ROADMAP

Title of the initiative: **New policy for genetically modified organisms (GMO) cultivation**
Type of initiative (CWP/Catalogue/Comitology):
Lead DG/contact person/details: DG SANCO
Expected date of adoption of the initiative (month/year): Date to be decided
Date of modification:
Version No:

Initial IA screening & planning of further work

A. Context and problem definition

(i) What is the political context of the initiative? (ii) How does this initiative relate to past and possible future initiatives, and to other EU policies?

President Barroso in his political guidelines for the current Commission made reference to the principle of subsidiarity and indicated that "in an area like GMOs (genetically modified organism) it should be possible to combine a Community authorisation system, based on science, with freedom for Member States to decide whether or not they wish to cultivate GM crops on their territory". The current initiative aims at implementing this political guideline in concrete terms / and within the existing legislative framework, if possible. The reasons for proposing this are that the authorisation system for the commercial cultivation of GMOs does not work in the way foreseen when designing the legislation: Safeguard measures against the cultivation of the maize presently authorised (MON810) are in place in six Member States, as well as total bans. Member States called on the Commission in 2009 to prepare proposals to give freedom to Member States to decide on cultivation of GMOs.

What are the main problems identified?

- Member States' dissatisfaction with the procedures on GMOs for cultivation given their limited power to decide whether to cultivate in their territories.
- Widespread opposition to the authorisation of GMOs for cultivation both at Member States and citizens' level.
- Against this background, difficulties in processing cultivation files (only 1 authorisation delivered in 12 years) and increasing number of national safeguard measures banning cultivation of authorised GMOs and of total bans at national level.

Who is affected?

- Biotechnology companies, facing an uncertain political context and limited access to the EU market.
- Farmers, who have a more limited choice of agricultural products.
- Producers and importers of GM seeds, who do not have access to the market and to the product.
- Consumers and wider public who receive contradictory messages as concerns the safety for human and animal health and the environment of GM crops.

(i) Is EU action justified on grounds of subsidiarity? (ii) Why can the objectives of the proposed action not be achieved sufficiently by Member States (necessity test)? (iii) As a result of this, can objectives be better achieved by action by the Community (test of EU Value Added)?

- One of the main objectives of the GMO legislation (protection of environment, human and animal health and protection of consumer interests) should be better served through a Community wide authorisation on the basis of science.
- A Community wide science-based authorisation would also serve the purpose of maintaining the internal market of seeds, food and feed related to the same GMOs.
- Combining this EU-wide authorisation with more subsidiarity for MS to decide on cultivation of GM crops may contribute to a better functioning of the common framework whilst allowing GM

seeds to be authorised and actually cultivated in accordance with national specificities (such as environmental, co-existence related or socio-economic reasons).

B. Objectives of EU initiative

What are the main policy objectives?

To leave the Member States the necessary freedom to decide whether or not they wish to cultivate GM crops on their territory whilst maintaining an EU-wide authorisation system to make sure that authorised GMOs are safe as concerns human and animal health and the environment.

Do the objectives imply developing EU policy in new areas or in areas of strategic importance?

GMOs have been legislated for more than a decade and cannot be considered to be a new policy area.

C. Options

(i) What are the policy options? (ii) What legislative or 'soft law' instruments could be considered? (iii) Would any legislative initiatives go beyond routine up-date of existing legislation?

Possible options include limiting applications to specific countries; limiting authorisations to certain territories; revision/abrogation of the co-existence guidelines to provide MS with more room of manoeuvre; consideration of socio-economic factors; and a combination of various options.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

The actions proposed cut across several policy areas and notably Internal Market and Enterprise, Trade, Agricultural and Environmental policy.

Explain how the options respect the proportionality principle

The options would be implemented in combination with a Community-wide system that would ensure meeting the objectives of maintaining the internal market and protecting human, animal health and the environment. They would therefore be proportional to the aim of giving more subsidiarity on GM cultivation.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the Impact Assessment Guidelines pages 32-37), even if these impacts would materialise only after subsequent Commission initiatives?

- Since the various options would aim to "make the system work", GM seeds would be authorised on the basis of an EU-wide scientific assessment and cultivated in a number of countries. Therefore a positive impact on biotechnology and seed companies would be expected as compared to the status quo.
- There may be a negative impact for non-GM farmers to monitor and prevent adventitious presence in some regions and/or countries. However, since the countries and/or regions where GMO cultivation would be possible would not be known in advance and would probably change on a case by case basis, it is not possible to make an ex-ante evaluation.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

NA in principle if the options are implemented within the existing legislative framework.

Could the options have significant impacts on (i) simplification, (ii) administrative burden or on (iii) relations with third countries?

Biotechnology is an important topic of transatlantic dialogue and therefore relations with the US (as well as other Third Countries producing GM seeds) need to be taken into consideration when developing this initiative, irrespective of the options.
The initiative could in principle reduce the administrative burden at Community level and increase it at national level, notably in the countries that would wish to limit GMO cultivation.

E. Planning of further impact assessment work

When will the impact assessment work start?

Only if new legislation is developed and an IA is deemed necessary, the Impact Assessment Steering Group would be set up as soon as it is decided to proceed this way

(i) What information and data are already available? (ii) Will this impact assessment build on already existing impact assessment work or evaluations carried out? (iii) What further information needs to be gathered? (iv) How will this be done (e.g. internally or by an external contractor) and by when?
(v) What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Ongoing evaluations of the GMO legislation as well as reports on socio-economic factors and on economic performance of GM crops would contribute to the related data collection, if needed.

Which stakeholders & experts have been/will be consulted, how and at what stage?

Member States, biotechnology industry, environmental NGOs and farmers.