Benefits and Risks of the Deliberate Release of Genetically Modified Plants (GM plants)

Implementation Plan
of the National Research Programme NRP 59

FNSNF
Swiss National Science Foundation

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What are National Research Programmes (NRP)?

The research carried out by National Research Programmes is targeted research that contributes to the solution of contemporary problems of national importance. Under the provisions of Article 6, paragraph 2, of the Law on Research of 7 October 1983 (as of 5 October 2004) the Federal Council selects the topics and foci to be researched in NRPs and mandates full responsibility for implementing the Programmes to the Swiss National Science Foundation (SNSF, Division IV).
Article 4 of the Federal Ordinance on the Law on Research of 10 June 1985 (as of 7 December 2004) describes the purposes and contents of NRPs as follows:

«[1] National Research Programmes are a means to direct and support coordinated research projects that have a common goal. Where needed, National Research Programmes should strengthen scientific research capacities.

[2] Topics of research are appropriate for National Research Programmes if, in general,

a. scientific research on the problem is of national importance;
b. Swiss research can make a significant contribution to the resolution of the problem;
c. solutions require research contributions from multiple disciplines;
d. the research goals cannot be met exclusively through basic research, through research within a specific section of the administration, or through industrial applications research;
e. research on the problem can be expected to produce research results that have practical applications within a five-year time period.

[3] The following criteria should be taken into consideration in setting forth the topics of National Research Programmes:

a. the programmes can provide the scientific basis for decision-making by government and the administration;
b. the programmes can be conducted with international collaboration and are also of great interest to Switzerland.»

1. Summary

The NRP 59 examines the benefits and risks of genetically modified plants (GM plants) under the ecological, social, economic, legal and political conditions of Switzerland. Its goals are to: (a) contribute to the identification and development of plant biotechnology applications that are conducive to achieving Swiss agricultural and environmental policy goals; (b) assess the present legal and administrative framework for GM plants, as well as the associated risk-assessment, risk-management, and decision-making processes; (c) develop procedural standards for risk research and monitoring that are geared to the Swiss context. The programme consists of 4 modules. Module 1 (ca. 50% of the NRP) focuses on biological, ecological, and public health aspects. It examines influences of the environment on the functionality and performance of GM Plants, influences of GM plants on ecological systems and human health, and conditions under which GM plants could - or could not - be used as production platforms for non-food products (*e.g.*, pharmaceutical substances). Module 2 (ca. 20% of the NRP) examines social, economic, ethical, educational, legal and political issues associated with GM plants in Switzerland. Module 3 (ca. 5-10% of the NRP) studies risk-assessment, risk-management, and decision-making processes associated with the release of GM plants. Module 4 (ca. 5-10% of the NRP) focuses on synthesis and overview studies that evaluate existing research and knowledge on topics in Modules 1-3. With the exception of field experiments (which are expected to start in spring 2008) most research in this NRP is scheduled to begin in spring 2007. An interim report summarizing what has been learned from the synthesis and overview studies in Module 4 as well as new, original research in Modules 1-3 will be issued in autumn 2009. The NRP will end in spring-summer 2011.

2. Introduction

The application of gene technology to modify plants has had a profound impact on plant sciences. It has opened up a multitude of opportunities to generate modified crops in ways that could not be achieved by conventional breeding. Genetically modified plants (GM plants) have found commercial application in many parts of the world. The expectations that accompany the introduction of crops resulting from this technology are high and include increased yields, higher nutritional content, resistance of crops to pathogens or adverse climatic conditions, and reduced use of insecticides and fungicides. In the non-food sector, GM plants might be used as biofactories for pharmaceutical products such as vaccines or to generate compounds that normally consume non-renewable resources. As is the case with most new technologies, however, the widespread application of GM crops comes with potential risks to public health and the environment that need to be weighed off against the benefits.

Currently existing knowledge on the risks and benefits of GM plants is extensive (for more information, see http://www.agbios.com/main.php; http://www.icgeb.org/~bsafesrv/bsfdata1.htm; http://www.defra.gov.uk/environment/gm/research; www.biodiv-chm.de; WHO 2001, Evaluation of Allergenicity of Genetically Modified Foods. Report of a Joint FAO/WHOExpert Consultation on Allergenicity of Foods derived from Biotechnology, Rome, January 2001). Moreover, large-scale research programmes in this area are at present under way in North America, Europe and several developing countries (most notably South Africa, China and India). Despite the wealth of data on GM plants and their effects that has emerged from these programmes, a comprehensive evaluation of benefits and risks of GM plants remains difficult. Much of the relevant knowledge is either ambiguous, not easily accessible, or may not, or only to a limited degree, be applicable to Swiss conditions. As to the latter, rather little background knowledge is available that can readily be applied to estimate the consequences of introducing GM plants in Switzerland.

While contributing to the provision of food in a sustainable manner, Swiss agriculture must, by constitutional mandate, also contribute to the conservation of natural resources and the upkeep of the rural landscape. In order to fulfil its **agricultural policy goals** (AP 2007, AP 2011), Switzerland invests considerable efforts in the development of long-term sustainable agricultural production systems. One of the main objectives of sustainable agriculture is to maintain or where possible increase the current level of productivity while decreasing the negative impacts on the environment and human and animal health. Negative impacts stem mainly from the use of herbicides, pesticides, and fertilizer, and from land-use management (*e.g.*, crop rotation), which may cause the emergence of resistant or tolerant weeds or micro-organisms, the pollution of soil and ground water, and the reduction of the biodiversity of flora and fauna.

At this stage, it is not clear - and in fact heavily debated among scientists, farmers, consumers, policy-makers, and the wider public - to what extent the **application of GM plants** could benefit Swiss agriculture, consumers, and the environment. Most research and development carried out on GM plants is geared towards extensive, large-scale farming systems. In Switzerland, however, small-scale agricultural sys-

tems are predominant. Consequently, a range of important questions pertaining to the use of GM plants in Switzerland need to be addressed:

- How could GM plants contribute to sustainable agriculture in Switzerland?
- Under what conditions could GM plants be applied to the benefit of Swiss farmers and consumers?
- Would GM plants become more acceptable to farmers and consumers if the potential benefits were demonstrated?
- How can potential risks emanating from GM plants be assessed and managed?
- Under what conditions can agriculture with and without GM plants co-exist?
- How would GMP-based agriculture compare with conventional and organic production methods?

Public debates associated with the **moratorium initiative** (the proposed five-year moratorium on commercial GM plants releases in Switzerland was approved in November 2005 by popular vote) have shown that the majority of voters remain sceptical with regard to the benefits of GM plants and are concerned about potential risks. At the same time, however, a large part of those voters who supported the moratorium, as well as those voters who rejected the moratorium, have emphasized the need for more knowledge about the benefits and risks of GM plants when deciding in 2009/10 on whether to end or extend or modify the moratorium.

Considering its short time frame and limited funding (*e.g.*, EU research programmes in this area extend over much longer time periods and are much larger) this NRP can only focus on selected topics with respect to the benefits and risks of GM plants. The emphasis will be on assessing the applicability of existing results from worldwide research in the Swiss context, and on filling important gaps between existing knowledge and practical application within the Swiss context wherever necessary. The most **important points that need to be addressed** are:

i. To what extent and how can plant biotechnology be used in ways that are conductive to achieving Swiss agricultural and environmental policy goals?
ii. As transfers of GM plants into non-GM plants crops could affect the economic interests of non-GM plants growers, how could the co-existence of any future GM plants and non-GM plants crops be managed in Switzerland?
iii. The present legal and administrative framework for research on and commercial applications of GM plants needs to be assessed. The same holds for related risk-assessment, risk-management, and decision-making procedures. Procedural standards for risk research and monitoring geared to the Swiss context need to be developed in this context.

The **Swiss scientific community** is well placed to meet these objectives. It holds a highly competitive international position in plant molecular biology and physiology, developmental genetics, environmental sciences, and social sciences and humanities research on science & technology issues.

3. International and National Context

The responsible deployment of modern biotechnology and GM plants needs to encompass the whole process from technology development and pre-release risk-assessment to benefit analysis and post-release monitoring. This is best achieved when technology development and bio-safety research are carried out as parallel, but closely interacting, processes (FAO expert consultation 2005).

3.1 International research programmes

Numerous programmes and projects exist that deal with topics that are thematically also covered by NRP 59. Below, some of the most important initiatives are listed, but the list is by no means comprehensive.

The **6th framework programme of the EU** was started in November 2002. The 5th priority of this framework programme carries the title "Food quality and safety" and has a budget of 685 million Euro. Furthermore, from 1984 – 2000, the EU supported projects to study the safety of GM plants with a total amount of 70 million Euro.

In March 2000, the German Federal Ministry of Education and Research (BMBF) launched a programme that was concluded in 2004, covering the following main topics:

- GM plants release safety research.
- The development of methods for the monitoring of cultivated GM plants.
- Communication management in biological safety research.

An additional BMBF research programme "Biologische Sicherheit gentechnisch veränderter Pflanzen" was launched in December 2003 and is still ongoing (http://www.biosicherheit.de)

In the UK, a large set of studies (Farm-scale evaluations) aimed at investigating the effects of GM plants crops on the environment have been conducted with the support of DEFRA (Department for Environment, Food and Rural Affairs) (http://www.defra.gov.uk/environment/gm/fse/index.htm;
http://www.defra.gov.uk/environment/gm/research/reports.htm)

In 2003, the US National Science foundation and the EU evaluated research questions relating to genetic engineering and social sciences ("Comparative Research on Biotechnology and the Public" – Report to the US-EC Task Force on Biotechnological Research).

In **Spain**, a post-marketing monitoring plan (PM-MP) (1998 - 2004) for genetically modified maize varieties protected against insect pests (Bt-176 corn) was carried out over a period of 6 years. A second PM-MP (for MON810 corn) was initiated in 2004 and is currently ongoing. These PM-MPs were designed jointly by the companies concerned and experts from the Spanish Committee on Biosafety (Ministerio de Medio Ambiente).

Research and development on transgenic plants is also carried out on a relatively large scale in countries like **South Africa, India, and China**. By the beginning of 2000, for example in South Africa alone 120 field experiments were registered and in China some 2000 scientists were occupied with “green” biological technology.

3.2 National programmes

Research priorities of the 'SPP Biotechnology' (http://www.snf.ch/SPPBiotech/Home_e.html; 1992-2001) included topics such as bio-safety research and biotechnology of higher plants. In the 'SPP Environment' (http://www.sppe.ch/de/sppe_set.html; 1992-2002), another example, the remediation of soil contaminated with oil and heavy metals was addressed. In the scope of a currently ongoing FOEN research programme (http://www.umwelt-schweiz.ch/buwal/de/fachgebiete/fg_biotechnologie/research/index.html), some particular questions relating to biological safety are being studied. This programme is much smaller than NRP 59, it does not include GM plants field experiments, and it only marginally addresses socio-economic questions.

The **Gene Technology Law** (in force since January 2004), and the **Ordinance on the release of organisms** into the environment (in force since November 1999 and continuously adjusted) constitute the legal framework within which genetically modified organisms including transgenic plants must be handled. In addition to this legal framework, a five-year **moratorium** on the commercial cultivation of GM crops was introduced in November 2005 by popular vote. Whereas proponents of the moratorium expect that the label of 'GMO-free' will be able to emphasize the quality of Swiss products, several members of the Swiss scientific community fear that the moratorium might undermine plant biotechnology research and teaching at Swiss universities and deter young scientists of pursuing a career in this field.

In summary, the current status of knowledge on the benefits and risks associated with GM plants is extensive and these issues are studied in many countries worldwide. Nevertheless, there are three compelling reasons for carrying out additional research in this area within the frame of NRP 59. *Firstly,* a systematic evaluation of the data that have been gathered abroad and, to a limited degree, also in Switzerland is difficult and remains incomplete, and relevant information and knowledge is not easily accessible. Moreover, there is only limited agreement on procedural standards for biosafety research on GM plants. *Secondly,* previous research has focused mainly on questions relating to the risks of GM plants; endeavours to demonstrate the potential advantages or benefits of this new technology were given correspondingly less attention. *Thirdly,* Switzerland is particularly suited for interdisciplinary research on this complex topic because of its ecological diversity, small-scale farming, cultural differences in how GM plants are perceived, and its specific political structures.

4. Goals of NRP 59

In view of the research that has already been carried out abroad and in Switzerland, and taking into consideration the specific local Swiss requirements, NRP 59 will pursue the following three goals:

First, contribute to the identification and development of plant biotechnology applications that are conducive to achieving Swiss agricultural and environmental policy objectives;

Second, assess the present legal and administrative framework for GM plants, as well as the associated risk-assessment, risk-management, and decision-making processes;

Third, develop procedural standards for risk research and monitoring that are geared to the Swiss context.

5. Main Research Topics

In order to reach the named goals of the programme, four research modules will be implemented:

Module 1: *Plant biotechnology and the environment*
This module deals predominantly with biological, ecological, and public health aspects (ca. 50% of the programme). The following three areas are to be covered:

- Influences of the environment on the functionality and performance of GM plants.
- Influences of transgenic plants on ecological systems and human health.
- Conditions under which GM plants can - or cannot - be used as production platforms for non-food products (e.g., pharmaceutical substances).

Module 2: *Political, social and economic aspects*
This module covers social, economic, ethical, educational, legal and political issues associated with GM plants in Switzerland (ca. 20% of the programme).

Module 3*: Risk-assessment, risk-management, and decision-making processes*
Module 3 (ca. 5-10% of the NRP) studies risk-assessment, risk-management, and decision-making processes associated with the release of GM plants.

Module 4*: Synthesis and Overview studies*
Module 4 (ca. 5-10% of the NRP) focuses on synthesis and overview studies that evaluate existing research and knowledge on topics in Modules 1-3. By the end of 2009, a synthesis cutting across all three modules will be produced.

Below, the four modules are described in more detail.

5.1 Module 1: Plant biotechnology and the environment

Because of time constraints, this research programme does not focus on the de novo development of GM plants. Cooperative research, using GM plants that are currently under development in Swiss public and private laboratories, is encouraged. This way, synergies can be created between on-going research programmes from different disciplines that will help maximise progress. Examples of GM plants interesting from a sustainable agriculture point of view are GM plants with (i) specific or broad spectrum disease and insect resistance/tolerance, (ii) enhanced nutrient uptake for improved plant growth, iii) plants with improved nutritional value as feed or food, (iv) non-food GM plants for improved crop management (*e.g.*, "trap plants" for nematodes, soil fertility), or (v) plants that are used as bioreactors for pharma- and neutraceutical compounds. In such cooperative research, efforts aimed at increasing the efficiency and safety of established or novel approaches will be supported.

Research areas:

A) Impact of the environment on the functioning and performance of GM plants

The range of benefits and risks of GM plants can be expected to vary depending on the location (given environment) and the context (*e.g.*, scale of release) in which they are used. Risks and benefits are largely determined by the plant species, the transgenic trait and the ecosystem into which the GM plants will be introduced and need to be judged (case-specifically).

To enable informed decision-making, more data and knowledge may need to be acquired on the regulation of expression and functioning of the transgene in the receiving organisms. The environmental conditions that provide for optimal performance and those that hinder the development of GM plants need to be identified.

Potential research topics:

- Epigenetic effects associated with the transformation and regeneration process (*e.g.*, silencing and insertional mutations).
- The relationship between the site of insertion in the plant genome and the stability of transgene transmission over several generations, its regulation and level of expression.
- Impact of transgene expression on plant metabolism and plant fitness.

Containment strategies and their reliability.

B) Impact of GM plants on the environment and human health

It has been proposed that reduced pesticide use, increased crop yield and easier weed control, could complement other sustainable agricultural practices and lead to significant environmental benefits. The responsible development and use of GM plants, however, also entails a careful analysis of potential associated risks. Any potential for increased establishment, persistence, and spread of GM plants in the environment needs to be identified. Probable points of entry, routes and potential health hazards and, most importantly, the potential effects on the environment and

human health need to be addressed. Unwanted spread of transgenes in and introgression into wild/weedy/crop relatives can go unnoticed for a long time. Conditions that govern the stability and regulation of transgenes in wild/weedy plants can differ from those that apply to crop plants raised under controlled conditions in planned breeding programmes. In certain areas, little research has been conducted to date that focuses on these processes.

Research projects are invited addressing either benefits or risks of GM plants:

- Effects of GM plants and their transgene product(s) on the ecosystem (*e.g.*, biodiversity, ecological functions, food webs, protected species); comparison of the spread of GM plants with that of normal plants or 'invasive plant species'.
- Unwanted dispersal of the transgene through pollen and seeds, including routes of spread (crop/crop, crop/wild/weedy, hybrid/wild and human activities), identification of potentially receiving ecosystems, containment strategies, etc., and their consequences (incl. potentially affected ecological functions, etc), development of tools to monitor transgene escape.
- Stability and regulation of transgene constructs following uncontrolled outcrossing and introgression into wild/weedy relatives.
- The impact of GM plants, and/or GMP-derived products on the soil ecosystem and its biota (*e.g.*, degradation, bio-geochemical cycling, soil fertility).
- Studies on the potential environmental benefits of GM plants, in particular with regard to pesticide use, crop yields, weed control, general soil tillage and soil protection. Such studies should focus specifically on Swiss conditions and address the question of how plant biotechnology could contribute to environmentally and economically sustainable agriculture in Switzerland.
- Studies that address – besides the benefits/biosafety issues - the topic of co-existence of genetically modified, conventional and organic crops in Swiss agriculture. It should be noted, however, that co-existence is not primarily an environmental risk issue. For this reason, this topic will necessitate a transdisciplinary approach that includes economic risk as well as agricultural management issues.
- The impact of GM plants and products thereof on human health. These studies can address potentially harmful effects (e.g. toxicological, immunological studies) as well as potential health benefits (e.g., elimination of common food allergens, increased nutritional value, etc.)

It should be noted that neither the conceptual nor the financial framework of NFP 59 allow for comprehensive clinical studies on the impact of GM plants on human and animal health. Therefore, only limited studies on the adverse effects on human and animal health will be feasible. Studies are also invited that focus on reviewing and re-evaluating existing data sets with the aim of facilitating a more accurate assessment of potential health hazards or benefits. Moreover, recent research in other countries indicates that only large-scale studies will reveal any real ecological impacts. Research in this NRP focusing on ecological implications will thus have to connect systematically to large-scale studies being carried out abroad.

It is envisaged that several projects listed under A) and B) will include field experiments using GMplants. Furthermore, within the frame of NFP 59, opportunities will exist for scientist to collaborate in GMP field experiments abroad.

C) New approaches and the use of GM plants as production platforms for non-food products

GM plants are finding increasing application for non-food product purposes. For instance, strategies are being developed to use GM plants in the field of phytoremediation, where plants remove contaminating pollutants from soils or water. GM plants can also serve as biofactories to produce compounds presently made using non-renewable resources, such as oils, fuels, and plastics. Plant biotechnology can also be used to increase the nutritional value of plants, to eliminate common allergens, and for pharmaceutical applications, including vaccine production. Furthermore, efforts are also underway to generate GM plants that pose less potential risks to the environment, *e.g.*, through a variety of technologies that restrict gene flows. Moreover, recent progress in chloroplast transformation has opened up new opportunities to develop GM plants that can be used as bioreactors to produce pharmaceuticals or other molecules of industrial interest. Chloroplast transformation may have several advantages over nuclear transformation, in particular with regard to the site-specificity of transgene insertion and stability of expression. Theoretically, there should also be no dispersal through pollen.

While such GM plants may promise great benefits, their use also gives rise to a different spectrum of environmental risks that need to be assessed proactively. NRP 59 will therefore foster contained use research (but not field release trials) aimed at improving both safety and efficacy of such novel systems.

Potential research topics:

- Development and further improvement of novel, promising expression systems.
- The use of GM plants as biofactories for non-food products.
- Methods to increase the nutritional value of GM plants vs. non-GM plants.
- Studies on the application of GM plants for pharmaceutical application (e. g. oral vaccine development, production of pharmaceutical substances at reduced cost, etc.).
- Methods to increase efficiency and safety (environment and human/animal health).
- The use of indicator gene(s) coupled to the transgene to facilitate the identification of the dispersal of the transgene.
- Regulation of transgene expression in chloroplasts (developmental and tissue specificity).
- The specificity of the localization of the transgene (no nuclear insertions).
- Verification of the lack of transmission of the transgene through pollen.
- The establishment and verification of the containment system necessary for different types of novel systems.

Cluster projects

In addition to a set of smaller research projects in Module 1, the steering committee is prepared to fund one or two larger clusters of projects in that module. These clusters should center on one field experiment and address in an integrated manner the questions raised in parts A-C of Module 1.

5.2 Module 2: Social, economic, and political aspects

The principal goal of this NRP – to assist in establishing which, if any, applications of plant biotechnology could be useful and acceptable in Switzerland – necessitates a systematic analysis of the political, social, and economic setting into which the technology and its applications might be placed. Public acceptance and non-expert attitudes with respect to agricultural biotechnology have a strong bearing on the further development and application of plant biotechnology in Switzerland. A large number of public opinion surveys and some experimental research on consumer behaviour in regard to GM products have been carried out in other countries, and a few such studies have also been conducted in Switzerland. Many questions remain to be addressed to which projects in the social sciences and humanities could provide important answers. The same holds true for economic issues, *e.g.*, the economics of co-existence of GM and non-GM crops.

We seek contributions that extend beyond the conventional surveys and media analyses of public support for, or opposition to, plant biotechnology and its applications (particularly related to food and feed production), notably in the following areas:

A) Focus on individual attitudes and behaviour

We invite contributions that examine the dynamics of attitudes and acceptance of or opposition to GM plants – *e.g.*, shifts of public risk debates from health to ecological or coexistence risks. Various approaches might be useful for identifying such determinants. Both affective and cognitive dimensions should be taken into account. Researchers are encouraged to utilise innovative methods to provide additional insights into how people perceive and evaluate GM plants and various applications of the technology. Comparisons of mental models that guide expert and laypersons' views on plant biotechnology will also be interesting. Based on such models, recommendations for communication strategies could be developed. Emotions that might influence views on GM plants should also be studied. The behavioural dimension should receive considerable attention as well. To that end, voting data on GM plant issues could be analyzed. Experiments with real products and contingent valuation or willingness-to-pay studies may also offer valuable insights into individual decision-making and behaviour. Finally, it will be interesting to see whether there are differences in attitudes and behaviour across cantons, language groups, the rural-urban divide, and other characteristics.

B) Focus on society

Individual attitudes and behaviour cannot fully explain why plant biotechnology is more accepted in some countries than in others. The social dimension is important for a better understanding of public responses to plant biotechnology. Stakeholder analyses or social network analyses could be helpful for a better understanding of the social amplification or strategically motivated under- or overstatements of benefits and risks associated with GM plants. Interaction effects between NGO campaigns, business PR, and public attitudes could also be studied in this context. In a pluralist democracy, such as Switzerland, communication of benefits and risks of plant biotechnology through the media system has important implications for public attitudes, activities by civil society groups, political agenda setting, and ultimately

government behaviour in this area. We invite contributions that examine the representation of benefits and risks of plant biotechnology in Swiss print media, radio, and television. We also invite contributions that study the effects of various stakeholders on media reporting, as well as the impact of media reporting on public opinion, stakeholder behaviour, and political agenda setting. Studies that explain differences in benefit and risk perception across different language areas of Switzerland are particularly welcome. Projects in this category should also help produce recommendations on how to bridge the currently existing gaps between scientific findings on benefits and risks of GM plants on the one hand, and popular perceptions of such benefits and risks, on the other hand.

C) Focus on economic issues

It is important to establish to what extent the consumer could ultimately benefit from the commercial application of GM plants. Proposals are invited that specifically tackle the topic of 'consumer benefits' in the Swiss agricultural context. From an economic point of view it is particularly important to compare the costs and benefits of co-existence of GM crop production with the costs and benefits of organic and/or conventional crop production. Such comparisons should be carried out for individual crops, such as corn, wheat, potato, grapes, canola, etc. The cost implications of various certification and labelling schemes are also of interest. Similar studies have already been carried out in other European countries and should serve as a basis of reference. The extent to which patent issues and regulatory burdens may affect the development and commercialization of GM plants by public institutions and the private sector in Switzerland could also be investigated. To the extent possible, the effects of different policy scenarios on public and private sector research and development in plant biotechnology could be studied.

D) Focus on ethical issues

Currently, there is no consensus in Switzerland on how particular ethical concerns pertaining to GM plants should guide decision-making in respect to research in closed systems, field experiments, and commercial releases of GM plants. Examples include the interpretation, in practice, of ethical criteria as set forth in the Swiss Gene Technology Law (*e.g.*, in respect to the dignity of creation applied to plants), particular levels of protection to be accorded in the name of the precautionary principle against potential risks emanating from field experiments or commercial releases of GM plants, public participation rights in decision-making processes, transparency in respect to research and development activities in plant biotechnology, etc. We invite studies that explore how such concerns can be defined, evaluated and operationalized, and on whether ethical concerns differ across societal groups (*e.g.*, professional groups, socio-cultural groups) and between Switzerland and other countries. One option to this end might be to systematically examine explicit or implicit guidelines of good ethical practices across different groups (*e.g.*, science, industry, NGOs). Comparisons of ethical concerns expressed by ethics experts versus concerns expressed by other stakeholders (*e.g.*, scientists, lay persons) and historical analyses pertaining to past controversies over new technologies compared to the actual GM plants controversy will also be interesting.

E) Focus on the research and educational system

How does the Swiss educational system deal with challenges posed by plant biotechnology? We are interested in understanding what students at various levels of the educational system (from primary to high school and professional schools and universities) learn about the technology, and the impact of this education on knowledge, attitudes, and (especially at university level) career planning. Content analysis of biology and other courses as well as survey studies could help in answering the first question. Experimental studies could clarify the impact of various forms and contents of teaching on attitudes with respect to plant biotechnology. Interview and survey studies could clarify the impact that the current debate may have on the next generation of Swiss plant scientists.

5.3 Module 3: Risk-assessment, risk-management and decision-making processes

One of the principal goals of this NRP is to assist in establishing transparent and widely accepted methodological standards for GM plants field experiments and other GM plants research, as well as associated interdisciplinary risk research and monitoring programmes. In addition to the need for more experimental data on potential benefits and risks, there is also an urgent requirement for baseline information and reliable parameters in this respect that can be used in long-term comparison studies and monitoring programmes.

To that end, this module focuses on the organization and functioning of risk-assessment, risk-management, and decision-making in approval processes. Both the Swiss Gene Technology Law (Gentechnikgesetz, in force since 1.1.2004) and the Ordinance on the Release of Organisms into the Environment (Release Ordinance, amended version to enter into force in 2006) constitute the current legal and administrative framework for plant biotechnology R&D in Switzerland. The three sole field experiments in Switzerland to date took place before this legal framework was put in place (1991, 1992, 2004). Hence there is some very limited first-hand experience with risk-assessment, risk-management, and approval processes with GM plants in Switzerland, but no experience with how recently established laws and procedures will work in practice.

We seek contributions to this module that examine the applicability of the existing legal and administrative framework, and identify potential weaknesses and options for improvement.

First, we seek projects that assess, from an ecological, social, political, legal, or ethical perspective, deficiencies in risk-assessment, risk-management, and decision-making with regard to plant biotechnology R&D that was previously carried out in Switzerland using open systems. This should be done (using the benefit of hindsight) in the context of the existing OECD, EU and other guidelines and procedures, as well as the new Swiss legal and administrative framework. In addition, we seek projects that examine the Swiss Gene Technology Law and the Ordinance on the Release of Organisms into the Environment (Release Ordinance) in comparison with corresponding legal and administrative frameworks of other OECD countries and recom-

mendations of the OECD, the EU and other international institutions, and also in the light of findings obtained through the activities of modules 1 and 2 of this NRP.

Second, we seek observational and experimental research projects that study the functioning of the Swiss Gene Technology Law and the Release Ordinance on GM plants in comparison with potential - albeit thus far hypothetical - alternatives. Such projects could for example focus on how scientific, administrative, and political decision-makers cope with informational, scientific, societal, or political constraints and uncertainties when passing judgments on critical approval or assessment issues and interpreting and applying the precautionary principle. Thus, the projects could examine critical issues in the application of the existing and potential alternative legal and administrative frameworks, for example: how are scientific and other experts selected and what is the impact of particular choices on administrative and policy decisions; how much and what kind of information is sufficient for assessing and deciding on a particular application for field release of GM plants; what kinds of information can be kept confidential and which information needs to be made public. Studies on the legal and administrative frameworks that control the approval process for field release trials and commercial applications in Switzerland should be placed into an international context and take into account relevant international developments in this particular field (for instance decisions by organisation such as the WTO or the EU).

Additional questions could include: how does one define the borders between ethical and unethical plant biotechnology R&D; the requirement of proof that R&D in open systems is required, and that particular results can not be obtained from research in closed systems; demands for particular types of risk-assessment and monitoring as well as safety measures; public information and participation requirements; interpretations of terms such as „state of scientific knowledge and experience“, absence of negative impacts on non-GM agricultural production and consumer choice. Experimental research could take place under artificial conditions (*e.g.*, with hypothetical decision-making situations) or under real-world conditions (*e.g.*, with decision-makers handling applications for release under this NRP). Finally, we are interested in contributions that explore whether the application of specific decision-making tools, *e.g.*, multi-attribute decision-making models, facilitate consensus in controversial areas, such as the siting of GM plants field experiments.

We expect project submissions for this module to involve interdisciplinary teams that are capable of assessing the possibilities and limits of integrated assessments of the benefits and risks of plant biotechnology R&D in open systems, and of the associated decision-making processes. The ability to place the proposed research in an international comparative perspective and to draw comparisons to conventional, integrated, and organic agricultural production is essential. Tight links and interactions with modules 1 and 2 are essential.

5.4 Module 4: Synthesis and overview studies

It lies neither in the capacity nor in the scope of this NRP to duplicate the many studies on benefits and risks associated with GM plants that have been carried out in other programmes. On the other hand, it may be possible to distil relevant and

valuable scientific data from the results of such studies that could help shape future research and decision-making processes specifically tailored for Switzerland.

To comply with the goal of the programme, projects are invited to analyse, compile and communicate what is known from existing medical/public health, ecological and social science research that has been performed in other countries, and to assess to what extent these studies are relevant to Switzerland. In addition to a detailed analysis, the output of such studies should include a summary that highlights potential practical consequences for Switzerland that are of relevance to politicians and the public. It is envisaged that up to five such compilation projects will be launched. Initial 'fast track synthesis studies' (max. 12 months) will also be supported that can subsequently be supplemented (either through a follow-up project, or by the steering committee) with knowledge acquired within the context of NRP 59.

It is the wish of the Swiss Federal Council that it be informed on the first relevant results generated in the context of NRP 59 in preparation for the political debate that will take place at the end of the moratorium on GM plants in 2010. In 2009 a 'synthesis document' cutting across the different research areas will therefore be produced. The document will encompass a summary of the existing knowledge based on the evaluation of different international programmes, complemented with findings obtained so far within the context of NRP 59. To achieve the latter, measures to assure an optimal flow of information will need to be put into place. Considering that the NRP 59 will only start in spring 2007, it is important to realise that interim results can only be based on a maximum of 2 series of field experiments, and under the proviso that approval and implementation of field experiments work efficiently.

NRP 59 projects are planned to run for a period of 4 years and will thus terminate in the spring of 2011. A final report of the NRP will be published thereafter.

6. Relevance to Switzerland

Almost all important international trade partners of Switzerland are involved in extensive research on the benefits and risks of GM plants. Some of these countries, above all the USA and Canada, are cultivating GM plants on a very large scale. The largest developing countries, in particular China, India, and Brazil, are also engaged in extensive research programmes and are currently integrating a variety of GM plants in their agricultural systems. Swiss borders are permeable, both pertaining to foreign trade in food and feed products as well as ecologically. Hence these international trends will not stop at the borders of Switzerland. Even if Switzerland should, in the longer term, decide not to authorize the commercial cultivation of GM plants in open systems, it is almost unavoidable that GM plants and products derived therefrom will show up in our environment and food chain. It is thus important, in any event, to obtain a solid scientific understanding of the benefits and risks of GM plants in general - and individual GM plants in particular - under the ecological, social, economic and other conditions of Switzerland. More specifically, the relevance of the NRP is as follows:

Society
Current public debates in Switzerland on GM plants are characterized by strong polarization and repetitive exchanges of well-known arguments, many of which are only marginally connected to scientific evidence on GM plants. This NRP can contribute to a stronger focus of public debates on scientific evidence concerning the benefits and risks of particular applications of plant biotechnology, and on public attitudes and concerns in this regard.

Policy-makers / Government
During parliamentary debates on the Gene Technology Law and, subsequently, the moratorium initiative, most members of parliament stressed the need for more research on the benefits and risks of GM plants. Given its short time frame and limited funding, this NRP cannot provide definitive answers as to what precisely the benefits and risks of particular GM plants, if cultivated in open systems in Switzerland, would be. However, new research results from this NRP, combined with a systematic assessment of the relevance of international research results for the Swiss context, can produce important information that will be relevant to both policy-makers and the public when they have to decide, in 2009-10, on whether to end, extend, or modify the current moratorium on the commercial cultivation of GM plants. This NRP will provide important insights into the functioning of, and options for improving, government regulations and procedures for the authorization of GM plants and for monitoring, risk-assessment, and risk-management in the context of cultivation of GM plants in open systems.

Economy / Agriculture
The results of this NRP will enable Swiss farmers to make better-informed judgements about whether particular applications of plant biotechnology could be beneficial for them, both in terms of (agronomic) productivity and consumer behaviour. It will also provide new insights into the costs and other implications, for the country as a whole, of particular forms of co-existence of GM plants-based, conventional, and organic food production.

Research

Public controversies over GM plants have had negative effects on R&D activity in plant biotechnology in Switzerland, both in the private and public sector. This NRP, in addition to the NCCR plant survival (http://www2.unine.ch/nccr), can contribute to maintaining a world-class research capacity in this area. Maintaining this capacity is essential for continuously - and with a long-term perspective - assessing the benefits and risks of GM plants, as they will unavoidably emerge over the next years and decades from R&D carried out in other countries and in Switzerland. Two additional activities to promote Swiss research in this field will be launched (see 7.4)

7. Implementation of the NRP 59

7.1 Research proposals and review process

In accordance with customary procedures for NRPs, the submission and review process for the research proposals will involve two steps: pre-proposal and full proposal. The pre-proposal process serves to identify promising research ideas, to fine-tune the research priorities for the NRP, and to facilitate coordination and integration among different research teams and their projects. The call for pre-proposals is envisaged for June 2006, with an early-September 2006 deadline. The deadline for full proposals should be in December 2006. Research should begin in March 2007, with the exception of field experiments, which are envisaged for spring 2008 (see below). Because of the very limited time frame, there won't be a second call in this NRP.

Pre-proposals should have the following format:

- Summary
- Topic of the project, rationale and main goals
- Approaches and methods to be used
- Possible applications of the results
- How the project will contribute to achieving Swiss agricultural and environmental policy goals
- National and international collaboration
- Time frame and milestones
- Required funding (personnel and consumables)
- Short curriculum vitae of all applicants (max. 2 pages) and a list of their most important publications

Pre-proposals must be in English and should not exceed five single-spaced pages (reader-friendly line spacing; Arial 11 or Times New Roman 12 font and font size; 2 cm margins). In addition to the pre-proposal, applicants must complete the coversheet for this NRP. Both the coversheet and the template for the pre-proposal can be downloaded from www.snf.ch. The pre-proposals will be subject to scientific peer review. Based on the reviewers' reports and its own evaluation, the steering committee will decide on which pre-proposals should be developed into full proposals (see the criteria listed below).

Full proposals will build on the pre-proposals and the reviewers' and steering committee's evaluations and comments and develop the research plan in greater detail. They must be in English and correspond to standard SNF rules for such proposals (see www.snf.ch).

All full proposals will be subject to international peer review and the principal investigators will be invited to present their projects to the steering committee and a panel of selected international experts at an **application colloquium**. This procedure allows the steering committee and the experts to query specific points and ask more detailed questions. Following the colloquium, the steering committee will convene to select the projects to be recommended for approval or rejection by the Research Council of the Swiss National Science Foundation (Division IV; Executive Council).

The duration of research projects in this NRP is limited to 48 months. Collaboration with international research groups or organisations (e.g., with the Consultative Group for International Agricultural Research, CGIAR) is possible and can be supported financially by the SNF (for instance by co-financing parts of the project carried out abroad) under the following conditions: i) that an added value can be demonstrated, ii) that Swiss research benefits from such collaboration, both in terms of content and methodology.

Pre-proposals in compliance with the official coversheet should be submitted no later than 31 August 2006 (date of postmark counts) to:

Swiss National Science Foundation
Division IV NRP 59
Wildhainweg 3
CH-3001 Bern
Phone: 031 308 22 22/
e-mail: shusi@snf.ch

The NRP 59 implementation plan and the coversheets and templates for pre-proposals and full proposals can be downloaded from www.snf.ch. Pre-proposals and full proposals (incl. coversheets) should be sent to the SNF both by postal mail and electronically in PDF-format by e-mail. For legal reasons, proposals sent only by electronic means cannot be accepted.

7.2 Selection criteria

Pre- and full proposals will be reviewed on the basis of the following criteria:

- **Scientific quality and originality**: pre- and full proposals should fulfil international state-of-the-art criteria with respect to scientific quality and originality as well as methodological standards.
- **Feasibility and compliance with the objectives of the NRP 59**: proposals should reflect the programme's scientific objectives and comply with its overall framework.
- **Applicability**: NRPs are explicitly called upon to assist in solving problems of national importance. As a consequence, priority will be accorded to projects that are implementation-oriented and have a high level of practical relevance.
- **Personnel and infrastructure**: Projects have to be carried out in a setting that provides adequate infrastructure and personnel.

Scientific assessment of pre- and full proposals is preceded by a formal inspection of proposals by the secretariat of SNF Division IV (*e.g.*, use of official forms, completeness of application, adequate formal presentation, submission within the set deadlines). Submissions that do not meet the formal criteria may be excluded from further processing.

SNF funds awarded are exempted from VAT taxation (art. 33, par. 6). The SNF does not issue contracts within the scope of its NRPs, but awards grants for the promotion of scientific research in Switzerland.

7.3 Field experiments

Certain key questions in Module 1 will have to be addressed through field experiments with GM plants. Due to the limited time frame and budget of the NRP 59 the development of new GM plants is not an option. Field experiments will have to proceed on the basis of existing GM plants made available by the private sector or public research institutions in Switzerland and abroad under modalities to be worked out by the principal investigators and their academic institutions. The availability for such research of GM plants and infrastructure for field experiments (including land) should be demonstrated preferably at the pre-proposal stage.

Since the governmental approval process for field experiments may take up to one year, the SNF strongly recommends that requests for field experiments be submitted to the Federal Office for the Environment (FOEN) simultaneously with the submission of the full proposal to the SNF. Requests for field experiments must meet the requirements set in the Release Ordinance on GM plants (Freisetzungsverordnung). Since those requirements are rather complex preparatory work for such requests should begin already when preparing the pre-proposal. All relevant documentation is available from the FOEN. Further questions can be addressed to Dr. Hans Hosbach: Hans.Hosbach@bafu.admin.ch. All field experiments in this NRP must be concluded by spring 2011. Some limited funding for preparing requests for field experiments will be made available in this NRP.

7.4 International exchanges and promotion of young scientists

The NRP 59 will implement two special types of grants that are expected to promote the career development of young scientists and have a sustained effect on programme development that is likely to extend well beyond the duration of this NRP.

Travel grants
Large numbers of field experiments are currently being carried out abroad, primarily in the EU, North America, South Africa, and Asia. These experiments are generating an abundance of data and knowledge that could be relevant to the NRP 59. Through research visits and short-term participation in selected projects, carried out under the auspices of the NRP 59, young scientists will be given the chance to gain valuable field and laboratory experience and contribute to the transfer of new technologies and information into Switzerland. This facility will be designed so as not to bypass or compete with existing postdoctoral fellowship programmes of the SNF. It will be strictly short term and tailored to fit NRP 59 needs. It is hoped that this will stimulate young scientists based in Switzerland to follow-up with a regular SNF fellowship abroad. For details regarding such travel grants, please address to the programme coordinator, S. Husi.

Promotion of young scientists
Following the footsteps of NRP 50, NRP 59 will create new opportunities for young and promising scientists to make the transition to independent junior group leaders. Post-doctoral scientists able to carry out work of high scientific quality will be encouraged to submit research projects to the NRP 59. If the applicants do not hold a permanent position, they may apply for their own salary support in their research proposals. In this case, the applicant needs to document that she / he will be em-

ployed by a home institution for the duration of the project and that the availability of the necessary scientific infrastructure is guaranteed. Written proof of support by the home institution must accompany the research proposal. The conditions favouring a long-term integration of the applicant in the home institution need to be described. The salary support of the applicant, in case of funding by the SNSF, is based on the usual salaries for corresponding positions at the home institution. This programme does not overlap with existing SNF programmes (*e.g.*, SNF Förderprofessur, which is more selective and not linked to a particular theme). It is designed for more junior candidates with the aim of specifically promoting the research covered by the NRP 59.

7.5 Stakeholder participation

With a view to the political relevance of this NRP, a stakeholder forum will be established. This forum will include representatives of various interest groups, the public administration, and scientific associations. It will serve as a platform for communicating and discussing research results as they emerge from this NRP, and for obtaining advice from stakeholders on how best to foster a constructive dialogue between scientists involved in this NRP and the wider public. Within the frame of these activities, special information and feedback events will be organized with heads of federal offices and political stakeholders.

In addition, this NRP will include a wide range of public outreach activities, such as press conferences, scientific workshops, and lecture series for the general public.

Projects involving field experiments will have to meet specific requirements for stakeholder dialogue and consultation. These requirements are set by the Release Ordinance for GM plants.

8. Schedule and Budget

On December 02, 2005, the Federal Council approved the launch of the National Research Programme 59 (NRP 59) "Benefits and Risks of the Deliberate Release of Genetically Modified Plants (GM plants)" and entrusted the Swiss National Science Foundation (SNSF) with its implementation. A total sum of CHF 12 million was allocated to NRP 59 for its four year research duration. The National Research Council then selected a Steering Committee and assigned it the task of writing this Implementation Plan based on the Programme Outline and Feasibility Study.
The Implementation Plan was approved by the Federal Department of Home Affairs, Mai 18, 2006

Call for pre-proposals:	June 7, 2006
Deadline for pre-proposals:	August 31, 2006
Decision by SC on pre-proposals:	October 15, 2006
Deadline for full proposals:	December 31, 2006
Decision by SNF on full proposals:	March 15, 2007
Beginning of research:	April 2007
Interim report by NRP 59:	Autumn 2009
Synthesis and overview studies	Autumn 2009
Conclusion of NRP 59:	Spring 2011

The total funding for this NRP is 12m CHF. The provisional allocation of this funding to different types of activities is as follows.

Module 1: 6m CHF
Module 2: 2.5m CHF
Module 3: 1m CHF
Module 4: 1m CHF
Implementation activities: 1.5m CHF

9. Programme Management

Division IV of the SNF Research Council
The SNF Research Council's Division IV consists of 20 members who represent a wide range of scientific disciplines. It has overall responsibility for NRPs and National Centres of Competence in Research (NCCR). Decisions by Division IV on whether to accept or reject research proposals are submitted to the Presidency of the SNF Research Council for ratification. Division IV delegates one of its members to the steering committee. This delegate submits the steering committee's decisions to Division IV and serves as the main liaison person between the steering committee and the SNF.

Steering Committee
The steering committee has primary responsibility for ascertaining the scientific quality of research carried out in this NRP, and for ascertaining that this research meets the overall objectives of the NRP. It organizes and participates in the review process for pre- and full proposals. It can call upon external experts for this purpose and enlist their support in various formats (*e.g.*, peer reviews by correspondence, review panels). It decides on approval or rejection of pre-proposals, and it decides on whether or not to recommend full proposals for approval by the SNF Division IV. It reviews interim reports from projects and decides on whether to propose acceptance, revise-and-resubmit, or rejection to the SNF Division IV. It monitors, on a continuous basis, progress made in the NRP's research projects and recommends adjustments or improvements if necessary. It organizes and participates in implementation activities with the help of an implementation officer, including scientific workshops, stakeholder dialogues, public lecture series, synthesis reports of the programme, etc.

Programme Coordinator
The programme coordinator is a staff member of the secretariat of Division IV of the SNSF. She/he is responsible for handling day-to-day management tasks and for ascertaining the implementation of decisions taken by the Research Council and the steering committee. She / he coordinates administrative and financial support functions in the NRP and assists the steering committee in project monitoring and coordination.

Implementation Officer
In consultation with the SNF Press and Information Office, the steering committee nominates an implementation officer. The Research Council decides on her / his appointment and mandate. The implementation officer's principal tasks are to organize public outreach and public relations activities of the NRP, facilitate communication between NRP project participants on the one hand and the media, stakeholders and policy-makers on the other hand, and facilitate communication among individual NRP projects and between the steering committee and the projects.

Steering Committee

Steering Committee Members:

Prof. Dirk Dobbelaere (President), Abt. für Molekulare Pathologie, Vetsuisse Fakultät, Universität Bern

Dr. Detlef Bartsch, Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL), Berlin, Germany

Dr. Karoline Dorsch, Eidg. Fachkommission für biologische Sicherheit, Ittigen

Prof. Karin Hoffmann-Sommergruber, Institut für Pathophysiologie, Universität Wien

Dr. Pia Malnoë, Agroscope Changins-Wädenswil and Département de Biologie Végétale, Université de Genève

Prof. Jules Pretty, Department of Biological Sciences, University of Essex, United Kingdom

Prof. Joachim Scholderer, Department of Marketing and Statistics, Aarhus School of Business, Aarhus, Denmark

Prof. Daniel Schümperli, Institut für Zellbiologie, Universität Bern

Dr. Jeremy B. Sweet, Environmental and Research, Consultant, Cambridge, United Kingdom

Prof. Josef Zeyer, Institut für Terrestrische Ökologie, ETH Zürich

Representative of the Federal Administration:

Dr. Hans Hosbach, Federal Office for the Environment, FOEN

Delegate of Division IV of the SNF Research Council:

Prof. Thomas Bernauer, Center for Comparative and International Studies (CIS), ETH Zurich

Implementation Officer:

(To be appointed)

State Secretariat for Education and Research (SER), Berne:

Dr. Claudine Dolt

Programme Coordinator, SNF, Division IV:

Dr. Stefan Husi
Swiss Science Foundation
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