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NOTE DES AUTORITÉS FRANÇAISES

Courtesy translation

Subject : Cartagena Protocol on Biosafety - Soumission regarding notification 2019-031 on Socio-économique considerations

Réf. : SCBD/CPU/DC/PD/PS/87987.

French authorities please the Presidency to find hereby a submission regarding the cited notification :

(a) Experiences using the voluntary Guidance as well as examples of methodologies and applications of socio-economic considerations

This submission consists in recalling the general framework of the socio-economic analysis of LMOs in France, and establishing the link with the guideline guidelines published by the AHTEG in 2017, and to present an example of implementation of this framework concerning the release of genetically modified mosquitoes to fight vector diseases.

(i) General framework of the socio-economic analysis of LMOs

Introduction

In France the High Council for Biotechnology (HCB), set up following the Grenelle de l'Environnement consultation by Law No. 2008-595 of 25 June 2008 on genetically modified organisms (GMOs), is an independent body whose role is to inform public decision-making on biotechnology-related issues, and in particular GMOs.

HCB has a dual structure, with, on the one hand, a Scientific Committee consisting of experts who assess the risks associated with genetically modified organisms and, on the other, an Economic, Ethical and Social Committee (EESC) made up of representatives from trade associations, trade unions, environmental protection associations and consumer associations as well as qualified individuals (in law, economics and sociology). The latter committee was set up because the authorities recognised the controversy surrounding biotechnology, a topic of social debate, and the need to consider possible options concurrently. Intended as a forum for discussion, the EESC advises on the social, ethical and economic aspects of biotechnology and its applications by means of more effective recognition of public opinion as reflected by representatives of associations and NGOs and political and economic participants in public decision-making. Consequently, the EESC is a distinctive institution that is not a committee of experts in the proper sense of the term but rather a committee of stakeholders and qualified individuals.

As regards the legal aspect, since, at the European level, Directive 2001/18/EC initially only concerned the environmental and safety assessment of GMOs. Taking account of socio-economic considerations of GMOs was introduced in 2015 with Article 26ter introducing the possibility for each member state to restrict or prohibit the cultivation of GMOs on its territory for reasons related to socio-economic impacts or effects.

At the French level, the EESC uses an evaluation grid that has been discussed and defined by its own members. An initial grid was thus drawn up in 2010 for the purpose of assessing dossiers transparently with clear indicators. This grid ensures a structured assessment of the various types of dossier that the EESC has to handle. The evaluation grid was updated in 2015 related to the evolution of European regulations, and completed by a report¹.

The novel composition of the EESC, consisting of stakeholders and qualified individuals, enables a range of opinions to be taken into account with the aim of comparing them neutrally.

Principles and objectives in the HCB approach to socio-economic analysis

Because of HCB's advisory status, the value of the EESC's socio-economic analysis lies as much in the process of learning and dialogue that it encourages among stakeholders as in the end product, in accordance with Principle 7 in document CBD/CP/SEC/AHTEG/2017/1/3 (p. 9).

For the EESC, socio-economic analysis complements the environmental and health assessment, thus reflecting Principle 6 of document CBD/CP/SEC/AHTEG/2017/1/3 (p. 8). Such analysis emphasises consideration of the production environment, the idea of coexistence, sustainable development goals and inclusiveness of public debate.

To reflect the changing situation the EESC has strengthened the previous version of its evaluation grid (2010) with particular attention to two aspects:

- Assessment of GMOs in the context of **alternative solutions** (including describing and placing the GMO in its technical production environment);
- Comparison of possible **innovation trajectories**, with the focus on identifying as clearly as possible the impact of authorisation or non-authorisation.

EESC discussion revolves around four key issues:

1. Why is the GMP being proposed and for which cropping systems?
2. Comparison of possible trajectories and identification of possible lock-in effects.
3. What are the impacts of cultivation of the GMP on social, cultural, environmental, health, planning and agronomic sustainability?
4. Understanding of and support for scientific and technological progress among the public and consumers.

Regarding Principle 4 of document CBD/CP/SEC/AHTEG/2017/1/3 (p. 8), HCB recognises the need to take account of data uncertainty and go beyond purely quantitative analysis. There are a number of ways to assess the economic, and sometimes social, impacts of technological and/or political choices. Today cost/benefit analysis (CBA) is the best-known and most widespread – so much so that it has been made mandatory in France prior to implementation of certain major projects. It is not incompatible with a trajectory approach, including comparison of different scenarios.

Nevertheless, for EESC work, CBA seems to have a number of limitations:

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http://www.hautconseildesbiotechnologies.fr/fr/system/files/file_fields/2016/03/30/propositionduncadremethodologiquep_ourvaluationsocio-economiquedespgm_0.pdf

- While CBA is designed to provide an objective and rational assessment of the implications of different types of decision, it requires a frame of reference in which the main risks and benefits can be identified and quantified, or even expressed in monetary terms, which is seldom the case today for agricultural biotechnology applications; moreover, in the EESC's opinion, limiting analysis to quantitative assessment would be restrictive in itself. There must always be a place for qualitative factors and considerations.
- Extensive and easily available coordinated numerical data would be required; yet at the European level, without actual implementation, availability of data on the socio-economic implications specific to the GMO issue is a problem, and more general agricultural data, although available, are not easy to use for an investigation of this subject.

(ii) Example of application with the socio-economic analysis of the release of GM mosquito to control vector diseases

A study published by the EESC in 2017 in response to a government request for guidance on the advantages and disadvantages of use of modified mosquitoes for vector control and the assessment criteria that should be applied will here be taken as a case study to illustrate the committee's steps in handling a dossier.² Although this dossier concerns a genetically modified insect rather than a genetically modified plant, the EESC framework of discussion for socio-economic analysis of a given type of biotechnology remains much the same whatever the subject. The example chosen, a referral concerning modified mosquitoes for vector control, illustrates how work is done within the EESC and how certain principles developed for socio-economic analysis are applied when a dossier is being considered.

There are two separate stages: organisation of the discussion (assessment preparation) and the EESC process of reflection (assessment and analysis).

- **Stage A: Assessment preparation**

Before the analysis was produced and in order to ensure a process of dialogue that would inform public decision-making as comprehensively as possible, the HCB Board set up a working group for the EESC whose members were drawn mainly from the latter committee.³ This working group was tasked with writing a report to brief the EESC on the issues and expectations relating to modified mosquitoes for vector control. The working group began its work in 2016 and finished in 2017, meeting some ten times over this period. The members of the EESC discussed these questions concurrently, and debate was organised, on the one hand, between EESC members and the working group set up for this committee and including some of its members, and, on the one other, between members of the EESC working group and members of the Scientific Committee working group, including assistance from experts outside HCB.

- **Stage B: Assessment and analysis**

Taking these various consultations and the principles of socio-economic analysis laid down in the *EESC recommendation on Directive (EU) 2015/412 and the social, economic and ethical analysis of cultivation of genetically modified plants* produced in 2015, the EESC then undertook a detailed examination of the GMO using existing literature in this field. On the basis of this data gathering, the discussions during the various

² High Council for Biotechnology, Economic, Ethical and Social Committee, *CEES recommendation concerning the referral dated 12 October 2015 on the use of mosquitoes with a biotechnologically modified genome to control disease vectors*, 1 June 2017, 29 pp.

³ At the same time, a second working group was set up by the HCB Board for the Scientific Committee to work on the scientific and technical issues relating to use of modified mosquitoes for vector control.

meetings and the pre-existing evaluation grid for preparing the recommendation, the broad outlines of how the EESC considered the issues involved in use of modified mosquitoes for vector control are described below.

The EESC recommendation begins by detailing the nature and context of the modified mosquitoes issue, namely the impact of mosquito-borne diseases on public health worldwide, combined with the observed limitations of existing vector control methods. Reference is made to the legal framework to establish the role of each of the players involved in vector control.

The EESC then lists innovations in vector control to put the appearance of modified mosquitoes in context and offer an overview of the new techniques available. The progress of experimentation in this field is outlined, together with commercial developments and the results of field trials.

This introductory information leads on to a closer analysis of the advantages and disadvantages of modified mosquitoes in the following four areas:

1. Problem to be solved: vector control;
2. Environment;
3. Ethics;
4. Decision-making.

In the first area, the EESC describes the technical benefits of release of modified mosquitoes whilst taking into consideration existing uncertainties. A critical review of cost/benefit analyses is then provided, suggesting that these criteria are of limited use given that there are no benchmarks or prediction models for simulating costs or transposing them between different techniques.

In the second area, environmental considerations, whether positive or negative, relating to use or non-use of modified mosquitoes are assessed with particular reference to the ecosystem issues inherent in any use.

The third and fourth fields cover ethical concerns and societal tensions around the issue.

The handling of this dossier offers an example of how the EESC has combined assessment of the GMO studied with alternative and/or complementary solutions whilst taking account of the GMO's possible innovation trajectories.

The EESC's final report was published in June 2017. In the wake of the Scientific Committee's opinion and the Economic, Ethical and Social Committee's recommendation, HCB held a symposium on 7 June 2017 on the topic 'Genetically modified mosquitoes: a new tool for vector control?' This made it possible to publicise HCB's findings for the twofold purpose of ensuring informed public decision-making on the issue of modified mosquitoes and contributing to public debate transparently and independently.

In practical terms, the recommendation is not intended to be set in stone and could be reassessed by EESC members if further developments were to alter the current state of knowledge. Thus the HCB Economic, Ethical and Social Committee's socio-economic analysis of a given GMO is meant to be a dynamic decision open to future re-examination depending on the evolution of knowledge and data on the GMO concerned.