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COMMUNICATION FROM Mr FISCHLER TO THE COMMISSION

Co-existence of Genetically Modified, Conventional and Organic Crops

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1. Background / political context

The issue of co-existence concerns the economic consequences of adventitious presence of genetically modified (GM) crops in non-GM crops. The issue has its origin in the principle that farmers should be able to cultivate freely the agricultural crops they choose, be it GM crops, conventional or organic crops. No form of agriculture should be excluded in the EU.

Much of the policy debate surrounding the introduction of GMOs in the EU has centred on concerns about potential risks to human health and the environment and on the right of consumers to choose between GM and non-GM products. The regulatory framework that has been developed responds to these concerns. Authorisations of GMOs are subject to a stringent risk assessment in respect of risks for human health or the environment. The rules on labelling and traceability will facilitate consumer choice.

However, the cultivation of GMOs in the EU will also have an impact on agricultural production. In particular, it raises the question of how to manage the adventitious admixture of GM and non-GM crops, resulting from seed impurities, cross-pollination, volunteers (self-sown plants, mainly from harvest fall-out carried over to the next growing season), harvesting-storage practices and transport, as well as its possible economic consequences. The ability of the agricultural sector to deliver a high degree of consumer choice is linked to its ability to maintain different production systems.

Against this background, the Commission has committed itself to:

"...take the initiative to develop, in partnership with Member States, farmers and other private operators, research and pilot projects to clarify the need, and possible options, for agronomic and other measures to ensure the viability of conventional and organic farming and their sustainable co-existence with genetically modified crops".

[Action 17 of the Communication on "Life Sciences and Biotechnology – A Strategy for Europe"]

The issue of co-existence has been raised on several occasions in Council and Parliament. Member States are now also focusing on this issue. A Danish report on co-existence has recently been discussed by the national Parliament, and a Swedish report will be finalised this spring. The UK government is awaiting the results of large-scale field experiments on the use of GM crops before taking any further steps regarding the use of GMOs in agriculture. Other Member States have also been studying measures to establish co-existence, including the possibility of creating GMO-free zones.

There are growing concerns that any perceived or actual problems related to co-existence could make Member States more hesitant to grant new authorisation for GMOs in agriculture.

2. The concept of co-existence

The issue of co-existence of different production systems is closely linked to the introduction of legal thresholds for the adventitious presence of authorised GM crops in non-GM crops. The current food-labelling threshold is 1%, whilst the Council agreement on the GM Food and Feed proposal establishes a 0.9 % threshold for food and feed. For seeds, the Commission is preparing a proposal establishing three different thresholds (0.3 %, 0.5% and 0.7%, according to the crop) for the presence of GMOs in conventional seed lots.

Adventitious presence above the threshold triggers the need for the crop to be labelled. It is assumed that this situation could cause a loss of income or difficulties in selling the crop. Co-existence is, therefore, concerned with the potential *economic impact* of the admixture of GM and non-GM crops at farm level, and with management measures to minimise admixture.

The most cited example of income loss is that of conventional and organic farmers who have to sell their crop at a lower price because of the adventitious presence of GM crops above the authorised threshold level. Whilst for conventional farming the policy is clear, and the possibility of economic damage is linked to the level of the GMO labelling thresholds, for organic farming the situation still has to be clarified. The organic farming regulation establishes that no GMO shall be used in production, but is not specific concerning the question of gene flow from GM crops into organic crops. The regulation does allow for the setting of a threshold for the adventitious presence of GMOs in organic products, but no threshold has been set. So far, in the regulatory Committee, Member States have been reluctant to establish such a threshold at Community level.

There is also, however, the opposite example, where a speciality GM crop could depreciate in value because of admixture with non-GM crops.

It is important to make a clear distinction between the economic aspects and the environmental and health aspects dealt with under Directive 2001/18/EC on the deliberate release of GMOs into the environment.

According to the procedure laid down in Directive 2001/18/EC, the authorisation to release GMOs into the environment is subject to a comprehensive health and environmental risk assessment. The outcome of the risk assessment can be one of the following:

- a risk of an adverse effect to the environment or health that cannot be managed is identified, in which case authorisation is refused;
- no risk of adverse effects on the environment or health is identified, in which case authorisation is granted without requiring any risk management measures;
- risks are identified, but they can be managed with appropriate measures (e.g. physical separation and/or monitoring); in this case the authorisation will carry the obligation to implement environmental risk management measures;
- a risk to the environment or health is identified *after* the authorisation has been granted, in which case a procedure for the withdrawal of the authorisation or for modifying the conditions of consent according to Article 20 of the Directive is initiated under the safeguard clause set out in Article 23 of the Directive.

No further justification exists for Member States to prohibit, restrict or impede the placing on the market of authorised GMOs.

Since only authorised GMOs can be cultivated in the EU and the environmental and health aspects are covered by Directive 2001/18/EC, the objective and the management issue to be addressed in the context of co-existence concern exclusively the economic aspects associated with adventitious presence of GMOs and the feasibility and the costs of measures to reduce the admixture of GM and non-GM crops.

The application of such measures is not a new issue in agriculture. Seed producers, for example, have a great deal of experience of implementing farm management practices to ensure seed purity standards.

3. Preparatory work carried out on the co-existence issue

In order to prepare the ground for the development of policy options, the Commission services have engaged in a thorough examination of the various aspects of co-existence. The focus has been on collecting, assessing and expanding the scientific evidence in this area, in particular as regards the economic consequences of the adventitious presence of authorised GMOs in non-GM crops and the potential farm management measures to reduce this presence.

A study on co-existence conducted by the Joint Research Centre was published last year. This contains model-based results on the spreading of authorised GMOs and possible management measures for addressing the economic consequences.

In addition, the Joint Research Centre has recently made a brief up-to-date summary of the scientific evidence as regards co-existence, based on its own work and other available studies, as well as national co-existence schemes that are currently being developed.

In 2001, the Scientific Committee on Plants (SCP) delivered an opinion on the probability of the adventitious presence of authorised GM seeds in conventional seed lots, which summarised the scientific information available at the time. In January 2003, the SCP stated that there is no significant scientific evidence to give reasons for the need to up-date its opinion from 2001.

One of the results is that appropriate and crop specific management practices are key to addressing the issue of co-existence and to ensuring that threshold levels are not exceeded. At the same time, the SCP concluded that a zero level of adventitious presence is unobtainable in practice.

The JRC study and a recent report on co-existence from a Danish expert group confirmed that the probability of admixture, as well as measures for reducing it, are highly crop-specific. The Danish study also suggests that under conditions of a limited GMO share (10%) and a general threshold of 1% for adventitious presence of GM crops in non-GM crops, co-existence can be ensured for most crops in Denmark (i.e., beet, maize, potatoes, barley, wheat, oats, triticale, rye, lupine, broad beans and peas). For some crops current farming practices may need to be modified, whereas in other cases difficulties with co-existence are virtually non-existent under these conditions. However, for oilseed rape, as well as for seed production of certain crops, ensuring co-existence may be more problematic and further evaluation is required, before guidelines can be developed.

It is also clear that location-specific differences in natural conditions, production patterns, farm structures and field sizes will to a large extent determine what are efficient and cost-effective measures for ensuring the co-existence of different production systems.

Farm management measures

The choice of measures will depend on the specific characteristics of the plant or seed variety in question, as well as the environment in which it is grown. Examples of possible agronomic and farm management measures are:

- isolation distances between fields
- buffer zones
- pollen barriers
- control of volunteers
- crop rotation and planting arrangements for differing flowering periods
- monitoring during cultivation, harvest, storage, transport and processing.

Most of these management measures apply to individual farmers. Given that the aim of the measures remains purely economic, the burden of applying measures to deal with co-existence should fall on the economic operators (farmers, seed suppliers, etc.) who intend to gain a benefit from the specific cultivation model they have chosen.

Some measures are more efficient if coordinated among neighbouring farmers (e.g. complementary crop rotation). In addition, certain management practices, such as planting arrangements for different flowering times or region-wide border management, actually *require* cooperation between neighbouring farms.

Although these measures still need to be defined more precisely, it is likely that the interdependence between neighbouring farmers needs to be taken into account in the search for cost-effective solutions.

The introduction of binding rules on farm management measures would, in such cases, make it necessary to decide not only on how to distribute the burden of these measures between the different types of production systems, but also how, and to what extent, public authorities could or should intervene in the relationship between farmers.

In summary, scientific information for launching a constructive policy debate on the economic consequences of adventitious presence of GMOs is already available. However, it must be noted that there are still important issues that will benefit from further study. This concerns in particular the costs of implementing "best-practice" measures, which will influence the costs of establishing separate GM and non-GM production lines and which will also have a bearing on the competitiveness of EU agriculture.

Another area where little is known is the magnitude of the potential economic loss due to the adventitious presence of GM crops in non-GM crops. This question is related to the price premium that one class of products might command over the other in the future.

It should also not be forgotten that much of the data on gene flow and management measures are based on research models and expert opinion, and are not yet sufficiently validated by field experience. More data from large-scale field trials, and indeed from the few regions in the EU where GMOs are actually grown, would be useful in this respect.

An encouraging trend is that an increasing number of initiatives are being taken by the Member States. In the UK, a code of good practice for herbicide-resistant crops is currently being tested under field conditions. In Denmark, possible farm management practices adapted to the national situation are being discussed. Member States are already playing an important role in developing measures for safeguarding co-existence.

In this context, it should be clear that the European Institutions, Member States and stakeholders must work together to find practical, proportionate and cost-effective solutions that are in the interest of all parties. To facilitate this process, the Commission will organise a Round Table on research results relating to co-existence as an opportunity for experts, stakeholders, and Member State representatives to discuss and exchange relevant information and experiences. The Round Table is scheduled on 24 April 2003.

The Commission will also pursue its efforts to increase the knowledge in this area. In addition to organising a Round Table on co-existence with experts and stakeholders, it will launch a follow-up of the study on "Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture", to be carried out by the Joint Research Centre.

Future studies on co-existence, combining the various aspects of co-existence, as well as environmental and other aspects related to the introduction of GMOs, will also be carried out under the 6th Community Research Framework Programme, in particular under the thematic priorities 5 (Food quality and safety) and/or 6 (Sustainable development, global change and ecosystems).

4. The issue of GM-free zones

Certain Member States have expressed the wish to introduce a ban on the cultivation of GM crops in certain parts (or all) of the national territory. For the more problematic crops such GMO-free zones would be an effective way of reducing GMO spreading to quasi-zero levels without having to implement further management measures inside the zones. Border management would, however, still be necessary.

Nonetheless, preliminary legal assessment suggests that a regulatory measure of this nature, at either national or Community level, has to be excluded, since the protection of *economic interests* alone cannot be invoked as a legally-valid justification for imposing such strong limitations on fundamental liberties. In addition, the establishment of GMO-free zones against the will of some farmers runs counter to the very principle of co-existence.

Voluntary local arrangements between farmers or between farmers and industry to ensure the absence of one or more GM crops in specific areas are, of course, always possible. Examples of such arrangements already exist for crops requiring high purity standards or separation, such as erucic acid oilseed rape.

5. Liability

The question has been raised as to whether the possibility to seek compensation for economic loss in the event of gene admixture needs to be regulated on Community level.

In respect of the principle of subsidiarity, the first step must be to find out whether the existing national laws do not already offer sufficient and equal possibilities in this regard. It may be assumed that most Member States still apply classic civil law on extra-contractual

liability, where the burden of proof lies with the plaintiff as concerns the link of causality and the defendant's fault or negligence.

However, irrespective of whether liability is regulated on the national or Community level, an economic loss caused by gene admixture raises the problem of how to establish the causality link between the action and the damage. A possible solution would be to provide for a presumption of fault, whereby the initial burden of proof lies with the operator who is suspected of not having respected the obligations imposed on him. Subsequently, the usual general rules on civil liability would apply to the process of establishing causality and fault. It is clear, however, that this approach requires the presence of mandatory management rules establishing a duty to conform to certain standards and conduct.

Given the difficulty to establish the causality link between the action and the damage, another solution could be to establish, or encourage the establishment, of collective funds that would be used to cover collective damages.

The liability issue is, therefore, closely linked to the policy options dealt with in this note and will have to be further examined once a policy approach has been decided.

6. Policy options

The object of any potential regulatory actions at Community level is agronomic and farm management measures for the purpose of reducing the economic consequences that can result from the co-existence of different farming systems.

Given the fact that there are significant crop-specific differences in the economic consequences as well in the choice of suitable segregation measures, it is suggested to focus on those crops that are most exposed to the risks of admixture and for which an authorisation for cultivation in the EU is already granted or pending. For other crops the introduction of GM varieties is still some years away.

The first priority would be to address co-existence for GM maize and oil seed rape, as there are GM events already approved for cultivation in the EU and further events are pending authorisation under Directive 2001/18/EC.

As far as actions at Community level are concerned, there are essentially two options:

Option 1: Community action limited to coordinating and advisory functions

In the light of the fact that appropriate measures to address co-existence will vary from one Member State to another and from one region to another, one option is to deal with co-existence issues at national level. This approach would give each Member State the possibility of defining measures that are tailor-made to its specific geographical, environmental, and agricultural conditions.

The Commission would limit its action to the gathering and coordination of information based on continued studies at Community and national level and observing the developments in the Member States. This action could be extended to include offering advice and issuing guidelines, eventually in the form of a code of good practice.

This approach would allow Member States to take appropriate measures on the management of the economic consequences of co-existence, subject to the general condition that the

national measures do not contravene Community law. In this respect, it would be necessary to ensure that the Member States respect the limited scope of authority left to them. The subsidiarity-based approach could be very efficient in terms of developing farm management measures that are adapted to local and regional situations.

Advantages:

- Flexible and easily adaptable to local and regional conditions, to developments in science as well as to practical experiences.
- Can provide a quick and efficient solution to the most pressing issues, notably co-existence with regard to maize.

Disadvantages:

- Country-specific solutions could lead to a certain degree of regulatory divergence across Member States. However, this need not necessarily affect the conditions of competition, although a certain risk in this direction can not be excluded.
- Need to confirm that any national actions are proportionate to the economic risk and that they do not undermine the objectives of Directive 2001/18/EC.

Option 2: Legislative action at Community level

The second approach can be divided into two sub-options, as follows:

a) Adoption of framework legislation, establishing the basic objectives and principles applicable to the introduction of management measures for co-existence. The Community rules would thus be limited to providing a common framework, leaving the Member States with the task of selecting the measures and regulating their details.

   Advantages:

   - Provides a certain degree of harmonisation.
   - Provides some flexibility for national solutions within clearly defined boundaries.

   Disadvantages:

   - Need to confirm that any national actions are proportionate to the economic risk and that they do not undermine the objectives of Directive 2001/18/EC.
   - Would take at least a year, or even longer, before adoption.

b) Adoption of legislation that regulates in detail the requirements to be imposed on farmers (and other operators) with regard to risk management. The legislation would have to take account of the various farming and environmental conditions that prevail in the Member States. It would also require a thorough cost-benefit assessment of each specific measure.

Advantages:

- Provides a high degree of harmonisation; no need to confirm that any national actions are proportionate to the economic risk and that they do not undermine the objectives of Directive 2001/18/EC.

Disadvantages:

- Would have to be very detailed and prescriptive to take into account the different geographical and climatic conditions of Member States and regions.
- Would take several years to establish.
- Highly questionable that it could respond to the particular conditions and needs of individual Member States, and provide the necessary flexibility for adjustment with respect to future developments in biotechnology.

For both sub-options, the legal basis for the legislation might be Article 37 of the EC Treaty, justified by the purpose of managing an economic risk related to agricultural activities.

7. Final remarks

The Commission has to decide on a course of action in order to ensure that farmers will be able to cultivate freely the agricultural crops they prefer, be it GM crops, conventional or organic crops. The issue of co-existence concerns only authorised GMOs, and therefore relates solely and exclusively to the economic consequences resulting from the adventitious admixture of different classes of crops. Risks to the environment or health are addressed in the GMO authorisation process under Directive 2001/18/EC.

Any approach to addressing the issue of co-existence needs to take into account the differences between crops and crop varieties with respect to their potential to spread to neighbouring fields. It is, therefore, suggested to focus on those crops for which GM varieties have been approved or are expected to be approved in the near future, and for which there is a comparatively high probability of admixture. Appropriate farm management measures are already being developed in some Member States. There is an indication that their application would ensure co-existence for a majority of crops with respect to the currently proposed threshold level. However, for a few crops, mainly oilseed rape, and to a lesser extent, maize, measures to ensure co-existence could involve significant changes in farming practices.

The fact that the most efficient and cost-effective measures for ensuring co-existence are likely to be different from one Member State to another and from one region to another, makes an approach based on subsidiarity appear to be most suitable. This does not, however, mean that some form of action at Community level to ensure equal conditions of competition across Member States will not become necessary at some stage.

Given the importance of the co-existence issue and the particular attention paid to it by Member States and stakeholder groups the Commission is invited to provide clear policy directions for the future work on co-existence.