



Umweltbundesamt GmbH

Spittelauer Lände 5
1090 Wien/Österreich

Tel.: +43-(0)1-313 04

Fax: +43-(0)1-313 04/5400

office@umweltbundesamt.at

www.umweltbundesamt.at

International Expert-Conference “Regional Aspects in Precautionary GMO Decision Making”,

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Summary and Conclusions

By **Helmut Gaugitsch**

Umweltbundesamt/Federal Environment Agency Austria

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During this Conference a variety of issues connected with the topic were addressed, with the Council Conclusions on GMOs of the December 2008 Environment Council as a starting point. The presentations and discussions allowed a lively exchange of views between the participants from EU institutions and Member States authorities and scientific advisory bodies as well as other stakeholders. The inputs and the results of the Conference will be summarized and documented in a volume of Proceedings. Until then the presentations given at the Conference are available at the AGES-Website. In the following an account of the major results and conclusions of the Conference is presented.

The basis for taking into account regional aspects in precautionary GMO Decision Making can already be found in the existing regulatory framework on GMOs in the EU. In principle, Directive 2001/18/EC as well as Regulation (EC) 1829/2003 contain specific provisions allowing or even requiring these regional aspects to be taken into account in risk assessment, decision making and monitoring of GMOs. On the same regulatory level there is an existing and well established EU framework on nature protection, the Birds Directive and Habitat Directive being the core pieces of this legislation.

The Council Conclusions of the December 2008 Environment Council refer to this legal basis and have further developed the common way of



thinking in the EU on these issues, formulating concrete steps on a way forward. Apart from the issues of strengthening scientific risk assessment, in particular the appraisal of socio-economic benefits and risks as well as the recognition of how sensitive and/or protected areas are at the heart of these Council Conclusions, which were the starting points for the discussion at this workshop. From that point of departure further concrete and detailed recommendations were discussed.

The general feeling in the Conference was that on the one hand we have well-established systems in place, however, in a variety of areas and at different levels further development and improvements are necessary. Improving the way how regional aspects are taken into account has to be discussed on the scientific and technical as well as on the legal and political level. The issue of socio-economic considerations is a cross-cutting issue which has regional, national, EU-wide and international implications.

Precaution

The whole debate is embedded in the overarching question on how to ensure precautionary decision making. This should be addressed with a long-term perspective. We are faced with the challenge of having to undertake risk assessment and risk management on the basis of data which include uncertainty. This leads to the general question of how we further develop a meaningful, strong and broad scientific debate and come up with solutions which are trusted widely. For this purpose new concepts may be necessary in order to be able to move ahead. Scientific uncertainty may require regional scientific debate involving the relevant experts in a multidisciplinary way. The additional time and resources this may entail might lead to a strong benefit on the other hand leading to decisions which are well-balanced and less questioned by stakeholders.

Scientific and technical level

Why is it important to take regional aspects into account? A couple of reasons have been identified based on experience with releases, cultivation and the preceding risk assessments of those kinds of applications. The example of nature protection shows that with respect to the overarching goal of protecting sites and species a fine-tuned balance between

an EU-wide and a national/regional approach is crucial for a well-functioning and fit-for-the purpose approach. This regards the development of regulatory frameworks as well as their implementation in a similar way. The example of the approach implemented in pesticide regulation adds strength to this conclusion.

Recommendations:

1. It will be important to further develop practical ways of applying both GMO legislation as well as nature protection legislation in a mutually supportive way. The examples of developing protection goals as well as criteria from the nature protection perspective, as well as performing impact assessments according to Art 6 of the Habitats Directive in certain cases were presented and regarded as good practice examples to meet that challenge at regional level.
2. The concepts of bio-geographical regions or comparable regional approaches have worked well in nature protection as well as in the area of plant protection products. The model of bio-geographical seminars in order to discuss and solve regional questions could well function also in the GMO area. New approaches to robust risk assessment as well as developing appropriate risk management measures could thereby successfully be achieved and contribute to finding common ground.
3. The current process of amending the EFSA Guidance on GMO environmental risk assessment should also take into account these discussions. Improved Guidance should contain specific recommendations on how to take into account regional aspects. Member States input is crucial for drafting appropriate guidance and the invitation by EFSA for such a process is very welcome. This is specifically important as this Guidance is meant to get legally binding status. In this context the need for improvement for scientists to gain access to appropriate testing material was discussed.
4. Networking of relevant EU Agencies could be another means of further developing the scientific and technical debate. E.g. EFSA, EEA, JRC, EMEA could informally and formally communicate on that matter with the assistance of existing networks at the member states levels.

Socio-economic Considerations

This issue seems to get more and concrete importance at the scientific and political level. It needs to be discussed more deeply what is meant by the recommendation to take socio-economic considerations into account. How and at which level is this possible and feasible?

Recommendations:

1. The provision of the Council Conclusions which invite MS to submit reports on socio-economic considerations as a basis for a Commission report by June 2010 should be taken up widely. In these reports Member States could make the attempt to develop and suggest criteria on how socio-economic considerations can be taken into account. Robust and well-designed studies at the member state level could be an excellent basis for these submissions. These studies should contain best practice examples by MS on how wider topics such as sustainability issues can be taken into account.
2. Along those lines the EU could take a more active role in the international discussions on this issue, e.g. in the framework of the Cartagena Protocol but also at the WTO level. This could lead to a wider international recognition of this topic.

Legal Improvements including the relevant procedures

Many of the issues discussed at the Conference can be implemented in the context of the existing legislation, e.g. in the context of a full implantation of Directive 2001/18/EC requirements. This may among others involve improved communication procedures among the various institutions and stakeholders (Commission, EFSA, Member States etc.), more clear and detailed guidance on environmental risk assessment at the regional level, improved coherence between GMO and nature protection regulation. However, some other suggestions regarding the consideration of regional aspects may require a change of the regulatory framework in order to implement them in an appropriate manner.

Recommendations:

1. Possibilities for an improved interpretation and comprehensive application of the existing framework in line with the Council Conclusions of December 2008 should be further explored.

2. In addition options for a modification of the regulatory framework should be analyzed quickly but also carefully. The pros and cons of the identified options should be discussed openly and the most efficient option(s) further pursued. The coherence with other Community legislation and international agreements such as the WTO should be taken into account but should not prohibit creative thinking of possible new approaches. Among other approaches, opt-in/opt-out options or two-phase decision making may be an appropriate means in order to strike the delicate balance between EU wide decision making and subsidiarity for certain decisions which should be taken at the national/regional level.