Genetically modified plants and foods

Challenges and future issues in Europe

Final report
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EPTA
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The conclusions in this report are the responsibility of the following eight members of the European Parliamentary Technology Assessment network (EPTA):

The Danish Board of Technology, Denmark

Contact: Lars Klüver
www.tekno.dk

Institute Society and Technology, Flanders

Contact: Robby Berloznik
www.samenlevingentechnologie.be

Institute of Technology Assessment, Austria

Contact: Michael Nentwich
www.oeaw.ac.at/ita

The Norwegian Board of Technology, Norway

Contact: Tore Tennøe
www.teknologiradet.no

Office of Technology Assessment at the German Parliament, Germany

Contact: Armin Grunwald
www.tab.fzk.de

Parliamentary Office of Science and Technology, UK

Contact: David Cope
www.parliament.uk/post/home.htm

Scientific Technology Options Assessment,
European Parliament

Contact: Theodoros Karapiperis
www.europarl.europa.eu/stoa/default_en.htm

TA-SWISS – Center for Technology Assessment,
Switzerland

Contact: Sergio Bellucci
www.ta-swiss.ch

Zentrum für Technologiefolgen-Abschätzung
Centre d'évaluation des choix technologiques
Centro per la valutazione delle scelte tecnologiche
Centre for Technology Assessment

Authors of the report:

Danielle Bütschi

Søren Gram

Jon Magnar Haugen

Rolf Meyer

Arnold Sauter

Stef Steyaert

Helge Torgersen

Additional contributors to the project:

Peter Border

Jarka Chloupkova

Jofey Craig

Els van den Cruyce

Jamie Rubbi-Clarke

Casper Linnestad

Willy Weyns

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FOREWORD

Biotechnology in general and genetic engineering in particular have been among the most controversially discussed modern technologies for decades. They are regarded as an important key to increasing economic competition on the one hand, but provoke concerns about health, safety and environmental issues on the other. The public perceptions of biomedical applications and of applications in agriculture and food production have clearly diverged. While there has been growing acceptance of medical applications, the public's rejection of genetically modified (GM) foods persists in many countries. Particularly in Europe, agricultural GM technology is still being contested. For over two decades, the proponents and opponents of GM have not succeeded in finding a common ground despite major efforts invested in conducting numerous projects, in organising dialogues and in developing and implementing elaborated regulatory tools.

Problems arose at different levels: in European Union (EU) Member States as well as within and among EU institutions. GM crops and food policy ran into troubles. For example, the coexistence of GM crops with conventional and organic crops, as well as the labelling and tracing of GM food products are topics of ongoing discussion. Repeatedly, there have been regulatory impasses over the approval of particular crop varieties. At a global level, there have been trade conflicts over GM products in recent years. Today, the future of GM crops in Europe is as unclear as ever. In contrast to the development and use of GM plants and foods in the United States and other countries, the cultivation of GM crops in Europe is very limited.

However, in spite of the apparent lack of change regarding this situation, it is possible to identify some movement and various changes which will lead to new challenges to European policies as well as to intensified public debate. Apart from past and present regulatory conflicts, important technological developments and far-reaching shifts in framework conditions have recently taken place which will considerably influence future debates:

- Novel varieties of crops with new traits are about to enter the regulatory approval procedures. A new generation of GM crops, capable of producing medicine and industrial chemicals, for example, is emerging.
- The demand for agricultural products has changed to include more energy crops. Market conditions for agricultural products have turned out to be highly volatile and are increasingly linked to the energy markets.
- Environmental challenges and the requirements of sustainable development have altered the conditions for agriculture in many places.

The question today is whether and how all this will translate into new challenges to the governance of GM technology in Europe. Can we expect old impasses to vanish or new ones to arise? Can we identify indications for change, and if so, in which direction? What could be tomorrow's issues in the GM debate in Europe?

What could be done in order to prepare policy makers and the European public for these newly emerging questions? These questions formed the main motivation to initiate and conduct the joint EPTA (European Parliamentary Technology Assessment) project "Genetically Modified Plants and Foods".

GM crops and foods have been a major topic for the EPTA (www.eptanetwork.org) members and associates. Building on their wealth of experience in the field of Technology Assessment (TA) on GM issues, the following eight members of EPTA have come together to identify the developments and challenges ahead:

- Centre for Technology Assessment (TA-SWISS – Switzerland)
- Danish Board of Technology (DBT – Denmark)
- Institute Society and Technology (I.S.T. – Flanders) (the former Flemish Institute for Science and Technology Assessment – viWTA)
- Institute for Technology Assessment (ITA – Austria)
- Norwegian Board of Technology (NBT – Norway), together with the Norwegian Biotechnology Advisory Board
- Office of Technology Assessment at the German Parliament (TAB – Germany) (project co-ordinator)
- Parliamentary Office of Science and Technology (POST – United Kingdom)
- Scientific Technology Options Assessment (STOA – European Parliament)

The final report of the project "Genetically Modified Plants and Foods" departs from the results of a considerable number of TA and TA-inspired projects in the past. Specific perspectives and positions from different countries, extracted from parliamentarian and other TA exercises, were brought together and evaluated with respect to a pan-European perspective. On the basis of this review, the joint EPTA project concentrated on *new* questions and possible *new* answers by identifying future challenges rather than by attempting to simply establish a mainstream view on contested issues of the past. Thus, the project applied a *forward approach* to the GM plants and foods field creating *added value* to existing work. The main conclusions of the joined effort are on

- The regulatory challenges for the European system in the upcoming years,
- Issues of a possible public debate in the future,
- Approaches for TA to handle the future issues.

As its main results, the final report includes a picture of the current state of affairs in the GM field, identifications of challenges ahead as well as some hints at possible paths to take in the future. These results are focused on *conclusions* rather than on policy recommendations. The conclusions address the European level and take into account new developments in the fields of technology and regulation. We hope that this report will be helpful in clarifying relevant issues of the next phase of the European GM debate, and that it will find its way to the European audience and beyond.

Armin Grunwald, Head of TAB

EXECUTIVE SUMMARY 1.

GM plants and their role in European agriculture as well as in the regulatory system and in society at large have long been controversial issues. In addition, recent developments with respect to new technologies, expanding international trade and the increasing demand for food and fuel have changed the general framework. The question is whether these developments challenge the established way in which GM plants and food have been dealt with in Europe so far.

Reviews of reports from EPTA member organisations on various aspects of GM plant application, their regulation and associated problems rendered a list of developments and consequently possible challenges to European policy on GM plants. Proceeding from this list of challenges, a questionnaire was developed, and 183 experts involved in the development, assessment and policy making on GM plants in Europe were invited to respond. These experts, 71 of whom completed the questionnaire, come from Austria, Belgium, Denmark, Finland, Germany, Norway, Switzerland and the United Kingdom. The questionnaire results and the experts' comments were analysed in the light of the results of the EPTA members' reports.

All in all, the regulatory system for GM plants and food in Europe does not seem to be fully prepared to meet all existing and foreseeable future challenges. Five key areas of challenges for the European system of GMO regulation in the years to come were identified, as were a number of possible approaches for future technology assessment activities.

CHALLENGE 1: NEW DRIVING FORCES FOR GM PLANT INTRODUCTION

Altogether, more factors were identified that encourage rather than discourage the introduction of GM crops, in particular the increasing use of and demand for bioenergy and biomass. This is a major difference to debates in the past. GM plants for non-food uses can be attractive to farmers. Further, such products may also find more demand from consumers, or at least be less prone to be avoided by sceptics as their GM origin is more obscure.

A decisive issue for the future cultivation of GM crops in Europe is the question of which aims agriculture is expected to fulfil. Sustainability is expected to be given strong weight, more particularly input and impact reduction while ensuring high product quality.

Area of action: The future of GM plants and food in Europe is not only determined by negotiations over regulatory details, it is also a question as to which kind of sustainable agriculture will be developed in Europe in the light of different, and sometimes conflicting, sustainability goals. A broad societal

dialogue on future sustainable European agriculture in a global context is, therefore, needed in order to determine the future role of GM plants and food.

CHALLENGE 2: NOVEL GM PLANTS, TECHNOLOGIES AND APPLICATIONS

Several classes of novel GM crops are currently under development. These include both crops for food uses, for instance crops with improved nutritional value, and crops for non-food uses such as energy, plastics or pharmaceuticals. A majority of the experts consulted think that a variety of such crops will be available and authorised for cultivation in Europe within the next 10 years. Such novel GM plants, especially those for the non-food sector, could pose regulatory challenges. In the case of plant-made pharmaceuticals, different approval procedures might have to be reconciled.

In general, discussions over criteria and procedures for risk assessment/management, may be ongoing in the future. At the same time, the potential risks from outgrowing or gene flow from non-food crops might pose additional problems for coexistence. On the other hand, crops developed to provide benefits in terms of health and food quality factors (e.g. nutritional enhancement) are also expected to appear, which may encourage public acceptance and consumer demand. This ambivalence is also mirrored in the discussion of whether benefits should be included in assessment procedures. While the proponents of GM technology may hope that such a measure could overcome public rejection, opponents claim that uncertainties are not tolerable in the absence of clear public benefit.

While understanding risks is expected to remain an important priority for European public research in the future, experts also expect resources for the development of new crops. Novel technologies such as smart breeding and cisgenics are regarded as important for plant breeding in general, but not as an alternative that could replace GM. However, they may blur the distinction between GM and non-GM plants.

Area of action: As is true for every field of technology, research policy is an important area of action. Crop development may again come to the forefront of public research. To make good use of any money that becomes available in this context, it would be necessary to assess not only the technical performance of newly developed plants but also the chances of these plants to meet societal goals. Concerning GM regulation, non-food GM plants might render an ongoing revision of the regulatory framework necessary. This pertains to parameters for risk assessment and management, confinement, coexistence and liability, as well as to the question of including benefit evaluation.

CHALLENGE 3: PUBLIC OPINION: STILL A DECISIVE FACTOR

Public attitudes are considered an important factor influencing both the use of GM technology and its development. Concerning future GM non-food products, a majority of experts expect public attitudes to become more positive over the next 10–15 years, while the level of acceptance of GM food products will remain unchanged. Factors considered highly important for consumer acceptance are free consumer choice and a high quality of information, as well as consumer benefits and the absence of risk issues related to health and the environment. Non-food GM plants may, however, also give rise to specific environmental and health concerns. In addition, expectations regarding the popularity of biofuels may be overoptimistic considering that they will be competing with food. It, therefore, remains unclear whether and how the overall public acceptance of GM plants will change.

Area of action: For the time being, there is little indication of an increase in overall acceptance. While it is possible that public perception will change as new consumer-oriented GM products become available, this cannot be taken for granted. Since public attitudes are subject to the influence of many factors, including ethical concerns, consumer protection policy is not the only one of relevance. A variety of other fields from agricultural policy to GM regulation are also relevant. An early discussion and open dialogue concerning the potential opportunities and possible problems can help to prevent disappointment on either side. Meeting the expectations regarding the high quality of information remains a major challenge.

CHALLENGE 4: COEXISTENCE AND LABELLING UNDER A GROWING USE OF GM PLANTS IN EUROPE AND THE WORLD

The concept of coexistence can be considered a political answer to the normative demand for freedom of choice. However, it also has implications for the (presumably descriptive) scientific risk assessment, as the behaviour, and thus risks, of a crop are more predictable if volunteering and intermixing can be ruled out. Due to small areas and the relatively short time of agricultural cropping, robust experience with the EU regulation on coexistence is still some way ahead. For the first generation of GM plants, many EPTA member reports and the majority of expert opinions conclude that coexistence can work in principle over the next 15 years. But experts are divided on many details, for instance whether coexistence will work for certain specific crops or for a broad range of them, for small- or large-scale cultivation, and whether all risks can be contained through such measures. While a majority expect first-generation GM plants to be grown within the next 10 years in Europe, fewer than half of the respondents believe this will be the case in their home countries. With regard to marketing, half of the respondents think that coexistence and labelling will generally work. The rest expect different scenarios such as failure of the labelling regime or the

blockade of GM food. Taken together, this suggests that the concept of coexistence remains a challenge, despite existing regulation and an extensive debate in the past.

Area of action: Doubts as to whether coexistence will work may pertain to particular items of regulation on the assessment and management of GM plants; however, they could also be taken as an indication that the expertise involved or elements of the authorisation process are at stake. In particular, independence from the vested interests of authorities involved could be better demonstrated by incorporating a broader spectrum of scientific opinions and/or representation of interests. Regarding authorisation, a recurrent problem seems to be the proper disentanglement of science and policy. The requirements for scientific evidence, on the one hand, and room for manoeuvre in politics, on the other, do not seem to be sufficiently defined. Likewise, a defined remit for political decision-making at the national level would be desirable, for example in order to restrict, or promote, the use of GM plants.

CHALLENGE 5: INTERNATIONAL TRADE RULES AND DOMESTIC DECISION-MAKING

The global increase in acreage covered by GM crops, pending international trade conflicts, the development of international regulations, and different approaches to risk assessment in various countries have challenged EU policy on GM plants. Regardless of the outcome of the recent World Trade Organization (WTO) conflict, most experts are convinced that the general principles of the EU regulatory system can be maintained. Concurrently, many respondents think that restrictive practices of individual EU Member States will have to change, and more harmonisation among them will be necessary.

Area of action: The recent WTO conflict highlights the need to reconcile different international agreements in order not to thwart the aims of these agreements. Therefore, not only areas specific for GM organisms (GMOs) might be considered to be at stake, but also the possible integration of environmental and social standards into WTO regulations. Many of the problems encountered at the WTO level are said to have derived from different interpretations by member states of the EU regulatory framework. Possible solutions would be to give more leeway to national sovereignty (subsidiarity) or to increase harmonisation among Member States. A considerable number of experts seem to consider further harmonisation and a reform of competent authorities/institutions an option for further improving the robustness of the EU regulatory system.

UPCOMING ISSUES FOR TECHNOLOGY ASSESSMENT

Agricultural biotechnology has been one of the most prominent technological fields TA has dealt with, and this will probably continue to be the case in the future. Four developments call for further interest and novel approaches.

- Technological developments extending the use of GM plants include energy plants, plants for nutritionally enhanced products, or plants for producing pharmaceutically active substances. In addition, crops with enhanced agricultural traits such as drought resistance could have enhanced survival capabilities and improved yield. Under environmental conditions of climatic change they might pose novel challenges for risk assessment.
- Changed general conditions for agriculture challenge established practices and aims, as shown by the example of fuel production from staple crops, and the increasing demand in food.
- Institutions and levels of decision-making are under continuous debate, for instance regarding the room left for national manoeuvre. A rising issue is the repercussion of international agreements, and of globalised trade in food and feed.
- Public attitudes towards GM plants and food may change in the future, which could have an impact on future political decisions. In the past, many factors not immediately related to GM technology as such but to broader social and cultural issues have been shown, or suspected, to influence public perception. In addition, with a larger number of Member States the diversity of the European landscape of public perceptions might even increase.

TA is required to help clarify available or requested technological solutions and their societal implications. TA should provide an improved understanding of social and cultural factors influencing these technological developments, their embedding into society, and the ways implications such as risks and benefits are perceived. Efforts should be taken to involve experts, stakeholders and citizens in dialogues about new developments. The development of novel forms of negotiation aimed at opening up new communication channels for actors who find it hard to speak to each other remains a task for TA.

Despite past extensive investigations, there is no doubt that the issue of GM plants will remain on the TA agenda. As different TA organisations dispose of different expertise and experience regarding approaches, transnational cooperation remains an attractive option.

BACKGROUND, CONTEXT AND AIMS OF THE PROJECT 2.

Biotechnology, and especially genetic engineering, has long been one of the most controversial modern technologies. On the one hand, it is seen as an important key to increasing economic competition and a source of innovation with a high potential for solving agricultural and environmental problems. On the other hand, it raises concerns about health and safety issues as well as ecological impacts and provokes certain ethical and moral objections.

The first GMO was produced in 1973. Over the past three and a half decades, great progress has been made in modern biotechnology. Today, it plays an important role in medicine and in agriculture. However, favourable public perception of biomedical applications has significantly and lastingly diverged from the perception of agrifood biotechnology. Extensive surveys such as the Eurobarometer have repeatedly shown that on average in the EU, public perception of GM plants is hardly positive at all, while that of GM food has long been, and still remains, decidedly negative, although there are significant differences between EU Member States.

This goes well with the observation that over the past 15 years, heated debates have taken place in many European countries among decision makers, experts and stakeholders about GM plants and foods.

While the proponents of GM plants argue in favour of the environmental benefits of GM crops (fewer fertilisers, fewer pesticides, less tillage) and on higher productivity perspectives, the opponents put more emphasis on health and environmental risks, as well as factors such as naturalness and the integrity of nature. An additional point of criticism is the ownership of seeds and the power of multi-national companies. Confronted with these opposing claims, consumers may have difficulties in seeing clear benefits for themselves and/or society at large (at least with regard to so-called first-generation GM food products, see below), which may have contributed to the general scepticism towards GM crops observed in surveys on public perception. This scepticism is claimed to have influenced EU regulation on GM plants – often regarded as restrictive compared to its US counterpart.

Whether a sceptical public is the "cause" and a restrictive policy the "effect" remains hypothetical. There are, however, various dimensions of public perception that often become condensed in the debate: Citizens may be concerned about the long-term impact on the environment or yield, for example, especially for farmers in developing countries. Citizens as political subjects may entertain general concerns about power relations, values and the way our lives should be organised. Citizens as consumers may follow different rationales, guided mainly by individual benefit and risk calculations. These are all

politically relevant but rely on, and are susceptible to, different lines of argumentation. It is not always clear which of these takes the lead in a public debate.

Therefore, when considering the future of GM plants and food in Europe and reflecting on the way this debate could evolve, it is necessary to take all dimensions into account. More specifically, it is necessary to consider whether GM technology will find a more positive response from the European public or not, and whether or not consumers will remain sceptical about GM crops and products.

The multitude of factors involved and arguments raised have made it difficult to devise a policy on GM plants and food that would be acceptable to the majority of the European public and suit the interests of industry and various sectors of agriculture as well. In response to public concerns on the one hand, and to regulatory difficulties and delayed decision-making at the European level on the other, the European Directive on deliberate releases (2001/18/EC) and other relevant EU regulations have put a new framework for GM crops and food in the EU into force. This framework puts more emphasis on the precautionary principle, specifies the criteria for risk assessment, stipulates a general and a case-specific post-market monitoring, and introduces a time limit for authorisations as well as a mandatory follow-up evaluation. In addition, the labelling regime has been changed.

In the first instance, the regulations focus on GM crops commercialised for fodder and for human consumption. In order to secure the coexistence of GM crops with conventional and organic crops and food products, proper labelling and traceability of GM food products have become major topics of concern and ongoing discussion.

Taken together, the regulatory framework for GM crops, feed and food has developed comprehensively. It was not until recently, however, that a number of new applications for GM product approvals were issued, so that it is still unclear how functional the regulatory framework really is. First experience revealed that some regulatory problems that were supposed to have been solved in fact still exist. It remains to be seen whether the EU regulation will prove capable of fulfilling expectations in daily practice.

While the regulatory framework is currently being put to the test with the first generation of GM crops, technical development has not come to a halt. New varieties with new properties are about to be launched and may enter the authorisation pipeline. In this context, it has been claimed that public perception could change due to new properties of GM products that carry consumer benefits. Further, an increase in demand and prices seems to call for more productivity in agriculture, which could also favour GM approaches.

Finally, the WTO ruling in 2006 has been interpreted as putting pressure on the regulatory approach in Europe. It highlighted different interpretations on both sides of the Atlantic with respect to the necessary level of evidence for possible risks that had caused tensions for considerable time without having been finally resolved.

These developments, amongst others, may lead to new debates, entail challenges for the European regulatory system and give rise to new tasks for TA. In order to discover more about future challenges, we devised a project that builds on the combined experience of eight major European TA institutions. In recent years, these institutions have contributed to the debates on the impacts and the prospects of GM plants. They have carried out a considerable number of projects on issues related to GM plants and food, including consensus conferences, expert surveys, or scientific assessments. The ensuing reports have flagged up many agricultural, technological, economical and political developments that could turn out to be challenging for the EU regulation on GM crops, feed and food. The present work under the umbrella of EPTA aims to make use of the many insights gained during these projects and of the different expertises of the colleagues involved. Although they give some consideration to developments at the European level, national TA institutions generally direct their efforts at national issues and the needs of national parliaments in the first place. However, we think that collectively we will be able to acquire a more comprehensive view and thus arrive at more substantiated general conclusions.

APPROACH 3.

Eight EPTA members and associates met to conduct the joint EPTA project "Genetically modified plants and foods". These were:

- Centre for Technology Assessment (TA-SWISS – Switzerland)
- Danish Board of Technology (DBT – Denmark)
- Institute Society and Technology (I.S.T. – Flanders) (the former Flemish Institute for Science and Technology Assessment – viWTA)
- Institute for Technology Assessment (ITA – Austria)
- Norwegian Board of Technology (NBT – Norway), together with the Norwegian Biotechnology Advisory Board
- Office of Technology Assessment at the German Parliament (TAB – Germany) (project co-ordinator)
- Parliamentary Office of Science and Technology (POST – United Kingdom)
- Scientific Technology Options Assessment (STOA – European Parliament)

The EPTA Council approved the joint EPTA project and its approach on 17th October 2006. A Project Manager Group with researchers from all participating EPTA members and associates organised and carried out the project work. The project's objectives were to provide information on the following:

- Regulatory challenges for the European system in the years to come,
- Points of public debate in the future,
- Approaches for TA to handle the issues identified.

In addition to using the collected knowledge and expertise of the participating TA institutions in order to identify relevant future topics, the project combined a look back into the past – by means of reviewing recent TA projects – with a view to the future through an experts' survey.

IDENTIFICATION OF ISSUES

All researchers participating in the project had been involved previously in at least one or, as a rule, several TA projects on issues related to GM plants. Therefore, we could assume that the combined expertise of all participants would cover a wide variety of topics previously addressed in national TA reports. The overall perspective, however, was set by the central question as to whether or not EU regulation is fully adequate to meet new challenges.

In a series of brainstorming sessions among the group of researchers (Project Manager Group), several issues were identified that merit further investigation. These sessions took place during the initial project meetings, and the results were further discussed via electronic communication.

REVIEW AND DISCUSSION OF RESULTS FROM PAST TA PROJECTS

The aim of the review exercise was to make use of previous TA project reports on questions pertaining to GM plants (including food and feed issues as well as non-food plants) in order to put together different pieces of knowledge from various perspectives. This served to learn more about the developments that gave rise to the present situation, and to identify questions that might still be relevant for the future. Apart from constituting an independent source of information, the reports also flagged up topics that could be investigated further through the following experts' survey.

Before starting the review process, the Project Manager Group developed common criteria for the selection of projects and a checklist for the reviews. Selection criteria were:

- The project was executed by an EPTA member, an associate member or a national or domestic TA institution.
- The project used an interdisciplinary or multi-dimensional approach.
- The project included recommendations, options and/or needs for action.

Additionally, one of the following criteria had to be fulfilled in order to restrict the sample to relevant and important reports:

- The project results served to back up a political decision.
- The project was an important participatory event or exercise at a national or regional level.
- The project and its results were highly visible and played a role in public debate.

In addition, we aimed at a broad variety of approaches, such as expert opinions and reviews of scientific findings, reports from expert committees or from hearings, stakeholder discourses and projects involving lay people such as consensus conferences and citizens' juries. All participating institutions reviewed a number of project reports from their own country (and one each from France and Finland) and drafted short summaries. In general, the reviews follow a common scheme:

- Background;
- Basic data about the project;
- Major outcomes;
- Impacts and follow-up;
- Identify major challenges.

A list of project titles can be found in Annex 2; the full texts of all project reviews are available on the project website as Annex 3 (www.eptanetwork.org/EPTA/projects.php?pid=150). In total, 29 reviews were produced. Six reports each came from Austria and Germany, four each from Denmark and Switzerland, three each from Belgium (Flanders) and Norway,

and one each from Finland, France and the United Kingdom. The unequal number of reports from various countries may be regarded as having been influenced by the differing measure of attention attracted by the issue in public debate, regulatory action, and work in TA institutions.

The range of projects covered very different topics related to issues of GM plants, as well as different TA approaches, in order to gain an overview of the status of the debate and of different opinions and standpoints in society. We are, of course, aware that from a methodological point of view, it might be difficult to compare results from such a variety of different exercises in any systematic way. However, in this step we primarily aimed at collecting pertinent issues and relevant views rather than performing a systematic comparison. Again, we strived to exploit the combined knowledge of the participating institutions generated over recent years on technical and regulatory issues and societal debates regarding GM plants and food.

PRELIMINARY CONCLUSIONS IDENTIFYING POINTS TO CONSIDER

In a next step, the major results of the reviewed projects as they appeared in the summaries or recommendations were screened for statements with regard to prospects for the future, predicted problems, possible impacts of decisions, and demand for future action. These statements were grouped in clusters according to their main point of reference. This resulted in three clusters:

- Technological challenges,
- Societal challenges, and
- Regulatory challenges.

Each group had a number of sub-clusters. These clusters were then condensed in several rounds of discussions among project members during the following project meetings and served as a basis for preliminary conclusions and points to consider, to be further corroborated or challenged by the following experts' survey.

EXPERTS' SURVEY

The aim of the survey was to collect information and opinions from experts (from a wide variety of backgrounds and fields of expertise) on major challenges in the area of GM plants and foods as identified in the previous step.

CHOICE OF EXPERTS

National experts of the following affiliations were identified by the members of the Project Manager Group, respectively, and invited to fill in a questionnaire:

- Science: Plant breeding, genetics/genome research
- Science: TA, ecology, society, innovation and policy research

- Administration: Ministries, competent authorities
- Industry: Biotech industry (incl. consulting)
- Industry: Plant breeding
- Stakeholder: agriculture, food, retailer, trade unions
- Stakeholder: environment and consumers

In total, 183 experts in the field of GM crops and food were invited to participate in the questionnaire. The number of experts invited again differed according to country, a factor largely depending on the national context. We do not claim that the survey is strictly representative –the restricted number of countries represented in the project alone would prohibit such a claim. Rather, we tried to cover variety as much as possible, with a broad range of expertises and affiliations.

The experts had different areas of expertise, with a considerable number sharing a technical background. The questionnaire we developed (see below) was not tailored to tap into a particular area of expertise, but covered a very broad set of issues, including societal ones. In other words, all experts would be confronted with issues where they had no professional expertise. For example, experts for breeding transgenic crops were asked for their views on public perception, an area in which they would not be expected to possess any professional expertise.

The reason we did this was that we considered these experts to have been exposed, time and again, to relevant issues outside their professional area, so that they could be expected to entertain a well-based opinion. Further, we believe it is interesting in its own right to give a picture of current thinking by prominent experts and stakeholders. These individuals' perceptions of the future influence their internal strategies and decisions, thereby forming an independent driving force for the future of GM plants and food. Moreover, they are often asked to give their opinion on regulatory and societal issues regarding GM plants, thereby playing an important though informal role in determining future policies. Thus, their views may be important in relation to legislation and decision-making, even if their knowledge does not derive from any immediate professional occupation but from contingent exposure.

DEVELOPMENT OF THE QUESTIONNAIRE

The questionnaire was developed on the basis of the points identified for consideration in the reviews, with the intention of covering the relevant topics. As this would have resulted in a questionnaire that was far too long, the project members chose the most relevant topics from their own TA experience. Inevitably, this implied a certain amount of deliberate shortening; however, this was necessary in terms of practicality. Topics to be taken on board were discussed intensely in several rounds, and a final choice made.

The resulting broad scope of questions, combined with the number of experts we wanted to involve, led us to rely on a questionnaire with closed questions.

Such a methodology is usually adopted for quantitative surveys. However, in this case, it was obvious that a strictly quantitative analysis would be hardly feasible, due to the relatively low number of respondents. We therefore left ample space for comments and thus allowed experts to display more thorough reflections, and thus included elements of a qualitative approach. A first version of the questionnaire was pre-tested with one to three experts per participating country.

The final questionnaire consisted of 15 closed questions (with the option of providing explanations or comments) and one open question on areas for further investigation. The sections of the questionnaire were:

I. Factors influencing the future of GM plants in Europe
   - I.1 General assessment
   - I.2 New GM plants, new applications
   - I.3 Public attitude and acceptance

II. Challenges for European/EU policy
   - II.1 Challenges linked to freedom of choice, labelling and coexistence
   - II.2 Challenges linked to new generation of GM crops
   - II.3 Global aspects of GM regulation

III. Challenges for research policy

IV. Areas of action

The whole questionnaire and the tables of results are documented in Annex 4 and 5, available on the project website (www.eptanetwork.org/EPTA/projects.php?pid=150).

SURVEY

The survey was conducted online from mid-November to the end of December 2007. Overall, 101 of the 183 invited experts opened the file; 30 of these then decided not to fill in the questionnaire; most of them discontinued after reading the introductory page. We received a full set of answers from 71 respondents. This gives a response rate of 39 %.

The survey was carried out in the home countries of participating institutions' plus Finland. Table 1 shows the distribution of respondents by country.

TABLE 1: COMPLETED QUESTIONNAIRES BY COUNTRY

Country	Number of participating experts
Austria	17
Belgium	6
Denmark	7
Finland	3
Germany	21
Norway	8
Switzerland	5
United Kingdom	1
Not assignable	3

In a self-categorisation as part of the questionnaire, the 71 respondents assigned themselves to different affiliations (Table 2). Nearly half of the experts ticked the category "university/research institute".

TABLE 2: COMPLETED QUESTIONNAIRES BY AFFILIATION

Affiliation	Number of participating experts
University/research institute	34
Industry	11
Governmental agency	13
Agricultural organisation	5
Environmental or consumer organisation	2
Other, please specify	6[a]

a These 6 respondents described themselves as: 'communication, journalist', 'environment and development organisation', 'NGO on critical technology assessment', 'used to work at NGO, now consultant', 'Trade Association Biotechnology', 'retail.

When interpreting this figure, one must realise that "science" was not specified and therefore included very different sciences. Consequently, plant scientists, sociologists, ecologists, bioengineers, philosophers, etc. all ticked this category. Regrettably, the participation from representatives of NGOs such as consumer and environmental groups was low. Sample controls revealed that some experts assigned themselves to universities/research institutes even if they had frequently performed work for NGOs or were prominent members. A similar situation might have occurred with scientists affiliated to industry. Regardless of the

underlying reasons, this bias tends to reduce the accuracy of such self-assignment.

ANALYSIS AND DISCUSSION

In a final step, the results from different parts of the Project Manager Group discussions, project reviews, and experts' survey were brought together. In the group discussions, the material was sorted and divided into chapters, and project members joined in "tandems" to perform a first analysis of each chapter. The main points to consider were discrepancies between the results of the Project Manager Group discussions and the project reviews, on the one hand, and the experts' survey on the other. The draft analyses were further refined in several rounds of discussions with all project members, whereby the original partition was in part revised. On the basis of the Project Manager Group discussions, a draft report was written, with one group member each responsible for a particular chapter and another one for its review. In a final round, conclusions were drafted and discussed among all members.

The draft report was peer-reviewed by six experts from different European countries. Comments from the peer review were discussed in a project meeting. Three project members were assigned the task of organising the writing of a new version which took the reviewers' comments into account. The second draft version was again reviewed by the same six experts. Taking into account the resulting comments, the report was discussed in a final round of all project members, and a final revision authorised.

Chapter 4 presents the main findings. For each section, background information is provided, which is mostly derived from the Project Manager Group discussions. This is followed by the results of the project reviews, leading to preliminary conclusions and resulting questions. Results from the experts' survey are then presented in the form of bar charts. This does not mean that we understood this survey to be predominantly quantitative. As mentioned above, we were more concerned about bringing in people with a broad set of backgrounds rather than obtaining the most representative sample. This also prevents any statistical analysis of the data. Nevertheless, on a few occasions we mention explicitly how responses are distributed according to the respondents' affiliations. In the final part of each sub-chapter, we discuss the results from the experts' survey and the results of the review analysis with a view to formulating conclusions. These conclusions provided a basis for identifying future challenges for different areas of political action and possible future TA exercises (in Chap. 5).

REVIEW AND SURVEY RESULTS 4.

THE FUTURE DEMAND FOR GM PLANTS AND FOOD: FACTORS AND PROSPECTS 4.1

BACKGROUND

For centuries, ways of enhancing productivity in the agricultural sector have been and continue to be in high demand. In this context, many agronomists argue that since GM crops are assumed to have a better performance than conventional ones, the demand for GM varieties and their cultivation will noticeably increase over the coming years.

In 2007, the estimated global area of GM crops was around 114 million hectares (representing approx. 5 % of arable land worldwide). GM crops were grown in 23 countries (James 2007). Twelve years after the commercial introduction of transgenic plants, there are still only two genetic traits (herbicide tolerance and/or insect resistance) and four crops that represent more than 99 % of the acreage: soybean (51 %), maize (31 %), cotton (13 %) and rapeseed/canola (5 %). The global area of GM crops has grown continually, including in some important emerging countries. The leading country is the USA with 57.7 million hectares, representing half of the total global area, followed by Argentina (19.1 million hectares), Brazil (15.0 million hectares), Canada (7.0 million hectares), India (6.2 million hectares) and China (3.8 million hectares). In contrast, the cultivation of GM crops in Europe is very limited. In 1999, the approval process for GM plants came to a temporary halt in the EU (until 2004). The GM crop area in Europe is still very restricted, with around 110,000 ha in 2007 (combined in the Czech Republic, France, Germany, Portugal, Slovakia and Spain), and only GM insect-resistant maize is approved for planting.

However, new technological, political, economical and societal developments may affect the way GM crops and related issues will be considered in European politics and among the public. This chapter explores the relevance of different driving forces that affect the demand for GM plants and food in Europe.

RESULTS FROM THE TA PROJECT REVIEWS AND FUTURE ISSUES

Several of the projects reviewed discussed factors that could influence the future of GM plants and food (while others primarily focused on a retrospective analysis). The following summary is based on information from eleven reports:

- *Austria, "GMO-free" claims and the avoidance of GMOs in food*
- *Germany, Green Biotechnology Discourse*
- *Germany, Gene technology Report*

- *Germany, Genetic engineering, breeding and biodiversity*
- *Germany, Transgenic plants of the 2nd and 3rd generation*
- *Denmark, New GM crops – new debate*
- *Denmark, Coexistence*
- *Norway, Coexistence*
- *Norway, GM food*
- *Switzerland, Genetic Technology and Nutrition*
- *UK, GM dialogue*

First, it is considered that technological developments will be a crucial driving force. Innovations include the development of plant varieties with better resistance to drought, cold, flooding, pests and diseases. Moreover, research is directed at developing the second and third generation of GM plants capable of producing pharmaceutical ingredients or industrial materials. Research developments also concern "energy plants" that produce biomass, which may be used for biofuels. Promoters of these developments expect them to bring benefits for both human health and the environment, even though many uncertainties remain. There are also hopes for business opportunities and for more efficient production methods *(Germany, Transgenic plants of the 2nd and 3rd generation; Denmark, New GM crops – new debate; see Sect. 4.2)*.

Second, economic factors must also be considered when discussing the future of GM plants and food. Europe is part of a globalised world, where more and more GM crops are being planted and exported. Will it be possible for Europe to stay apart from this global trend, considering that substantial quantities of GM soy and maize are imported into European countries? Can European countries and their agricultural sectors remain competitive without breeding GM plants? *(Austria, "GMO-free" claims and the avoidance of GMOs in food; Denmark, Coexistence; Norway, Coexistence;)*.

Other structural factors may affect the future of GM plants and food as well. These relate to the increasing world food demand, which requires more efficient agriculture at global and local levels. Parallel to this, the increasing use of biomass and bioenergy as an alternative to fossil energy could also affect the demand for GM plants *(Germany, Gene Technology Report)*. Furthermore, concentration trends in the food chain may have an impact. The seed industry is undergoing a fundamental change as big agrochemical companies heavily invest in agrobiotechnology and absorb small seed companies *(Germany, Genetic engineering, breeding and biodiversity)*. The retail sector is also experiencing a trend towards concentration, with a few retailers dominating the market and thus being able to dictate the kind of products to be sold (e.g. GM-free products). At the same time, consumers demand an ever wider and more diverse supply of food products, from fresh products to a broad range of processed food. There is a trend towards specific "categories" of food: "light" products, organic food, food produced according to sustainability principles, fair trade

food, etc. Such a multitude of consumer demands may also support a market for innovative technologies.

Moreover, there are regulatory factors that affect the future of GM plants and food. EU regulation of GMOs is based on the precautionary principle and the freedom of choice (which entails segregation and labelling), and adopts a process-oriented approach. It is different from the US system, which is predominantly product-based and does not include any mandatory labelling of GM products *(UK, GM dialogue)*. The question of how these two systems could coexist and whether the EU system is robust in particular with respect to WTO rules, is discussed in more detail in Sect. 4.6.

The impact of the trends mentioned will be influenced by public reactions. Most surveys - as confirmed by various TA projects reviewed - show that one of the most important concerns relating to GM plants and food is their possible detrimental impact on health (antibiotic resistance, allergic reactions, etc.). The impact of GM plants on the environment is another important public concern in Europe. How will perceptions of risk evolve in the future? How will people react to and perceive new applications, new production systems and new policies? *(Germany, Gene technology Report; Germany, Green Biotechnology Discourse; Norway, GM food)*.

PRELIMINARY CONCLUSIONS AND RESULTING QUESTIONS

A wide range of factors potentially influence the future demand for and use of GM crops, and it is hardly possible to foresee which of these will be the most important in the future. The TA projects reviewed did not reveal one single factor or driving force or even a few of them that will be particularly influential; rather, there will be a mix of factors depending on the context.

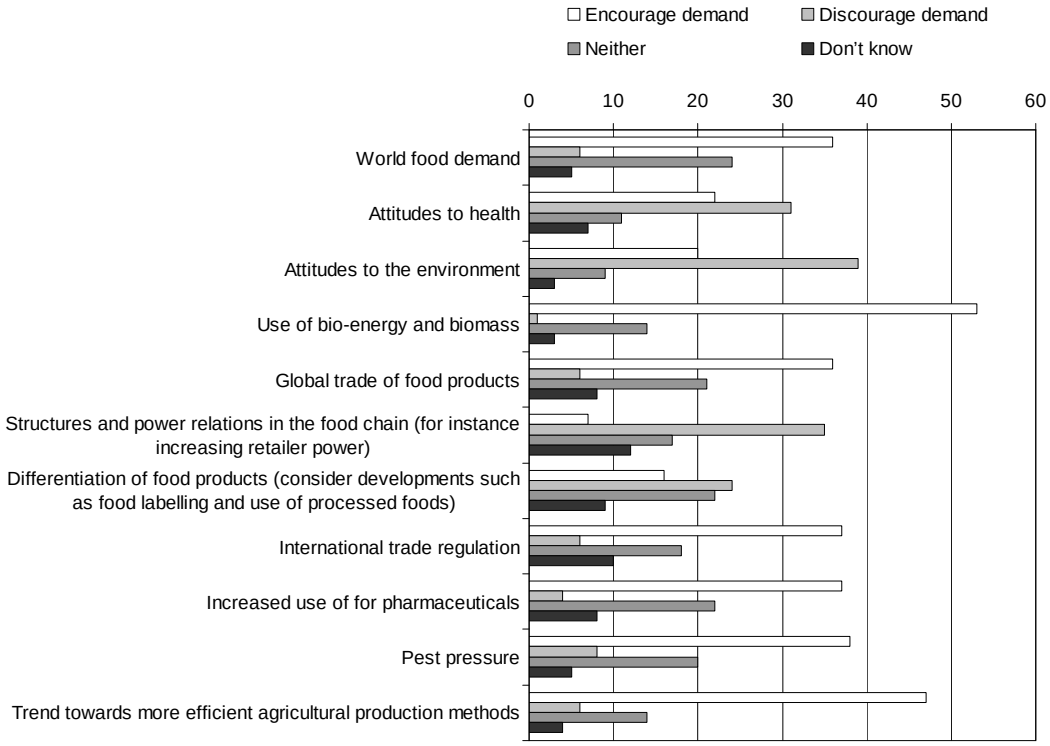
We therefore decided to begin the survey by asking the experts to give their overall view on the importance of different factors that could positively or negatively influence the future situation of GM plants and food in Europe. The two following questions pertained to their expectations on the future demand in general and whether the already existing "first generation" of GM crops would be grown to a noticeable extent over the coming years in Europe.

RESULTS OF THE EXPERT SURVEY

INFLUENCING FACTORS

All the factors listed (Fig. 1) were perceived as relevant for the future demand for GM plants and food, judging from the low rate of respondents ticking ‘Neither’ or ‘Don’t know’. Accordingly, the future of GM plants and food would be affected by a mix of factors.

FIGURE 1: INFLUENCING FACTORS FOR THE FUTURE OF GM PLANTS AND FOOD IN EUROPE (*Question 1A; n = 71)*



Question: Many factors will influence the future of GM plants and food in Europe. Below is a list of frequently cited major factors. Please indicate for each factor whether you think it will encourage or discourage the demand for GM plants and foods. Please feel free to add other important factors not listed.

Looking at the results in more detail, it appears that three in four experts considered the use of bioenergy and biomass to be a factor encouraging the demand for GM plants and food. This result must be seen in the light of the increasing demand for alternative energy sources. Respondents seemingly expected that GM plants might be required to satisfy this fast-growing market.

The trend towards more efficient agricultural methods was also considered an important factor, with two-thirds of respondents expecting it to encourage GM demand. This certainly reflected a recent trend in increasing prices for some agricultural products.

Around half of the respondents (44 % and 55 %, respectively) considered attitudes to health and the environment as discouraging the future demand of GM plants, nearly a third (31 % and 28 %, respectively) as encouraging. While the latter probably assumed that a new generation of GM crops might be

acknowledged to bring benefits to human health and the environment, the former assumed that GM crops will be perceived as inferior in these respects.

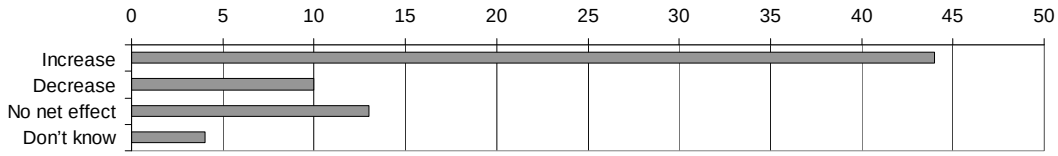
Overall, experts from industry had a higher-than-average tendency to expect different factors to encourage GM demand. This especially pertained to global trade (eight in ten compared with the average of five in ten for all respondents), world food demand and international trade regulation (for both: seven in ten compared with five in ten on average) and in particular concerning the differentiation of food products (five in ten compared with two in ten on average). Interestingly, fewer than half of the experts from industry expected GM plants for pharmaceuticals to play a role in encouraging demand for GM plants, compared to six out of ten researchers – perhaps because the development of such plants is still confined to the researchers' labs, whereas industry experts recognise the economic difficulties of such applications.

Some respondents also named other factors that might have an impact on the future of GM plants. One mentioned that if GM crops became significantly cheaper this might increase demand for them in times of rising prices for agricultural products. On the other hand, another respondent expressed the opinion that, as the average household income in the EU was rising, this could increase the demand for GM-free and organic products. Since the survey was carried out in late 2007 and the economic situation has changed meanwhile, this statement may be taken as highlighting the importance of the current economic context. For another respondent, "consumers' perception of collusion between public administrations and multi-national companies will (continue to) minimise demand". Food scandals and related fears (regardless of whether the food was of GM origin or not) might also hinder future demand for GM plants and products. The role of NGOs and the media was emphasised as well: depending on their power and credibility, they might influence public opinion on GM plants and food.

THE PLACE OF GM PLANTS AND FOOD IN EUROPEAN AGRICULTURE

Overall, a majority of experts expected most of the cited factors as encouraging demand for GM plants and food. But this does not directly indicate what the overall effect will be, as certain factors may outweigh others. We therefore asked whether the demand to introduce new GM plants in European agriculture will increase or decrease. Six out of ten experts expected an increase, less than one-fifth considered that it would remain stable, and only one-seventh expected a decrease (Fig. 2).

FIGURE 2: FUTURE DEMAND FOR NEW GM PLANTS IN EUROPEAN AGRICULTURE (*Question 1B; n = 71)*

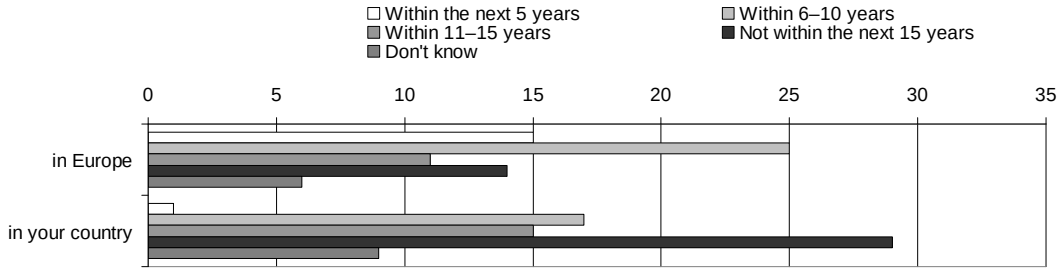


Question: Overall, would you think that the demand to introduce new GM plants in the European agriculture will increase or decrease?

It is of no surprise that respondents from the industry sector had the highest expectations regarding a growth in demand for GM plants and food (nine in ten), followed by the group of researchers (seven in ten).

Due to the uncertainty of the introduction of new generations of GM crops (see Sect. 4.2), we were interested to learn if the experts also predicted whether the existing "first generation" of GM crops (such as insect-resistant and herbicide-resistant plants) would be grown to a noticeable extent over the coming years. As shown in Fig. 3, more than half of the experts estimated that first-generation GM plants would be grown on more than 5 % of the available European cropland within the next 10 years. This was a surprising result, knowing that only limited areas are currently cultivated with first-generation GM crops in Europe, and that no noticeable changes have occurred during the past years.

FIGURE 3: FUTURE CULTIVATION OF FIRST-GENERATION GM PLANTS IN EUROPE (*Question 2; n = 71)*



Question: Do you think that the "first generation" of GM plants (such as insect-resistant (IR), herbicide-resistant (HR) and virus-resistant (VR) plants) will be grown in Europe to a noticeable extent (say more than 5 % of the available agricultural crop land) in the next 15 years)?

It is a striking result of the survey that experts had a completely different view on the subject when asked about cultivation in their own country: only a quarter of them predicted that first-generation GM plants would be grown in their own

country to a noticeable extent within the next 10 years (Fig. 3). This result, contradictory at first glance, was probably influenced by the national provenance of our experts. Amongst the countries represented, the only commercial planting of GM crops– on a very small scale – is in Germany. Many respondents probably expected countries which have shown a more positive attitude towards the use of GM crops in the past (e.g. Romania or Spain) to grow them to a larger extent in the near future.

In accordance with their view on the development of future demand in general, industry experts, and to a lesser extent researchers, entertained the highest expectations that first-generation GM crops will be grown to a noticeable extent in Europe and in their respective countries. All industry experts (except one who ticked 'Don't know') considered that first-generation crops will be grown in Europe within the next 15 years (compared to four out of five overall), and three quarters (compared to half the experts overall) of them considered that they will be grown in their own country.

DISCUSSION

Overall, the general conditions for agriculture are changing. First, food supply is high on the agenda in response to increasing demand and jumps in food prices. The role of agriculture for food security and development is also back on the development agenda as two recent assessments show:

- World development report 2008 (World Bank 2007)
- International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD 2008a + b)

The focus on food supply also has an impact on debates on GM plants both in Europe and worldwide. With regard to perspectives in developing countries, the views on the potential contributions of modern biotechnology towards productivity enhancement, improvements for small-scale farmers, and reaching the Millennium Development Goals, remain divergent – as has been the case ever since the 1980s. TA projects also came to differentiated and ambivalent conclusions, including that a number of important development goals could not be achieved through GM plants (e.g. *Denmark, Genetically modified crops in developing countries*). In the responses to the present survey, world food demand does not rank highest in encouraging demand for GM technologies. On the other hand, the survey indicates that a trend towards more efficient agricultural production methods will encourage GM-demand (Question 1).

Recent years have seen a dramatic increase in the importance of biomass as a renewable resource, especially for biofuels (for example EC 2006, GBEP 2007, Meyer et al. 2007, SRU 2007). This is illustrated both by the actual increase in biofuel production and by the formulation of ambitious goals for future biofuel use.

At the same time, crop breeding for bioenergy is more or less at its beginning. Reflecting this situation, experts considered the use of bioenergy and biomass to be a very important encouraging factor for GM introduction. But it has to be kept in mind that the biofuel policy itself is becoming increasingly controversial, as can be seen from the demand for a moratorium in biofuel use (for example EEA 2008).

Experts saw attitudes to the environment and to health as well as the structures and power relations in the food chain as discouraging factors for the future of GM plants and food in Europe, in line with the results from the TA project reviews.

In summary, the experts expected the demand to introduce new GM plants in Europe (Fig. 2) to increase. Accordingly, the majority of respondents expected a rise in the cultivation of first-generation GM crops that have in principle been available for a considerable time also in Europe (Fig. 3). Expectations concerning the time frame for introducing first-generation GM plants in European agriculture differ remarkably among different groups of experts. However, it is rather surprising to see that for many of them, cultivation of first-generation GM plants will substantially increase in Europe, or at least in some European countries. These rather high expectations may reflect observations that the acreage of agricultural land cultivated with GM crops worldwide keeps increasing each year, and expectations that this trend will also involve some European countries.

In conclusion, experts see driving forces arising that will influence the demand for GM plants and food, and they expect the use of such plants in Europe to increase. Chapter 5 will discuss whether these expected developments could have consequences for GM regulation and for further TA projects.

NOVEL GM PLANTS, TECHNOLOGIES AND APPLICATIONS 4.2

BACKGROUND

The appearance of novel applications of GM crops has been announced and expected for many years. One main focus of scientific and political debate is on GM plants with modified properties for the user (so-called “output traits”, as opposed to agronomic or "input traits", which serve to optimise agricultural production). These plants are designed to produce pharmaceuticals or industrial raw materials (so-called molecular pharming); they are also expected to feature improved, especially healthier contents as a source of food. The latter could be particularly attractive to final consumers, while most of the other possible novel applications would serve industrial purposes in the first instance.

Recent interest has focused on options for using GM plants as a source for renewable energy production. The potential contribution of GM technology is seen in increasing the biomass yield in general or that of specific components such as fatty acids. Such plants may eventually be associated with environmental advantages and thus become more persuasive in public perception than the existing "first" generation of GM plant crops. On the other hand, some novel traits for new areas of application, such as the production of pharmaceuticals, may throw up serious new questions for risk assessment and management.

However, the suitability of genetic engineering to address such complex breeding aims as yield is controversial. It may also be put to the test by other advanced technologies such as smart breeding, which makes use of molecular genetics to support conventional breeding approaches.

RESULTS FROM THE TA PROJECT REVIEWS AND FUTURE ISSUES

Only two of the 29 projects reviewed overall explicitly dealt with new applications of GM plants – also called the second and third generation ("second generation" describing those GM plants which are closer to commercialisation, and "third generation" referring to those being researched or at a very early stage of development):

- *Denmark, New GM crops – new debate*
- *Germany, Green genetic engineering – transgenic plants of the second and third generation*

One further report focused on relevant applications, but only marginally touched on the topic of GM plants (*Flanders, Industrial biotechnology* and *Functional Food)*, while another (*German, Gene technology Report)* predominantly covered technological questions (also in related areas of modern plant breeding).

The Danish citizens' jury assessed the new uses of GM plants as predominantly beneficial, but had different attitudes towards the use of GM plants for medical, other industrial, or ornamental purposes. One important demand made was that applications should not give rise to more harmful agricultural practices than the corresponding traditional modes of production (particularly concerning fertiliser or pesticide usage). Thus, a precondition for allowing the new plants was that the environmental consequences of new practices should be thoroughly assessed (*Denmark, New GM crops – new debate)*.

Another challenge identified was the retention of a free consumer choice. Some reports even implied that GM products also for non-food and non-feed purposes could or should be labelled. In addition, public research should be strengthened to provide a counterweight to private research and development, as public research was considered necessary to maintain sufficient control of the new GM plants. The clearest message from the citizens' jury, however, was not about

tangible advantages, disadvantages and conditions with regard to GM plants, but about the necessity of informing the public about these issues as part of an open and balanced debate (*Denmark, New GM crops – new debate)*.

A major outcome of the TAB project, which was based predominantly on the analysis of scientific expertise, was that fundamental uncertainties remain regarding the developmental status of most GM plants for molecular farming as well as for the production of functional food, so that the economic potentials are very difficult to assess. In several cases, expectations of attainable product yields have not been fulfilled even after many years of development. In the course of maximising content, it seems that undesired side effects tend to emerge which then result in lower yields. While this does not make the concept (economically) unusable, it does affect the range of substances that can be produced on a commercially competitive basis.

In addition, approaches based on GM plants have to compete with well-established or more intensively investigated technologies in the chemical and pharmaceutical sector, and particularly in the food industry, where food ingredients are gained by chemical synthesis, microbial production or isolation from natural sources. The resource-intensive and comparatively long development period for new GM varieties, as well as regulatory requirements, represent a disadvantage over more rapid and flexible alternatives. According to the TAB report, the most probable perspectives are localised in the field of pharmaceutical production, as a growing demand for biotechnological, high-value drugs and a need for additional production capacities can be deduced from recent market developments. With regard to the production of low-priced, so-called bulk chemicals, a major restriction was identified in the form of GM-specific regulation and management measures which increase the production costs (*Germany, Transgenic plants of the second and third generation*).

Since most GM plants modified for output traits are at an early stage, the risk discussion is still in its infancy and has so far concentrated on the question of how to reliably prevent gene flow or outgrowing and contamination of staple food. However, at least for GM plants producing pharmaceutical substances, the conditions for risk regulation (i.e. risk assessment, risk evaluation and risk management) are fundamentally different. Compared to existing GM plants with agronomic traits, they bear an inherent risk due to the possible medical and physiological impact of their new ingredients. At the same time such crops exhibit benefits (e.g. of a life-saving drug) which may be given weight if the approval procedure were amended in the direction of a comparative risk-benefit analysis (compare Sect. 4.5).

All in all, a thorough examination of the current European regulation was recommended to check its appropriateness for molecular farming. The overall conclusion of the TAB project was that, due to the limited emphasis on "molecular farming" within the debate on GM plants, there was an overall need

at the EU and national levels for a more thorough consideration of opportunities and potential risks of GM plants modified for output traits (*Germany, Transgenic plants of the second and third generation*).

The report by the Berlin-Brandenburg Academy of Sciences and Humanities (BBAW) brought up the question of alternative novel methods or technologies for plant breeding *(Germany, Gene technology Report)*. "Smart breeding", the use of genomic information to empower and refine conventional breeding strategies, may be able to handle complex traits like yield or tolerance to abiotic stress (drought, salinity, etc.). At the same time, it uses molecular techniques without producing GM plants and thus avoids all aspects of GM-specific risk regulation and measures. "Cisgenic" approaches using only species-immanent traits for genetic modification are also on their way. Some experts and stakeholders ask whether cisgenics may blur the distinction between GM and non-GM plants, and one may ask if this technology will influence the public attitude towards GM technology.

PRELIMINARY CONCLUSIONS AND RESULTING QUESTIONS

Novel applications of GM plants have been announced for a long time, but have not yet appeared at all on the European market and only to a negligible extent elsewhere. So the basic question remains whether a technological breakthrough (i.e. a plant variety with new characteristics ready for marketing) can be expected in the next few years. We asked for the experts' assessments of the availability of different traits, including a number of output traits, as well as new agricultural input traits.

Such "technical" availability does not mean that the GM plants can be introduced to the market – they still have to be authorised. At least for some novel output traits, it is obvious that serious risk questions have to be resolved, including the design of reliable risk management procedures (see below). Thus, a second question concerns the possible and expected authorisation of different categories of new GM plants as a prerequisite for their future market appearance.

The fulfilment of both requirements, the technical availability and the market approval does not automatically imply that a GM plant will actually be taken into use – this again depends on the demand by growers and the acceptance of possible users or, for pharmaceutical GM plants, the cost of the substance produced. Such acceptance and demand may vary according to the characteristics of the very heterogeneous categories of new GM plants. They depend on a variety of parameters such as the expected area of cultivation (which could be very small and possibly covered by glasshouses for pharmaceutical crops or special high-value chemical compounds) and the agronomical needs and measures (which could be more or less similar to established agricultural practices). Furthermore, how "close" the application is

to the consumer will also play a role; uses as a source of food may be more sensitive than a very specialised "consumer-remote" purposes (e.g. phytoremediation, the extraction of toxins from the soil). These aspects could not be explored in detail in a questionnaire, but should be kept in mind in interpreting the answers received.

The usual scientific risk assessment procedures rely heavily on the concept of substantial equivalence, both in EU and US approval regimes. By proving that there are only minor differences between the GM plant and its conventional counterpart, the risk assessment focuses on the genes transferred and the specific traits they confer, and to a much lesser extent on the properties of the new plant as such. However, when the result of the genetic modification is a major change in the plant's physiology or a new synthesis of specific molecules in large amounts, GM plants are no longer equivalent to existing varieties. Therefore, their safety may need a more thorough or different type of investigation compared with existing "first-generation" GM plants. In the questionnaire, we asked the experts if they shared this view and, if so, in which areas they would possibly expect regulatory challenges.

RESULTS OF THE EXPERT SURVEY

AVAILABILITY – AUTHORISATION – DEMAND – ACCEPTANCE OF NEW GM PLANTS

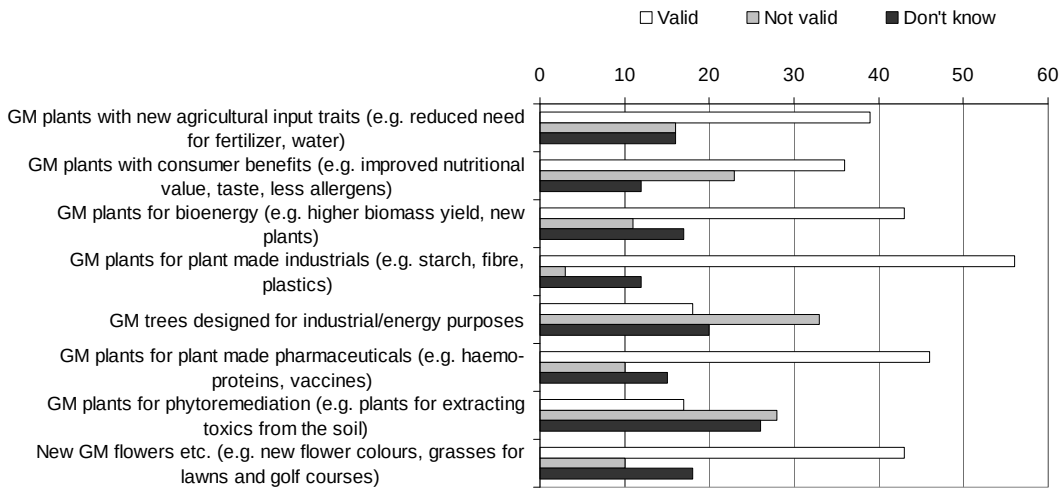
Overall, the respondents tended to expect new GM plants to be introduced in the coming decade. With the exception of trees for industrial or energy purposes and plants for phytoremediation, the majority of respondents expected all other categories of plants listed to be available and authorised for cultivation in Europe within the next 10 years. The experts did not add any other category to those listed in the questionnaire.

Asked whether the various plants *"will become available"*, "GM plants for plant-made industrials" scored highest (four in five, see Fig. 4), followed by plant-made pharmaceuticals, plants for bioenergy and new GM flowers (about three in five each). "GM plants for phytoremediation" and "GM trees designed for industrial/energy purposes" received the lowest support (about one in four), while "GM plants with consumer benefits" got support from half of the respondents, comparable to "new agricultural input traits".

The answers to *"will be authorised"* (Fig. 5) show a similar pattern except for "GM plants for pharmaceuticals": They are regarded as less likely to be authorised although they would be available (less than half vs. three in five). This difference may reflect that such products can be supplied in most cases from restricted cultivation in greenhouses without authorisation for commercial planting. In general, one reason for the relatively low support for GM pharmaceutical plants, trees and plants for phytoremediation may be that they

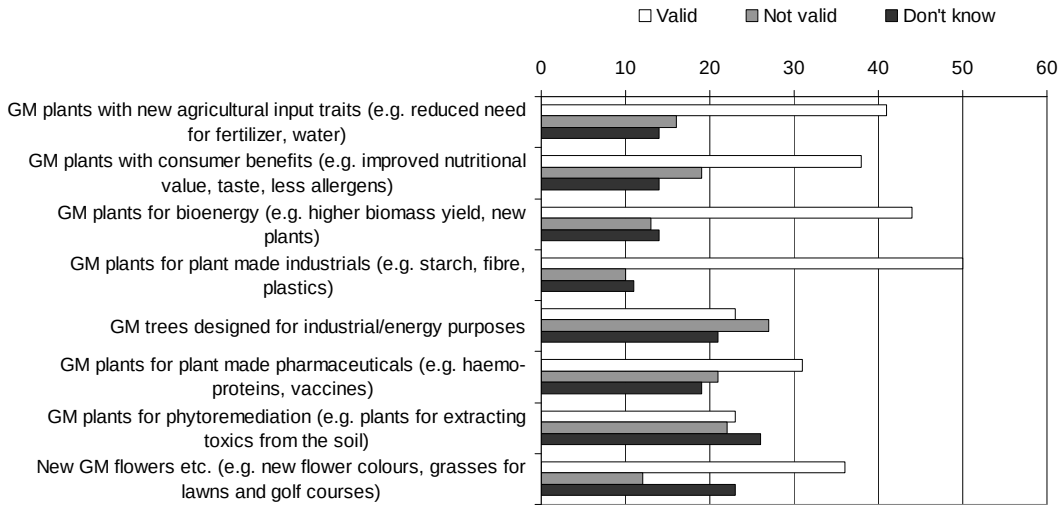
might be associated with different kinds of risk, which could be seen as requiring different assessment regimes (see Fig. 11).

FIGURE 4: AVAILABILITY OF NOVEL GM PLANTS (*Question 3A; n = 71)*



Question: Currently there are several classes of new GM plants in development. Please check if you believe the statement: "Such crops will become available within the coming 10 years."

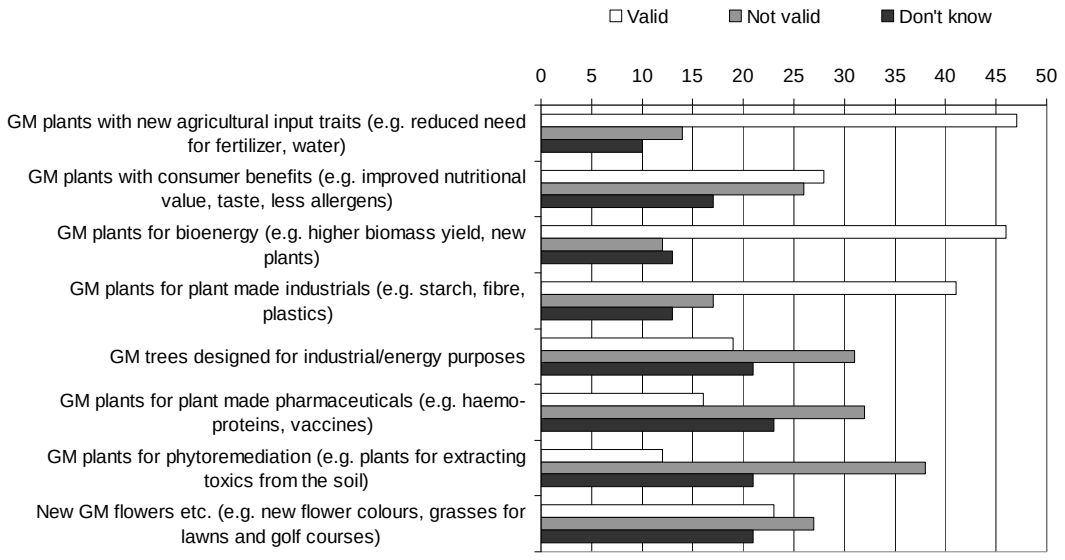
FIGURE 5: AUTHORISATION OF NOVEL GM PLANTS (*Question 3B; n = 71)*



Question: Currently there are several classes of new GM plants in development. Please check if you believe the statement: "Such crops will be authorised for cultivation in Europe."

The question of *"demand from farmers"* (Fig. 6) tapped into expectations concerning the interest and willingness to grow the respective GMP. By comparing with the question on *"acceptance with consumers"* (Fig. 7), we can deduce a possible conflict between a high demand from farmers compared to low acceptance from consumers anticipated for "GM plants with new agricultural input traits" (seven vs. three in ten). A similar, though weaker discrepancy arose for "GM plants for bioenergy" (seven in ten vs. half), and an opposite relation for "GM plants with consumer benefits" (two versus three in five). Maybe a reason for the latter is that respondents believed that crops with consumer benefits would only make up a niche market, so the average farmer would not benefit from it.

FIGURE 6: DEMAND FROM FARMERS FOR NOVEL GM PLANTS (*Question 3C; n = 71)*



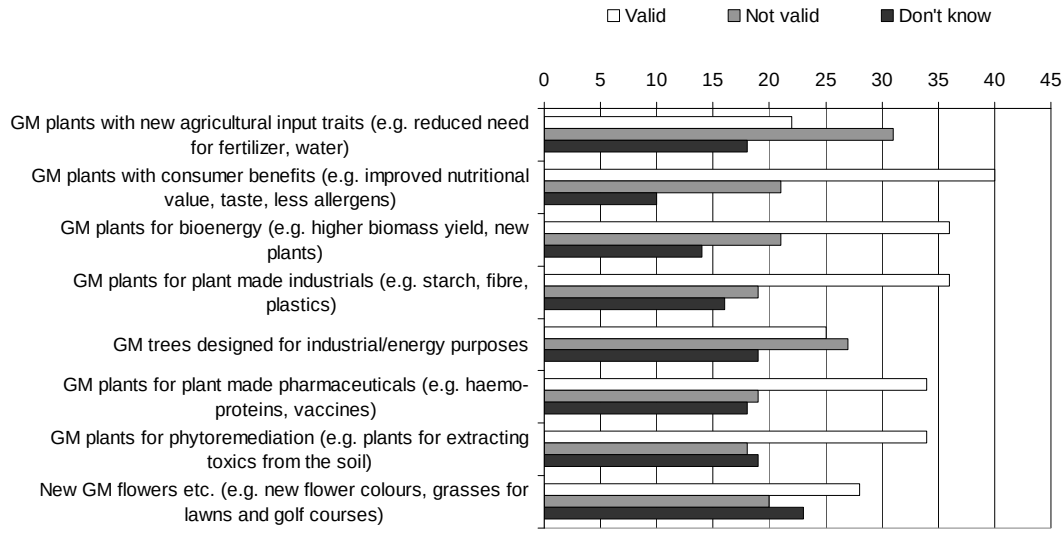
Question: Currently there are several classes of new GM plants in development. Please check if you believe the statement: "Such crops will find significant demand from farmers."

The assumed low interest of farmers in growing GM plants for pharmaceuticals is not surprising, because such plants will probably be cultivated, if at all, only on a contract basis. The high numbers of "Not valid" for "GM plants for phytoremediation", "GM trees designed for industrial/energy purposes", and "New GM flowers" also reflect their nature as non-agricultural plants which are not relevant for most farmers.

The relatively high expectation for consumer acceptance of "GM plants for bioenergy", "GM plants for plant-made industrials" and "GM plants for pharmaceuticals" is in line with the responses to Question 6 where a majority of experts perceived that GM non-food products would meet more positive public

attitudes (see Fig. 12 in Sect. 4.3). It also fits with the cautious but affirmative vote of the Danish citizens' jury on these issues (*Denmark, New GM crops – new debate)*.

FIGURE 7: ACCEPTANCE WITH CONSUMERS OF NOVEL GM PLANTS (*Question 3D; n = 71)*



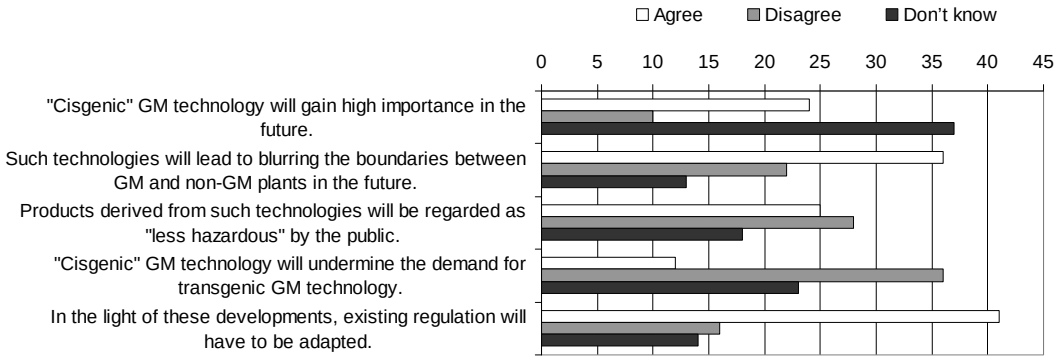
Question: Currently there are several classes of new GM plants in development. Please check if you believe the statement: "Products from such crops will find acceptance with consumers."

Concerning "*demand from farmers*", several participants commented that "*Farmers will probably be willing to grow anything for which there is a demand, either from consumers or from industry.*" Regarding "*acceptance with consumers*", one respondent commented: "*Every single person is a consumer, so obviously this is not a homogeneous group. What percentage of consumers is needed to answer "valid" - 10%, 30%, the majority? I have interpreted this as acceptance by a majority of consumers. There will be a minority that will not accept any GM crops (this is about 15% of all consumers*)."

FUTURE IMPORTANCE OF SPECIFIC ADVANCED GENETIC BREEDING TECHNOLOGIES

Questions on the future importance and implications of smart breeding and cisgenic technologies are of interest because both have the potential to provide novel varieties that may be more acceptable to a sceptical public since the degree of "manipulation" may be perceived to be less severe.

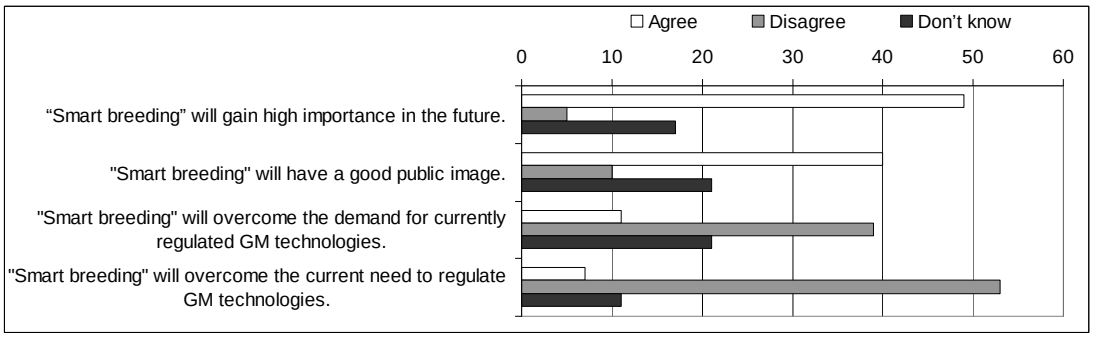
FIGURE 8: FUTURE IMPORTANCE OF "CISGENIC" GM TECHNOLOGY (*Question 4A; n = 71)*



Question: In the future, technical developments such as "cisgenic" GM technology may become more important. While traditional "transgenic" plants result from gene transfers which use recombined DNA from other species, "cisgenic" plants result from gene transfers which use only recombined DNA from the same species. Please indicate if you agree or disagree with the following statements.

The importance of cisgenic GM technology does not seem to be very clear as responses show a high rate of "Don't know" answers (more than half; Fig. 8). The statements that this technology "blurs the boundaries" and a "need for adapting existing regulation" ensues each met with quite high support from more than half of the respondents. On the other hand, the statement "Cisgenic GM technology will undermine the demand for transgenic GM technology" met with the lowest support, which indicates that respondents expect cisgenes to at best supplement, rather than replace, transgene technology.

FIGURE 9: FUTURE IMPORTANCE OF "SMART BREEDING" (*Question 4B; n = 71)*



Question: "Smart breeding" is another new technical development. "Smart breeding" derives from traditional methods of plant breeding but includes tools on the basis of modern recombinant DNA technology such as molecular markers. Please indicate if you agree or disagree with the following statements.

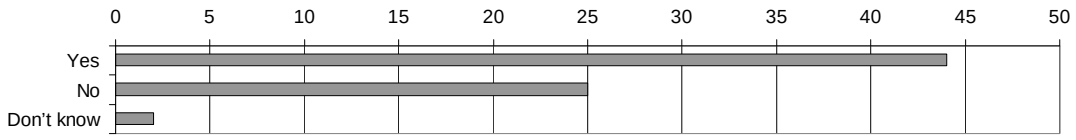
Whether the public would regard products derived from such technologies as "less hazardous" was controversial (one-third agree, slightly more disagree). In the written comments respondents emphasised that *"Most consumers will, if asked to distinguish, see cisgenics as less hazardous than transgenics, but that doesn't mean they will accept them in their back yard or on their dinner plates."* A similar consideration was: "*I guess cisgenic will be defined - publicly as well as in terms of regulation - as transgenic. Argument: rearrangement within the genome calls for precaution as well."*

Compared to cisgenic GM technology, many more (seven in ten) considered "smart breeding" to be important: more than half saw a "good public image" (Fig. 9). However, smart breeding is not considered an alternative to GM technologies (more than half disagreed), and it will not overcome the current need of GM plant regulation (three in four disagreed). One respondent noted *"that all these techniques will contribute to the development of plants for different purposes"*.

REGULATORY ISSUES OF NOVEL GM PLANTS FOR THE NON-FOOD SECTOR

Almost half of the experts agreed that novel GM plants for the non-food sector would pose new regulatory challenges, while one in four disagreed (Fig. 10).

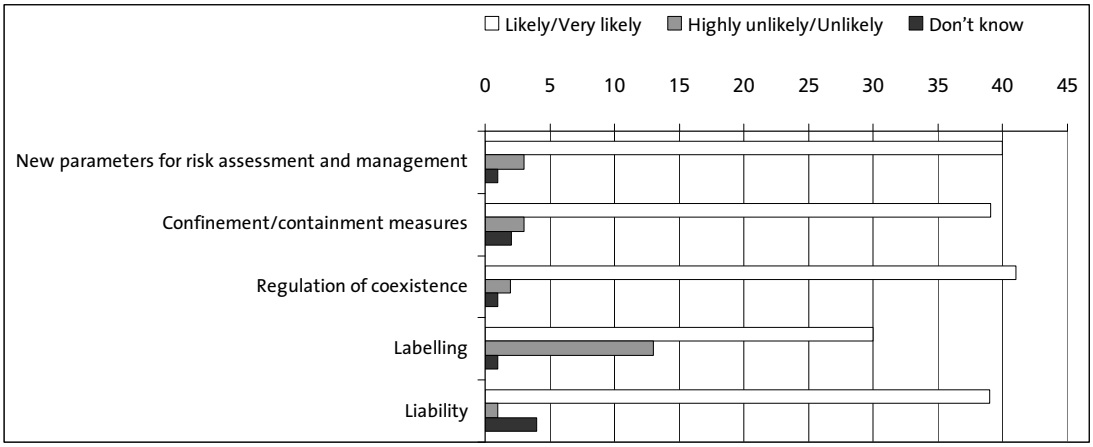
FIGURE 10: NEW REGULATORY CHALLENGES CAUSED BY NOVEL GM PLANTS?
(Question 10A; n = 71)



Question: Newly developed GM plants for the non-food sector (e.g. GM plants for plant made pharmaceuticals, for industrial raw materials, and for bio-energy) are sometimes said to have new properties compared to gm plants for food and therefore pose new regulatory challenges. Do you or don't you agree with the following statement?

Those who expected regulatory challenges were then asked what kind of challenge they would expect (Fig. 11). Aspects such as "new parameters for risk assessment and management, "confinement / containment measures", "regulation of coexistence" and "liability" were all regarded as very likely or likely to be on the agenda during the next 10-15 years by around nine in ten of the experts. In comparison, "labelling" was identified as a highly likely or likely issue by only seven in ten. This could reflect the fact that non-food/feed products may not necessarily have to be labelled.

FIGURE 11: AREAS OF NEW REGULATORY CHALLENGES OF NOVEL GM PLANTS (*Question 10B; n = 44)*



Question: If you ticked "Yes" *[in question 10B]*, please assess which regulatory challenges non-food GM plants will raise in the next 10-15 years, and whether this will be very likely, likely, unlikely or highly unlikely. Please feel free to add other regulatory challenges not listed.

The experts did not add any other category to those proposed in the questionnaire, but in the written comments it was emphasised that *"Regulators also need to address issues such as ethics, sustainable development and societal utility"* and that *"In general, since most non-food GM plants presumably will produce high value products, there will be a natural interest to keep them confined from other crops in order to preserve the value of the products."* Another participant added that *"Answers refer primarily to plants producing pharmaceuticals. Some other non-food traits, e.g. for bioenergy, would not raise new regulatory challenges."*

DISCUSSION

Will new GM crops with novel properties be available, and will they come onto the market? Will new regulatory challenges arise, and what about alternative or complementary novel methods/technologies such as smart breeding and cisgenics?

Amongst the experts asked, the overall expectations that such new GM plants would be developed and in principle be available "within the coming 10 years" remained high. A more precise forecast was not requested, thus no conclusions can be drawn about when the experts expected such crops to be market-ready and authorised in Europe.

Interpreting the rough forecast for different categories remains difficult. As already mentioned, GM plants with improved output traits have been

announced for many years, but no information is available on whether the technological development has been substantially accelerated. In some cases, high expectations could be due to wishful thinking (or continuing fear) rather than informed judgement. The TAB report showed that many research and development projects in the past failed in their late stages (*Germany, Transgenic plants of the second and third generation*), which makes it difficult to forecast the fate of current projects. A plausible reason for the high expectations concerning industrial applications probably is the availability of a particular GM crop, the BASF starch potato "Amflora" – whose authorisation was applied for more than 10 years ago. However, the "Amflora" example also illustrates that industrial GM crops may have difficulty obtaining authorisation even in a case that has been extensively tested for a long time and assessed, according to the European Food Safety Authority (EFSA) GMO Panel, to be unlikely to have adverse effects. It is not clear whether this will change in the foreseeable future.

The pattern of the experts' expectations regarding demand from farmers and acceptance by consumers vis-à-vis GM crops with new input traits and functional food properties were basically in line with familiar opinions: respondents regarded farmers to demand more agricultural traits and consumers to demand improved nutritional value (irrespective of the factual rejection of GM foods in Europe until now). However, the acceptance of growers and consumers seem to diverge for other applications as well. One reason may be that certain types of crops are closer to the consumer, and thus more sensitive.

For food crops, there should be a strong relation between consumers' demand and farmers' production. In contrast, for plant-made pharmaceuticals, industrial substances and crops for bioenergy it is the pharmaceutical, chemical and energy industry that creates demand. On the one hand, this might change the role of farmers, who in the future might be working increasingly on a contract basis – a development that is also taking place with food production, as the requirements of identity preservation and quality control constantly rise. On the other hand, as the produce becomes refined to fuels, plastics or pharmaceuticals, their agricultural and thus GM origin becomes obscure. More "remote" value chains such as these may be less sensitive to GM opposition, although recent actions against the "Amflora" potato were similar to former campaigns against GM food crops.

The future role of cisgenics and smart breeding seems to be somewhat unclear. Although they were considered important for plant breeding in general, the majority of experts did not expect them to substantially reduce the demand for transgenic technologies. There might be a gain in popularity, however; and some existing regulations might need to be adapted in order to cover cisgenics.

GM plants for the non-food sector, and especially in the case of plant-made pharmaceuticals, were expected to pose various regulatory challenges. This confirms the results of the TAB report (*Germany, Transgenic plants of the*

second and third generation). A majority of respondents considered it likely or very likely that new parameters for risk assessment and management, confinement and/or containment measures, regulation of coexistence and liability will be put on the agenda over the next 10-15 years.

Taken together, the appearance of new categories of GM crops remains difficult to predict. However, if they occur in the coming years, at least some of them will evoke novel regulatory questions.

PUBLIC ATTITUDES AND ACCEPTANCE 4.3

BACKGROUND

The history of GM plants in Europe is a history of strong debates between decision makers, experts and various stakeholders, including industry, consumer groups and environmentalists. Proponents of GM plants argue in favour of the environmental benefits of GM plants (less fertiliser, less pesticide, less tillage) and higher productivity perspectives. Opponents emphasise potential health and environmental risks as well as a variety of non-technical issues, such as the multiple purposes of agriculture, pending dependence on multi-national companies and questions of ethics and (food) culture.

Over the years, this debate has found resonance in and received inputs from the public in European states' to varying degrees. The ensuing reluctance to buy GM products has almost prohibited their commercial introduction. Public scepticism might have had an influence on the EU regulation on GM plants and food as well, which some claim to be rather restrictive. When considering the future of GM plants and food in Europe, it is thus important to reflect on the way public debate will evolve and, more specifically, whether or not agricultural GM technology and its products will find more acceptance over time.

However, it must be kept in mind that acceptance or the lack of it is the result of a process of shaping public opinion with many factors involved. Therefore, any such reflection must take into account numerous possible reasons for the perception entertained by the European public.

Overall, repeated European surveys[1] have identified growing scepticism throughout the 1990s and a slight change over the last couple of years. Regarding GM food, the majority still seem to be sceptical (Gaskell et al. 2006). Several explanations have been proposed. Firstly, since the so-called first-generation of GM crops was mainly developed in order to suit the needs of the producers, one line of explanation stresses the rational choice of consumers:

[1] In particular, six Eurobarometer surveys on biotechnology in 1991, 1993, 1996, 1999, 2002 and 2005, see http://ec.europa.eu/research/press/2006/pr1906en.cfm

since buying GM food products would not as yet bring clear individual benefits, and the potential risks claimed by opponents could not be entirely dismissed, consumers tend to remain sceptical. Consequently, with new GM plants delivering products which might be considered beneficial for the consumer, or products other than food or feed, some expect attitudes to change.

However, even if one takes into account consumer calculation of risks and benefits, this alone may not be sufficient to explain how attitudes are formed. Analyses of surveys have shown that, regardless of considerations of risk or personal benefit, if someone has moral objections to genetic modification this acts as a "veto" (Gaskell et al. 2006). Such objections can be directed, for example, towards the perceived role of GMOs as "tinkering with life", which would collide with a certain understanding of nature.

Such general arguments lead to another line of explanation that emphasises someone having a general opinion of GM plants (Lassen et al. 2002; Lassen and Jamison 2006). Reasons may be based on arguments of the general environmental effects, common welfare and/or democratic accountability. For example, such arguments could pertain to GM plants considered to reduce or create environmental risks either directly or through the way agriculture is conducted. Whether or not risk management will be able to mitigate risks is controversial, as is the question of whether coexistence will secure consumer choice or, if it fails, will result in negative effects for non-GM agriculture. Patenting may contribute to enhancing research to secure the world food supply, but it may also give rise to problems of equity and dependence on "big business". There are also links to voices criticising the way food scandals have been dealt with and how expert committees and regulatory bodies have failed to provide and act upon expertise, independent of special interests. Accordingly, the perceived lack of accountability has contributed to a reluctance to accept reassurance from experts that there is no risk (PABE 2001). This again is linked the debate on the risk issue, but at a different, societal level.

In other words, several lines of argumentation may explain the perceptions measured in a survey. In addition, it must be kept in mind that there may be a gap between the role of the citizen supporting or rejecting GM technology on the one hand and the role of the consumer purchasing GM food products or not in practice on the other, whereby one and the same person could take on both roles at different times.

RESULTS FROM THE TA PROJECT REVIEWS AND FUTURE ISSUES

A number of TA reports from various institutions, many of them involving lay panels or other forms of involving non-experts, have tried to shed light on the reasons behind past and present public perceptions and on factors that may influence them in the future, such as participation, communication and public debate. Project members used information from the following summary of some

of the most important points to consider from the reviews of these reports in forming their hypothesis. Relevant TA projects reviewed were:

- *Denmark, Genetically modified foods*
- *Denmark, New GM crops – new debate*
- *Finland, Debate concerning the plant gene technology*
- *Flanders, New impulses for the debate on genetically modified food*
- *Germany, Green Biotechnology Discourse*
- *Norway, GM food*
- *Switzerland, Genetic Technology and Nutrition*
- *United Kingdom, GM dialogue*

Other reports mentioned public perceptions as a factor to be taken into account, such as

- *France, Co-construction*
- *Flanders, Industrial biotechnology*
- *Flanders, Functional Food*
- *Austria, Precautionary Expertise*
- *Germany, Transgenic plants of 2nd and 3rd generation*
- *Switzerland, The future of plant biotechnology*

Almost unanimously, the project reviews suggest that consumer attitudes, and the ensuing reluctance of retailers to put GM products on the shelves, have strongly influenced the economic performance of GM food. Consequently, the question of how attitudes will develop over the next 5-10 years is likely to be the key to any future success of GM crops (*United Kingdom, GM dialogue*). This applies to current GM plants for food, future developments, and GM crops for non-food purposes/applications. In some countries, consumers may even have become less confident and more sceptical over the years (*Norway, GM food*). This may also have to do with a loss of trust in the scientific community and in regulatory bodies and not only with the risks associated with the technology alone (*France, Co-construction*). There are contrasting experiences in Finland, however, where acceptance seems to have improved (*Finland, Debate concerning the plant gene technology*).

In general, it is difficult to determine whether acceptance has changed in practice. What can be said, however, is that perceptions are split: some reports emphasised strong dissent among members of stakeholder panels over risk, benefits and major definitions such as on the precautionary principle and ecological damage (*Germany, Green Biotechnology Discourse*).

Surveys over the last decade have repeatedly pointed out that consumers are quite sceptical towards food products from first-generation GM plants, as they do not see clear benefits for themselves, and also fear risks related to health and the environment. This argument was also emphasised in citizens' panels and consensus conferences (for example *Denmark, Genetically modified foods*).

However, a Swiss panel of non-experts considered no danger to be proven, and although no final judgement could be made on the presence or absence of a risk, some members considered that GMOs should not therefore be banned (*Switzerland, Genetic technology and Nutrition)*.

Several reports quote expectations that acceptance of new GM food products could grow as future products may entail obvious benefits to consumers (for instance healthier nutrition or better food quality, *Germany, Green Biotechnology Discourse)*. Non-food products may also find more acceptance, as health issues are less sensitive, and new products may be associated with clear advantages. In particular, GM plants for medicines received support because of the importance of the product, in contrast to ornamental flowers. Therefore, a "conditional yes" can be expected – which seems to depend on the perceived societal usefulness of the product compared with its possible risks (see also Sect. 4.2) *(Denmark, New GM crops – new debate*).

However, attitudes are not only the result of a simple balancing of (environmental or health) risks and (societal or personal) benefits. Citizens are also concerned with general issues such as equity regarding benefit allocation (*Flanders, Functional Food*) and justice, in particular with regard to developing countries (*Denmark, Genetically Modified Foods*). Several reports highlighted that attitudes towards nature play an important role, too *(Switzerland, Genetic Technology and Nutrition)*, and that ethical considerations should be taken more seriously (*Denmark, Genetically modified foods*). Finally, aspects of food culture may also influence perceptions (*Flanders, Functional Food*).

This said, however, non-experts also understand and evaluate national economic arguments such as concerns for the research area (*Switzerland, Genetic Technology and Nutrition*). However, economic benefits are not only considered to be associated with the introduction of GM technology, as in agriculture there may be disadvantages from using GM plants for the national agricultural system (*Norway, GM food*). For example, if the organic sector considered particularly vulnerable to contamination with GM plants is prominent in a country, economic losses from jeopardising this sector could be considerable.

More procedural factors have also been proposed as possibly influencing public attitudes, such as communication and participation in decision-making processes. Several reports point to the desire for broader participation and involvement of the public and stakeholders to help ensure that as many relevant questions as possible are addressed. Citizens call for an intensified dialogue between the general public and researchers, and some voted for the public to already be involved in the decision-making processes on GM plants when the technology is at the research stage (*Switzerland, Genetic Technology and Nutrition; Switzerland, The future of plant biotechnology; Flanders, New impulses for the debate on genetically modified food; Austria, Precautionary Expertise for GM Crops*).

Moreover, the importance of understandable, down-to-earth communication about GM plants was identified, although it was emphasised that the social acceptability of GM plants does not only depend on the level of information. In other words, more information does not necessarily mean more people will accept the technology. (*Flanders, New impulses for the debate on genetically modified food; Switzerland, The future of plant biotechnology in Switzerland*). This confirms the criticisms of many social scientists about the "deficit model" of the Public Understanding of Science approach.

PRELIMINARY CONCLUSIONS AND RESULTING QUESTIONS

Public attitudes are a major factor determining the prospects of new GM plants, both for food and non-food purposes. It is therefore important to gain more insight into the possible trajectories of developing public perceptions. However, since perceptions are a result of multi-factorial influences, it will be difficult to predict such a trajectory.

There are contradictory indications as to which direction the development will take. On the one hand, some countries have experienced a loss of acceptance, at least for products from first-generation GM plants. For some people, the label "GM" seems to be associated with deep-rooted aversion, regardless of any actual benefits. The risk issue, especially regarding the environment, has not been settled for good, and general questions of ethics and equity still hamper the prospect of the technology. Labelling and consumer choice might not be the solution for those who consider GM products unacceptable for the latter reasons. This indicates there will be little change from the status quo.

On the other hand, new products promise consumer and health benefits or aim to deliver products other than food, where health risks no longer play the same role. Over time, arguments related economic advantages or ecological benefits may gain a foothold. Such arguments have been brought forward to support the notion that acceptance may improve in the future. In addition, a habituation effect cannot be ruled out once products are on the market.

We conclude that for the time being, it is impossible to seriously predict how public attitudes will actually develop. However, for future regulatory decision-making and strategy building this is not the only important question to be asked. Rather, we think it equally or even more important to know what the experts who influence the shaping of public opinion and who advise regulators and other decision-takers deem to be the most likely development – almost irrespective of whether such a development comes about or not. The perceptions of experts will, for instance, ultimately have an influence on what decision-takers consider relevant for their decisions.

Following this rationale, we devised some questions for our expert survey aimed at challenging our preliminary conclusions on the development of public

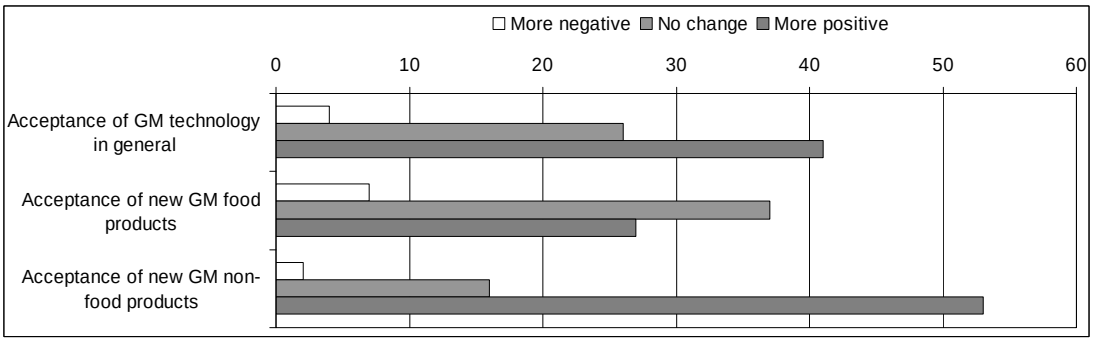
perceptions of GM plants in the future. If policy decisions are influenced by the way experts perceive what the public thinks of GM plants and food in Europe and how ordinary people might act in the future, the question is what do experts consider to be crucial in determining public perceptions. Is it risk or personal benefit? Do common welfare arguments play a role? Will future risk management succeed in assuring confidence? And is it the citizen or the consumer who will decide the future fate of GM plants and food in Europe?

RESULT OF EXPERT SURVEY

PUBLIC ATTITUDES OVER THE NEXT 10-15 YEARS

In order to address these issues, we put the question: "*Will public attitudes to GM crops and food change in the next 10 to 15 years?*" with three sub-questions, in which we asked for the experts' opinions on public acceptance of GM technology in general, new GM food products, and GM non-food products. This distinction is important, as acceptance may vary according to the type of products.

FIGURE 12: **PUBLIC ATTITUDES (*Question 6; n = 71*)**



Question: Will public attitudes to GM crops and food change in the next 10 to 15 years?

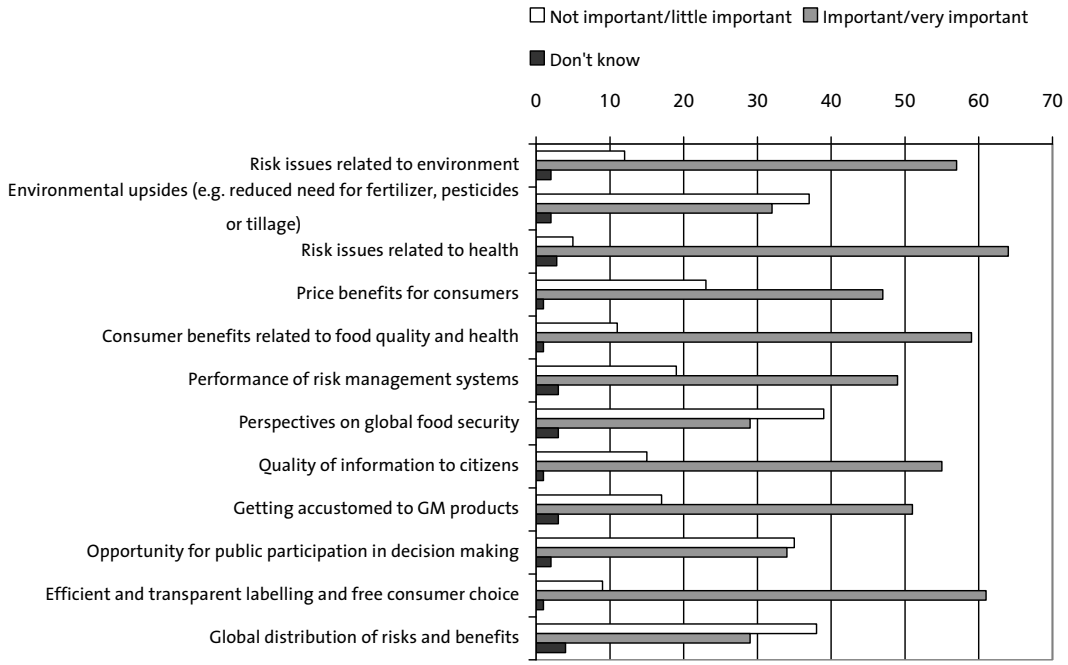
A (small) majority of experts expect a more positive attitude towards GM technology, with an important difference between food and non-food products (Fig. 12). Overall, three in four expected more positive attitudes towards new non-food GM products and only about one in three for new food products. Thus, a majority of experts consider the next generation of GM food products to be met with scepticism. On the other hand, a significant majority expect positive attitudes in relation to non-food products. It should be noted that for all items in the question, industry experts and those from universities and research institutes have higher expectations of a positive change than others.

It is interesting to note that even though only one-third of the experts expect more positive attitudes for new GM food products, half of them expect these products to be on the market within the next 10 years (Fig. 3, Sect. 4.1). Obviously, some experts think that public attitudes will not prevent the marketing of new GM food products. Concerning new non-food products, the number of experts expect public attitudes to grow more positive is about the same as those who expect GM plants for bioenergy, industrials and ornamental flowers to be on the market within 10 years.

INFLUENCING FACTORS

In a second question, we wanted to know which factors may influence acceptance, regardless of whether positively or negatively: "*Currently the consumer acceptance of GM plants and food varies across Europe. Many factors have been associated with public acceptance. Please rank the factors in the list below in their importance for consumer acceptance over the next 10 to 15 years*". The emphasis here was laid on consumer attitudes.

FIGURE 13: FACTORS INFLUENCING PUBLIC ATTITUDES (*Question 5; n = 71)*



Question: Currently the consumer acceptance of GM plants and food varies across Europe. Many factors have been associated with public acceptance. Please rank the factors in the list below in their importance for consumer acceptance over the next 10 to 15 years. Please feel free to add other factors not listed.

The answers indicate that risk will remain an important factor (Fig. 13): Nine in ten experts considered issues related to health risks as important or very important. Interestingly, two-thirds of the industry experts (compared to slightly more than half on average) considered them to be very important. At the same time, four in five (and all of the industry experts) found the factor "consumer benefits related to food quality and health" to be important or very important, suggesting that they might see a possibility that acceptance could improve in case such benefits would materialise.

In previous studies, "price benefits for consumers" were understood as genuine consumer benefits, but citizens did not necessarily look at the price as an important advantage (*Denmark, Genetically modified foods*). Similarly, in our study, experts did not regard price benefits to be as important in influencing public attitudes as food quality and health.

The results suggest that, for the consulted experts, public attitudes would mainly depend on personal health benefits or risks that are associated with GM products. The high number of industry experts emphasising health and food quality supports the idea that industry is aware of the consumer focus on food safety and health issues.

In the same vein, experts considered environmental risk to be high on the agenda. Four in five considered "risk issues related to the environment" to be of major concern in the future, too. In Question 11 (see Fig. 19 in Sect. 4.5), "environmental benefit" was considered to be the most likely aspect to be included in future assessment procedures, which is somehow at odds with the finding that one of the four least-scoring factors for acceptance was "environmental upsides (e.g. reduced need for fertiliser, pesticides or tillage)." This suggests that most experts did not expect this argument, which is often brought forward by industry, to find any public resonance. It could also indicate that experts expect the public to be more concerned about risks to the environment from GM plants than to have confidence in such plants solving environmental problems.

Global issues were considered to be less important for consumer acceptance. Low values for "perspectives on global food security" and "global distribution of risk and benefits" may indicate that experts considered consumers to assess GM products from an individual or European perspective. Likewise, "opportunity for public participation in decision making" attracted low scores. Most directly this could be taken as dismissive of a deficit model, which would hypothesise consumer acceptance to correspond to the level of public participation. On the other hand, those who appreciate the role of such participation in creating acceptance also tend to be more enthusiastic about such participation in general (Question 15; see Fig. 23 in Sect. 4.7). Whether they expect this to result in higher or lower public acceptance remains, however, an open question.

In contrast, information and communication scored highly. Four in five experts considered "quality of information to citizens" to be important or very important, as did almost nine in ten for "efficient and transparent labelling and free consumer choice" (compared with two thirds for "performance of risk management systems"). Thus, they seemed to expect that consumers would focus on safety and on clear and reliable information in deciding whether to buy products, but not on active participation in decision-making.

GM plants have now been produced for more than a decade. A majority of experts seemed to expect that people could get used to GM products. Seven in ten experts (and, again, all industry experts) considered "getting accustomed to GM products" would be important or very important for consumer acceptance.

DISCUSSION

The survey results indicate that experts expect consumers to be sceptical towards GM food products, mainly for reasons of (a perceived lack of) safety for human health and the environment. Together with the finding that they consider consumer benefits to be important factors influencing acceptance, this may reflect a perception that the future of GM plants and products could mainly be a question of personal benefit and risk balancing. This is in line with the finding in Sect. 4.2 that experts consider new GM food crops with consumer benefits to be on the market within the foreseeable future. Apparently, experts think that benefits such as food quality or health effects will foster consumer acceptance. A possible habituation effect is also expected to play a role, while price premiums are not considered to be equally important.

The emphasis on the individual consumer can also be deduced from the weight given to information and communication. This is unquestionably a necessary prerequisite for making an informed choice, both with regard to buying a product and making up one's mind on a political question. In the light of the reluctance to grant importance to the issue of participation in decision-making, many experts seem to conceive the question of acceptance as being resolved by the market – provided full information is granted to allow the consumer to make a rational decision on whether or not to buy – or by established politics.

Expectations are also high with regard to public attitudes towards GM non-food products. However, it is not quite clear how consumers will be able to make choices, for instance where biofuels produced on a GM basis are mixed with conventional fuels. Here, the aspect of the individual consumer making a personal and rational decision clearly has its limits, and the citizen balancing his own personal values is addressed. Citizens' deliberations may be equally rational, but they may also be influenced by more general considerations that do not necessarily concern individual benefits or risks alone.

In contrast to numerous TA reports, where time and again citizens have expressed the opinion that societal issues and ethical concerns should be addressed seriously, many experts seemed to be of the opinion that normative demands would become less important for future attitudes than individual benefit and risk balancing. Were our experts not aware of the societal dimension of the issue? We believe this is not the case: many of them come from countries known to harbour a critical public, such as Austria, Denmark, Germany, Norway and Switzerland, so it is more than likely that they have consciously perceived the ongoing public debate and more general societal and ethical questions.

However, recent survey results seem to indicate that consumers are not very aware of buying food that contains GM products, despite claiming to oppose the use of GM technology for food purposes (Consumerchoice 2008). This seeming discrepancy may relate to the "consumer" expressing buying preferences as opposed to the "citizen" expressing general value judgements. We interpret the opinion of the experts given above as pertaining more to consumer choice. From the point of view of industry and food retail, market acceptance might be considered to solve the problem of alleged public opposition to GM plants and food, while the political issues behind it are more related to values and might remain unaddressed.

From a TA perspective, the ethical and societal arguments frequently brought forward in participatory procedures as well as the results emerging from large surveys that indicate unease in significant parts of the population do not go away, even if some products do find buyers. Rather, they indicate issues that may not only be related to GM plants, such as concerns about the behaviour of regulatory bodies and industry, deteriorating food culture, or increasing dependence on the interests of multi-national companies. These issues, which are related to citizens' concerns rather than those of the consumer, can probably not be comprehensively addressed in the restricted context of a debate on the risks and benefits associated with GM plants, but they also cannot be dismissed as irrelevant either.

FREEDOM OF CHOICE, COEXISTENCE AND LABELLING 4.4

BACKGROUND

For a considerable time, there has been public reluctance to buy agricultural products derived from GM plants. At the same time, the biotechnology industry has promised agricultural producers that the need for inputs will be reduced, yield increased, and environmental benefits provided. Thus, for political reasons, a compromise had to be found that would allow the introduction of such products on the market for producers and consumers without entailing any

consequences for those who, for whatever reason, did not want to cultivate GM plants or buy these products. The latter should be guaranteed a continued supply of products that are GM-free, at least, for practical reasons, under a very low threshold level for unintended GM contens.

In a recommendation released in 2003, the European Commission issued guidelines for member states to ensure the coexistence of GM crop cultivation and conventional and organic farming. Since other regulations on admission to the market took care of environmental and health risk aspects and the labelling of GM products, the purpose of such provisions was merely to allow individual producers and consumers the freedom to choose whether or not to use those GM plants and products allowed onto the market. For farmers, this means that any influences from GM plants onto non-GM plants during production (such as through unintended cross-pollination and volunteering) and harvest (through contamination) must be minimised on a crop-specific basis.

In recent years, states have devised instruments to (a) require GM farmers and actors in the food chain to take practical segregation measures to minimise the chance of intermixing, and (b) make those who fail to take these measures liable for any losses incurred on others. Some states also (c) require actors to contribute to a common liability fund that compensates losses of more diffuse origin. There are thus a variety of measures in place that should guarantee freedom of choice, although some states have not yet fully implemented all required measures.

Controversies arose as to whether coexistence is feasible in practice and whether the ensuing burdens are distributed fairly. The risk of failure to maintain segregation may differ according to crop, but also according to agricultural practices or environmental conditions, and should be subject to regional variations. Some actors claim that coexistence may only be feasible for certain crops, depending on their reproductive biology and/or for a certain scale of cultivation. Others claim that challenges relate mainly to institutional or procedural issues, for instance reaching a general agreement between farmers in a region whether or not to cultivate GM crops. Under the current EU legislation, there is no way of imposing a general decision to use or not to use GM crops in a certain area, as this should be left to individual choice. However, such provisions are up for debate.

Policies aim to maintain coexistence along the entire food chain to ensure consumers have free choice of products with or without GM. GM products must be traced and labelled in order to provide appropriate consumer guidance. However, distinguishing GM products from non-GM products for the purpose of labelling has inspired debate. For instance, there have been controversies over the amount of GM ingredients that can be tolerated in non-GM products. The threshold was set at 0.9 %, provided that the ingredient in question has been through the EU risk assessment and authorisation procedure, and the admixture

is unintended. In addition, some claim that labelling should not be restricted to the marketing of primary products from GM plants, but should also be mandatory for products where GMOs are used as inputs in secondary production, for example meat from animals fed on GM feed.

Finally, the relation between risk assessment, risk management and coexistence is not entirely clear. One interpretation is that these three measures supplement each other. First, it is mandatory to carry out an environmental and health risk assessment before a GM variety is admitted to the market. If any non-negligible risk can be demonstrated, the variety will not be authorised or appropriate measures will have to be taken to mitigate the risk. But even if no risk can be demonstrated, products from GM plants have to be segregated and labelled as such to allow freedom of choice. This rationale implies that while regulatory authorities would ensure that only crops that will be managed safely are admitted to the market, individuals should still be allowed to decide whether to use them or not. According to this interpretation, it would follow that the responsibility to contain risks falls strongly in the hands of regulatory authorities.

Alternatively, coexistence is not only enforced to enable freedom of choice, but also as a tool for risk management. First, coexistence measures would render it possible to trace back and contain risks that suddenly appear and which had not been anticipated during risk assessment. Secondly, there could also be cases where risk assessment concludes that a specific crop will be safe under certain conditions. Coexistence measures would then be necessary to ensure that the crop is kept under these conditions.

The latter approach would be all the more important if food crops were modified for non-food purposes. Such plants might give rise to undisputed hazards if they accidentally intermixed with food crops and entered the food chain. Some substances produced might be poisonous or at least inedible, so crops must be strictly segregated. In addition, the possibility of the relevant genes being transferred and expressed should be kept to the absolute minimum.

Lastly, it is also reasonable to argue that safety is never absolute and that not all concerns can be catered for. Accordingly, coexistence and labelling can be seen as means to enable individuals to pursue their preferences regarding whatever risks may remain. Such risks can take on different meanings. Apart from individual health hazards, risks for the environment that would not necessarily infringe on the individual's personal interests could also be addressed, as could risks of other types (e.g. economic risks to farmers not applying GM crops) not subject to risk assessment.

To conclude, coexistence is intended to provide a way of performing different methods of agriculture in parallel and thus rendering the freedom of choice possible. However, there are indications that the feasibility of coexistence cannot be taken for granted. It remains to be seen whether GM agriculture does not

preclude other forms, in particular organic farming. We therefore wanted to explore whether coexistence schemes can adequately provide freedom of choice for producers and consumers.

RESULTS FROM THE TA PROJECT REVIEWS AND FUTURE ISSUES

A number of TA projects in Austria, Denmark, Flanders, Germany, Norway Switzerland and UK explored coexistence and labelling. However, all projects explicitly dedicated to such issues were undertaken prior to the introduction of the relevant regulation. Thus, there is no ex-post assessment of the actual instruments set in place. Even if it cannot be deduced from these reports whether the instruments available adequately address the problem or not, particular points to consider emerged. The following summary is based on ten reports:

- *Austria, "GMO-free" claims and the avoidance of GMOs in feed*
- *Austria, Coexistence*
- *Denmark, Coexistence*
- *Flanders, New impulses for the debate on genetically modified food*
- *Flanders, Functional food*
- *Germany, Green Biotechnology Discourse*
- *Norway, Coexistence*
- *Switzerland, Coexistence*
- *Switzerland, Genetic Technology and Nutrition*
- *UK, GM dialogue*

In general, the reports underline the need to provide for free choice, not least in response to as yet unresolved risk claims and contradictory opinions on the potential benefits and detriments (*Denmark, Coexistence*). In some countries, coexistence seems to be considered a political solution to facilitate the introduction of GM plants (*UK, GM dialogue*). Free choice implies that correct labelling is provided and that the existence of conventional and organic farming must be guaranteed (*Denmark, Coexistence; Switzerland, Genetic Technology and Nutrition*). To this end, it is mandatory for completely separate distribution channels to be installed (*Flanders, New impulses for the debate on genetically modified food)*.

Several reports come to the conclusion that coexistence is feasible in principle, however, only under certain conditions (*Switzerland, Coexistence; Denmark, Coexistence; Austria, Coexistence*). The European rules for authorising GM plants are adequate in general, but may be leaky in some cases (*Flanders, New impulses*). Since the risk of spreading and intermixing cannot be eliminated, technical precautions must be taken and enforced. Such measures must be tailored to the crop type, the agricultural system and the geography – a point already emphasised in the European Commission's recommendations. Ultimately, it is necessary to consider the scope of cultivation of GM crops as well (*Denmark, Coexistence*). However, in many reports doubts are expressed

as to whether coexistence will be possible for all crops. Even in cases where coexistence appears feasible, the necessary measures to maintain segregation between GM and non-GM plants and their products entail rather demanding crop-specific logistics along the entire production, processing and distribution chain (*Austria, Coexistence*).

The reports frequently highlight practical challenges related to establishing thresholds for unintended GM ingredients in non-GM products. Two fields are considered to be particularly problematic: contamination of organic products and of seed sold as non-GM (*Germany, Green Biotechnology Discourse; UK, GM dialogue*). In both cases, reports quote demands for threshold levels below those foreseen and close to the level of detection, which would be a considerable challenge to industry.

Since intermixing cannot be ruled out, according to many reports, systems of compensation and liability are considered imperative, and it was stressed that rules should be uniform across Europe (*Denmark, Coexistence; Norway, Coexistence; Switzerland, Coexistence; Switzerland, Genetic Technology and Nutrition*). Reports also raise questions about the considerable costs of commitments and measures to minimise the effect of segregation failure, such as extra checks and quality controls, which would raise the costs of non-GM products and would have to be borne by the GM sector (*Flanders, New impulses for the debate on genetically modified food, Austria, Coexistence*).

Some sceptical reports raise doubts as to whether coexistence as conceived by the European institutions would be feasible at all and, even if it were feasible, whether it would be worth the considerable social and economic cost entailed (*Austria, Coexistence, Norway, Coexistence*). In addition, and in the light of doubts about whether unilateral EU policies are possible at all, given the global market for seed, food and feed, any European regulatory approach might be doomed to failure (*Austria, "GMO-free"; Norway, Coexistence*).

Although the general impression from most of the reviews is that labelling is supported in principle, there are also questions over whether consumers can handle a possible information overload (*Flanders, Functional food*). In addition, different interpretations of the term "GMO-free" seem to exist in the public, and there are demands for labelling not only primary products, but also derived, or secondary, ones such as meat from animals fed on GM crops (*Austria, "GMO-free"; Norway, Coexistence*).

Taken together, the reports seem to imply a conditional 'yes' in response to whether coexistence would be feasible, although a general consensus on this question between experts and stakeholders seems to be difficult to reach (*Germany, Discourse*). Elaborate, costly and rather far-reaching measures must be taken in order to guarantee segregation and labelling, and many there questions still remain unanswered regarding the practical implementation and the division of burdens.

PRELIMINARY CONCLUSIONS AND RESULTING QUESTIONS

The proper functioning of coexistence and labelling is a prerequisite for turning the concept of freedom of choice into reality. Despite criticism, it is still considered an appropriate answer to the concerns of both citizens and consumers, the interests of individual farmers who wish to perform very different forms of agriculture and the (often diverging) interests of trade and industry.

The question is whether coexistence is feasible and, if so, for which crop, under which conditions and at which costs. While the reports reviewed (theoretically) seem to provide a cautiously positive answer, the lack of experience so far and some incidence of contaminations that have occurred over recent years in other countries preclude a final judgement. Whether coexistence is now feasible and will be so in the future depends mainly on whether the instruments for coexistence can be shown to work for "first-generation" GM plants. In particular, it will be crucial to see whether all GM products that qualify for labelling in principle will also be so in practice. This, however, can only be assessed if the relevant products are placed on the market, which again is subject to the proper functioning of coexistence. It seems that we have a catch 22 situation regarding the answer to the question whether coexistence can function.

RESULTS OF THE SURVEY

WILL COEXISTENCE WORK FOR FIRST-GENERATION GM PLANTS?

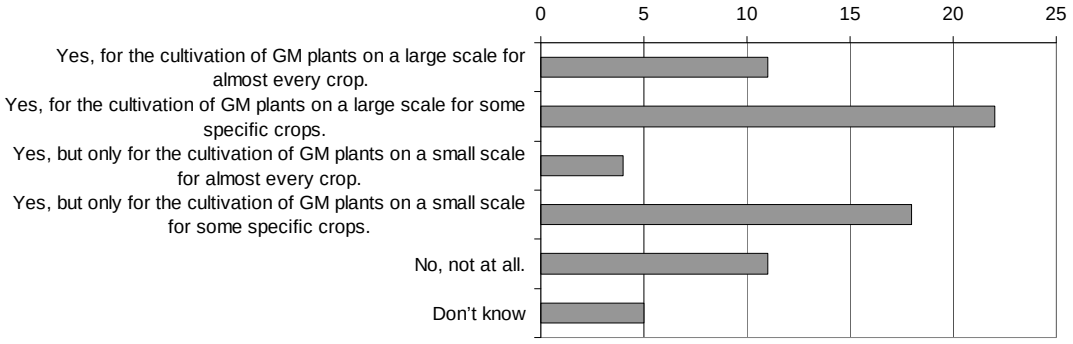
In the light of different answers given in the project reviews, we wanted to know whether experts thought that coexistence would work for "first-generation" GM plants (e.g. insect- or virus-resistant and herbicide-tolerant plants) over the next 15 years.

Overall, it emerged that opinions among the experts approached were split (Fig. 14): roughly one-third of the respondents thought that coexistence might work for some specific crops for large-scale cultivation, compared to one-quarter who considered it would work only for cultivation on a small scale. One in six expected that coexistence could work on a large scale for almost every crop, while a similar number thought it would not work at all. Experts from industry had more confidence in coexistence, with 8 out of 11 expecting that coexistence would work on a large scale.

In their comments, respondents further explained their views. A respondent who believed coexistence could work stated: "*Only for a few crop types in certain small scale farming regions will it be very difficult for GM crops to coexist.*" A more sceptical respondent referred to historical examples: "*Contamination is unavoidable, e.g. StarLink, US rice, etc. There are too many places where contamination could take place, so it is impossible to separate.*" Somewhere in

between, another respondent argued crop-specifically: "*In my opinion coexistence might be possible for non-food potatoes but not for canola or sugar beet.*" A respondent who ticked the "Don't know" option enlarged the view from the purely technical to the organisational level: "*I'm sure that technically efficient measures can be devised for some crops in some places (and not for others). However, I'm less confident the industry is ready for such a clear commitment to the polluter pays principle.*"

FIGURE 14: WILL COEXISTENCE WORK FOR FIRST-GENERATION GM PLANTS?
(Question 7; n = 71)



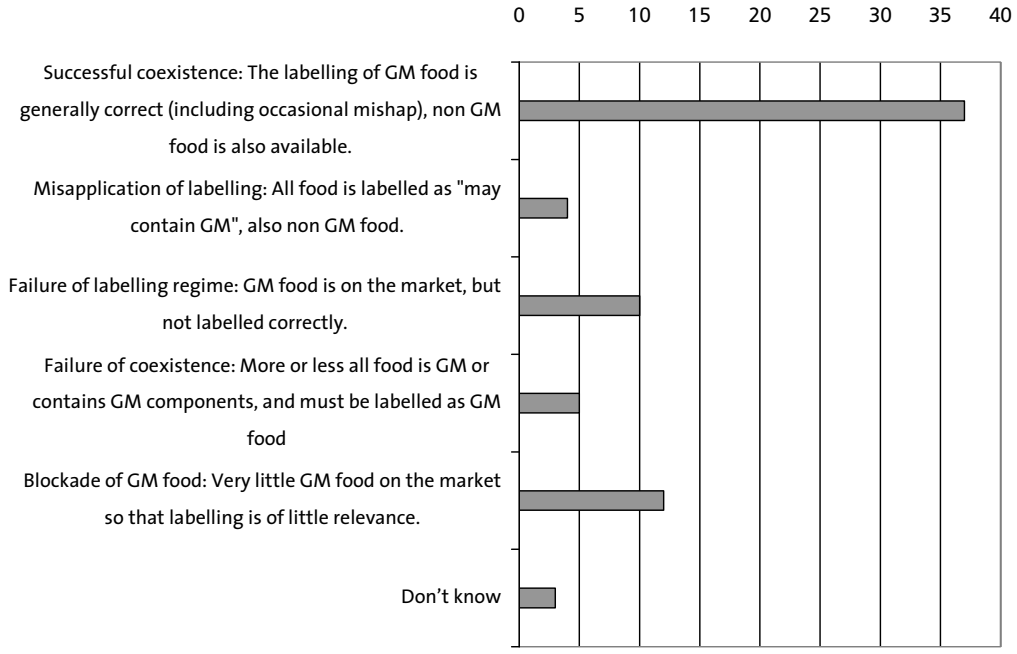
Question: Coexistence measures are a central part of risk management under GM-cultivation. Coexistence is also a central prerequisite for freedom of choice. Coexistence may be a challenge, depending on type of crop and location. Do you think that coexistence will work for the "first-generation" of GM plants (e.g. insect-resistant, herbicide-resistant and virus-resistant (VR) plants) in the next 15 years? (Please tick one possibility).

In conclusion, responses to this question indicated that the issue of coexistence has not been settled and a consensus has not yet been achieved.

CAN CONSUMER CHOICE BE MAINTAINED?

Question 9 (Fig. 15) was reciprocal as it covered a similar issue, this time viewed not from the producers' but from the consumer perspective. Referring to the close connection between coexistence and labelling, we asked the experts for their opinion on which of five different scenarios they expected to come true regarding the possibility of maintaining consumer choice. Notably, the majority of respondents believed that coexistence and labelling would work generally (Fig. 15). The second largest group of respondents, however, considered that GM food would only play a marginal role in the future. The other alternatives offered were attracted fewer responses. Thus, respondents did not believe that European consumers are about to experience a lack of GM-free alternatives.

FIGURE 15: CAN CONSUMER CHOICE BE MAINTAINED? (*Question 9; n = 71)*



Question: Coexistence and labelling of GM food are closely connected. There are different opinions over how well the current EU regulations would cope with the extended use and growing of GM plants in Europe. Please indicate which scenario in your opinion is most likely. (Please tick one scenario)

To further analyse how respondents saw the relationship between coexistence and labelling we compared responses to Question 9 and Question 7. It was evident, for instance, that those who supported the scenario of successful coexistence/correct labelling in Question 9 had diverse perspectives on the feasible scale of GM-cultivation in Question 7. And vice versa: a high proportion of those who did not show any confidence in coexistence in Question 7 thought that GM food would generally be blocked from the market in Question 9.

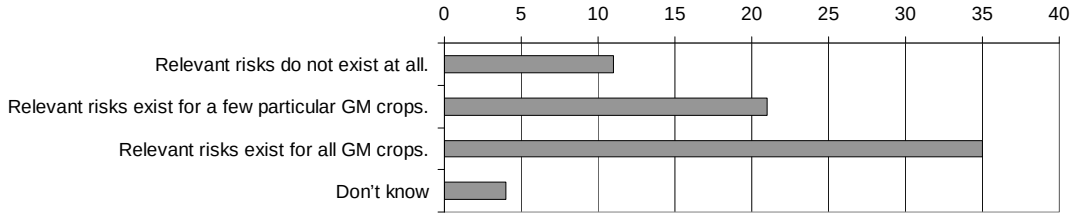
A respondent who ticked the "successful coexistence" option commented: "(….) *it is highly questionable whether non-GM food will be available in the future. Of highest importance is the question of seed and threshold levels for non-GM seed.*" Another expert stated that "*the reality is a blockade of GM food on the market, but one could have successful coexistence allowing up to 0.9 % of approved GMs in products* (….)." In addition, one respondent questioned the wisdom of leaving everything to consumer choice alone: "*Labelling is important in relation to human health concerns but hardly addresses the environmental risks.*"

DO COEXISTENCE SCHEMES ADDRESS RISKS?

The latter remark brings us back to the discussion from the Introduction of whether coexistence and labelling merely provides for freedom of choice, or also is part of risk management. From this discussion we can deduce a controversy over whether current risk assessment, as a basis for coexistence schemes, will be able to contain all relevant risks. If not, risks not covered could possibly be passed on to third parties, which is considered problematic. In Question 8, therefore, respondents were asked to provide their views on whether there could be relevant environmental or economic risks that would not be contained by current risk assessment and coexistence schemes.

The majority of respondents believed that risks might occur that would not be contained by current risk assessment and coexistence schemes, while only one in six believed that such risks do not exist at all (Fig. 16). Almost half of the respondents thought that such risks might occur for all GM crops. To further explore the judgements of the sub-sample who believed risks remain, we asked how serious they considered such risks to be and whether they found it feasible to come to a fair distribution of risks and burdens. The question allowed multiple responses.

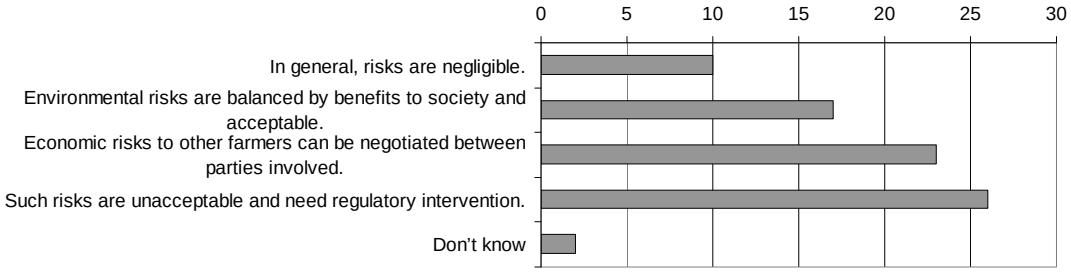
FIGURE 16: DO COEXISTENCE SCHEMES ADDRESS RISKS? (*Question 8A; n = 71)*



Question: For the cultivation of GM crops some experts have discussed whether there could be relevant environmental or economic risks (e.g. to farmers not applying GM crops) that would not be contained by current risk assessment and coexistence schemes. Please tick the statement that comes closest to your opinion.

Only one in eight responded that remaining risks are negligible, and, taken together with those who believe they do not exist at all (mentioned above), these two groups make up an total of 20 respondents (Fig. 17). At the opposite end of the spectrum, one in three (26) found the remaining risks to be unacceptable and to require regulatory intervention. The remaining respondents, approximately one in four, can be interpreted to judge that risks remain that should not be ignored but could be handled by current regulation.

FIGURE 17: HOW TO MEET RISKS? (*Question 8B; n = 56)*

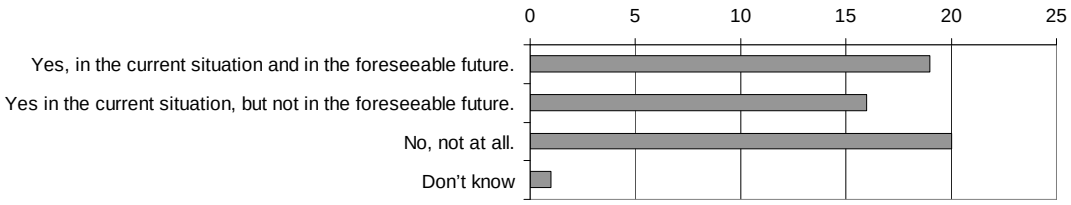


Question: If you think that relevant risks might exist [*in question 8A*], please tick those statements that come closest to your opinion (multiple answers possible).

The strong call for regulatory intervention contrasts with the rather lower rejection of coexistence and labelling discussed in previous sections. One explanation may be that saying "coexistence will not work at all", as in the previous section, is a more categorical rejection than saying "there are risks that would not be contained by current coexistence schemes, and such risks are unacceptable and need regulatory intervention", which permits solutions other than rejection.

Against this background, the next question explored whether the same sub-sample of 56 respondents deemed current regulations sufficient. One in three (of the sub-sample) agreed, while more than one in three found them entirely insufficient (Fig. 18). Somewhat smaller was the number of those who considered them adequate today but expected problems in the future.

FIGURE 18: ARE REGULATORY PROVISIONS SUFFICIENT? (*Question 8C; n = 56)*



Question: Do you think that current regulatory provisions are sufficient to deal with such risks [*see question 8B*], today or for the foreseeable future?

The 36 respondents who found current regulations insufficient, now or in the future, were further asked how these risks should be addressed. Rather than new regulation, stronger liability and new approaches to risk assessment were the most frequently mentioned remedies.

DISCUSSION

Can coexistence be considered a viable concept, and will it work? Without coexistence, no sensible labelling would be possible, and the freedom of choice could not be realised. Indications towards an answer in one or the other direction have been inconclusive so far.

Many experts believed that GM food will be labelled correctly and that non-GM food will continue to be available, indicating confidence in current systems of traceability and labelling. According to Question 7 (Fig. 14), most respondents in our expert survey expected coexistence to work in general, which is in accordance with the majority of the TA reports reviewed.

However, at the same time, both the reports and the expert survey indicated that coexistence might be rather intricate and dependent on many conditions. We can take this as a reason why a number of our respondents have no confidence in current coexistence schemes. Apart from those who bluntly reject the overall approach to coexistence for one reason or another, some respondents believe that coexistence could work for crops with a certain reproductive biology only and/or provided that certain precautions are taken, including a consideration of the scale of cultivation.

In conclusion, coexistence may be considered a viable concept, but one that would be difficult to realise for all crops and perhaps impossible under certain circumstances (INRA 2008). Agronomic research results show that it may depend on the individual case, the crop, the plant variety, the location and the agricultural context (neighbouring crops, field size, etc.) whether coexistence is deemed to work or not. Therefore, it is not surprising that answers to the initial questions are found to be contradictory.

Some light may be shed on the reasons behind this discrepancy by considering risk aspects, even if coexistence was intended as a means to escape from, or to circumvent, contentious risk debates. Despite widespread expectations that coexistence as such may be implemented, almost half the respondents expected current schemes for risk assessment as a prerequisite for coexistence to be insufficient to contain all relevant risks. Some may have thought the assessment might not be able to cover risks adequately, or they might have considered particular topics relevant that are not subject to risk assessment. In other words, under the auspices of coexistence the debate on risk has not come to a halt.

If current provisions are not considered to be sufficient, this points to the need to recalibrate approaches to assessing, authorising and/or managing GM crops. Some respondents put their hopes in a compensation system, which directs attention to the fair distribution of the benefits from cultivating GM crops and the burdens from unintended consequences. Therefore, a discussion of benefits and the aims of agriculture appears necessary.

BENEFIT ASSESSMENT AND AIMS IN AGRICULTURE 4.5

BACKGROUND

Ever since the need for assessing possible risks of GM plants became topical, criteria have been a point of discussion. Various reports have thrown up the question of whether today's assessment criteria are adequate. A particular point where opinions diverge is whether benefit should be taken into consideration, and if so, what "benefit" means.

The European regulation of GM plants only foresees an assessment of environmental and health risks. Nevertheless, the Norwegian regulatory approach also includes an obligation to consider "benefits to society". In the German law which aims to promote genetic engineering, benefits are at least indirectly included in the regulation. In this latter case, however, only risks to human health and the environment are currently considered in practice, while societal or moral concerns are considered impossible to assess objectively. Similarly, The Austrian law governing genetic engineering stipulated in its original form that genetic engineering applications should not be socially unsustainable, but this could not be translated into regulatory criteria.

Over recent years, and separate from debates on risk, a public debate has developed on the benefits of GM plants and food. Here different arguments have been introduced. On the one hand, it was argued that the first generation of GM plants provided benefits to farmers only (if at all), and that they carried no benefits for consumers. Accordingly, if uncertainties in risk assessment remained, they were considered unacceptable. This highlighted the question of the degree of risk that might be acceptable or conversely, what degree of risk could constitute a veto.

On the other hand, it was expected that a new generation of GM plants would bring benefits for consumers, such as increased nutritional properties, which should be weighed against potential risks. GM plants might also replace conventional plants and processes that were also not risk-free, or they might reduce other risks. Thus, at least in public debate, there is a discussion that benefits might possibly outweigh certain risks.

For policy-making, the problem is how to respond to demands for considering benefit or the lack of it in dealing with the issue of GM plants. One option would be to consider benefit at a political level, without formally integrating its assessment into the case-to-case authorisation procedures. This would imply general policies such as the decision to promote those GM applications that carry a consensus that they would bring societal benefit, or to promote alternative pathways if not. Currently, opinions seem to be deeply split on this issue.

Another possibility would be to explicitly devise a case-based assessment in the authorisation procedures for products, but there are few precedents for such an approach. So far, the most prominent example is with the authorisation of drugs, where such an approach follows acknowledged criteria for efficacy and lack of side effects and further involves a comparison with established drugs.

For transgenic crops, both the criteria and the comparator are contested. So far, the normative framework for regulating novel agricultural varieties is derived from the sum of current aims of the established practice in agriculture. This framework is in principle applied to GM plants as well; in other words, they must (at least) meet the same criteria as "conventional" non-GM plants cultivated in today's agriculture. However, even these conventional aims of agriculture are under discussion and continue to shift, as can easily be deduced from the debates surrounding the formulation of the European Common Agricultural Policy. New developments such as the quest for sustainable agriculture might interfere with more traditional aims such as high productivity.

In addition, tasks other than producing food have been assigned to the agricultural system, such as landscape protection or providing a basis for tourism, leading to increased importance for the concept of multi-functional agriculture. Such multiple tasks might also have an influence on how the risks or benefits of growing particular GM plants might be assessed in the future. Such very basic considerations have influenced the debate on GM, conventional and organic agriculture, and tap into a variety of issues in different countries. Therefore, specific domestic aspects cannot be discounted when the options for including benefit in the assessment criteria for GM plants are discussed.

RESULTS FROM THE TA PROJECT REVIEWS

Several reports from EPTA members came up with the issue of benefit assessment in various contexts. This summary is based on the following reports:

- *Denmark, GM crops in developing countries*
- *Flanders, Functional Food*
- *Germany, Green Biotechnology Discourse*
- *Germany, Risk assessment and post-marketing monitoring*
- *Norway, Sustainability and societal impact of GM food*
- *Switzerland, Future of plant biotechnology*

Three main questions come to mind that would be necessary to address: firstly, the kind of benefits discussed; secondly, the way such benefit could be assessed, and thirdly, the way the result of such assessments could be taken into account.

With regard to the kind of benefits, several potential ones have been assigned to GM plants. For example, certain GM crops are said to assist in ensuring sustainable agricultural production and food supply particularly in Third World countries (*Denmark, GM crops in developing countries)*. On the domestic front,

consumer benefits might arise from GM foods in the form of improved food products which lead to healthier nutrition (*Germany, Green Biotechnology Discourse)*. There might even be scientific evidence of health benefits from GM functional food products to be taken into account. However, proving them might be difficult (*Flanders, Functional Food*), and a consensus over whether and what kind of a benefit could be expected seemed difficult to establish (*Germany, Green Biotechnology Discourse*). An interesting perspective comes from a Swiss lay panel that established a link between benefits and a particular understanding of risk: accordingly, if the potential benefits from GM plants are not be realised in the future because research on them does not take place today, this might be considered a risk (*Switzerland, Future of plant biotechnology)*.

Various views were expressed on how to assess benefit. Here, the ruling normative framework determines the choice of criteria. However, few reports explicitly highlight the normative dimension arising from the multi-tasking nature of agriculture. The issue came up when a normative framework for desirable agricultural practice or sustainable agriculture was considered to be missing (*Germany, Risk assessment and post-marketing monitoring)*. The most elaborate investigation came from Norway, the country with most experience in discussing benefit criteria. It came to the conclusion that any kind of pragmatic benefit assessment would have to rely on checklists to be amended case-specifically according to the properties of the product and the contingencies of its production and use. Where the necessary information for such an assessment could be derived from, however, remained unclear (*Norway, Sustainability and societal impact of GM food)*. Benefits might also be assessed indirectly through comparative risk analysis: risks related to a new technology such as GMOs could be compared to the risks of the technology it is replacing, which might be considered a benefit (*Switzerland, Future of plant biotechnology)*.

Thirdly, where a benefit can be established, how should this be taken into account in regulatory decision-making? Norway is the only country so far where benefit assessments have been officially integrated in the authorisation procedure for GM plants. Here, an assessment of societal benefit as well as of the contribution to sustainability is mandatory even for experimental releases; however, its implementation has not yet been fully accomplished (*Norway, Sustainability and societal impact of GM food)*. One question was whether benefits should be considered as an additional requirement or a factor that might soften up the requirement for the absence of risks for health and the environment.

Implicitly, and irrespective of whether benefits can be demonstrated in an assessment or not, the Swiss lay panel emphasised that the relation between scientifically established risk and societal preferences must already be balanced today. Since a zero risk level cannot be achieved, an acceptable level of risk had to be determined (*Switzerland, Future of plant biotechnology)*.

PRELIMINARY CONCLUSIONS AND RESULTING QUESTIONS

While the idea of taking benefits into account is attractive to many, the implementation of a workable system of assessment, the establishment of relevant criteria and of an acceptable way of incorporating the findings from such an assessment into regulatory decision making remain to be solved. In other words, the practical dimensions of benefit assessment must be determined. It is therefore unclear whether such assessments will ever become reality. What are the criteria, if indeed there are any, against which benefit might feasibly be measured?

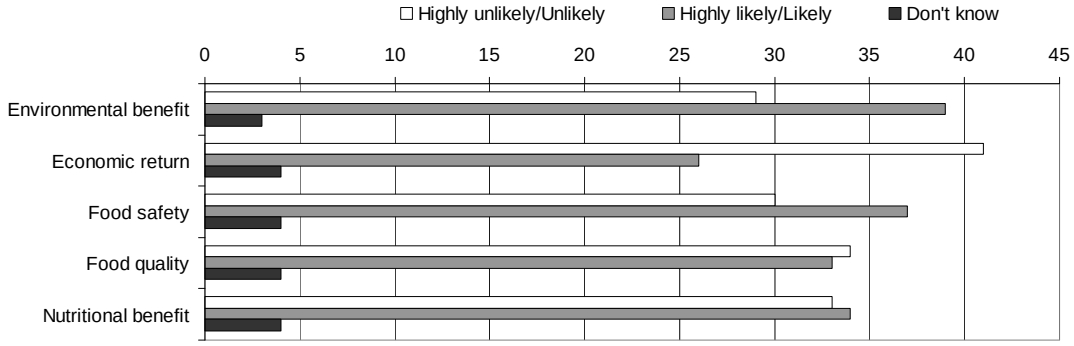
Closely linked to the question of whether and how to assess benefits is the question of aims in agriculture. A benefit can only be measured according to a particular aim, and what might constitute a benefit for one aim might be detrimental to another competing aim. Which aims will gain in importance in the future?

RESULTS OF THE QUESTIONNAIRE

BENEFIT ASSESSMENT

Different forms of assessment can be envisaged that take into account parameters other than environmental and health risks. We, therefore, wanted to know whether experts could consider criteria other than risk (in conventional terms), in particular whether it was considered acceptable and feasible to include benefits in the assessment of GM plants, as is the case with pharmaceuticals.

FIGURE 19: BENEFIT ASSESSMENT (*Question 11; n = 71)*



Question: So far, the assessment procedures for GM plants and food only takes into account potential risks. Some actors have advocated that also potential benefits should be taken into consideration as applied in areas such as pharmaceuticals.
Below is a list of potential benefits that could be included in such considerations. Please assess how likely it is that in future different benefits will be considered for GM approvals. Please feel free to add other groups not listed.

The responses showed that experts were split over the likelihood that benefits would be considered for GM approvals (Fig. 19). A majority of respondents thought it likely that environmental benefits would be taken into such consideration, while the opposite is true for pending economic return. The experts were divided on the likelihood of taking food quality and nutritional benefits into consideration, while a slight majority considered food safety a probable field where benefits could be taken into account in the future.

Despite the substantial proportion of those who considered the consideration of benefits likely or very likely, many comments emphasised the regulatory difficulties involved in such a step. One respondent expressed that "*there are a number of serious difficulties in the inclusion of extensive benefit analysis. However, it is something that clearly could be considered*." Another questioned whether licensing is the right place to include a benefit assessment: *"Regulators only take care of risks. The Market takes care of the benefits and the risks."* Obviously, for this expert benefits could only be conceived on a personal level amenable to market forces.

Benefits were clearly considered subject to interests and values, in contrast to health risks that were deemed unacceptable to everybody. A number of respondents highlighted that drug assessments were the only example in product regulation where benefits would be taken into consideration, and contrasts were drawn: "*In the health sector people are willing to take a risk if there is enough benefit. In GM crops people will not be willing to take any risk"* and: *"taking pharmaceuticals, we consider that we may have to take risks. Eating food is something different."* Medical benefits usually were seen as weighing heavier than possible side effects if people were to regain their health – but food consumption as an important part of everyday life was considered different, and risks deemed unacceptable.

Some comments addressed the issue of comparisons between conventional and GM crops. They proposed attributing a benefit to conventional crops compared with their GM counterparts due to the absence of uncertainty associated with the technology, all other parameters being equal. Support for such systematic and a priori suspicion of risk with GM crops, however, was only encountered sporadically among the comments. In addition, public perception remained a controversial problem. Although *"these initiatives may substantially improve public perception, and so potentially pave the way for profitable GM crop production"*, another expert stated that *"…in the current public perception setting, I don't believe that positive considerations would be taken into account."*

AIMS IN AGRICULTURE

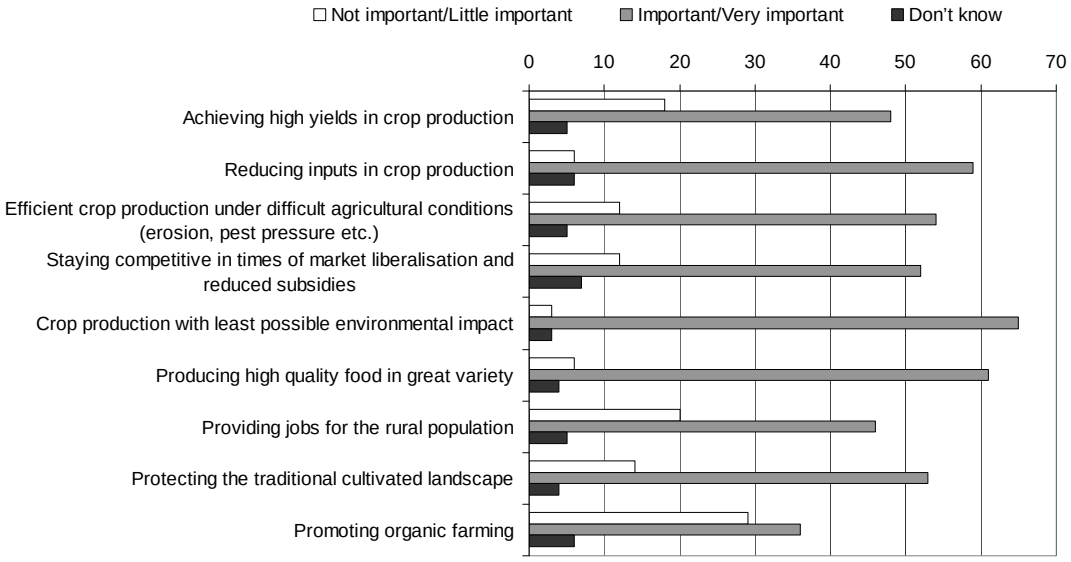
In order to determine whether a GM crop conveyed a benefit, it would be necessary to know which aims are assigned to agriculture at large. For comparative risk assessment, too, aims are important because comparisons must

be drawn with established practices in agriculture. In Europe, these practices vary according to climate or soil, but also according to the tasks assigned to agriculture. For example, in addition to efficiently producing crops or providing jobs, agriculture is called to protect the traditional landscape and the natural environment. Thus, agriculture must pursue different aims, against which the performance of GM cultivation could be measured.

In the light of a certain lack of coverage in the reviews, we wanted to know which tasks of agriculture respondents considered likely to become salient in the foreseeable future. We presented a list of tasks and asked the experts to rank them.

In total, the majority of experts agreed that the aims for future agriculture proposed in the questionnaire would become salient (Fig. 20). For most aims, those who ranked the aim to become important outnumbered the others by at least two to one. The only exception pertained to the promotion of organic farming, whose salience was doubted by two in five experts. This probably reflected the controversial nature of the debates on organic farming among proponents and opponents.

FIGURE 20: **AIMS IN AGRICULTURE (*Question 12; n = 71*)**



Question: In order to assess risks and benefits of GM cultivation, it must be compared to established practices in agriculture. In Europe, these practices vary according to climate or soil, but also to the tasks assigned to agriculture. For example, and apart from efficiently producing crops or providing jobs, agriculture should also protect the traditional landscape and the natural environment, among others. Thus, agriculture must pursue different aims, against which the performance of GM cultivation will be measured. Please rank the aims in the list below in their importance over the next 10 to 15 years.

The most unanimous vote was seen for crop production with the least possible environmental impact, which more than nine in ten expected to become important. Only slightly less popular with the experts was the production of high-quality food in great variety and reducing inputs in crop production. This again could be seen as relating to minimising environmental impact. Following this argumentation, there seemed to be a consensus among the experts that the general aim of sustainable agriculture would likely be a guiding principle in the future.

However, caution must be applied in interpreting the results since they may reflect different conceptions of the underlying basic terms. For example, environmental impact has always been difficult to define, and the future conditions of agriculture (such as pest infliction or drought) are difficult to foresee.

DISCUSSION

Experts were split over the likelihood that assessing benefits would be part of future assessment procedures, but a substantial proportion think it likely. Considering the doubts expressed in some comments, the question arises as to why there is such a support. One reason simply might have been the wording in the questionnaire, where the word "consider" rather than "assess" was used. This might have allowed an interpretation that topics were to be considered on a general level and not in the case-by-case assessment and approval procedure.

On the other hand, environmental benefits turned out to be considered more likely to be implemented than economic criteria, which might reflect a general emphasis on the aim of state action in sustaining the public good rather than safeguarding individual benefit. It might also indicate the implicit aim on the part of some experts to pass over problems of acceptance in a situation where the benefits of GM plants, in the opinion of some, might not be sufficiently appreciated.

This raises the question of who could be considered to benefit from the introduction of benefit assessments in some form. It could work in different directions; some may argue that if a GM crop does not bring additional benefits, this should veto the crop entirely. On the other hand, GM advocates would hope that the consideration of environmental benefits would strengthen their case.

The main question remains as to the level, if there is one, at which such state action should be implemented in order to make it both practically sound and politically legitimate. Should it be at a political level, with open commitments for particular forms of agriculture such as promotion of high productivity, large-scale production or of small-scale, diversified and/or organic farming where possible and desired? Or should it be at a regulatory level where formal

procedures are incorporated? As comments suggested, the latter seems to be hampered by some rather basic problems. From a practical point of view, there are almost no examples of benefit assessment in product authorisation procedures to draw upon, apart from medical substances and devices. For the latter, societal benefits have always been linked to health gains, which can be established by scientific means.

From the perspective of political legitimacy, societal benefit is difficult to determine because of a lack of generally accepted criteria. Usually, marketable products are considered to deliver personal benefits in the first place, and the market is considered to be effective in determining such personal benefit and providing the appropriate signals to producers. In contrast, societal benefit, if accepted to be different from the sum of individual benefits, is a much less obvious concept. If it is considered at all, it is often deemed subject to political preferences rather than market forces, and generally accepted methods to determine such benefit are difficult to establish. It remains to be seen whether a suitable regime can be found that will live up to the expectations entertained by some with regard to benefit assessment.

The normative framework at the basis of any benefit assessment depends on the acknowledged aims in agriculture. From the survey, it appeared that reducing the input and impact on the environment while sustaining food quality and variety were expected to become salient in the future. Such a result is not very surprising, as the aims mentioned can be considered part of the sustainability propagated as the overall frame for future European agriculture (and in other world regions). Nevertheless, the clear result is noteworthy; reducing input and environmental impact while sustaining high quality is obviously considered almost indisputable among the participating experts. By contrast, the promotion of organic farming has attracted more doubts. It seems to be too controversial an approach for a future paradigm for agriculture. This suggests that conventional farming will remain a central starting point for a more sustainable agriculture.

Nevertheless, it remains a matter of a broader debate whether the aims experts regarded as likely to be dominant in the future would become so in reality. There are many competing aims, including those directed towards mostly economic parameters, which may become more dominant in the future. If GM plants are to find a place in European agriculture, they will have to fit into the aims pursued by a future agricultural system. Thus, their future is dependent on the developments of this system rather than on particular pieces of legislation alone.

GLOBAL ASPECTS OF GM REGULATION 4.6

BACKGROUND

The trade in agricultural (and food) products has increased substantially over the last 20 years with the expansion in trade by leading export and import countries and with new countries participating in the globalisation of markets. In the current round of multi-lateral trade negotiations in the WTO, the so-called Doha Development Agenda (DDA), major objectives include the further opening of the market and the relationship between WTO rules and multi-lateral environmental agreements. Discord on agricultural issues was one of the main reasons why DDA negotiations have not yet been successfully concluded.

The practice of GM regulation in the EU was previously already challenged before the WTO. In 2003, the United States, Canada and Argentina complained about the delay in approving and marketing new GM crops (the so-called de facto moratorium) in the EU, which was considered to go against WTO rules. The WTO dispute settlement panel came to the conclusion that the EU had violated the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) (WTO 2006) by

- An alleged general EU moratorium of approving GM products for commercialisation,
- Product-specific SPS measures,
- EU Member State safeguard measures against GM products.

The EU defended its regulatory regime with reference to its Cartagena Protocol on Biosafety commitment, which takes a precautionary approach to regulating GMOs. The WTO dispute settlement panel rejected the precautionary defence of the EU and ruled that the Cartagena Protocol is not relevant if disputants are not party to the agreement. In this way, the panel accentuated the schism between the WTO and the United Nations system. However, there could have been an alternative: The panel could have declined to rule, given the lack of consensus on risk assessment and risk management options in multi-lateral agreements (Suppan 2006). This means that at certain times different systems of international agreements can come to different conclusions regarding risk regulation. There is reason to believe that conflicts between differing agreements and approaches on trade and risk regulation will be with us for some time.

Substantially, the WTO ruling could be seen as indicating that only those restrictions that are rooted in the demonstration, if not proof, of particular risks would be acceptable within international trade regulations. This highlighted not only the different approaches taken by the US and its allies, on the one hand, and the EU, on the other: It also became obvious that among EU member states, the implementation practice differed to some extent, despite a common

regulatory framework, so that some Member State's practices came into conflict with WTO rules.

RESULTS FROM THE TA PROJECT REVIEWS AND FUTURE ISSUES

The solution to such controversies remains open. Although this could turn out to be an important topic for future regulation of GM plants in Europe, most TA reports over recent years have only addressed international issues in passing. The reports reviewed also concentrated on the debates and regulation in their own countries of origin and in the EU. A small number of reports assessed the risks and opportunities for GM crop use in developing countries. In all cases, the global aspects of GM regulation were not the main focus. Nonetheless, a number of reports did address the global increase of GM crop acreage, the question of international trade conflicts, the development of international GM regulations and the different approaches to risk assessment and regulation in some way. The following points are based on information from six reports

- *Austria, The Role of Precaution in GMO policy*
- *Germany, Green Biotechnology Discourse*
- *Norway, Reconvening the lay people's panel on GM food 4 years after*
- *Norway, Sustainability and societal impacts of GM food*
- *Switzerland, Genetic Technology and Nutrition*
- *UK, GM dialogue*

In the first place, regulatory challenges were identified in the context of international dependencies and international harmonisation. One of the challenges identified was how the EU would respond to the WTO dispute panel's findings on the implementation of GM crop regulations in the EU (*UK, GM dialogue)*.

Furthermore, there was a demand for laws and regulations to be co-ordinated at the international level *(Norway, Sustainability and societal impact of GM food*). Two countries within Europe that are not EU member states, Switzerland and Norway, maintain a close relationship, but retain regulatory approaches to GM plants that differ in some respects from those in the EU. Proceeding from the specific regulations in Norway and Switzerland, reports from these countries identified challenges for their unilateral policies:

- As an open question, it was discussed to what degree a unilateral Swiss policy is possible, and to what extent there is a need to use of GMOs in Switzerland *(Switzerland, Genetic Technology and Nutrition)*.
- The criteria of sustainability and societal benefit in the Norwegian legislation appear to be unique and raise questions of access to relevant information about the products and the willingness of applicants to provide such data just for Norway. In consequence, Norway cannot fully undertake the relevant assessments, and due to this lack of documentation, Norwegian authorities may end up not authorising any given product. However, the EU might not

> consider such terms legitimate for rejecting an authorisation, which might be necessary under Norway's commitment as member of the EEA. Thus, a number of questions regarding the harmonisation of regulation within the EU/EEA remain. *(Norway, Sustainability and societal impact of GM food)*.

Another considerable challenge identified is to find ways to proceed from the precautionary principle to an applicable approach and concrete actions, and to define its relation to the risk assessment framework. The precautionary principle should not be used as a technical barrier to trade or a tool for protectionism (*Austria, The Role of Precaution in GMO policy*). The further definition and operationalisation of the precautionary principle was specified as a task in various reviews (*Austria, The Role of Precaution in GMO policy; Germany, Green Biotechnology Discourse)*.

One argument taken up by several reports was that the "sound science" approach (as prevalent in US policies), with its tendency to delay safety obligations until the causal chain between a harmful impact and its source has been fully established, runs counter to the precautionary principle. This underlies several pending or already manifest conflicts between the US and EU (as materialised in the WTO dispute). The EU could possibly build on a "de facto coalition" with developing countries in favour of the precautionary principle in order to strengthen its position and promote its understanding of precaution (*Austria, The Role of Precaution in GMO policy)*.

In summary, conflicts involving WTO regulations in the context of applying the precautionary principle and/or sustaining unilateral safeguard measures were identified as important future challenges for current European regulation.

PRELIMINARY CONCLUSIONS AND RESULTING QUESTIONS

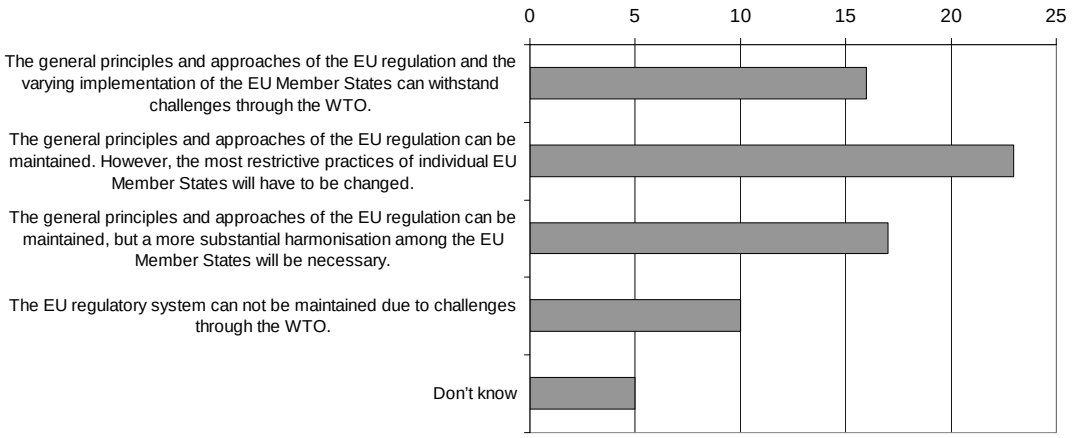
It is probable that in the future, more types of GM crops will be released, both in exporting countries and in Europe. Therefore, there is a possibility that, in the future, the US and other countries might continue to challenge the current EU regulation which is based on the precautionary principle and the case-by-case risk assessment and authorisation that is so far mandatory. To explore the judgments of the experts, two questions on global aspects of GM regulation were included in the questionnaire. One question pertained to the consequences *for* the EU regulation and the other to the consequences *of* the EU regulation, in other words, on its future robustness and on its future influence on non-European countries.

RESULTS OF THE EXPERT SURVEY

In the light of the increasing global use of GM crops and WTO conflicts, and with regard to the consequences for EU regulation, the experts saw a good chance that the EU regulatory system for GM crops and foods might survive

(Fig. 21). Only a minority (one out of seven respondents) thought that the EU regulatory system could not be maintained due to future WTO challenges, etc. Nearly four in five were convinced that at least the general principles and approaches of the EU regulation could be maintained.

FIGURE 21: ROBUSTNESS OF THE EU REGULATORY SYSTEM (*Question 13A; n = 71)*



Question: It is probable that more types of GM crops will be released both in export countries and in Europe. The current EU regulation, based on the precautionary principle and case-by-case risk assessment and authorisation, might be challenged by the US and other countries also in the future. Please give your judgement on how robust the EU regulatory system will turn out to be to challenges for example at the WTO in the next 10 to 15 years. (Please tick one possibility)

This question also addressed the topic of varying implementation of the EU regulation in the EU Member States and what this means in the context of WTO challenges (Fig. 21). One in four respondents assumed that the varying implementation by the EU Member States could withstand challenges from the WTO, while more than half of the experts (40 respondents) expected that restrictive practices of individual EU Member States would be challenged. Of the latter, 23 respondents (or one-third of all respondents) found that the most restrictive practices of individual EU Member States would have to be changed, while 17 answered that more substantial harmonisation among the EU Member States would be necessary. Together, this can be interpreted as an indication that some amendments on national level and/or more harmonisation on the EU level could move onto the political agenda over the coming years.

The written comments give some insight into the assumption underlying these assessments. The compatibility of the general principles and approaches of the EU regulation with international regulations and the political standing of the EU are not the only reasons for the expected robustness of the EU regulatory systems. At least in some cases, changes to the GM regulation systems in other

countries, a change (or the need for a change) in WTO rules and/or a decreasing influence of the WTO were assumed, as highlighted by the following comments:

> *"The need to develop a regulatory frame which is addressing the regulatory needs of the public is not only a European topic. It may even be that the US will change its risk regulation frame."*

> *"The influence of the WTO will probably decrease in the future. The political system is moving to a multi-polar world with neoliberal globalisation losing influence."*

> *"Better change the WTO regulations to take into account the demand of citizens thus democratise decision making also in the context of WTO."*

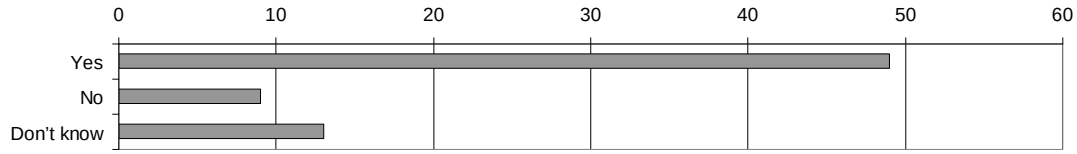
However, some respondents considered the restrictive practices of some EU member states as "politically" driven (and thus discrediting the system), in contrast to sound science:

> *"While the EU regulations with their basis on scientific appraisal are well accepted in many countries, the de-facto blockade by the Member States discredits the EU process."]*

The differing emphasis in these comments highlights the fact that considerable uncertainties are seen in the future development of multi-lateral agreements and global governance as well as in the EU's role here, and not only in the GM regulation proper.

With regard to the question on the consequences of EU regulation (Fig. 22), nearly seven in ten experts believe that it will continue to be influential on a global scale. This is in line with the assessment of the EU regulation to be generally robust.

FIGURE 22: THE FUTURE ROLE OF THE EU LEGISLATION (*Question 13B; n = 71)*



Question: The EU legalisation has been a model for regulations in some other countries. Will the EU regulation continue to be influential in the future? (Please tick one possibility)

The EU labelling regime is thought to be particularly influential:

"Food labelling in particular is emerging as a regulatory field where governance beyond Europe moves towards EU principles and standards (not traceability, which is too expensive to implement elsewhere)"

"The EU model will remain very influential, especially through its labelling regime. This regime has an impact all over the world, for products that will be imported into the EU."

The opinion that the EU's GM regulation will influence those of other countries does not in itself indicate whether this is regarded as a positive or negative feature. But that can be illustrated by the following comment: *"I can only add: Unfortunately!"*

DISCUSSION

Will the EU be able to uphold the principles of its regulatory approach, in particular the precautionary principle? And can individual countries, even as Member States of the EU, proceed with their own interpretation of the EU regulation through an "adapted" implementation of EU rules?

Challenges clearly arise from conflicts inside the EU that are based on different implementations and policies in various Member States, who have repeatedly been shown to exploit their remit within allowed tolerance of the EU regulatory or even outside it. Therefore, the EU regulatory approach is not as consistent internally as it may appear from the outside. Experience so far could suggest that this will not be easily overcome; however, a majority of experts considered a challenge to be probable and many thought that action would ensue. The survey shows that an amendment of the most restrictive practices by individual EU Member States and/or more substantial harmonisation of the implementation of EU regulation could come onto the political agenda.

While countries such as Norway and Switzerland are not full members of the EU, large portions of the relevant EU regulation nevertheless have a strong influence. Either it is mandatory, through the EEA (Norway), or de facto hard to circumvent, due to bilateral agreements and strong trade relations. Experiments in these countries are, therefore, interesting to follow up. So far, their special regulatory approach has survived for quite some time, despite the obvious discrepancies. Perhaps this is a way of flexibly adapting the GM regulation to national peculiarities without openly diverging too far from the common EU path.

The regulatory variation in the microcosm of the EU (although it covers quite a large and important area) might be considered enhanced at an international level. Different approaches between the EU and the US (e.g. regarding the role of functional equivalence and the precautionary principle) have so far been reconciled in a pragmatic rather than a conceptual way. This does not seem to cause grievances unless there is a particularly painful instance, as has been the

case with the "de facto moratorium" in the EU. The experts seemed to have different opinions of whether the EU approach is more adequate or not.

Nevertheless, the majority of experts interviewed considered the EU approach to be robust in the future as well. Overall, they seemed to think that conflicts with WTO agreements would probably not be enough to change the EU regulation on GM plants and foods. Whether this was mostly due to the international de facto power relations in this question or on a perceived conceptual superiority is not addressed here. However, even some of those who did not seem to approve of the EU approach considered it to be quite viable. This can also be seen in the amount of influence they considered the EU regulatory approach would continue to have at an international level in relation to other (developing) countries.

This prompts the question as to what will happen in those future challenges that the majority of experts anticipated. If the EU approach turns out to be sustainable, something must happen to the rules that the challenge will be based upon.

POLICY FIELDS 4.7

BACKGROUND

If one proceeds from the picture that emerged from the project reviews and the expert survey so far, the question is what can be learned from this and where do we go from here? In particular, we were interested in identifying and assessing policy options.

While this is common in many TA exercises, particularly if they include public or stakeholder participation of some sort, it is especially difficult in this case. The long-lasting debate has quarried robust interests and firm opinions, which pose great challenges to political decision-making and demands a very subtle way of proceeding. We therefore decided to leave the question of policy options open. Rather, we identified several policy fields at a very general level where action could be taken, and to ask the experts to give us their opinion.

The last part of this analysis is therefore slightly different from the former. The issues addressed in earlier sections were the future of GM plants in Europe and what is most likely to happen in relation to challenges for policy and research. In this final section, we turned to more normative issues related to policy fields.

RESULTS FROM THE TA PROJECT REVIEWS

Many TA project reports come up with a list of options for actions to be taken not only with respect to policy but also with respect to identifying fields for

further TA studies. The following summary is based on information from six reports:

- *Austria, Precautionary Expertise for GM Crops*
- *Denmark, New GM crops – new debate*
- *France, Co-construction of a research programme*
- *Norway, Sustainability and societal impact of GM food*
- *Switzerland, Genetic Technology and Nutrition*
- *Switzerland, The future of plant biotechnology in Switzerland*

In many of the project reviews, a variety of policy options were identified subject to the focus of the study and the form of TA that was chosen. In general, many reports took up the point of interaction with the public, which is certainly an important issue, but not one that comes immediately to the forefront in the present context of challenges for European GM policy.

The other options for state action that came up can be grouped on a very general level according to different policy fields:

- Amendment or implementation of existing regulation;
- Institutional reforms including the taking different actors on board;
- Research policy

Subject to the general assessment of whether or not the European framework was sufficient in particular aspects, various stakeholders in the project reports called for amendments or adaptations to existing rules and pieces of legislation. Demands expressed in those reports where public participation was essential often pertained to considering uncertainty aspects and issues of benefit and risk distribution and ethics in a broader sense (*Norway, Sustainability and societal impact of GM food*) or some sort of benefit for society (*Switzerland, The future of plant biotechnology in Switzerland*).

Institutional reforms have been a major issue ever since the debate on GMOs started. More recently, the EU has engaged in institutional reforms in order to render risk assessment and management more credible and less prone to influence by national policies (Levidow et al. 2005), which resulted, for instance, in setting up centralised agencies such as EFSA. In contrast, demands by stakeholders for more participation on their own part in decision-making have been issued frequently. In addition, public involvement in various guises has also been discussed (*Austria, Precautionary Expertise for GM Crops*).

Almost every project review stipulated the need for research on issues that are not very likely to be taken up by the private sector. Research funding was often mentioned in discussions on other issues such as coexistence or risk management as a precondition to gaining necessary insights. Many of the challenges identified indirectly concerned the role of publicly funded research. It is seen as a means to maintain sufficient control over new GM plants and as a balance to private research and development (*Denmark, New GM Crops – New Debate;*

Switzerland, Genetic Technology and Nutrition). From this perspective, public research could disentangle the outcome of R&D activities and applications (*France, Co-construction of a research programme*). The need for free and unbiased public research was also stressed as a means to determine the possibilities of scientific research and to recognise the limits of knowledge (*Switzerland, The future of plant biotechnology*); Public research could define research priorities in terms of identified agronomical problems that are considered politically relevant (*Switzerland, The future of plant biotechnology*).

PRELIMINARY CONCLUSIONS AND RESULTING QUESTIONS

Unease over whether the assessment of GM plants and food is adequate has long been prominent. In particular, the question of who to ask and involve in the assessment and decision-making process has never been resolved. Another contested field is how gaps should be bridged between national methods of implementing general frameworks and/or differences between divergent international frameworks. Closely linked to such questions is the problem of institutional reform at both EU and national levels.

A second area of concern is the role, magnitude and direction of publicly funded research. Although many stakeholders support an increase in the proportion of such research, it is not clear what the money eventually should be spent on. Preferred research aims may be linked to more general stances with respect to the desirability of GM or non-GM solutions.

RESULTS OF THE SURVEY

In order to identify areas of action for government institutions, we listed possible actions and asked respondents to indicate whether these should be prioritised.

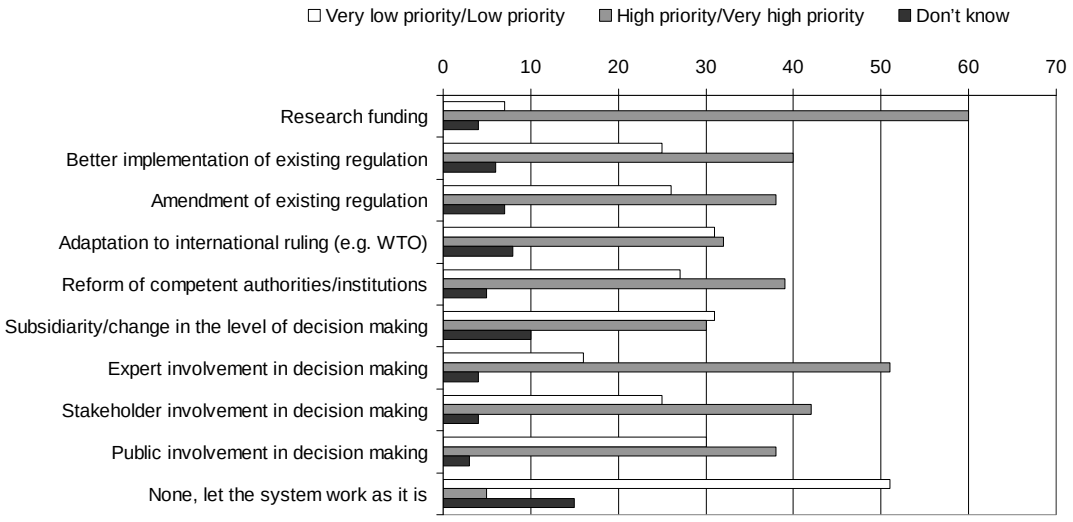
The answers revealed that around three-quarters of the experts would not like to just let the system work as it is (Fig. 23). This certainly can be interpreted as an indication that respondents are not very content with the status quo.

The major field identified was research funding, which was prioritised by almost nine in ten respondents. This is, however, no surprise in the light of the fact that the majority of the experts were researchers themselves.

Other types of action that received priority (by slightly more than half of the respondents, although one-third did not approve) related to better implementation of regulations and, to a lesser extent, to amending such regulations. Regarding the direction of such an amendment, one may draw conclusions from other survey questions. In preceding sections, we have seen that a number of respondents were not confident with current approaches to coexistence and liability, and that they supported the development of new parameters for risk assessment and management, especially with an eye to future

non-food GM crops. In addition, some respondents explicitly commented that regulation must be simplified and streamlined.

FIGURE 23: PRIORITISATION OF POLICY FIELDS (*Question 15; n = 71)*



Question: In order to meet challenges that have been explored in this questionnaire, it could be necessary for government institutions to take further action. Please prioritise the areas below in which you consider action needs to be taken. Please feel free to add areas of action not listed

Adaptation to international (WTO) rulings and the issue of subsidiarity received ambiguous support, with those who would prioritise the field equalling those who would not. Obviously, the issue of international harmonisation versus letting countries pursue their paths is something the group of experts had conflicting opinions about.

With regard to institutions, a majority prioritised the reform of competent authorities/institutions, which might indicate a measure of discontent with institutional performance. In terms of who else should be involved in the decision-making process, there seemed to be some enthusiasm for the involvement of experts, which again is not very surprising. However, stakeholder involvement also received priority from a majority of respondents, and even involving the public was not rejected on the priority list.

Looking at the way responses are distributed over the different categories of respondents, experts from universities/research and those from governmental agencies follow the general trend of being most supportive of 'research funding' and 'expert involvement in decision making'. Experts from industry also support 'expert involvement in decision making', but also 'adaptation to international ruling'. Taken together, the remaining group of experts (from agricultural organisations, environmental and consumer organisations and 'others)' are more

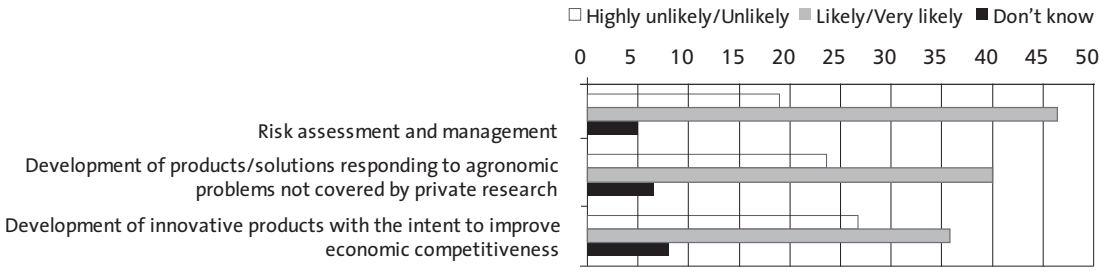
supportive of 'stakeholder' and 'public involvement in decision making', although even in these groups there is strong support for 'research funding'.

A comparison of how respondents prioritise expert involvement with how they prioritise public involvement also reveals interesting insights. Out of the 50 respondents who said that action to involve experts in decision-making should have high or very high priority, almost half said that action to involve the public should have low or very low priority. On the other hand, out of 36 respondents who said that action to involve the public should have high/very high priority, less than a third said that expert involvement should have low/very low priority. In contrast, there is a tendency that those who think stakeholder involvement should be prioritised also think the same about public involvement. In addition, higher enthusiasm for public involvement in decision-making also tends to go along with higher appreciation for the role of such involvement in forming consumer acceptance (Sect. 4.3).

On the topic of research funding, the high priority assigned requires better clarification of the type of research the experts might have had in mind. In particular, how do the experts see the role of publicly funded research: as a counterbalance to private research, basically oriented towards risks and the restriction of possible negative effects or as a means to improve the economic competition of the region by developing innovative products? In the survey we presented three options to the experts and asked them to judge the likelihood that they would become an objective of publicly funded research in their own country over the coming years.

The answers showed that two-thirds of the experts considered risk assessment and management to be a likely objective, and more than half that it would be filling in the gap left open by private research. A similar number found the aim of developing (innovative) products to be a likely candidate for publicly funded research (Fig. 24). The distribution of answers did not differ according to the experts' backgrounds (research, industry, government, NGO).

FIGURE 24: OBJECTIVES OF PUBLICLY FUNDED RESEARCH (*Question 14; n = 71)*



Question: In view of new developments in the research on GM plants, what will be the objectives of publicly funded research in your country in the coming years? Please feel free to add other objectives not listed.

DISCUSSION

Only a small minority of experts indicated a preference for leaving the current management system for GM plants and food alone and letting it work as it is. Thus, this is a call to policy makers to take action. The overwhelming majority of respondents supported a call for more research funding. While we cannot directly draw conclusions on what directions such research should take, preceding sections have revealed a number of topics that may be worthy of attention (see also below).

Apart from research funding, respondents encouraged stronger involvement of experts and, to a lesser degree, stakeholders but also the public in decision-making. Some respondents tended to encourage the first while discouraging the latter, and vice versa. This may indicate different opinions regarding the general ability of non-experts to make informed judgments in such complex and controversial matters. The demand for a stronger role for experts could be interpreted as indicating that, according to many respondents, current policies were not sufficiently funded in science. Respondents also prioritised a better implementation of existing regulations as well as some amendments. The nature and direction of such amendments remains an open question, however. The same can be said about the reform of competent authorities/institutions. Nevertheless, in the light of the discussions in preceding sections, the interested reader might be able to draw his or her own conclusions.

Regarding the role of publicly funded research, the experts expressed the opinion that its scope will probably be rather broad over the coming years. Accordingly, it could be an instrument for supporting regulation of topics such as risk assessment, but maybe also coexistence, screening, labelling, etc. where commercial research would perhaps not be directed. At the same time, experts did not rule out that publicly funded research could also be an instrument in research and innovation policy in order to improve economic competitiveness. Interestingly, the distribution of opinions in this question did not differ very much regardless of the experts' background (university/research institute, industry, NGO), which might indicate there is a consensus among experts from different fields on this point.

CONCLUSIONS 5.

EPTA members and many other European institutions have carried out numerous research projects and written many reports on issues concerning GM plants and food. The present report is the result of a collective effort of eight EPTA member institutions who used their combined knowledge to gain more comprehensive and substantiated insights than each could reach alone. By analysing past TA results and supplemented by an expert survey, we tried to identify challenges for the European system of GMO regulation in the years to come. The aim was to find out

- Whether and how the situation had changed in recent times due to different general conditions,
- What kind of technical, societal, regulatory and political challenges could be identified,
- Where future areas of action could be located, and
- How TA (institutions) could address these issues.

In the following section, we present a selection of our main findings, together with some implications as we see them, which may touch on areas of action relevant for policy. We do not claim that these are particularly novel but, taken together, they may shed a different light on an issue many stakeholders consider to have been talked to death.

DEMAND FOR ACTION

An overall conclusion from our results is that the regulatory system for GM plants and food in Europe does not seem to be fully prepared to meet all existing and foreseeable future challenges. This notion is seriously supported by the experts' survey, as most experts asked expressed some degree of discontent with the status quo regarding GM plants and food in the light of the challenges ahead. Only five of the 71 respondents supported the statement “let the system work as it is”. This suggests that many consider it necessary to take action.

New solutions or fundamentally new views do not seem to be immediately at hand, nor are there any indications that these might develop in the near future. However, analysis of the survey results in comparison with the review findings provided us with valuable hints. These allowed us to corroborate and supplement results from past research exercises and reports, as well as from our ongoing technology-monitoring activities. Overall, we identified five main challenges for policy making on GM plants and food, and discuss possible TA contributions related to these.

CHALLENGE 1: NEW DRIVING FORCES FOR GM PLANT INTRODUCTION 5.1

The general overall conditions for agriculture are changing, and this may influence the future of GM crops. Nevertheless, it remains difficult to draw conclusions for future developments. For instance, the TA project review results did not reveal a single or major driving force for or against GM technology implementation. However, our expert survey confirmed a recent development in scientific and public debates (see Sect. 4.1): not only is the demand for food on the agenda, but also that for biomass as a renewable resource. Such added emphasis on biomass per se may increase the incentive to use GM technology.

Productivity gains through raising agricultural efficiency or mitigating pest pressure have traditionally been perceived to promote the use of GM technology, whilst the ever more globalised trade of food products contributed to its distribution across the world. The experts considered that these factors would also be influential in the future. Indeed, such a future seems realistic: in parallel with a rising demand for bioenergy and biomass, the majority of experts expected that GM plants will be available and authorised for cultivation in Europe for such purposes within the next 10 years. Non-food uses such as these may be less sensitive to avoidance by sceptical consumers: firstly because the products are less sensitive than our diet; secondly because they involve new value chains where it is the industry, rather than consumers, who make up the (direct) demand. However, regulatory challenges and controversies concerning biosafety may be intensified (see Sect. 4.2).

At the same time, the overall aims that society sets for agricultural practice will have a profound influence on the chances of new GM crops in the future. Nine in ten experts regard methods for crop production with the least possible environmental impact to be an important aim for the next 10-15 years. They also expect the production of high-quality food in great variety and the reduction of input into crop production to be important, which again can be seen as related to the environmental impact to be minimised. We can, therefore, deduce a strong emphasis on sustainability and on reducing input and impact on the environment while sustaining food quality and variety.

RESULTING AREA OF ACTION

The general conditions for European agriculture keep changing, and the driving forces for GM plant introduction are closely linked to these changing conditions. Global challenges to agriculture make it necessary to reconcile various and sometimes conflicting demands: rising world food demand and replacing fossil fuels; volatility of market prices and sustaining rural income; decreasing arable land area and preservation of biodiversity, to name but a few. In the light of these factors and the quest for sustainability as an overall aim, conflicts in terms

of goals are unavoidable – as one expert commented, we need "sound decision making between conflicting interests towards sustainable development." The question is therefore which kind of sustainable agriculture Europe will develop over the next few decades. Most probably, this answer will shed more light on the prospects of GM plants in Europe than any specialised regulatory debate over the use of GM technology and its products. In some ways, the question of "GM – yes or no?" could become less important than the question "What are the aims and duties of our agricultural sector?" (see Sect. 4.5). This implies a range of more specified questions such as "What role should European agriculture play for non-food – compared with food – production?" or "Which aims other than agricultural production should be pursued?" or "What are the conditions under which particular tasks should be fulfilled?"

The most important area of action, therefore, is agricultural policy. This has always been a highly controversial field, so it is no wonder that stakeholders and scientists have different views on the future shaping of agriculture and the role of GM plants and products. Considerable efforts have already been made on exploring and discussing sustainable agriculture. However, in the light of changing conditions, it will be necessary to resume the discussion.

Challenge 1: New driving forces for GM introduction

In addition to continuing encouraging and discouraging factors of the past, the increasing demand for bioenergy and biomass poses new challenges. This will change the agricultural framing conditions.

Resulting area of action: Agricultural policy

› *The possible future role of GM plants could be determined in a broad societal dialogue on future sustainable European agriculture in a regional and global context.*

CHALLENGE 2: NOVEL GM PLANTS, TECHNOLOGIES AND APPLICATIONS 5.2

Several classes of novel GM crops are currently under development in Europe as well as in other countries. The majority of experts thought that most would be available and authorised for cultivation in Europe within the next 10 years, with the exception of trees for industrial or energy purposes and plants for phytoremediation.

Newly developed GM plants for pharmaceuticals and other non-food applications will be important, but could pose regulatory challenges. Nearly all experts consider it likely or very likely that new parameters for risk assessment and management, confinement and/or containment measures, regulation of

coexistence and liability will be put on the agenda over the next 10-15 years. We can, therefore, conclude that the discussion on adequate criteria for risk assessment for novel GM plants will be ongoing for the foreseeable future.

Traditionally, health aspects of GM food have primarily been discussed in terms of risks. However, some future GM plants are designed to bring health benefits, for instance through improved nutritional value or pharmaceutical substances. Most respondents expect that in the medium term such consumer benefits will appear and proceed to influence acceptance with GM plants. A third of respondents expect that attitudes to health may encourage, rather than discourage, the demand for GM plants and food. However, at the same time new risks may appear from gene flow or outgrowing and contamination of ordinary food staples. Such uncertainties over health risks from novel plants must be seen in relation to problems of coexistence (see Challenge 4).

Experts were ambivalent in answering the question of whether benefits should be included in assessment procedures. Previous research by EPTA members has shown that stakeholders have different expectations when discussing the inclusion of benefits: some hope that such a move could allow small uncertainties over risks to be balanced against benefits, others claim that neither for farmers nor for consumers is there any real benefit and that small uncertainties over risks are not tolerable.

New technologies such as cisgenics or smart breeding are said to blur the distinction between GM and non-GM and to meet with less resistance from a sceptical public. The survey shows that these are considered important for plant breeding in general, but the majority of experts do not regard them as alternatives to GM technology as such. Some existing regulations might need adaptation to cover cisgenics, however.

RESULTING AREAS OF ACTION

As for every field of technology development, research policy is the area of action. The European research landscape of GM plant development is fragmented, and some member countries have redistributed their national activities towards other fields. However, survey results suggest that, firstly, there is a demand for more public sector research on new GM plants. As one expert commented, “more of the technology development needs to come back to the public sector and open-source technology protection (need to be) developed.” Secondly, plants that are newly developed could be checked as early as possible whether they meet European agricultural aims and current coexistence schemes. How to meet this challenge appropriately also needs to be dealt with at the European level.

Even though experts do not expect new developments in plant breeding to be a substitute for GM technology, different approaches must compete for research funds. To set priorities, it is not only necessary to assess technical performance

but also the chances of newly developed plants satisfying the intricacies of public debate (see Challenge 3). In this way, the relationship between genetic modification and new 'intermediate' technologies such as cisgenics and smart breeding could be clarified.

The second important field is GM regulation policy in the EU. Many proposals have been made to improve, streamline or enhance regulatory policy, to the degree that the balance achieved is sometimes considered too fragile to challenge. However, as the general framework keeps changing, regulatory revision is probably necessary. Properties of newly developed GM plants for the non-food sector could make it necessary to consider amendments and additions in risk assessment and risk management parameters, confinement and/or containment measures, regulation of coexistence and liability. In addition, the question of benefit evaluation might be put on the political agenda. Taken together, the status quo of regulation might again be up for revision.

Challenge 2: Novel GM plants, technologies, and applications

Several classes of new GM plants will probably be available and authorised for cultivation in Europe within the next 10 years. This poses a number of research and regulatory challenges.

Resulting area of action: Research policy

› *The aims of public sector research could be better aligned with European agricultural aims.*
› *The most promising GM and non-GM approaches could also be selected in terms of public acceptance.*

Resulting area of action: GM regulation policy

› *The regulatory framework for non-food GM plants could be reconsidered.*

CHALLENGE 3: PUBLIC OPINION – STILL A DECISIVE FACTOR 5.3

In many European countries, public attitudes are considered an important factor influencing both the use of GM technology and its development. Therefore, influences on consumer acceptance must be analysed in order to assess whether public attitudes are changing, and if so in which direction. The majority of experts thought that a more positive attitude towards GM technology is likely over the next 10-15 years. This is mainly be due to the potentially growing acceptance of new GM non-food products, while the (lower) acceptance of GM food products will remain unchanged (see Sect. 4.3).

However, it is uncertain whether the expectations towards overall higher acceptance will prove to be realistic. Non-food GM plants can also raise environmental and health concerns, especially where doubts exist over the performance of coexistence schemes (see Challenge 4). In the light of recent debates on whether biofuels are a sensible option for reducing carbon dioxide emissions or whether they compete with food production, expectations that plants for renewable bioenergy will elicit more positive public perceptions may turn out to be overoptimistic.

In the past, developments that were seemingly unrelated to the issue of GM plants and food have made their mark on the debate and influenced acceptance. This shows that public perception is multi-faceted and that it is not only a matter of the technology at stake or of consumer risks or benefits. Neither is consumer acceptance a matter of specific technological knowledge of particular products. Rather, the whole context of food production and regulation as well as the relationship between actors in the food chain, from the farmer to the end consumer, determine the fate of potential products. Attempts at deliberately guiding public perception by influencing a single factor have proved to be futile.

In conclusion, both old and new topics, expectations and arguments can be expected to make their mark on public debates and influence public attitudes in the future. Whether and how the overall public acceptance of GM plants will change remains unclear.

RESULTING AREA OF ACTION

Although consumer benefits are important, public attitudes are subject to many influences, including ethical concerns, and the area of action is less clear than for other challenges. For the time being, little indicates increasing acceptance. It cannot be taken for granted that with new consumer-oriented GM products, and with bioenergy as a new track of GM plant production, the public perception of the GM technology will change.

The challenge of public opinion is closely linked to other challenges such as the future role of GM plants in European agriculture (see Challenge 1), a realistic evaluation of benefits and risks of new GM crops (see Challenge 2), and the performance of coexistence schemes (see Challenge 4). Accordingly, both consumer protection policy and a variety of other fields from agricultural policy to GM regulation come into the picture – it is a truly cross-sectional task. An ongoing dialogue between consumers, scientists and various stakeholders over potential chances and possible problems might help to avoid disappointments and the emergence of scandal stories.

Challenge 3: Public opinion – still a decisive factor

Against the background of established arguments, new topics, expectations and concerns can be expected to influence public debates and public attitudes in the future. Although there is a difference in acceptance between food and non-food products, it remains unclear whether and how the overall public acceptance of GM plants will change.

Resulting area of action: Consumer protection policy and cross-sectional tasks

› *An open dialogue on potential chances and possible problems could be enhanced.*

CHALLENGE 4: COEXISTENCE AND LABELLING UNDER A GROWING USE OF GM PLANTS IN EUROPE AND THE WORLD 5.4

In the European regulatory system, authorisation of a GM plant is based on a scientific risk assessment. In addition, coexistence must be allowed for, and appropriate labelling is required, in order to guarantee consumers the freedom of choice. The concept of coexistence can be considered an answer to the political demand for freedom of choice, but it also influences the parameters of scientific risk assessment. As the two pillars for the authorisation and management of GM crops build on different rationales, they might not always be easy to reconcile.

Until now, only first-generation GM plants with herbicide tolerance and/or insect resistance have been grown in some European countries, often on small areas and for a relatively short time. Therefore, robust experience with the EU regulation on coexistence is still some way ahead. There is still thus some uncertainty whether the concept of coexistence will prove viable under all circumstances.

Reports from many EPTA members come to the conclusion that coexistence is feasible in principle. In support of this finding, only a minority of experts believed that coexistence will not work at all for first-generation GM plants. In line with this, most respondents expected them to be cultivated in Europe at least in the medium term.

When it comes to more detailed questions, however, experts are divided. Will coexistence work for some crops only or for a broad range? Can it work only on a small scale or also for large-scale cultivation (see Sect. 4.4)? The practical context seems to be more important than feasibility in principle. A caveat also pertains to the type of risk that coexistence measures address. Half the respondents believe current schemes are insufficient to contain all economic and

environmental risks – depending on what is deemed relevant. Again, experts are split over how to process remaining risks – weigh them up against societal benefits, seek economic compensation, or rely on regulatory intervention?

Coexistence measures aim at implementing freedom of choice, and half of the respondents believed that GM food will be labelled correctly and that non-GM food will continue to be available. The others expected different negative scenarios such as the misapplication of labelling or the entire failure of coexistence and the ensuing blockade of GM food.

Controversies over coexistence can sometimes be traced back to differing degrees of confidence in systems of risk assessment and authorisation. Some doubts arise as to whether institutions involved in such an assessment are fully independent from vested interests – for example, one expert suspects that "EFSA … is just established to put its rubber stamp on all GMOs." Crossing the boundaries of conventional expertise and interest representation is sometimes considered a remedy. However, experts have different opinions on whether more scientific expertise or more stakeholder or public participation (or all three) should be implemented.

In addition, misfits between parts of the regulatory system and politics are highlighted. For example, one expert calls for "the conflict between the scientific decisions and the political actions" to be resolved.

RESULTING AREAS OF ACTION

Overall, questions remain over the concept of coexistence as a core element of European GM plant regulation, which also concerns the limited use of GM plants in Europe so far. Coexistence and labelling are considered to function reasonably well under certain conditions. However, there are doubts that this will be the case for all cases of GM crop cultivation. Despite regulation and an extensive debate in the past, problems in the future cannot be excluded with specific crops and large-scale cultivation. Therefore, continuous monitoring and perhaps a revision of coexistence rules are required.

As the implementation and warranty of coexistence is intimately bound up with approval procedures for GM crops in general, further possible areas of action are related to basic aspects of risk assessment and/or management of GMOs. Reports from EPTA members have highlighted that the expertise involved in regulatory decision-making and the way parts of the regulatory system work together may come under scrutiny. A number of comments addressed the independence from vested interests of bodies involved (such as EFSA) as a prerequisite for public and stakeholder trust. A practical solution could be to incorporate a broader spectrum of scientific opinions and to enable a broader representation of interests, including those of civil society, and of different forms of expertise such as citizens' knowledge.

Moreover, disentangling science (embodied in risk assessments by EFSA and national authorities) and political decision-making (on the EU and national level) has been a major aim of regulation, but it does not seem to have been accomplished in a fully satisfactory way. Therefore, a way must be found to better define the requirements of scientific evidence and the room for manoeuvre in politics.

A further, recurrent problem is the remit for political decision-making at the national level, e.g. on restricting or promoting the use of GM plants in a particular area. This issue is discussed in the context of Challenge 5.

Challenge 4: Coexistence and labelling under growing use of GM plants in Europe and the world

In Europe, GM plants have been grown on relatively small areas and only for a short time. Therefore, there is still a lack of robust experience with the EU regulation on coexistence. With specific crops and large-scale cultivation, problems cannot be excluded in the future.

Resulting area of action: GM regulation policy

- *Aspects of GM regulation on the requirements for maintaining coexistence and freedom of choice might have to be revisited.*
- *Incorporation of different types of expertise and interests could enhance and demonstrate independence from vested interests.*
- *The relation of science and policy could be better defined, with a clear remit for policy also on the national level.*

CHALLENGE 5: INTERNATIONAL TRADE RULES AND DOMESTIC DECISION-MAKING 5.5

The recent WTO conflict between the US and its allies and the EU has put pressure on some aspects of the European regulatory practice concerning GM plants and food. It made clear that the future shaping of international trade rules will greatly influence GM regulation in the EU. However, European ideas on how to regulate such issues might also be influential outside Europe and affect international agreements as well.

Apart from the concrete instance mentioned, the global increase in acreage covered by GM crops, pending international trade conflicts, the development of international GM regulations and the different approaches to risk assessment and regulation in various countries could turn out to be a challenge in the future, too. The question is whether the European regulatory system will be able to cope with this.

Despite the outcome of the WTO conflict, the experts saw a good chance the European regulatory system surviving, even in view of increasing global GM crop use. Most are convinced that at least the general principles can be maintained, but many think that restrictive practices of individual EU Member States will have to change and more harmonisation among the EU Member States will be necessary (see Sect. 4.6).

Accordingly, the robustness of the EU regulatory system is based on the perceived compatibility of general principles and approaches of the EU regulation with international trade regulations as well as on the political standing of the EU. In addition, some experts consider a change to the GM regulatory system in non-EU countries or a change of WTO rules possible or at least desirable.

RESULTING AREAS OF ACTION

International trade policy is the obvious area of action. However, the trade conflict surrounding GM plants and food only pertains to one of several arenas within the WTO regulations. Therefore, not only those areas specific to GMOs might be considered at stake, but also the possible integration of environmental and social standards into WTO regulations. The relation of treaties, conventions and agreements reached under the auspices of different supra-national bodies (e.g. WTO and UN) will have to be clarified in order not to thwart the aims of these different agreements,. This is, however, beyond the scope of national influence and the issue of GM plants.

With regard to GM regulation policy, problems are said to have arisen from discrepancies between the implementation of the European regulatory framework in different Member States. Two possible solutions come to mind: giving more leeway to national sovereignty (often captured under the term ‘subsidiarity’) with respect to GMO regulation, or enforcing harmonisation among member states also with regard to minor details. In the past, the compromises reached did not always deliver fully satisfactory results, and many experts consider further harmonisation and/or institutional reforms necessary. It remains to be seen how far subsidiarity can be upheld under the auspices of WTO rulings.

Challenge 5: International trade rules and domestic decision-making

Uncertainties about the compatibility of the European GM regulation with international trade regulations remain. At the same time, international trade rules may be up to reforms.

Resulting area of action: International trade policy

› *Reconciling discrepancies between various international treaties could be intensified.*

Resulting area of action: GM regulation policy

› *National implementation could be harmonised, including institutional reforms.*

UPCOMING ISSUES FOR TECHNOLOGY ASSESSMENT 5.6

Over the years, technology assessment has made great efforts to clarify particular aspects of agricultural biotechnology, one of the most prominent technological fields that TA has ever dealt with. Not only with respect to technical analyses but also regarding public involvement, this issue has featured prominently among TA themes for two decades. Thus, one may question whether there is any particular shortcoming since almost every issue has already been focused on.

Nevertheless, some upcoming issues may prove to warrant increased attention from the point of TA. At least four developments call for renewed interest and novel approaches:

› First, there are a number of *technological developments that extend the use of GM plants* beyond the current range of applications, such as energy plants, plants for nutritionally enhanced products or for producing pharmaceutically active substances. Furthermore, crops of a new generation with enhanced agricultural traits such as drought resistance and other low-input properties throw up questions of enhanced survival capabilities (and thus invasiveness) together with improved yield under difficult environmental conditions. They are said to be much more common in a future determined by climatic change, so they might pose novel challenges for risk assessment.
› Second, apart from technological novelties, *changed general conditions for agriculture* continue to challenge established practices and aims. The example of fuel production from renewable resources, initially hailed as a tool to save fossil fuels and to mitigate carbon dioxide release, has shown that the general framework can change over a very short time. Volatile food prices and a depletion of staple stocks have re-opened the debate over whether it will be necessary to boost food production not only in developing countries but also in areas where overproduction has been a problem.
› The third area is decision-making. On the one hand, there are recurring conflicts about institutions and levels of decision-making, for instance

between the EU bodies and Member States, and about singling out what belongs to the science of risk assessment versus the politics of risk management. On the other hand there is the repercussion of international politics, including the WTO conflict, on national agricultural production. Trade liberalisation, globalised trade in food and feed, and international rules for the use of technology (or its prevention for example through patents) can challenge established practices at very short notice.

- Fourth, public attitudes towards GM plants and food may change in the future. This might not only influence the strategies of relevant actors such as farmers, food retailers, or NGOs, but also impact future political decisions. The direction of such a change, however, is impossible to predict. In the past, many factors not immediately related to GM technology as such but to broader social and cultural issues have been shown, or suspected, to influence public perception. In addition, national differences are obvious, and with a larger number of Member States the diversity of the European landscape of public perceptions might even increase.

Taking past experiences with R&D on transgenic plants into account, new forms of co-ordinated involvement of experts, stakeholders and citizens need to be organised in the process of the development of new generations of plants. The task of TA is to help clarify technological solutions and their societal implications. TA is one area that could contribute to developing new forums to open negotiating channels between actors who have found it hard to speak to each other or arrive at sustainable compromises.

Further discussion is needed on the TA approaches that are required and suitable. It largely depends on the expertise and experience of the TA institutions involved. This could be an indication to seek transnational co-operation, for example under the auspices of EPTA.

Relevant issues for TA identified:

- *Assessment of novel GM plants, especially those with enhanced agricultural traits*
- *Assessment of technological solutions offered or demanded to meet changed framework conditions for agriculture, and their societal implications*
- *Identification of impacts of international treaties and trade liberalisation and of possible solutions to meet them*
- *Understanding social and cultural factors influencing technological developments, their embedding into society and the ways implications such as risks and benefits are perceived*

These issues require the development of new forums for dialogue and a better co-ordinated involvement of experts, decision makers and the public in issues related to GM plants and food.

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http://www.wto.org/english/news_e/news06_e/291r_e.htm

ANNEX 1: LIST OF TABLES AND FIGURES

TABLES 1.

FIGURES 2.

ANNEX 2: LIST OF PROJECT REVIEWS

In brackets:
[Short titles]

The full texts of all project reviews are available on the project website as Annex 3 (http://www.eptanetwork.org/EPTA/projects.php?pid=150).

Austria:

- Review of the Austrian Federal Environment Agency monograph "Ecological Monitoring of Genetically Modified Organisms" (2000)
  [Austria, Ecological Monitoring of Genetically Modified Organisms]
- Review of the EU funded international research project "Precautionary Expertise for GM Crops" (2004)
  [Austria, Precautionary Expertise for GM Crops]
- Review of the monograph "Risk Assessment of GMO Products in the European Union. Toxicity assessment, allergenicity assessment and substantial equivalence in practice and proposals for improvement and standardisation" (2004)
  [Austria, Risk Assessment of GMO Products in the European Union]
- Review of the Austrian Agency for Health and Food Safety "Feasibility Study on 'GMO-free' claims and the avoidance of GMOs in food" (2005)
  [Austria, "GMO-free" claims and the avoidance of GMOs in food]
- Review of the study "Coexistence" on behalf of Federal Ministry of Health and Women (2005)
  [Austria, Coexistence]
- Review of the Federal Environment Agency conference "The Role of Precaution in GMO policy" (2006)
  [Austria, The Role of Precaution in GMO policy]

Denmark:

- Review of the DBT project "Genetically modified foods" (1999)
  [Denmark, Genetically modified foods]
- Review of the DBT project "Genetically modified crops in developing countries – challenges for the development aid" (2003)
  [Denmark, Genetically modified crops in developing countries]
- Review of the DBT project "Co-existence between GM crops and non-GM crops" (2004)
  [Denmark, Coexistence]
- Review of the DBT project "New GM crops – new debate" (2005)
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Finland:

- Review of the Finnish debate between public administration, researchers and general public concerning the plant gene technology
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- Review of UK projects since 2000
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