Haut Conseil des Biotechnologies

EESC recommendation on Directive (EU) 2015/412 and the social, economic and ethical analysis of cultivation of genetically modified plants

Date: *27 September 2016*

On 4 November 2015 the High Council for Biotechnology (HCB) received a referral from the Minister of the Environment and the Minister of Agriculture[1] requesting it to clarify how HCB would assess the socio-economic impacts of cultivation of GMOs[2] in the light of Directive (EU) 2015/412.

In response to this referral, the HCB Board set up a working group whose members were drawn mainly from HCB's Economic, Ethical and Social Committee (EESC).

The working group wrote a report[3] that was gradually amended following successive readings at EESC meetings on 29 June, 12 July and 13 September 2016 (the latter meeting being attended by certain members of the HCB Scientific Committee) and was then finalised.

On the basis of this working group report, the HCB secretariat drew up a draft recommendation that was discussed in the EESC on 13 September and amended accordingly to become the final version contained in this document.

[1] See full text of referral in Appendix 1.

[2] The referral uses the term 'GMOs' when referring to the Directive, which concerns cultivation of genetically modified plants (GMPs). The reply to the referral therefore covers cultivation of GMPs in an open environment. However, the term 'GMO' will be employed when reference is made to legal texts that use it. It will also be used in some places in order not to obscure the debate over the different meanings of the term.

[3] The report by the 'socio-economic referral' working group – commended by the EESC and on which this recommendation is based – can be consulted on the HCB website (subject to permission from the Board). It contains a list of the working group's members and their positions.

1. Introduction and background

1.1. The Directive

On 11 March 2015, the European Parliament and the Council of the European Union adopted Directive (EU) 2015/412 (amending Directive 2001/18/EC) with regard to the possibility for Member States of restricting or prohibiting the cultivation of GMOs in their territory.[4]

This Directive, already talked of at the turn of the decade, was adopted in 2015 in response to the stalemate reached by the EU authorisation procedure for cultivation of GMPs. There was never, or virtually never, a qualified majority among Member States for either acceptance or refusal of applications for EU-wide marketing authorisation (MA). This situation drove the Commission to take MA decisions by itself.[5] Furthermore, in recent years several Member States have taken steps to prohibit cultivation in their territories of the only authorised GM maize (Bt MON 810), based on national legislation that is for the most part both scientifically and legally unsound.

The directive may be characterised as atypical in terms of EU policy.

Firstly, on the specific issue of GMPs, it weakens EU principles by making authorisation of GMP cultivation a largely national matter, thus giving back responsibility to Member States. Secondly, it legitimates recourse to social, economic, political and ethical arguments to restrict or prohibit cultivation of a GMP, which could be controversial in terms of international commercial law and particularly World Trade Organization (WTO) agreements. As they stand, these agreements recognise trade restrictions connected mainly with potential health or environmental risks, which could result in disputes at the international level.

Many Member States have made immediate use of the Directive: seventeen out of the twenty-eight have notified the European Commission and applicants (Monsanto, Pioneer, BASF, etc.) of their wish not to have herbicide-tolerant or Bt maize grown in their national territories (plus two Member States providing notification for only part of their territory: Belgium and the United Kingdom).

[4] OJEU L 068, 13.3.2015.

[5] A broadly similar directive, but in this case for import of GMPs, was proposed by the Commission in 2015 but rejected both by the European Parliament and by Member States owing to the major legal uncertainties to which it would have given rise in terms of international commercial law and feasibility of implementation in EU territory.

1.2. Scope of Directive 2015/412

At the time when HCB received the referral, Directive 2015/412 had already been transposed into French law and had thus come into effect. However, this does not mean that the scope of the Directive is exempt from scrutiny – far from it. Two main issues have been identified.

The first question relates to the scope of the Directive at EU level. Here it should be noted that a directive whose purpose is the smooth functioning of the internal market gives substantive jurisdiction to national authorities. Although the Directive endeavours to explain this point,[6] the reasoning remains unclear, since to lessen differences of opinion within the Union, differences are to be allowed among its Member States. The possible impacts of the Directive's implementation and renewed national responsibility for decisions concerning GMP cultivation (and therefore possible prohibition of cultivation) on free movement of seed, incremental competition among farms and cross-border coexistence ought to be taken into consideration. The French authorities must therefore also take account of the consequences of decisions by other countries.

The second question relates to the scope of the Directive within France. As the law stands, the national authorities have exclusive jurisdiction over special policy for GMO release.[7] However, the Directive allows adoption of measures restricting or prohibiting cultivation in all or **part** of the territory.[8] Furthermore, France is marked by considerable geographical, climatic and therefore agricultural variety, which could entail different measures. The ability of local and regional authorities to take decisions for each part of the territory must also be discussed.

1.3. Overall approach and general principles used by the EESC for this referral

1.3.1. Overall approach

The referral has had a structuring dimension for the EESC, giving it an opportunity to bolster an approach that is still in its infancy and clarify the role and methods of HCB, and particularly the EESC, regarding social, economic and ethical analysis of GMOs.

The reply must be read in terms of HCB's remit: although the Directive is confined to restriction or prohibition of cultivation, the EESC will continue, under the law of 25 June

[6] Directive 2015/412, Recital 8: 'The grant of that possibility to Member States is likely to improve the process for authorisations of GMOs [...] This Directive should therefore facilitate the smooth functioning of the internal market.'

[7] Environment Code, Article L.533-3, and Conseil d'Etat, Application No. 342990, Municipality of Valence, 24 September 2012.

[8] The same principles would call into question the fundamentals of the internal market if applied to the marketing of GMOs.

2008 establishing HCB, to consider the whole range of positive and negative impacts, whether risks or benefits, of **acceptance** and **refusal** of GMP cultivation.

The reply to the referral offers a general framework for social, economic and ethical analysis of GMP cultivation that is meant to allow for improvement.

1.3.2. General principles for social, economic and ethical analysis

The EESC's task is to **advise** the Government rather than make the final decision. It is not meant to provide a cut-and-dried answer when asked for an opinion on an application for cultivation. The significance of the analysis lies as much in the process of learning and dialogue that it encourages among stakeholders as in the final product.

Before beginning this analysis, and in order to accommodate this process of dialogue, it is necessary to ensure an accurate description of the **subject being analysed** (i.e. cultivation of a GMP) by placing it in context and discussing its characteristics. This description, which is crucial, will determine the scope of the analysis.

The analysis must be guided by comparison of **trajectories** (see below).

It is also necessary to take account of data-related **uncertainties** and go beyond purely quantitative analysis.

Lastly, the social, economic and ethical analysis should be seen as **complementing** the environmental and health assessment.

2. Scope of grounds in Directive 2015/412 and state of EESC analysis

Question 1: *HCB will determine the scope and content of the grounds listed in Directive (EU) 2015/412 for assessment of GMO cultivation in the French context (metropolitan France and overseas).*

Question 2: *Does the type of assessment currently conducted by the EESC based on the opinion from the HCB Scientific Committee or as offered by the European GMO Socio-Economics Bureau or other European or international agencies allow GMO analysis relating to these various grounds?*

Because of the considerable overlap between these two questions, it was decided to answer them together.

2.1. The question asked (scope and content of grounds)

The Directive lists seven grounds:

(a) Environmental policy objectives,
(b) Town and country planning,
(c) Land use,
(d) Socio-economic impacts,
(e) Avoidance of GMO presence in other products,
(f) Agricultural policy objectives,
(g) Public policy.

These seven grounds have the following characteristics:

- They are regarded only as reasons for prohibition and therefore not intended to cover all aspects of social, economic and ethical analysis of GMO cultivation (or prohibition of cultivation).

- They **are not defined**.

- The list of grounds is **not deemed to be exhaustive**. Member States are also allowed to base their measures on 'other legitimate factors including those relating to cultural traditions'.[9]

- **The various grounds can be invoked individually or in combination** (apart from the public policy ground, which cannot be used on its own).

- These grounds are not on a par and do not have the same consequences for social, economic and ethical analysis. It seems appropriate to start with 'socio-economic impacts', which is likely to encompass the other grounds considered by the Directive.

Potential impacts of a socio-economic nature can take a wide range of forms. They include not only the economic impacts of growing a GMP (yield, organisation of work, national competitiveness, etc.) but also the social impacts (effects on farm size, agricultural employment, consumers, etc.). These impacts cover those directly connected both with actual cultivation of a GMP and with the associated management measures, particularly those concerning coexistence and separation of supply chains. Further impacts will concern private individuals – farmers using GMPs or not using them, middlemen, etc. – but also public authorities as a whole. Consequently, all impacts not directly environmental or health-related can be described as socio-economic.

2.1.1. The 'socio-economic impacts' ground

There is no objective definition of these impacts either in HCB documents or in the law of 25 June 2008. Directive 2015/412 does not define the concept either. The European Commission has acknowledged a lack of consensus on a general definition of the concept, noting that 'the understanding of the meaning and scope of the socio-economic dimension of GMO cultivation varies widely among the Member States and the stakeholders'.[10] The usual option, as in France, is to divide this ground into subsidiary elements.

Thus, in the EESC, the 'economic' impacts likely to be generated by GMP cultivation are listed in the form of a large number of questions contained in an 'evaluation grid for authorisation applications for GMP cultivation'.[11]

This grid, produced at the beginning of HCB's first term, is still generally relevant for determining all the non-environmental and non-health-related advantages and disadvantages of cultivation or refusal of cultivation.

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[9] Directive 2015/412, Recital 15.

[10] COM(2011) 214 final, 15.4.2011, §1.2.

[11] EESC evaluation grids, April 2011, available at: http://www.hautconseildesbiotechnologies.fr/fr/system/files/file_fields/2015/09/30/grillesdanalysecees_0.pdf (in French).

The 'social' impacts, however, should be specified. Some are socio-economic, such as the impact on number and quality of jobs for farmers and farm employees, whether they use GMPs or not, and what GMPs can offer consumers in comparison with what already exists. Some of these impacts are more 'purely' social in nature: the effects on food safety and eating habits, on possible social conflicts associated with coexistence of crops, on the direction of government research and on sharing of knowledge with society, and on local areas in social, commercial, and political terms (image, tourism, development policies). To understand such impacts, several elements must be considered, including 'consumers', 'eaters' and 'the public'.

The links between these social and socio-economic elements and the ethical dimension have also been taken into consideration. The ethical dimension is cross-cutting by nature and does not constitute a ground in itself. Nevertheless, a few questions addressed in the analysis inevitably imply ethical consideration (GMPs: why, how and for whom?). Ethics is thus the backdrop for all aspects of socio-economic analysis.

2.1.2. Other grounds in the Directive

2.1.2.1. 'Environmental policy objectives' and 'agricultural policy objectives'

Inclusion of 'environmental policy objectives' and 'agricultural policy objectives' among the grounds immediately raises questions. While some policy objectives are indeed clearly advertised and there is some work (in the fields of political science, sociology, grey literature, etc.) describing public policy on agriculture and the environment, the possibility of using it for an EESC analysis for a given dossier at a given time remains complicated, since this type of work is done retrospectively or for foresight studies or even for planning purposes, whereas a policy context, by its nature, depends on current conditions.

However, to identify public policy objectives of this kind, it is useful to consult the GMO Act of 25 June 2008, for example, which enshrines 'the freedom to consume and produce GM or non-GM food without prejudice to the integrity of the environment and the specific characteristics of traditional and high-quality crops'.[12] Objectives such as food safety and reduced use of pesticides have regularly been cited in past EESC recommendations.

In addition, various policy objectives can be gleaned from an examination of the many foresight studies in the fields of agriculture, planning and the environment.[13]

2.1.2.2. 'Town and country planning' and 'land use'

These grounds are expressly cited in some of the questions in HCB's current evaluation grid ('What might be the impact of cultivation of the GMP on arable land use and distribution?' and 'Could dissemination of the GMP entail a reduction in agricultural landscape diversity?').

[12] Section 2.

[13] INRA's *Agrimonde Foresight Study* and Solagro's *Afterres2050* are just two examples.

The 'town and country planning' ground also directly crosses paths with 'crop coexistence' as well as 'land use', which may also relate to environmental policy objectives.

This ground can, however, be linked in new ways to other aspects that ought to be better recognised, especially as they are referred to in various regulations: powers of national and regional parks, product quality marks, and labels guaranteeing origin. It might also be considered, following Austria's lead, that tourism consideration and impacts on the landscape should be included under this ground.[14] The 'town and country planning' and 'land use' grounds imply consultation with local political authorities prior to any decision on GMP cultivation, with strict regard for the exclusive jurisdiction of the national authorities over special policy for GMO release.[15]

2.1.2.3. 'Coexistence of crops'

The issues involved in coexistence of crops – cost of coexistence measures (and apportionment of this cost), obstacles (technical, geographical), result (in terms of 'organic' or 'GM-free' labelling), cost of possible losses[16] – must be considered partly under 'town and country planning' and partly under 'coexistence', to which the Directive expressly refers. The Directive specifies that restriction or prohibition may be warranted by 'specific geographical conditions, such as small islands or mountain zones, or the need to avoid GMO presence in other products such as specific or particular products'.[17]

The EESC has long included these considerations in its socio-economic analysis in the shape of five questions (which must be kept[18]) relating to coexistence.

2.1.2.4. 'Public policy'

The concept of public policy does not immediately admit of a definitive and exhaustive definition: this indeterminacy is even part of its definition. Some countries have tried to justify restricting and/or prohibiting marketing of GMOs with the related argument of

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[14] *Socio-economic aspects in the assessment of GMOs*, report by Environment Agency Austria, 2011.

[15] Conseil d'Etat, Application No. 342990, Municipality of Valence, 24 September 2012.

[16] See, for example, the European Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops, OJEU C 200 of 22.7.2010, pp. 1-5: while it does not use the term 'socio-economic', this recommendation states that the objective of coexistence measures is to prevent 'potential economic loss' (Recital 4).

[17] Directive 2015/412, Recital 15. Directive 2015/412 amends Article 26a of Directive 2001/18/EC regarding appropriate measures to avoid the unintended presence of GMOs in other products. From 3 April 2017, states cultivating GMOs will be obliged, rather than entitled (as at present), to introduce coexistence measures to avoid possible cross-border contamination 'in border areas of their territory'.

[18] What might be the impacts of cultivation of the GMP on: 1. Other crop and animal supply chains, including those relating to beekeeping and 'high-quality' products? 2. Seed production (certified, farm-saved and farmers' seed)? 3. National and regional agronomic policy, and particularly medium-term plans? 4. Policy choices of the French regions investing in GM-free supply chains or GM-free agricultural policy? 5. Arable land use and distribution?

public morality, which the Court of Justice of the European Union has not yet had occasion to reject specifically.[19]

According to the Directive, this ground can be raised only in combination with another ground and not on its own.

2.2. The EESC approach

The seven grounds that can be invoked for the purposes of the Directive can be used to exclude all or part of a country's territory from an authorisation to cultivate a GMP (issued at EU level). Although the question is here asked in a specific context, it is not new to the EESC, since these seven grounds **largely correspond** to fields of analysis already developed by the committee, as described in its early evaluation grids[20] and used in various recommendations on GMP cultivation (mainly during HCB's first term). The structure of the various categories of analysis may differ, but the main points addressed are broadly similar. The same is true of the grids of two other European countries and the European GMO Socio-Economics Bureau (ESEB)[21] but with shades of difference.[22]

EESC work is intended to provide the most comprehensive and exhaustive analysis possible rather than assessment as such, taking a neutral and comparative approach and therefore without reference, in principle, to the specific arrangements of Directive 2015/412 (national objections to an MA).

This approach is necessitated by the controversial nature of the various types of biotechnology that have sparked debate in society and that therefore require parallel consideration of the various options without, in principle, settling on either prohibition or authorisation.

This has entailed use of social, economic and ethical analysis fairly specific to this field[23] for almost twenty years as well as provision for public participation (both in France and abroad). Such provision seeks to ensure that public decision-making takes better account of the views of the public and economic and political stakeholders. This was one of the reasons for setting up the HCB Economic, Ethical and Social Committee, which, since 2009,

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[19] See CJEU, 16 July 2009, Commission of the European Communities v Republic of Poland, Case C-165/08, 2009/C 220/16, in which Poland invoked the justification of public morality. However, the Court was not required to rule, since Poland failed to provide sufficient proof that its national legislation was actually pursuing the stated objective of protection of public morality and had been satisfied with a general presumption that Polish society attached particular importance to religious (Catholic) values.

[20] http ://www.hautconseildesbiotechnologies.fr/fr/system/files/file_fields/2015/09/30/grillesdanalysecees_0.pdf (in French).

[21] See existing work on socio-economic assessment of GMPs by Austria, Norway and (at EU level) the ESEB.

[22] The working group report reviews the differences in approach between the countries and institution.

[23] Socio-economic assessments of certain chemicals are sometimes produced for the purposes of the REACH directive but by other methods and from a different perspective, since the intention here is to minimise negative social and economic impacts of use of substances presenting previously identified risks. In the case of GMPs, pursuant to Directive 2001/18/EC, identification of an environmental or health risk will in any case entail refusal of marketing authorisation for the plant concerned.

has brought together trade unions and farmers' unions, elected representatives, NGOs and representatives of consumers, patients and businesses (in the agricultural and medical sectors) involved in biotechnology development, as well as qualified individuals in the fields of economics, sociology and law.

As such, the EESC is a distinctive institution that is not a committee of experts in the true sense but rather a committee of stakeholders and qualified individuals.

2.3. Conclusion and recommendation

Directive 2015/412 relies on grounds that have already been extensively addressed in EESC work, although the formal organisation, or 'classification', of the various types of argument is not always identical with that proposed by the Directive.

The EESC's output and analysis are not the product of expertise strictly speaking but stem from a process of exploration and clarification of the issue and the positions taken, a process informed and discussed by stakeholders and qualified individuals.

While it is not the EESC's role to lay down policy guidelines for national decision-making on these subjects, it can, with its current method of working and on the strength of the methodological proposals set out below, help to clarify issues and impacts for the various public policy options available.

On this basis, the EESC makes two recommendations:

- Bolster the principle of open-minded analysis of social, ethical and economic aspects, which is essential to public decision-making regardless of the prohibition/authorisation alternatives for a GMP.
- Take the opportunity to process applications in the light of this Directive in order, if the need arises, to identify trends that will implicitly or explicitly structure public decision-making and the future of supply chains. Accordingly work, particularly through the EESC, to build on experience and feedback.

3. What methodology or methodologies should be used for these referrals?

Question 3: *What methodology or methodologies might HCB propose for carrying out this analysis, showing its/their feasibility and possible limitations in terms of HCB expertise and the data available?*

3.1. The question asked

The question relates to choosing a methodology, i.e. a tool that can be used for a range of cases and circumstances.

It is asked not in the abstract but in relation to HCB and the role that the EESC can play in the light of its characteristics and expertise.

3.2. The EESC approach

Discussions within the EESC seek to provide a comprehensive structured view of the issues that matter to its various members. This approach is based on **mastering the data** (which may be scientific or data and experience gathered at the local level when they

exist) and **putting them in context**. Thus, although it is aware of various tools that could be used for the economic or even socio-economic dimension (such as cost/benefit analysis (CBA)), the CEES has explored other approaches that it considers more relevant.

3.2.1. An evaluation grid

The EESC has examined the validity of an evaluation grid produced during HCB's previous term, put it in a broader context and related it to tools such as CBA.

A new **evaluation grid**, shown in the appendix, recapitulates all the questions relating to GMP cultivation identified by the EESC over the course of the recommendations that it has had to produce and largely corresponds to the elements of analysis needed to reflect the grounds of the Directive. Its purpose is to **guide** the committee's **exploratory approach** and **ensure that it is thorough**. It is therefore an essential tool but **only a tool**: it is a support that is not restrictive. It is meant to be read and completed according to the specific features of the applications being assessed. Although applicants may have to supply information to add to this grid, they will probably come up against the same data problems and methodological limitations as the EESC itself.

3.2.2. A trajectory approach

To supplement this established grid, which maps and clarifies the positions and viewpoints of the various stakeholders, the EESC has found it necessary to identify **various innovation trajectories** and determine how they correlate with different public policy options. These trajectories relate to possible changes in farming systems, with each change being characterised by a preference for a particular type of technology to solve the problems encountered.

3.2.2.1. Reasons for a trajectory approach

While the EESC has opted for a trajectory approach, in principle more consistent with its composition and working methods, there are several 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, to such an extent that it has been made mandatory in France prior to implementation of certain major projects.[24] It is not incompatible with a trajectory approach, such as when comparing different scenarios.

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

- Although CBA is designed to provide an objective and rational assessment of the consequences 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 assessments would be restrictive in itself. Scope must always be left for qualitative factors and considerations.

[24] Decree 2013-1211 of 23 December 2013 on public investment assessment procedure pursuant to section 17 of the 2012-2017 Public Finance Planning Act (Law 2012-1558 of 31 December 2012).

- It would be necessary to have extensive, interconnected, numerical data available; yet at the European level there are very few data specific to the GMO issue, and more general agricultural data (admittedly extensive) are not easy to use for an examination of this subject.
- Lastly, a cost/benefit analysis entails the use of an often complex methodology by expert practitioners, whereas the EESC brings together a range of expertise that is usually of a different nature.

3.2.2.2. Methods used for the trajectory approach

Trajectory comparison is an extension of the EESC's current approach, which, to fully assess the socio-economic impacts of GMPs, compares them with the impacts of other possible solutions to a given problem (for example, with conventional or organic methods of pest or weed control or with other methods of improving nutritional, technology or health standards).

The idea is to take a **problem-based approach** – i.e. to define as broadly and intelligibly as possible the problem that the proposed biotechnology innovation is supposed to address – and then determine the nature and causes of that problem and the various options available to solve it, sometimes in connection with decisions on the role and future of the country's farming industry.

The **approach is dynamic**, as it considers the temporal dimension of impacts resulting from choices made, as well as the spread and take-up of technology by stakeholders, and the occurrence of 'lock-in' phenomena. The latter arise out of existing relations between players and the sharing of common standards, or 'path dependence', which promotes existing innovations or innovation in line with the current system, making new trajectories more difficult.

3.2.3. Data used

This process of analysis can use **various types of data:**

- Data from the **literature** (in so far as they are available and relevant).
- **Knowledge from experience**, possessed by EESC members, which can relate to the whole range of elements considered in the committee's work: economic and agronomic practice in farming and the food-processing industry, the interests and operating methods of the various players, social and ethical aspects, and the relationship to consumers and the public at large. The arguments and points of view of the various stakeholders on the options, the 'futures', that they consider workable and/or desirable are also data of prime importance.
- It may also be helpful for HCB to make use of existing work and foresight studies on farming-related subjects for the trajectory approach. Putting together relevant foresight studies is a cumbersome process requiring time and expertise, but

various bodies have produced recognised studies of this sort on which the EESC might draw following discussion.[25]

3.3. Conclusion and recommendations

In addition to contextualisation and description of the subject prior to analysis, as explained above, the main methods used will therefore be the following:

- The new EESC **evaluation grid** (see appendix), amended as a result of this work. It will underpin discussion, establishing a broad area for examination but one that is broken down into relative detail for practical purposes. It can be adjusted for individual dossiers.
- The innovation trajectories approach, combined with broader consideration of developments in, and the future of, farming and the food-processing industry as well as environmental and food concerns.
- Organisation of discussion and exchange of views within the EESC, which is valuable in itself and of obvious interest to the public authorities. This allows mapping and clarification of stakeholders' positions and concerns.

The EESC accordingly makes the following recommendations:

- Avoid a closed, 'turnkey', process, which, based on incomplete information (owing to the problem of data, amongst others), can give the illusion of simple binary answers, whereas we are dealing with a complex and unpredictable field and public decision-making is in reality a product of largely political choices.
- As and when necessary, use tools that provide insight into the issues through foresight studies in a wide range of fields (public policy trends relating to agriculture, the environment, innovation trajectories), backed up by discussion.
- Create working conditions conducive to this process by **allowing the EESC** to:
    - **clarify referrals as close as possible to source** with the authorities;
    - have **sufficient time** for high-quality analysis, **taking account of availability of HCB members and resources**;
    - have recourse, **if necessary, to outside expertise.**
- Make available to the EESC the results of previous public consultations on GMOs so that it can incorporate them in its own analysis. The new Article L.533-9 of the Environment Code provides that, in addition to proposed decisions authorising or prohibiting deliberate release into the environment and placing on the market of GMOs, proposed decisions amending the geographical scope of authorisations concerning cultivation, together with applications to reincorporate areas into

[25] See, for example, the *Agrimonde Foresight Study* (INRA), *Afterres2050* (Solagro), Marion Guillou's report on agro-ecological transitions for the French Minister of Agriculture, *Agriculture Energie 2030* (French Ministry of Agriculture) and *Nouvelles ruralités à l'horizon 2030* (INRA foresight study, 2008).

these authorisations, must be 'the subject of online public information and participation'.[26]

- Go beyond CBA whilst recognising that the committee's mapping and clarification of the issues that matter to stakeholders and its identification of innovation trajectories could constitute a particularly valuable contribution for a CBA intended to stick closely to the situation on the ground and stakeholder concerns. In this respect, joint work should definitely be contemplated.

4. Criteria for analysis by group

Question 4: *HCB will give its opinion on the appropriateness of case-by-case analysis or group analysis of GMOs by crop or trait for assessment of marketing authorisation applications for cultivation with reference to the assessment grounds set out in the Directive.*

4.1. The question asked

The question of 'aggregating' analysis of different GMPs with similar traits has already come up (proposal for generic recommendations) and has been considered on a number of occasions by HCB.[27]

4.2. The EESC approach

Consumers, and the public at large, seldom think about GMOs plant by plant. Their attitudes and behaviour usually result from a general perception of GMOs. 'GMO' has become a blanket term.[28] Yet, in actual fact, GMOs entail consideration of many different dimensions: 'our relationship to future generations, our relationship to living organisms, our relationship to innovation […], the model of production […], our cultural and anthropological relationship to food and food transgressions, freedom of choice for consumers and the right to information, the model of social justice […]'.[29] Communities of thought, reflecting group attitudes, can be detected in society.

Because of this, **it is proposed to use different levels of socio-economic analysis**:

- **The first, cross-cutting, level** should provide general information, valid for as many GMPs as possible, on cross-cutting issues such as coexistence and

[26] Because public consultation will be on proposed decisions, it cannot be included in prior EESC analysis. However, the results of past consultations on similar proposals will be taken into consideration.

[27] High Council for Biotechnology (2012), *Bilan et propositions d'évolution à mi-parcours du premier mandat* ('First term: mid-term review and development proposals'), report for Prime Minister, 20 June 2012. See also the record of the Board meeting of 4 March 2015 and the address by Ms Christine Noiville, President of the High Council for Biotechnology, at the opening plenary session of the second term of HCB on 6 February 2015.

[28] J.-M. Pastor, *Les enjeux économiques et environnementaux des organismes génétiquement modifiés* ('Economic and environmental implications of genetically modified organisms'), Information Report No. 301, 16 May 2003, Economic Affairs Committee (French Senate), p. 102.

[29] B. Chevassus-au-Louis (ed.), *OGM et agriculture : options pour l'action publique* ('GMOs and farming: options for public action'), report by French Planning Office, La Documentation française, Paris, 2001, p. 98.

intellectual property. This level has already been partially examined by the EESC, which has adopted several cross-cutting **recommendations**.

- **The second, specific, level** should consider the individual features of the GMP.
- **The third, more generic, level** should assess the issues raised by cultivation of a group of GMPs. At this third level, **there is no routine analysis of individual GMPs in order not to duplicate work**. It is possible to identify 'families' or groups of GMPs (such as Bt maize specifically for European corn borer control) for which generic analysis is warranted (since some questions produce the same answers), as is preparation of generic recommendations. This approach has the advantage of not having deadlines, provided that it is not used specifically for individual dossiers, and does not prevent the EESC from adapting the relevant recommendation to a particular dossier or to reflect changing social, economic and ethical data.

4.3. Consideration of the question

These three separate levels of analysis (cross-cutting, specific and generic) have so far proved well-suited to the questions asked of the EESC.

The EESC approach of establishing various possible trajectories based on the problem which the GMP is addressing seems as if it could be particularly fruitful here. Leaving aside official applications covering one or more specific GM traits, discerning aggregation around such problems (mainly agronomic questions, but also GMPs for industrial or food use, for example) would appear to be possible. This would save both time and resources (even if the drafting of a 'generic' recommendation can be quite a lengthy procedure) and/or allow more comprehensive analysis and sometimes greater scope by enabling the problem to be placed in the broader contemporary agricultural, agronomic, economic and technological landscape with more detailed argument and more extensive information.

4.4. Conclusion and recommendation

Group analysis of GMOs by crop or trait is appropriate if the classification of the applications has been carefully thought out and has been discussed in the EESC.

On the basis of application workflow and the trajectory concept, it is possible to identify coherent groups and recurrent themes.

It is recommended that attention be given to gradually establishing a set of elements for analysis to underpin these general approaches.

5. General conclusions

The EESC concludes more generally that:

- The methods already adopted by the EESC are consistent with the requirements of the public authorities as and when they come to implement the Directive.
- The EESC will continue to offer analysis of all the social, economic and ethical impacts of the GMPs under consideration and of the associated technological trajectories in their full complexity.
- The EESC is not an assessment body: the discussion associated with social, economic and ethical analysis must allow public decision-makers to have a clearer understanding of a decision's implications and of any uncertainties.
- Socio-economic assessment of the impacts of biotechnology requires validated data, which are important for ex ante analysis. It is therefore necessary to promote active accumulation of data and foresight studies and identification of trajectories.
- Preparation of the applicant's dossier is a key moment in accumulating these data and determining the position of the proposed technology: it should be sound management for public authorities to seek the necessary information from stakeholders and applicants, with methodological assistance from HCB.
- In this respect it would be helpful for the EESC to be involved in monitoring of research programmes on innovation and the economy and in socio-economic monitoring of cultivation authorisations, which has been recommended repeatedly by the EESC.
- The EESC will endeavour to ensure that its framework of analysis allows for improvement and can adjust to the changes in procedures and applications that might be brought about by the emergence of new plant breeding techniques in the near future.

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Operational summary

EESC recommendations on social, economic and ethical analysis of proposals for GMP cultivation in 15 points

1. The EESC's task is to advise the Government rather than make the final decision.
2. EESC work is intended to provide the most comprehensive and exhaustive **analysis** possible **rather than assessment**. It is based not on expertise but on a process of exploration and clarification of the issue and the positions taken.
3. The significance of the analysis lies as much in the **process of learning and dialogue** that it encourages among stakeholders as in the final product.
4. Taking a neutral and comparative approach, and although the Directive is confined to restriction or prohibition of cultivation, the EESC will continue, under the law of 25 June establishing HCB, to consider the whole range of impacts of both **acceptance** and **refusal** of GMP cultivation.
5. The social, economic and ethical analysis complements the environmental and health assessment.
6. It is important to bolster the principle of **open-minded** analysis of the social, ethical and economic aspects, irrespective of the prohibition/authorisation alternatives for a GMP.
7. A closed, 'turnkey', process, which, based on incomplete information (owing to the problem of data, amongst others), can give the illusion of simple binary answers, must be avoided, since we are dealing with a complex and unpredictable field and public decision-making is a product of political choices.
8. Prior to analysis, it is necessary to **contextualise and discuss** the actual description of the subject being analysed (i.e. cultivation of a GMP).
9. An innovation **trajectories** approach, combined with broader consideration of possible developments in, and the future of, farming and the food-processing industry as well as environmental and food concerns, should be adopted. This approach is dynamic and is based on consideration of the problem that the GMP is meant to address.
10. The analysis will be founded on an updated set of questions designed to be used as non-restrictive guidance.
11. The analysis will go beyond CBA and strictly quantitative analysis whilst building on HCB work for future CBA.
12. It is worth taking the opportunity to process applications in the light of Directive 2015/412 in order, if the need arises, to develop guidelines that will implicitly or explicitly structure public decision-making and the future of supply chains.
13. Working conditions conducive to this process should be created, allowing the EESC to:
    - clarify referrals as close as possible to source with the authorities;
    - have sufficient time for high-quality analysis, taking account of availability of HCB members and resources;
    - have available and master the different **types of validated data needed for ex ante analysis**:
        - Data from the literature,
        - Knowledge from experience, possessed by EESC members,
        - Findings from surveys of the public, consumers, eaters, etc.,
        - Outside expertise for some points,
        - Results of previous consultations.

    Accordingly,
    - It is necessary to promote active accumulation of data and foresight studies and identification of trajectories;
    - Public authorities should seek the necessary information from stakeholders and applicants, with methodological assistance from HCB;
    - In this respect it would be helpful for the EESC to be involved in monitoring of research programmes on innovation and the economy and in socio-economic monitoring of cultivation authorisations.
14. **Group analysis of GMOs** by crop or trait, based on application workflow and the trajectory concept, is appropriate: attention should be given to gradually establishing a set of elements for analysis to underpin these general approaches.
15. The EESC will endeavour to ensure that its framework of analysis for GMP cultivation **allows for improvement** and is able to adjust to the changes in procedures and applications that might be brought about by the emergence of new plant breeding techniques in the near future.

6. Appendix 1

7. Appendix 2: Evaluation grid

Proposal for a new HCB grid for cultivation of a GMP ***Where appropriate, the questions should be considered from the dual angle of impacts associated with cultivation authorisation and impacts associated with prohibition of cultivation.***				**Directive ground[30]**
1	***GMP*** **Why is the GMP being proposed and for which cropping systems?**			
1.1			What innovation/progress/improvement/contribution in relation to current solutions does the GMP provide?	a-d-e-f
1.2			Does the GMP meet a requirement or a demand (e.g. from farmers likely to use it, consumers, processors or public health officials)?	a-d-e-f
1.3			What are the GMP's expected or foreseeable impacts on farms adopting it (yield, ease of use, financial benefit, etc.)?	a-d-f

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Directive 2015/412 grounds					
a	Environmental policy objectives	d	Socio-economic impacts	f	Agricultural policy objectives
b	Town and country planning	e	Avoidance of GMO presence in other products	g	Public policy *(cannot be invoked on its own)*
c	Land use				

1.4			What are the GMP's expected or foreseeable impacts on supply chains adopting it (processing tools, etc.)?	a-d
1.5			Could cultivation of the GMP change flows and sources of raw materials and their derived products for the industries using them (e.g. possible dependence on world market in the event of heavy infestations of the European/Mediterranean corn borer)?	d-f
1.6			What are the expected or foreseeable impacts of GMP cultivation (or refusal) on the competitiveness and productivity of French and European farming?	d-f
1.7			What are the expected or foreseeable impacts of GMP cultivation (or refusal) on consumers (in terms of price, behaviour, quality and health)?	d
1.8			On the basis of the data available to the EESC (especially the Scientific Committee opinion), does the GMP crop pose an agronomic or environmental risk?	a-f
1.9			On the basis of the data available to the EESC (especially the Scientific Committee opinion), does the GMP crop or the product derived from the GMP pose risks to public health or animal health? Are there any uncertainties with regard to health security?	d

2	***Comparison of possible trajectories and identification of possible lock-in effects***			
2.1		Other possible solutions (trajectories)	What other possible solutions exist for achieving the same objective as that of the GMP?	a-d-e-f
2.2			If other possible solutions exist, how is the GMP placed in relation to them in terms of - agriculture (effectiveness, cost, consumption of inputs, etc.), - use (ease of implementation, nutrient production, preservation)?	d
2.3		Effect on public policy	What might be the impacts of cultivation of the GMP on national farming policy (in France and abroad) and regional farming policy, particularly on medium-term plans?	d-others?
2.4			What might be the impacts of cultivation of the GMP on policy choices of the French regions investing in GM-free supply chains or GM-free agricultural policy?	d-others?
2.5			What might be the impacts of cultivation of the GMP on arable land use and distribution?	b-c
2.6		Reversibility	Will the authorisation decision be reversible if new or initially unforeseen problems occur? In particular, if authorisation is revoked, would uncontrolled proliferation be possible?	d-c-f

2.7	Coexistence	What might be the impact of cultivation of the GMP on implementation of coexistence?	d-e
2.8		What might be the impacts of cultivation of the GMP on implementation of the biomonitoring provided for by the law of 25 June 2008?	d-e
2.9		What provision has been made for monitoring (including economic and social) and biological controls following cultivation of the GMP?	d-e
2.10		How will the costs pertaining to these arrangements be apportioned (among those using the GMP, those not growing it, and public authorities)?	d-e
2.11		What might be the impacts of cultivation of the GMP on other crop chains?	c-d-e-f
2.12		What might be the impacts of cultivation of the GMP on animal supply chains, particularly that relating to beekeeping?	d-e-f
2.13		What might be the impacts of cultivation of the GMP on 'high-quality' supply chains?	c-d-e-f
2.14		What might be the impacts of cultivation of the GMP on seed production (certified, farm-saved and farmers' seed)?	c-d-e-f
2.15		To what extent is dissemination of the GMP compatible with diversity of production methods and farming technologies?	d-e-f

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3	***Sustainable development*** **What are the impacts of cultivation of the GMP on social (including cultural), environmental, health, planning and agronomic sustainability?**			
3.1			On the basis of the data available to the EESC (especially the Scientific Committee opinion), will the GMP crop have an agronomic or environmental impact?	a-f
3.2			On the basis of the data available to the EESC (especially the Scientific Committee opinion), will the GMP crop or the product derived from the GMP have impacts on public health or animal health? Are there any uncertainties with regard to health security?	d
3.3			Will use of the GMP make it possible to reduce use of plant protection products?	a-c-f
3.4			Has the GMP's effect on target and non-target fauna and flora been compared with the different treatments and control methods already available or used by farmers?	a
3.5			Will dissemination of the GMP (and any herbicides associated with it) entail a risk of onset of resistance in target organisms?	a
3.6			Could the GMP have an impact on preservation of natural resources (biodiversity in the wild, water, soil, etc.)?	a
3.7			Could cultivation of the GMP lead to more energy-efficient and lower-carbon cropping and treatment systems?	a-d-f
3.8			Could dissemination of the GMP entail a reduction in agricultural biodiversity?	c-d-e-f
3.9			Could dissemination of the GMP entail a reduction in agricultural landscape diversity?	b-c-d-e-f

3.10			Could cultivation of the GMP change the number and quality (earnings, working conditions, etc.) of jobs for farmers and farm employees, whether or not they use it?	d-f
3.11			Might exploitation of the intellectual property rights protecting the GMP result in farmers' dependence on commercial or technological monopolies or oligopolies?	d-f
3.12			What will/might be the consequences of exploitation of intellectual property rights on the ability of farmers and seed producers to innovate with regard to plant varieties?	d

4	**Understanding of and support for scientific and technological progress among the public and consumers**	d

4.1			Have the public and consumers been able to voice their views on the planned cultivation of the GMP? What information, consultation or cooperation has there been?	d
4.2			Will the public and consumers be properly informed about the genetic modification, the products derived from the GM plant and their possible presence in food?	d
4.3			How do the public and consumers approach the issue of GMP dissemination?	
4.4			Could adoption or rejection of cultivation of the GMP send a signal to biotechnology innovators in France that would guide their research in public bodies or private companies?	d-f?