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Proposal for a joint EPTA Project on „Genetically modified plants and foods“

1. Background

Biotechnology, and especially genetic engineering, is one of the most controversially discussed modern technologies. This technology is seen on one side as an important key to economic competitiveness growth, and on the other hand provokes concerns about health and safety issues and about ecological impacts.

The first genetically modified organism was produced in 1973. In the last three decades, great progress was made in modern biotechnologies. Today, they play an important role first of all in medicine and agriculture. The public perception of the bio-medical and agri-food applications has clearly diverged at the same time.

In the year 2005, the estimated **global area of genetically modified (GM) (or transgenic) crops** was around 90 million hectares. GM crops were grown in 17 countries. Leading country is the USA with 49.,8 million hectares (55 % of global total). The most important GM crop was soybean with 54.4 million hectares (60 % of global GM area) (ISAAA report 2005). The global area of GM crops has grown continually. In contrast to this development, the cultivation of GM crops in **Europe** is very limited. In the year 1999, a de facto mora-

torium on GM crops was introduced in the European Union, which was in force until 2004.

Many citizens in the EU are opposed or sceptical about GM food. In the past fifteen years, heated **debates** about genetically modified plants and food have taken place in many European countries. These debates have common characteristics and specific national developments.

Many **TA projects** in Europe have reviewed und contributed to these debates. They used different approaches, as consensus conferences or scientific assessments. GM crops and foods are a major topic for the EPTA members and associates (see annex).

The new **European Directive on deliberate releases** (2001/18/EC) and the following EU regulations have put into force recently a new frame for GM crops and foods in the EU, including an emphasis on the precautionary principle, an enforced risk assessment, a time limit for authorisations, an introduction of follow-up evaluations and a change in the labelling regime. These laws are especially focused on GM crops commercialized for fodder and for human consumption. The co-existence of GM crops with conventional and organic crops, as well as the labelling and tracing of the GM food products, are actual topics of discussion.

At the same time, a **new generation of GM crops**, capable of producing medicine, industrial chemicals etc., is emerging. This development leads to new questions for the risk assessment and regulation, and for the discussion on the advantages and disadvantages of these new GM crops.

For the **future**, central questions are the sustainability of the EU regulation on genetically modified (GM) crops and food, and the problems emerging from the operationalisation of the new EU regulation. As important developments, which are or will be challenges for the EU regulation, can be identified:

- Technical development of biotechnology: In the future, it will be possibly more difficult to draw a clear distinction between GM and non GM plants.
- Trade conflicts: The EU system (with the labelling of the technology and the precautionary principle) is different to the US system and leads to conflicts within the WTO regulation.
- Coexistence: The broader use of GM crops in the EU will raise probably great problems in sustaining the coexistence.

2. The joint EPTA project “Genetically modified plants and foods”

Project’s objectives

The project results should provide information on
– regulatory challenges for the European system in the next years,
– points of public debate in the future,
– approaches for TA to handle the future issues.

The project will concentrate on new questions and possible new answers, rather than to attempt to simply establish a mainstream view on contested issues in the past from comparing the findings of previous projects in the field.

The joint project results will be addressed to policy makers, TA practitioners and the general public.

Project’s approach

A combination of two major methods is foreseen to achieve the project’s objectives: A look in the past with project reviews and a look in the future with a questionnaire survey.

Reviews

The reviews should include the relevant TA projects of the EPTA members and other important TA activities as national participative events carried out over the last six years. An overview of the TA activities on GM crops and foods should be gained with the reviews. The aim is to learn where we are today, how the debate has evolved and what is still relevant for the future. The reviews will be drafted by the project participants. The other EPTA members will be asked to contribute with reviews. The project group will draft a checklist so that the reviews follow a common scheme. Criteria for the selection of projects/activities/reports were discussed. The conclusion was that a strong set of criteria is not workable and the selection should base on comprehensiveness. Studies only on scientific/technological, economical or sociological issues will not be included.

Questionnaire

The questionnaire is indented as a broader survey on the three objectives / key questions of the project. The aim is to collect information and informed guesses from TA practitioners and important people on new challenges in the area of GM plants and foods. It is foreseen to send the questionnaire to all EPTA members. The questionnaire can be filled out by the experts (e.g. project managers) of the member organisation (with feedback from experts) or further distributed by the member organisation to be filled out by 5 to 10 experts (from science, administration, industry, NGOs etc.).

The joint project will focus on GM plants and their use as feed and food, but also include new applications as plant-made-pharmaceuticals or plant-made-industrials. GM animals are not included, because totally other risk and ethical problems arise from them and a use for food production is not expected for the next years.

Project status and new partnerships

Initially, the project was proposed by TAB (Germany) and the initiative presented at the EPTA Council meeting in autumn 2005. Thereafter, the Danish Board of Technology (Denmark), ITA (Austria) and POST (United Kingdom) joined the initiative. A first project meeting took place in February 2006.

A report on the progress of the joint project preparations was given to the EPTA Directors Meeting in spring 2006. The Project Group has tried to incorporate the recommendations form this Directors Meeting in this new proposal. Findings from the evaluation of the first common EPTA project on “privacy” were also drawn in consideration for this proposal.

With this project description **it is suggested to the EPTA Council Meeting 2006 to give the project the status of a “joint EPTA project”**. The acceptance of this suggestion means:

– EPTA members or associates can join the project, if they live up to the criteria for partnership, and inside the timeline for new partnership.
– The Project Group will report on the advancements of the project to EPTA Directors’ Meetings and Council Meetings.

– The project can be announced as a joint EPTA project and its results can disseminate as results of a joint EPTA project.

The following **criteria for partnership** will count for all partners – both the initiating institutions and new partners:
– The institution is member or associated member of EPTA.
– It has finished, ongoing or decided projects of its own that are relevant to the specific aims of this joint project.
– Such projects should have produced or should result in documented synthesis, conclusions and policy options that can be brought into this joint project.
– As decided projects are meant only projects that have been formally ratified by a competent body of the institution, and which has been allocated the necessary resources for project execution.
– The institution accepts this Joint EPTA Project Framework as the basis for the partnership.
– Contributions of the participating institutions will be on their own expenses and resources.
– The institution will present the needed documentation for the above points to the Coordination Group.

The understanding of project and documentation in the Joint EPTA Project Framework applies also for this project.

The **timeline for new partnerships** in this joint project will be:
– October 2005: A first announcement of this project was made at the EPTA Council Meeting.
– October 2006: The EPTA Council is asked to decide on the status as a joint EPTA project. Expressions of interest for partnership can be given, which will result in a time-limited status as partner.
– March 2007: The deadline for expression of interest is on the EPTA Directors Meeting.
– September 2007: The final deadline for fulfilling all criteria for partnership and last possibility to join the project.

The general understanding for the joint project is that all partners will **contribute actively** to making internal as well as external deliverables, activities and administrative procedures, and that all partners work actively for the aims of the joint project.

Nonetheless, this joint project also aims to incorporate contributions (especially reviews, answered questionnaires) from EPTA members and associates not part of the Project Group in the project work. Therefore, contacting partners in these institutions are partly found and will be needed.

Project's work-plan

The Project Manager Group has already started with preparatory works as project proposal and work-plan, draft checklist for reviews, and draft questionnaire.

After the approval as a joint project, the following work-plan is foreseen for the joint project on GM plants and food (see overview at the end):

Review phase
(November 2006 – March 2007)

Working steps in the review phase are:
- drafting of the final checklist for reviews,
- sending out of checklist and organisation of reviews,
- colleting of reviews and check of reviews (including revision of reviews if necessary),
- collecting of further relevant information,
- discussion of the review results in the Project Group,
- drafting of review synthesis (following the checklist structure) and conclusions for questionnaire,
- presentation of the review phase results at the EPTA Directors Meeting in spring 2007.

The outcome of the review phase will be a synthesis of the review results and implications for the following questioning.

Questionnaire phase
(April 2007 – August 2007)

Working steps in the questionnaire phase are:
- drafting of the final questionnaire,
- sending out and follow-up of questionnaire,

– collecting of questionnaire,
– evaluation of the questionnaire results and preliminary conclusions from the questioning,
– discussion of the questionnaire results and preliminary conclusions in the Project Group,
– discussion of the questionnaire results with experts on a workshop (optional),
– presentation of the questionnaire phase results at the EPTA Council Meeting in autumn 2007.

The outcome of the questionnaire phase will be a preliminary overview on questionnaire results and a first draft on conclusions.

Evaluation phase
(September 2007 – December 2007)

This phase aims to put together all the collected material and to draw the final conclusions. Working steps in the evaluation phase are:
– further structuring and comparison of the collected material,
– including of further information as necessary,
– first drafting of the over all findings and conclusions,
– discussion of the draft over all findings and conclusions in the Project Group,
– project workshop on the outcomes,
– discussion and decision on the structure of the final report.

The result of this phase will be an evaluated synthesis of outcomes, including a comprehensive list of upcoming topics and an assessment of future TA possibilities. Additionally, further research needs will be described.

Final report phase
(January 2008 – March 2008)

The final task is to produce a report with good argumentative quality and high readability. The draft final report is foreseen for end of February 2008 and will be presented at the EPTA Director Meeting in spring 2008. After the EPTA Director Meeting, the report will be finalised.

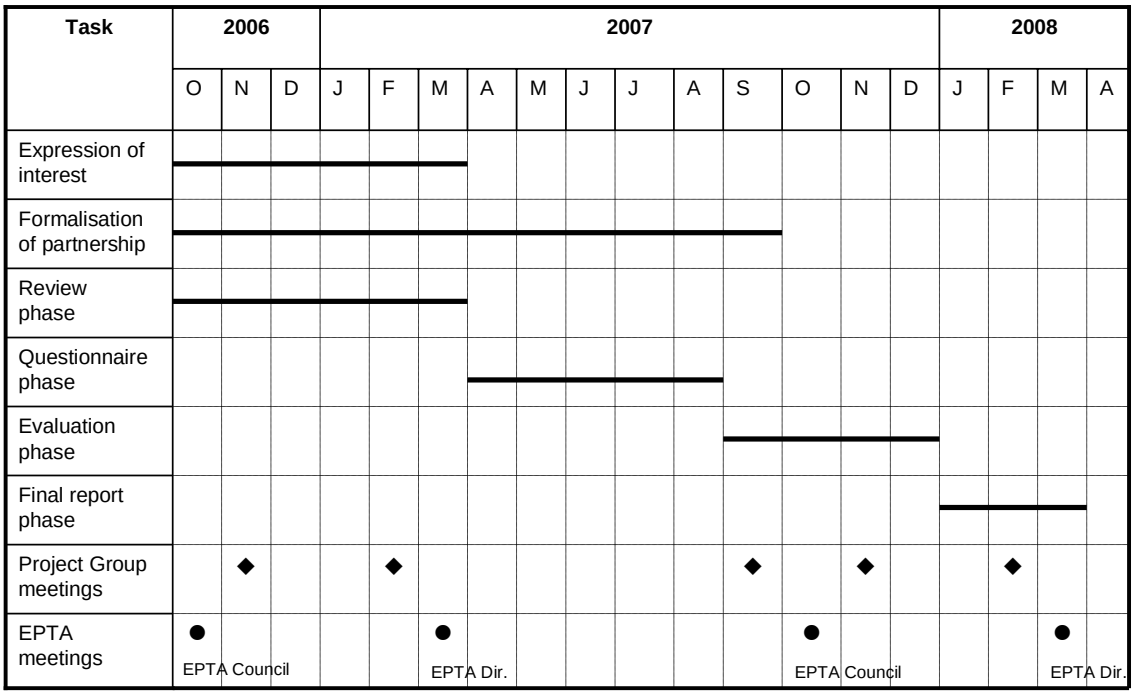
Dissemination phase
(April 2008 -)

Depending on the decisions in the Project Manager Group, a dissemination phase will be established, in which both national and EU dissemination activities will take place. A communication plan behind the dissemination will be prepared and decided in connection to the EPTA Director Meeting in spring 2008. A discussion on the dissemination activities has already started in the Project Group (e.g. dissemination symposium with EPTA and EU Commission representatives).

Project Manager Group meetings

The following Project Manager Group meetings are foreseen:
- 2. meeting: start up and distribution of work – November 2006
- 3. meeting: discussion and evaluation of reviews - February 2007
- 4. meeting: discussion and evaluation of questionnaire – September 2007
- 5. meeting: discussion of draft findings and conclusions – November 2007
- 6. meeting: discussion of draft final report – January/February 2007

Work-Plan joint EPTA project "Genetically modified plants and foods"



Project's organisation

An internal structure for the project's work organisation is foreseen, which on one side is as work-focused and effective as possible, and on the other side respects certain formal procedures for a joint project inside the frame of the EPTA network. The project's **organisation** consists of the elements:

– the Project Manager Group,
– the Coordination Group and
– optionally a Parliamentary Advisory Group.

The core of the project organisation is the **Project Manager Group**, which will

– arrange and coordinate all project activities,
– make all project deliverables,
– coordinate with and give input from national projects,

– disseminate the results both internationally and nationally.

In the moment, the Project Manager Group consists of Peter Border (POST – United Kingdom), Soren Gram (DBT – Denmark), Armin Grunwald (TAB – Germany), Rolf Meyer (ITAS/TAB – Germany) and Helge Torgersen (ITA – Austria). TAB is willing to take over the organisational coordination of the Project Group.

All EPTA members and associates are invited to take part in the project and join the Project Manager Group. It is foreseen that EPTA members and associate can join the project until the end of the questionnaire phase in September 2007 (see part "new partnership"). The Flemish Institute for Science and Technology Assessment (viWTA) and TA Swiss have expressed interest and announced to decide later on their participation, depending on their work-programme and their available resources.

As mentioned before, the joint project on genetically modified plants and foods intends to involve knowledge and contributions from as many EPTA members and associates as possible. So for example, the Committee for the Future of the Finish Parliament and the Norwegian Board of Technology are willing to contribute to the reviews and questionnaire, and comment on project papers and deliverables.

The **Coordination Group** consists of the directors (or deputy directors or international officers or their designed representatives) of the partners. The role of the Coordination Group is to:

– carry overall responsibility for the execution of the joint EPTA project,
– be a forum for the institutional relations in the project,
– ensure proper dialogue between the partners and maintain relations to the EPTA network,
– accept new partners,
– decide on changes in the objectives of the joint project,
– take responsibility for the national ratification of the results, if required,
– decide on any project related matters, which cannot be handled by the Project Manager Group.

The Coordination Group will meet in the context of the EPTA Council and Directors' meetings. In urgent cases, a telephone conferencing will be used if possible.

Further, the EPTA Directors will be informed on progress and results of the project by representatives of the Project Group through presentations.

Additionally, it is suggested to create a **Parliamentary Advisory Group**, consisting of parliamentarians from participating and interested EPTA members and associates. The tasks of the Parliamentary Advisory Group should be:

- to maintain the relations to the parliamentary side of the EPTA network and to national parliaments,
- to give input from ongoing parliamentary debates,
- to accompany the project execution and to give advice at strategic project points,
- to support the dissemination of the project results.

Annex

Projects of EPTA members on genetically modified plants and food

Most of the EPTA members have executed projects on genetically modified plants and foods. A first survey is given in the following overview.

Institution	***Project title***	***Year*** *(of final report)*
Committee for the Future, Parliament of Finland (Finland)	Gene technology (report)	1998
Danish Board of Technology (Danemark)	New GM crops – new debate (citizens jury)	2005
Danish Board of Technology (Danemark)	Coexistence between GM crops and non-GM crops (hearing)	2004
Danish Board of Technology (Danemark)	Genetically modified crops in developing countries (report)	2003
Danish Board of Technology (Danemark)	Moratorium on Genetic Technology (conference)	2000
Danish Board of Technology (Danemark)	Genetically modified foods (consensus conference)	1999
ITA (Austria)	Precautionary expertise for GM crops (report)	2004
ITA (Austria)	The scientific basis of applying the Precautionary Principle in biotechnology-related potential trade conflicts (report)	2001

Institution	***Project title***	***Year*** *(of final report)*
ITA (Austria)	Biotechnology and other Aspects of Food Safety (part of OECD report)	2000
ITA (Austria)	Safety Regulation of Transgenic Crops (report)	1998
Norwegian Board of Technology (Norway)	Genetically modified food products (consensus conference)	2000
OPECST (France)	Biotechnologies in France and Europe (report)	2005
OPECST (France)	From understanding genes to making use of them (report and citizens conference)	1998
POST (United Kingdom)	GM crops in the UK (note)	2004
POST (United Kingdom)	Labelling GM foods (note)	2002
POST (United Kingdom)	GM crops and foods update (note)	1999
POST (United Kingdom)	GM threshold for non-GM foods (note)	1999
POST (United Kingdom)	Genetically modified food (report)	1998
Rathenau instituut (The Netherlands)	Food genomics (report, hearing)	2003
Rathenau instituut (The Netherlands)	Genetically modified organisms (report)	1999
STOA (European Parliament)	Genetically modified food (report)	1999
TAB (Germany)	Green genetic engineering – transgenic plants of the 2nd and 3rd generation (report)	2005
TAB (Germany)	Risk assessment of transgenic plants (report)	2000

Institution	***Project title***	***Year*** *(of final report)*
TAB (Germany)	Genetic engineering, breeding and biodiversity (report)	1998
TAB (Germany)	Impacts of modern biotechnologies on developing countries (report)	1995
TA-SWISS (Switzerland)	Genetic technology and nutrition (publiforum)	1999
viWTA (Flanders, Belgium)	New stimuli for the debate on genetically modified food (symposium and public forum)	2003 / Ongoing?