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MILJØVERNDEPARTEMENT

Royal Ministry of the Environment

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Your ref

Our ref
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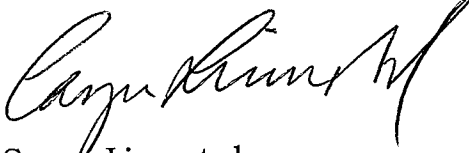
Norwegian submission - Questionnaire about the socio-economic implications of the placing on the market of GMOs for cultivation

Dear Ms. Chantal Bruetschy,

With reference to your invitation dated July 29, 2009 regarding the questionnaire about socio-economic implications of the placing on the market of GMOs for cultivation, please find enclosed the Norwegian comments.

Yours sincerely,


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ANNEX 1

**QUESTIONNAIRE about the socio-economic implications
of the placing on the market of GMOs for cultivation**

16 July 2009

A – Introduction note

Article 31.7 (d) of Directive 2001/18/EC¹ provides that the Commission should send to the European Parliament and the Council a specific report on the operation of the Directive including inter alia an assessment of the socio-economic implications of deliberate releases and placing on the market of GMOs. These implications are defined in Recital (62) of the Directive as the socio-economic advantages and disadvantages of each category of GMOs authorised for placing on the market, which take due account of the interest of farmers and consumers. In its 2004 report, the Commission noted that there was no sufficient experience to make such an assessment (the Directive became fully applicable as of 17 October 2002 and several Member States had not transposed yet so only little experience of its implementation was available).

Moreover Regulation (EC) No 1829/2003, its articles 7 and 19, asks the Commission to submit a draft of the authorisation decision taking into account, together with the opinion of the Authority in charge of the scientific assessment, "other legitimate factors relevant to the matter under consideration".

At its meeting on 4 December 2008, the Environment Council adopted conclusions on GMOs mentioning among other things the appraisal of socio-economic benefits and risks of placing GMOs on the European market for cultivation. In particular the Council conclusions indicated the following:

"The Council:

7. Points out that under Regulation 1829/2003 it is possible, under certain conditions and as part of a case by case examination, for legitimate factors specific to the GMO assessed to be taken into account in the risk management process which follows the risk assessment. The risk assessment takes account of the environment and human and animal health. Points out that under Directive 2001/18/EC, the Commission is to submit a specific report on the implementation of the Directive, including an assessment, inter alia, of socio-economic implications of deliberate releases and placing on the market of GMO.

Invites the Member States to collect and exchange relevant information on socio-economic implications of the placing on the market of GMOs including socio-economic benefits and risks and agronomic sustainability, by January 2010. INVITES the Commission to submit to the European Parliament and to the Council the report based information provided by the Member States by June 2010 for due consideration and further discussions.

¹ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

This possible consideration of socio-economic factors in the authorisation of GMOs for cultivation has also been raised by several Member States in the Environment and Agriculture Councils of the last months².

In order to respond to the invitation of the Council conclusions of 4 December 2008 and to the requirements of the legislation, the Commission invites Member States to submit all information they would consider relevant by January 2010 at the very latest.

In order to help Member States in structuring their responses, the Commission drafted a non exhaustive list of areas and stakeholders which could be concerned. In addition, for each of these categories, we have introduced in the annex a list of leading questions which could be used where considered appropriate.

When preparing their contribution Member States are invited to report *ex post* on the socio-economic impact of GMOs that have been approved in the EU and cultivated in their territory. Additionally, Member States are also invited to assess *ex ante* the possible implications of GMOs of currently pending approvals as well as those which are under development according to the best of their knowledge. One possible source of information in that respect is that recent report produced by the Joint Research Centre titled "The global pipeline of new GM crops" (available at <http://ipts.jrc.ec.europa.eu>).

The submissions must be as explicit and informative as possible and supported by evidence and data. When feasible, the socio-economic analysis – be it *ex post* or *ex ante* – should be quantified. In case documents are attached, they should be accompanied by a summary of the relevant part and a specification about the argument or topic that is being defended.

Where stakeholders are consulted at national level (e.g. farmers and consumers), we would appreciate it if their responses would be incorporated in your submission in an aggregated fashion. The list of stakeholders consulted, as well as any other pertinent information, may indeed be attached to the questionnaire.

Please note that the contributions must only deal with "socio-economic implications of the placing on the market of GMOs including socio-economic benefits and risks and agronomic sustainability" for each category of GMOs. These contributions should cover cultivation of GMOs and placing on the market of GM seeds.

If you choose to fill in the annexed questionnaire, please consider that answers should be broken down by the purpose of the genetic modification (herbicide tolerant, insect resistance, etc) if this affects the content of the responses.

DEADLINE FOR CONTRIBUTIONS: January 2010

² Environment Council of 2 March 2009, Agriculture Council of 23 March 2009 and Environment Council of 25 June 2009

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ANNEX

Lead questions per area and stakeholder

For each question, answers should be broken down:

- *by the purpose of the genetic modification if this affects the content of the responses,*
- *between ex ante and ex post considerations.*

Norway has no cultivation of GMOs on its territory and therefore the following input from Norway is based on *ex ante* observations. The observations are based on information obtained from Norwegian authorities, from a public consultation held in Norway Oct-Dec 2009 and information obtained from the processing of GMO notifications in Norway.

1. - Economic and social implications

Upstream

1.1. Farmers

Has GMO cultivation an impact regarding the following topics? If so, which one?

- farmers' revenues (output prices and agricultural yields);

Under 1.1. the questionnaire is broken down to deal with revenue and production costs separately. Agricultural yield is dependant both on the traits of the agricultural plant itself and of "external" factors such as seasonal variations in climate, the input of e.g. fertilizer and plant protection chemicals. The actual profits for the farmer must therefore take into account both revenue and costs and the actual yield may be due either to the cultivar grown (GM or non-GM) or "external factors". The information below must be considered with that in mind.

Agricultural yields

The actual yield from fields of GM-crops may be positive (increased yield) or negative (reduced yield) and is a relevant factor when considering socio-economic impacts. Several reports on this issue are available.

Reference	Country/countries evaluated	Main conclusions
Doug Gurian-Sherman (2009)	USA	No increase in intrinsic yield for soybean and corn. No increase operational yield for herbicide-resistant soya and corn. Positive operational yield (7- 12 %) for Bt-corn (ECB) when pest pressure high. Little or no

		advantage at moderate or low pest pressure.
Gómez-Barbero and Rodríguez-Cerezo	Spain	MON810 gave yield increase, but there were regional differences. MON810 cultivation has benefitted farmers and seed produces, but for consumers and feed producers there is no change.

Some relevant questions when regarding GM-crops and yield:

Which traits have shown the greatest promise with regards to yield?

Which countries/regions/agricultural conditions have benefitted most?

Are there increased benefits (with Bt-crops) for countries that have fewer alternative pest control measures?

Has the crossing of (MON810) with locally adapted varieties improved yields?

- farmers' production costs;

Use of herbicides/pesticides

Reports from the U.S as presented in Benbrook (2009) suggest that the situation of farmers' production costs with regards to use of chemicals differ between herbicide tolerant (HT) crops and Bt-crops. Data from USDA and NASS surveys indicate that the use of HT crops in the years 1996 – 2008 have increased the use of herbicides by 382.6 million pounds. For Bt maize and cotton the trend has been the opposite with a reduction in the use of pesticides by 64.2 million pounds. Europe has so far only cultivated Bt maize (MON810) and reports from Spain (Gómez-Barbero and Rodríguez-Cerezo) show a reduction in the number of insecticide applications for farmers using Bt-maize.

Some points to consider regarding the use of herbicides/pesticides:

- Reports from the U.S. indicate that the use of HT crops and Bt-crops have quite opposite results with regards to application of agricultural chemicals (increase/decrease in volumes). The figures from the U.S. indicate that Europe should be aware of the possibilities of increased herbicide use if HT cotton, soybean or maize are approved for cultivation. Environmental consequences that could follow from increased herbicide use e.g. resistant weeds (which could necessitate the use of greater volumes and concentrations of Roundup and/or the increased use of other herbicides) should be taken into careful consideration. The EU pesticide directive is highly relevant in this respect when defining the standard for herbicide applications in GM-crops.
- For Bt crops it is worth noticing the clear recommendation in Benbrook (2009) of the importance of sustaining the efficacy of Bt crops amongst others through resistance management plans.

Seed prices

The IAASTD report "Agriculture at Crossroads" discusses some implications of increased concentration of R&D within the private sector and writes (pg 94) with regards to seed prices: "There is additional concern that the anticompetitive impacts of concentration have led to higher seed prices. USDA data suggest that cotton seed prices in the US have increased 3-4 times since the introduction of GM cotton and that GM fees have substantially raised the price of cotton seed in developing nations, such as India."

In Spain (Gómez-Barbero and Rodríguez-Cerezo) prices for GM-seed were reported to vary from region to region and were in all cases higher than non-GM seed.

In some cases governments have actively regulated the price of GM-seeds by establishing price caps at levels lower than what companies charged, such as in India (Sadashivappa and Qaim; 2009). The authors discuss the need for a balance (in India) between profits for the farmers and return of interest for the developers – and argue that although government interventions might be right in some cases they should be targeted and based on careful analysis to avoid long-term consequences for agricultural innovation.

- labour flexibility;
- quality of the harvest (e.g.mycotoxines);

In some cases Bt-crops may have "unintended" positive effects on the quality of the harvest due to e.g. lower levels of mycotoxins in the products. This has been reported in Bt-maize where a reduction in plant damage by pest insects has led to a reduced infection of *Fusarium*, thereby reducing the levels of the toxin fumonisin in the plant products (Munkvold & Hellmich (1999); Hammond *et al.* (2003); Wu (2007)).

- cost of alternative pest and/or weed control programmes;
- price discrimination between GM and non-GM harvest;
- availability of seeds and seed prices;
- dependence on the seed industry;
- farmers' privilege (as established by Article 14 of Regulation (EC) No 2100/94 on Community plant variety rights) to use farm-saved seeds;
- the use of agriculture inputs: plant protection products, fertilisers, water and energy resources;
- health of labour (possible changes in the use of plant protection products);
- farming practices, such as coexistence measures and clustering of GMO and/or non-GMO production;
- cost of coexistence measures;

Coexistence measures in the whole production line from the field, through the distributors, in food and feed processing and through to the retailers will have a cost for the society. Both Norwegian farmer organisations and grain handling companies have expressed their concerns for unintended spread in the field, unintended contamination/mixture of GM and non-GM production lines (distribution/processing etc).

Freedom to choose is considered important in Norway and encompasses both consumers and farmers and their right to choose GM-free food, feed and seed. The issue of GM-free seed is, also in Norway, particularly important for organic farmers as the classification systems do not allow presence of GMOs in organic produce.

- conflicts between neighbouring farmers or between farmers and other neighbours

In addition to conflicts between (GM and non-GM) farmers this category could also include conflicts between farmers and GM-companies. Issues of liability and redress related to GM crops have a clear economic impact on both companies and farmers as illustrated by the Bayer CropScience LL-rice cases in the U.S.:

(<http://www.stltoday.com/stltoday/business/stories.nsf/story/5075056DB7F3020186257683000BD26F?OpenDocument>)

- labour allocation- insurance obligations;
- opportunities to sell the harvest due to labelling;
- communication or organisation between the farmers;
- farmer training;
- beekeeping industry.

Any other impacts you would like to mention:

1.2. Seed industry

For each question, answers can be broken down by the range of relevant stakeholders, including:

- *plant breeders;*
- *multiplying companies;*
- *seed producing farmers;*
- *seed distributors;*

And/or:

- *GM seeds;*
- *conventional seeds;*
- *organic seeds;*

And/or:

- *industrial / arable crops;*
- *vegetable crops...*

Has GMO cultivation an impact regarding the following topics? If so, which one?

- employment, turn over, profits;
- the production of seeds (easiness/difficulty to find seed producers, easiness/difficulty to find areas to produce these seeds...);
- marketing of seeds;
- the protection of plant breeders rights; - the protection of plant genetic resources.

Does the marketing of GM seeds have an impact on the seed industry and its structure in the EU (size of companies, business concentration, competition policy)? Please specify per sector.

- for plant breeders;
- for seed multiplication;

- for seed producers;
- for the availability of conventional and organic seeds;
- creation/suppression of barriers for new suppliers;
- market segmentation.

Any other impact you would like to mention:

Downstream

1.3. Consumers

Has GMO cultivation any impact regarding the following topics? If so, which one?

- consumer choice (regarding quality and diversity of products);

Ref. 1.1 “Cost of coexistence measures”

- the price of the goods;
- consumer information and protection;

Consumer protection

ARGM

With regards to the issue of public protection Norwegian authorities have, amongst others, focused on the use of antibiotic resistance marker genes (ARMG) in GMOs. The presence of ARMG is prohibited in food and feed through two regulations under the Norwegian Food Act:

Regulation of 4 March 2000 No 257 prohibiting certain kinds of genetically modified foodstuffs and foodstuff ingredients. Entered into force 1 of June 2002.

The Norwegian Parliament decided in June 1997 to prohibit the production, import and sale of all products containing genes from genetically modified organisms coding for resistance to antibiotics. The Regulation of 4 March 2000 No 257 is a consequence of this decision.

Regulation on feedstuffs

§8 in the Regulation on Feedstuffs prohibits the processing, import and marketing of feedstuffs containing genes coding for resistance to antibiotics where those genes have been introduced through the use of genetic modification and may be detected in the end product.

Norwegian advisory bodies such as the Norwegian Biotechnology Advisory Board and statements from organisations and the public also speak clearly against the use of these marker genes.

Mycotoxins

Ref 1.1 “Quality of the harvest”

Any other impact you would like to mention:

1.4. Cooperatives and grain handling companies

Has GMO cultivation any impact regarding the following topics? If so, which one?

- work organisation;
- handling and storage;
- transport;
- administrative requirements on business or administrative complexity.

Any other impact you would like to mention:

1.5. Food and feed industry

Has GMO cultivation any impact regarding the following topics? If so, which one?

- range of products on offer;
- employment, turn over, profits;
- work organisation;
- crop handling (drying, storage, transport, processing, etc...);
- administrative requirements on business or administrative complexity;

Any other impact you would like to mention:

In the case of contamination of imported food, feed and seed by unauthorized GMOs the food and feed industry may experience loss of revenue due to the withdrawal of the products from the market (e.g. the cases of LL-rice (2006), linseed (2009)). The actual costs for Norwegian food producers/distributors/retailers in those two cases are not available.

1.6. Transport companies

Has GMO cultivation any impact regarding carriers (insurance, cleaning, separate lines...)? If so, which one?

1.7. Insurance companies

Does the GMO cultivation have any impact regarding insurance companies (e.g. in terms of developing new products)? If so, which one?

1.8. Laboratories

Has GMO cultivation any impact regarding the following topics? If so, which one?

- employment, turn over, profits;
- feasibility of analyses;
- time necessary to provide the results;
- prices of the analyses.

Any other impact you would like to mention:

1.9. Innovation and research

Do GMO cultivation and the technology spill over have an impact on the following topics? If so, which one?

- investment in plant research, number of patents held by European organisations (public or private bodies);
- investment in research in minor crops;
- employment in the R&D centres in the EU;
- use of non-GM modern breeding techniques (e.g. identification of molecular markers);
- access to genetic resources;
- access to new knowledge (molecular markers, use of new varieties in breeding programmes, etc.).

1.10. Public administration

Has GMO cultivation any impact regarding the actions of the national public administrations and the necessary budget (national and local level) for example policing and enforcement costs

Any other impact you would like to mention:

Economic context

1.11. Internal market

Does the placing on the market of GMO seeds have an impact on the functioning of the EU internal market on seeds? If so, which one?

Does it have an impact on the internal markets for services (if so which impact and which services), for agriculture products and on workers' mobility? If so, which one?

Does GMO cultivation have an impact on monopolies? If so, which ones (emergence/disappearance)?

Does it provoke cross-border investment flows (including relocation of economic activity)?

Any other impact you would like to mention:

1.12. Specific regions and sectors

Answers can be broken down on the purpose of the level (national, regional, local) and according to region.

Has GMO cultivation any regional and local impact in those regions regarding the following topics. If so, which one?

- agriculture incomes;
- farms' size;
- the farm production practices (e.g. increase or decrease of monoculture);
- the reputation regarding other commercial activities of the region/localities.

Any other impact you would like to mention:

2. - Agronomic sustainability

2.1 Agricultural inputs

Does the cultivation of EU approved GMOs for cultivation have an impact regarding the use of pesticides against target insect pests (i.e. corn borer)?

Ref 1.1

Does the placing on the market of GMOs have an impact, and if so which ones, regarding the use of pesticides or/and on the patterns of use of chemical herbicides?

Ref. 1.1

2.2. Biodiversity, flora, fauna and landscapes (other impacts than the ones considered in the environmental risk assessment carried out under Directive 2001/18 and Regulation (EC) No 1829/2003)

Does the cultivation of EU approved GMOs have an impact regarding the number of non agriculture species/varieties?

Does GMO cultivation have an impact on agriculture diversity (number of plant varieties available, agriculture species, etc?)

Does GMO cultivation have an impact, and if so which one, regarding:

- protected or endangered species;
- their habitats;
- ecologically sensitive areas;

Does GMO cultivation have an impact, and if so which one, regarding:

- migration routes;
- ecological corridors;
- buffer zones.

Does GMO cultivation have an impact, and if so which one, regarding:

- biodiversity;
- flora;
- fauna;
- landscapes.

Any other impacts you would like to mention:

2.3. Renewable or non-renewable resources

Does the placing on the market of GMOs have an impact, if so which ones, regarding the use of renewable resources (water, soil...)?

Does the placing on the market of GMOs have an impact, if so which ones, regarding the use of non-renewable resources?

Any other impacts you would like to mention:

2.4. Climate

Does GMO cultivation have an impact regarding our ability to mitigate (other than by possibly reducing CO₂ emissions from fuel combustion – see next section) and adapt to climate change? If so, which ones?

Any other impacts you would like to mention:

As Norway does not cultivate GMOs we have no documented examples in this category. Norwegian agricultural authorities are, however, concerned about possible positive or negative effects of the predicted climate change on Norwegian agriculture. It is, therefore, highly relevant to investigate any positive or negative effects that GMOs may have both on climate gas emissions from agriculture and also effects on the vulnerability of Norwegian agriculture due to climate change.

2.5. Transport / use of energy

Does the cultivation of EU approved GMOs have an impact regarding energy and fuel needs/consumption? If so, which ones?

Does the cultivation of EU approved GMOs have an impact regarding the demand for transport in general terms? If so, which ones?

Any other impacts you would like to mention:

3 - Other Implications

GMOs are regulated in Norway according to the *Norwegian Gene Technology Act* (<http://www.regjeringen.no/en/doc/Laws/Acts/Gene-Technology-Act.html?id=173031>) which defines five criteria (health and environmental safety, benefit to society, sustainable development and ethical considerations) that must be considered before approving any given GMO for release. Notifiers must perform an impact assessment according to the Regulations relating to impact assessment pursuant to the Gene Technology Act (<http://www.regjeringen.no/en/dep/md/documents-and-publications/acts-and-regulations/regulations/2005/regulations-relating-to-impact-assessmen.html?id=440455#>) to be evaluated by the Norwegian authorities.

Aspects of the Norwegian criteria benefit to society and sustainable development are similar to and relevant for the concept socio-economics in the EU. Annex 4 in the Norwegian regulation on impact assessment provides guidance on how to assess these criteria.

Annex 4 also includes the criteria ethical considerations, which must also be taken into account for any given GMO release. An example of how the Norwegian Biotechnology Advisory Board (NBAB) has evaluated the criteria ethical considerations may be found in the case of the glufosinate-ammonium HT maize line T25. The NBAB found it to be ethically unjustifiable (as well as not being sustainable) to approve maize line T25 for use as food and feed to Norway if this promotes the use of glufosinate-ammonium herbicides in countries of cultivation. This is based on the documented health risk linked to the use of glufosinate-ammonium and the fact that the use of this herbicide class is banned/severely restricted in the EU and Norway based on health risk to farm workers. The NBAB considers it unethical to expose farmers in countries of cultivation to a risk that is not accepted in Norway or the EU.

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