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Position Paper

Regulatory and associated political issues with respect to Bt transgenic maize in the European union

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Abstract

Legislation at the national level in Europe as well as that developed by the European Union (EU) generally permits release and commercialization of genetically modified organisms (GMOs). However, only 10 plant/event combinations were registered as of 2002: three maize events (Bt176, Mon810, and Bt11), with the other seven divided among carnation (3), oil-seed rape (2), tobacco (1), and raddiccio (1). Of these, only one maize event (Bt176) has been registered as a legal variety, and this was in Spain, where 22,000 ha have been planted annually since 1998. In this paper, we first provide an overview on the complexity of EU GMO legislation. Then we discuss the minor role that results of EU-funded biosafety research have had on governmental policy. Finally, we provide information about initiatives for post-commercialization monitoring plans of Bt maize in Europe. As a result of the slow progress to date, we conclude that commercialization of GMOs will be seriously delayed in the EU for the next several years.

Author Keywords: Bt maize; Biosafety research; GMO monitoring; EU regulation

Article Outline

1. Introduction

The deliberate release of genetically modified organisms (GMOs) is highly restricted at present in the European Union (EU). Although legislation at the national level as well as that of the EU generally permits release and commercialization of GMOs, only 10 plant/event combinations have been registered by 2002: three for maize (Bt176, Mon810, and Bt11), with the other seven divided between carnation (3), oil-seed rape (2), tobacco (1) and raddiccio (1). Of these, only one maize cultivar (Bt176) has passed legal approval and been registered in Spain, where 22,000 ha have been planted yearly since 1998 (Brookes, 2002). The other two maize events cannot be used for large-scale commercialization because national variety registrations were refused in most countries. All existing registrations were approved prior to 1997. Since then, public concerns have influenced governmental decisions to establish a de facto moratorium. Most arguments used against GMOs are about their risks for the environment and human food. Our aim here is to give an overview of the GMO legislation framework within the EU. In addition, we highlight some of the major research projects that deal with Bt maize biosafety, which is being intensively funded by the EU. Finally, we provide details about the first regulatory initiatives for post-commercialization monitoring plans.

1.1. EU legislation

Several implemented EU directives focus on GMOs: (a) Novel Food (258/97/EC), (b) traceability and labeling (Art. 8 of 258/97/EC, and Regulation EC 1139/98), and (c) experimental releases and placing on the market (2001/18/EC). Ongoing legislative initiatives deal with traceability and labeling of GMOs and the authorization of these in food and feed. As long as some areas are not sufficiently regulated, 6 of 15 EU member states (France, Italy, Denmark, Luxemburg, Austria, and Greece) block any new authorization of GMOs in the EU through their minority vote. At the same time, scientific advisory bodies are increasingly losing influence. One example is the Scientific Committee on Plants (SCP). This body has the mandate to answer scientific and technical questions relating to plants intended for human or animal consumption, production or processing of non-food products in relation to characteristics liable to affect human or animal health or the environment, including the use of pesticides. The opinion of the SCP concerning the adventitious presence of GM seeds in conventional seeds (adopted by the Committee on 7 March 2001) was largely ignored within the European executive bodies. Worse, the European Parliament took a much stronger position (0.5%) on acceptable threshold levels of GMO for labeling than what seems to be economically and scientifically practicable (1% as proposed by the EU commission). Even governments such as Austria are still taking positions that are technically impossible to achieve, like "zero tolerance" for GMO "contamination" of conventional seeds.

However, the concept of ecological risk assessment and risk management of GMO, as it is defined in the new EU directive 2001/18, relies on pre-commercialization biosafety research and post-commercialization monitoring, which can be "case-specific" or general ("general surveillance"). Risk is defined as the product of *exposure* and *effect* (hazard). There is consensus among scientists that risk assessment must target both the exposure (e.g., frequency of Bt transgenes and their expression products), and the specific effects associated with the new technology (Saeglitz and Bartsch, 2002). Because laboratory and field biosafety studies can only target a limited number of species and parameters (Schmitz et al., 2003) broad and long-term

monitoring programs are indicated to detect potential side effects (e.g., population decline based on lethal and sub-lethal effects, biometrical changes, and changes in species composition).

1.2. EU biosafety research

Over the last 15 years, 81 international biosafety research projects have been supported by the EU. These projects have involved over 400 teams from many different disciplines and represent a combined community financial contribution of about €70 million. Summaries of all these projects are available at the official EU website.[1] Within the same period, national programs (e.g., in Germany) provided significant new knowledge on the environmental effects of GMO. Based on the literature available in biosafety databases, we found no evidence that the use of GMO contradicts sustainable agriculture and nature conservation per se (Bartsch and Schuphan, 2002). Biosafety research on the environmental effects of Bt maize in Europe has been conducted as early as 1996, and extensive national research programs currently are carried out in countries such as Spain (Castanera and Ortego, 2000), France (Bourguet et al., 2002), and Germany (Schuphan et al., 2002). Additionally, several current EU-funded projects target Bt maize effects. One such project is coordinated by Ruud de Maagd ,[1] from Plant Research International, Wageningen, and another project is coordinated by Ingolf Schuphan, Aachen University of Technology:
http://www.rwthaachen.de/bio5/ww/is_homepage/is_current_research_/is_koord2/is_koord2.html
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1.3. EU wide monitoring of GMO

Biosafety research cannot solve every open or basic question on general ecology (Kareiva et al., 1997). Following the best pragmatic use of a case-by-case and step-by-step approach, a well-designed monitoring program is necessary after commercialization. A combination of case-specific monitoring and general environmental surveillance will help to assess the risk assumptions made prior to commercialization of Bt maize (Schmitz et al., 2003). Intelligent monitoring should use causal analytic approaches based on the comparison of transgenic and isogenic plants. However, as in other field studies, researchers will be confronted with the difficulty of identifying a single effect. This is partly due to the high complexity of the ecosystem, "natural" fluctuations, and regional differences in the bioeconoses. Finally, any measurable effect of Bt transgenes on non-target herbivores must be evaluated to determine whether the effect is acceptable or unacceptable.

So far, the only plans for monitoring Bt maize are those established by the US Environmental Protection Agency in 2001 to determine resistance development in the European corn borer. Only draft protocols exist in the EU (Bartsch and Schuphan, 2000). There is no monitoring plan for the effects of Bt maize on non-target organisms. Only initial studies are available: Schmitz et al. (2003) developed and applied tools for selecting relevant herbivore species for the field monitoring of Bt toxin effects via pollen deposition: approximately 7% of the German Macrolepidoptera species primarily occur in farmland areas and were selected as being potentially affected by Bt pollen exposure. Among these species, 14% (e.g., 1% of total) were found to be potentially exposed on a regional scale.

The European Council decision of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/1B/EC provided definitions and clarifications on how: (a) monitoring strategies, (b) monitoring methodology, and (c) analysis, reporting, and review should be used. The notifier is the only one repsonsible for the establisment and information reporting of

all monitoring details, according to the directive. Although the guidance note allows utilization of existing public and private monitoring networks, the additional costs for companies will increase significantly. Thus, a delay of commercialization can be expected.

1.4. Outlook

European Ministers of both Agriculture and Environment are deeply divided about the future of GMO in the EU. David Byrne, the current European commissioner for Health and Consumer Protection, is optimistic about lifting the GMO moratorium (Byrne, 2001). But as long as politicians are influenced by environmental groups opposing GMOs, they keep on being deeply divided about risks and benefits of GMO in Europe (e.g., see Owens, 2003). Within the near future, the EU might try to resist world-wide trends to introduce GMO into agricultural practice.

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[1] http://europa.eu.int/comm/research/quality-of-life/gmo/01-plants/01-08-projects.html.