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November 2000

Risk assessment and post-marketing monitoring of transgenic plants

Summary

TAB Working report no. 68

TAB
Office of Technology Assessment
at the German Bundestag

SUMMARY

Even ten years after the passage of the German Genetic Engineering Act (GenTG) and the Deliberate Release Directive 90/220/EEC, the debate in Germany and Europe generally over the »safety« of genetically modified plants has not abated, let alone reached any conclusion. The situation is very different in the Americas. In the USA, Canada and Argentina, the second half of the 90s saw increasingly widespread cultivation of transgenic maize and rape seed, transgenic soybeans, cotton and potatoes, with virtually no sign of public debate over the benefits and risks of transgenic plants. At the same time a hostile attitude to »the Green genetic engineering revolution« emerged in Europe (and specifically in the UK and France), which had previously been apparent mainly in the German-speaking nations.

At the European level, discussions on an amended Deliberate Release Directive 90/220/EEC had been in progress since 1997. Developments in the EU member states culminated at the political level in the summer of 1999 in a de facto moratorium on approval of transgenic plants for marketing by the Council of Environmental Ministers, combined with the demand that the reforms in progress be completed before any new approvals are issued. Besides various modifications – which are still controversial and unresolved as of November 2000 – the amended Directive is intended in any case to include the requirement of both case-by-case and general longer-term monitoring of the effects of transgenic plants (currently generally described as »post-marketing monitoring«).

In Germany, marketing approval for the maize variety Bt176/ »Windsor« (about to receive variety approval from the »Bundessortenamt« – German Federal Plant Variety Agency) was suspended in February 2000 under Article 16 of the Release Directive, which constitutes a safeguard clause. This can be applied if new findings on potential hazards cast doubt on the original basis for approval. This event has sparked off forceful political and scientific controversy in Germany, which has also involved the German Bundestag and its committees on a number of occasions.

Finally, in June 2000 the German Chancellor announced an initiative seeking to agree a three-year transitional phase with the companies involved during which commercial cultivation of transgenic plants would be possible only on a limited scale and in combination with increased research into safety aspects, and particularly an intensive monitoring programme. The Federal Ministry of Education, Science, Research and Technology had already established a new promo-

tional key area – »Safety research and monitoring« – in March 2000, intended to close specific major gaps in the knowledge of biosafety questions over the next two years.

SUBJECT AND OBJECTIVES OF THE PRESENT REPORT

At the suggestion of the Committee on Food, Agriculture and Forestry and as resolved by the Committee on Education, Science, Technology and Technology Assessment, TAB was commissioned to produce a status report on risk assessment and post-marketing monitoring of transgenic agricultural crop plants which specifically covers

- the status in safety research (inc. post-marketing monitoring) and the debate on risks,
- the state of regulation and treatment of licensing procedures in the EU for the release, marketing and variety licensing of agricultural crop plants,
- the state of implementation of the Novel Food Directive (licensing and labelling)

and the implicit possibilities for action in the areas of research, statutory regulation and design of the licensing procedures. In accordance with the commission, it is not the purpose of this report to provide a novel answer to the outstanding questions on the safety of handling transgenic plants or develop separate proposals for post-marketing monitoring. Instead, the aim is to supply a focused overview of the status of the scientific and political debate. In this process, particular attention is paid to aspects of the subjects and associated questions which are likely to become increasingly important in future.

STATUS OF THE SCIENTIFIC DEBATE ON RISKS

There has been general consensus in science and politics for some years on the basic strategy for safety research and risk assessment for genetically modified plants. In principle, based on scientific findings, plausible assumptions and scenarios, each individual trait is subjected to (case-by-case) risk assessment, and experience with the genetically modified organism is built up in a step-by-step process. In contrast to this consensus on the logical phases in risk determination, there is still scientific and political controversy about the interpretation of the results of safety research and the resulting measures in dealing with transgenic plants.

General environmental impacts, which have been debated for many years and are covered under the licensing procedure, are gene transfer to wild relatives and hybridization (vertical gene transfer) and horizontal gene transfer. These processes can occur irrespective of the nature of transgenic characteristics (although possibly influenced by these) and could potentially mean uncontrolled and irreversible spreading of the plants (keyword: non-reversibility) or at least the transgenic trait. A common feature of all three events is that research in release experiments is subject to very tight limits. In addition, these are very basic but more or less nonspecific biological phenomena which are dependent on a large number of interactive factors, and despite research (over decades, in some cases) many aspects are only incompletely understood.

A second level of consideration relates to the specific effects of the transgenes, e.g. herbicide, insect or virus resistance or modified components on the relevant (agricultural) ecosystem. The fact that they proceed by definition from the individual transgenic traits means that the possible impact chains are more accessible to study on a limited scale, in the laboratory or greenhouse or in release experiments, than the general environmental impacts. Besides development of resistance by pests, possible impacts which could become increasingly important in future are in particular so-called abiotic resistance, or tolerance which would offer a clear increase in fitness outside agricultural areas.

Controversies regarding both general and specific impacts relate primarily to three different levels.

> first, the fundamental likeliness of occurrence (e.g. of outcrossing or development of resistance by insect pests),
> second, the degree of possible damage (e.g. reducing biological diversity or adversely affecting organic farming), and
> third, the possible or necessary measures to avert risk (e.g. size of the protective zones around fields with transgenic plants or design of resistance management).

Science – and hence biological safety research – is concerned strictly speaking with identifying and calculating the likelihood of occurrence of specific events, and whether the event being studied or anticipated represents damage is a question that takes us into the realm of value judgements. A failure to distinguish between these two levels often leads to confusion and particularly acrimonious and virtually irreconcilable disputes, for example on risk assessment in approval procedures for transgenic plants.

Generally, the state of data appears deficient in many respects, as while there have now been over 1,300 release experiments in Europe alone, fewer than 1% of release experiments worldwide have been linked with accompanying ecological research (although in Germany the figure is 15%). Another reason why there is virtually no »real knowledge about risk« is the safety requirements needed for the accompanying ecological research. Critical voices point out that the lack of evidence of adverse ecological impacts suggests more that the wrong questions are being asked (with a resulting lack of corresponding studies) than the absence of any risk. Conversely, it is true that conventionally bred plants (i.e. not using genetic engineering) have never been subjected to biological safety testing, so that the impacts of transgenic varieties are always more thoroughly researched than those of conventional varieties. Many scientists also stress that the new characteristics of transgenic plants are in principle much more clearly defined – and hence more easily documented and researched – than the results of conventional breeding.

It is undoubtedly necessary to continue and intensify safety research in order to reduce the major gaps in our knowledge of the possible impacts of cultivating transgenic plants. This applies to the plants already developed to the point of practical application, and a fortiori to the new varieties with altered composition of contents on which the principle of »substantial equivalence« can no longer be applied. A decision on which studies have priority always requires consideration by scientists and the promotional institutions in the light of the current state of knowledge. One problem which currently seems to be getting little attention is the problem of new marker genes or systems, which are intended to replace the antibiotic resistance genes currently used and which have to be thoroughly tested before use in transgenic food plants.

However, a whole series of questions will in any event be impossible to answer in research projects with a limited life. First, the results of scientific research always generate not only answers but also new questions, and second because long-term indirect or effects can generally only be observed in the course of longer-term cultivation of transgenic plants on a significant scale. This realisation has led over the past few years to virtual unanimity among all involved on the development and implementation of long-term monitoring of transgenic plants under cultivation.

With respect to use as food, transgenic plants are studied particularly for possible health risks, for toxicity and allergenicity. Both properties have previously been described following the principle of »substantial equivalence«, i.e. on the basis of comparison with non-transgenic plants of the same variety. Apart

from fundamental criticism of the concept (which has been voiced repeatedly), the development of transgenic plants with changed (primary) composition or moving towards »health-promoting« transgenic foods has been the subject of intensive scientific debate in the past year. For example, in the framework of the last G8 summit the OECD – which helped develop and promote the concept of »substantial equivalence« – launched a broad-based initiative to reconsider the concept and the general treatment of risk assessment for transgenic plants.

RISK ASSESSMENT IN THE APPROVAL PROCEDURES

A question of central political importance on the issue of transgenic plants is the regulation of marketing or approval. The (European) approval procedure provides for risk analysis in which the data provided by the applicant on relevant safety aspects of the plant variety in question is reviewed and evaluated on the basis of current scientific knowledge and opinion. Approval can only be issued if no damaging impacts on humans or the environment are to be expected. As the state of scientific knowledge and opinion is still very incomplete and will probably remain so for some time, decisions on evaluation must be taken in many respects without the benefit of reliable or unambiguous scientific information. There is also considerable latitude as a result of differing normative requirements, assumptions and objectives.

The present report looks in detail at how far the status of the scientific risk debate, and specifically the ecological aspects, is taken into account in the opinions in the framework of the approval procedures for marketing under Directive 90/220/EEC of both the EU scientific committees and national agencies (in Germany, Austria, the UK and – in part – Sweden), and how differences identified in the opinions can be explained. It is clear that

> scientific contributions and arguments have been very much selectively used and variously interpreted,
> diverging conclusions have been drawn from gaps and areas of uncertainty in our knowledge, and
> above all, the possible consequences have been very differently evaluated in terms of the scale of damage and resulting implications.

In the core or target questions for risk assessment (and hence the entire approval procedure) on which possible consequences of marketing transgenic plants qualify as damaging impacts and which impacts are acceptable or unacceptable,

the differing normative standards of the various countries make themselves particularly felt:

- Germany and the UK assess the acceptability of an ecological risk in the context of conventional agricultural practice. The assessment is whether a transgenic plant poses an additional or greater risk compared with conventional practice; if not, the possible impact is regarded as acceptable. By this standard, most of the disputed consequences appear entirely acceptable. German court rulings define the term »damaging impact on the environment in its interactions« relatively narrowly. This covers only direct impacts, and not indirect or long-term impacts.
- By contrast, Sweden and Austria take as the standard »sustainable agriculture«, i.e. in this case agriculture with a minimum possible use of »chemicals« and an ecological orientation, where Austria also explicitly includes socio-economic considerations which within the meaning of Directive 90/220/EEC have so far not been considered or are not required in risk assessment. This results in most cases in rejection of approval applications, even if the likelihood of occurrence of possible damage is regarded as minor but impossible to determine more accurately.

As the choice of these standards constitutes a normative political act, science can only provide limited assistance. The political institutions should accept more fully and subsequently act on the recognition that science – and specifically scientific policy advice – is able less to close gaps in our knowledge and so derive recommendations for action than to identify these gaps in our knowledge, make the underlying scientific controversies more transparent, and so characterise the political and social scope for action and design.

The actual political challenge lies in a fundamental and »sustainable« improvement in the approval procedures. Irrespective of the specific amendment to the Deliberate Release Directive 90/220/EEC, all those involved in the debate about the risks of transgenic plants should make a particular effort to distinguish scientific statements (about the likelihood of events) from subjective and basically political assessments in terms of content and argument, or at least to label these accordingly.

STATUTORY PROVISIONS AND AMENDMENTS

The Deliberate Release Directive 90/220/EEC has been subject to criticism from all quarters since its adoption. Key points in the debate were and are:

> the concept of risk assessment and definition of damage,
> the relationship between horizontal and sectoral regulation,
> centralised approval procedure for the EU,
> time limit on approval for marketing,
> introduction of post-marketing monitoring,
> (GE-specific) provisions on liability,
> labelling for all products, and
> public involvement in the approval procedure.

This Directive has been under review since 1997, and the process of amendment is now very advanced. Only a few controversial points are still involved in mediation between the European Parliament, Commission and Council. This means that there is very limited scope now for influencing the results of the amendment process.

After the amended Directive is adopted, this will have to be enacted in German GE law, i.e. an amendment to the German Genetic Engineering Act will be required.

In addition to implementing the amended EU Directive, a number of unresolved questions have been identified which imply the following possibilities for action:

> Identifying and evaluating indirect and long-term impacts will in future play an important role in release and marketing approvals. A number of fundamental research projects are required here to provide at least partial answers and avoid leaving questions entirely to post-marketing monitoring. Within the framework of the »Safety research and monitoring« promotional key area in the German Federal Government's program »Biotechnology 2000«, a new key topic »Fundamentals, methodology and models for assessing indirect and long-term impacts of transgenic plants« should accordingly be set up.
> A range of agronomic properties of transgenic agricultural plants (specifically herbicidal tolerance and insect resistance) will require resistance management. Marketing approval under the amended Directive will probably only be possible with corresponding restrictions. For appropriate resistance management the relevant optimal management strategy and resistance monitoring will have to be determined. Just as important are organisational questions and approaches for monitoring. The competent specialist agencies should be given the capability to carry out the necessary research work and concept development.
> In the next few years a new generation of transgenic plants is expected characterised specifically by modified composition, and part of which will qualify as functional foods. The impacts on human health, and specifically also the

indirect and longer-term nutritional impacts, will accordingly pose entirely new questions. Here, the foundations for risk analysis and assessment should be established as early as possible, and corresponding research activities initiated.

> Even after the amendment, there will still be no definition of damaging impacts, so that there will still be considerable scope for different assessments. Not least, the question will be which agricultural paradigm the impacts of GE agricultural plants are measured against. It will not be possible to derive a normative framework for this paradigm simply from the debate about GE applications: instead, this will require a serious definition and specification of the term »sustainable agriculture« as a stated goal of European agricultural policy.

> In the EU (and hence in Germany), horizontal and vertical regulations coexist in the field of GE applications. In future there will also be a need to reconcile the amended Directive 90/220/EEC and the Novel Food Regulation EC/258/97. With regard to human health, these two regulatory instruments should as far as possible require the same testing procedures, criteria and standards. As far as possible, duplicate assessments should be avoided. In the process of optimised consultation, the German Federal government should assist the EU Commission and for this purpose submit its own proposals.

> The debate over establishing a central assessment or even approval procedure will be continued in the medium and long term. Corresponding discussion of or initial identification of the German position seems to be required.

POST-MARKETING MONITORING

In the last few years, the view has increasingly gained ground that comprehensive marketing of transgenic agricultural plants and the associated large-scale cultivation should be accompanied by strategic study and longer-term monitoring (in addition to case-by-case risk assessment and stepwise release into the environment) of long-term and possibly indirect and unanticipated impacts on humans and the environment which cannot be ruled out. The amended Deliberate Release Directive 90/220/EEC will in all likelihood require not only general surveillance but also case-specific monitoring. In Germany, the terms in-cultivation monitoring and general environmental monitoring of transgenic plants have established themselves, although not as synonyms.

In post-marketing monitoring, three dimensions or distinctions have special relevance:

> monitoring based on cause-and-effect hypotheses (even if partly unexplained or uncertain) versus unexpected or rare events,

> surveys of the agricultural ecosystem (and adjoining marginal structures) versus surveys of the environment generally,
> monitoring for limited periods versus long-term or unlimited monitoring.

In Germany proposals and contributions on objectives and concepts, priorities and areas for survey and possible implementation stages have been submitted by various top Federal agencies, working groups, scientific institutions and interest groups. The state of work and debate is characterised by the situation that all relevant areas have been identified, the necessary status-quo analyses completed and the first steps taking in operationalisation for the majority of relevant aspects in the relevant working parties, although full agreement and joint proposals have not yet been achieved.

The state of concept development, the corresponding research work and the unsettled questions give rise to short-term and long-term need or opportunities for action. The following political decisions should be made relatively soon:

> Definition of terms and operationalisation of objectives: There is currently no consensus among the working groups and institutions involved about the definition and objectives of post-marketing monitoring. The various terms used with respect to monitoring and its sub-areas need to be clearly and uniformly defined. Based on the preliminary work, definitions and the scope and objectives of monitoring should also be politically established.
> Decisions on responsibilities and funding: The responsibilities for data collection, analysis, consolidation and documentation and data evaluation need to be clarified. Specifically, it is necessary to determine where the central coordination unit should be located and what authority it should have. With respect to funding it must be determined which costs (or what part thereof) should be born by applicants and which by the Federal and Länder authorities.
> Public information and involvement: Public interest in the concept for and design and results of post-marketing monitoring can be expected to grow. Based on initial approaches, public involvement should be developed in information and debate on concepts for monitoring, in analysing and providing results from monitoring and in information and debate on the consequences of the results of monitoring.

Longer-term problem and design areas which should be tackled:

> Limiting post-marketing monitoring to pre-marketing safety research and risk assessment: A review and assessment of any adverse effects of GMOs takes

place before release and marketing as part of the approval procedure. Monitoring should supplement the precautionary principle in the approval procedure by documenting unexpected and indirect impacts. An important controversy will develop regarding the question of which gaps in our knowledge and uncertainties in assessment in the context of pre-marketing safety research and risk assessment need to be resolved, and which questions can be postponed in future to post-marketing monitoring. The clearest possible distinction should be developed between these two areas.

> Criteria for the incorporation of results from monitoring in the approval procedure: If adverse GE-specific effects are observed during monitoring, this should lead to action in the cultivation process. This action may also lead to a modification or withdrawal of marketing approval. Assessment of monitoring data can be expected to become a highly contentious future area of conflict. To be able to evaluate phenomena for their relevance to safety under the German Genetic Engineering Act, corresponding criteria must be developed. The development of a concept for evaluation supported by various groups is a highly important task, but also one which is extremely demanding and difficult to manage.

Work must be continued within the existing working groups on developing technical, substantial and organisational aspects. Specifically, proposals must be formulated on concrete survey areas, monitoring parameters, test designs, sample grids and data collection, recording methods, controls and reference locations, data documentation etc. In addition, cooperation should be sought with other European states in order to avoid duplicating work, to benefit from experience in other countries, and to arrive at as closely coordinated an approach as possible in the EU states.

EXPERIENCE WITH THE NOVEL FOOD REGULATION

The Novel Food Regulation (258/97/EC) went into effect in the EU member states on 15 May 1997. Since this date, various foods defined as »novel« have been subject to special regulations in addition to the general legislation on food. In particular, a mandatory safety assessment before marketing and specific labelling were introduced. To date, genetically engineered foods (one of several categories of novel foods) have remained at the focus of public interest and vigorous social controversy.

So far, ten products made of various genetically modified maize and rape seed varieties have received notification, i.e. after determining their »substantial

equivalence«, no separate safety assessment was made for these. Conversely, no single food from a transgenic plant has been approved to date in an approval proceeding under the Novel Food Regulation. Only a few applications were filed, and there are only two cases where opinions have been issued by the Scientific Committee on Food or national agencies.

So far, no uniform practice in procedure and decision-making has emerged in notification and approval proceedings under the Novel Food Regulation. However, experience to date indicates that the Novel Food Regulation and Commission recommendations on the documentation required for a safety assessment form in principle a suitable statutory and procedural framework for reviewing novel foods for safety to health. By contrast, there are deficiencies in the scope, coverage and methodology of the safety assessment and the interpretation of the data available for this, which creates scope for interpretation. This will become particularly relevant if the requirements for the safety assessment are raised for future novel foods, e.g. foods consumed raw, or novel foods with modified ingredients.

Although raw materials and intermediate products based on maize or soybeans partly from GMOs are also imported into the EU and processed here, there are only isolated instances of labelled products. The labelling requirements which have been in force since May 1997 have so far not been able to help consumers recognise the actual use of GE raw materials. There are various reasons for this, which are discussed in the report.

Implementation to date of the Novel Food Regulation indicates a range of approaches for addressing problems and deficiencies in implementation:

> For the area of genetically engineered food as a subgroup of »novel« foods under the Novel Food Regulation:
  - one problem with the Novel Food Regulation is that very different catego ries of food are covered jointly. The recommendations of the EU Commission on safety assessment of novel foods should be made more precise with regard to specific guidelines for foods from GMOs.
  - The exemption of additives and aromas from the coverage of the Novel Food Regulation is criticised in some quarters for the fact that this excludes manufacture-specific aspects of these (e.g. GE manufacture) from the safety assessment. If this is regarded as relevant, additives and aromas from GMOs (and specifically from GE plants) should be regulated on the same principles and at the same level of safety as comparable ingredients or foods.

> With respect to notification of foods and ingredients from GE plants:
  - So far there have been differences in interpretation of the criteria used to infer »substanti al equivalence« as a basis for notification. To change this situation, clear, uniform and binding criteria should be established under which notification without specific safety assessment is sufficient.
  - If transgenic plants are not approved in the EU and the safety assessment is not yet completed, notification should only be made exceptionally for novel foods from these GE plants.
  - The current design of the notification procedure violates requirements for openness and transparency, recognised as important principles at least since the EC Commission White Paper on food safety. With the exception of the UK, neither the applications nor the initial review by a national agency are open to public inspection. Applications and opinions should be publicly accessible.

> With respect to approval procedure for foods and ingredients from GE plants:
  - In the comparison between novel and conventional food, the emphasis is on specific components which are informative and characteristic of the relevant plant. Unintended side-effects relevant to health in the GE plants only attract attention if they fall within the range of studied components and lead to noteworthy changes in concentrations there. To reduce uncertainty here, recommendations should be formulated on the range of components used for comparison (nutrients, toxins, antinutrients) which are appropriate for the plant species in question. In addition, international databases should be set up of variety-specific and species-specific information on the components required to determine the equivalency status of a GMO product and its natural variations due to location, climaticzone, cultivation techniques and species. Another approach would be to develop new methods which document patterns of substances which might allow conclusions regarding unexpected secondary effects, rather than specific individual substances.
  - The European Food Agency proposed by the EU Commission should help improve risk analysis substantially, for which purpose it will need corresponding material funding. Its job should be to collect systematically all the data and information relevant to safety assessment, to coordinate the further development of scientific methods and advice from expert panels (scientific committees) with particular emphasis on maintaining openness and transparency.

> With regard to the deficiencies in labelling presented above:
  - Enforcing the existing labelling duty: Compliance with existing rules must be ensured. Appropriate sanctions should be considered for violations. Legal certainty should be enhanced by defining relevant current, standardised

test procedures.

- Transferring the level of proof to ingredients: If evidence of a GMO requiring labelling is shifted from the final product to the level of individual ingredients, this would expand the number of actually labelled foods. On the one hand, this would substantially increase the effort in labelling and monitoring it, on the other hand it could improve the information contained in the labelling.
- Partial abandonment of evidentially-based labelling for specific ingredients characteristic of a product: The use of genetic engineering in producing a food only results in labelling if this food (or the ingredients) can be shown to contain GMO-specific material. This situation could only be changed if abandonment were planned of evidentially-based labelling. Actual use of GE plants in the production of food could only be better reflected if labelling (at least for characteristic ingredients) were no longer based on evidence of GMOs. The »evidential gap« would then have to be closed by a system of documentation tracking the products.
- In view of the limited coverage of mandatory labelling regulations, supplementary information concepts close to the product should be developed and implemented by the food industry generally. Information can help counter the widespread uncertainty among consumers. To put such projects on the broadest possible social basis it is advisable to involve a range of actors, such as consumer associations, universities and other scientific institutions in their conception and implementation. State institutions could act as initiators and moderators.

OUTLOOK

The future of Green genetic engineering in Europe seems virtually impossible to assess in the autumn of 2000. On the one hand there is the expectation of applicants that the pending approval procedures for marketing transgenic agricultural plants will be resumed soon and that conflicts will be substantially reduced as a result of the adoption of a revised Deliberate Release Directive. On the other hand there is the warning or hope that the current »blockade« in the EU on marketing transgenic plants will continue for years.

A new generation of transgenic plants with modified composition and potentially health-promoting properties (particularly the so-called functional foods) is expected to reduce or even eliminate consumer reservations about GE food. These second-generation transgenic plants will, however, pose entirely new questions

in safety assessment, and their health benefits will probably be strongly disputed. There is accordingly no foreseeable end to controversy here.

The continuation and expansion of safety research and the introduction of monitoring will increase our knowledge of transgenic plants and reduce existing gaps in it. At the same time, however, it is likely that new and unresolved questions will arise on the possible impacts of cultivation of transgenic plants, and that results will be interpreted in different ways. Experience to date shows that »surprises« (i.e. unforeseen ecological or economic impacts) must always be expected. A realistic appraisal is very important for the general perception. Safety questions should not be described as answered or answerable in the near future unless the state of the data and our knowledge is correspondingly secure.

The following conclusions can be drawn from this situation:

> No excessive expectations should be raised for the amended Deliberate Release Directive 90/220/EEC and the introduction of post-marketing monitoring. Their potential for resolving problems will inevitably remain limited until such time as fundamental agreement is reached on definitions of damage and desirable agricultural practice.
> Both the amended Deliberate Release Directive and the Novel Food Regulation require operationalisation and specific guidelines for implementing the safety assessment and approval procedures. This is the only way to reduce discussions about the scope, coverage, methodology and interpretation of the safety assessments. This should build on the current state of the scientific risk debate. To this extent it will be an ongoing task, rather than a one-time exercise.
> New instruments – such as post-marketing monitoring or revised labelling regulations – should only be introduced when their integration into existing statutory provisions and their implications have been carefully considered and widely discussed. To avoid new areas of conflict and controversy, e.g. in post-marketing monitoring a distinction should be made as early as possible between this and pre-marketing safety research and risk assessment and the criteria for incorporating information from monitoring in the approval procedure should be clarified.
> Finally, new areas of conflict should be identified at the earliest possible state and investigated in advance. Attention is drawn particularly to the announced second-generation transgenic plants, which are e.g. supposed to have a health-promoting effect as »functional food«. These will probably result in a shift in the debate from possible ecological impacts towards potential health impacts and also pose entirely new and possibly even greater problems in safety assessment than the current transgenic plants.

The Office of Technology Assessment at the German Bundestag is an independent scientific institution created with the objective of advising the German Bundestag and its committees on matters relating to research and technology. Since 1990 TAB has been operated by the Institute for Technology Assessment and Systems Analysis (ITAS) of the Karlsruhe Institute for Technology (KIT), based on a contract with the German Bundestag

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