

## EUROPEAN SEED ASSOCIATION AND CURRENT TOPICS IN THE EUROPEAN SEED SECTOR

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### SUMMARY

ESA - European Seed Association was founded in November 2000 and merges former member associations as well as individual companies into one single EU wide organization representing the totality of the European seed industry active in research, breeding, production and marketing of seeds. Today, ESA represents more than 30 national seed associations from EU Members States and also non EU member European countries and with that several hundred seed companies throughout Europe. Next to the association members, ESA's membership also comprises more than 40 individual company members, both multi-national as well as highly specialized small and medium sized enterprises and associate members from seed related industries.

ESA is a classical industry organization representing the interests of its membership, the European seed industry, towards the relevant European institutions and international instances. In its mission ESA focuses on working for an effective protection of intellectual property rights relating to plants and seeds; a fair and proportionate regulation of the European seed industry; and freedom of choice for customers (farmers, growers, industry, consumers) in supplying seeds as a result of innovative, diverse technologies and production methods.

One of the major projects that has kept ESA and its members busy for years now is the ongoing review of several pieces of seed-related EU legislation. The EU legislation on seed marketing, on plant health, on GMOs as well as on plant variety rights are all under review and are expected to undergo some changes in the coming years. Given that all these topics are clearly of crucial importance for all ESA members, as influencing their day-to-day business, ESA has been actively working on achieving a fair regulation for the European seed industry in all these aspects.

The evaluation exercise concerning all abovementioned pieces of law has already been concluded and the projects have now entered the phase where draft legislative texts have to be drafted by the competent European institutions. The revision of the EU seed marketing and plant health legislations is expected to be finalized in 2012/2013 and the GMO and plant variety protection legislations in the following years. In order to achieve the desired goals of its membership ESA will continue to lobby for the positions of the European seed industry throughout the legislative procedure.

Key words: European seed association, legislation, intellectual property

### **European Seed Association**

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In the recent years legislative reviews of almost all pieces of EU law regulating the different aspects of the seed sector (seed marketing, plant health, plant variety protection, etc.) have been in the focus of the work of ESA. On the other hand, another crucial topic, intellectual property protection for plants and seeds and in particular the question of interface between patents and plant breeder's rights, has also cost several years of discussion and work and resulted in the adoption of a new industry position in September 2011. It can be expected that these issues remain in the main focus for the coming years as the current discussions will not result in new EU legislation before 2013/2014. Nevertheless, it is worthwhile to have an insight to the current state of affairs on a number of these matters.

### **The EU regulatory framework for plants and seeds**

Back in the 1960s the EU seed marketing legislation was adopted to set the framework for the free movement of seeds among the Member States of the European Union; to create the ‘common market’ for seeds within the EU. The key objective of the legislation is to operate a system which promotes innovation by ensuring that only good quality seeds of improved varieties are put on the European market; allows the quick and effective transfer and sharing of such innovations that new plant varieties represent with the users, i.e. farmers and growers; and enhances the competitiveness of European agriculture. So far this European common market for seeds has been very effective in realizing these goals; the seed marketing legislation has, in principle, been a very successful tool in facilitating the entry of ever better plant varieties to the EU market.

However, it has to be admitted that the current legislation is very complex consisting of 12 basic EU directives and many implementing regulations that have been transposed into the national laws of the 27 EU Member States. By now, this complexity has achieved the level where the need to improve and simplify the legislative framework comes clear. Therefore the European Commission decided to review the regime with the aim of making it better suited to the needs of plant breeders, farmers and to the needs dictated by the current and future global challenges.

The European seed marketing legislation sets the conditions under which varieties of determined plant species can be marketed within the EU, which conditions relate to two main procedures: variety listing and seed quality assurance. The legislation defines a number of uniform criteria and minimum requirements to ensure that only clearly identifiable plant varieties are put on the market, supported by adequate agronomic information favouring thus the interests and protection of farmers. A variety that is tested, proves to fulfil all the necessary criteria and is identified by an acceptable variety denomination becomes listed and is included in the EU Common Catalogue, making it freely marketable within the EU.

To be listed, varieties have to be distinct, uniform and stable (DUS), in order to ensure that farmers and growers have a choice of clearly identifiable and comparable varieties and have to be measured for their variety performance in respect of which information has to be provided to the consumer. In the case of agricultural plant species such variety performance is ensured by the value for cultivation and use (VCU) requirement which reflects the expression of the importance that legislator, society, seed industry and farmers attribute to ensuring the ever improving performance of agricultural plant varieties brought to the market while in the case of vegetable species variety performance is measured differently.

It is vital that not only the genetic expression of the variety but also the physical quality of the seed correspond to well-defined criteria to the benefit of farmers, growers and final consumers. In the case of agricultural species seed quality is guaranteed via obligatory seed certification whereas for vegetable species no obligatory seed certification applies but the quality of the seed is assessed and maintained in other ways, usually through in-house quality assurance systems.

As a matter of fact, ESA is of the opinion that the EU seed marketing legislation should be maintained with its key features (DUS, VCU, seed certification) as currently regulated while a number of aspects of the regime should be improved in order to make the legislation better suited for the needs of the industry and create a more efficient system with less financial and administrative burdens. Elements of ESA's position include achieving better efficiencies in DUS testing, working for a more extensive involvement of the private sector in testing and certification but strictly under official supervision, advocating for a more enhanced role for the Community Plant Variety Office in the implementation of variety denomination rules and in the management of the EU Common Catalogue which should become a more user-friendly, real-time on-line tool.

In 2009 the European Commission decided to combine the review of the seed marketing regime with that of the European plant health legislation and of the harmonized EU framework for food and feed controls (Regulation (EC) No. 882/2004) and to present a legislative package by the end of 2012.

In principle, ESA supports this initiative as it sees the opportunity to make the regulatory framework better adapted to both the EU of 27 Member States and to the developments of the sector. In respect of plant health the main request of ESA focuses on the establishment of the principle and possibility of delegation of official tasks to private operators under official supervision to carry out plant health related inspections and tests. Besides this key element, also a better involvement of stakeholders in the governance of the EU plant health policy and its implementation; improvement of the rules for re-export certificates of seed; and improvement of the plant passport system figure on ESA's agenda. As regards food and feed controls, ESA supports making use of the existing harmonized EU control framework also for the purposes of seed marketing and plant health while leaving the sector specific elements in place whenever it appears appropriate.

### **Intellectual Property for plants and seeds**

#### *Towards a revised Community Plant Variety Rights system*

In 1994 Regulation (EC) no. 2100/94 was adopted by Members States of the EU with the aim of creating a Community plant variety right (CPVR). The EU regulation is based on the 1991 version of the UPOV Convention and creates a unique system of intellectual property rights with the advantage of providing protection for new plant varieties covering the whole territory of the European Union. As under UPOV 1991, a variety for which protection is sought has to be new, distinct, uniform and stable and dispose of a suitable variety denomination in order to be able to benefit from a CPVR. The scope of the right covers the acts as provided for in Article 14(1) of UPOV 1991 and extends also to the harvested material of the protected variety as well as to varieties which have been essentially derived from a protected variety guaranteeing thereby a better protection against infringements and cheap copying. Under the CPVR system a derogation - allowing farmers to use farm saved seed of protected varieties belonging to

some 21 crop species on their own holdings against an equitable remuneration to the right holder - has also been enacted (see Article 14 of regulation 2100/94). The management of the CPVR system is ensured by the Community Plant Variety Office (CPVO) which is an independent EU agency based in Angers, France.

In principle, the CPVR system has proved to be a very effective system allowing breeders to protect the results of their time-consuming R&D work via a single IP title covering the full territory of the EU. However, besides the fact that the legislation is now 15 years old and needs to be evaluated in view of new challenges, it has to be admitted that the system has some significant weaknesses which should be remedied. Therefore, in May 2010 the European Commission decided to launch a review of the regulation to identify areas necessitating improvements.

European plant breeders are to a large extent satisfied with the performance of the CPVR system and think that it has stimulated sustained investment in plant breeding by creating a framework for fair return on investment. As the UPOV Convention, also the CPVR system provides for the compulsory exception to the breeder's right, the so-called "*breeder's exemption*" which – by allowing for the use of protected varieties for further breeding as well as for the marketing of such newly bred varieties without any obligations towards the right holder – has greatly enhanced the innovative power of the European plant breeding sector and thus has proved to be a cornerstone of the system. On the other hand breeders experience that the lack of effective and uniform possibilities for the enforcement of CPVRs has been the weak point of the system and needs urgent improvement. Therefore the focus of ESA's work in respect of this review is on achieving better enforcement possibilities for breeders in all aspects of CPVRs and in particular in the field of collecting information and royalties on farm saved seed use. Besides this major issue, clarification of a number of provisions (such as harvested material, EDVs, etc.) as well as improvements in order to achieve better efficiency and harmonization with other pieces of seed legislation (such as the seed marketing legislation) are also necessary.

#### *The question of interface between patents and plant breeder's rights*

Since decades European plant breeders have been benefitting from the *sui generis* intellectual property system of plant breeder's rights (PBR) based on the UPOV 1991 Convention which provides effective IP protection for new plant varieties as such and fits the specific nature and needs of the industry. As already explained above, an important cornerstone of the UPOV-type PBR systems is the "*breeder's exemption*". This feature can be regarded as a kind of "open source" model and has always been relied upon by breeders for further improvement on each other's varieties and boosted innovation in plant breeding.

Besides PBR however, another type of intellectual property right, patents, have started to become more and more widespread and important in the European seed sector in the last few decades. First, patents in the seed sector were granted on GM traits, inventive breeding techniques and other technological tools but nowadays patents

interfere more and more with traditional breeding work (based on crossing and selection). While in theory plant varieties as such are excluded from patent protection and are protected by plant breeder's rights, in practice – as a result of the specific nature of biotechnological patents – plant varieties often, in the end, fall under the effect of certain patents, which may block access to varieties for further breeding which varieties otherwise would be free under PBR. This problem of interface between the two IP systems has driven ESA to recently adopt its position on this important matter.

The core element of ESA's position is that *free access to all commercially available plant genetic material for further breeding has to be safeguarded*. The position aims to achieve this via creating freedom-to-operate in the field of crossing and selection. The position is proposing a solution to the above described interface problem in two steps: (i) by arguing for a limitation of patentable subject matter and (ii) by proposing the introduction of a limited breeder's exemption (extended research exemption) into patent laws.

*(i) Limitation of patentable subject matter*

1. Breeding processes based on crossing and selection (i.e. essentially biological processes) are excluded from patentability.
2. This principle must also be applied to biological material resulting from the application of such “essentially biological processes”.
3. The effect of any product patent on biological material must not extend to any biological material which has the same properties, but has been produced independently, i.e. without using the patented material, by means of an “essentially biological process”.

Building upon the already existing (and - in the Broccoli decision<sup>1</sup> - recently confirmed) exclusion from patentability of ‘essentially biological processes’ (i.e. breeding processes based on crossing and selection) the position claims that logically also biological material resulting from the application of such essentially biological processes should be excluded from patent protection. In practice it entails that a plant or plant trait should be patentable only if it is produced by a process which is not based on crossing and selection. This would be the case if, for example, a process consisting of genetic modification, technically induced mutagenesis, protoplast fusion or another technical process not based on crossing and selection is used. According to the position, the decisive question for patentability should therefore be the process which is used for the production of the biological material. Last, in order to fully safeguard freedom-to-

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<sup>1</sup> Decision of the Enlarged Board of Appeal of the European Patent Office of December 9, 2010 in cases G1/08 and G2/07. The *Broccoli decision* states that non-microbiological processes containing or consisting of the sexual crossing of whole plant genomes and the subsequent selection of plants are not patentable under Article 53(b) of the European Patent Convention. It further clarifies that this principle does not change even if there are additional technical steps involved in the process where these technical steps serve merely to enable or assist the performance of the crossing or the selection steps.

operate in the field of crossing and selection the position claims that the effect of patents granted on plant-related inventions should not extend to biological material having the same properties as the patented material but produced independently, without the use of the patented material, and by a breeding process based on crossing and selection.

*(ii) Introduction of a limited breeder's exemption (extended research exemption) into patent laws*

The rights conferred by a patent shall not extend to the use of biological material for the purpose of breeding, or discovering and developing a plant variety.

It is rather straightforward from the above described position on patentability that the European seed industry wishes to see less patents granted in the field of plants and seeds. By this it can be achieved that only real inventions benefit from the exclusive right a patent means leaving routine breeding work operate without any hindrance. On the other hand, it is also the common opinion of the sector that once a patent is granted its value should be respected – without prejudice to the principle of freedom-to-operate in the field of crossing and selection. Therefore, in respect of the issue of commercialization of biological material containing a patented element, ESA takes the view that it should be left to the bilateral agreement of the patent holder and the breeder of the new variety to find a deal for commercialization. ESA however calls upon the patent holders to follow fair, reasonable and non-discriminatory conditions in their licensing policies.

After having set the main direction it now remains to be seen how these requests of the European seed industry can be achieved. Identifying possible approaches that may lead to a fast and binding implementation of the above position will be in the focus of the work in the coming months.

## **EUROPSKO UDRUŽENJE SJEMENARA I AKTUALNA SITUACIJA U EUROPSKOM SEKTORU SJEMENARSTVA**

### **SAŽETAK**

ESA Europsko udruženje sjemenara osnovano je 2000. godine objedinivši bivše članice udruženja i pojedinačne tvrtke u jedinstvenu organizaciju Europske unije koja u potpunosti predstavlja europsku industriju sjemena aktivnu u istraživanjima, oplemenjivanju, proizvodnji i marketingu sjemena. Danas ESA zastupa više od 30 nacionalnih udruženja sjemenara država članica Europske unije kao i onih izvan nje odnosno nekoliko stotina sjemenskih tvrtki iz cijele Europe. Osim nacionalnih udruženja sjemenara članice ESA-e su i više od 40 pojedinačnih bilo multinacionalnih ili specijaliziranih malih odnosno srednjih tvrtki kao i pridruženih udruženja sa sjemenom povezane industrije.

U radu je dat prikaz aktualne zakonske regulative s područja sjemenarstva u Europskoj uniji te je obrađen pravni aspekt intelektualnog vlasništva u području biljnih sorti i sjemenarstva.

Ključne riječi: Europsko udruženje sjemenara, zakonska regulativa, intelektualno vlasništvo

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### Plant health

[http://ec.europa.eu/food/plant/organisms/index\\_en.htm](http://ec.europa.eu/food/plant/organisms/index_en.htm)

### Plant variety rights

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### ESA and its positions

<http://www.euroseeds.org/position-papers>

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