Response to notification 2011-016: European Union and its Members States submission of information on socio economic considerations.

*Decision BS-V/3, para 23.*

Notification SCBD/BS/CG/KG/jh/74729, in the context of the decision BS-V/3, invited Parties, other Governments and relevant organizations to provide information on socio-economic considerations, including guidance material and case studies on, inter alia, institutional arrangements and best practices.

The past or present experience with GMO commercial cultivation in Europe is limited to 7 countries and to herbicide-tolerant (HT) soya, insect-resistant (Bt) maize and starch potato in the European Union. Therefore the amount of statistically relevant information on the ex-post socio-economic impacts of GMO cultivation is rather limited. It focuses mainly on impacts at farm level (seed production, farmers).

The submission in response to notification 2011-016 includes the report from the European Commission on socio-economic implications of GMO cultivation, which consists of two parts: the summary and an annex consisting of the summarised contributions of each Member State. Furthermore, complementary information with attachments by several Member States is provided to be added to the notification 2011-016.

**Austria**

Austria’s main concerns with regard to socio-economic considerations linked to the use of LMOs are related to its agricultural structure, which is very small structured (average farm size about 19 ha), and has a high proportion of organic farming (approx. 16%).

Due to the level of public rejection, the biggest Austrian retail chains have decided not to market any products, which are labelled as containing LMOs/GMOs. This labelling is mandatory under the EU legislation.

Cultivation of LMOs might lead to higher production costs for organic farmers but also for farmers, which produce LMO-free products, due to precautionary measures to avoid contamination and due to higher control costs. These higher costs might jeopardize the efforts by farmers to choose a production system which does not use LMOs.

The main issue with regard to socio economic considerations is therefore the adoption of clear co-existence rules and their implementation in order to maintain organic or LMO-free production. The legislative and executive power with regard to coexistence rules lies within Austria’s nine federal provinces, all of which have adopted respective legislation.

Austria has published a study on policy development with regard to GMOs which after a thorough analysis of the current situation comes to the conclusion that there is a need for 1) research on possible socio economic effects and impacts and 2) for policy development taking into account the input of a broad range of stakeholders. The study is attached to this submission. (See attachment 1)

Other studies to investigate further, non agricultural, effects and possibilities for criteria and indicators to allow a standardized assessment are currently being carried out in Austria.

**Bulgaria**

**Bulgarian legislative framework**:

-Genetically modified organisms Act (adopted June 2005, amended march 2010)

-Ordinance on Deliberate release into environment and Placing on the market on genetically modified organisms (adopted October 2005)

The amendments in genetically modified organisms Act introduce prohibitions for deliberate release and placing on the market of GMOs, as a result of strong negative public opinion.

At present Bulgaria has no specific experience concerning socio-economic impacts of genetically modified organisms, including guidance material and case studies on.

Since the Genetically modified organisms Act was adopted and amended, till now, there are no received by Bulgarian competent authorities’ notifications for deliberate release and placing on the market.

**Czech Republic**

From the international point of view, Article 26 of the Cartagena Protocol on Biosafety leaves the **option** to Parties of including socio-economic considerations (SEC) in their decision making process. However, potential inclusion of the SEC is very sensitive issue as Parties have to comply with their other international commitments, e.g. WTO, SPS etc. (currently running online forum at the BCH website discusses in detail which other international obligation Parties may need to follow). In addition, no international consensus on a definition of socio-economic aspects in terms of the Cartagena Protocol exists; relevant discussion that was set up on the basis of COP-MOP/5 decisions is at its very beginning.

Ex ante (i.e. before release of GMO into the environment)

SEC are not obligatory part of the assessment processes in the Czech Republic as scientifically sound risk assessment is a key element for relevant Czech competent authorities. For that reason, no general guidelines on SEC are developed in the Czech Republic. According to the legal analysis made by the Commission Legal Service in 2008, the socio-economic aspects could be taken into account only under certain conditions, based on case-by-case assessment. We are of the opinion that the application of the case-by-case principle prevents from the definition of any general criteria prior to the assessment of a concrete GMO and concrete conditions of its intended use.

The real socio-economic value of a notified product should be established by the market itself. The regulators are just obliged to ensure that only safe products are placed on the market, those that have undergone a strict risk assessment process.

It should be also noted that extensive research activities regarding GM crops in field trials have been carried out in the Czech Republic. In 2010, field trials with 6 GM crops were carried out on 22.9 ha (incl. buffer zones). The trials have been conducted for both research and agronomical purposes. However, those for research purposes conducted in cooperation with research institutes and / or universities continued in 2010 whereas most field trials managed by main seed companies to test agronomical performance were suspended.

In addition, a group of reputable Czech researchers issued “The White Book”, summarizing most important research results, experience with the GMOs and effect of regulations on research activities.

Post ante (i.e. after release of GMO into the environment)

GM crops are cultivated in the Czech Republic since 2005 (GM maize MON 810 resistant to European corn borer), respectively 2010 (‘Amflora’ potatoes with changed amylopectin content). In 2010, GM crops were grown on less than 5000 ha (GM maize on 4680 ha, ‘Amflora’ potatoes 150 ha), which represented ca 0.14 % of agricultural land in the Czech Republic.

The cultivation is regulated through the **rules of co-existence**, which define principles of cultivation with respect to conventional cultivation, organic farming and cultivation of GM crops and therefore can be considered as a part of SEC. The Czech Republic follows the Commission Recommendation on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming. Principles and rules of co-existence and obligations for growers of GM crops are enclosed as attachments 2, 3 and 4.

In early 2010, The Ministry of Agriculture published a **summary report on experience of the Czech growers with Bt maize** in period 2005-2009. Data for the report were obtained through questionnaire sent to farmers every year. Information related to SEC is also mentioned in the document. The above-mentioned publication is attached as Annex 5.

The Czech Republic also participated in the **survey on the socio-economic implications of the placing on the market of GMOs for cultivation** arranged by the European Commission in response of the Council conclusion of December 2008. The summary of the Czech report is enclosed as attachment 6.

**Germany**

In the current discussions to fulfil the requirements of Art 26 of the Cartagena Protocol an understanding should be reached if and to what extent and, as appropriate, which socio-economic aspects could be taken into account in or alongside the safety assessment, as part of the risk management decision on the approval of individual GM plants.

A survey asking different stakeholders in Germany on the integration of socio-economic aspects in the assessment of genetically modified organisms (GMO) showed the divergent and partly polarized view on the issue. It consisted of general information on the complex problem that mainly referred to the aspects on which the particular interest of the respective stakeholders was focussed.

To get a more complete picture in order to draft criteria in relation to the application of socio economic considerations an intensive moderated discussion process on the national level would be needed.

The following summary gives an overview of the comments received from stakeholders which could perhaps feed in the international discussions in relation to Art. 26.

1. In a first step the exchange of information should not aim at enabling a comprehensive and final assessment of the pros and cons of the use of agro-genetic engineering worldwide. This would actually not only require a comparison of cultivation systems (conventional, organic, GM cultivation), but also an extensive overall stocktaking taking diverse other indicators into account (ranging from soil composition, climate, political stability etc.).

2. The increasing awareness in relation to the inclusion of socio-economic aspects in connection with the assessment of genetically modified organisms (GMO) is documented by the rising number of scientific publications and reports which address this issue. However, these studies can only be used to a limited extent.

Studies that examine the impact of or the economic effort involved in the use of GMOs often only describe certain aspects that can be used to a limited degree in the final formulation of criteria (see e.g. two recently published studies on the global application rate of herbicides (glyphosate) that come to opposite conclusions: Charles Benbrook, Impact of Genetically En­gineered Crops on Pesticide Use: The First Thirteen Years, The Organic Center, No­vember 2009 and Graham Brookes, Focus on environmental impacts - Biotech crops; evidence, outcomes and impacts 1996-2007, PG Economics, October 2009).

Analyses that either describe the pros or the cons are (frequently at the same time) qualified by studies that prove the opposite.

3. It also seems important to point out that the EU would have to draw on limited experience because of the GMO crop area is small. In order to be able to make an assessment of agro-genetic engineering in the context of intensive farming in the EU, we would have to refer to experience that encompasses larger crop areas, e.g. in order to be able to take the impact of a large-scale cultivation of, for instance, herbicide-resistant plants into account. It will also be necessary to examine whether statements that are based on experience gained in other parts of the world are transferable to the specific circumstances in the European Union.

4. In order to prevent a time-consuming redundancy in the elaboration and formulation of criteria, if available, documentation already containing socio-economic criteria could be evaluated on a case by case basis and taken into account in. From the European perspective it should be examined whether they also cover issues that are relevant to the European situation.

5. In the public debate that is marked by great controversy, socio-economic criteria might as "other factors" prove, apart from the purely scientific safety assessment, helpful in the decision on approval as part of a procedure for the approval of GMOs. An inclusion of these socio-economic aspects in the GMO assessment, in addition to the purely scientific risk assessment, can only be based on concretely defined criteria. Feasibility aspects also with a view to acceptance should be taken into account when it comes to formulating the criteria.

It is therefore of fundamental importance for the manageability of socio-economic criteria, to precede the specification of the criteria with a comprehensive and clear outline/definition of the contents.

The example of socio-economic relevance for coexistence illustrates the vast differences in the ideas on contents and scope (some assert that co-existence means absolute zero-tolerance whereas others consider co-existence to be realised when admixtures do not exceed the 0.9% threshold) that result in different consequences.

6. Furthermore, possible criteria have to be measured in light of the WTO rules under legal aspects and based on the Treaty of Lisbon.

7. A distinction must be made between socio-economic implications of GMO cultivation and the development of corresponding criteria on the one hand and the environmental risk assessment to be carried out as part of the GMO procedure for approval on the other hand.

**Hungary**

Since Hungary is not involved in the commercial growing of GM crops, Hungarian farmers have no experience in this regard, or with their effect on farming environment. A survey conducted among domestic farmers has shown that they tend to be rather negative towards GMOs. However, they do not think that as a single course of applying smaller amount of plant protection products would be a strong enough reason for the introduction of GMOs. Farmers do not agree with the argument that using GMOs would definitely and always entail economic profits. Hungary’s main concerns associated with the socio-economic considerations in connection with the use of GMOs are related to its agricultural structure. Hungary has a farm structure consisting of small size farms and a considerable proportion of the land is cultivated organically (approx.130000 ha).

Cultivation of LMOs might lead to higher production costs for organic farmers and also for traditional farmers wanting to produce LMO-free products, due to the precautionary measures to avoid contamination and the higher costs of certification. These higher expenses might jeopardize the efforts by farmers to choose a production system which does not use GMOs.

The main issue regarding socio economic considerations is the adoption and implementation of clear co-existence rules in order to maintain organic or GMO-free status.

Hungary has commissioned and published a study on the economical impact of introducing GMOs into agricultural practices. After a thorough analysis of the current situation in other countries growing GM crops, the report comes to the conclusion that there is a need tor 1) research the possible socio economic effects and impacts of growing GM crops, and 2) to develop a policy only after the views of a broad range of stakeholders have been taken to account. The above study is attached to this submission (See attachment 7).

Other studies to investigate different, non agricultural uses of biotechnology, their effects and possibilities for allowing an assessment of their impacts are currently being carried out in Hungary.

**Italy**

The Italian State has embraced the provisions contained in the Recommendation 2003/556/EC, with the approval of the Decree Law of 22 November 2004, n.279, converted into Law No. 5 of 28 January 2005.
This law has introduced into national legislation the principle of coexistence with the separation of the chains and the freedom of consumer choice in the decision on the type of product to use, or organic, conventional or transgenic crops.

1. On March 17, 2006, following an appeal by the Marche region on the Law 5 / 2005, the Constitutional Court delivered a Judgement of the n.116 which ruled that the "rules of coexistence among different types of agriculture (conventional biological and with that making use of GMOs) is the exclusive responsibility of the Regions and Autonomous Provinces "as cultivation for production clearly affects the agriculture field.
According to the ruling Council of State, the regions to exercise the legislative power to regulate the procedure for implementing the principle of coexistence in the various regions, known to be very different in terms of morphological and productive.

2. The Regional Inter-Technical Working Group has developed the document "*Guidelines for the regional regulation of coexistence between conventional, organic and genetically modified*" approved by the Conference of the Regions in 2010. That same year, the regions have seen fit to withdraw the document approved in as many local administrators have recognized the difficulty of ensuring an effective system of segregation of sectors, essential for coexistence. Also worth mentioning are the special characteristics of the Italian territory that restricts the scope for intensive cultivation on a large scale, a fragmentary knowledge of the different ecosystems and a lack of previous experience you do not have a skilled workforce capable of providing and exercising careful process control and monitoring. To date, you do not have a legal instrument to regulate coexistence.

3. Italy has launched two projects LIFE + 2008, one of which pursues the aim of:
• Validation of a methodology for monitoring and managing potential environmental effects of GMP;
• the proposed specific objectives of environmental protection for sensitive areas and protected vivcine agricultural areas;
• the selection of monitoring indicators relevant to the management and monitoring of GMP cultivation.
A second project that defines a spatial simulation model of pollen dispersal in a scenario where there is cultivation of GM crops and GM-free.

**Poland**

***General comments***

The Polish public opinion on GMOs differs according to age, education, occupation and place of residence but we can identify some common elements. Generally the Polish society is vividly interested in GM food related issues, having a strong negative attitude towards it and the cultivation of GM plants (there is also dominated by negative feedback with the exception of a part of farmers). The scientific community is also split on the issue: biotechnologists declare themselves mostly in favour of GMOs, environmentalists - against).

From the economic point of view GM feeds are of great importance because they are now the core of the feeding of livestock in Poland (mainly in the poultry production sector).

***Cultivation of GM Crops***

An important factor taken into account by the state administrative bodies during decision making process on authorization of GMOs for the cultivation purposes is their possible negative impact on organic farming. Organic farming is becoming an important segment of agricultural production in Poland and meets with a strong public support. Recent data suggest that organic farming in Poland is constantly evolving and thriving. According to the public opinion poll in 2010 there were over 20 thousand organic farms. This is a 20% increase compared to 2009. In 2010 the number of organic farms reached 20 626. In the period 2003 - 2010 ecological area increased 8.5-times and now represents approximately 2.8% of the total area used for agriculture in Poland. The last year is characterized by constant growth dynamics in the development of organic agriculture in Poland, both the number of organic farms, the number of processing plants and the area under cultivation in the system of organic farming. In this context there are legitimate concerns expressed by environmentalists, ecologists and part of the society that GMO crops can adversely affect the development of organic farming while the existing rules on coexistence do not prevent the long-term cross-breeding between conventional and GMO crops species and also mixture organic material with GMO components.

Now in Poland GMOs are not being grown on a large-scale so that the cultivation of GMOs does not currently have much economic significance. The only one genetically modified plant cultivated by the Polish farmers is genetically modified maize MON 810 (unique identifier MON-ØØ81Ø-6), conferring resistance to Lepidoptera insects (mainly the European corn borer). We don’t possess complete data on the tilled area, it is probably several thousand hectares every year. In Poland farmers in the southern part of the country are interested in Bt crops (maize) because this is a zone infected by the target pest - European corn borer. The other GM plants approved for cultivation in the EU - namely potato EH 92-527-1 (unique identifier BPS-25271-9) are not being grown in Poland. The cultivation of this crop in Poland is rather impossible because Poland is a big potato producer in the EU and the processing industry is in 100% stocked by conventional potato producers. Hence, taking into consideration the additional costs including among other the coexistence seems to be probable that this product won’t gain public acceptance. The Polish farmers willing to grow GM crops in the future believe that the principles of coexistence based on Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming constitute a heavy burden for them.

***GM Food and Feed***

Another important aspect raised in the public discussion in Poland in relation to GMOs is GM food and feed. Moreover some people put equal sign between GMO and GM food. According to recent surveys about 70% of the Polish society is opposed to the presence of such a food on the Polish market, an even larger percentage (90%) indicates the need for the specific labelling and surveillance of GM food by the proper authorities. Concerns relating to health issues (possible adverse effects of GM foods in the case of long-term consumption) and marketing risks (the possibility of losing the status of “natural food” producing country) are dominant. According to various studies about 60% of the population fear the disease risks posed by GMOs (mainly of metabolic nature). Recently there are demands on the need for special legal regulations to allow producers labelling food of animal origin (e.g. meat, eggs, milk, cheeses) as produced without GMOs (from animals fed on conventional or organic fodder only). This option is lobbied by NGOs that perceive this solution as an opportunity to limit the use of GM feed in animal feeding. The issue of GM feed is a matter more complex because the economic factor plays the large role here. Poland imports annually over 2 million tones of GM soybean per year. According to the specialists in animal feedstuffs and economists specializing in agricultural markets so large quantity of GM material cannot be replaced in 100% by the conventional raw material from own production whose costs would be comparable to the cost of imported GMOs. In the Polish economy GMOs have a significant economic dimension only in respect to feeds and feed components. Food manufacturers are willing to use GM feeds while avoiding the use of GM ingredients in the final products offered to consumers. Vegetarian products such as soybean derived foods are very often marked as "produced without GMOs". Although there is no legal requirement for such a labelling the common open market forces such a marketing practice. At the moment a special government program aimed at increasing domestic production of leguminous plants in order to partially replace proteins obtained from GM imported soybean with conventional proteins is in the pipeline. It is expected that eventually home production could provide for approximately 30% of the demand for feed protein components.

***Research and Medicine***

The major part of the Polish society (about 75%) opt in favour of the possibility of carrying out research activities with GMOs and use of GMOs for medicine purposes. There are perspectives for production of drugs and vaccines obtained through methods of modern biotechnology and registration research in this field are ongoing. Insulin is an example medicine produced in bioreactors of one Polish pharmaceutical firm with the use of genetically modified bacteria. In terms of other scientific studies with GMOs in contained conditions first of all persons and institutions concerned express their opinion on the subject matter. However contained use of GMOs does not raise public objections. The situation in relation to field trials is more complex. In accordance with national regulations before making any decision on the deliberate release of GMOs into the environment for experimental purposes the local community (relevant as regards a location of the planned field trial) must be informed. The opinions of the community are always taken into account by the competent authorities. The last decade shows that society is increasingly aware of it and exercises its rights in this regard. Nevertheless field experimentation in Poland is very limited (few decisions per year only).

***Socio-economic factors in decision-making process***

There is in Poland support of some groups (including non-governmental organizations, politicians) to incorporate these factors into decision-making process and the opposition of others (such some scientists) who are afraid of the "dilution" risk assessment process by pushing the scientific evidence concerning the safety of GMOs into the background. The inclusion of socio-economic factors into the assessment of GMOs may take place at two levels:

- in the authorization process prior to the placing GMOs on the market and / or

- when the decision to introduce a national ban on the use of GMO is considered.

Currently in Poland among people who support consideration of these factors the prevailing opinion is that they should be taken into account in both these processes. Of course during the authorization GMOs on the EU level cannot be taken into account all possible factors specific for the countries but there a set of key factors to be analyzed during the authorization of new GMOs should be established. Individual countries should also be entitled to prohibit GMOs (especially with regard to activities sensitive from the environmental point of view), based on that specific factors of social or economic nature, specific for a country or a country region.

Such an approach would contribute to enhancement of public confidence in government decision makers and the new GMO products from the one hand and ensure the economic interests of individual operators from the other.

***Conclusions***

From the economic point of view GM feeds are likely to play still a crucial role in the Polish agricultural (fodder) sector in the next few years. There are also prospects for the development of national pharmaceutical industry utilizing GMOs. The continuing and deepening public hostility to GM foods suggests a lack of development capacity in this field. The trigger for agriculture could be the appearance of some new GM products on the market, for example plants resistant to environmental stress, GMOs with altered composition (pharma crops) etc. In Poland some studies in this direction have been conducted (e.g. genetically modified flax with fibers to be used in medicine in case of hard healing wounds). Cultivation of such varieties will probably not meet with social reluctance and can even gain acceptance.

Socio - economic factors should be considered during the GMO authorization process. Individual countries should also be entitled to make sovereign decisions on GMOs (especially on the cultivation of GM crops) - having also regard to the interests of social groups and their own economies.

**Slovak Republic**

Slovakia has limited experience with GMO cultivation. GM maize MON 810 began to be commercially grown in 2006 and the cultivation area was only 30 ha. Since then the cultivation area has increased to 875 ha in 2009 and 1248 ha in 2010. However, the GM areas of MON 810 represent only small percentage of the total agriculturally utilized area in the Slovak republic.

Until now no study about socio-economic implications of cultivation of GMO on farmers and producers has been done in our country. Anyway, we are of the opinion that there are some important influences. The obligation of labelling the products, raised from GMO, has bad influence on producers, who are declaring that this duty will increase the expenses for each product from GMO. Pursuant to this obligation the producers won´t buy the yield crop from farmers.

Also the farmers consider the cultivation of GM crops positive, they have good yields and they use less herbicides. On the other side, some processing companies have designed their own limits for adventitious presence of GM maize in seed for the purchase, which are considerably lower (eg 0.02%) than a labelling threshold. For this reason, some farmers have problems to sell their conventional maize yields, which were grown close to the GM maize areas.

**Attachments to the submission 2011-016**

* 1. Attachement 1:

**Austria**: Assessing socio-economic impacts of GMOs-Issues to consider for policy development-final report- Dr. Armin Spök,IFZ – Inter-University Research Centre for Technology, Work and Culture Schlögelgasse 2, A-8010 Graz, Austria, <http://www.ifz.tugraz.at>

1. Attachement 2:

**Czech Republic**: Principle of co-existence

Marie Křístková, Ph.D., Ministry of Agriculture (abbreviated and updated

1. Attachement 3:

**Czech Republic**: Obligations for commercial cultivation of genetically modified maize in the Czech Republic

1. Attachement 4:

**Czech Republic**: Obligations for commercial cultivation of genetically modified potatoes

1. Attachement 5:

**Czech Republic**: Experience with Bt. maize- Marie Kristkova Phd. Plant Commodities Department at the Ministry of Agriculture of the Czech Republic

1. Attachement 6:

**Czech Republic**: Summary of socio-economic impacts

1. Attachement 7:

**Hungary**: Economical impact of the introduction of GMOs into the Hungarian Agriculture-György Pataki and Réka Matolay, Budapest, October 2008.