

## **White Book on Genetically Modified Crops: EU Regulations and Research Experience from the Czech Republic**

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This Book was prepared under the auspices of the 7FP REGPOT-2008-1 project “Building up Modern Biotechnologies for Agriculture” (acronym MOBITAG, GA 229518). Most Czech scientists working with genetically modified organisms (GMOs) relevant for agriculture and related activities were invited to express their opinions and provide a short annotation on their research. Their names and addresses are provided at the end of the book, following a conjoint appeal calling for a revision of the current EU legislation on genetically modified crops. This book, including a call from Czech scientists, is neither an advertisement nor an advocacy for the deployment of GM crops – it is a call for the use of critical intelligence and knowledge in the decision making process on this technology. The book and its contents can be distributed freely

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### **1. Purpose of this Book**

Current efforts to combat starvation on a world scale are undermined by a continuous increase in the human population accompanied by a decrease in the acreage of arable land. The threat of food shortage is exacerbated by increasing demands on food safety and quality. High production of high quality food depends largely on efficient cultivars that have hitherto been obtained, primarily, by random mutations. The selection of “spontaneous” mutations and the hybridization of selected plants had been sufficient for millennia, and the highly productive cultivars we grow in the fields today were largely obtained with the aid of mutations induced either by radiation or chemicals. Whilst these techniques remain useful tools of plant breeding, it is feared that many thousands of mutagenic interventions that have already been carried out have practically exhausted the endogenous genetic resources of most crops.<sup>1</sup> Fortunately, the innate resources can now be enriched by procedures that are known as genetic modifications (GM) since this technology provides access to a significantly increased gene pool.

Genetic modification applied to crops today should be called transgenesis because they include the transfer of one or more useful foreign genes into the target plant, thereby conferring a new trait, such as resistance to an insect pest if the transgene encodes an insecticidal protein. As in any other technology (soil tilling, herbicide application, biological control of insect pests, etc.), the production of GM crops constitutes human interference with nature and must be deployed with care. The risks and benefits of GM crops must be compared with other techniques serving the same purpose, for example insecticide application in insect pest control, before their practical deployment is considered. In the case of commercialized GM crops, scientific evidence as well as practical experience<sup>2</sup> has demonstrated that they bring considerable economic benefits to farmers and are more environment-friendly than comparable technologies. **However, in spite of their successful worldwide cultivation, the use of GM crops in the European Union has become a controversial subject and the technology is completely rejected by some member states. Since such a condemnation of a modern**

**technology may endanger EU competitiveness**, it should be thoroughly analyzed using unbiased scientific methods.

...Czech scientists working with GM crops responded to this invitation by compiling this White Book that summarizes the results of their analysis of relevant EU legislation and provides examples of conducted research. The Czech scientific community has a long tradition in the investigation of GM crops: it has contributed to the development of genetic modifications, participated in formulating national regulations on genetically modified organisms (GMOs), and has substantially contributed to debates addressing rational concerns, and eventual acceptance, of GM crops by the majority of the public. **Czech Republic is among the few EU countries where farmers have gained practical experience with the cultivation of GM crops and this provides positive feedback on current research activities.**

**Many European scientists are disturbed by the fact that political factors and ideology prevent unbiased assessment of GM technology in some EU countries, with a negative effect on the whole Community. Being aware of the responsibility their country bears during the EU Presidency, Czech scientists decided to formulate their position in support of a scientific approach to GM issues.** As with any other technology, the deployment of GM crops will bring benefits with minimal negative effects when used in a rational, scientifically designed way. We hope that this White Book will encourage the politicians as well as the general public to accept this objective viewpoint.

## **2. EU Approach to Agricultural Biotechnologies**

### **2.1 Concise History of EU Regulations**

US President Barack Obama recently signed a memorandum on the importance of scientific integrity in government decision making.<sup>4</sup>

*The Memorandum states that public policy should be guided by the most accurate and objective scientific advice available and that The public must be able to trust that advice, as well, and to be confident that public officials will not conceal or distort the scientific findings that are relevant to policy choice.*

**Unfortunately, recent European legislation concerning GM crops does not consider scientific findings but appears to be based on an unjustified belief that transgenesis is the only selection method generating risk<sup>5</sup>.** Other biotechnology methods, such as distant hybridisation and mutagenesis induced by radiation or hazardous chemicals, are claimed inherently safe without a need for any control. This “confidence trick” is deliberately applied to an unsuspecting public.

**Policy makers neglecting scientific evidence and adhering to unjustified beliefs betray their electorate that expects management of public affairs in the interest of the EU population. However, the *à priori* condemnation of the use of genetic modifications in plant breeding reduces the competitiveness of EU agriculture and is thereby against the interests of EU citizens. Furthermore, the public is misinformed about the principles of genetic manipulation and about the safety of this procedure compared to other plant breeding methods such as radiation or chemical mutagenesis...** The current EU rules regulating the development, testing, and deployment of GM crops are very similar to the legislation regulating the use of poisons, narcotics, explosives and chemical weapons (state licence for handling, labelling, protocols setting and saving, personnel specific training, plans of accident handling, regular reports to the state authorities, specific licence for export and import, etc.). Such regulation inevitably arises suspicion in the minds of the public and is easily interpreted as proof that GM crops are dangerous. The misinformed public then rejects GM technology and eventually demands political representatives to ban everything related to the GM crops.

The EU approach to GM crops was initially more objective, but has changed over the years...

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4 Available at: <[http://www.whitehouse.gov/the\\_press\\_office/Fact-Sheet-on-PresidentialMemorandum-on-Scientific-Integrity/](http://www.whitehouse.gov/the_press_office/Fact-Sheet-on-PresidentialMemorandum-on-Scientific-Integrity/)>

5 Morris, S. H (2007) Parallel biopolitical universes. *Nat Biotechnol* 25, 33–34; available at: <<http://www.nature.com/nbt>>.

## ... 2.2 Rational Rules for Assessing the Risks of Biotechnologies

**With an unbiased approach we have to assume that the deployment of GM crops may bring, as other technologies, certain benefits but it may also damage the environment and human and animal health. Only a scientific evaluation of the benefits and risks can set the level of acceptable risk as a basis for a wise decision of the acceptance or refusal of the technology in any given situation. Proper assessment of the benefits and risks must be done by comparison with alternative technologies that serve the same general purpose. For example, by comparing farming of a pest-resistant GM crop with the cultivation of similar non-GM varieties that are protected against pests by insecticide treatments or by the application of bioagents. Risk assessments are worthless if done without appropriate controls under the assumption that the current “standard” (“conventional”, “traditional”, etc.) methods pose no risks. Economics should also be taken into account, in particular in evaluations of the long term use. For example, since the seeds of insect-resistant GM crops are more expensive than the non-GM counterparts, farmers will plant the non-Bt cultivars when pest infestations are low...**

### ... 2.2.1 Principles of the risk assessment process

#### ... B) The concept of risk

1. Risk is given by the probability of damage resulting from exposure to a hazard. There is no human activity in the field of ecology with zero risk.
2. As the risk scale does not start with zero, only relative risk can be assessed by comparison with alternative human activities.
3. Acceptable risk must be defined based on the ratio benefit/risk, implying that risk assessment must be complemented by benefit assessment.
4. It should correctly be distinguished between the particular risk of a crop and the complex risk of all agrotechnologies linked to the crop planting (use of machinery, chemicals, timing of planting and harvest, etc.).

#### C) The position of GMOs

1. There are no scientific data showing the exceptional position of plants expressing a trait based on transgenesis. Thus there is no ground for their regulation to be any different to plants obtained by traditional breeding methods.
2. However, the EU Commission issued on 2 February 2000 "Communication on the Precautionary Principle"<sup>12</sup>

The point v) of this states: Decision-makers need to be aware of the degree of uncertainty attached to the results of the evaluation of the available scientific information. Judging what is an "acceptable" level of risk for society is an eminently political responsibility. However, according to point vi): Where action is deemed necessary, measures based **on the precautionary principle** should be, inter alia:

#### a) *proportional* to the chosen level of protection,

- b) *non-discriminatory* in their application,
- c) *consistent* with similar measures already taken,

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12 Communication from the Commission on the precautionary principle. COM(2000) 1, Brussels, 02. 02.

- d) *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
- e) *subject to review, in the light of new scientific data, and*
- f) *capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.*

3. Risk is given by the probability of damage; since the term probability, by definition, expresses an uncertainty (the fact that certain information is not available), the risk assessment includes the “precautionary principle”. The request to include this principle in the risk assessment is superfluous.

### 2.2.2 Steps in the risk assessment process

... *Risk deduction.*

... *Experimental and control testing.*

... *Testing of the risks to health.*

... *Experimental testing of the environmental risks.*

... *Conclusion.* Studies of the various effects of GM crops are meaningless without properly designed controls and cannot be accepted as a basis for decision making processes. Unfortunately, reports presented in the public media often lack or ignore proper controls and provide background for the disinformation of the policy-makers and general public.

### 2.2.3 The precautionary principle

**The precautionary principle (PP) has been a subject of numerous analyses<sup>20</sup>.** A very comprehensive study was published by Sabrina Shaw and Risa Schwartz as a report of the United Nations University.<sup>21</sup> These two WTO officials tried to correlate the policy based on the PP and executed by EU with the patterns of rational decisions. They found common points indicating that the PP could be consistent with scientific risk evaluation – provided that the rules set in the “Communication on the Precautionary Principle” (see 2.2.1) in 2000 were strictly observed. However, the precautionary principle is very often misused to justify unrealistic catastrophic scenarios and consequent political conclusions...

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**<sup>20</sup> Kogan L. A.: Monograph Documents Advance, Impact of Europe’s “Risk-Free” Regulatory Agenda. Washington Legal Foundation, November 4, 2005; and Kogan L. A.: Precautionary Preference: How Europe’s New Regulatory Protectionism Imperils American Free Enterprise. Institute for Trade, Standards and Sustainable Development, Inc., Princeton, July 2005.**

<sup>21</sup> Shaw S., Schwartz R.: Trading Precaution: The Precautionary principle and the WTO. United Nations University, Institute of Advanced Studies. November 2005