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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

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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.

discussions criteria and procedures general, over 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

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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 further harmonisation reform consider and a of 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.