"GMOs and research"

WORKING GROUP 4.

1. Introduction

The great majority of problems and uncertainties in the use of GMOs in agriculture could be probably overcome if a greater amount of independent researches were available. This should be targeted on the impact of transgenic crops on health, environment and on local agriculture systems over a long period of time.
The network will therefore examine the GMO research themes at a specific working group level.

2. Objectives

The working group "GMO and research" shall have the following objectives:

- to recognize how the research can contribute to Network efforts;
- to recognize research themes related to GMOs that could support initiatives of Network;
- to promote the implementation of research projects on themes of interest to the Network, either with support of European Community, or coordinating regional research projects;
- to propose how ensuring that GMO experimental crops are carried out in compliance with serious and strict protocols on security and in areas specifically authorized for the purpose.

3. Research activities and the Network

Research activities can improve knowledge and information on impact of GMO crops on the environment and on implications of coexistence for the organization of agricultural productions. Community legislation often provides that decisions and actions relating to GMOs should be based on scientific evidence.

The GMO-free network can boost and coordinate impact research at local level. It can also encourage governments and public research institutions to invest more in the evaluation of risks connected to GMOs, on the assumption that to ensure an effective coexistence, higher level of research into the environmental and economic impacts of transgenic crops, in relation to specific areas, are needed .

As regards experimental use of GMOs in open spaces, Regions and Local Authorities of Network undertake to ensure that GMO research is carried out in compliance with serious and strict protocols on security and in areas specifically authorized for the purpose.

Some of the suggested themes looked at by the working group refer to the research on GMOs in open space, with partial superimposition of arguments with the group number 2, involved in the revision of the 2001/18 Directive, for the part connected to the deliberated emission of GMO for any other purpose than commerce (part B).

4. Research themes

Research themes, that could support initiatives of the Network and that could be basis of research activities carried out in partnership by Regions, are the following:

- impact of introduction of GMOs cultivation on local agricultural systems, and in particular, as regards economical and social aspects, differences between north and south areas of

Europe, organic, typical and quality production, conservation of genetic resources in agriculture…

- economical and technical problems relating to conversion of lands cultivated with GMOs. It will be underlined that experiments have only been carried out to introduce GMOs and never to study conversion from GMO crops back to non-GMO farming: microbiologic impacts on soil, GM-seeds remaining in soil and thus forbidding non-GM cultivation with economic impacts on land use & land value…

It's necessary, also, that research groups and institutions at local level control research, results and risk assessments carried out from private researchers or central experts, in order to assure transparency, independence and deeper examination of existing scientific data on GMOs.

5. European Framework Programmes

The implementation of research activities on themes of interest to the Network could be promoted by means of Framework Programs for European Research, technological development and demonstration activities.

At present the 6th Framework Program 2002-2006 is in progress, while the European Commission are working on the Seventh, which is outlined in the proposal of Decision of the European Parliament and of the Council, presented on 6th April 2005.

The last framework programs have always taken into consideration biotechnology-related themes and especially GMOs. They have benefited from ever increasing funds due to the increasing importance of biotechnologies for the development of European industry and for EU policies on the protection of the environment and of consumers.

The European Union website (see annex of this document) shows that since the Fourth Framework Programme (1994-1998) research projects on socio-economic implications of Life sciences and the biotechnology sector have been carried out. During the Fifth Framework Programme (1998-2002) the themes were enriched by actions related to food, nutrition and health. During the current Sixth Framework Programme, "Food quality and safety" is a key thematic priority area with a budget of €685 million. This meaningful change in the importance given by European Community to themes related to safer and healthier food production, as well as environment and health safe agriculture, is stressed by the budget of €2455 million provided in the proposal of Seventh Framework Programme (2007-2013) for the thematic area "Food, agriculture and biotechnology" (Communication from the Commission "Building the ERA of knowledge for growth" – COM (2005) 118 final).

Research results from the activities funded under the last Framework Programmes are the basis for planning joint actions by European GMO free Regions and Local Authorities Network.

More, the forthcoming Seventh Framework Programme is a big chance for the Network to: coordinate regional research programme with research activities carried out in other European regions and member states or at European and international level; draw the attention of high-level scientists to themes related to the impact of GMOs introduction on local agricultural systems.

6. Research databases

The complexity of technical, legal and political choices in the field of GMOs use drove many organizations and institutions to build specific databases containing information about research activities carried out all the world, initiatives on risks assessment, field trials etc.

Databases on GMOs research activities and risk assessment were found in the websites of the European Commission (for instance Cordis RTD-results database), FAO, WHO, UNEP, OECD etc. Research databases are build by Member States (for instance, Documentation centre for the continuous monitoring of scientific, economical, social and legal research on GMOs by Italian Government and CD ROM published by APAT – Italian Environment Protection Agency). Moreover, a lot of information is available on GMOs production company websites.

Under the research project "GMOs in agriculture", Italian government has set up a in order to produce up-to-date dossiers about every thematic area, either periodically or on request. Moreover, a database about GMOs was published on).

The information available could be selected in order to build a specific research database of the European GMO free Regions and Local Authorities Network.

7. Research in laboratory or greenhouses

Experiments concerning genetically modified higher plants, like gymnospermae and angiospermae, only need explicit consent in the case of field trials. Not all research activities carried out in laboratory or under contained conditions are regulated. The choice of measures to prevent the transgenes from "escaping" into the natural environment is left to researchers' discretion and there are no provisions for any inspections or other control measures.

Under paragraph 24 of the introduction of Directive 2001/18/EC, the introduction of GMOs into the environment should be carried out according to the "step by step" principle, with a gradual reduction of containment only if an assessment of the earlier steps, in terms of protection of human health and the environment indicates that the next step can be taken. This procedure doesn't seems to be followed but GMOs pass directly from laboratory to fields.

As a result it proposes that Community legislation should provide that also GM crops in in laboratory or in greenhouses must be notified and consented by national competent authority, which grants the consent based on binding opinion of Regions and Local Authority, within whose territory the research is to take place. Regions, if appropriate, could check conditions of confinement during the growth of the plants and could ask the scientist in charge environmental risks assessments related of the step-by-step release of GMOs in their territory.

8. Field trials

Although several regions of the network do not favour field trials and do not wish to conduct such experimentations, in other regions genetically modified plants have been cultivated in the open field for two reasons: to evaluate their characteristics for agriculture and markets; to study their environmental impact. Most of the field trials concern evaluation of new varieties which will be placed on the market. Only 10% of the releases concerns public research activities.

In accordance with Directive 2001/18/EC, Part B, any person shall, before releasing GMOs for experimental purposes, submit a "notification" to the national competent authority which will give a written consent after examining, particularly: the environmental risk assessment made by the "notifier"; results of public inquiry or consultation in accordance with Article 9. Location and size of the release site may chosen by the notifier without any particular restrictions. Precautions taken to minimise or prevent dispersal of any reproductive organ of the GMO, like pollen and seeds, during and after the release, are indicated in the notification and in the consent of the national competent authority within whose territory the research is to take place. At the end of field trial, and

at any intervals laid down in the consent, the notifier shall send the national competent authority the result of the release in respect of any risk to human health or the environment (Art. 10). The monitoring plan in order to identify adverse effects of GMO release is proposed and carried out by the notifier (Art. 6).

The list of field trials permitted in Europe since 2002, with related summary notification information format (SNIF), is available on the website of the Joint Research Centre of the European Commission (http://gmoinfo.jrc.it). This website also contains information about field trials carried out before 2002.

With regard to GMOs field trials the following observation are possible:

- Regions and local Authorities are excluded from information flows and from experimental release authorisation procedure. The Directive 2001/18/EC does not provide a specific procedure for informing local governments about notifications submitted that interest their own territory. Local administrations get to know through the public consultations and only have a short period (in Italy, for instance, they only have 30 days) to express their opinion. This term is too short to allow local governments to carry out the necessary checks and evaluations for the environmental risk assessment, especially if one considers the necessary coordination between the various competent structure (Environment, Agriculture, Health). The consultation of local administrations is very important in respect of the precautionary principle, principle that preventive action should be taken, and the principle of subsidiarity. Therefore, notifications shall also sent to Regions or Local Authorities within whose territory the research is to take place and the consent shall grant by national competent authority on basis of binding opinion of the competent local administration.
- Release conditions. The measures to minimise/prevent GMO dispersal outside the experimental sites, prior to, during and post-release, shall be indicated in the notification (Dir. 2001/18/EC, Annex III B, paragraph F-G). Further measures can be required by the national competent authority in the written consent to the release. The choice of measures that shall be taken is very important, in particular as regards isolation from soil, water and sexually compatible plant species and crops, because genetically modified plants can be harmful. Therefore, the isolation shall be complete and experimental crops shall be permitted only in contained conditions. The Network should promoted definition of homogeneous security protocols, applied all over the European territory, from independent experts.
- Release site. The choice of location where field trials are carried out is left to the notifier. When the release takes place in a field made available by farmers or takes place on land not belonging to a public research institution, problems could occur such as: the loss of important information relating to the site because of land sale, change of use, etc.; damages for the farmers because of delayed adverse effects of the experiment that occur in the middle-long term.; difficulties in evaluation, for every site proposed by the notifier, of the possible risks for organic and quality agriculture, natural protected areas, etc. Therefore, experimental GMOs shall be cultivated in contained conditions and in land belonging to public research institutions.
- Environmental risk assessment. Experimental notifications shall include the environmental risk assessment (Art. 6 of Directive 2001/18/EC), which means identifying and evaluating potential adverse effects of GMOs, either direct or indirect, immediate or delayed, including cumulative long-term effects, on human health and environment, including *inter alia* flora and fauna, soil fertility, soil degradation of organic material, the feed/food chain, biological diversity, animal health and resistance problems in relation to antibiotics (Annex II of Directive 2001/18/EC, "Principles for the environmental risk assessment"). Assuming that

regardless of the precaution taken, field trials, by their very nature, can result in the transfer of transgenes out of the site or their persistence in the ground after the end of experiment, it is necessary for the risk assessment to include, even, any adverse effects on agricultural biodiversity, local agricultural systems and food chain, and in particular, as regards organic, typical and quality productions as well as socio-economical and cultural aspects. Like it is provided in Italy by the implementation of Directive 2001/18/EC (Legislative decree n. 224/2003), notification for experimental purpose shall also include a risk assessment for local agriculture on the basis of common assessment guidelines.

- GMO impact research. As the analysis of GMO field trials carried out up to now has shown, most concern evaluation of their characteristics for farming and markets, while scientists interested in impact field trials have had difficulties finding experimental GMO crops for their tests. GMO field trials, past or in course, shall be used for research and monitoring the impact of GMOs carried out by independent researchers, e not only by the notifiers. The Community legislation shall provide that research and monitoring into experimental release sites by public and independent research institutions are obligatory.