Trilogue on the draft regulation on new genomic techniques (NGTs): ECVC's proposals on patents and sustainability

The two main issues in the search for a compromise in the trilogue are the two topics discussed in this document: patents and sustainability criteria. Below you will find the related proposals of the European Coordination Via Campesina (ECVC), which represents small and medium-sized European farmers.

A. Patents

1. What is the problem?

Patents on NGTs and NGT products are a major concern for farmers and small and medium-sized seed producers, due to the risks arising from:

- The abusive extension of the scope of patents, protecting NGTs and plant products obtained by those NGTs, to plant products[1] resulting from peasant or traditional breeding or "essentially biological processes" (EBP);
- Unfair infringement proceedings;
- Adventitious or accidental contaminations;
- The lack of easily accessible information on the plant varieties or heterogenous material covered by these patents.

2. Why do we have those problems?

Directive 98/44/EC was adopted 27 years ago, before the emergence of NGTs. The Council considers that it would be inappropriate to "reopen" it. However, without reopening the whole Directive, it is possible and essential to complement it, to specify how it should apply to the specificities of NGTs and products derived from NGTs.

The draft NGT Regulation states that plants derived from NGT1 are "similar" to plants that are or may be derived from peasant or traditional selections ("essentially biological processes"), which are not patentable under Directive 98/44/EC. Articles 8 and 9 of that directive define the products to which patents on biological materials or genetic information apply: all plants, irrespective of the varieties or cultivars to which they belong, which contain those biological materials or genetic information and express the function described in those patents. Therefore, "native" plants or plants derived from essentially biological processes containing those same biological materials or genetic information, and expressing their function, fall under the protection of those patents. **In the event of legal proceedings for a presumption of infringement, which may justify the seizure of seeds, crops derived from those seeds and products derived from those crops, it is the alleged**

[1] The draft Regulation only concerns plants, which is why patents on animals and micro-organisms are not addressed in this document.

infringer and not the patent holder who must prove that they have not used the patented invention. However, that evidence will not be accessible, if they do not have access to the information on the methods allowing to distinguish products resulting from the patented invention from any other product which does not result from the use of that invention.

Directive 2001/18/EC addressed this issue for genetically modified plants by making the publication of such processes mandatory. But the European Commission's proposal for a NGT regulation removes this obligation.

Another problem arises in case of accidental (and unavoidable) contamination of plants or plant products by patented plant products obtained by NGTs.

3. ECVC's proposals to address these issues

I. **The first solution, partly taken up by the European Parliament, is to clarify the scope of Articles 8 and 9 of Directive 99/44/EC.** They should be complemented to indicate that the patent protection does not extend to organisms which contain the biological material or genetic information described in the patent and express its function, but which cannot be distinguished from biological material or genetic information contained in organisms obtained by EBP.

   For more detailed information on this solution, see ECVC's information note on patents on plants obtained by NGTs, including ECVC's amendment proposal to limit the scope of patents (pp. 10-11).

II. **Alternatively, an equivalent solution is to reintroduce into the draft NGT Regulation the obligation to publish the detection and identification methods for GMOs obtained by NGTs and their products.** This analytical traceability is also absolutely necessary for the monitoring of post-market NGTs, and for withdrawal from the market in case of harmful interaction with human health or the environment. The EU-funded research programme on the detection of NGTs, Darwin, recently published an information note that concludes that methods for the detection of NGT products can be developed without major technical barriers, especially when the developers of these GMOs provide the necessary genetic data, as required by current EU legislation[2].

III. In the two previous cases, **farmers and small seed producers should also be protected in the event of contamination and, in order to do so,** (a) the protection of a patent should be removed in the event of an adventitious and unavoidable presence in a plant product of biological material or genetic information covered by that patent and (b) plant varieties and heterogenous material covered by patents should be indicated in official catalogues.

4. False solutions proposed in the trilogue

- **A 'full breeder's exemption", with an amendment of EU Directive 98/44/EC:** this proposal is only useful for breeders and not for farmers, which therefore excludes farmers who practice on-farm breeding, referred *to as 'on-farm dynamic management'* in the draft PRM Regulation. This exemption does not therefore resolve the question of the abusive

[2] Directive 2001/18/EC and Regulations 1829/2003 and 1830/2003.

extension of the scope of patents on NGTs to native traits contained in peasant or traditional seeds, and to plant products derived from these seeds.

- **A 'limited breeders' exemption':** it already exists for European unitary patents and in various national laws. It does not solve the problem of the abusive extension of the scope of NGT patents to 'native' traits or traits obtained by EBP.
- **Compliance with a non-binding code of conduct for licensing:** in the absence of binding obligations and effective controls, such code would be ineffective.
- **Excluding products obtained by "random" mutagenesis from patentability:** that exclusion already exists in European law in so far as a patented process must be *"reproducible by a person skilled in the art",* and is therefore, by definition, not random. Moreover, NGTs, the sole object of the Commission's proposal for a new European regulation, can be obtained by target mutagenesis processes, not random mutagenesis. NGTs and products derived from NGTs are therefore not covered by such an exclusion.
- **Implementation of the legislative amendments referred to above in the European Patent Convention (EPC) and the Unified Patent Court (UPC):** this implementation will not make these legislative changes more relevant.
- **Disclaimer requirement:** The European Patent Office has adopted an obligation, when applying for a new patent, to disclose where necessary a disclaimer, i.e. the indication of the products excluded from the scope of the patent. Such an obligation is an illusory solution, because it can unfortunately only concern products known to the breeder claiming a patent. No breeder can know all the biological material and genetic information contained in all the plants cultivated globally. Furthermore, it only applies to plants and seeds which are "notoriously well known", registered in the common catalogue of varieties, deposited in official public collections or which are the subject of official scientific publications describing in detail their characteristics and the biological materials or genetic information they contain. It does not concern most peasant seeds and many traditional varieties, which will therefore always be threatened with appropriation by patents covering the 'native' characteristics they contain.
- **Databases of varieties covered by patents:** The database proposed by the Commission for NGT 1 plants is only declarative, without any official verification, and therefore largely insufficient. It concerns only patented plants without an indication of the marketed varieties covered by these patents, which is the only important information for farmers and small seed producers. Finally, there is no indication that it will be easily accessible to the public, including farmers. A private database initiated by Euroseeds (PINTO) lists the varieties covered by patents, but their indication remains voluntary, at the will of breeders of these varieties. Access to this database is also not available to most farmers.
- **'Patent clubs' (licensing platforms):** they are only useful for patent holders, not for small-scale seed producers and farmers. They represent a privatization of patent law to the benefit of the holders of the largest portfolios of patents.

B. Sustainability criteria

As an organisation representing small-scale farmers practising peasant agroecology, ECVC opposes the idea that the sustainability of a plant can be assessed on the basis of a single trait, as is currently proposed in the trilogue negotiations. **Sustainability can never be reduced to a single**

genetic trait : on the contrary, it is always polygenic and, of course, depends on the agricultural model and the territories in which the plant is cultivated. It is absurd to consider that such complex characteristics as adaptation of plants to certain climatic stresses, resistance to certain diseases, reduced use of chemical inputs, etc. can be linked to a single trait obtained by a genetic modification performed in a lab, and can be expressed in the same way in all territories and regions. It is on the contrary, the use of locally adapted varieties, the adaptation of plants to their environment (which precisely requires to re-use seeds from the harvest), and the cultivation conditions that determine whether a plant is sustainable or not. ECVC is therefore opposed to the creation of a list of sustainability criteria allowing certain GMOs to fall directly into the category 'NGT 1'.

<u>Nevertheless, as is also the case for transgenic GMOs, many plants obtained by NGTs that would be introduced on the European market if the NGT Regulation were adopted will concern plants with proven non-sustainability characteristics, in particular:</u>

- **Herbicide tolerance traits,** which lead in the long term to increased use of herbicides, soil depletion, the creation of resistant weeds, and are linked to health problems among farmers;
- **Insecticide production traits,** which pose a high risk of harmful interaction with the environment, including pollinators.
- **Traits linked to production of antifungal substances,** which pose a high risk of harmful interaction with the environment, in particular with fungi essential for plant survival, productivity and/or seed fertility.

For those reasons, those traits must be placed on a list of 'non-sustainable traits' excluding plants containing them from the 'NGT 1' category.