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Update on ongoing discussions on the regulatory proposal of the European Commission on New Genomic Techniques ("NGTs"): recommendations to reach the Trilogue

Conscious of the urgent need of European agriculture to quickly access New Genomic Techniques (NGTs) to accelerate the adaptation of crop varieties to climate change, AFBV and WGG have developed this note to inform stakeholders on the positions taken by the Council of the EU and the European Parliament ("EP") following the European Commission's proposal for a regulation on NGTs published on 5 July 2023[1] (the "Proposal"), and make recommendations that could facilitate reaching a qualified majority by the EU Council followed by a compromise acceptable to all stakeholders in the Trilogue.

To facilitate understanding, the discussion will be approached as follows:

1. Rationale for the choices underlying the Proposal: *lex specialis* for Targeted Mutagenesis and Cisgenesis (including intragenesis) resulting in a regulatory framework encompassing four categories of plants: conventional, NGT-1 plants, NGT-2 plants and GM plants.
2. Differentiated regulatory treatment between NTG-1 versus NTG-2 plants.
3. Status of negotiations at the level of the Council: adjustments to the text made by the Spanish and Belgian Presidencies, and list of the main topics that continue to be discussed in the Council under the Hungarian Presidency. Brief analysis of the changes made by the Council or still under discussion.
4. Brief analysis of the main amendments made by the European Parliament[2] on 7 February and 24 April 2024.
5. Recommendations on IP[3] for the Trilogue.
6. Conclusions

1. Choice of a *lex specialis*

Rather than modifying existing GM legislation, the Proposal creates a specific regulation that will apply to two categories of technologies included in NGTs: (1) targeted mutagenesis and (2) cisgenesis (which includes intragenesis).

"Category 1" plants (NGT-1) are assimilated to conventional plants and, therefore, are exempted from the requirements of the GMO legislation, in the same way as organisms exempted in Annex IB of Directive 2001/18/EC.

"Category 2" (NGT-2) plants with more complexities than conventionally bred plants continue to be subject to GM legislation but with adjustments, since they are not *transgenic* plants but modified genetic material from the breeders' gene pool (including all taxonomic species with which it can be cross-bred, including by using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses).

The principle of a *lex specialis* is currently accepted by the EP and a significant majority (17) of the Member States (MS) of the Council (although they do not constitute a qualified majority, as they represent less than 65% of the EU's population).

2. Differentiated *regulatory treatment* of NGT-1 versus NGT-2 plants.

The case of NGT-1- plants: they will be exempted from GMO legislation – so they will not be subject to authorization, risk assessment, traceability, labelling, or special monitoring.

On the other hand, their status as NGT-1 is conditional on the satisfaction of a procedure for verifying the equivalence status:

a. An application (with submission of information) must be made to the competent authority of the Member State (MS) concerned, prior to field trials, or in the absence of EU trials, to EFSA, prior to marketing.
b. The competent authority of the MS (or EFSA) subsequently carries out a verification of the compliance of the plant with the equivalence criteria of Annex I (types of genetic modification).
c. Finally, a decision on the status of the plant is taken at the level of the MS or the EU, valid throughout the EU.

All plant reproductive material ("PRM") (i.e. living plants and parts of living plants intended for breeding, such as seed bags), including those intended for breeding and scientific purposes, must be labelled with the words "NGT Cat 1" and the identification number of the NGT-1- plant from which the variety is derived. Information is made available in a public database.

NGT-1 plants are banned in organic farming.

NGT-2- Plants: GMO legislation applies – they are therefore subject to authorization, risk assessment, traceability, labelling and monitoring with adaptations:

a. Adaptation of the requirements for risk assessment, to be specified in a future implementing act
b. Possibility, upon justification, to derogate from the detection method (if it is not possible to detect, identify and quantify a product in a unique way)
c. Possible derogation for post-marketing monitoring, upon justification
d. Renewal authorization with no validity limit (while limited to 10 years for GMOs)
e. Optional labelling of the trait in question
f. Mandatory coexistence measures by Member States without opt-out
g. Financial and regulatory incentives for NGT-2 plants deemed sustainable (see Annex III categories)

3. Negotiation status at EU Council level

The Commission's Proposal has been managed first under the Spanish Presidency (2nd semester 2023), then under the Belgian (1st semester 2024) and Hungarian (2nd semester 2024) presidencies, in the Council's "Agriculture" configuration (AGRIFISH). A first draft compromise was presented under the Spanish presidency on 11 December 2023[4], but did not achieve a qualified majority (a minimum of 15 MS must vote in favor, and the MS in favor must represent at least 65% of the EU's population).

Under the Belgian Presidency, a new compromise text was presented and agreed on 7 February 2024, at the COREPER meeting, by 17 States[5], but still not representing a qualified majority. This text is not public, but we were able to access a copy.

In March 2024, the Belgian Presidency proposed to condition the regulatory status of NGT-1-plants on the absence of patent coverage. This proposal was not accepted.

A working group continues to meet under the Hungarian presidency (2nd semester 2024), which will be followed by the Polish (1st semester 2025) and Danish (2nd semester 2025) presidencies.

We comment below on the adjustments made by the EU Council in the text dated 7 February 2024, and other topics still under discussion:

A. Exclusion of herbicide tolerant plants from Cat 1

This proposal seems neither necessary nor desirable. We understand that it aims to discourage the development of herbicide-tolerant (HT) varieties, or to strengthen their supervision. It is important to keep in mind that HT plants and varieties can easily be obtained by spontaneous mutation, random mutagenesis, TILLING or other conventional breeding techniques. A more logical and non-discriminatory solution would be to treat all HT varieties in the same way in the proposed regulation on plant reproductive material ("PRM")[6] (uniform authorization, traceability and monitoring requirements), regardless of the techniques used to obtain them.

B. Consideration of ploidy for criteria Annex I

In the Council text of 7 February 2024 amending Annex I, it is specified[5]:

> "A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications per monoploid genome..."

The scientific community had already observed that if one wanted to cap the number of possible modifications for an NGT-1- plant, it was necessary to take into account ploidy for species with multiple genomes. The amendment proposed by the Council is consistent with recital 18 bis proposed by the EP[7]:

> 'The maximum number of genetic modifications authorised for inclusion in Category 1 NGTs should be proportionate to the number of genomes they contain.'

C. Opt-out possible for Cat 2 (as for transgenic GMOs)

As Category 2 plants do not meet the conditions of Annex I because they have a more complex set of genetic modifications, the Commission has proposed to subject them to the same regulatory regime as GMOs, but with adjustments. The Commission did not want opt-outs to be possible for NGT-2 as in the case of GMOs. We agree with the Commission and consider this possibility to be undesirable and counterproductive. Indeed, if opt-outs were allowed, the possibility for breeders or farmers to use such plants in the EU would become unpredictable, as the Commission had pointed out, and would therefore discourage their development and use.

For example, the low-gluten wheat advocated by the Commission and JRC[8] would probably not be able to see the light of day if it were to be classified as Cat 2 with an opt-out.

D. Mention all traits resulting from genetic modification in the case of voluntary labelling of Cat 2 plants

Mentioning all the characteristics conferred seems reasonable for the sake of transparency.

E. Addressing the question of Patents: delivery of the Commission's study by the end of 2025

The Commission is expected to provide the study by the end of 2025. But the IP impacts of NGTs should not be addressed in the Commission's NGT proposal (aimed at the regulatory status of these plants) -- proposals for amendments to EU IP law should instead be dealt with by separate acts after stakeholder consultation and evaluation following an impact assessment, without limiting the scope to patents alone.

F. Establishment of a group of experts appointed by Member States to monitor the consequences of patents

As the subject matter is different from the regulatory status, it is appropriate to deal with it outside the Proposal. If the creation of such a group of experts were to prove useful, it should only be set up after the Commission's study has been received and should focus on two IP systems: patents for plants and PBRs for varieties.

G. Romania's concerns[9] regarding the definitions of the Cartagena Protocol[10] (under discussion)

We believe that NGT-1 plants should not be considered as LMOs (GMOs) under the Cartagena Protocol for the following reasons:

1) if the modified sequence obtained by targeted mutagenesis or cisgenesis already exists in the breeders' gene pool, then it is not **novel,** and as such does not fall within the definition of an LMO which requires that the modification be a "novel combination";
2) if the modification is obtained by targeted mutagenesis, it can only be (1) a substitution or insertion of a maximum of 20 nucleotides or (2) a deletion (regardless of size), such modifications being able to be carried out in a natural way by recombination and, therefore, not overcoming "the natural barriers of reproductive or recombination physiology", as required by the definition of the protocol.

In order to reassure Romania and other stakeholders, it would be desirable to insert in the Proposal a new explanatory recital (14b) after Recital 14, the text of which would reflect the above-mentioned argument:

> 'It is understood that category 1 NGT plants are not considered to be living modified organisms within the meaning of the definition of the Cartagena Protocol, either because they reproduce genetic combinations already existing in the breeders' gene pool, or because the modifications made can be carried out naturally by recombination, and, therefore, do not overcome the natural barriers of reproductive physiology or recombination. »

H. Equivalence criteria for Cat 1 (under discussion)

The clarifying changes made in the Council's text are useful (they allow random cisgenic insertions and cap the total number of changes at 20 per haploid genome).

For example, if random insertions (not causing gene disruption) were not allowed under Annex 1, the disease-resistant potato or apple varieties advocated by the JRC[11] and the Commission, presented as obtained by NGT (cisgenesis), would be considered GMOs, subject to opt-outs, and therefore unlikely to be marketed in the EU.

I. Risk assessment for Cat 1 (under discussion)

This subject should be closed following EFSA's observations[12] in response to ANSES's opinion:

> " The average number of spontaneous mutations per generation, according to the references cited by ANSES, is 10^{-8} and 10^{-10}, which for a genome such as maize would lead to 20-30 mutations for every single progeny. This figure is 1,000-10,000 times higher when random mutagenesis is used, according to the references cited by ANSES. **Therefore, it is scientifically justified to consider that a plant showing 20 modifications or less compared to its parental could be the result of spontaneous mutations**."
>
> "With regard to all equivalence criteria, EFSA's GMO Panel (EFSA) considers that the available scientific literature shows that plants containing the types and number of genetic modifications used as criteria for the identification of category 1 NGT plants do

indeed exist as the result of spontaneous mutations or random mutagenesis. It is therefore scientifically justified to consider these plants as equivalent to conventionally bred plants. »

"[W]ith respect to the potential risks from NGT plants, the EFSA GMO Panel did not identify any additional hazard associated with the use of NGTs compared to conventional breeding techniques, which include random mutagenesis using physical or chemical agents."

J. Traceability and labeling for Cat 1 (under discussion)

Conventional plants are not subject to traceability or labelling describing the breeding method; the Commission's proposal to require labelling for all PRM (including those used in breeding and research) and a publicly available database for verified NGT-1 plants ensures transparency for consumers and non-use in organic farming.

K. Opt-out, coexistence with organic (under discussion)

The opt-out possibilities make development and return on investment unpredictable. There is no problem of coexistence with organic farming in the case of exempted GMOs (which are not subject to labelling for PRM and for which no comprehensive database is publicly available).

L. Delegated acts (degree of freedom left to the Commission) (under discussion)

Articles 5 § 3 and 22 § 8 of the Proposal authorize the Commission by delegated acts to amend the equivalence criteria in Annex I and the list of NGT plant traits established in Annex III in order to adapt them to scientific and technological progress. These delegations are for five years, extendable, and can be revoked by the Council or the EP at any time – and therefore seem justified and reasonable.

M. Intellectual Property (under discussion)

See our recommendations (Section 5 below) on the topic of IP for the Trilogue.

4. Comments on the amendments[7] made by the EP in February and April 2024

Category 1

a. Requirement to contain a sustainable trait and no HT trait to meet equivalence criteria

To meet the equivalence criteria, the EP requires that the NGT-modified plant must contain at least one sustainable trait (see the list in Annex III) and no unstainable traits (i.e., HT).

This amendment does not seem necessary given that sustainability is an evaluation criterion that will be measured at the level of registration for all varieties that are candidates for listing within a species:

"In the French registration system, agricultural varieties of the same species are grouped together and evaluated in the same trial locations and according to the same protocols. This ensures identical conditions for VATE [**Agronomic, Technological and Environmental Value]** evaluation for all the varieties under study. By pooling the experimental resources of the various partners, the official testing network managed by GEVES maximizes the accuracy of the data and consequently their reliability, used for the decision to register in the Official Catalogue or disseminated for use by crop sectors and farmers." [13]

The French VATE system for agricultural species "prefigures the provisions relating to the VSCU (**Value for Sustainable Cultivation and Use)** system envisaged in the proposed PRM regulation published by the European Commission on 5 July 2023"[13]. Sustainability is addressed for all

varieties in Article 52 of the proposed PRM[6] Regulation, without reference to the breeding technology.

As for the herbicide tolerance (HT) trait, this is also planned to be regulated within the PRM Regulation according to Article 47 §1(f) and §3, for all varieties of a species in the same way, without specifying the technology used to obtain the HT trait. As in the case of the Council, the EP considers that the HT character is incompatible with the equivalence criteria. As mentioned earlier, it is relatively easy to obtain HT traits by spontaneous mutation, as well as by random mutagenesis and TILLING, among other conventional breeding techniques. Discriminating on the basis of the technology used does not make sense at the regulatory level when the results are completely equivalent.

b. Requirement to provide a monitoring plan

Specific monitoring for NGT-1 varieties would be discriminatory because they are considered equivalent to conventional varieties.

c. Labelling up to the consumer level and documentary traceability at all stages

This requirement, for which the EP did not provide an explanation or justification, does not exist today for exempted GMOs (for example, CMS cauliflower, obtained through cell fusion, is not subject to labelling for consumers or traceability). The Commission's proposal promoting transparency and non-use in organic farming is a good compromise.

d. Ban in organic farming; legal adventitious presence allowed in organic farming; Commission report to assess the planned ban on organic farming after 7 years

Banning NGT-1 varieties at this stage in organic farming, while at the same time permitting adventitious presence in organic farming and committing to reviewing the ban in seven years' time: these are the elements of the reasonable compromise proposed by the EP. If the impact of the ban needs to be assessed, the Commission is in any case planning a first report on the implementation of the Regulation three years after the first decision taken under Article 6 or 7 of the Proposal (see Article 30, paragraph 1).

e. Modification of the equivalence criteria: a maximum of 3 per coding sequence, no chimeric protein; re-evaluation of the criteria by the Commission every 4 years

This set of amendments seems reasonable: rather than creating a ceiling for the total number of modifications, the EP bans chimeric proteins and limits the number of modifications in a coding sequence to three. As regards the delegation granted to the Commission to re-evaluate the criteria (Article 26 of the Proposal), it is for a period of five years, renewable, and the first report on the delegation must be submitted no later than nine months before the end of the five-year period.

Category 2: Tougher conditions for derogation from detection and monitoring requirements

As NGT-2 plants are not transgenic, stricter conditions for derogation seem unjustified.

Categories 1 and 2: Amend Directive 98/44/EC[14] to make NGT plants non-patentable; Patent study by the Commission required by June 2025

The Commission has committed to providing its study by the end of 2025 as requested by the Council. Concerning the application of IP to NGT plants, we recommend reading the eleven AFBV proposals[3]. In the following section, we recommend the implementation of four of these proposals, which we consider to be priorities for the Trilogue.

5. Recommendations on the subject of IP for the Trilogue

Unless the parties to the Trilogue otherwise agree, we recommend waiting for the conclusions of the Commission's study, scheduled for 2025, before starting legislative initiatives on the subject. We reiterate that any legislative proposal must comply with the "Better Law-making" framework, which involves an impact assessment and consultation with affected parties.

Of the eleven IP-related proposals previously published by AFBV, there are four on which the Commission could act as a priority:

1) **Amend the proposed PRM Regulation[6] making it mandatory to publish with regular updates the status of patents that may cover a marketed variety in the Official Catalogue of Species and Varieties of Cultivated Plants of the EU[15], for species covered by this regulation, and, for other species not covered in the Catalogue, in the CPVO database[16]**, referring to the relevant articles of Regulation 2100/94/EC[17] and Council Directive 2002/53/EC[18] of 13 June 2002. Later, if the patent legislation were to be modified, it could be envisaged that the absence or non-publication of the status of a patent covering a variety would render it unenforceable against third parties.

   The aim of this proposal is to create greater transparency around patents that may cover commercially accessible varieties, in order to facilitate freedom to operate analysis and the possibilities for negotiating licences, as existing databases (PINTO[19] and ILPV20) are neither exhaustive nor binding.

2) Clarify in an interpretative notice covering IP applicable to plants[21] that in Art. 27(c) of the Agreement on a Unified Patent Court (UPCA)[22] **the term "biological material" includes the NGT tools used to create the NGT plant and the variety derived from it, and that the regulatory and legal procedures for the protection and registration of varieties may be carried out within the framework of the exemption provided for in this article, while patents are still in force, as well as seed production that precedes commercialization.**

   The objective of this proposal is to create greater certainty and clarity on the scope of the breeder's exemption which, in order to meet the needs of breeding, must include germplasm itself, tools needed to improve and modify germplasm, all regulatory steps prior to marketing, and commercial seed production prior to launch.

3) Specify in the same interpretative notice that in the case of compulsory licenses, **the criterion of "considerable economic interest"** used in Article 12, para. 3 (b) of Directive 98/44/EC[14] **as well as the criterion of "public interest"** used in Article 29 of Regulation 2100/94/EC[17] **are satisfied by the registration of a variety having a trait obtained by NGT with a known and measurable economic advantage (e.g. disease resistance) or increased tolerance to measurable environmental factors (e.g. drought resistance)**, compared to other registered varieties, and that FRAND (fair, reasonable and non-discriminatory) conditions should apply to compulsory licenses under the above articles for plants obtained by NGT (i) that are covered by a patent or (ii) which are varieties considered to be essentially derived from a variety protected by PBR.

   The objective of this proposal is to create predictable and fair conditions for the marketing of patent-dependent varieties and for NGT varieties that depend on a PBR-protected variety, both of which need a license to be marketed under fair,

reasonable and non-discriminatory conditions, as is already the case for patent-covered varieties in the PINTO and ILPV databases.

4) Propose to the European Patent Office (EPO) to formally confirm that **the disclaimer clause of EPO Rule 28(2)23 covers not only the plant containing a gene or a native trait, but also the gene and the corresponding trait**.

The objective of this proposal is to remove any uncertainty about the scope of the disclaimer by reassuring the breeder in the event that the breeder is working on a trait found in its breeding material that could be dependent on a patent on the same trait obtained as a result of the use of NGT techniques.

These four proposals are likely to be acted upon more quickly than others, because they are well understood by stakeholders, three of them do not require a legislative act and another could be inserted into a text currently under discussion (the PRM Regulation). They are necessary to create transparency on which varieties are covered by a patent, to facilitate the analysis of freedom to operate and the negotiation of licenses, to provide concrete solutions to enable the implementation of compulsory licenses, to clarify the scope of the breeder's exemption and to reassure small breeders about native genes that may be present in their gene pool.

6. Conclusions

On numerous occasions for almost ten years, AFBV and WGG have stressed the urgency for agriculture to be able to use the tools of genome editing to accelerate the breeding of varieties adapted to climate change, changing consumer needs and sustainability requirements. Since December 2019, at the request of the EU Council, the Commission has been working to find a pragmatic solution. After 42 months of work, the Commission has issued a proposal that can be of great benefit to EU breeders and farmers.

Since the publication of the Proposal on 5 July 2023, an important subject has emerged, which risks preventing some Member States in the Council and some MEPs from supporting the Commission's proposal: that of the patentability of plants, and in particular those that are NGT-derived.

While acknowledging that industrial property can present challenges for all actors, we believe that it is necessary to ensure essential protection of innovation for inventors while maintaining access to plant genetic resources for breeders and farmers. On 5 July 2023, in its Q&A [24] following the publication of the NGT proposal, the Commission acknowledged that it is

> "important to calibrate a balanced framework which supports farmers' and breeders' access to patented techniques and material, promotes seed diversity at affordable prices, and safeguards breeding and cultivation of unpatented conventional and organic crops, while also strongly encouraging innovation in plant breeding by preserving investment incentives, such as patents."

We believe that a decision on whether (or not) to patent plants and NGT products at EU level should comply with the modalities in force in the EU under the Interinstitutional Agreement on Better Law-Making of 12 May 2016[25]. Under Better Law-Making, *any* draft regulation must be subject to an impact assessment, stakeholder and public consultation, feedback and an ex-post evaluation of existing legislation under Section III.

While acknowledging that the request for a report on the role and impact of these patents is largely justified, it is essential to await the receipt of the report and any proposals that may result from it before initiating any legislative proposal.

We strongly believe that it is in the EU's interest that the plant variety and patent protection systems coexist peacefully in the interest of promoting European varietal innovation for crop improvement. The four proposals made in the previous section do not call into question the two systems that coexist, but seek to address the reasonable concerns of all stakeholders in the short and medium term, and could be part of the Commission's recommendations in its report and be acted upon quickly (three do not require a legislative act and one can be addressed in the PRM Regulation under discussion), so as not to delay the adoption of a compromise on the proposed Regulation in the Trilogue. Ideally, it would be desirable for the PRM Regulation to be adopted at the same time as the NGT Proposal so as not to delay the placing on the market of NGT varieties. If the adoption of the PRM Regulation is likely to be significantly delayed, the possibilities for the CPVO to adopt the first recommendation independently, if its internal rules permit, should be examined now.

For all the reasons set out above, AFBV and WGG hope that the Commission's NGT regulatory proposal will be adopted by the EU Council largely in the form already agreed by 17 member states on 7 February 2024, in order swiftly to trigger the Trilogue, pending the Commission's report on patents which should be available in one year at the latest. From the outset of the Trilogue discussions, the four proposals mentioned above could complement the legislative framework under discussion in order to achieve the balanced framework desired by the Commission.

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AFBV and WGG remain available to all stakeholders to answer any questions that may arise from this note, which is a collective work, initiated by Philippe Dumont to which Franck Berger, Yvette Dattée, Klaus-Dieter Jany, Thierry Langin, Christian Leclerc and Pascual Perez contributed.

References:

[1] Proposal for a Regulation of the EP and the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 https://food.ec.europa.eu/document/download/c03805a6-4dcc-42ce-959c-e4d609010fa3_en?filename=gmo_bio-tech_ngt_proposal_2023-411_en.pdf

[2] In April 2024, the AFBV published an analysis of the main amendments made by the EP to the Commission's Proposal. https://www.biotechnologies-vegetales.com/commentaires-sur-les-amendements-au-projet-ngt-de-la-commission/

[3] Also in April 2024, in order to address concerns expressed on the issues raised by the EP relating to intellectual property ("IP"), the AFBV shared on its website eleven new proposals that could be taken into account in the recommendations that will follow the Commission's study on the impact of patents on plants derived from NGTs. https://www.biotechnologies-vegetales.com/propositions-pour-faciliter-lidentification-lacces-et-lutilisation-de-la-propriete-industrielle-liee-aux-nouvelles-technologies-genomiques/

[4] Spanish Presidency compromise text. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_16443_2023_INIT

[5] Belgian Presidency Compromise proposal on the NGT Regulation, private copy

[6] Proposal for a Regulation on the production and marketing of plant reproductive material in the Union https://food.ec.europa.eu/plants/plant-reproductive-material/legislation/future-eu-rules-plant-and-forest-reproductive-material_en

[7] Amendments adopted by the European Parliament on 7 February 2024 on the NGT proposal https://www.europarl.europa.eu/doceo/document/TA-9-2024-0067_EN.html

[8] Socioeconomic impact of low-gluten celiac-safe wheat developed by gene editing https://publications.jrc.ec.europa.eu/repository/handle/JRC131711

[9] Comments from Romania beginning at p. 43: https://data.consilium.europa.eu/doc/document/ST-12514-2024-ADD-1/en/pdf

[10] Text of the Cartagena Protocol: https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf

[11] Economic and environmental impacts of disease resistant crops developed with cisgenesis https://publications.jrc.ec.europa.eu/repository/handle/JRC131721

[12] Scientific opinion on the ANSES analysis of Annex I of the EC proposal COM (2023) 411 (EFSA-Q-2024-00178) https://www.efsa.europa.eu/en/efsajournal/pub/8894

[13] https://www.geves.fr/actualites/evaluation-de-la-durabilite-en-vue-de-linscription-au-catalogue-officiel-francais/

[14] Directive 98/44/EC on the legal protection of biotechnological inventions. https://eur-lex.europa.eu/legal-content/FR/TXT/?uri=celex%3A31998L0044

[15] https://food.ec.europa.eu/plants/plant-reproductive-material/plant-variety-catalogues-databases-information-systems_en

[16] CPVO database: https://cpvo.europa.eu/en/applications-and-examinations/cpvo-variety-finder

[17] Regulation 2100/94/EC on Community plant variety rights. https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:31994R2100

[18] Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species https://eur-lex.europa.eu/legal-content/FR/ALL/?uri=celex:32002L0053

[19] PINTO **database** set up by Euroseeds: https://euroseeds.eu/pinto-patent-information-and-transparency-on-line/

[20] ILPV **Database** : International Licensing Platform-Vegetables - https://www.ilp-vegetable.org/

[21] See Commission opinion of 8 November 2016: https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:52016XC1108(01)

[22] Agreement on a Unified Patent Court (UPCA): https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:175:0001:0040:fr:PDF

[23] EPO Rule 28(2): https://www.epo.org/fr/legal/epc/2020/r28.html. See also EPO Guideline on the Disclaimer: paragraph 5.4. Plant varieties and animal breeds, essentially biological processes for the production of plants or animals - https://www.epo.org/fr/legal/guidelines-epc/2023/g_ii_5_4.html

[24] https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_3568

[25] Interinstitutional Agreement between the EP, the Council of the EU and the European Commission on Better Law-Making of 13 April 2016 https://eur-lex.europa.eu/legal-content/FR/TXT/PDF/?uri=CELEX:32016Q0512(01)