COMMITTEE ON ECONOMIC, ETHICAL AND SOCIAL ISSUES (CEES)

RECOMMENDATION ON "NEW PLANT BREEDING TECHNIQUES"

SUMMARY

Paris, 2017, november, the 2\textsuperscript{nd}
(accepted by CEES september the 19\textsuperscript{th})
Methodology

This summary sets out the main conclusions of the recommendation formulated by the HCB Committee on Economic, Ethical and Social issues (CEES). The recommendation is based on the report from the Working Group established within the CEES, on the opinion given by the HCB Scientific Committee and on all the points of view expressed and included in the CEES discussions. The CEES was unable to benefit from all of the competences it might have drawn on because of the resignation, in 2016, of seven member organisations. However, their publicly expressed positions were taken into account. This choice was agreed to by all of the CEES members; it does not commit the organisations absent from the discussions.1

NPBTs and NPBT-derived plant varieties: a complex issue

- The techniques known as NPBT (New Plant Breeding Techniques) are very heterogeneous and their potential and risks have only been identified in very general terms to date;
- It is difficult to predict which traits may be offered by plant breeders and which may be adopted by farmers;
- It is not known whether all or only some of these techniques will or will not come under the scope of application of Directive 2001/18 on GMOs and related regulations;
- The possible consequences of NPBTs on potential plant variety innovations, on agricultural practices and production, on the nature of products put on the market and on the perceptions and reactions of consumers and players in the sector cannot easily be anticipated at present.

Positions vary widely among the different players

The studies conducted by the CEES identified the main questions that arise over NPBT varieties as regards assessments, traceability and biological detection, labelling, coexistence with other crops, and industrial property. For each of these points, the Recommendation lists the main issues and the positions of the CEES member organisations and experts.

Need for an appropriate framework to manage the risks that arise

The HCB Scientific Committee (SC) has identified different risks associated with NPBTs and considers that these risks should be assessed on a case-by-case basis.

In view of these considerations, the CEES envisaged guidelines for the use of NPBT-derived varieties, based on both the precautionary principle and a principle of proportionality and, in particular, taking into account the purposes that the proposed traits would serve (without excluding techniques used in order to obtain the modifications and to propose new traits from the scope of the assessments).

1 The summary was written by the HCB Secretariat and is not a substitute for the Recommendation itself.
A core issue: possibilities for an "intermediate" assessment process

In view of the diversity and specificity of NPBTs and of the plants that may be derived from them, the CEES noted the limitations of existing methods of assessment (Directive 2001/18 of 12 March 2001 on deliberate dissemination of GMOs in the environment; procedure for registering plant species and varieties in the official Catalogue).

The principle of introducing a specific "intermediate" process to assess NPBT-derived varieties that may not come under the scope of Directive 2001/18/EC seems relevant to the great majority of the current CEES members (the resigning organisations are in favour of bringing all NPBT varieties under the scope of Directive 2001/18).

In practice:

- A system of referral could bring each NPBT variety, on a case-by-case basis, either under the scope of the Catalogue alone, or under Directive 2001/18/EC, or under the “intermediate” process (the latter two to be followed by the Catalogue registration procedure).

- An “intermediate” assessment process would have to: encompass the introduction or modification, via an NPBT, of one (or more) trait(s) in a given species; be conducted on a case-by-case basis, while setting rules of similarity/comparability to avoid reiterative studies on comparable cases; be adapted to the specific features of each NPBT; produce assessments in proportion to the uses considered; include social, ethical and economic analyses at an early stage; include monitoring of the introduction of each NPBT variety in crop farming and its various consequences. However, the different CEES members do not rank the requirements for these different points at the same level. The assessments should also contribute to the implementation of sustainable, diversified and innovative agriculture, answer questions raised among the public and be consistent with the level of confidence that public opinion demands.

The CEES therefore discussed possible referral criteria, how an "intermediate" assessment process could be organised, how it would operate in practice and, finally, needs for research.

First of all, while the great majority of the CEES members are in favour of a case-by-case referral process, their opinions are divided as to the criteria to be used for referrals: some consider that only biological characteristics should determine referrals to one assessment process or to another, while others consider that social, economic and ethical and/or end-use criteria for the varieties assessed should also be included as from this stage.

Concerning the organisation of assessments, there is broad agreement within the CEES on the need to introduce an "intermediate" process of social and economic analysis and for analyses of the purposes for which the proposed varieties would be used. Some members therefore suggest that there is a need to amend the assessment procedures used by the CTPS (French standing committee on plant varieties) and for Catalogue registration. They believe that specific requirements could be addressed by extending or strengthening the current assessment process for any variety applying for Catalogue registration. This would be the preferred option for most agricultural players (in particular those representing the most representative organisations). Other members suggest that an official body with a wider range of competences would be needed to better encompass civil society representation and economic, social and ethical competences. The HCB, which includes a wide range
of competences to address the health, environmental, social, economic and ethical issues raised by biotechnologies, could prefigure this new body. This option would meet the expectations of some representatives from the mass retail sector, trade unions, consumer and patients' associations, and also of key experts.

As regards the conduct of assessments in practice, in the case of a referral to an “intermediate” assessment process, this should be based on information to be provided by applicants (which, to the majority of the members, would be the vade-mecum proposed by the HCB’s Scientific Committee). The body responsible for the assessment should be in a position to issue and ensure compliance with its recommendations on rules for marketing varieties, for example on biological detection of the variety in question, traceability, information for the public or product labelling, measures for coexistence, monitoring (environmental, social and economic) and end-uses, in order to investigate effects at the systems or territorial level.

Furthermore, for the purpose of informing the public and all players concerned, most members consider that implementation of a specific "intermediate" assessment process should be centralised and dependent on the availability of data, in particular via 1) a register of NPBT-derived plant varieties available in France; 2) a database of patents protecting the components of the varieties concerned; 3) a register of land parcels where these varieties are cultivated. The representatives of the agricultural and seed production sectors consider that compiling a database on patents would be a complex matter and could duplicate the tools already used by professionals (PINTO), although the other CEES members point out that this database is neither compulsory nor exhaustive. Serious concerns were also expressed over the risks of making geographical information on crop sites available (possibilities for crop destruction).

Finally, concerning needs for research, there is broad agreement among the CEES members that the various uncertainties that exist over NPBTs should be resolved. However, opinions are divided as to whether the necessary research should be conducted before or in parallel with any future development of NPBT varieties. It was suggested, however, that more in-depth studies should address: environmental impacts from a systems perspective; the accelerated pace of evolution of cultivated varieties that NPBTs would allow and the resulting impacts on agro-ecosystems; the possibilities for biological detection of varieties derived from the different NPBTs; the undesired effects of the different NPBTs (with a view to the precautionary principle), and relationships between NPBTs and industrial property.

The CEES recommendation also addresses traceability and labelling issues. At present, the introduction of routine biological traceability of NPBT varieties raises a number of technical issues, especially for varieties carrying traits that could have been obtained naturally (sexual hybridisation or spontaneous mutation). Given these considerations and the clearly contrasting positions of the organisations as to the relevance and the role of routine biological traceability and possible labelling of NPBT-derived products, the CEES members are divided between:

- those who consider that only varieties for which biological detection is possible should be authorised for marketing and that these should be labelled accordingly;
- those who consider that documentary traceability (possibly supplemented by some elements of biological detection when these can be easily implemented) could provide a basis for compulsory labelling;
• those, finally, who consider that the characteristics of NPBT varieties that could have been obtained naturally (sexual hybridisation of spontaneous mutation) do not warrant either compulsory labelling or biological traceability.

Opinions are similarly divided as regards coexistence between crops.

**Finally, on industrial property issues**, the majority of the CEES members notes that a series of recent changes in French law and within the European Patent Office could resolve the questions being raised over the patentability of NPBTs and NPBT-derived products, especially those concerning access to genetic resources.

Given the uncertainties nevertheless raised by some organisations as to the risk that access to these resources may continue to be blocked, the CEES recommends an in-depth legal study on this point.

This recommendation should enable the authorities to gain a more thorough grasp of the terms under which the NPBT issue is being raised today, of the arrangements that can be considered and how these are perceived in society, through the views of the CEES stakeholders and experts. The points of reference it provides should guide the necessary policy decisions on this complex and socially sensitive issue that demands constant vigilance.

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