainly on the development of non-GM seeds. Although the boundary between these two categories is in some respects artificial (see attached report, p. 13 and further), it nevertheless expresses their very different positions on methods for protecting new plant varieties, the former favouring patents and the latter PCPVs. On methods for protecting new plant varieties under American law, see the attached report from the CEES working group (cf. *infra* note 6), p 9.

<sup>3</sup> On the definition of a native gene or character (which refers in general to an existing gene or character in a living species or to any mutant form of a gene or allele that may be obtained through spontaneous mutation or by mutagenesis, whether physical (radiation) or chemical (mutagenic agents), see *infra*, p. 20, note 57, and attached WG report, especially p. 50 and annex 2.

<sup>4</sup> On this point, see *infra*, p. 10.

This is the context in which the HCB Committee for Economic, Ethical and Social Issues organized its voluntary investigation into the question of changing IP rights in the field of plant breeding as applied to the production of higher plants in France and in Europe<sup>5</sup>. In order to clarify the issues for the CEES, the effects of these changes on the structure of the seed production industry, the CEES established a working group (WG) to investigate the organization of agricultural production and the satisfaction of social demand, without restricting its investigations to GMOs and addressing the concept of plant biotechnologies from a broad perspective<sup>6</sup>.

In the analysis conducted by the CEES and the WG, the following were considered as core issues:

- **Legal protection for innovation.** The CEES offers the reminder that at present, IP is the main instrument for protecting innovations. When designed to ensure fair treatment, IP protection is an efficient way of remunerating inventors and disclosing innovations, the alternative for economic players being to preserve the secrecy of inventions, which would slow down or raise barriers to innovating activities. Protection for innovations also helps to stimulate innovation<sup>7</sup> in a strategic sector where very substantial investments are made in research and where many challenges for society are awaiting responses (food security, adapting agriculture to climate change, etc.). IP protection must in any event observe due limits (strict conditions for granting rights, compliance with competition law, etc.). The CEES considers, more specifically, that it must be designed in the light of the following imperatives.

- **The diversity of innovation.** The CEES considers that respect for GM production as asserted in the Act of 2008<sup>8</sup>, stakeholder independence and the diversity of social demand and of agrarian systems imply that none of the innovation models (patent protection for technological innovations, PVPC protection for new plant varieties, small-scale on-farm selective breeding<sup>9</sup> without intellectual property restrictions) should monopolise the field to the point of jeopardising the survival of the others. The members of the CEES thus believe it essential to respect the plurality of innovation models through a dense and diverse network of breeders (large companies developing seeds marketed across the world, SMEs or micro-enterprises developing varieties of regional (Europe, Asia, etc.) or local value, "on-farm plant breeders"<sup>10</sup>, etc.); they believe that this is the necessary condition for maintaining the diversity of seed production and supply as demanded by farmer and consumer choice and, ultimately,

<sup>5</sup> Other organisms - animals, plants and microorganisms - used in very different fields (pharmaceuticals, bio-production, etc.) do not raise the same problems and are not addressed in this recommendation.

<sup>6</sup> Members of the working group: Ph. Gracien (CEES/GNIS), G. Kastler (CEES/Confédération paysanne), co-presidents of the group; G. Bariteau (INRA/legal division), N. Bustin (CPOV), D. Evain (CEES/FNAB), M.-A. Hermitte (CEES), P.-B. Joly (INRA), N. Morcrette (INRA/legal division), B. Remiche (UCL/ Sybarius law firm), E. Ronco (Cleary Gottlieb Steen & Hamilton - law firm), M. Vivant (law school, *Sciences Po*), B. Teyssendier de la Serve (ex INRA), F. Thomas (IRD), B. Verdier (CEES/ADF). This report was written by: Ch. Noiville (CEES) and F. Girard (Faculty of Law, Grenoble-Alpes University). The following were interviewed by the working group: F. COUTAND, patents engineer, Groupe Limagrain (currently Head of Patents Vilmorin & Cie), F. DESPREZ, Chairman and Chief Executive Officer of Établissements Florimond Desprez, President of UFS and ESA, J. DONNENWIRTH, Head of Intellectual Property, Pioneer France, G. FREYSSINET, Scientific Division, Limagrain Services Holding, E. KOSSONAKOU, Legal Department, European patent office (EPO), N. LOUWAARS, Director, Plantum NL (Dutch Association of companies in the plant reproduction sector), F. MEIENBERG, « No patents on seeds », G. PELLETIER, Research Director, INRA Versailles, Academy of Sciences, D. SEGONDS, Chairman of the Board, RAGT Group, Chairman of GNIS, Christophe TERRAIN, FNSEA, S. YEATS, director, division 2.4.0.3, EPO. Also consulted in parallel: P. BESSIERE, Senior European Patent Attorney, Syngenta International Seeds & Biotech, S. BONNY, INRA-*Economie publique*, J. GAUTIER, CEO Gautier Semences, Muriel LIGHTBOURNE (OCVV), C. TABEL, Research Director for RAGT, Chairman of the Intellectual Property Committee, UFS, F. TETAZ, intellectual property consultant, Cabinet Regimbeau. **The Working Group report may be downloaded at [www.hautconseildesbiotechnologies.fr](http://www.hautconseildesbiotechnologies.fr)**

<sup>7</sup> At least when these are considered appropriate.

<sup>8</sup> The French GMO Act of 25 June 2008 states in Art. 2 that "genetically modified organisms may only be cultivated, marketed or used subject to due respect [...] for agricultural structures, local ecosystems and production and marketing systems that are described in a fully transparent manner as containing no genetically modified organisms [...]."

<sup>9</sup> This type of innovation is developed by small-scale farmers who refer to themselves as "on-farm plant breeders" and who select, propagate and conserve their "varieties" under conditions of final use, i.e. in their crop fields.

<sup>10</sup> See previous note.

for guaranteeing the technological pluralism recommended in their studies on coexistence of GM and non-GM production<sup>11</sup>.

- **Genetic diversity and access to genetic diversity.** Increasing agricultural yields in the last 60 years have relied on selective breeding, within a limited number of species, of high-yield varieties adapted to a technically optimized environment (use of synthetic fertilizers and phytosanitary products). While IP law has been shaped to support this model of innovation, it is only one component among others (regulations on registration in the official catalogue of varieties, standards for seed propagation and marketing, agricultural policy, the rationale of supply and demand, etc.). The fact remains that sustainable agriculture as aimed for by the “Grenelle” Acts will need to be productive in increasingly changeable environments that cannot all be “optimized” or “artificialised”; this demands, among other factors, the development of inter- and intra-species genetic diversity in cultivated plants. The CEES believes that changes in IP must be appraised in the light of this question. In particular, it believes it essential to maintain the necessary access to the creation of plant varieties (varieties protected by plant breeders’ rights, older varieties now in the public domain, new plant varieties conserved in *ex situ* collections or renewed *in situ* by on-farm breeders, related wild species). The necessity of maintaining access implies the need to provide at once for what is *common*, i.e. inappropriable, and for what is appropriated but still accessible to others in various ways - as in the *creative commons* model in software development – or subject to collective use and management rights<sup>12</sup>.

Having set out the principles that guided the investigations, this recommendation is presented in two parts. Based on the WG report, it first reviews the current situation as regards IP in the field of plant breeding and lists the main questions that arise (I). These questions are then analysed and a series of legal changes put forward (II).

## ***I. Review of the current situation and questions arising***

### **A. Changes in rules for the protection of new plant varieties**

**1-** Since the 1970s, new plant varieties have been protected under French law, and subsequently under European law, by the Proprietary Variety Protection Certificate (PVPC), which was introduced to cater for the specific processes involved in breeding new plant varieties. In Europe, if not always elsewhere, it is widely recognized that plant varieties have profoundly specific features compared to other industrial products, in particular because they are themselves a source of raw material crucial to plant breeders. The UPOV Convention<sup>13</sup> therefore established a *sui generis* mechanism covering

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<sup>11</sup> See the majority recommendation at [http://www.hautconseildesbiotechnologies.fr/IMG/pdf/120117\\_Coexistence\\_Recommandation\\_CEEES\\_HCB.pdf](http://www.hautconseildesbiotechnologies.fr/IMG/pdf/120117_Coexistence_Recommandation_CEEES_HCB.pdf) and, for the list of the 8 organisations opposing this motion, note 4. F. Jacquemart (for *France Nature Environnement*) and Rachel Dujardin (for *Greenpeace*) emphasise that the diversity of innovation does not constitute sufficient grounds for accepting a technique or a product, and also point out that the considerations in this recommendation only concern the commercial aspect of the question. P. de Kochko (for Friends of the Earth) considers that in view of the glaring inequalities between the different innovators concerned by this recommendation, technological pluralism is an illusion; it cannot respect the choices of farmers and consumers, or ensure the diversity of seed supplies. He observes that today, what passes for technological pluralism is, on the contrary, a hegemony of the largest stakeholders and a catastrophic erosion of cultivated biodiversity

<sup>12</sup> See WG report, p. 69 and further.

<sup>13</sup> In the different versions (UPOV 1991 being the most recent) incorporated into French law - Acts of 11 June 1970 and 8 December 2011 - and in European Union law – Regulation 2100/94/EC of 27 July 1994.

several imperatives: a. a monopoly rights for the breeder for the use of a plant variety that is new, distinct, homogeneous and stable; b. a possible exemption, known as the “farm-saved seeds exemption”, that allows farmers, under strict conditions (payment of a licence fee to the PCPV holder in particular), to re-sow their fields without having to purchase more of the protected seeds (*cf. infra*<sup>14</sup>); c. a second exemption - mandatory in this case - that allows free access for anyone to the protected variety as a plant genetic resource for purposes of research and selective breeding (“intellectual access”) but also for the purpose of marketing the new varieties produced (“economic access“); any person may therefore freely use a protected variety to create a new variety without charge and without needing permission from the initial rights holder (except in certain cases, *cf. infra* p. 11).

**2-** The situation changed substantially with recognition of the *patentability of biotechnological inventions*. Although patenting was considered for a long time as ill-suited to the specific processes involved in breeding cultivated plant varieties, precisely because it does not allow for the breeders’ exemption but only for a research exemption<sup>15</sup>, it is now included among the tools for protecting innovations from this sector, as a consequence of the jurisprudence established by the European Patent Office (EPO) in Article 27.3 b. of the TRIPS Agreement (on Trade Related Aspects of Intellectual Property Rights) and subsequently by Directive 98/44/EC of 6 July 1998 on legal protection for biotechnology inventions, adopted with a view to encouraging investments in biotechnology by providing strong legal protection. *While stating that plant varieties* (which may be protected by a PVPC) *and “essentially biological processes for obtaining plant varieties”* are not patentable, the Directive nevertheless establishes the patentability of a whole series of innovations involving plant breeding (motion put forward by the EPO in the 1980s and ratified in its own examination guidelines).

Provided they are new, result from an inventive activity and are applicable in industry<sup>16</sup>, EU directive 98/44/EC recognises the patentability of: 1. microbiological processes and technical processes, whether essentially biological or not (e.g. genetic engineering processes such as transgenesis, mutagenesis or cell fusion)<sup>17</sup>; 2. plants, provided that the “technical feasibility” of the invention is not limited to a particular plant variety, in which case PCPV protection should be sought (for example, GM corn borer-resistant maize plants are patentable because the transgene can be inserted into any maize variety, as are protein-enriched plant populations)<sup>18</sup>; 3. genes and gene sequences, even if the structure is identical to that of a natural element, provided that they are isolated or produced by means

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<sup>14</sup> On the complex legal history of this exemption (not mentioned in the 1961 and 1978 UPOV Conventions, authorized by most of the signatory States, prohibited by the French Act of 11 June 1970, then established as an optional exemption subject to conditions by the 1991 UPOV Convention - then reinstated in European law – Regulation 2100/94/EC of 27 July 1994 - and in French law – see Acts of 4 August 2008 and 8 December 2011), *cf. WG* report, p. 11.

<sup>15</sup> For details on this point, see *WG* report p. 12 and further, and, on the technical, economic and political factors that led to the patentability of biotechnology inventions, p. 13 and further.

<sup>16</sup> On these patentability criteria, see *WG* report, p. 17 and further.

<sup>17</sup> Directive 98/44/EC, Art. 4.1.b) and 4.3. By microbiological process is meant “a process involving micro-organisms”, EPO Enlarged Board of Appeal, 20 December 1999, Case on Transgenic plants/Novartis II, G 1/98, § 5.2), which, in the legal sense, covers bacteria, plant cells, plasmids, single-cell fungi (including yeasts), algae, protozoa, and sometimes viruses (see EPO Examination Guidelines, G-II, 5.5.1). By technical process is meant, for example, genetic engineering processes (EPO, EBA, 20 December 1999, Novartis II, G 01/98, or EPO Board of Appeal, 21 February 1995, Plant cells/PLANT GENETIC SYSTEMS, T 356/93). On the distinction between a microbiological process and a technical process, see EPO, EBA, Novartis II, § 3.7. An “essentially biological” process (53(b) CBE), finally, is simply a natural phenomenon on which human intervention has no decisive effect. This is the case for a non-microbiological process for producing plants that consists of cross-breeding complete plant genomes and subsequent selective breeding from the progeny. Whether the said process includes, as an additional stage or as part of any of the crossing and selection stages, the use of a microbiological process that assists or facilitates the stages involved in cross-breeding complete plant genomes or in the subsequent selection of plants (e.g., use of genetic markers) or not is immaterial; see EBA 9 December 2010, Plant Bioscience, G 2/07, EBA, 9 Dec. 2010, State of Israel - Ministry of Agriculture/Tomatoes, G 1/0.

It should be noted that the boundaries between the 3 categories (microbiological, technical and essentially biological processes) are not clearly defined and cannot be referred to with any certainty to determine whether techniques such as TILLING, zinc-finger Meganucleases, etc. belong to one or other category.

<sup>18</sup> Dir. 98/44/EC, Art. 4, § 2; see also: EPO, EBA 20 December 1999, *Novartis II*, G 01/98, § 3.1.

of the technical process and that their function and industrial application are explicitly described in the patent application<sup>19</sup>.

Patent protection thus gradually became established in the field of plant breeding, driven by strategies and means that have changed profoundly as techniques have evolved and reinforcing the hold of patent protection in this sector. While it may have been thought, in 1998, that Directive 98/44/EC concerned only strictly biotechnological inventions - essentially transgenesis, transgenes and transgenic plants - the terms in which it is drafted were in fact broad enough to allow patent protection to extend gradually to a new generation of inventions not explicitly referred to in the Directive and considered by some as pertaining to conventional plant breeding (i.e., using essentially biological processes, “native” genes and traits, etc.)<sup>20</sup>. This is the change in the situation that now requires investigation.

## **B. Stakeholder strategies and IP “map”**

Having opted for PVPC protection for their varieties, “conventional” breeders have continued to request this type of protection as a priority (2). Companies with an agrochemicals background, on the other hand, have tended to use patent protection, with which they are traditionally more familiar<sup>21</sup>. The scope of patents has thus broadened considerably, mainly to the benefit of new strategies among these stakeholders (1).

### **1) Concerning patent protection**

#### ***The strategically broadened scope of patent claims***

*Patent continue to be claimed for the inventions for which Directive 98/44/EC was initially adopted in this field, i.e.: a. transgenic plants (for which operators claim double protection, under a PCPV for the plant variety and under a patent for the inserted trait and the GM plant); b. genes that have been isolated and for which a function and an application are proposed (e.g. an epsps gene isolated from a micro-organism and modified for insertion into the genome of a plant to make it resistant to a herbicide); c. processes (e.g. gene insertion, etc.).*

*In parallel, since 2000, a increase has been observed in a new category of claims for a range of innovations where the scope of the claim is broader: products resulting from processes used together with conventional plant breeding, “native” genes and traits, etc. Along with transgenesis, modern methods used to assist and accelerate conventional selective breeding and to target characters more closely (marker-assisted selection, high throughput analyses, etc.) can now identify characters of interest (yield, resistance, etc.) in the plant species themselves, describe them, identify associated alleles and then introgress these characters through repeated back-crossing<sup>22</sup>. These technological advances have prompted some breeders to seek patent protection for “native” genes, in other words genes naturally present in a given species, but also for plants expressing a given character (“sweet-sour” melons, low-moisture tomatoes, aphid-resistant lettuces, fatty acid enriched sunflower, etc.) that does not depend on inserting a transgene but is associated with the expression of one or more alleles*

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<sup>19</sup> Directive 98/44/EC, Art. 5, § 2 and 3.

<sup>20</sup> On the elasticity of the terms in the Directive, see WG report p. 16 and 21 and further.

<sup>21</sup> See *supra* note 2.

<sup>22</sup> Introgression of a character consists of repeatedly crossing a line carrying the character in question with an elite recipient line. As the descendents are crossed with the recipient line over several generations (known as “backcrossing”), individuals that do not have the desired character are gradually eliminated.

On the factors that have led to these developments, see WG report p. 19 and further.

of one or more “native” genes, despite the fact that there is nothing new here compared to conventional selective breeding, which has always been based on the identification and subsequent introgression of native characters, and for which conventional breeders have never claimed patent protection.

### **EPO practice and jurisprudence**

EPO practice and jurisprudence, which is still in construction, is relatively favourable to these new protection strategies, and this is a contributing factor in the shifting line of demarcation that initially appeared to distinguish plant accessions that could be protected by a PVPC - i.e. plant varieties – from patentable inventions, i.e. GM plants, transgenes and microbiological processes.

*The EPO does have strict rules where plant accession processes are concerned (not patentable when they are essentially biological, patentable when they are microbiological or technical): these processes must not simply consist of a natural phenomenon but must involve human intervention with a determining effect on the object obtained, a criterion that could be applied to protect processes such as targeted mutagenesis or “TILLING” (Targeting Induced Local Lesions in Genomes), but which excludes patentability for processes used to cross complete genomes, where human intervention is not decisive (for example, the EPO has ruled that marker-assisted selection is not patentable, cf. the so-called “Broccoli” case (EBA, 9 Dec. 2010, Plant Bioscience, G 2/07) and the “Wrinkled tomato” case (EBA, 9 Dec. 2010, State of Israel - Ministry of Agriculture/Tomatoes, G 1/08).*

*Where products are concerned, however, the EPO tends to be more flexible.* Thus, for example, it seemed initially that *plants* could be patented only if they were *transgenic or obtained by a microbiological or not essentially biological selection process* (and if the technical feasibility of the invention was not limited to a particular plant variety). It now appears, however, that a plant can be patented whatever the method of production used, provided that it is not a plant *variety* (only varieties as defined by the UPOV Convention are non-patentable, but this does not apply to species, to unstable varieties within the entire population of a generation, etc.). The EPO Enlarged Board of Appeal, to which was recently referred the question of the patentability of plants obtained by essentially biological process, will shortly announce its ruling on this point. However, it is already clear that numerous patents have been granted to protect plants obtained by conventional crossbreeding (which is “essentially biological” as defined by patent law, even if markers have been used to facilitate sorting of plants of interest among the progeny), which express characters of resistance, taste, etc.

The fact that these patents are being granted is effectively endorsing the *patentability of “native genes” or characters* whenever the inventor, by means of a technical process, has shown a relationship between a given plant gene or allele<sup>23</sup> and the character of interest (which Article 3.2 of Directive 98/44/EC effectively provided for from the outset by stating that: “biological material which is isolated from its natural environment or produced by means of a technical process may constitute an invention, even if it previously occurred in nature”).

### ***Overall pattern of patents issued***

EPO statistics for 2012 show that, among the most recent patents, *a rapidly increasing number concerns native genes and characters (resistance to water stress, to certain pests etc.) and non-transgenic plants that are mostly obtained by essentially biological processes*<sup>24</sup>. These patents concern numerous characters that are dependent on various sites in the genomes of different plant species (melons, cucumbers, tomatoes, lettuces, etc.) and which have always been bred selectively to

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<sup>23</sup> If necessary using a simple statistical correlation (QTL).

<sup>24</sup> See WG report, p. 19-20 and 25.

create new varieties. The Dutch company *Rijk Zwaan*, for example, has patented lettuces that are resistant to *Nasanovia* aphids<sup>25</sup>. The patent does not protect the process (in this case, a standard crossbreeding process using markers, and therefore essentially biological), but the plants that ultimately express the resistance character without expressing the character for dwarfism specific to the plant from which the breeder derived the gene for resistance<sup>26</sup>.

More generally, the EPO applies a comprehensive approach when granting biotechnology patents, in which the intention is to give precedence to the pioneering nature of techniques over classic patentability criteria. There is agreement among observers on the flexible interpretation of *inventive activity* that prevails, and on the acceptance of *broad claims* (for example covering not only genetic sequences isolated and described by the inventor, but also sequences that, in other species, appear to have the same structure and the same functions), although in recent years, the EPO has demanded the reformulation of claims that are too broad. For example, BASF holds a European patent on genetic sequences coding for proteins that confer resistance in plants to drought, heat, cold or salinity, as well as a on very large number of plants into which these sequences could be introduced (maize, wheat, rye, oats, triticale, rice, barley, soy, groundnuts, cotton, rape, canola, cassava and many others), although it is unlikely that the patent holder has been able to demonstrate ownership of the invention of all the aspects claimed<sup>27</sup>.

The CEES further observes that, *in the field of biotechnology, some inventions involve overlapping patent claims*; even if these do not always amount to “*patent thickets*”, as commonly found in the information and communication technologies (meaning a dense web of overlapping patents on different processes, elements, components, etc. that are all needed to actually use an invention), these overlapping patents tend to complicate the innovation process, especially for public research establishments and SMEs, which need to have the capacity to identify potential patent barriers as well as a strategy to overcome these, and which find themselves in difficulties when their work proves to be dependent on patents granted, at least when they themselves do not have patents to offer in exchange.

Analysis of industrial strategies shows that a patent is not only a right to reserve an innovation but also, and increasingly, a strategic negotiating instrument (this is not specific to plant breeding but raises particular problems in this sector<sup>28</sup>). The point, obviously, is to secure a strong position in an real negotiating situation. It is, moreover, legitimate for a rights holder to bring a patent infringement suit against anyone infringing these rights and to pursue the suit even if a licensing offer is made. However, here as elsewhere, the legitimate exercise of a right can degenerate into an abuse of that right. Although this may not be the case for most of those involved, the fact is that some exercise their IP rights purely and simply for purposes of intimidation. When a large well-known company systematically arranges for customs seizures without subsequently starting legal procedures that may validate or invalidate the seizures, intimidation is clearly the sole purpose of the exercise. Although some members of the WG object vehemently to the expression, it is not surprising that others have referred to the practice as “judicial terrorism”<sup>29</sup>.

## 2) Concerning PCPV protection

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<sup>25</sup> *Ibid*, p. 20 and 43.

<sup>26</sup> For other examples see WG report, p. 20 and further, and p. 25.

<sup>27</sup> See argument to this effect in M. Lightbourne, (2013). *Génomique, ressources génétiques et droits de propriété industrielle* (Genomics, genetic resources and industrial property rights) in S. Blondel, S. Lambert-Wiber, C. Maréchal (dir.), *La protection juridique du végétal et ses enjeux économiques* (Legal protection of plants and economic issues), Economica, Paris, p. 37. On this patent, see WG report p. 23 and 24.

<sup>28</sup> Cf. *infra* p. 17.

<sup>29</sup> See WG report, p. 27.

In parallel with patents, PCPV protection of plant innovations is still the preferred means of protection in the “conventional” seed industry. However, in response to technological developments and changes in patent law, these players have been seeking ways of strengthening the PCPV mechanism since the 1990s, on two fronts in particular.

**Protection against the risk of appropriation by competitors, especially patent applicants, of selective breeding work.**

The development of transgenesis raised fears that seed companies might simply introduce a foreign gene into a variety obtained through a lengthy selection process, and obtain PCPV protection for the new variety without having to bear the investment costs borne by the pioneering breeder. To prevent this from happening, the UPOV convention, in the 1991 version, introduced the concept of the “Essentially Derived Variety” (EDV), i.e., derived from an initially protected variety. A breeder of an EDV may obtain a right to protection but cannot exercise it without permission from the PCPV holder and without paying a licence fee. For similar reasons, some breeders attempt to protect themselves against certain reverse engineering techniques, which are used to identify the genetic characteristics of the parent lineages of a PCPV-protected variety, thus allowing much faster development of competing varieties that are close to, but not essentially derived from, the initial variety, by means of contracts that preclude the use of these techniques.

**More effective assertion of breeders’ IP rights to farmers**

With a concern for more effective representation of their IP rights, especially in view of competition from patented plants (which already exists on the world market, where patents prohibit the use of farm-saved seeds in many countries, but is still hypothetical on the European market), breeders have called for licence fees to be paid by farmers making use of the “*farm-saved seeds exemption*”. This exemption from breeders’ IP rights allows farmers who have purchased seeds of a PCPV-protected variety to re-sow their fields with part of the harvest from the variety used (common practice among many farmers despite being banned under case law on the basis of the French Act of 11 June 1970 on the protection of plant variety rights<sup>30</sup>); to breeders, this means that the practice - now authorized but as an exception only - may be implemented only under the two conditions set out in the law<sup>31</sup>, i.e., the variety must belong to one of the 21 species for which the exemption is authorized and the farmer must pay a licence fee to the breeder (although according to Regulation 2100/94/EC, “smallholders” are exempted from licence fees).

### **3) Industrial companies and IP**

Historically, the changing structure of research and industrial companies has been influenced in part by changes in industrial property rights. Changing rules for the protection of plant innovations are part of a broader trend towards the privatization of research on the one hand, and increasing concentration of seed industries and worldwide plant biotechnology research on the other hand. This trend, which first emerged in the late 1970s, accelerated from the mid-1990s. The level of concentration is now very high, as evidenced by three complementary indicators: In 2009, the three leading seed companies (Monsanto, DuPont-Pioneer, Syngenta) accounted for over 34% of the entire seed market worldwide, for all plant species; of the three, Monsanto and DuPont-Pioneer applied for more than 60% of all patents concerning plants to the US Patents Office (USPTO) from 2004 to 2008; over 80% of transgenic events currently used around the world are patented by Monsanto.

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<sup>30</sup> See *supra* note 14.

<sup>31</sup> Regulation 2100/94/EC and Act of 8 December 2011 (Art. L. 623-4 of the Intellectual Property Code, referred to hereafter as the “IPC”).

This level of concentration in the seed industry is not only linked to biotechnology developments and parallel changes in industrial property: it has also been the result of necessity, particularly in Europe, in view of the considerable increase of research costs of all kinds.

It nevertheless remains that this structural trend is reinforcing the underlying trend towards increasing concentration of research on a small number of species by a small number of companies: a large proportion of fundamental and applied research efforts are focused on soybeans, maize and cotton; less work is being done than previously on many species (which some believe have become “orphaned” while others point out that these particular species enable an entire fabric of small and medium enterprises to continue their plant-breeding activities).

### **C. The positions of socio-economic players**

As may be expected, these changes have not been received in the same way by the different socio-economic players. They have been well received by companies with an agrochemicals background (which stress that Europe is lagging behind in the field of plant biotechnology and advocate broad patentability in this field), but they are raising concerns among “conventional” seed companies and farmers, and “on-farm plant breeders” whose work intersects with these two categories. All of these groups are concerned by the increasing monopoly being exercised over increasingly broad segments of plant genetic diversity.

#### **More specifically:**

. *Breeders with an agrochemicals background*, in general, simultaneously advocate a strengthened PCPV mechanism and wide-ranging patentability in this field. They argue that new breeding techniques demand substantial investments that can only produce returns with robust patent protection, which they believe the PCPV mechanism does not sufficiently provide, particularly for “characters” (“traits”). In their view, once a variety containing such a character is publicly accessible, the character can be transferred simply and quickly to any other plant by simple selective crossbreeding, including by third parties not associated with the innovating party. The patenting system therefore provides effective protection, and is therefore suited to the protection of modern technological innovations in this field and of the resulting plants. Although by no means a “secondary” issue for breeders with an agrochemicals background, access to the genetic resource is not considered a problem as they frequently make use of cross-licensing, which enables them to circumvent appropriation issues that could potentially block their activities.

. *conventional breeders*: 1. are concerned by the fact that *patents or patent claims are being made for an increasing number of genes, especially native genes and characters associated with native genes*, when crossbreeding for desired traits - and therefore genes - has always been the foundation of their work; 2. are also concerned by the fact that, with the increase in patenting, they are working within an increasingly uncertain legal situation since it is not always possible for them to identify the patented material or the exact scope of the patents, which exposes them to a risk - which cannot reasonably be assessed in advance - of being sued for patent infringement by companies whose power is such that these breeders cannot take on the financial risk of a lawsuit (*cf. infra* the case of the Gautier seed company); 3. fear that this can only reinforce the concentration of the seed industry around a few large companies; 4. call for clear and harmonious coexistence between PCPVs and patents (see *Union française des semenciers*, UFS; European Seed Association, ESA; and International Seed Association, ISF).

. *Farmers* (all farmers’ unions): 1. stress the unprecedented *risk of infringement* to which they are exposed should the varieties they grow contain, whether naturally or accidentally, patented genes or

characters; 2. in a context of increasing concentration of the seed industry and faced with certain IP licensing strategies they describe as “aggressive”, they are also concerned by the *economic dependence* that can result, especially if market access for varieties is determined by a few large seed companies with large patent portfolios (which would still further limit the diversity of seeds available on the market).

. *Finally, some categories of farmers* are concerned by the tightening of the IP system overall, whether patents or PCPVs, to the detriment of practices they consider essential to secure the future of agriculture. In this regard, certain organizations are concerned by: 1. the fact that as things stand with IP, they cannot use *farm-saved seeds from new protected varieties* freely and without charge (position of the *Confédération Paysanne*, *Coordination Rurale* and the MODEF); 2. changes in IP rights are reinforcing a market for *seeds from homogeneous and stable industrial varieties, to the detriment of varieties that do not meet these criteria* (old varieties, landrace varieties that have evolved through selective breeding in the field by “on-farm plant breeders”, etc.; they stress that, as agronomic research has already demonstrated<sup>32</sup>, landrace varieties are better suited to less intensive farming and to environmental demands in agriculture (conservation of genetic diversity, adaptation to diversified and changing environments, etc.) (position of the *Confédération paysanne*, FNAB and farmers who work with “short distribution circuits”).

Having identified these concerns, the CES analysed the current or medium term effects of IP on the breeding of new plant varieties, on recipients and on the diversity of agricultural systems. Based on the WG’s investigations, the CEES hereby formulates recommendations to guarantee a balance between the private and collective issues that underlie the matter at hand.

## **II. Analyses and possible new options**

The issues identified fall into three categories, which are addressed here in turn. Firstly, does the current state of IP block innovation in plant varieties (A)? ; Secondly, does it expose farmers to a risk of increasing dependence on the seed industry (B)? Thirdly, is it creating increasing uniformity in plant varieties marketed, thus harming agro-biodiversity (C)? For each of these points, the CEES considers different scenarios and recommends a series of changes (see annexed list of members present and represented during the discussion and adoption of this recommendation).

### **A. IP and potential barriers to new plant varieties**

Conventional and “on-farm” breeders fear that the changing landscape of IP rights will bar them from the processes they use to create new plant varieties. This point will be examined in light of applicable law on (1) PCPVs, (2) patents.

#### **1) PCPVs and potential barriers to new plant varieties**

The PCPV mechanism was specifically built up to allow free access to the plant genetic resources contained in protected varieties, whether for breeding or marketing purposes, but two developments are raising questions as to the exact effects they may have on the process of creating new varieties: the idea of “essentially derived varieties” (EDV), and the proposal now formulated by some breeders for a temporary embargo on the breeders’ exemption.

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<sup>32</sup> See the scientific literature cited in the WG report.

### ***EDVs in practice***

The UPOV convention introduced the “EDV” idea out of concern for better protection for PCPV holders. When a variety is described as “essentially derived” from an initial protected variety, its developer cannot use the EDV without a licence from the holder of the PCPV protecting the initial variety. The CEES sought to determine whether the provisions of such licence agreements are liable to raise barriers to the use of new varieties that have thus become “dependent”. Given the grey areas in the legislation and the absence of case law, the CEES worked with the material it was able to obtain about professional practice and, where litigation is concerned, with arbitration rulings (from the ISF in particular). It observes that in order to appraise the genetic distance between the EDV and the initial variety, professionals seek to determine whether the molecular threshold [*seuil de derivation*], which is established for each species<sup>33</sup>, has been exceeded, which may reverse the burden of proof. If no molecular EDV threshold has been established for the species in question and the parties have not been able to come to an agreement, the arbitration court gives a discretionary ruling, although it is not possible to clearly establish whether a genotype or phenotype should be used to appraise the essential nature of the derivation (on this point, the professional practices observed differ from the few rulings available on the subject). In any case, the CEES observed that as currently applied in practice, the EDV idea is generally well received by plant breeders, who consider that it has had a salutary deterrent effect without raising any barrier to innovation. As implemented today, the EDV principle appears to ensure a good balance between protecting breeders from the proliferation of varieties that are virtually identical to their own, and the barriers to innovation that would result from overprotecting these same breeders<sup>34</sup>.

### ***Proposal for a temporary embargo on the “breeders’ exemption”***

The proposal recently formulated by some breeders is more questionable. The idea is to amend PCPV legislation to introduce a temporary embargo on the breeders’ exemption<sup>35</sup>. The reasoning is as follows: reverse engineering techniques now make it possible to determine, from hybrid materials, the parent lineages (which were kept secret until now by PCPV holders) and thus to rapidly develop competing varieties that are very similar but not essentially derived from the initial variety. To strengthen the PCPV mechanism against these new technical possibilities, some breeders have proposed that access to their protected varieties, including for research, should be barred for a period of four to five years. The CEES has strong reservations as to this proposal, to which it would prefer PCPV protection of parent lineages. It considers that, if an embargo were introduced, this would substantially change the overall balance of the PCPV mechanism, which would become an additional factor of reduced access to genetic variability. Some members add that a change of this kind of would imply, in order to ensure that “embargoed” varieties have not been used by competitors, ratification of the shift towards genetic and/or molecular marking of the distinctive characters that define PCPV-protected varieties, which would still further undermine those breeders who are least equipped for molecular biotechnology development.

**OUT OF CONCERN TO AVOID THE RISK OF VOIDING THE BREEDERS’ EXEMPTION OF SUBSTANCE, THE CEES RECOMMENDS THAT AN EMBARGO ON THE BREEDERS’ EXEMPTION SHOULD NOT BE INTRODUCED INTO PLANT BREEDERS’ RIGHTS**

<sup>33</sup> On the establishment of this threshold, see WG report, p. 34 and further.

<sup>34</sup> In the WG report, some WG members observe, nevertheless, that in the medium term, increasingly exact molecular descriptions of varieties could change the situation, at least if they tend to reduce the distance between varieties. Professionals will need to anticipate this possible difficulty so that new varieties are not considered too easily as EDVs.

<sup>35</sup> Given that, as indicated in the WG report, plant breeders do not have a common position on this subject.

### **“Shrink-wrap” contracts to prevent reverse engineering**

In parallel, the CEES investigated the so-called “shrink-wrap” licences through which certain PCPV holders attempt to protect themselves from the effects of these same reverse engineering techniques<sup>36</sup>. Through these licences, which are widespread in the field of software (and whose stipulations are indicated on the packaging, hence the name), some breeders holding PCPVs have developed contractual provisions that prohibit seed purchasers (who are deemed to have accepted the stipulations by opening the packaging) from determining the parent lineages.

Having analyzed the documentation provided by the WG<sup>37</sup>, the CEES considers that these licences are highly questionable from the point of view competition and profoundly detrimental to the overall balance of plant breeders’ rights. The WG members argue that the rules concerning the scope of a PCPV are public<sup>38</sup>, which means that they cannot be waived; they add that, as in all monopoly exemptions, the breeders’ exemption is pivotal to the system sought by the legislation, which is understandable given the importance of access to genetic variability; because any contractual amendments to this exception jeopardizes the balance sought, any agreements that limit or remove the freedom to use biological material for plant breeding and development purposes, whether with protected varieties or parent lineages, should be deemed null and void.

**OUT OF CONCERN TO AVOID THE RISK OF VOIDING THE BREEDERS’ EXEMPTION OF SUBSTANCE, THE CEES RECOMMENDS THAT CONTRACTS THAT CHALLENGE THE OVERALL BALANCE OF PLANT BREEDERS’ RIGHTS, SUCH AS “SHRINK WRAP” LICENCES DESIGNED TO PROHIBIT REVERSE ENGINEERING, SHOULD BE CONSIDERED NULL AND VOID.**

## **2) Patents and potential barriers to new plant varieties**

Patent protection of new plant varieties is already proving to be a barrier to innovation in this field and demands a series of recommendations.

### **Contributing factors**

The factors contributing to these barriers are<sup>39</sup>.

*-Increasing numbers of patents whose legal scope is uncertain:* Given the increasing number of patents and the sometimes uncertain scope of the object protected, it is difficult to determine with any certainty whether certain techniques or products can be freely used; as a result, selective breeding programs cannot be undertaken without risks to the breeder of using patented material unknowingly.

*-Lack of information on claims to patents and/or patents granted:* It is very difficult for breeders to get access to information that would enable them to check whether patented material is present in the varieties they handle or produce (patents databases, managed by the EPO for example, do not indicate in which varieties the patented material is incorporated); plant breeders, who feel they are “working in a minefield”, have great difficulty in verifying their “freedom to operate”<sup>40</sup>, even though some recent practices could help them to do so (for example, Syngenta now provides a list of its patents for the European market on its web site, along with patent licensing conditions).

<sup>36</sup> On other contracting practices liable to raise barriers to the innovation process, such as certain “Material Transfer Agreements”, see WG report p. 49.

<sup>37</sup> See WG report p. 54 and further for the arguments of the Working Group members, 1 of whom considered that these contracts are lawful.

<sup>38</sup> See ruling to this effect by the French Cour de Cassation, 1 February 2001, n°981958 (and WG report, p. 47-48).

<sup>39</sup> For a more detailed discussion, see WG report p.39 and further.

<sup>40</sup> Large companies such as Limagrain have the means to analyze their own freedom to operate. However, this requires them to employ two people to check the all patent claims published - around 1000 each month. Limagrain has also tested the pooling system within an Economic Interest Group, Vigibio, comprising several companies.

- *High transaction costs* in a context where there is a need to know of the existence and scope of a great many patents, which may be affordable for single patents but taken together tend to make selective breeding programmes excessively costly.

- *Absence of a stricto sensu breeders' exemption in patent law.* A research exemption is provided for in European patent law; in the short term it could also incorporate, as in French law (CPI, ), a limited breeders' exemption (applicable to EU unitary patents, as provided for by the Unified Patent Court agreement, now in the process of ratification). This exemption would allow breeders to freely propagate a plant containing one or more patented elements. But whatever the outcome, if a variety still ultimately contains these elements, the breeder will not be able to market it without requesting a licence and without paying a licence fee, even when the breeder has no intention of using or laying claim to the functions of these elements. Thus placed in a position of dependence, breeders could possibly "remove" the patented material, but this would assume they had identified it beforehand, and secondly that the removal is technically and financially possible, which is not always the case. By asserting the principle that genes in general are patentable, whether of human, microbial, animal or plant origin, Directive 98/44/EC fails to take into account the specific nature of plant genes and the particular difficulties that result, where plant genetic material is concerned, from the absence of a *stricto sensu* breeding exemption in patent law.

- *Scope of patent monopoly.* 1. where the object of the patent is a process, protection extends to the biological material directly obtained through that process, and to any other material derived and obtained [...] through propagation or multiplication, provided that it has *the same characteristics as the initial biological material* (Directive 98/44/EC, Art. 8 § 2). 2. where the object of the patent is a product, protection extends to all biological material directly derived from that biological material through propagation or multiplication [...] and possessing those same characteristics (Directive 98/44/EC, Art. 8 § 1). 3. in the case of a gene, protection extends to all material [...] in which the gene is incorporated and *in which the genetic information is contained and performs its function* (Directive 98/44/EC, Art. 9); in its interpretation of this provision, the ECJ<sup>41</sup> pointed out that what is patented is therefore protected only when the DNA sequence is *capable of performing the function for which it was created* (*Monsanto vs. Cefetra, Gr. Ch., 6 July 2010, case n° C-428-08*)<sup>42</sup>; but this is not enough to ensure that a plant breeder<sup>43</sup> using a patented gene will not be guilty of patent infringement (a case in point concerns the *cry* genes that perform their insecticide function inherently, or the *epsps* gene that *may* confer tolerance to a herbicide, even if the breeder or farmer does not make claims as to this characteristic). In any case, whenever they are in a position of dependence, breeders cannot make use of their variety - and cannot use their own seeds - without a licence to use the object of the patent, failing which they are guilty of patent infringement.

- *Provisions on patent infringement:* The position of breeders as regards the current legislation (Art. L. 613-3 and L. 615-1 para. 3 CPI) needs to be pointed out here. On the one hand, some of their actions may not be such as to incur liability (i.e., payment of damages), but may nevertheless objectively constitute an infringement (and would therefore be prohibited). On the other hand, regardless of whether a breeder has acted in good faith or not and knowingly or not, as the "manufacturer" of the infringing product, they are recognized as guilty of patent infringement whenever they reproduce the patented material, even unknowingly<sup>44</sup>.

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<sup>41</sup> The European Union Court of Justice in Luxembourg is the highest court of justice in the EU and is responsible above all for interpreting European legislation, for which it guarantees uniform application in all EU member states.

<sup>42</sup> Which is not the case when, for example, a transgenic plant containing a gene for glyphosate tolerance is processed into flour. On this ruling, see WG report, p. 28 and 40.

<sup>43</sup> Or the farmer: see *infra*, p. 23 and further.

<sup>44</sup> On these points, see WG report p. 38 and further. As understood by the WG members, Art. L. 613-3 IPC defines acts as "objective infringements", in other words acts that infringe patent rights whether committed in good faith or not. Art. L. 615-1,

### ***New contributing factors***

The CEES observes that new potential barriers to innovation are being raised together with the broadening scope of patentability. In this regard, it notes the effects produced by *the increasing number of patents on plants and on native characters and/or genes*. These patents are proving to be much greater barriers than patents on GM plants or isolated genes whose structure and function have been modified by genetic engineering. In the latter case, breeders are only guilty of patent infringement if they exploit the isolated gene or if the gene is inserted into the genome of their variety (which is very rare in Europe where breeders produce few GMOs). On the other hand, when the patented gene or character is *naturally* present (i.e. “native”) in a variety used by the breeder, the latter may be considered as dependent upon the patent. This means, for example, that any lettuce variety that contains the *Nasanovia*-resistant character described by the *Rijk Zwaan* patent will be dependent upon that patent, which has resulted in some companies, such as *Gautier Semences* in France, having to pay licence fees to be able to continue their long-standing activities of marketing lettuces they have bred themselves and which contain this character<sup>45</sup>.

**The CEES underlines the new risks arising from the patentability of this new generation of inventions**, whether the patents are on products (where protection extends to any biological material obtained from the product by propagation or multiplication and *possessing the same characteristics*) or on processes (in which case any product *obtained by means of the process* is covered by the patent).

In the case of products, patenting descriptions of existing plants in effect means preventing the free use of these plants as a source of innovation, including through breeding by conventional methods<sup>46</sup>. The barrier effect is all the greater because all varieties of a given species have the same genes in common (which differ only in their “allelic variations”), just as different species also have most of their genes in common (which, besides allelic variations, differ in their organization within the genome), so that the character or characters associated with the expression of an allele of a given gene may be applied to, at least, all of the varieties of a given species and sometimes the varieties of other species. A comparable barrier could emerge in the medium term if, as anticipated by some geneticists, targeted mutagenesis were to take over from gene introgression. The reason is that this technique makes it possible to create, rapidly and precisely, single or additional mutations or to substitute sequences within plants, and in particular to copy known gene sequences of given varieties into other varieties or even into other species, thus avoiding lengthy and costly backcrossing. Some of these mutations could occur spontaneously (natural mutation and recombination) or be triggered by random mutagenesis, or they could simply be copies of known gene sequences. If such products were to be recognized as patentable - on the grounds that they are not yet understood in the state of the art at the time of the patent claim - the effect would inevitably be a barrier to the creation of new varieties: the commercial varieties developed in this way would contain patented mutations in different areas of the genome and could therefore not be freely reused to create new varieties, while varieties that naturally contain the same patented sequences could not be used either without a licence from the patent holder.

In the case of patented processes, the difficulty lies in the fact that when there are two identical products, the burden of proof that the process used by the breeder to develop his own product is

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al. 3, IPC then only allows a ruling on the liability of the infringer, which is excluded when the acts were not “knowingly committed”. In any case, this rule does not apply to the “manufacturer” of the infringing product - the term is no doubt inappropriate when applied to a plant breeder, but would appear to be applicable when the plant breeder *propagates* and/or *reproduces* protected biological material.

<sup>45</sup> See WG report, p. 40.

<sup>46</sup> Because conventional breeding can dispense with transgenes but cannot dispense with native genes and characters. Patents on genes, native characters and plants that contain them then run counter to the very nature of plant breeding, which implies the possibility of freely combining the genes of the species in question; only the end result may be protected by IPR.

different to the patented process rests with the breeder. The problem here is that it can be impossible to bring such proof when the process leaves no molecular trace in the product (at least no trace that can establish that the product has been obtained by means of the patented process); this will be the case when the breeder has used mass selection or any kind of technique such as targeted mutagenesis (it will be extremely difficult for breeders to prove that they have used these processes and not the patented process).

### ***The limits of current legal and contractual solutions***

These situations (patents with a broad scope, overlapping patents, patent dependence, etc.) are by no means specific to the creation of new plant varieties; they occur in other fields such as pharmaceuticals or mobile telephony. To overcome these difficulties, operators come to agreements through cross-licensing or patent pooling. These practices work well on large-scale markets occupied by powerful operators, and are one of the factors of increasing economic concentration. However, they do not work so well on the seed market, where operators range from small to very large enterprises, profits are smaller and licensing conditions often perceived as unfair by the weakest partner, even though some companies like *Syngenta* or *EnzaZaden*<sup>47</sup> have developed a licensing policy to seek a sector-specific solution<sup>48</sup>. For breeders who cannot obtain or exploit a PCPV without infringing a patent, Directive 98/44/EC provides for an option to apply for a “non-exclusive compulsory licence in respect of interdependence between plant varieties and inventions”, but the conditions are too restrictive to be applied in practice (the patent must predate the PCPV, the license must be “necessary for the exploitation of the variety to be protected”, the variety must constitute “significant technical progress of considerable economic interest compared with the invention claimed in the patent [...]”). As regards patent pooling attempts in the last decade, aiming to avoid or facilitate the negotiation of licences, they have either failed or made little progress (contrary to what has been observed in the field of human genomics for example).

In this context, the CES observes that there are two possible scenarios: 1) acceptance of these developments, which would make patents the predominant tool for protecting new plant varieties and would have the effect of increasing concentration of the seed industry around a few large companies, 2) amendments to IP rules in order to preserve a dense fabric of plant breeders and, at the same time, the pluralism in innovation needed to cater for soil and climatic particularities (more diversified research avenues, better protection of genetic resources against excessive homogeneity, etc.).

### **OUT OF CONCERN TO PRESERVE THE DIVERSITY OF INNOVATION, THE CEES SUGGESTS 5 CHANGES AS FOLLOWS.**

**Access to information on patents.** Because relevant information is lacking, the CEES has assessed the disadvantages of the *status quo*, which leaves it up to breeders to find relevant information although they have neither the time nor the means of doing so at present. Concurring with the authors of the report on “Seeds and sustainable agriculture” [*Semences et agriculture durable*<sup>49</sup>], the CEES considers it preferable for breeders to have early access to relevant information on patent claims and patents issued, to enable them to verify whether any patented material is present in the plant material they handle

<sup>47</sup> See WG report, p. 45.

<sup>48</sup> In some cases, the negative effect is limited by a broadly consensual licensing policy, which was the case for the INRA patents enabling the creation of hybrid rapeseed lines. However, besides the fact that such strategies are by no means systematic, the increasing numbers of breeding tools that are patented, and therefore not freely accessible, has increased research costs in general and thus contributed to increasing concentration (see WG report, p.42).

<sup>49</sup> P. Vialle, *Semences et agriculture durable* (Seeds and sustainable agriculture), report to the Ministry of Agriculture, Paris, 2011.

or produce and, in doing so, to determine whether they are free to use that material. The CEES therefore proposes: 1. that this information should be made available in a publicly accessible database in which the data includes, for each marketed variety, the link with the relevant patents; 2. that it should be the responsibility of the professionals holding patents to inform breeders (and farmers, see *infra*) accordingly; the CEES notes the advances made in this direction by the European Seed Association (ESA) and the French union of seed companies (*Union française des semenciers* - UFS)<sup>50</sup>; in order to guarantee the effectiveness of these arrangements, the CEES considers that the absence of this relevant information should be penalized by the non-admissibility of patent infringement suits that may be brought by the patent holder (the idea being that if patent holders have not provided the relevant information, they cannot sue for infringement).

**Reinstating the requirements of statutory patent law** As IP is an exception to the principle of entrepreneurial freedom (and therefore to the freedom to copy), the members of the CEES point out that patentability can only apply to *inventions* that are fully and comprehensibly *described* and that strictly fulfil the *conditions of patentability*, in particular regarding novelty and inventive activity (the latter to be understood as non-obviousness to persons skilled in the art, and therefore according to available knowledge and excluding the possibility of deducing non-obviousness purely from the resolution of technical difficulties). Finally, patent claims that are too broad should be outlawed, and the ideas that seem to be mooted in this direction at the EPO should be pursued.

**Strict approach to the patentability of processes** The CEES stresses the importance of patenting processes only when human intervention has had a decisive effect on the object obtained and when the process is applied directly at the genome level (provided that the patent holder, in the event of infringement proceedings, is able to prove that it was the patented process that was used and no other). The EPO should keep to the direction outlined in its rulings on the *Broccoli* and *Wrinkled Tomato* cases, to prevent any circumvention of the non-patentability of essentially biological processes.

**Strict approach to the patentability of products** Regarding the patentability of products derived from plant biotechnologies, the CEES discussed the following scenarios that various bodies are currently considering.

1. *Introduction of a comprehensive breeders' exemption into patent law to ensure that, as with the PCPV mechanism, breeders may freely use patented material for the purposes of selective breeding and marketing of a new variety (with no change to the scope of the monopoly over processes).* This proposal formulated in a recent Dutch report<sup>51</sup> would maintain broad access to genetic resources. However, it would require substantial amendments to the legislation and would, in substance, make patents on products purely and simply inoperative, and therefore valueless, since it would make it possible to use, free of charge, not the genetic material on which the innovation is based (as with a PCPV, where the innovation remains the monopoly of the holder), but the innovation itself. Some members also have doubts as to the economic relevance of this proposal when a patent concerns a GMO for which the patent holder has to bear substantial marketing authorisation costs.

2. *Restricting the scope of patentability by excluding from it:*

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<sup>50</sup> See <http://www.euroseeds.org/patent-database>

<sup>51</sup> Louwaars N., Dons H., van Overwalle G., Raven H., Arundel A., Eaton D., Nelis A., (2009). *The future of plant breeding in the light of developments in patent rights and plant breeder's rights*, Centre for Genetic Resources/Foundation DLO, Wageningen.

- a. *Plants derived by essentially biological processes* (even if these plants do not constitute varieties as defined by UPOV: unstable varieties, species, etc.),

- b. *all genes, including isolated genes whose structure and function have been modified*; those in favour of this scenario consider that making genes patentable is profoundly objectionable, as recognition of their patentability would imply appropriation of the knowledge itself and not of its “invention” in the strict sense (to the point where some CEES members see a similarity between the colonization of new territories in the 16th century and appropriation of the living world by multinational companies)<sup>52</sup>. They observe, in this context, that genes should be considered as part of the common heritage of humanity and therefore should not be subject to any kind of patent protection, to ensure that one of the fundamental demands of research can be met, i.e. the free circulation of knowledge. However, this scenario would require extensive amendments to the legislation, which, for political reasons, would be extremely difficult to implement at the international level. It could also potentially disrupt competition between new patent claimants and those who already hold patents on genes.

- c. *native genes (alleles) and characters*<sup>53</sup>. No gene that exists in a living species or any mutant form of a gene or allele that may be obtained through spontaneous mutation or mutagenesis, whether physical (radiation) or chemical (mutagenic agents)<sup>54</sup>, should be patentable. The only exceptions to this exclusion would be genes resulting from molecular engineering that are not a copy of a gene in the above category and are unlikely to be obtained by mutagenesis in the context of selective plant breeding for seeds.

Having assessed the degree of relevance of these scenarios:

- most members of the CEES recommend that all genes should be excluded from patentability, including those modified in the laboratory (they consider this to be the only technically feasible scenario, even though it requires substantial amendments to the legislation<sup>55</sup>);

- otherwise (i.e., if it is impossible to implement this first recommendation):

- they support the proposal for introducing a comprehensive breeding exemption in patent law<sup>56</sup>;

- they consider it necessary in any case to exclude *native genes (alleles) and characters*<sup>57</sup> from patentability, as well as *plants derived by essentially biological*

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<sup>52</sup> See WG report, p. 49.

<sup>53</sup> Following on from the UFS proposal (UFS, 2011, *Protection des Innovations dans le domaine de l'amélioration des plantes.- Nécessité d'une protection forte et pistes en vue d'une coexistence harmonieuse des systèmes de protection*, Paris).

<sup>54</sup> The CEES has not taken a position on synthetic biology. However, **it is obvious that such a proposal cannot be interpreted as postulating the patentability of synthetic genes on principle.**

<sup>55</sup> G. Kastler, F. Jacquemart, R. Dujardin, D. Evain, P. de Kochko, P. Morin, A. Faucon, J.-M. Sirvins, M. Alles-Jardel, P. Gaudray.

<sup>56</sup> F. Jacquemart, G. Kastler, R. Dujardin, D. Evain. Two members (S. Lemarié and J. Lechenet), who do not agree that all genes should be excluded from patentability, nevertheless consider that it may be useful to introduce a breeders' exemption into patent law. The other members do not believe this would ever be effective.

<sup>57</sup> Although they agree that it may be difficult to define a “native” gene precisely and to establish a clear boundary between a “native gene” and a “gene modified by engineering” (mainly because it is impossible to distinguish native alleles from those obtained by targeted mutagenesis).

A **native gene (allele)** is understood here by the CEES as a gene which is part of the gene pool of the target species or a species that can be crossbred with it (including by embryo rescue), whether these are wild ecotypes or cultivated varieties, and which is capable of being produced from another native gene (allele) through random mutation events and may be introduced (recombined) in a variety of the species by cross-breeding (with or without the use of DNA markers). By **native character** is meant a character of any physical or chemical nature whose expression may be observed in any plant, whether a wild ecotype or cultivated variety of a plant species or sexually compatible species (including by embryo rescue) and which may be recombined by cross-breeding (with or without the use of DNA markers). A character that results or may result from random mutation(s) - using chemical or ionizing agents, including those selected by TILLING, etc. - of genes responsible for the expression of a native character remains a native character.

processes; they call on the EPO Enlarged Board of Appeal, which is to give its ruling on the patentability of these plants, to give a negative ruling. **All the members of the CEES are in favour of this solution as a bare minimum.**

**Amendments to relevant legislation on patent infringement.** Finally, in the interests of fairness, in cases of dependence upon patents already granted (and **given that the first recommendation from the CEES remains that native genes should be excluded from patentability immediately**) the CEES considers that the legislation on patent infringements requires amendment:

1. *As regards the conditions applying to infringement suits:* without prejudice to 2, the actions of breeders or on-farm breeders prior to the effective delivery of the relevant information should not provide grounds for infringement proceedings; consequently, the **admissibility of an infringement suit** should be subordinated to prior information delivered to breeders or on-farm breeders by patent holders, their licensees, sub-licensees and distributors (the idea being that blocking the patent holder's right to file a suit will be an incentive to provide the necessary information as early as possible);

2. *Core issues:*

- a breeder or on-farm breeder should be recognized as guilty of patent infringement if it is established (the burden of proof resting on the patent holder) that patented material has been knowingly exploited (in the case where the necessary information was posted from the outset to the database or was acquired by the breeder by other means)<sup>58</sup>;

- a breeder or on-farm breeder should not be recognized as guilty of patent infringement when they have developed and exploited a variety without their prior knowledge of patented material (for example when the information was not in the database or was included in it at too late a date); the breeder should then be able to:

- claim "personal possession prior to" the delivery of the patent, demonstrating proof of prior "possession" of the invention; this would allow the breeder to continue to use the invention on his own account (but not to grant a license for its use)<sup>59</sup>;
- simply continue to fully and freely exploit their variety, provided that they do not lay claim to the characteristic conferred by the patented material if that characteristic is new and not "native"<sup>60</sup>.

## B. IP and the risk of farmers' dependence on the seed industry

The CEES then discussed the question of whether the nature of IP as it stands at present is such as to place farmers in a position of increased dependence on the seed industry. Two issues were addressed: firstly, the question of farm-saved seeds, which give rise to two competing demands: to ensure a return on investments, for the seed industry, and for farmers, freedom to re-sow their fields (1); secondly, the unprecedented risk of infringement to which farmers may be exposed if their crops should accidentally or naturally contain any patented material (2).

### 1) The question of farm-saved seeds

<sup>58</sup> Article L. 615-1 of the IPC should clarify this point.

<sup>59</sup> This solution would require redrafting of Article I. 613-7 IPC to specify that "possession of an invention should also be understood from the [development, by the breeder, of a variety, or its equivalent, obtained by means of a conventional process for which the biological material is later patented]".

<sup>60</sup> Some members of the CEES argue that it would be right for breeders not to make any claim based, for example, on the fact that their variety accidentally contains a gene making it tolerant to glyphosate, but that they should be entitled to lay claim to a characteristic that is otherwise naturally present in their variety (resistance to aphids, absence of gluten, etc.).

French and European law provides for the “farm-saved seeds exemption”, in the case of both PCPVs and patents. Whether the seed is protected by a PCPV or a patent, farmers may therefore, for 21 species and in return for a licence fee paid to the breeder (from which “smallholders” are exempted), propagate the protected reproductive material, so that they do not need to repurchase seeds of these protected varieties each year.

It remains to be determined whether the farm-saved seeds exemption, as currently applied, ensures a fair balance between the interests of breeders and those of farmers. On the one hand, breeders and seed companies stress the importance of this type of remuneration for their activities: they argue that the sector is increasingly competitive, particularly with the presence of patent holders who have highly effective means of collecting their licence fees; they also believe it fair that farmers should contribute to the financing received by breeders for creating new varieties, stressing the high costs of research (12 to 15% of turnover) and the need to maintain diversity in this field of research. While the FNSEA and CNJA agree with these arguments, others are vigorously opposed (*Confédération paysanne*, *Coordination rurale*, MODEF). Those against point to the advantages of using farm-saved seeds (security and flexibility of the seed stock, fewer inputs, locally adapted seeds). They consider that they already contribute to financing for plant breeding, both by buying seeds through commercial distribution networks and because they themselves “maintain crop diversity” (through their adaptive selection work, through informal exchanges of seeds amongst themselves, etc.). Citing their contributions, past and present, to the creation and continuing renewal of crop diversity, they claim an “inalienable right” to sow their fields freely with seeds from their own harvest, whatever the species considered (it should be pointed out here that in French law, using farm-saved seeds was initially banned by the courts and subsequently authorized under certain conditions in 1994 with regard to the European PCPV, in 2008 with regard to patents and in 2011 with regard to the French PCPV). They add that it would be unfair to have to pay a licence fee when international law (the International Treaty on Plant Genetic Resources for *Food* and Agriculture, abbreviated to the “International Seeds Treaty” or ITPGRFA, see *infra* p. 25) advocates benefit-sharing with farmers who have contributed to the conservation and improvement of plant genetic resources and continue to do so (to which breeders reply that this treaty rests on a principle whereby the breeding exemption that allows access for anyone, including on-farm breeders and farmers, to the genetic variability of PCPV-protected varieties, is in itself a form of non-monetary benefit-sharing).

The CEES therefore discussed the balance that needs to be found in this context, observing that as there are no reasons for determining a conclusion in one way or another, this discussion could only be guided by socio-economic considerations.

**ALTHOUGH IT COULD NOT RECONCILE THE OPPOSING VIEWS BETWEEN ITS MEMBERS<sup>61</sup>, THE CEES BELIEVES THAT THE FOLLOWING POINTS SHOULD BE DRAWN TO THE ATTENTION OF POLICYMAKERS AND PROFESSIONALS WHO MAY BE INVOLVED IN NEGOTIATING AGREEMENTS.**

**Like the exercise of IPR holders’ rights, the farm-saved seeds exemption is written into French and European law** (which is understandable if only for reasons of freedom of choice in agricultural production methods - given that for some, it is also a factor of stability in seed prices, the economic performance of farms, etc.).

**This being so, the amount of the remuneration must ensure a fair balance between the interests of seed companies and those of farmers;** there *may* be grounds for a

<sup>61</sup> The following members are against any form of remuneration: G. Kastler, D. Evain, P. de Kochko, J.-M. Sirvins, P. Gaudray. The following members are in favour of the system established by the Act of 2011: M.-A. Hermitte, J. Lechenet, M. Alles-Jardel, S. Lemarié, M. Callon. Members abstaining on this point: F. Jacquemart, R. Dujardin, P. Morin, Ch. Pernin, S. Pradelle, A. Faucon.

redefinition, with a view to greater flexibility, of the number of species covered by the exemption and of the “smallholder” exemption from license fees<sup>62</sup>.

**Farmers who do not seek to reproduce a seed identically** (conservative breeding), but to use it as the point of departure for selective breeding of landrace varieties in the field, should be entitled to do so without paying a licence fee (re-sowing takes place in this case by virtue of the breeders’ exemption). Since the burden of proof is on the claimant to a right, the onus should be on the IP rights holder to establish that “conservative breeding” is taking place (for example by showing that the farmer has a plot for seed propagation which is separate from the crop fields and/or that the farmer is using the variety denomination).

## 2) Risks of patent infringement

Is the increasing number of patented varieties liable to place farmers, for the first time, in a position of patent infringement, either because they are growing crops with seeds from a variety that contains *patented material of which they are unaware* (case of a patented native gene or character)<sup>63</sup>, or because patented material is accidentally present in their crops (contamination in a package of seeds or gene flows in their field), or because they are seeking to take advantage of its presence without having purchased the patented seeds? Assumptions such as these have been taken seriously since the case of *Schmeiser vs. Monsanto Canada Inc.* that came before the Supreme Court of Canada<sup>64</sup>. This case is a not really representative, however, because the ruling was made on the basis of Canadian rather than French law, and secondly because the farmer in this case had *knowingly* harvested Monsanto glyphosate-resistant rapeseed, which he had kept and subsequently re-sown in some of his fields. Even if he had not treated his crops with glyphosate - his intention having been to use the genetic base of the variety, which is why he was not ordered to pay punitive damages (i.e. to hand over his profits as a penalty for a fault with a view to gain), he had reproduced the transgene and was therefore guilty of infringement under patent law.

*This case nevertheless sheds light on new issues that farmers may have to face. Under French law, a farmer could objectively be found guilty of patent infringement, whether or not he acted in good faith (acting in good or bad faith only has an effect on the damages to be paid)*<sup>65</sup>. In the case of a dispute, it could be argued, to avoid a conviction, that the farmer not only did not act deliberately, but also acted with no possibility of controlling the situation, into which he was effectively forced. However there is no certainty that a judge would uphold this argument. Similarly, it would be possible to cite the *Monsanto vs. Cefetra* precedent, which holds that patented material is protected only when the gene is “*capable of performing*” its function; however, any patented gene present in a farmer’s crop could be considered *likely* to perform its function. The risk is obviously limited in the case of a herbicide tolerant gene, at least if the farmer does not use the associated herbicide, but a court could rule differently and consider that the gene is nevertheless “*capable of performing*” its function”. The risk is considerable, however, in the case of a gene coding for an insecticide or a gene that, for example, increases the Omega 3 fatty acid content, because both perform their functions inherently, independently of the farmer’s intentions. Therefore, as the concept of infringement now stands, it would be very difficult to argue that the farmer is not guilty of infringement, even if he was unaware of the presence of the patented gene and/or could not remove it from his crop. Although probably limited in practice in France, as long as the cultivation of patented crop plants does not become widespread, the risk of legal action does exist,

<sup>62</sup> On the conditions pertaining to this twofold suggestion, see WG report p. 58.

<sup>63</sup> This would be the case for a farmer who did not purchase the patented seeds, because once a farmer has purchased seeds, s/he can not only market the crop but also re-sow part of the harvest (being entitled to the exemption for farm-saved seeds under Article L. 613-5-1 IPC, in accordance with the provisions of Regulation 2100/94/EC).

<sup>64</sup> See more detailed discussion and references in WG report p. 58 and further.

<sup>65</sup> IPC, Art. L. 615-1 para. 3.

even if the threat is only wielded for purposes of intimidation by the patent holders. The risk is particularly great for farmers using farm-saved or landrace seeds, in which potentially patented genes or characters are liable to accumulate year after year in their fields.

**GIVEN THIS CONTEXT, THE CEES CONSIDERS THAT THE FOLLOWING CHANGES ARE DESIRABLE.**

1. Information for farmers: farmers should be informed of the presence of patented material in the seeds they purchase. At present, GM seeds must bear a "GMO" label, but the label gives no indication as to the possible presence of patented material. Furthermore, an increasing number of patents are delivered on non-GM seeds. In this context, additional information for farmers seems necessary<sup>66</sup>.

2. Conditions applying to infringement proceedings: without prejudice to 3, the actions of breeders or on-farm breeders prior to the effective delivery of the relevant information should not provide grounds for infringement proceedings; consequently, the *admissibility* of an infringement suit should be subordinated to the prior delivery of information to breeders or on-farm breeders by the patent holders, their licensees, sub-licensees and distributors (the idea being that blocking the patent holder's right to file a suit will be an incentive to provide the necessary information as early as possible);

3. Patent infringement criteria:

- farmers should be found guilty of patent infringement only if it is established (*by the patent holder, who bears the onus of proof*) that a variety containing patented material was used by the farmer *knowingly and with the intention of exploiting the patented function or functions*<sup>67</sup>.

- when it has not been established that a farmer used a plant containing the patented material *knowingly and with the intention of exploiting the patented function or functions*, the farmer should be able to continue to use the product of his harvest *freely and with no limitation in time if he does not lay any claim to the patented function, provided that this function derives from a new and not a native character*<sup>68</sup>.

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<sup>66</sup> On seed packages, delivery slips and invoices and/or in the future database mentioned above p.18. On this point see WG report p. 62.

<sup>67</sup> Article L. 615-1 IPC should be amended to provide for this.

<sup>68</sup> See note 60 above. For example, a farmer should be entitled to continue to lay claim to the low-gluten character of his variety if that character is expressed naturally by the variety, independently of the patented character.

## C) IP and genetic diversity of cultivated plants

In the last two centuries, plant breeding has taken place from an increasingly limited genetic base. Although IPR have been only one of the many factors determining this trend, the WG discussed the adaptations that could contribute, in this area, to the redeployment of interspecies and intra-species diversity in crop plants. The first question concerns the conservation of plant genetic resources through the international network established by the international Treaty on Plant Genetic Resources for Food and Agriculture (“International Seed Treaty”) (1). The second question focuses more specifically on strengthening the role of “on-farm plant breeders” in the conservation of crop plant biodiversity *via* the determination of a legal status for landrace varieties<sup>69</sup> (2).

### 1) Conservation of plant genetic resources under the multilateral system established by the “International Seed Treaty”

Access to genetic resources is crucial to the activities of plant breeders. This is what led to the adoption of the “International Seed Treaty” (ITPGRFA) in 2001, under the auspices of the FAO<sup>70</sup>. This treaty recognizes “the special nature of plant genetic resources for food and agriculture” and in particular, the fact that they are “the indispensable raw material for crop genetic improvement” and “essential in adapting to unpredictable environmental changes and future human needs”. It therefore sought to encourage conservation of these resources, the creation of networks to facilitate access to them under certain conditions of “fair and equitable” benefit-sharing and the development of cooperation for these purposes. This is known as the multilateral system for plant genetic resources for food and agriculture (PGRFA)<sup>71</sup>.

The conservation of resources is considered in two ways that are complementary: *ex situ* and *in situ*.

The Treaty promotes *ex situ* conservation as a priority and, in particular, sound management of *ex situ* collections. Ex-situ collections include what are commonly known as “gene banks” - collections of seeds or plant tissue conserved under controlled conditions, and collections of open-grown plants that make up reserves from which plant populations, individuals or characters of interest may be used. The common characteristic of these collections is that they are managed outside their natural environment. Responsibility for their management lies with national or international public or private sectors.

Second in priority is *in situ* conservation, for which the Treaty calls on States to encourage “farmers’ and local communities’ efforts to conserve on-farm their plant genetic resources for food and agriculture”. For the purposes of sustainable use of these resources, the Treaty calls on States to encourage the implementation of agricultural policies and systems that enhance diversity and plant breeding efforts in association with farmers.

The multilateral system established basically encompasses all resources that are “in the public domain”. While it refers explicitly to the *ex situ* collections managed by the CGIAR, the system is based on the broadest possible inclusion of PGRFAs of every kind. The Treaty does not provide

<sup>69</sup> At least plants that do not meet the UPOV criteria (distinctiveness, homogeneity, stability - DHS).

<sup>70</sup> Adopted by the UN conference on 3 November 2001 and approved by the French Parliament on 11 July 2005, the “International Seed Treaty” (ITPGRFA) has been partly incorporated into domestic law (cf. Act of 8 December 2011 mentioned previously).

<sup>71</sup> It encompasses all PGRFAs of the 64 species listed in its annex 1 that are managed by the contracting parties and belong to the public domain, as well as the *ex situ* collections managed by the International Agronomic Research Centres of the Consultative Group on International Agricultural Research (CGIAR). States are furthermore urged to invite “all other holders of PGRFAs”, whether physical or corporate persons, to contribute these to the multilateral system.

explicitly for the inclusion of resources cultivated *in situ*, but does not preclude this. There is a precedent in this regard, from Peru, which is of interest despite the non-European context. Six Indian communities that had formed an association working with the Cuzco Park for the conservation of Peruvian potatoes notified the Treaty Secretariat in 2008 of the contribution of genetic resources they were conserving *in situ*, making them easily accessible in accordance with the Treaty's rules. Noting that to date, contributions to the multilateral system are essentially from the international *ex situ* collections managed by the CGIAR and that efforts from States to include their own national collections are as yet inadequate, the CEES has observed the Peruvian initiative with interest as it may offer a new way of contributing to the multilateral system and inspire similar activities in France.

#### THE CEES WISHES TO STRESS TWO POINTS IN THIS CONTEXT:

**It notes that to date, French participation in the multilateral system is not sufficiently active** (with only two private collections - of maize and wheat - contributed to the multilateral system) and that by virtue of Article L. 660-3 para 2. of the Rural Code (Act of 8 December 2011), the scope of the French collection that should be enriching the multilateral system could be broadened<sup>72</sup>. It considers that this collection should include all of the collections managed by public organizations and that private collections should be encouraged to add to its content (NB: in the WG report to the CEES, some WG members considered that the national collection should also include landrace varieties and varieties registered in the catalogue and/or protected by a PCPV<sup>73</sup>). It calls for the necessary means to be rapidly deployed for this purpose.

**It considers that the French government should adopt a public policy for the conservation of plant genetic resources.** Such a policy would demand: 1. The designation of an authority responsible for coordinating and implementing the policy, to be recognized nationally and internationally and open to all interested parties, including farmers (Art. 9 of the Treaty); 2. the allocation of financial and human means to ensure access to the collections for public establishments.

## 2) *In situ* conservation and legal status of landrace varieties derived by small-scale plant breeders

Because landrace species and varieties are the result of interactions between a genotype and an environment, their conservation *in situ* is essential in parallel with static *ex situ* conservation. This is why the FAO recommends that farmers should be reinstated at the core of conservation systems, stressing their pivotal role in the circulation and adaptation of cultivated plant germplasm to economic and ecological changes affecting cultivation systems. It is this dynamic management approach that "on-farm breeders" claim to represent. They do not merely duplicate commercial varieties, but seek to adapt them, in the field, to their production objectives and to the prevailing ecological conditions on their farms. The result are "landrace" varieties that are better suited to local conditions, in other words eco-types expressing common characters derived from variable recombinations of different genotype groups, and which therefore do not fulfil the criteria for catalogue registration and PCPVs.

The CEES notes the relative aspects of this type of plant breeding: Although there are no verifiable figures that can be relied on, it has been estimated in the case of maize, for example, that a few hundred hectares (GNIS estimation) to several thousand hectares (estimation from certain agricultural organizations) are sown each year with landrace varieties, as against 3 million hectares with certified hybrid maize varieties. In parallel, the contribution of these landrace varieties to the conservation of

<sup>72</sup> See WG report, p. 67 and note 20.

<sup>73</sup> Although these are already accessible by virtue of the breeders' exemption.

genetic diversity in cultivated plants is not currently assessed. The CEES observes nevertheless that these varieties (old varieties that are no longer on the market, original populations, etc.) are a contributing factor to diversity, particularly in view of the adaptation of crops to environmental changes. They also broaden the range of seeds on offer, as demanded by certain farmers and consumers. For this reason, and because on-farm plant breeders are included among socioeconomic players, the questions they raise must be taken into consideration in discussions on changes to the IP system.

*Their representatives (the Confédération paysanne in particular) point out that in recognition of their contributions to the conservation and improvement of PGRFAs, the “International Seed Treaty” acknowledges farmers’ rights and in particular the right to take part in decision-making concerning the use of PGRFAs and to receive an equitable share of the resulting benefits. On these grounds: 1. On-farm plant breeders demand the right to freely exchange and sell the seeds of the landrace varieties they cultivate; they underline the specific nature of their breeding and dynamic conservation activities, which take place in their crop fields and not in specific separate plots, as well as the resulting particular quality of their seeds; they consider that prohibiting reproduction and exchanges of their seeds on the grounds that the remainder of the harvest is sold on agricultural markets in effect rules out any form of small-scale plant breeding; 2. they also want to be able to pursue their activities without being considered as counterfeiters of the varieties they use, since these varieties - which are sometimes protected - are the basis for a selective breeding process that does not seek to duplicate the same variety exactly; 3. Finally, because they contribute to the conservation and improvement of PGRFAs “from generation to generation”, and because landrace varieties are sometimes used as the basic material for breeding varieties that are subsequently IPR-protected, they consider that they should have free access, without charge, to seeds derived from the cultivation of protected varieties, by virtue of the benefit-sharing principle applying to the sale of new varieties.*

***The CEES has been apprised of the WG’s analysis of these arguments. It observes that as the law stands:***

- For on-farm plant breeders, possibilities for PCPV protection for their landrace varieties are uncertain; they depend on the distinctiveness, homogeneity and stability of the population, but also on the way the legislative texts are interpreted (in particular, the notions of a “variety” defined by “the characters derived from a certain genotype or a certain combination of genotypes”, and of “stability”, which is defined as the “suitability for being propagated unchanged”, are wide open to interpretation);
- most landrace varieties cannot be registered in the official catalogue<sup>74</sup>, which implies that their seeds cannot be marketed (EUCJ, *Kokopelli*, 3<sup>rd</sup> ch., 12 July 2012, case n° C-59/11) or exchanged between farmers, unless such exchanges are not for “commercial purposes” (a notion that is also open to interpretation).
- under European and French law, no specific returns are stipulated for on-farm breeders whose plant populations may have been used as the basis for breeding a subsequently protected variety<sup>75</sup>.
- “on-farm breeders” are potentially exposed to a specific risk of infringement proceedings (a risk which is additional to those described above and for which the WG has formulated recommendations), since landrace varieties could be considered as “essentially derived” (EDV) from protected varieties that were initially used, at least for the first multiplications. However, the legal experts on the WG

<sup>74</sup> Some landrace varieties that meet the UPOV definition of a variety are registered in the official catalogue.

<sup>75</sup> The International Seed Treaty stipulates that when a new variety developed from a resource in the multilateral system is ultimately patented, a percentage of the resulting profits is paid into a benefit-sharing fund. It furthermore points out that when the new variety is protected by a PCPV, the breeders’ exemption is in itself a non-monetary form of benefit-sharing. As argued by some members, farmers do not necessarily benefit from this non-monetary form of benefit-sharing as it is not guaranteed by the Treaty.

considered that this is a limited risk, as it would imply firstly that landrace varieties satisfy the definition of a “variety” set out in the UPOV Convention - which is not certain - and secondly that plants cultivated in specific plots - separate from those used for the crop - are marketed; if not, the on-farm breeder would be entitled to the breeders’ exemption. It is nevertheless the case that on-farm breeders frequently breed their plants in their crop fields, which implies that they could be sued for reusing or exchanging farm-saved seeds.

**CONCURRING WITH THE AUTHORS OF THE REPORT ON “SEEDS AND SUSTAINABLE DEVELOPMENT” (2011), THE CEES CONSIDERS THAT, IN THE NAME OF DIVERSITY, there is a need to explore avenues that would enable on-farm breeders to exercise their activities, without destabilizing the current framework applying to legal protection for plant varieties and the regulations applying to seeds. The CEES considers it important that the working group established by the Ministry of Agriculture specifically to address these questions should find solutions that are acceptable to all. Therefore, for information, it draws the working group’s attention to the following points.**

- First of all, having previously defined the criteria that distinguish “evolutionary plant breeding” from “conservative breeding”, cf. *supra*<sup>76</sup>, the CEES points out that on-farm breeders are entitled to the breeders’ exemption. Logically, therefore, the restrictions on using farm-saved seeds should apply only to farmers who practice conservative breeding in order to reproduce, as a fixed variety, all of the distinctive characters and only the distinctive characters of a protected variety.
- Secondly, the CEES draws attention to the necessity, as set out in the “Grenelle 1” Act of 5 August 2009, of opening up the official catalogue (at least a form of the catalogue) to landrace varieties, which would allow market access to those for which an application for registration is made<sup>77</sup>. The CEES stresses that the resulting access to the market should be governed by clear rules.
- Finally, the CEES considers that the rules on exchanges of landrace seeds need to be amended. Such exchanges should be considered legal if they do not create a parallel market to the commercial seed market; therefore, direct transfers, from the producer to the end user, of small quantities of landrace seeds should be permitted.

*However, the CEES has not taken a position on the following questions:*

- Redefinition of the UPOV Convention’s definition of a “variety”. The redefinition proposed by some members of the CEES<sup>78</sup> would expressly include landrace varieties as “varieties” as defined by UPOV; landrace varieties could then serve as a reference for appraising the novelty of varieties for which a PCPV is claimed. A variety would then be constituted by: “a plant grouping within a single botanical taxon of the lowest known rank” (Article L. 623-1 of the IP Code). Genetically, at least two main types of varieties must be distinguished: 1° “Landrace varieties”, made up of individuals with phenotypic characters that are similar but whose wide variability allows them to evolve according to the conditions in which they are cultivated. These varieties are defined by the expression of characters that result from variable combinations of several genotype groups. 2° “Genetically fixed varieties or combinations of fixed varieties”, “1° defined by the expression of characters resulting from a certain genotype or a certain combination of genotypes”; “2° distinct from all other plant groupings by the expression of at least one of the said characters”; “3° considered as an entity in the view of their suitability for being propagated unchanged”. They propose an addition to Article L. 611-19 of the IP Code as follows: “The following are not patentable: [...] 2° plant varieties as defined in Article L.

<sup>76</sup> It is pointed out here that in its report, the WG is divided as to the usefulness of amending texts on patent infringement to ensure that only an identical reproduction of the protected variety can be described as an infringement. If absolutely necessary to ensure legal certainty, the WG considered that article 623-4 of the IPC should be amended as follows: “seeds propagated by open pollination with no conservation breeding and/or no mass selection for local adaptation cannot constitute a variety derived essentially from a PCPV-protected variety”. See WG report, p. 75.

<sup>77</sup> A twofold difficulty nevertheless lies in the fact that since landrace varieties evolve with repeated propagation of populations in conditions of open pollination and/or mass selection, they may encompass very large groups of plants and thus anticipate any new variety. See WG report, p. 73.

<sup>78</sup> And which would determine the criteria for catalogue registration defined by the CPVO or UPOV according to species.

623-1 of this Code” (to avoid patent protection for varieties that do not meet the DHS criteria). Some members of the WG did not agree with this change. They consider, firstly, that it would disrupt the PCPV system to no real purpose in their view, and secondly that it would substantially complicate appraisals of the distinctiveness criterion (which could no longer be applied to distinguish any new variety from previous landrace varieties, these being evolutionary by definition)<sup>79</sup>.

- “Benefit-sharing” for on-farm plant breeders. For their contribution to the conservation and development of plant genetic resources, on the one hand, and by virtue of the “benefit-sharing” principle set out by the “International Seed Treaty”, on the other hand, some members of the CEES call on plant breeders with IP rights to provide financial support for the dynamic management of seeds by on-farm breeders. They propose that this support should be provided either through a tax on non-reproducible seeds sold in France (patented seeds, F1 hybrids, varieties protected by a PCPV that prohibits or restricts the use of farm-saved seeds and therefore farmers’ access to genetic diversity), or through a percentage levied on fees paid in return for farm-saved seeds exemptions (these fees are currently used for joint research programmes on wheat run by breeders, INRA and technical institutes). Some WG members were not in favour of this proposal, for three reasons. They argue first that benefit-sharing is already in place under the “International Seed Treaty” via national benefit-sharing funds. Secondly, they consider that the breeders’ exemption is in itself a form of benefit-sharing, as mentioned in the “International Seed Treaty”. Finally, they consider that additional benefit-sharing rules at the national level would not be legitimate as conventional breeders also contribute, in their own way, to the conservation of plant genetic resources.

#### **Annex: CEES members present and represented for the adoption of this recommendation**

Monique Alles-Jardel (High Council for Public Health), Michel Callon (qualified person appointed for his expertise in sociology), Patrick de Kochko (Friends of the Earth), Rachel Dujardin (Greenpeace), Daniel Evain (*Fédération Nationale d’Agriculture Biologique* - National Organic Farming Federation), Arnaud Faucon (*Confédération Générale du Travail* - Trade Union), Patrick Gaudray (*Comité Consultatif National d’Ethique* - National Consultative Committee on Ethics), Marie-Angèle Hermitte (qualified person appointed for her legal expertise), Frédéric Jacquemart (*France Nature Environnement* – environmental NGO), Guy Kastler (*Confédération Paysanne* – farmers’ union), Jacques Lechenet (*Les Entreprises du Médicament* – federation of pharmaceutical companies), Stéphane Lemarié (qualified person appointed for his expertise in economics), Paulette Morin (*Comité Interassociatif sur la Santé – Alliance Maladies rares* – federation of health and rare diseases associations), Charles Pernin (*Consommation, Logement et Cadre de Vie* – consumer association), Sylvie Pradelle (*UFC Que Choisir* – consumer association), Jean-Marie Sirvins (*Union Nationale des Apiculteurs de France* – French beekeepers’ union).

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See WG report, p. 76.