



Names of all contributors to the briefing:	(G1),	(E3)
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Steering note for the Deputy Director-General

Context

You will meet for the first time the **second** of the Community Plant Variety Office (CPVO), **second**. This is an amicable visit.

Participants



Topics

CPVO would like to present itself and raises a number of issues, most of which were recently discussed in more detail in the annual Sante-CPVO meeting of 7 September 2020:

- 1. Presentation of CPVO activities
- 2. Priorities of DG SANTE
- 3. Cooperation DG SANTE and CPVO
 - 3.1 Involvement of CPVO in relevant policy roadmaps
 - 3.1.1 Farm to Fork strategy: how to contribute
 - 3.1.2 EU IP Strategy
 - 3.2 Update of Basic Regulation/Implementing Rules on Farm Saved Seed following jurisprudence of the CJEU
 - 3.3.1 Update on the legal provisions on the duration of protection
 - 3.3.2 Study on the benefits of the EU PVP system to be carried out by the Observatory
 - 3.3.3 NBTs way forward DG SANTE Seeds Study

Our objectives

To learn to know CPVO and its key persons.

To recognise the work carried out with a high level of professionalism and appreciate the good cooperation between SANTE and CPVO.

To listen to CPVO, clarify some of the issues raised and use the opportunity to inform about general policy developments of the new Commission.

The interlocutor's objectives

To learn to know SANTEs new DDG and to communicate about the importance of intellectual protection of plant varieties for the society.

To express the position that CPVO is in favour amending the basic Regulation on Community Plant Variety Rights (CPVR).

To express willingness to contribute to the Commission's strategic work.

To communicate on CPVOs active role in the area of plant breeding.

Difficulties to expect: None

1. Presentation of CPVO activities

State of play/background information

The Community Plant Variety Rights (CPVR) system, based on the International Union for the Protection of New Varieties of Plants Convention (the "UPOV Convention, 1991 Act"), provides protection of new plant varieties (a form of intellectual property similar to a patent) valid throughout the EU. The Community Plant Variety Office (CPVO) implements the system. In operation since 1995, the Community Plant Variety Office (CPVO) is an independent de-centralised agency established under the Council Regulation on CPVR in 1995. It is located in Angers, France, with a total staff of 50 agents. National systems (based on UPOV convention) co-exist in all the Member States except Cyprus, Greece, Luxemburg and Malta and since the introduction of the CPVR system the level of applications has gone down.

CPVOs mission is to deliver and promote an efficient Intellectual Property Rights system that supports the creation of new plant varieties for the benefit of the society. Its tasks include the examination of applications submitted by plant breeders on new plant varieties, the co-ordination of technical tests carried out by national examination offices for the grant of CPVR and the subsequent decision taken on such applications. The CPVO is directed by its for the grant of the subsequent decision taken on such applications.

until 31 August 2021) under the control of an Administrative Council which is composed of representatives of all Member States (current and a manual states)

/BG). The Commission (Bernard van Goethem member, as alternate) is a non-voting member. The Administrative Council of the CPVO takes normally its decisions by a simple majority.

CPVO is financially totally independent from the general budget of the EU: its is formed from the fees paid by the plant breeders who want to protect their new variety of plants at EU level. It has a yearly budget of about 20 million Euros.

The work of CPVO has proven successful. Since its creation there has been a constant annual increase of the number of protected varieties. The CPVO receives about 3500 applications per year and manages almost 30,000 titles in force. It is appreciated by stakeholders, recognised at international level. It is developing to a 'Centre of Excellence for plant varieties' while maintaining its balanced budget.

CPVO is celebrating this year its 25th Anniversary, however, due to the COVID situation the anniversary event has been postponed to spring 2021. The Commissioner was initially invited to participate to the Anniversary and to visit CPVO in September 2020.

Lines to take

- Recognise the well functioning and successful plant variety rights regime.
- Appreciate the work of CPVO which is highly recognised in the EU and world wide.
- Hope that all of this can be celebrated in 2021.

2. Priorities of DG SANTE

State of play/background information

Political guidelines for the next Commission 2019-2024

The aim of EUs **Green Deal** is to become the world's first climate-neutral continent is the greatest challenge and opportunity of our times. We will need to invest in innovation and research, redesign our economy and update our industrial policy.

Climate change, biodiversity, food security, deforestation and land degradation go together. We must preserve the vital work our farmers to provide Europeans with nutritious, affordable and safe food. This is only possible if they can make a decent living for their families. We will support our farmers with a new "Farm to Fork Strategy" on sustainable food along the whole value chain.

Food security relies on seed security.

New and improved seed varieties are essential towards ensuring better yields for food production and to adapt to changing climatic and environmental conditions, thereby contributing to long-term food security. At the same time, CPVR legislation is playing a key role to ensure a more diversified EU agriculture and food consumption. Through plant breeding we can, for example, reduce the need for plant protection products; fight against plant diseases; and combat the changing patterns of heat, cold and precipitation.

Moreover, the Commission is working on a digital transformation that will benefit everyone - **Digital Agenda**. Effective digital government can provide a wide variety of benefits including more efficiency and savings for public services and businesses, increased transparency, and greater participation of citizens in political life.

Lines to take

- Recognise the importance of innovation in plant breeding and the new improved plant varieties play in addressing the many challenges.
- CPVO and the CPVR regime have an important role to play in implementing Green Deal, F2F strategy and the Digital Agenda of the Commission.

3. Cooperation DG SANTE and CPVO

3.1 Involvement of CPVO in relevant policy roadmaps

3.1.1 Farm to Fork strategy: how to contribute

State of play/background information

F2F strategy was adopted on 20 May 2020. In the last Inter-Agency meeting of SANTE informed of the main elements of the Strategy, focusing in particular on the potential impact on the agencies.

In relation to plant breeding, the strategy states that **new innovative techniques**, including biotechnology and the development of bio-based products, may play a role in increasing sustainability, provided they are safe for consumers and the environment while bringing benefits for society as a whole. **They can also accelerate the process of reducing dependency on pesticides**. In response to the request of Member States, the Commission is carrying out a study which will look at the potential of new genomic techniques to improve sustainability along the food supply chain. **Sustainable food systems also rely on seed security and diversity**. Farmers need to have access to a range of quality seeds for plant varieties adapted to the pressures of climate change. The Commission will **take measures to facilitate the registration of seed varieties**, including for organic farming, and to ensure easier market access for traditional and locally-adapted varieties.

The EU will also promote the global transition to more sustainable food systems in **international standard setting bodies**, relevant multilateral fora and international events. At the same time, the EU will also take an active role to lead the work on international sustainability standards and environmental footprint calculation methods in multilateral fora to promote a higher uptake of sustainability standards.

SANTE is organizing 15 to 16 October 2020 a conference on the F2F strategy with an open registration.

Lines to take

- Highlight that CPVOs core business on granting plant variety rights supports the objectives of the F2F strategy in terms of supporting innovation in plant breeding.
- Inform that an active role will be played by the EU in international and multilateral fora, including standards setting bodies, to promote a global transition towards more sustainable food systems. An EU event could be together organised on this in the context of the 2021 sessions of UPOV (The International Union for the Protection of New Varieties of Plants).
- Inform about the upcoming F2F conference: 15 to 16 October 2020 and open registration.
- The CPVO will be given the opportunity to present its role in Plant Health, innovation and biodiversity in the first international conference on Plant Health in June 2021 in Helsinki, in the framework of the Commission's presentation of the Farm to Fork strategy.

3.1.2 EU IP Strategy

Under the new Commission DG GROW started in 2019 the preparation for an IP action plan. It will set out the Commission's vision on the role of IP in these challenging times, and propose concrete initiatives to improve the IP framework and the way it is used in practice. The initiative was announced in the Commission

Communications "A New Industrial Strategy for Europe"6 and "An SME Strategy for a Sustainable and Digital Europe" of 10 March 2020.7 The IP action plan will also contribute to the Commission's priorities set out in the Green Deal and the Digital Agenda

IP industries intensively using intellectual property rights play an essential role in the EU's main economic ecosystems. IP rights, such as patents, trade marks, designs etc., promote the deployment and diffusion of inventions and creations to the benefit of the EU economy. Well-calibrated and balanced IP policies can build resilience and boost Europe's competitiveness, putting the EU on track towards economic recovery from the crisis following the Covid-19 break. By stimulating technological developments, IP can also play an important role in promoting a greener and digital economy. This, in return, should put the EU's businesses in the lead of global competition.

The preparation has progressed well but the inclusion of biotechnologies including plant breeding and CPVR was limited as no concrete major legislative initiatives are being planned. During the process CPVO was informally consulted. The roadmap was in public consultation from 10 July 2020 - 31 August 2020 and results are currently being analysed.

Lines to take

- Inform that the roadmap was in public consultation and the results are being currently analysed.
- Note that a high number of comments were received from plant breeders associations and breeding companies noting the scare quoting of CPVR Regulation and requesting its revision.
- Inform that SANTE will again consult CPVO for developing the next version of the IP strategy/action plan.

3.2 Update of Basic Regulation/Implementing Rules on Farm Saved Seed following jurisprudence of the CJEU

The CPVR legislation was evaluated in 2011 and it was concluded that there is broad support for the stated objectives of the legislation. The regime functions well overall, stakeholders were content and wish to retain the system in its current form, albeit with some carefully targeted adjustments. However, so far no legal action in relation to the basic CPVR legislation has been planned except the proposal for extending protection duration for certain species (co-decision procedure, see agenda point 3.3). The plan was to first revise the legislation on marketing seeds, which is much older, and outdated with a number identified problems.

It is to be noted that in relation to the public consultation on the IP action plan roadmap, a high number of comments were received from plant breeder associations and breeding companies noting the scare quoting of the CPVR system and requesting revision of the Regulation. The issues relate to e.g. a recent court case in relation to provisional protection and problems in enforcing plant variety rights as regards farm saved seed. The latter is a sensitive issue with long history and requiring careful balancing between breeders and farmer rights. Despite the work invested (working group on farm saved seed) Euroseeds and Copa-Cocega could not achieve an agreement on how to improve collection of information from farmers when using seed of protected varieties for their own use. Moreover, the issues raised during the evaluation are still valid, SG has been asking for a number of administrative changes (Lisbonisation, implementation of guidelines for agencies, voting right for Commission in CPVOs Administrative Council, change of CPVO name etc.) and LS (an amendment requested after CJEU case on farm saved seed).

SANTE is looking into the issue, however, due to limited resources it is not possible to commit to such an exercise at the moment as the amendment of the seed marketing legislation and acts in relation to organic seed varieties are under preparation and there are significantly increased IT and international activities.

Lines to take

- Note that in relation to the public consultation on the IP action plan roadmap a high number of stakeholders requested the revision of the CPVR Regulation. CPVO will be consulted on DG SANTE comments.
- Explain that despite the need there is currently no resources in SANTE to commit to such an exercise, however, SANTE will look into the issue with a longer term perspective.

3.3 Update on the legal provisions on the duration of protection

The Commission is currently in the process of preparing a proposal for extending protection duration for certain species (co-decision procedure) as requested by the CPVO AC. The planning is to send the legal proposal to the EP and Council before the end of the year.

Lines to take

- Inform that the Commission is in the process of preparing the legal proposal on extending the duration of protection and the plan is to adopt the proposal before the end of the year.
- Welcome CPVOs technical support during the discussions in EP and Council.

3.4 Study on the benefits of the EU PVP system to be carried out by the Observatory

On the request of the Commission and the CPVO, the European Observatory on infringements of Intellectual Property Rights managed by the EUIPO (European Union Intellectual Protection Office - trade marks) has taken up the task to carry out a study on the benefits of the EU plant variety protection system. In collaboration with the CPVO (also involving the SANTE, members of the CPVO's Administrative Council, breeder associations and other relevant parties), this study will attempt to quantify the economic contribution in the EU of the PVR system

(with an emphasis on EU-level rights). The study will also consider the potential for the PVR system to help to meet the Green Deal objectives, as well, the potential contribution to the United Nations (UN) Sustainable Development Goals (SDGs) could be considered. So far the Observatory has prepared a first draft of the Terms of Reference (ToR) for the conduct of the Study. The formal adoption of the final ToR is expected at the meetings of the Observatory's Working Groups scheduled to take place in the month of October from 20 to 22 2020.

Lines to take

- Welcome the study on the benefits of the EU PVP system that would also contribute to the UPOV activities on studying the benefits of the UPOV system.
- Inform that SANTE is interested to follow the study.

3.5 New genomic techniques way forward - DG SANTE Seeds Study

The Commission study on new genomic techniques

In the past years, CPVO has been frequently in contact with SANTE regarding the legal status of new plant varieties bred with new genomic techniques.

The European Court of Justice ruling from July 2018 on "new mutagenesis techniques" brought clarity on the legal situation. The Court clarified that organisms obtained by mutagenesis techniques mainly developed since the adoption of the Directive on the deliberate release of GMOs (2001/18/EC) do fall within the scope of the Directive. These techniques can alter the genome of a species without the insertion of foreign DNA and in certain cases result in mutations similar to those that can occur in nature.

Several stakeholders (academia, farmers, breeders, industry) consider that these techniques should not be regulated as GMOs and that the GMO framework is disproportionate and not suitable for these products. They also consider that opportunities for innovation will be lost as implementation of the GMO legal framework is complex and burdensome.

Other stakeholders, environmental NGOs in particular, are satisfied with the Court of Justice ruling and want to maintain organisms produced with these techniques, under the GMO legislation, mainly to ensure safety and consumers' right for information (the GMO legislation includes labelling requirements).

Many of the EU's trading partners have decided to regulate products of these innovative techniques differently from conventional GMOs or not to regulate them at all basing this decision on the fact that these products could have been also developed through traditional breeding techniques or do not contain foreign genetic material.

In November 2019, the Council adopted a Decision requesting the Commission to deliver a study on the status of certain innovative breeding techniques ("novel genomic techniques", NGT) by 30 April 2021. The Decision also requests the Commission to submit a proposal (accompanied by an impact assessment), if

appropriate in view of the outcomes of the study. This follow up will only be decided once the study is finalised.

In the context of this study, DG SANTE organised a targeted stakeholder consultation to gather input from EU-level stakeholders (academia, business operators, NGOs) and Member States. EU agencies such as CPVO were not consulted.

Lines to take

- Inform that the Commission, at the request of the Council of the European Union, is currently carrying out a study on the status of the New Genomic Techniques (NGTs) under Union law. The study will cover different aspects including implementation & enforcement, research, opportunities, challenges and safety. The study will be finalised by April 2021.
- Stress that only after the finalisation of the study, the Commission will assess any potential policy action in this field.
- Enquire how CPVO sees the future of biotech innovation in plant breeding in Europe and why from their perspective new techniques are important for Europe.

Seeds study

The Commission's study, as requested by the Council on 8 November 2019, on the European Union's options to update the existing legislation on the production and marketing of plant reproductive material is ongoing. An external consultant (ICF) has been employed, a kick-off meeting took place on 15 July 2020, a questionnaire is under preparation to be sent to the relevant stakeholders and targeted stakeholders will be interviewed. The issues raised by the EP, the Council and by the stakeholders are being addressed. The study has been delayed by the COVID-19 pandemic and should be finalised in spring 2021.

Lines to take

• Assure that CPVO will be consulted for the Seeds study.

Defensive points

Amendment of CPVR Regulation

Why are you not taking any action as regards the revision of the CPVR Regulation?

- Clarify that SANTE recognises the need for amendments in the CPVR Regulation.
- The issue on farm saved seed needs a careful balancing between breeders and farmers rights. Despite the work invested (working group on farm saved seed) Euroseeds and Copa-Cocega could not achieve an agreement on how

to improve collection of information from the farmers when they use seed of protected varieties for their use.

• Explain that despite the need there is currently no resources in SANTE to commit to such an exercise, however, SANTE will look into the issue with a longer term perspective.

Contribution to Commission strategies

Why has CPVO not been consulted in a timely manner on Commission's strategies?

- SANTE has done its best to consult CPVO in relation to the IPR strategy e.g. through informal exchanges.
- SANTE recognises that the preparatory consultations take place with very short deadlines. A public consultation took place over 4 weeks for both the F2F and the IPR strategy.

French notifications on in vitro mutagenesis¹

Will the Commission start an infringement procedure against France if France finally adopts the notified decrees as proposed?

 The Commission has expressed its concerns on the notified measures in its detailed opinion. Any further steps will be considered after the French authorities have responded to the Commission's observations in the detailed opinion, in accordance with the rules of Directive 2015/1535.

Curricula vitae

is the of CPVO since 2011 and will leave his post next year after Ten years of service (no legal possibility for prolongation). Before that he worked 2003- 2011 as CPVOs and 2001- 2003 as in the law firm Linklaters Brussels and 1996-2003 in Swedish law firm Magnusson Wahlin Advokatbyrå. He is and has a



¹ On 6 May 2020, in the framework of the "Single Market Transparency Directive" (Directive (EU) 2015/1535), the Commission received three notifications from France on draft legal acts concerning certain techniques of genetic modification (in vitro mutagenesis). The notified draft acts aim at (i) revoking, under national law, the exclusion of in vitro mutagenesis from the application of the GMO legislation; (ii) suspending in France the ongoing cultivation and marketing of herbicide tolerant oilseed rape varieties obtained by in vitro mutagenesis techniques. The Commission issued a detailed opinion on the French notified acts.

is the Communication Officer in CPVO and entered into service in 2019. Before that he worked in DG Connect. He is and has a

NB: The President of the Office shall be appointed by the Council from a list of candidates which shall be proposed by the Commission after obtaining the opinion of the Administrative Council. The term of office of the President shall not exceed five years. This term of office shall be renewable. Currently, SANTE is waiting the final agreement of the HR cabinet for publishing the post. The aim is that CPVOs Administrative Council would be consulted on the short list in its spring meeting (March) next year.

Annexes

Additional annexes

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