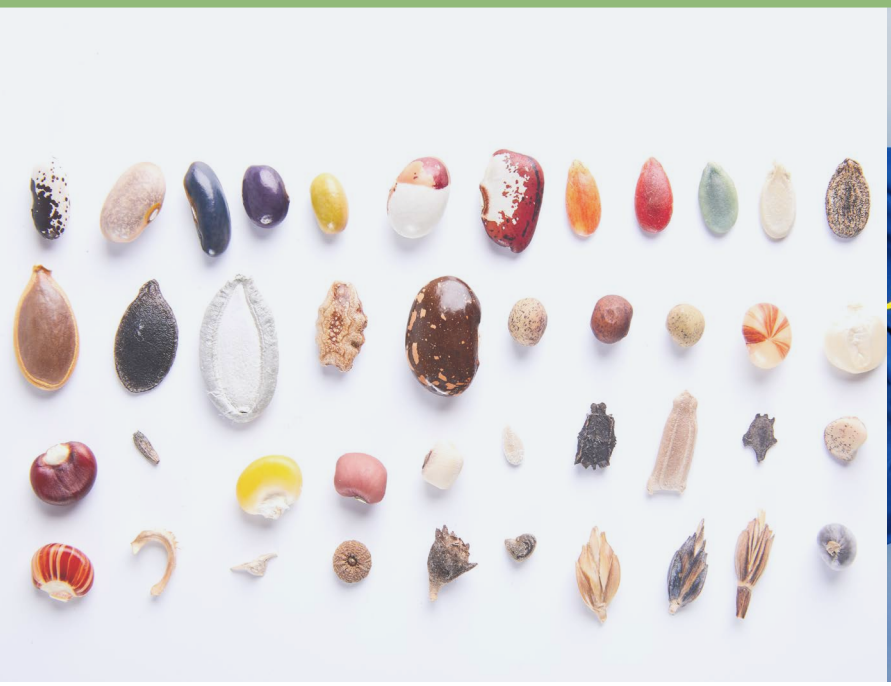
SEEDING EUROPE

GUIDE TO EU SEED POLICY

report
SEEDING EUROPE
MAY
2023



Acknowledgments

This guide was developed within "SEEDING EUROPE", an ERASMUS+ project focused on adult education. The main motivation of the project was to involve more small-scale organizations and active citizens in European policy-making processes related to seeds.

SEEDING EUROPE aimed to reinforce the capacity of associations and individuals working to conserve and increase seed diversity - small scale farmers and seed savers - to understand and monitor the public policies that impact the conservation and use of seeds, and advocate for an enabling legislative environment both at European and national levels.

By developing, translating, and publishing this "GUIDE TO EU SEED POLICY", the project aimed to produce a long-lasting tool, based on different capacity-building activities.

You may access the recordings of the webinars organised throughout the project on the EC-LLD YouTube channel.

We would also like to wholeheartedly thank all the participants of the webinars, and more particularly the workshop held in Brussels in March 2023 for their interest, active participation, and valuable suggestions for the drafting of the guide.

We sincerely hope that the guide will help citizens and social organisations better understand the foundations and principles of EU policy action in matters related to seeds, and thus enable their better-informed participation in ongoing and future legislative processes.

The SEEDING EU team,

Fulya BATUR, for *KYBELE*
Matthias LORIMER, for *Let's Liberate Diversity!*
Katherine DOLAN, for *Arche Noah*

ARCHE NOAH is an association for the conservation and development of crop diversity.
We preserve and care for thousands of endangered vegetable, fruit and grain varieties with the aim of bringing these traditional and rare cultural assets back into gardens, fields and markets.
Over 150 private seed guardians and numerous partners help us to ensure the decentralised and locally adapted preservation of the diversity of varieties. Educational programmes, publications and the commitment to a better political and legal framework for diversity in the seed market are an important part of our work. Over the last decade, we have been organising yearly policy workshops on seed laws for organisations from all over Europe.

KYBELE is a one-person company providing legal advice, training and consultancy services in agricultural and environmental law, which is specialised in international, European and national legislation governing seeds and genetic resources.
Kybele is managed by Fulya BATUR, who holds a PhD in law and brings in over ten years of experience in adult education and research, and more than five years of experience in policy guidance.

European Coordination Let's Liberate Diversity! (EC-LLD) is an international network of organisations working to encourage, develop and promote the dynamic management of cultivated biodiversity on farms and gardens. The association brings together 21 grassroots members that share the same concern: our food systems are too uniform and the promotion of biodiversity is the key to achieving food sovereignty and security for future generations. The three pillars of activities are: capacity building on issues regarding seed policy and legislation, training on Community Seed Banks management and being an exchange platform that facilitates the exchange of practices and information between farmers, seed savers, NGO members and newer local realities.

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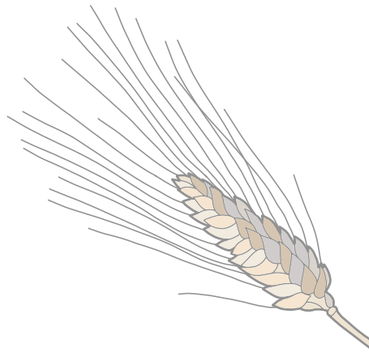
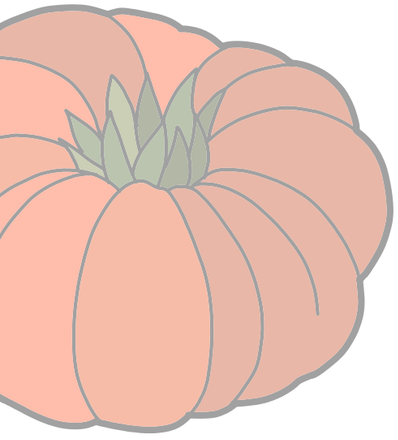


Foreword



This Guide to European seed policy is designed to raise the awareness and knowledge levels of actors engaged in the saving, development, and production of seeds in all species of cultivated plants.

As a didactic and stand-alone document explaining the European seed policy landscape and associated procedures, the Guide wishes to enable better-informed participation of the seed diversity movement in policy-making processes.

As the Guide's primary goal is to make sure that actors understand the legislative texts that impact their daily activities and be able to discuss their gaps and shortcomings with policy-makers, it will rely on the terminology used in these laws and policies, despite the differences that might exist with the ongoing collective work on the preferred terminology to describe the diversity of cultivated plants, its benefits, and the activities carried out around it.

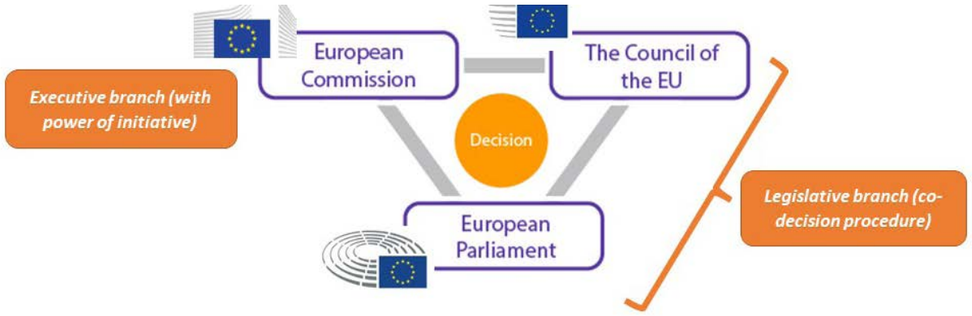
To that end, it will first describe the European policy-making process itself, identifying the competent institutions and their respective roles (PART 1), before delving into existing policies and instruments that relate to seeds and their diversity (PART 2).

Acronyms and definitions of key terms are given in the Glossary.

Fulya Batur

PART 1
EUROPEAN POLICY-MAKING

1.1. European Institutions



The EUROPEAN PARLIAMENT ("EP") is one of the two institutions that constitute the legislative branch of European law-making. Its task is to adopt new legislation for the European Union ("EU") and represent the European people.

705 Members of Parliament ("MEP") are directly elected from all EU Member States, with a predefined number of seats per country, calculated on the basis of different factors, with an important focus on population size (to ensure representativity of the European people).

The next European elections, which will be the tenth election since the organisation of its first direct elections in 1979, are scheduled to be held from 6th until 9th June 2024.

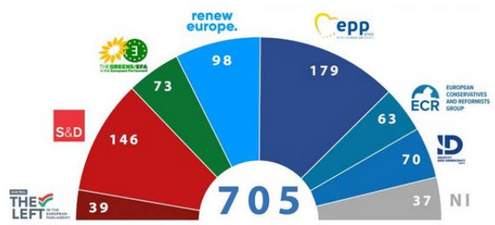
European elections are based on national party lists, but MEP's then congregate into European-level political groups : European People's Party (EPP), Socialists & Democrats (S&D), Renew Europe (RE), Greens/EFA, The Left, Conservatives (ECR), Identity & Democracy (ID), and non-affiliated few. Each political group has its own team of advisors who follow the work of the MEP's in different thematics.

The EP works in different COMMITTEES to prepare its position on policy issues. All legislative texts however need to be adopted in so-called PLENARY, which regroups all MEP's.

Each MEP has its own official webpage on the EP website, where one can find all the information needed to contact them, from their email address to their telephone number and exact location of their offices (both in Brussels and Strasbourg), along with the names of their assistants.

Although the EP's official seat is in Strasbourg, where the plenary sessions take place, most of the upstream work in Committees happen in Brussels.

The EP's powers have been gradually reinforced since its creation, especially with the Treaty of Lisbon. It has equal footing with the Council of the EU as a legislator in the co-decision process.

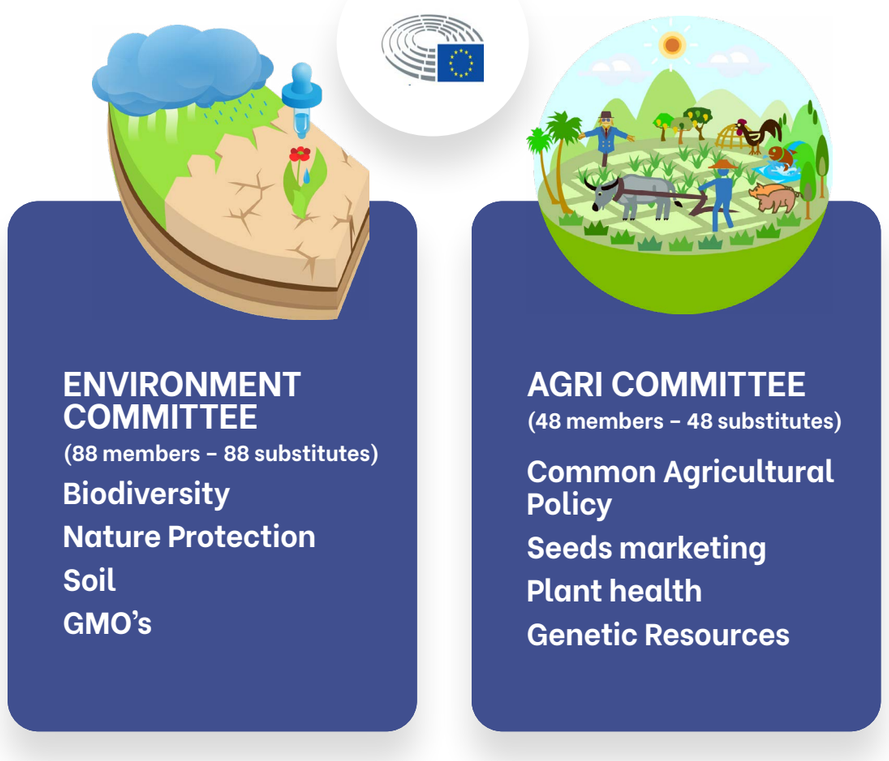


What about seeds?

There are two main Committees at the EP that are responsible for policies relating to seeds, the composition of which reflects the general balance of representation of political parties within the EP, and the number of which is set in the EP Rules of Procedure:

- **Committee on Environment and Public Health (COM ENVI)**, with 88 full and 88 substitute members at the time of writing, competent for biodiversity conservation, nature protection, soil and food safety issues such as the release or import of genetically modified organisms or the authorisation of pesticides.
- **Committee of Agriculture and Rural Development (COM AGRI)**, with 48 full and 48 substitute members in the current legislature, competent on the Common Agricultural Policy, seeds marketing, plant health and genetic resources, amongst other topics.

Other Committees such Development (DEVE), or International Trade may also deal with files that relate to seeds.



COUNCIL OF EU

The COUNCIL OF THE EUROPEAN UNION is the second institution to compose the legislative branch of the European Union. Its task is to represent the EU Member States and work to adopt new EU legislation.

It is composed of heads of States and governments, in different configurations according to the topic at hand. The Council's work is prepared by Special Committees that report to the Committee of Permanent Representatives (COREPER), which is composed by the EU Member States' ambassadors that are based in Brussels (permanent representatives).
Every six months, an EU Member State takes on the presidency of the Council, leading all the meetings of the institutions, including the trilogue negotiations. Sweden holds the presidency until the end of June 2023, after which it will be held by Spain until 31st December, Belgium until June 2024 and then Hungary until the end of 2024.

What about seeds?

For matters related to the diversity of cultivated plants, the main interlocutor is the **AGRIFISH Council**, which regroups Ministers of agriculture from all EU Member States, and is competent for the CAP, genetic resources, seed marketing, plant health and the sustainable use of pesticides. Upstream work is done in the **Special Committee on Agriculture (SCA)** and its Working Group on "Genetic Resources and Innovation in Agriculture".
The **ENVI Council,** regrouping Ministers of environment, is competent for food safety, including GMO's.

EUROPEAN COMMISSION

The EUROPEAN COMMISSION is the institution representing the executive branch of EU policy making. Its task is to implement European legislation and be the guardian of the Founding Treaties of the EU. It also has the power to initiate the EU legislative process.

Different Commissioners, supported by 30,000 bureaucrats, have the power to submit legislative proposals, and are tasked with following the implementation of European law.
The Commissioners are nominated by the European Council, taking into account the results of the EP elections. They are then auditioned by the new EP, and approved in a single plenary vote of consent.
The Commission is divided into different DIRECTORATE GENERALS ("DG"), which are akin to national Ministries.

What about seeds?

Different Commission DG's are responsible for policy portfolios that impact seeds (at the time of writing):

- **DG SANTE** is responsible for plant health, seeds marketing, the authorisation of phytosanitary products and the regulatory framework for genetically modified organisms.
- **DG AGRI** is responsible for agricultural policy and rural development.
- **DG ENV** is responsible for the EU's environmental policy, including biodiversity and soil quality frameworks, while **DG CLIMA** over oversees the EU's climate policy.
- Other Commission DG's are also involved, such as **DG GROW** for intellectual property rights, or **DG INTPA** for the EU's global action (international partnerships).

DG SANTE
· Seeds marketing
· Plant health
· GMO's
· UPOV

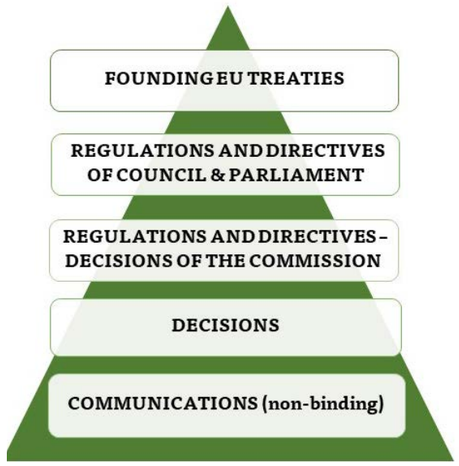
DG AGRICULTURE
· Common Agr. Policy
· Organics
· Genetic Resources

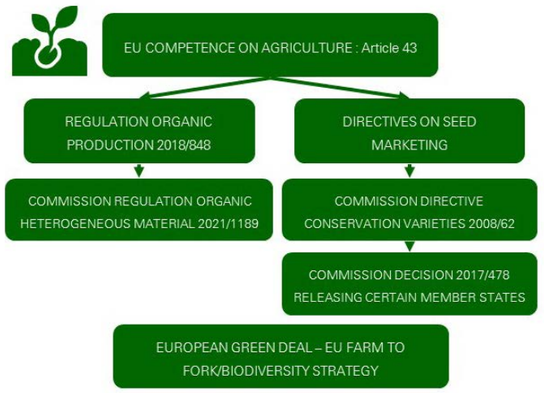
DG ENV
· Biodiversity
· Nature Protection
· Soil

DG GROW
· Intellectual Property

There are additional EU institutions, which have an advisory role in the policy-making process (such as the **European Economic and Social Committee**, representing civil society, and the **Committee of the Regions**, representing local and regional entities), a judiciary role (such as the European Court of Justice), or an internal control role (such as the **European Ombudsman**).

1.2. Instruments of European Law





At the very top of the EU pyramid of laws are the Founding Treaties, which not only create the EU as an international organisation, but also determine the division of competences between national authorities and the EU institutions, setting the general principles that determine the boundaries of EU action.

They have been amended numerous times, the latest being the Lisbon Treaty signed in 2007, which has been effective since 2009. **Based on these Treaties, two main binding instruments of European law can be used by the European co-legislators to act on their areas of competence:**

> a **REGULATION** (of the COUNCIL and the PARLIAMENT) is a "law" that is directly applicable in all Member States, without the need for a specific national law, which means that the rights and obligations of the Regulation can be indisputably invoked by citizens, and be applied by national judges.

Example related to seeds

The new Organic production regime (Regulation 2018/848), as well as rules concerning plant health (Regulation 2016/2031) are both enshrined in Regulations.

> a **DIRECTIVE** (of the COUNCIL and the PARLIAMENT) is a "law" that is not directly applicable in Member States, which need to 'transpose' the European rules in national laws and/or decrees. This tool gives much more margin of manoeuvre to national authorities.

Example related to seeds

The regime governing seed marketing is set in 12 different European Directives, which explains the wide differences that exist in the EU with regards to seed saving and marketing.

In these Council and Parliament REGULATIONS or DIRECTIVES, the co-legislators can decide to give the Commission the power to further specify certain aspects of the general rules.

This leads to the adoption of a **COMMISSION REGULATION** or **COMMISSION DIRECTIVE**. The European Commission can work on and adapt :

> **DELEGATED ACTS ("DA")** on the basis of a specific delegation of power in a BASIC ACT (i.e. either a REGULATION or DIRECTIVE of the European Council and Parliament), that defines the objectives, content and scope of the delegation of power.

> **IMPLEMENTING ACTS ("IA")** to ensure uniform conditions for the implementation of European law,

While Delegated Acts include more policy-making choices, Implementing Acts only deal with the details needed to set an EU law (Council and Parliament Regulation or Directive) in action.

Both Implementing and Delegated Acts are prepared by the European Commission according to the comitology procedure with heavy involvement of national authorities, regrouped either in a Committee or an Expert Group. The European Parliament is involved only at the approval stage for Delegated Acts, and can be informed of Implementing Acts.
Stakeholders are consulted through the "Have Your Say" website of the European Commission once the drafts (of Implementing of Delegated) Acts have been finalised in the Committee or Expert.

> At each level of power and competence, **DECISIONS** can also be adopted, when dealing with a specific situation or an individual case. Decisions are binding on those to whom it is addressed (e.g. an EU country or an individual person/company/entity) and is directly applicable.

EU institutions can also adopt different non-binding instruments, such as **COMMUNICATIONS**, which detail the institution's approach to a specific policy field, without having any legal effect.

Example related to seeds

Commission Delegated Regulation (EU) 2021/1189 of 7 May 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species (OHM marketing rules); Commission Directive 2008/62/EC of 20 June 2008 providing for certain derogations for conservation varieties.

Example related to seeds

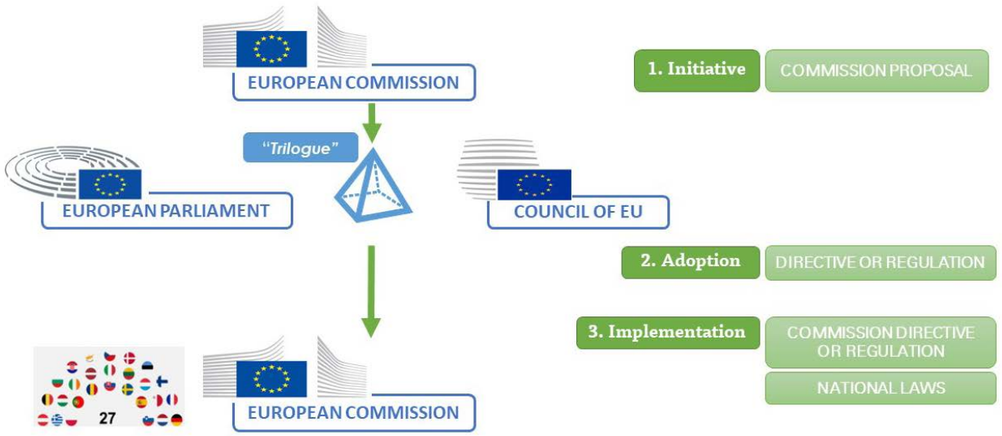
Council Decision 2005/834/EC of 8 November 2005 on the equivalence of checks on practices for the maintenance of varieties carried out in certain third countries ; Commission Implementing Decision (EU) 2021/1214 of 22 July 2021 authorising Poland to prohibit the marketing on its territory of a certain variety.

Example related to seeds

Communication from the Commission to the European Parliament, the European Council, The Council, The European Economic and Social Committee and the Committee of the Regions, The European Green Deal, Com/2019/640 Final.

1.3. EU Policy-making Procedure

In most policy fields (including agriculture and the environment), the EU follows the so-called co-decision procedure, which involves the Council of the EU and the European Parliament.
On a more limited number of topics, the involvement and powers of the Parliament are more limited (such as defence). In matters related to environment and agriculture, the co-decision process is the rule, putting both the EP and the Council on an equal footing as co-legislators.
As non-binding texts do not follow the complex co-decision procedure, but can as a principle be deliberated and voted within each EU institution, this section will **focus on the procedure relating to the main EU policy instruments, which are Regulations and Directives of the EP and the Council of the EU.**
Three steps can be identified in this context, with numerous internal steps to be taken by competent institutions at each stage
1. The initiative of the Commission,
2.The adoption of Council and EP Regulation or Directive following trilogue negotiations, and
3. The implementation of the adopted text.



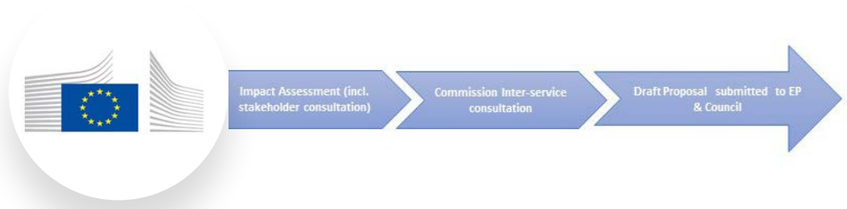
1. Initiative (Commission proposal)

The EU policy-making process officially starts with the submission of a COMMISSION proposal for an EU Regulation or an EU Directive to the attention of the European Parliament and the Council of the EU.
This proposal can be triggered by a request of the Member States (through a Council decision), the European parliament, the European Investment Bank, the European Central Bank, or by citizens through the recourse to a European Citizens' initiative (which needs to collect one million signatures across EU Member States to be taken into consideration by the European Commission, such as the Save the Bees and Farmers petition accepted in October 2022).

Before a draft is submitted by the Commission, quite substantive upstream work happens to collect data and assess the potential impacts of a legal proposal on different issues. Commission services need to follow so-called "Better Regulation Guidelines", which requires them to use different tools for evidence-based policy-making and a democratic participatory process. As a result, the Commission's proposals are accompanied by an Impact Assessment document that outlines different policy options.
This document is often supported by a study, habitually carried out by external consultancies contracted to carry out different stakeholder consultation activities (such as open public consultations published on the Have your Say website, interviews, surveys or workshops) and analyse the data generated by such activities.

The draft document prepared by the lead Commission DG is then circulated to other relevant services to receive their comments on the text, before it is adopted by the Cabinet of Commissioners, and submitted to the EP and the Council of the EU. Even though one DG is assigned as having the lead on a certain policy file and legislative proposal by the Cabinet of Commissioners (the highest level of decision), other DGs are consulted in internal processes coined "Inter-Service Consultations".
Other Commission services will thus see the draft developed by the main DG, and have the opportunity to comment on it according to their competence and priority action areas.

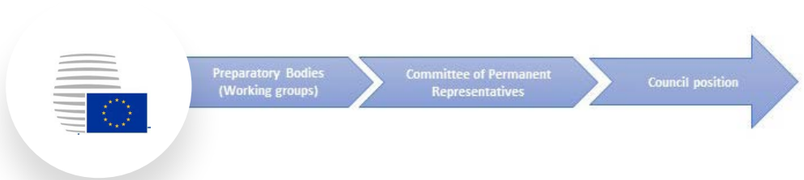
This process was developed to increase the consistency and coherence of European policies.



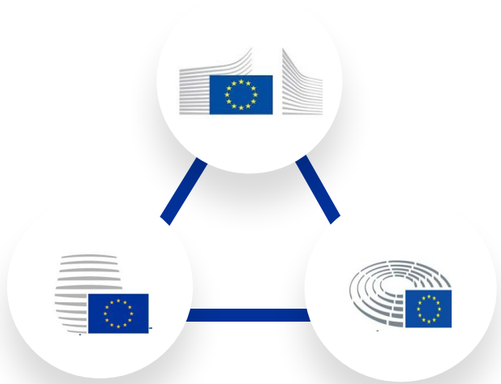
2. Adoption (Directive or Regulation)

When the Commission draft is published, two parallel processes start in the two EU institutions with legislative powers, ie the Council of the EU and the European Parliament, who then enter into trilogue negotiations with the European Commission.

At the **Council of the EU**, the file is directed to the relevant preparatory body of the competent Council configuration. These bodies bring together the staff of the Permanent Representations (i.e. the "embassies" of Member States in Brussels), who are in constant liaison with the staff of the competent national and/or regional Ministries back in the capitals of each Member States. Once the upstream work is advanced enough, the Committee of Permanent Representatives (COREPER) takes over to decide whether the file is ready to be submitted to the vote of the competent Council configuration (i.e. all Ministers of EU Member States, who vote either on a qualified majority or unanimity rule).
This vote leads to the adoption of a ***Council position***, and opens the way to "inter-institutional negotiations" with the European Parliament.



At the **European Parliament**, a quite lengthy internal process starts with the designation of the competent ***EP Committee*** (taken by the Conference of Presidents). This step is quickly followed by the designation of a Rapporteur on the file, the key person who will analyse the Commission proposal in depth, and propose some initial amendments to the draft text in a "draft report". To better coordinate the EP's efforts, other European political parties designate "Shadow Rapporteurs" who will be the main MEPs to follow this specific dossier, and coordinate with the Rapporteur office.
When the Rapporteur's draft report is published, all other EP Committee members can submit their amendments to the Commission proposal, which need to be collected by the Rapporteur. Usually, the Rapporteur will strive to collate similar amendments and propose "Compromise Amendments" which are negotiated together with all Shadows and the coordinators of the political groups. Both Compromise Amendments and those amendments submitted by MEPs (alone or as a group) are then voted on during a Committee meeting.
The result of this Committee vote leads to a ***draft report*** of the EP on the Commission proposal, which usually needs to be submitted to a plenary vote before the negotiations with the Council of the EU can begin.



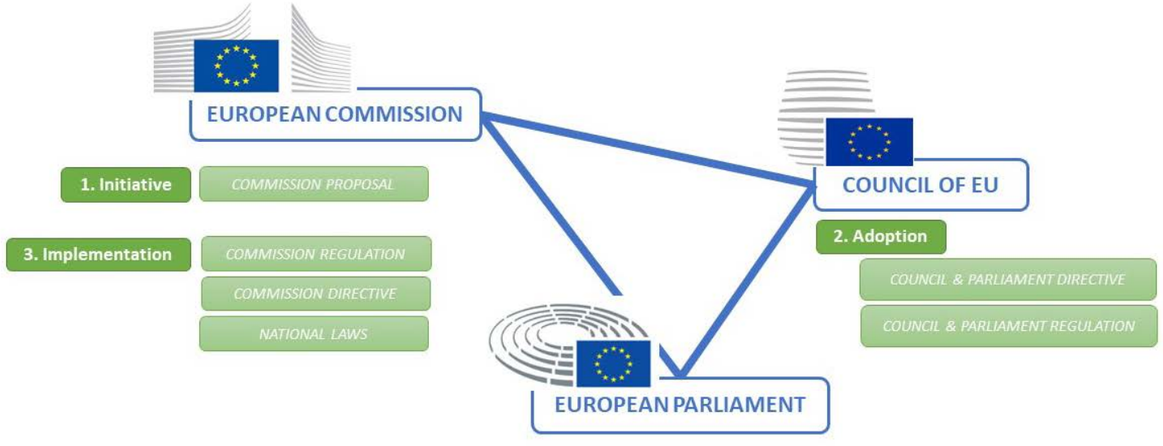
Once the respective positions of the two legislative institutions (ie the EP and the Council of the EU) on the Commission's proposal have been adopted, an unofficial mechanism to facilitate the reaching of a compromise starts: tri-partite inter-institutional agreements, i.e. **trilogues**. **These are meetings where the three institutions sit down together numerous times over the course of months (or years) to try to reach a final text that can be accepted by all.**
The **EP** is represented by the team of the Rapporteur, assisted by shadows and groups advisers. Representing the will of the people, it defends the EP report voted in plenary. The **Council of the EU** is represented by the team of the country holding the rotating Presidency, assisted by national staff of the Permanent Representation. Representing the will of the Member States, it defends the Council position as prepared by COREPER and its working parties, and voted by the competent Council configuration.
The **Commission** is represented by the DG which has the lead on the topic, and is present in the meetings to guard the spirit of the EU Founding Treaties.
When the trilogue negotiations succeed, the informal tripartite agreement, which takes the form of a draft Regulation or Directive, is voted by the European Parliament and the Council of the EU, according to their own rules of procedure and voting quorums. After both votes are confirmed, the Regulation or the Directive of the Council and the EP is formally adopted.

3. Implementation (Commission Directive or Regulation / National Laws)

Once a legally binding EU Regulation or EU Directive of the Council and Parliament is adopted, its provisions need to be implemented.

The general principle is that Member States hold such implementing responsibility as sovereign States through national laws, decrees or any other regulation adopted according to national procedures enshrined in each country's Constitution.
However, the EU legal texts usually give some implementing powers to the European Commission, especially when the provisions need to be executed in a uniform fashion.

This triggers EU procedures for the adoption of so-called Implementing and Delegated Acts, as Regulations or Directives of the European Commission. Following the "comitology" procedure, the Commission draft is discussed in expert groups, which involve the staff of national Ministries sent by all capitals of EU Member States.
Before its adoption by the Commission at the level of the Cabinet of Commissioners, the draft act is published on the Have Your Say website to gather comments from stakeholders, whether industry, civil society, public institutions, researchers, or anyone wishing to provide feedback on the text.



PART 2
THE EU LAW OF THE SEED

2.1. Environmental Preservation
2.2. Risk Prevention
2.3. Market tools

Introduction

Seeds are highly regulated resources.

They are also regulated by legal and policy instruments that follow very different objectives, which leads them to often disprove or even contradict one another.
While biodiversity policy wishes to conserve the natural environment to avoid its degradation (Section 2.1), other instruments aim to protect the environment (and beyond) from all risks that could be caused by the development, introduction and cultivation of seeds and plants into the EU territory, ensuring food safety, as well as seed and plant health (Section 2.2).

Other policies rather operationalise market tools to regulate and monitor the seed market, setting the conditions of access to such market, or providing advantages to certain actors to reward innovative products or processes (Section 2.3).

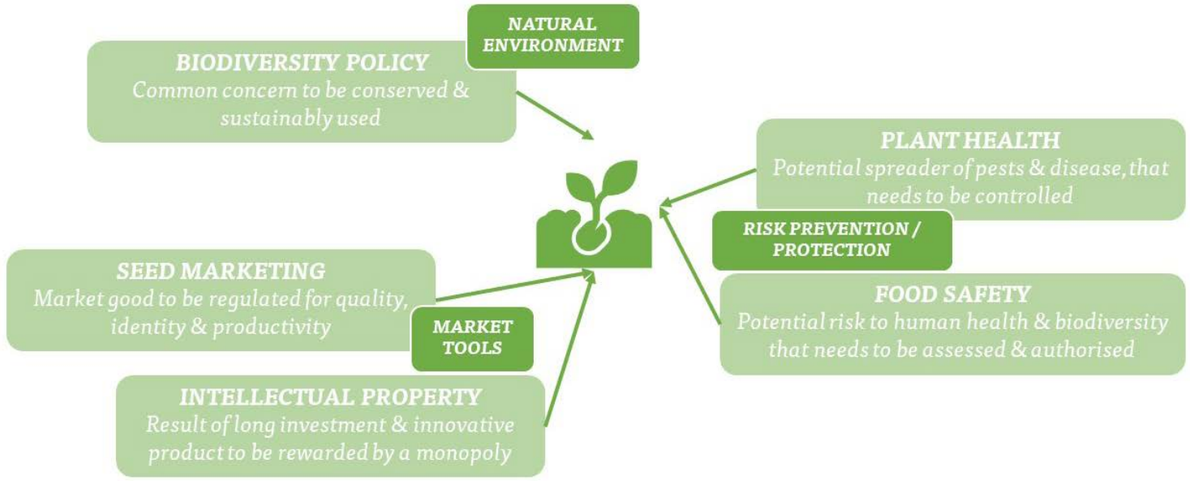
Seeds are also indirectly impacted by other policies, such as the Common Agricultural Policy, which shapes the direction of European agriculture, or the upcoming EU Framework on Sustainable Food Systems, which intends to prescribe rules on sustainability requirements and labelling for EU food products and operations.

The law of the seed is a complex web of laws and regulations that are prescriptive and context-specific. Human rights to seeds have also been formally recognised in 2018 to peasants and people living in rural areas in the UNDROP by the UN General Assembly.

Universal in nature and holistic in their approach, seed rights are impacted by the law of the seed, i.e. all the rules and regulations that impact seeds.

Seed rights warrant alignment of these rules and regulations, in conformity with States' duty to respect, protect and implement human rights in their territories.

For more information on the UNDROP and its articles that relate to seeds, you can read the dedicated publications of the Geneva Academy here.



2.1. Natural Environment: Biodiversity Conservation, Sustainable & Equitable Use

Policies, rules, and regulations that wish to preserve the natural environment aim to address (and redress) the degradation of ecosystems witnessed by scientists worldwide.

Amongst other overarching goals, these policies wish to reverse the decline of biodiversity, both wild and cultivated. With regards to genetic resources, EU biodiversity policy also wishes to ensure that they are used sustainably, but also equitably, to palliate the lack of compensation from industry-rich countries that use and generate commercial benefits from the resources they collected and continue to collect or use from biodiversity-rich countries, dating back from colonial times.

As these policies aim at the preservation of the environment, they fall under the remit of DG Environment and/or Climate in the European Commission, the Committee of Environment in the European Parliament, and the Environment Council in the Council of the EU, although both the EP Committee on Agriculture (COMAGRI) and the AGRIFISH Council have the reigns in matters strictly relating to genetic resources used in food and agriculture.

International policy and legal instruments

First addressing specific environmental issues at national or regional level, nature protection laws have found echo in the international arena in the 1990's. Following the United Nations Conference on Environment and Development (also known as the Rio Earth Summit) organised by the UN Environment Programme (UNEP), many countries of the world, including the EU, have signed and ratified different international treaties to bring common solutions to the universal problem of environmental degradation.

Convention on Biological Diversity

The 1992 UN Framework Convention on Climate Change, the Convention to Combat Desertification, and the **Convention on Biological Diversity ("CBD")** all recognise States' sovereignty over their territory, yet prescribe common actions and dictate State obligations to preserve our environment.

The CBD, which entered into force on 29th December 1993, focuses on biological diversity, both in its wild and cultivated forms, along with the ecosystems in which this diversity is found. Reaffirming countries' sovereign rights over genetic resources, the CBD requires countries to conserve biodiversity, and use it both sustainably and equitably.

The CBD establishes the responsibility of States to develop national strategies for the conservation of all biodiversity (not just cultivated plants), both in situ (i.e., found in the natural and human environment) and ex situ (i.e., found in gene banks or zoos).

Every two years, countries that have ratified the Convention and observers meet during the Conference of the Parties (COP) to assess progress over the implementation of the objectives.

Over time, they have adopted different Strategic Plans, including the Aichi Biodiversity Targets for 20111-2020, and more recently, the Kunming-Montreal Biodiversity Framework. This framework document established four long-term goals for 2050, including that "the genetic diversity within populations of wild and domesticated species, is maintained, safeguarding their adaptive potential ».

Access and Benefit-Sharing: the Nagoya Protocol

Under the CBD, building on national sovereignty, countries have the right to determine the conditions under which genetic resources may be accessed and used, all the while recognizing the **traditional knowledge** held by indigenous and rural communities over such resources. The idea of equity warrants the distribution of monetary and non-monetary benefits generated from such access and use in a bilateral contract subject to the obligations of the CBD's **Nagoya Protocol on Access and Benefit-Sharing ("ABS")**. Access to genetic resources is subject to Prior Informed Consent ("PIC") and mutually agreed terms ("MAT"), which are usually contained in a contract, at times coined Material Transfer Agreement ("MTA"). Although the EU itself, and all EU countries have signed and ratified the CBD, some EU countries are still to ratify the Nagoya Protocol.

As molecular biology and sequencing activities were not developed as much as they are today, the CBD did not specify whether and how its provisions applied to information on genetic resources obtained in digital format, leading to the thorny issue of **"digital sequence information" (DSI)**. Biodiversity-rich countries of the Global South have long advocated that obligations to get prior consent and trigger benefit-sharing also apply to the wealth of knowledge on genetic resources that is contained in public and private databases in digital format. This shift is needed to to make sure that ABS obligations do not become an empty shell easily circumvented by users.

On the other hand, developed and biotechnology-rich countries rather pointed at the impracticalities of such an approach, emphasising its potential detrimental consequences, such as the decrease of research or development and knowledge about biodiversity in the long term.

After a long deadlock and years of technical talks coordinated by the CBD Secretariat based in Montreal, the latest COP established that countries should ensure that "the monetary and non-monetary benefits from the utilization of genetic resources and digital sequence information on genetic resources, and of traditional knowledge associated with genetic resources, are shared fairly and equitably, including, as appropriate with indigenous peoples and local communities, and substantially increased by 2050". In this context, a **multilateral mechanism** for benefit-sharing from the use of digital sequence information on genetic resources will be established in the years to come, including the creation of a global benefit-sharing fund.

International Treaty on Plant Genetic Resources for Food and Agriculture

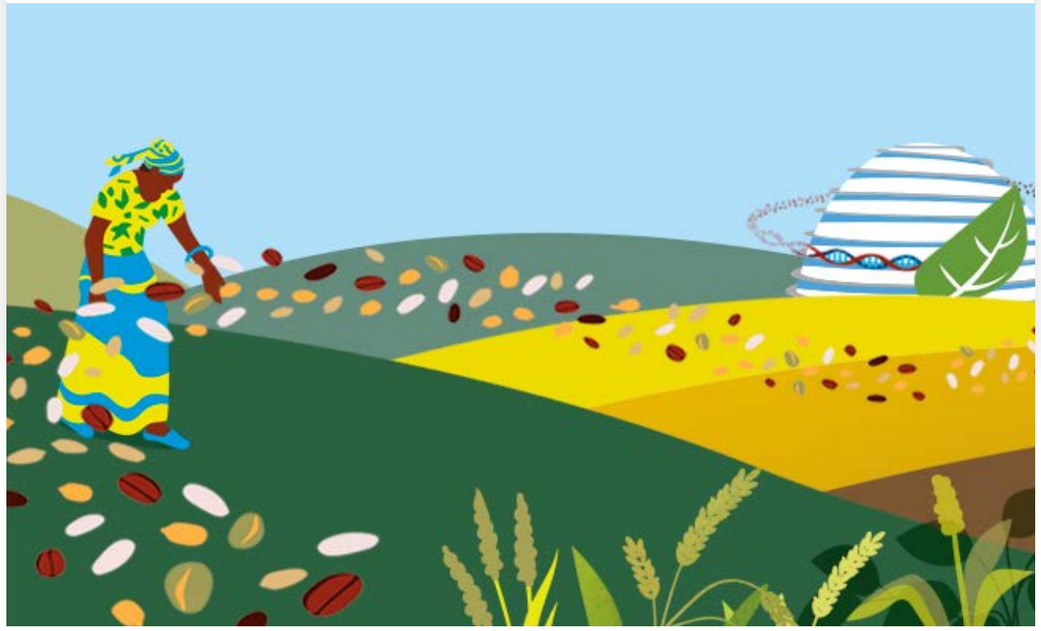
In parallel to the CBD discussions coordinated by UNEP, which target the conservation of biodiversity in a more holistic approach, specialized instruments targeting seeds have also been developed under the leadership of the Food and Agriculture Organisation (FAO).

Building on the International Undertaking on plant genetic resources for food and agriculture, which was adopted in 1981 as a non-binding instrument spelling out commitments to conserve and sustainably use genetic resources as "common heritage of mankind", the binding **International Treaty (ITPGRFA)** was finalised in 2001 with the same goals, and adopted in 2004.

Aligned with the general provisions of the CBD, the ITPGRFA recognises the specificities of cultivated diversity and the need to consider food security.

It establishes an ad hoc multilateral framework for the exchange of agricultural plant genetic resources listed in an Annex to the Treaty, based on a single contract coined standard Material Transfer Agreement adopted in 2006, with clauses on benefit-sharing. The ITPGRFA also recognizes farmers' rights and their contribution to the conservation and sustainable use of seeds.

Both the European Union and all of its Member States have ratified the ITPGRFA and are thus bound by its provisions.



European policy and legal instruments

European biodiversity policy is centred around the establishment of coordinated protected areas and Action Plans, with little common EU action on agricultural plant diversity, and an ABS policy focused on compliance checks rather than the recognition of traditional knowledge.

Biodiversity Strategies and Action Plans clearly focused on protected areas

Considering its obligations under the CBD, the EU has adopted different policy instruments to achieve internationally-established targets.

To that end, the European Commission adopts different non-binding Biodiversity Strategies, the latest covering the timescale between 2020 and 2030, coined "Bringing back nature into our lives" adopted in May 2020.

This Strategy is part of the European Green Deal, a non-binding instrument establishing the priorities of the European Commission to become the first climate-neutral continent in light of the existential threat caused by climate change and environmental degradation, and aiming to reduce net greenhouse gas emissions by at least 55% by 2030. The EU 2030 Biodiversity Strategy puts emphasis on the creation and maintenance of a network of protected areas in the EU, as well as on nature restoration, together with strengthened implementation and international action.

Just like its predecessors, the new EU Biodiversity Strategy does not delve too much into seed biodiversity, but rather focuses on the EU's oldest environmental laws, the Birds and Habitats Directive (coined "Nature Directives") that establish the largest coordinated network of protected areas in the world, the Natura 2000 network.

It nonetheless outlines that "the decline of genetic diversity must also be reversed, including by facilitating the use of traditional varieties of crops and breeds", adding that "this would also bring health benefits through more varied and nutritious diets".

The new EU Biodiversity Strategy then informs that measures will be taken to revise the current seed marketing rules "to facilitate the registration of seed varieties, including for organic farming, and to ensure easier market access for traditional and locally adapted varieties", in parallel to the Farm to Fork Strategy adopted on the same day to ensure that EU food systems are fair, health and environmentally-friendly.

Agricultural plant diversity, the forgotten pieces of the puzzle?

The diversity of cultivated plants, whether at species or variety level is not tackled as a priority in EU biodiversity policy.

Even though the EU and its Member States have ratified the ITPGRFA, it is interesting to note that to this day, there is no EU strategy or ad hoc policy on genetic resources for food and agriculture. This leads to a mosaic of European, national/regional structures aiming to conserve and manage plant, animal, and forest genetic resources. Acknowledging the deficit of coordinated action, the European Commission ran two preparatory actions (financed by the European Parliament) and a Horizon 2020 research project to develop a coherent framework. The GenRes Bridge project thus launched its document "a Genetic Resources Strategy for Europe" in 2021, while a specific document was developed on Plant Genetic Resources by the ECPGR network (European Cooperative Programme for Plant Genetic Resources, which mainly regroups national gene banks and research institutes).

Recognising the inextricable link between the conservation and use of seeds, the documents call for coherence, consistency and compatibility amongst the policy and legislative landscape through a European coordination and information centre. These proposals have not yet been integrated into binding texts.

ABS rules focused on compliance checks with little regard to traditional knowledge?

Aside from nature protection, the EU has also acted with regards to access and benefit-sharing (ABS) rules, where it is competent to oversee the **implementation of the Nagoya Protocol**.

A directly applicable Regulation 511/2014 on measures controlling user compliance was adopted in 2014, accompanied by a Guidance Document updated in 2020.

The very detailed guidance document specifies the scope of the EU Regulation, along with its core obligations. The main principle is one of "due diligence", "to ascertain that the genetic resources and traditional knowledge associated with genetic resources which [are utilised by users] have been accessed in accordance with the applicable ABS legislation or regulatory requirements' of the provider countries of these genetic resources [and that benefits are fairly and equitably shared upon mutually agreed terms].

Conservation or multiplication activities with seeds do not qualify as a "use of genetic resources" in the sense of the EU ABS legislation, but all research, development and breeding activities that go beyond the description or characterisation of genetic resources may trigger ABS obligations.

In these cases, users need to make sure that they have accessed the material in compliance with international, European, and national ABS legislation that is applicable, requesting authorisations/permits and negotiating benefit-sharing contracts if and when necessary. Seeds accessed with the standard Material Transfer Agreement of the ITPGRFA will not fall under the more complex Nagoya rules, as explained in the "DYNAVERSITY Manual on Community Seed Banks: access to germplasm and benefit-sharing models", which explains in greater detail the concept of ABS for seed diversity communities .

It is interesting to note that the current EU rules relating to the recognition of traditional knowledge of indigenous or rural communities attached to seeds remain quite weak. Rarely do national laws recognise the existence of such knowledge inside their territories, arguably in contradiction with the UNDROP rights to seeds recognised to peasants and rural communities.

There are little to no mechanisms set in place to avoid misappropriation aside from the EU Nagoya Regulation and a few countries that require the disclosure of origin in patent applications (such as Belgium).

2.2. Risk Prevention: Food Safety (GMO) & Plant Health

EU seed policy contains additional instruments that do not aspire to conserve it directly, but rather aim to protect it, by preventing the emergence and spread of detrimental effects on the environment linked to the import or the cultivation of seeds.

Here, seeds are viewed as potential spreaders of pests and diseases that are harmful to the environment or to the economy, or as potentially causing a risk to human health and biodiversity. Two main categories of risks are addressed in the EU: first, the spread of harmful pests and diseases that jeopardise plant and seed health, and secondly, the health and environmental risks posed by the introduction of genetically modified organisms (GMOs). These risks need to be assessed and controlled through different authorisation processes and be alleviated through restrictions.

As these instruments are linked to food safety, they fall under the remit of DG SANTE in the European Commission, the Environment Council in the Council of the EU, and at the European Parliament, are shared by the Committee of Environment COMENVI (for GMOs) and the Committee of Agriculture and Rural Development COMAGRI (for plant health).

2.2.1. Genetically Modified Organisms

With the speedy development of modern biotechnology and molecular biology, and the invention of transgenesis (i.e., the insertion of foreign DNA into living organisms), the idea that biodiversity should not only be conserved, but also should be protected from external harm due to the introduction of new organisms started to emerge at the end of the 1990's.

The term "biological safety" was coined to describe the actions taken considering the precautionary principle (enshrined in Article 191 of the Founding EU Treaties), to protect biodiversity, but also human health, from the potential risks that could be caused by certain products of biotechnology: "genetically modified organisms" (GMOs).

International instruments: from biodiversity to biosafety

Countries having ratified the CBD were compelled to address the potential risks deriving from the introduction of these new organisms into the natural environment. That is why the Cartagena Protocol on Biosafety to the Convention on Biological Diversity was adopted quite early on, in 29 January 2000, entering into force on 11 September 2003.

This international agreement aims to ensure the safe handling, transport, and use of living modified organisms (LMOs) resulting from biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health.

Building on Principle 15 of the Rio Declaration on Environment and Development related to precaution, the Cartagena Protocol established a clearing-house mechanism to facilitate the exchange of information about living modified organisms amongst countries and facilitate the Protocol's implementation. The Protocol refers to LMOs rather than GMOs, as organisms that possess "a novel combination of genetic material obtained through the use of modern biotechnology" and include agricultural crops that have been genetically modified for greater productivity or for resistance to pests or diseases.

European policy and legal instruments:

The EU has arguably one of the strongest process-based biosafety regulatory frameworks in the world regarding the introduction of GMOs into its territory.

Seeds with genetic material that have been altered in a way that does not occur naturally by mating and/or natural recombination can only be commercialised in the EU if the organism has been authorised for deliberate release pursuant to Directive 2001/18/EC, or for food and feed purposes pursuant to Regulation (EC) No 1829/2003. Before GMO's or products containing a GMO can be cultivated or put on the market in the EU, they need to undergo specific environmental risk assessment, while providing for risk management and monitoring processes.
All assessment reports need to be made public. GMO developers also need to provide adequate traceability mechanisms to ensure freedom of choice for all operators, while their commercialization is subject to labelling obligations for consumer protection and information purposes.
An amendment of Directive 2001/18 in 2015 further allowed states and regions to prohibit GMO crops not only for human health and environmental risks, but also to protect conventional or organic agriculture against GMO contamination (or adventitious presence), 17 EU Member States and 4 regions decided to ban GMO cultivation on their territory, while cultivation of authorised GMOs is today only a reality in Spain.

The EU GMO policy is currently undergoing a significant shift with regards to **"new genomic techniques"** in the jargon of the European Commission, i.e., new techniques stemming from biotechnology that can "edit" the genes without necessarily inserting foreign DNA, like Crispr-Cas.

In 2018, the European Court of Justice confirmed that organisms obtained by mutagenesis qualified as GMOs and would thus be subject to the European biosafety regulations.

Since then, the European Council prompted the European Commission to do a study on the issue in 2019 and started the process leading to the expected publication of a legislative proposal on new genomic techniques by the European Commission in July 2023.

In the study published in 2021, the European Commission concluded that NGT products should be enabled through policy actions considering their potential to contribute to sustainable agri-food systems in line with the objectives of the European Green Deal, all the while addressing concerns and not undermining other aspects of sustainable food production, e.g. as regards organic agriculture, or consumer choice.
The formal impact assessment process was launched by the European Commission in Spring 2022, with surveys, interviews and an open public consultation opened for 3 months. The consultation contained little information on the different policy options envisaged by the European Commission on the topic.

While it is certain that the legislative proposal will only be concerned by plants obtained by targeted mutagenesis and cisgenesis, it is unknown whether the process-based approach of EU biosafety policy will be maintained, and whether NGT plants will be subject to a notification system, a lighter risk assessment, or to the currently applicable rules.

The proposal is expected to be tabled early July 2023, together with the proposal on seed marketing rules, discussed below.

2.2.2. Plant Health

Seeds and the ecosystems in which they are cultivated need not only to be protected against genetically modified organisms, but also against the most harmful organisms that cause diseases that are destructive for the seeds and plants themselves, but also for the environment in which they grow, and for the people that grow them.

By protecting the seeds or seedlings as well as the plants they grow into against phytosanitary risks, policy measures destined to ensure plant health also intend to protect the farmers and growers against socio-economic risks, as well as the environment as a whole. EU plant health policy contains a system that first determines the risks caused by known pests to the economy and the environment, and then, according to that classification, foresees different measures, from eradication to the reduction of the risk at an acceptable level. It also contains important traceability and control mechanisms.

Currently, the EU's plant health policy is dominated by the comprehensive and restrictive EU Regulation 2016/2031 on protective measures against pests of plants, which was part of the European Commission's package proposal of 2013 on official controls and seed marketing.

Classifying risks

The risk classification system makes a distinction between:

a) Union quarantine pests, which have an unacceptable economic, environmental, and social impact and do not yet exist in the EU, therefore warranting measures to prevent its entry through prohibition and eradication, especially for those listed as "priority" or in "protected zones". These are listed in Commission Implementing Regulation 2019/2072, as an evolving list of pests that is regularly amended (starting at 174, it now lists 186 pests, including the infamous grapevine flavescence dorée, so make sure to look at the latest consolidated version of the text.

b) Union regulated non-quarantine pests (RNQP), which have an unacceptable economic (but not an environmental or social) impact, are already present in the EU, and therefore warrant measures to limit the pests' reach by controlling the vectors of its transmission. These pests are also listed in the same Commission Regulation 2019/2072, and especially its Annex IV, which lists the pests that qualify as RNQP's and where seeds are the vectors of transmission. The text also sets thresholds applicable to their presence (usually at 0%), and the measures to be taken by operators to counter their spread. The number of RNQP's is quite high in the ornamentals and fruit sectors, which relies more on propagating material other than seeds, more susceptible to diseases, compared to cereals, where only 2 RNQP's are listed for rye seed.

Some organisms can be neither a quarantine pest, nor a RNQP. For instance, the infamous brown rugose Tomato virus (also known as the Jordan virus, quite lethal for peppers and tomatoes) has been subject to stringent emergency measures adopted in a Commission Implementing Regulation (2020/1191), which require unequivocal seed testing in all Capsicum and Solana seeds, regardless of their origin.

Strengthening precaution, traceability and control mechanisms

Next to the classification of pests, the EU Regulation is also built around the principles of **precaution, traceability, and control.**

It thus requires all **professional operators** to be formally registered, when they are "involved professionally in, and legally responsible for" planting, breeding, producing, importing, marketing, storing, or processing plants or plant products, including seeds. All farmers qualify as such, while persons who "act for purposes which are outside that person's trade or business, [and] acquire plants or plant products for personal use" need not be registered. Some operators are not only registered under the plant health Regulation, but they can also be "authorised" to issue required phytosanitary documentation, which have been traditionally issued by public authorities in the past.

Traceability is further ensured through the issuance of **official documents** certifying the absence of all regulated pests, either through a **"phytosanitary certificate"** at its entry into the EU from outside the 27 for all plants and plant products, while "**plant passports"** accompany the plants and plant products that are vectors of RNQP's while they "move" within the EU (and not just when they are marketed). In the past, both were traditionally issued by public authorities. Today, most of them are issued by private entities that are authorised to do it by public authorities, subject to additional oversight, as the number of documents have significantly risen with the rising number of plant passports in the new regime.

Although plant passports are in principle required at any movement of seeds or plants falling under a RNQP, some exceptions exist to the rule, the most significant one covering the **direct supply to final users**, which do not require the use of plant passports, except for so-called 'distance sales' (Article 81 Regulation 2016/2031). However, no general exception that allows public authorities not to apply plant passport requirements to the movement of seeds for the conservation of genetic resources for food and agriculture that are directly under threat, as foreseen in the Swiss plant health law in a "special authorisation" procedure (article 37 of Swiss ordinance on plant health).

Further **control** is established through a system of inspections carried out by national authorities at least once a year in registered operators' fields and facilities. It is coupled with quite important archiving obligations for professional operators. All operators need to set up an internal tracking system that ensures they keep and seek all relevant documents and actions related to phytosanitary rules, from records of suppliers or recipients for each plant/seed, to information on plant passports

The European Commission submitted a report to the European Parliament and the Council of the EU on the experience of the extended plant passport system in December 2021 . The report highlighted that the system had been effective in protecting the EU against harmful pests, as it had increased levels of awareness and preparedness against outbreaks. It also recognised the measures' burdensome and difficult nature, pointing especially to provisions on distance sales, which show quite important differences from one Member State to another in terms of implementation. However, no sizeable reform is foreseen at the time of writing on EU plant health rules. These rules are nonetheless intricately linked to the EU legislation governing the marketing of seeds, which contains additional seed quality criteria concerning the absence of pests in marketed seeds, and is currently undergoing a sizeable reform process.

2.3. Market tools: Intellectual Property Rights & Seed Marketing

Next to the conservation of biodiversity and the protection against environmental damage that can be caused by seeds, EU seed policy also wants to ensure the free movement of goods as prescribed by the EU Founding Treaties and establish a fully functioning EU seed market with common rules to level out the playing field between operators. In this context, seeds are not viewed as genetic resources to be conserved or protected, but rather as market goods that either need to be regulated to ensure their quality, identity, and productivity (seed marketing), or the production and development of which needs to be incentivised by public policy (intellectual property).

Even though these policies are both market instruments, the division of competence is quite complex, as in the European Commission, DG SANTE oversees both UPOV and seed marketing legislation (in the same unit managing Plant Health), and DG GROW (Internal Market, Industry, Entrepreneurship) deals with patents.
At the level of the Council of the EU, the COMP (Competitiveness) Council deals with patents, while the AGRIFISH Council oversees seed marketing legislation, UPOV.
At the European Parliament, competence is divided between the Committee of Internal Market and Competitiveness IMCO (for patents) and the Committee of Agriculture and Rural Development COMAGRI (for seed marketing and UPOV).

2.3.1. Intellectual Property Rights

Although the notion of intellectual property dates back to Ancient Greece as a recognition of great intellect and inventiveness, rights have started to be attached to creative or inventive pursuits in medieval Europe from the 15th century onwards. Intellectual property laws seek to incentivize human creativity and inventiveness, by formally giving a “privilege” to those who fulfil certain criteria for a certain period of time, so that they can reap the fruits of their work.
There are different types of intellectual property that can indirectly be attached to plants and seeds, such as trademarks or copyright protection. But the two main titles that affect the multiplication and use of seeds come from the world of **industrial property**: namely plant variety protection and patents.

Industrial property rights are **exclusive prerogatives to control most if not all further uses of the product.** Despite their negative monopoly effect on competitiveness, these property titles are granted to incentivise research and development, by increasing the chances of recouping the investments made in product development through wide control (and royalty collection) opportunities for a limited time, usually around 25 years.
They need to be formally applied for, and granted by a public authority, which checks whether the conditions are met to concede the competitive advantage coming with an intellectual property title to an economic operator.

International instruments

European inter-State cooperation in the field of industrial property started as early as the 19th century, but a major turning point was the signature of the 1973 European Patent Convention ('EPC'), as a binding International Treaty setting common patentability requirements across different countries.

From 16 countries at its signature, the EPC now has 38 signatories, including all 27 EU Member States, but also countries like the United Kingdom, Switzerland, or Turkey. Quite significantly, the EPC established the European Patent Office ('EPO') in Munich, Germany, with powers to grant patents that can be validated in all participating countries.

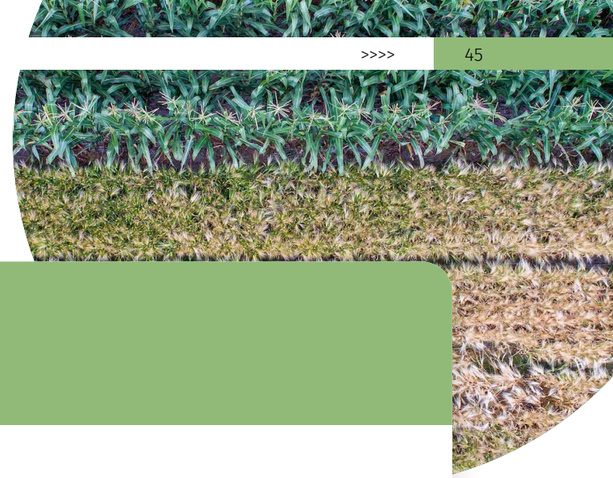
Patents are granted to inventions that are new, involve an inventive step and are susceptible of industrial application by the EPO according to the EPC and its implementing regulations. The exclusivity is granted for 25 years, requiring anyone using the invention to ask for authorisation to use the invention, and pay licensing fees, the amount of which is freely set by patent-holders.

These developments were echoed in the particular world of plants. European plant breeding companies played a key role in the creation of the Union for the Protection of Plant Varieties ('UPOV') in 1961 as an international organisation regrouping at the time only 12 European countries. Revised in 1972, 78 and lastly in 1991 (when UPOV had 19 signatories), the international UPOV Convention gradually gave breeders more sizeable exclusive rights to control the sale, storage, reproduction, and the multiplication of their variety, when they prove that their variety is not only novel, but also distinct, stable, and uniform ('DUS').

Intellectual property rights have greatly developed across the globe with the rise of international trade law, and especially with the signature of the **Trade-related Intellectual Property Rights ("TRIPS") Agreement** under the umbrella of the World Trade Organisation in 1994. As a binding international convention, the TRIPS text obliges countries that want to enter the WTO to recognise that patents are « available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application » (Article 27).

Countries are still allowed to exclude plants, animals, and essentially biological processes from the world of patents, but they must allow patents on micro-organisms, and on non-biological or microbiological processes.

In addition, they must provide for the protection of plant varieties, either by patents or through a sui generis system. Although this system can be devised more flexibly, the UPOV structure has been presented quite assertively as the key for countries to comply with the TRIPS Agreement. This brought UPOV membership levels to the 78 States where it stands today.



EU instruments

With regards to **plant variety rights**, Regulation 2100/94 (EU PVP Regulation) implements the 1991 Act of the UPOV Convention at EU level, even though some EU Member States have only ratified the 1978 Act of the UPOV Convention, like Italy and Portugal, while others like, Cyprus, Greece, Malta and Luxembourg, are not members of UPOV. Even if these countries do not have national plant variety protection offices that grant these titles, those that are awarded under the EU PVP Regulation are nonetheless valid throughout all EU Member States.

EU plant variety protection titles are granted by an EU agency, the **Community Plant Variety Office (CPVO)**, established in Angers, France. In parallel to the UPOV 1991 Convention, a variety is considered novel in the EU only if it has not been sold in the EU seed market within a specific timeframe, notwithstanding whether it previously existed in nature or in farmers' fields. The CPVO officially carries out the DUS testing of the varieties for which protection is sought. It relies on UPOV protocols for variety testing, which are developed in collaboration with the competent national authorities of all UPOV contracting States, including those outside the EU. Once granted, the exclusive title is valid for 25 years and allows the right-holders to deny the use of protected varieties, and/or request royalty payment for their production, multiplication, sale, import, export and storage. These prerogatives extend also to varieties that have been essentially derived from a protected variety. While the protected variety can be used freely for research and breeding purposes, its propagation in farms is subject to royalty payment, except in certain limited cases detailed in the Commission Regulation 1768/95 implementing the so-called "agricultural exemption" of the CPVO rules.

The EU Action Plan on Intellectual Property, adopted in November 2020, mentions an "update of intellectual property protection", with an improvement of the system to protect plant varieties. The Plan thus signals a targeted reform of the EU PVP legislation starting in 2023, although significant delay is expected on the file.

With regards to **patents**, the situation is more complex due to the existence of an international organization, the EPO, independent from the European Union, but with intricate ties to one another. Indeed, the EPC's Implementing Regulations, which integrate the 'case law' provided by the EPO's internal appeal procedure, also include the full text of an instrument of EU law, Directive 98/44 on the legal protection of biotechnological inventions ('EU Biotech Directive'). This means that the EPO, when deciding whether to grant a patent or not, follows EU law, despite the fact that the EPO is not formally an EU institution or agency. Exceptions to patentability regarding plant varieties and essentially biological processes exist and are quite strong in the EPO system, even though it operates under a general principle of patentability for inventions related to plant biotechnology.

While plant selection and crossing cannot open the door on their own to patent protection, the inclusion of a "technical step" may open the door to the monopoly title, either for an inventive process (linked to the development of a variety), or the product of such process (such as plant characteristics that are not t limited to a single plant variety). The EPO patent examiners check whether the patent application fulfils all the patentability conditions, and the decision can be opposed by third parties using the internal dispute-settlement bodies, the Boards of Appeals. Once granted, it is national patent laws that govern the scope of protection granted to the innovator by the patent, whether the title is granted by the national patent offices or by the EPO. The EU Biotech Directive, which needs to be transposed in national EU patent laws, espouses a strong and absolute patent protection approach, with wide ranging prerogatives. It nonetheless conditions these prerogatives to certain limits, allowing the use of the patented invention for research and farming purposes, under conditions. The complex linkages between EU legislation and the wider world of the EPO has intensified with the new Unitary Patent System, which will enter into force in June 2023. An international convention between 17 EU Member States (at the time of writing) who wish to enhance their cooperation in matters related to patents, the Agreement on a Unified Patent Court (UPC) was signed in 2013, but took 10 years to start bearing effects. The Agreement goes hand in hand with two EU Regulations, one creating a European patent with unitary effect (EU Regulation 1257/2012), and one on the translation arrangements (EU Regulation 1260/2012).

The UPC system does not change the patentability of living organisms, nor does it change the role of the EPO in the patent granting stage. It strengthens the protection given to European patents, which will be uniformly applied across UPC countries, and shifts the revocation and infringement procedures from national jurisdictions to the newly created Court, and its different divisions (which include a Life Sciences division in Munich).

Both plant variety protection and patents can be present on the same plant variety and its seeds, each restricting the possibility to use the variety for cultivation or breeding differently. These two property titles may trigger obligations for subsequent users (such as farmers or seed savers) to request authorization (and generally pay royalties) from different entities to use the same seeds.

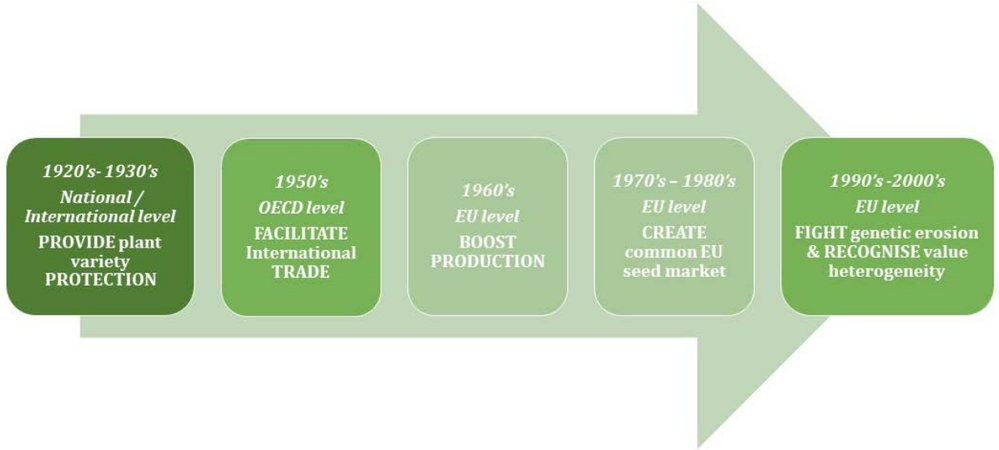
2.3.2. Seed Marketing Rules

Rationale & objectives of policy action

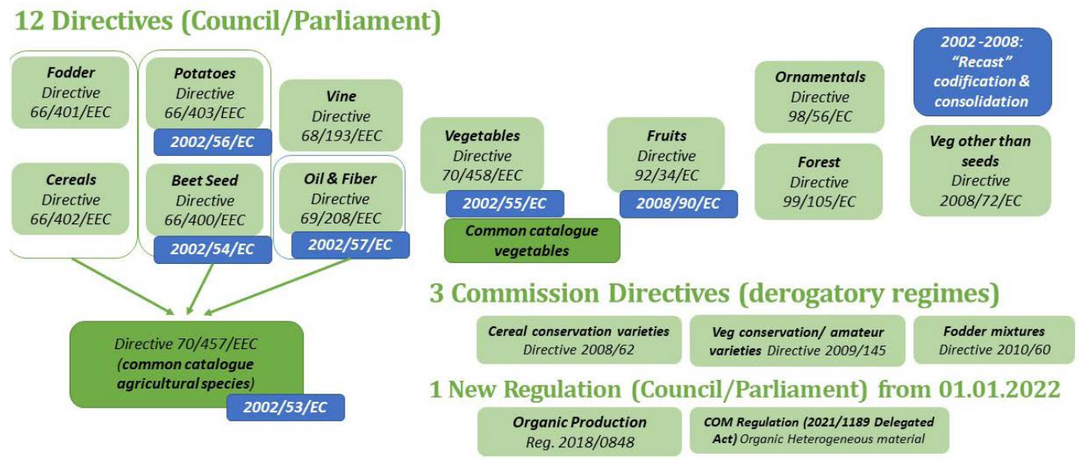
EU seed marketing legislation started to develop in the 1960's to ensure the **identity, quality, and productivity of seeds** for the needs and interests of the agricultural industry. As farmers did do not have access to information on the seeds they were buying before they cultivated them, public authorities protected them by controlling the identity and quality of seeds before it was is sold to farmers. Seed marketing legislation also developed to boost production in a context of under-production. It thus built on existing national and international plant variety protection legislation and aimed to facilitate international trade through common standards set out in the Organisation for Economic Cooperation and Development (OECD).

The policy discourse slightly shifted from the 1990's onwards, with the adoption of the CBD and subsequently of the ITPGRFA, and the integration of **biodiversity-related concerns** in a legislation not designed for environmental protection, but as a tool to regulate the seed market. The EU legislator cited the objective of biodiversity conservation in its motivations for action for the first time in 2008, as it opened the seed market to conservation and amateur varieties (as will be explained further below). The policy intended to scale up the plant varieties that could only be exchanged at small scales by allowing them access to the market, decreasing the chances of losing these varieties by potentially increasing their use.

In its 2020 Farm to Fork Strategy, the European Commission explicitly recognized the need to reform the seed marketing rules considering the announced transition towards more sustainable food systems. The Commission argues that **"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".



Main provisions of EU seed marketing legislation



Even though the objectives of the EU seed marketing legislation have gradually been adjusted to consider the principles and obligations coming from international environmental law, the policy continues to activate only market tools, as it was initially designed. EU seed marketing legislation is mainly governed by **twelve different Directives at EU level** (EU Seed Directives), which each regulate the conditions upon which seeds of a variety in a specific crop species can be marketed in the EU. The Directives need to be transposed at national level, which means that there are effectively 27 different seed marketing regimes in the EU, with quite important differences based on different national laws.

***EU Seed Directives**: Council Directives 66/400/EEC now amended into Directive 2002/54 (beet seed), Directive 66/401/EEC (fodder plant seed), Directive 66/402/EEC (cereal seed), Directive 66/403/EEC now amended into Directive 2002/56 (seed potatoes), Directive 68/193/EEC (vine), Directive 69/208/EEC now amended into Directive 2002/57 (seed of oil and fiber plants), Directive 70/457/EEC now amended into Directive 2002/55 (vegetable seed), Directive 98/56 (ornamentals), Directive 1999/105 (forest reproductive material), Directive 2002/53/EEC (common catalogue agricultural plant species), Directive 2008/72 (vegetable propagating and planting material) and Directive 2008/90/EC (fruit propagating material).*

EU SEED MARKETING DIRECTIVES

The main idea of the legislation is that only quality seeds from registered varieties can be officially marketed in the EU, bearing an official label and seal. Both registration and seed quality controls by public authorities are done prior to the marketing of seeds.

To be registered in a national list or catalogue, a plant variety needs to be distinct, uniform, and stable (DUS) as a rule of thumb, mirroring the criteria to receive plant variety protection. The DUS tests are done following protocols and criteria set out by the Community Plant Variety Office (in line with UPOV), established to grant an intellectual property title, and not as an authorisation to access the market. There are exceptions to this general rule in the different crop species that are regulated. Amongst them, it is interesting to know that the ornamentals sector relies on operator registration rather than variety registration due to the high diversity of the market, while fruit material is subject to a variety information system more relaxed than the mainstream regime applicable to most crop species. In agricultural crop species, applicants/breeders need to further show that their plant variety has Value for Cultivation and Use (VCU), which examines its added value compared to already marketed varieties.

Variety registration is a very costly affair, from the administrative fees to the costs of technical trials ranging from 2000 to 12000 EUR (depending on the species) for the official testing alone, taking years to complete and requiring significant public investment in terms of logistics and infrastructure.

Theoretically, all registered varieties should be available for sale on the EU common seed market, but that is not always the case in practice. Once their variety is registered, breeders of nationally listed varieties are required to pay annual fees to keep their varieties listed and apply for renewal every ten years to avoid the listing of varieties no longer found in the EU common market.

Varieties that pass the examination tests are registered in the national catalogue of the EU Member State where the application was made by the supplier/breeder. The EU Seed Directives have established **two Common Catalogues**, one for vegetable crop species, and one for agricultural crop species, along with an official **EU list for fruit species.**

In these cases, the registration of a variety into the national catalogue/list in one EU Member State grants access to the market of all EU Member States. The EU plant variety database is maintained by the European Commission and is available online as stand-alone documents for agricultural crop species and for vegetable species, and in a searchable format in the EUPVP 'Common Catalogue Information System", which has been expanded recently, and allows the use of different search criteria.

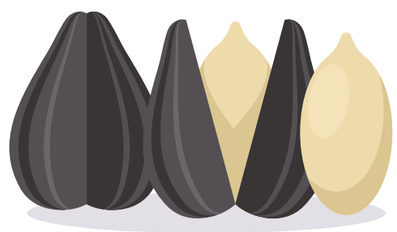
The database maintained by the CPVO provides further insight not only into protected varieties, but also into past and currently registered varieties, available free of charge after the creation of a profile. The CPVO Variety Finder indicates that a total of 130.000 varieties are currently registered in all EU Member States' national lists in all regulated crop species, whether agricultural, vegetable or fruit species, with more than 20.000 registered in vegetables, and close to 30.000 in agricultural crop species. All listed fruit material are compiled in the Commission's Fruit Reproductive Material Information System (FRUMATIS), which regroups 1083 entries from national lists. All registered plant varieties are considered to be close to one another in terms of intra-species diversity, and it is getting more and more difficult to distinguish them from one another, which leads to the adoption of ever more detailed criteria to differentiate their shape or characteristics.

Seeds of registered varieties cannot as a principle be marketed without being **certified**, according to quality criteria set out in the EU Seed Directives and national legislation. Some quality criteria, like humidity rates or the absence of pests, are not directly linked to seed lot certification, while the more stringent criteria relating to isolation distances (to maintain identity) are. Seed lot certification requirements apply more lightly in the vegetables seed sector, where standard seeds can be sold, subject to post-marketing controls by public authorities or agencies.

The EU Seed Directives also contain rules related to the **packaging** of seeds, generally requiring an official seal, along with rules on **labelling**, generally relying on an official label, at times with exceptions for small packages.

The EU Seed Directives only apply to a **limited number of crop species** that are expressly listed within the legal texts themselves (although Member States can and do decide to regulate more or less of them). They also only apply to the **"marketing" of seeds**, defined in most of the EU Seed Directives as the 'sale [...] aimed at commercial exploitation of seed to third parties, whether or not for consideration'. As a result, 'trade in seed not aimed at commercial exploitation of the variety [...] shall not be regarded as marketing'. This notion has been the subject of long debates at national level, leading to the adoption of very different interpretations. In Denmark, authorities have issued instructions for the non-commercial use of seeds, clarifying that seed laws only govern the marketing of seeds for agricultural and horticultural production, i.e. commercial production (for more information, a comparative analysis was done by different seed saver organisations in the region).

In France, it is now possible to sell seeds of varieties in the Public Domain that are not registered on any official national or EU catalogue, directly to non-professional users (Law n° 2020-699 of 10 June 2020 relating to the transparency of information on agricultural and food products).



COMMISSION DIRECTIVES: Derogatory Regimes

This picture has also been complemented by three Commission Directives, acting on the basis of a delegation of power from the European Council and Parliament (found in the main EU Directives), to redress the detrimental impacts of the EU seed marketing legislation on biodiversity.

Following a first attempt at the end of the 1990's, these derogations were revised at the end of 2000's due to the lack of uptake, and allowed the marketing of seeds from conservation and "amateur" varieties, along with fodder mixtures under a different (yet extremely similar) regime.

Conservation varieties are defined as landraces at risk of genetic erosion, which need to be registered through a process that deviates but does not fundamentally differ from the main procedure (Commission Directive 2008/62/EC of 20 June 2008 for agricultural landraces and Commission Directive 2009/145/EC of 26 November 2009 providing for certain derogations, for acceptance of vegetable landraces. The adaptation of the DUS criteria to allow the registration of conservation varieties is left mostly to national authorities. In addition, sizeable restrictions are set for the marketing of conservation variety seeds, which need to remain in the landraces' region of origin, and cannot exceed "the quantity necessary to sow 100 hectares, or 0.5% of the seed used in the same species in the country ». This marketing regime has been unevenly successful across the EU, with Sweden and Italy accounting together for close to half of the 402 agricultural conservation varieties currently registered in the EU Common Catalogue with 76 varieties each, against countries with none to very little registrations, such as the Netherlands (8 conservation varieties), Croatia (3), Hungary (1), Belgium (1) or Denmark (0). The picture is also quite unequal when it comes to the 189 EU vegetable conservation varieties, where registrations from Spain (58) and Italy (44) make up for more than half of the marketable varieties, startling compared with France (8), Germany (6), Belgium (2), or Austria (0).

In these countries, the second derogatory regime that exist for vegetables is generally used more frequently. **Amateur vegetable varieties** have no intrinsic value for commercial crop production and have been developed under particular conditions (Commission Directive 2009/145/EC).
Neither facing genetic erosion, nor restricted to a region of origin, but only to the sale of seeds in small packages, 'amateur varieties' are usually registered based on an official description. This category is the EU policy shift's largest success, with 812 varieties that can be commercialised throughout the EU common market, again with quite high shares in certain countries, such as France (295), or Austria (139).
Building on different European and nationally funded research projects that developed participatory plant breeding approaches bringing together researchers and farmers to explore plant populations and seed diversity, new ways to diversify the seed market were explored.

Activating the powers given to her by the EU Seed Directives many years back, the European Commission launched in 2014 a **temporary experiment on cereal populations** (EU Commission Implementing Decision 2014/150/EU) to allow the marketing of non-certified seeds from notified non-uniform populations of wheat, barley, oats, and maize. The experiment ran in six EU Member States (United Kingdom, Italy, France, Denmark, Germany, Netherlands).

Its final report was not the most optimistic regarding the performance of the populations (except for results in the UK on Wakelyns wheat), yet highlighted that these diverse populations could be identified using morphological characteristics and statistical analysis, with traceability ensured through document-keeping.

EU ORGANIC REGULATION

These elements fed directly into the last major change in the EU seed marketing legislation, through the adoption of the new EU Organic Regulation 2018/848 in May 2018.

This binding text with direct effect allows the marketing of standard seeds from "organic heterogeneous material" based on a notification describing the characteristics and history of the material in all regulated crop species, without official registration or seed lot certification.
All the details relating to the procedure are found in the Commission delegated Regulation 2021/1189, which also contains adapted rules with regards to packaging, labelling and maintenance requirements and have been clearly explained in a dedicated booklet.

Based on the Preamble of the EU Organic Regulation, two temporary experiments have also been launched under the EU Seed Directives to allow the registration of **"organic varieties suitable for organic production" ("OV")**, which are set to start on 1st July 2023 on a limited number of species : barley, maize, rye & wheat for Commission Implementing Directive (EU) 2022/1647 ; and carrot and kohlrabi for Commission Implementing Directive (EU) 2022/1648.

Both texts list the conditions that organic varieties need to comply with in relation to DUS tests, focusing on the elements and requirements which organic varieties can deviate from.
The Commission Directives also establish a yearly reporting system for Member States until the 31st of December 2030 on the number of applications and the results of DUS examinations for organic varieties.

Towards a (new) reform

On the same day that it requested the European Commission to submit a study on NGTs in 2019, the European Council also asked for action with regards to seed marketing legislation.

But this was not its first try to revise the latter.

The Commission had already tabled a proposal for the consideration of the European Parliament and the Council in May 2013, building on studies and impact assessment work that had been carried out from 2008 onwards. Intending to regroup all the different Directives into a single EU Regulation, the proposal 2013/0137 was rejected by the European Parliament in February 2014 for its "one size fits all" approach, the extension of powers to private actors and the CPVO, the many delegation of powers to the European Commission (making the text an unknown "black box" to sign off on) and because it did not facilitate and encourage biodiversity maintenance in agriculture and horticulture.

The second try at a seeds marketing reform was signalled by the European Commission in April 2021 with the publication of its Working Document recognising that the legislation was not fit to achieve the objectives of the European Green Deal and its Farm to Fork Strategy, based on a study done by an external consultancy.
The inception impact assessment (i.e., a short roadmap explaining the reasons behind the foreseen EU legislative action) was published quickly thereafter, igniting the larger-scaled work to fully assess the impacts of different policy options envisaged. While the 2013 process heavily relied on procedural elements and the division of competence, this time the focus seems to be flexibility and sustainability.

Having been delayed a few times, the proposal of the European Commission is now expected early July 2023, which will start the internal processes of both the European Parliament and Council of the EU through their competent bodies.

GLOSSARY & ACRONYMS

A. European Institutions

DG = Directorate-General of the European Commission: thematic divisions within the European Commission akin to Ministries at national level, acting in the direction set out by the College of Commissioners

EP = European Parliament: co-legislator of European Union policy, whose competences have steadily increased throughout European institutional history.

MEP = Member of the European Parliament directly elected through national lists every 5 years.
COMAGRI: European Parliament Committee on Agriculture and Rural Development

COMENVI = European Parliament Committee on Environment

COREPER = Committee of Permanent Representatives 'ambassadors' of EU Member States in Brussels, tasked to follow and prepare the work of the Council of the EU as co-legislator.

AGRIFISH: Configuration of the Council of the EU with competences mainly related to EU agriculture and fisheries policy.

IA = Impact Assessment
Procedure required by the 'Better Regulation Guidelines' of the European Commission that wishes to assess the impacts of a legislative proposal, looking at different policy options, and adjusting detrimental effects accordingly.

TRILOGUE: Tripartite meeting between the two European co-legislators, the European Parliament, and the Council of the EU, along with the European Commission, to find common ground between the Commission's proposal, the Council's position, and the Parliament's report on the proposal. When negotiations arrive at a compromise text, it needs to be voted according to the co- legislator's internal rules to be adopted.

EU REGULATION: instrument of European law adopted by the European Parliament and the Council of the EU, which has direct effect across the territory (its rights and obligations are directly applicable to all EU physical and moral persons).

EU DIRECTIVE: instrument of European law adopted by the European Parliament and the Council of the EU, which needs to be transposed in national laws due to its flexible nature.

COMITOLOGY: Procedure that allows EU Member States (Council of the EU) to oversee the work of the European Commission regarding the implementation of adopted EU legislation, usually through the establishment of expert groups or technical committees where national experts sit.

COMMISSION IMPLEMENTING ACT: Commission Directive or Regulation that implements an EU Directive or Regulation.

COMMISSION DELEGATED ACT: Commission Directive or Regulation adopted within the boundaries of a delegation of legislative power by the European Parliament and the Council of the EU in an EU Directive or Regulation.

B. The Law of the Seed

BIODIVERSITY CONSERVATION

UNEP = United Nations Environment Programme

CBD = Convention on Biological Diversity

COP = Conference of the Parties to an international agreement, which regroups all signatory States (and observers) every single or 2 years to discuss its implementation

FAO = United Nations Food and Agriculture Organization

ITPGRFA= International Treaty on Plant Genetic Resources

ABS: Access and benefit-sharing

PIC: Prior Informed Consent

MAT: Mutually agreed terms

MTA: Material Transfer Agreement
DSI: Digital Sequence Information

RISK PREVENTION

GENETICALLY MODIFIED ORGANISMS

GMO = Genetically modified organism

LMO = Living modified organism developed using modern biotechnology, regulated by the Cartagena Protocol

NGT = new genomic techniques

PLANT HEALTH

QP = Union Quarantine Pests, which cause unacceptable economic, environmental and social impact and do not yet exist in the EU

RNQP = Union regulated non-quarantine pests, which cause unacceptable economic impact and are already present in the EU

PHYTOSANITARY CERTIFICATE: official document issued by public authorities for a plant or plant product to enter into the EU, acknowledging that plant health measures have been respected and ensuring traceability.

PLANT PASSPORT: official document issued either by public authorities or authorised professional operators for a plant or plant product that moves within the EU, acknowledging that plant health measures have been respected and ensuring traceability.

MARKET TOOLS

INTELLECTUAL PROPERTY RIGHTS

EPC = European Patent Convention
International agreement that binds 38 countries, including all 27 EU Member States, with its own patentability requirements and its own patent office

EPO = European Patent Office
Established by the EPC, the EPO grants European patents on the basis of the EPC and its Implementing Regulations, which include EU legislation.

UPC = Unitary Patent Court
Created by EU legislation, with the participation of a limited number of countries, to ensure that European patents granted by the EPO have uniform protection across these countries' territories, and have a common dispute-settlement mechanism.

TRIPS = Trade-related Intellectual Property Rights Agreement of the World trade organisation

PVP = plant variety protection

UPOV = Union for the Protection of Plant Varieties

DUS = Distinctiveness, Uniformity and Stability
Criteria for the granting of plant variety protection

CPVO = Community Plant Variety Office

SEED MARKETING LEGISLATION

DUS = Distinctiveness, Uniformity and Stability

VCU = Value for Cultivation and Use

CATALOGUE: official list of registered varieties, the seeds of which are allowed to be sold in the seed market
National catalogues lists the applications accepted by national authorities, while the Common EU catalogue regroups the entries from national lists across all EU Member States in vegetables and agricultural crop species, that can be marketed in the entire EU seed market.

OHM: Organic Heterogeneous Material

OV: Organic Varieties

Credits

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