SPROUTS FROM BRUSSELS

Seeds & Crop Biodiversity in European Policy

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Welcome to Sprouts from Brussels! This newsletter wishes to inform the seeds and crop biodiversity movement across Europe on the policy developments which may have an impact on their activities. If you wish to be part of the conversation, and receive this briefing every month, subscribe here! If you wish to read previous issues, click here!

ECLLD Seed Policy Dialogue

Register to the ECLLD Seed Policy Dialogue on the Commission study on options to reform the seed marketing rules, Thursday 20th May at 5pm!

In order to discuss policy developments that affect crop diversity movements, the European Coordination Let's Liberate Diversity (ECLLD) has launched a **series of virtual Seed Policy Dialogues**. These monthly meetings will be a place to exchange on the different policy updates compiled in the Sprouts newsletter and dig deeper into a specific topic brought forward by the ECLLD Members.

This month's dialogue will be held on **Thursday 20th May from 17:00 – 18:30 CEsT** and will focus on the upcoming revision of the seed marketing rules in the EU. The webinar will be held in English, with interpretation to French and Italian. You can register here to attend.

Adoption of Delegated Act on Organic Heterogeneous Material

Delegated Act on Organic Heterogenous material finally published by the European Commission.

The draft Delegated Act (DA) on **Organic Heterogeneous Material** (OHM), regulates the rules to be followed for the production and marketing of diverse seed populations. The Act has finally been formally adopted by the European Commission on 7th May 2021, and is available in all 23 official languages of the EU. The European Council and Parliament now have two months to formulate objections to the text, which will enter into force on 1st January 2022, in parallel to the Basic Act of the Organic Regulation 2018/848.

The Delegated Act includes the possibility to **exchange seeds of OHM for research and breeding purposes** freely, outside of the notification rules, in limited quantities (which are not prescribed in the text). The content of the notification dossier that allows the marketing of seeds of OHM is quite flexible, as it relies on a bundle of indicators for the identification of the material. **OHM itself needs to be described** through an account of its **characteristics** (through phenotypic characterisation of key common characters and a description of

heterogeneity, coupled with related documentation and available test results), the **type of technique used** for breeding or production (which can relate to cross-composite population breeding, on-farm management and selection practices, or other techniques), the **parental material** used in such breeding or production techniques, and reference to the **country of production or breeding,** with indication of the year and the relevant pedo-climatic conditions. It is interesting to note that the reference to Directives 2008/62/EC and 2009/145/EC (conservation and amateur varieties) has been removed, leaving the choice to pick any of the existing legal categories with the operator to market organic seeds. Once the OHM notification dossier containing these elements has been approved according to the Organic Regulation itself (which states that the national seed authorities have three months to request additional information, after which the notification and its content is deemed to be acknowledged, and can be listed accordingly, when such national listing is set up in the Member State), seeds of OHM can be put on the market.

These seed lots will need to comply with different requirements, linked to their **identity** (based on the parental material or its history, the country of breeding or production, and their characteristics), have good **sanitary quality** (related to the Plant Health Regulation 2016/2031), but also quality criteria such as **analytical purity and germination rates** (stemming from the species-specific seed marketing Directives). Seeds of OHM with lower germination rates may still be marketed if it is indicated on the label or package. **Packaging and labelling** rules are also quite flexible, since they do not require official labels, or official seals, and also provide exceptions for small packages defined more loosely than the seeds marketing Directives, which can be sold unmarked and unsealed to final users. Even though some **traceability** requirements are put in place, requiring operators to keep records for five years, the additional **controls** operated by seed authorities should be risk-based. **Maintenance** of OHM is required only when possible.

The Delegated Act has considerably changed during the past year and is today flexible enough to accommodate for a wide range of realities on the ground. It will be exciting to see how crop diversity actors take ownership of these opportunities and translate them into practice, and also how the provisions will be implemented by national authorities.

Upcoming Seeds Marketing Reform

Study on options to reform EU seed marketing laws published by the Commission, listing four options for regulatory action, which will be analysed in the Inception Impact Assessment currently in preparation.

Mandated in November 2019 by the European Council to carry out a study on the options to reform the EU seeds marketing rules, the European Commission has **published** the study carried out by the external consultancy ICF on 29th April, accompanied by a Commission Staff Working Document lining up options for the future reform.

In its formal letter addressed to the Council, the European Commission highlights that, even though the problems that were identified during the last (failed) reform in 2013, some **additional issues** need to be addressed: namely the "new technical developments in the seed production and breeding sector, coupled with an increasing demand for sustainability in agriculture and an increasing need for conservation of agro-biodiversity and adaptation to climate change". The Commission considers that "**action needs to be taken** in the field of plant and forest reproductive material", aligning the legislation to the objectives of the European Green Deal. Fasten your seat belts, the landscape of seeds marketing in the EU is up for a significant change!

Content of the Study & Options for reform

The **fact-finding study conducted by ICF,** a 160 pages-long document, details the findings of the stakeholder interviews and different surveys conducted by the consultancy during the second half of 2020. The study points to six problems with the current legislation: the lack of coherence with the plant health legislation, unfit testing for non-conventional varieties, insufficient enforcement, slow and burdensome registration procedures, differences in administration, and variable costs between Member States. The study recognizes that the historical emphasis on commercial agricultural crops and varieties has neglected the needs of distinct communities of seed users; pointing out the lack of clarity in the terms used in the legislation, and the lack of flexibility, which does not allow national authorities to amend inappropriate registration criteria for example. The consultancy thereby recommends the Commission to ensure that registration and testing criteria are better suited to different variety categories, to establish mechanisms to

update the technical criteria, and improve the terminology used to better define commercial exploitation and activities conducted not for profit. The study also delves into the world of the amateur seed market, and the functioning of the current system of conservation and so-called 'amateur' varieties. While the main motivations of gardeners have been identified as growing edible produce, enjoyment, and improvement of their garden's appearance; the main contentious point is to determine the acceptable trade-off between a higher choice of varieties and the quality of the material. The consultants also highlight that even though the availability of seeds is quite high in the EU, there is a growing desire to have more traditional, regional, local and organic varieties on the market. The study also points out technological developments in variety testing and traceability mechanisms (such as blockchain and digital object identifiers), which could be used to alleviate the current administrative burden of the system.

Based on these findings, the European Commission, in its **Staff Working Document,** identifies slightly different problems, and proposes different options for the way forward. The issues that are highlighted by the Commission are drawn from the ICF study, but are more over-arching. Indeed, the institution points to the "complex, incoherent and fragmented legal framework", along with the "complexity and rigidity of procedures", a "lack of harmonized rules on official controls", which all create "internal market problems and non-level playing field", and interestingly, "obstacles to innovation". The points made by ICF regarding non-conventional varieties and the amateur gardeners' market are lost in translation, found between the lines of these wider problems. Quite worryingly, when addressing the complexity and incoherence of the framework, the European Commission underlines that the derogations to the main regime are not well-defined, and interpreted very differently by Member States, especially since the Directives do not allow the exchange of seeds between farmers. This analysis of the legislative framework is extremely rigid and troubling, especially since the Commission mentions the United Nations Declaration on the Rights of Peasants (UNDROP) only as a footnote, indicating that the rights to seeds enshrined in the Declaration are viewed as human rights by some stakeholders, thereby negating its legal standing in international law.

Even though it is the first time that the European Commission recognizes that the main objectives of the EU seeds marketing framework need to be aligned with the Biodiversity and Farm to Fork Strategies, it is unclear how such alignment will be translated into practice. The nebulosity remains complete when reading the different policy options detailed by the Commission, which range from either doing nothing (option 0), to adjusting slightly the Directives to improve procedures and coherence (option 1), by mainly allowing testing and production by operators under official supervision, ensuring coherence with the Organic Regulation (but unclear as to how?), and aligning the legislation to the Regulations on Plant Health and Official Controls. This would mean quite heavy bureaucracy and potentially a mandatory registration for all professional operators in a context where the definition of seeds marketing would not be specified or modified. The third way forward represents a more comprehensive reform (option 2), with clear support of the European Green Deal objectives, more flexibility in variety registration, amendment of the VCU testing criteria and rules for the use of modern technologies in testing. The Commission then details two directions that can be taken by the reform, either a balance between flexibility & harmonization (option 2A), where sale to amateur gardeners would be excluded from the scope of the legislation, and an *ad hoc* framework would cover farmer seed exchange. Controls would be risk-based but remain within the seeds marketing Directives, and not be directed towards the Official Controls Regulation, as stated in option 2B, which is about full flexibility with higher guarantees for users. This option would regulate farmer exchanges and sale to amateur gardeners, restricting the derogatory conservation variety regime to a minimum. The final proposal is likely to have elements of the different options, but the crop diversity movement and peasant organizations will need to become very active in order to see a new regime which is closest to their needs and demands.

Stakeholder reactions

Although reactions have been few on the topic, they preclude the interests that will collide during the reform process.

Indeed, the seed industry organisation Euroseeds welcomed the Commission's objective to make the EU seed legislation more comprehensive, strengthening its uniform application and integrating new technologies developments and managerial possibilities (i.e. the use of biomolecular markers in variety testing, and the possibility to conduct testing and seed production "under official supervision"). The industry association nonetheless stressed that the current legislation allowed "sufficient

flexibility to accommodate specific needs of niche markets and different markets". They are thus concerned that elements of the policy options presented appear to be inconsistent with the objectives of "fostering market-driven innovation through improved varieties in the interest of sustainable food security and serving the needs of seed users".

On the other hand, IFOAM Organics Europe welcomed the recognition that current rules do not "provide a good basis to introduce adapted testing requirements for the development of organic varieties suitable to organic production". In a parallel fashion, the seed savers' association Arche Noah has welcomed the alignment of the future legislation's goals with the European Green Deal, highlighting the many good reasons to free diversity from its bureaucratic shackles. The association nonetheless expressed its concerns regarding the fact that the European Commission does not rule out equating the exchange of seeds with their commercialization, in contradiction to Austrian law and international law.

Next steps

The Commission study and Working Document are now presented to the representatives of EU Member States but also to stakeholders that sit in the SANTE Advisory Group on Plant Health, which will meet on 19th May.

The Commission's DG SANTE Plant Health Unit is now working on an **Inception Impact Assessment,** which is a detailed Roadmap for further legislative work, and precedes official impact assessments. This inception document will be open for public consultation on the official Have Your Say website for a length of three weeks after its publication. The European Commission will then start working on a full impact assessment, which will be carried out by an external consultancy (remember that the European Parliament had criticized the quality of the impact assessment in 2013). It will be open for public consultation for a duration of three months. The legislative proposal is expected to be published by the end of 2021, triggering the ordinary legislative procedure before the European Parliament and the Council.

As mentioned in its letter to the Council, we already know that the **legislative proposal** will aim to "put into effect amendments in order for the legislation to be in line with the European Green Deal and the Farm to Fork, Biodiversity and Climate Adaptation Strategies, uniformly applied, efficient and effective, more open to integrating new and future developments, ensuring a high level of protection of the environment, more sustainable and supportive of biodiversity and climate proof". Quite the ambitious project to be followed closely by crop diversity actors.

EC Study on "New Techniques in Biotechnology" Published

European Commission study on new genomic techniques published, welcomed by industry organizations, and vehemently criticized by civil society and peasant groups, as it announced targeted policy action for products developed using targeted mutagenesis and cisgenesis, which include the infamous Crispr-Cas genome editing techniques.

Back in November 2019, Member States mandated the European Commission to carry out a study on "new genomic techniques" (NGT), which has been published on 29th April 2021. The document, which is 117 pages long, has **different elements,** a scientific and market state-of-the-art analysis, clarification of the legal status of organisms produced by NGTs, a state-of-play on the implementation and enforcement of the genetically modified organisms (GMO) legislation, as regards NGTs, safety and risk assessment considerations (prepared by EFSA), an overview of research and innovation in the field, EU countries and stakeholders views on potential benefits/opportunities and challenges/concerns associated with NGTs and their products, labelling, Small and Medium Enterprises (SMEs), intellectual property, information on public dialogues and national surveys, information on ethical aspects of NGTs and their products.

The main findings of the European Commission are that **NGT products have the potential to contribute to sustainable food systems** with plants more resistant to diseases, environmental conditions and climate change effects. The institution concludes that products can benefit from higher nutritional qualities such as healthier fatty acid content, and reduced need of agricultural inputs such as pesticides. At the same time, the study also highlighted **concerns associated with NGT products** and their current and future applications. Concerns included the possible safety and environmental impact, for example, on biodiversity, the coexistence with organic and GM-free agriculture, as well as labelling. However, the study finds that "there are strong indications

that the current 2001 GMO legislation is not fit for purpose for some NGTs and their products, and that it needs adaptation to scientific and technological progress".

In its letter to the Portuguese Presidency of the Council, the European Commission clearly states its desire to "take action in the field of NGTs, which can contribute to the objectives of the Green Deal and Farm to Fork strategy and to a more competitive economy, which are at the centre of current priorities of the EU". The Commission will therefore "initiate a **targeted policy action** on plants derived from certain new genomic techniques **(targeted mutagenesis and cisgenesis)**, which will entail carrying out an impact assessment. For other organisms (animals and microorganisms) and other new genomic techniques, the Commission intends to continue to **build up the required scientific knowledge**, in view of possible further policy actions".

Stakeholder reactions

Reactions to the study have been unsurprisingly positive from the side of the industry, with Euroseeds welcoming the publication, and urging quick action to "allow for a differentiated legal and practical approach to products derived from innovative plant breeding methods, similar to most other parts of the world", and avoid "undue lengthy [legislative] processes". The biotechnology industry's lobby group Europabio welcomed the study as "a positive step towards delivering innovation' for a climate-neutral and sustainable European economy, while the industrial farmers' group Copa-Cogeca considers this as a "game-changer for farmers and agri-cooperatives", urging the Commission to "make up for lost time". The contested European Plant Science Organisation's working group on agricultural technologies also welcomed the study, and the recognized "necessity to update the European legislation on GMOs in order to address innovation and biosafety concerns appropriately without preventing scientific and societal progress".

On the contrary, the European Commission study and its future plans for targeted mutagenesis and cisgenesis have been vehemently criticized by the organic movement, as IFOAM Organics Europe raised a "red flag on assumed benefits deregulating new genomic techniques", while the Demeter Federation highlighted that the European Commission threatened freedom of choice. The European Coordination Via Campesina denounced that the European Commission wants to change the GMO legislation after refusing to properly harmonise and apply it. Civil society actors echoed these concerns, as Friends of the Earth Europe flagged that the European Commission backed the removal of safety checks for new GMOs. Aiming to influence national Ministries, a joint appeal "Keep Gene Scissors under control!", has been released by science, agricultural, beekeeping and environmental protection organizations (Small Farmers Organisation (AbL), the Aurelia Foundation, the Gene-ethical Network (GeN), the Society for Ecological Research (GeSöF), the Initiative for GE-free seeds and breeding (IG Saatgut), Save our Seeds! (SOS) and Testbiotech), warning that the report does not sufficiently address the risks to health and the environment - and may well lead to political decisions being made which harm the precautionary principle.

Next steps

In parallel to the study on seeds marketing, the Commission will **consult** Member States and stakeholders on its findings and plans. In the immediate future, it is very likely that the **impact assessment** procedure will be initiated towards a proposal to amend the GMO Directive for plants derived from targeted mutagenesis and cisgenesis, which include genome editing techniques using Crispr-Cas technology. In the words of the Commission, this proposal will aim at a "**proportionate regulatory oversight** for the relevant plant products by adapting, as warranted by the future impact assessment, the risk assessment and authorisation procedures and the labelling/traceability requirements".

SPROUTS FROM BRUSSELS Glossary

This Glossary is intended to provide some guidance to better understand the institutional structure of European policymaking. Please get in touch if you wish to see additional terms defined here.

European Institutions

The **EUROPEAN COMMISSION** is the executive branch of the European Union. 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 Commission is divided into different **DIRECTORATE GENERALS ("DG"),** which are akin to national Ministries. Due to the multi-disciplinary nature of crop diversity, a few DG's are responsible for policy portfolios that impact seeds. 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, while DG ENV is responsible for the Union's environmental policy, including biodiversity and soil quality frameworks.

The **EUROPEAN PARLIAMENT** is one of the two institutions making up the legislative branch of the European Union, with its directly elected 705 Members of Parliament ("MEP") from all EU Member States. Its powers have been quite reinforced since the Treaty of Lisbon, and now the Parliament has a say in all policy files linked to crop diversity. It works in different **COMMITTEES** (ENVI and AGRI are both competent for matters related to crop diversity), but all texts need to be adopted in so-called **PLENARY,** which regroups all MEP's. Even though European elections are carried out on the basis of national lists, MEP's then congregate into European-level political groups : the European People's Party (EPP), Socialists & Democrats (S&D), liberals Renew Europe (RE), Identity & Democracy (ID), Greens/EFA, Conservatives (ECR), leftists GUE, and the non-affiliated few.

The **EUROPEAN COUNCIL** is the last institution of the legislative branch of the European Union, composed of heads of States and governments, in different configurations according to the topic at hand. For matters related to crop diversity, the main interlocutor is the AGRIFISH Council, but also the ENVI Council to a certain extent.

Instruments of European Law

There are two instruments in European law: a **REGULATION** (of the COUNCIL and the PARLIAMENT) 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. With regards to crop diversity, the new Organic production regime, as well as rules concerning plant health are both enshrined in Regulations.

A **DIRECTIVE** on the other hand, 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, which explains the wide differences that exist between national seed marketing regimes, the principles of which are set in 12 different European Directives.

In a REGULATION or a DIRECTIVE, the European Parliament and the European Council can decide to give the Commission the power to further specify certain aspects of the general rules, which will lead to a **COMMISSION REGULATION**. There are two types of Commission legislative action in this framework: **IMPLEMENTING ACTS** are adopted to ensure uniform conditions for the implementation of European law, while **DELEGATED ACTS** are adopted 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. Both Implementing and Delegated Acts are prepared by the Commission 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 Act, while stakeholders are consulted through the "Have Your Say" website of the European Commission once the drafts (of both Implementing and Delegated) Acts have been finalised, four weeks before their adoption by the competent structure(s).